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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, 2005

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM \_\_\_\_ TO \_\_\_\_

COMMISSION FILE NUMBER: 0-13976

AKORN, INC.

(Exact Name of Registrant as Specified in its Charter)

LOUISIANA  
(State or Other Jurisdiction of  
Incorporation or Organization)

72-0717400  
(I.R.S. Employer  
Identification No.)

2500 MILLBROOK DRIVE  
BUFFALO GROVE, ILLINOIS  
(Address of Principal Executive Offices)

60089  
(Zip Code)

(847) 279-6100

(Registrant's telephone number)

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required 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 an accelerated filer (as defined in Exchange Act Rule 12b-2).

Yes  No

At April 30, 2005 there were 25,978,487 shares of common stock, no par value, outstanding.

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|                                                                                               | <u>Page</u> |
|-----------------------------------------------------------------------------------------------|-------------|
| PART I. FINANCIAL INFORMATION                                                                 | 3           |
| ITEM 1. Financial Statements (Unaudited)                                                      | 3           |
| Condensed Consolidated Balance Sheets-March 31, 2005 and December 31, 2004                    | 3           |
| Condensed Consolidated Statements of Operations-Three months ended March 31, 2005 and 2004    | 4           |
| Condensed Consolidated Statements of Cash Flows-Three months ended March 31, 2005 and 2004    | 5           |
| Notes to Condensed Consolidated Financial Statements                                          | 6           |
| ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations | 18          |
| ITEM 3. Quantitative and Qualitative Disclosures About Market Risk                            | 27          |
| ITEM 4. Controls and Procedures                                                               | 27          |
| PART II. OTHER INFORMATION                                                                    | 28          |
| ITEM 1. Legal Proceedings                                                                     | 28          |
| ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds                           | 29          |
| ITEM 3. Defaults Upon Senior Securities                                                       | 29          |
| ITEM 4. Submission of Matters to a Vote of Security Holders                                   | 29          |
| ITEM 5. Other Information                                                                     | 29          |
| ITEM 6. Exhibits                                                                              | 29          |

**AKORN, INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
**IN THOUSANDS**  
**(UNAUDITED)**

|                                                                                                                                                                           | <u>MARCH 31,</u><br><u>2005</u> | <u>DECEMBER 31,</u><br><u>2004</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|------------------------------------|
| <b>ASSETS</b>                                                                                                                                                             |                                 |                                    |
| <b>CURRENT ASSETS</b>                                                                                                                                                     |                                 |                                    |
| Cash and cash equivalents                                                                                                                                                 | \$ 3,219                        | \$ 4,110                           |
| Trade accounts receivable (less allowance for doubtful accounts of \$74 and \$435 respectively)                                                                           | 3,354                           | 6,582                              |
| Inventories                                                                                                                                                               | 10,693                          | 10,421                             |
| Prepaid expenses and other current assets                                                                                                                                 | <u>2,695</u>                    | <u>1,280</u>                       |
| <b>TOTAL CURRENT ASSETS</b>                                                                                                                                               | <b>19,961</b>                   | <b>22,393</b>                      |
| PROPERTY, PLANT AND EQUIPMENT, NET                                                                                                                                        | 31,317                          | 31,893                             |
| <b>OTHER LONG-TERM ASSETS</b>                                                                                                                                             |                                 |                                    |
| Intangibles, net                                                                                                                                                          | 11,239                          | 11,618                             |
| Other                                                                                                                                                                     | <u>193</u>                      | <u>1,018</u>                       |
| <b>TOTAL OTHER LONG-TERM ASSETS</b>                                                                                                                                       | <b>11,432</b>                   | <b>12,636</b>                      |
| <b>TOTAL ASSETS</b>                                                                                                                                                       | <b><u>\$ 62,710</u></b>         | <b><u>\$ 66,922</u></b>            |
| <b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>                                                                                                                               |                                 |                                    |
| <b>CURRENT LIABILITIES</b>                                                                                                                                                |                                 |                                    |
| Current installments of debt and debt in default                                                                                                                          | \$ 3,596                        | \$ 3,590                           |
| Trade accounts payable                                                                                                                                                    | 2,772                           | 5,397                              |
| Accrued compensation                                                                                                                                                      | 604                             | 499                                |
| Accrued expenses and other liabilities                                                                                                                                    | <u>1,486</u>                    | <u>1,674</u>                       |
| <b>TOTAL CURRENT LIABILITIES</b>                                                                                                                                          | <b>8,458</b>                    | <b>11,160</b>                      |
| <b>LONG-TERM LIABILITIES</b>                                                                                                                                              |                                 |                                    |
| Long-term debt, less current installments                                                                                                                                 | 6,857                           | 6,790                              |
| Other                                                                                                                                                                     | <u>1,834</u>                    | <u>1,646</u>                       |
| <b>TOTAL LONG-TERM LIABILITIES</b>                                                                                                                                        | <b>8,691</b>                    | <b>8,436</b>                       |
| <b>TOTAL LIABILITIES</b>                                                                                                                                                  | <b><u>17,149</u></b>            | <b><u>19,596</u></b>               |
| <b>SHAREHOLDERS' EQUITY</b>                                                                                                                                               |                                 |                                    |
| Common stock, no par value — 150,000,000 shares authorized; 25,343,598 and 25,132,684 shares issued and outstanding at March 31, 2005 and December 31, 2004, respectively | 60,615                          | 59,571                             |
| Series A Preferred Stock, \$1.00 par value 257,172 shares authorized and issued, 242,172 shares outstanding at March 31, 2005 and December 31, 2004                       | 26,178                          | 25,787                             |
| Series B Preferred Stock, \$1.00 par value 170,000 shares authorized, 141,000 shares issued and 138,500 outstanding at March 31, 2005 and December 31, 2004               | 13,322                          | 13,109                             |
| Warrants to acquire common stock                                                                                                                                          | 14,096                          | 14,160                             |
| Accumulated deficit                                                                                                                                                       | <u>(68,650)</u>                 | <u>(65,301)</u>                    |
| <b>TOTAL SHAREHOLDERS' EQUITY</b>                                                                                                                                         | <b>45,561</b>                   | <b>47,326</b>                      |
| <b>TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY</b>                                                                                                                         | <b><u>\$ 62,710</u></b>         | <b><u>\$ 66,922</u></b>            |

See notes to condensed consolidated financial statements.

**AKORN, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
**IN THOUSANDS, EXCEPT PER SHARE DATA**  
**(UNAUDITED)**

|                                                     | <b>THREE MONTHS ENDED</b> |                   |
|-----------------------------------------------------|---------------------------|-------------------|
|                                                     | <b>MARCH 31,</b>          |                   |
|                                                     | <b>2005</b>               | <b>2004</b>       |
| Revenues                                            | \$ 10,181                 | \$ 11,660         |
| Cost of sales                                       | 6,838                     | 7,642             |
| <b>GROSS PROFIT</b>                                 | <b>3,343</b>              | <b>4,018</b>      |
| Selling, general and administrative expenses        | 3,368                     | 2,896             |
| Amortization and write-down of intangibles          | 379                       | 683               |
| Research and development expenses                   | 1,342                     | 329               |
| <b>TOTAL OPERATING EXPENSES</b>                     | <b>5,089</b>              | <b>3,908</b>      |
| <b>OPERATING INCOME (LOSS)</b>                      | <b>(1,746)</b>            | <b>110</b>        |
| Interest expense                                    | (526)                     | (1,327)           |
| <b>LOSS BEFORE INCOME TAXES</b>                     | <b>(2,272)</b>            | <b>(1,217)</b>    |
| Income tax provision                                | 15                        | —                 |
| <b>NET LOSS</b>                                     | <b>(2,287)</b>            | <b>(1,217)</b>    |
| Preferred stock dividends and adjustments           | —                         | —                 |
| <b>NET LOSS AVAILABLE TO COMMON STOCKHOLDERS</b>    | <b>\$ (2,287)</b>         | <b>\$ (1,217)</b> |
| <b>NET LOSS PER SHARE:</b>                          |                           |                   |
| BASIC AND DILUTED                                   | <u>\$ (0.09)</u>          | <u>\$ (0.06)</u>  |
| <b>SHARES USED IN COMPUTING NET LOSS PER SHARE:</b> |                           |                   |
| BASIC AND DILUTED                                   | <u>25,237</u>             | <u>19,887</u>     |

See notes to condensed consolidated financial statements.

**AKORN, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**IN THOUSANDS**  
**(UNAUDITED)**

|                                                                             | <b>THREE MONTHS<br/>ENDED MARCH 31</b> |               |
|-----------------------------------------------------------------------------|----------------------------------------|---------------|
|                                                                             | <b>2005</b>                            | <b>2004</b>   |
| <b>OPERATING ACTIVITIES</b>                                                 |                                        |               |
| Net loss                                                                    | \$ (2,287)                             | \$ (1,217)    |
| Adjustments to reconcile net loss to net cash used in operating activities: |                                        |               |
| Depreciation and amortization                                               | 1,751                                  | 1,387         |
| Amortization of debt discounts                                              | 253                                    | 251           |
| Write-down of long lived assets                                             | —                                      | 325           |
| Advances to Strides Arcolab Limited                                         | (1,500)                                | —             |
| Non-cash expenses related to preferred stock                                | —                                      | 486           |
| Changes in operating assets and liabilities:                                |                                        |               |
| Trade accounts receivable                                                   | 3,228                                  | (1,711)       |
| Inventories                                                                 | (272)                                  | (873)         |
| Prepaid expenses and other current assets                                   | 272                                    | (271)         |
| Trade accounts payable                                                      | (2,625)                                | 683           |
| Accrued expenses and other liabilities                                      | 105                                    | 103           |
| <b>NET CASH USED IN OPERATING ACTIVITIES</b>                                | <b>(1,075)</b>                         | <b>(837)</b>  |
| <b>INVESTING ACTIVITIES</b>                                                 |                                        |               |
| Purchases of property, plant and equipment                                  | (83)                                   | (228)         |
| Purchase of intangible asset                                                | (75)                                   | —             |
| <b>NET CASH USED IN INVESTING ACTIVITIES</b>                                | <b>(158)</b>                           | <b>(228)</b>  |
| <b>FINANCING ACTIVITIES</b>                                                 |                                        |               |
| Repayment of long-term debt                                                 | (83)                                   | (667)         |
| Net borrowings under lines of credit                                        | —                                      | 1,559         |
| Proceeds from warrant and stock option exercises                            | 37                                     | —             |
| Proceeds under stock option and stock purchase plans                        | 388                                    | 178           |
| <b>NET CASH PROVIDED BY FINANCING ACTIVITIES</b>                            | <b>342</b>                             | <b>1,070</b>  |
| <b>INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>                     | <b>(891)</b>                           | <b>5</b>      |
| Cash and cash equivalents at beginning of period                            | 4,110                                  | 218           |
| <b>CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>                           | <b>\$ 3,219</b>                        | <b>\$ 223</b> |
| Amount paid for interest (net of capitalized interest)                      | \$ 25                                  | \$ 155        |
| Amount paid/(refunded) for income taxes                                     | 72                                     | (38)          |

See notes to condensed consolidated financial statements.

AKORN, INC.  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
(UNAUDITED)

**NOTE A – BUSINESS AND BASIS OF PRESENTATION**

*Business:* Akorn, Inc. and its wholly owned subsidiary, Akorn (New Jersey), Inc. (collectively, the “Company”) manufacture and market diagnostic and therapeutic pharmaceuticals in specialty areas such as ophthalmology, rheumatology, anesthesia and antidotes, among others. Customers, including physicians, optometrists, wholesalers, group purchasing organizations and other pharmaceutical companies, are served primarily from three operating facilities in the United States. In September 2004, the Company, along with a venture partner, formed a mutually owned limited liability company, Akorn-Strides, LLC (the “Joint Venture Company”). See Note M – Business Alliances.

*Basis of Presentation:* The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. As a result of the debt refinancing and equity transactions disclosed in Note H, the Company has substantially reversed its historical liquidity concerns. The Company believes that its current line of credit, together with cash generated from operations, will be sufficient to meet its near-term cash requirements.

Although the Company has refinanced its debt on a long-term basis and extinguished other debt, as described above, it continues to be subject to ongoing FDA compliance matters that could have an adverse effect on the Company. See Note L — “Commitments and Contingencies” for further description of these matters.

*Consolidation:* The accompanying unaudited condensed consolidated financial statements include the accounts of Akorn, Inc. and Akorn (New Jersey) Inc. as well as the accounts and results of the Joint Venture Company. Intercompany transactions and balances have been eliminated in consolidation. These financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and accordingly do not include all the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements.

*Adjustments:* In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included in these financial statements. Operating results for the three-month period ended March 31, 2005 are not necessarily indicative of the results that may be expected for a full year. For further information, refer to the consolidated financial statements and footnotes for the year ended December 31, 2004, included in the Company’s Annual Report on Form 10-K.

**NOTE B — USE OF ESTIMATES**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ materially from those estimates. Significant estimates and assumptions for the Company relate to the allowance for doubtful accounts, the allowance for chargebacks, the allowance for rebates, the reserve for slow-moving and obsolete inventory, the allowance for product returns, the carrying value of intangible assets and the carrying value of deferred income tax assets.

**NOTE C — STOCK BASED COMPENSATION**

The Company applies APB Opinion No. 25 “Accounting for Stock Issued to Employees” in accounting for options granted to its employees under its stock option programs and applies Statement of Financial Accounting Standards No. 123 “Accounting for Stock Issued Employees” (“SFAS 123”) for disclosure purposes only. The SFAS 123 disclosures include pro forma net income (loss) and earnings (loss) per share as if the fair value-based method of accounting had been used.

If compensation for employee options had been determined based on SFAS 123, the Company’s pro forma net income (loss) and pro forma net income (loss) per share for the three months ended March 31, would have been as follows:

|                                                                                                                | <b>Three Months ended March 31</b> |                   |
|----------------------------------------------------------------------------------------------------------------|------------------------------------|-------------------|
|                                                                                                                | <b>2005</b>                        | <b>2004</b>       |
| Net income (loss) as reported                                                                                  | (2,287)                            | (1,217)           |
| Add stock-based employee compensation expense included in reported net income                                  | —                                  | —                 |
| Deduct total stock-based employee compensation expense determined under fair-value-based method for all awards | (287)                              | (463)             |
| Pro forma net income (loss)                                                                                    | (2,574)                            | (1,680)           |
| Add preferred stock dividends and adjustments                                                                  | —                                  | —                 |
| Pro forma net loss available for common stockholders                                                           | <u>\$ (2,574)</u>                  | <u>\$ (1,680)</u> |
| Basic and diluted loss per share of common stock                                                               |                                    |                   |
| As reported                                                                                                    | \$ (0.09)                          | \$ (0.06)         |
| Pro forma                                                                                                      | \$ (0.10)                          | \$ (0.08)         |

#### **NOTE D — REVENUE RECOGNITION**

The Company recognizes product sales for its ophthalmic and injectable business segments upon the shipment of goods or upon the delivery of goods, depending on the sales terms. Revenue is recognized when all obligations of the Company have been fulfilled and collection of the related receivable is probable.

The contract services segment, which produces products for third party customers based upon their specifications and at pre-determined prices, also recognizes sales upon the shipment of goods or upon delivery of the product as appropriate. Revenue is recognized when all obligations of the Company have been fulfilled and collection of the related receivable is probable.

Provision for estimated doubtful accounts, chargebacks, rebates, discounts and product returns is made at the time of sale and is analyzed and adjusted, if necessary, at each balance sheet date.

#### **NOTE E — ACCOUNTS RECEIVABLE ALLOWANCES**

The nature of the Company's business inherently involves, in the ordinary course, significant amounts and substantial volumes of transactions and estimates relating to allowances for doubtful accounts, product returns, chargebacks, rebates and discounts given to customers. This is a natural circumstance of the pharmaceutical industry and not specific to the Company and inherently lengthens the collection process. Depending on the product, the end-user customer, the specific terms of national supply contracts and the particular arrangements with the Company's wholesaler customers, certain rebates, chargebacks and other credits are deducted from the Company's accounts receivable. The process of claiming these deductions depends on wholesalers reporting to the Company the amount of deductions that were earned under the respective terms with end-user customers (which in turn depends on which end-user customer, with different pricing arrangements might be entitled to a particular deduction). This process can lead to "partial payments" against outstanding invoices as the wholesalers take the claimed deductions at the time of payment.

Unless otherwise noted, the provisions and allowances for the following customer deductions are reflected in the accompanying financial statements as reductions of revenues and trade accounts receivable, respectively.

#### **Chargebacks and Rebates**

The Company enters contractual agreements with certain third parties such as hospitals and group-purchasing organizations to sell certain products at predetermined prices. The parties have elected to have these contracts administered through wholesalers that buy the product from the Company. When a wholesaler sells a product to one of the third parties that are subject to a contractual price agreement, the difference between the price paid to the Company by the wholesaler and the price under contract is charged back to the Company by the wholesaler. The Company tracks sales and submitted chargebacks by product number for each wholesaler. Utilizing this information, the Company estimates a chargeback percentage for each product. The Company reduces gross sales and increases the chargeback allowance by the estimated chargeback amount for each product sold to a wholesaler. The Company reduces the

chargeback allowance when it processes a request for a chargeback from a wholesaler. Actual chargebacks processed can vary materially from period to period.

Management obtains certain wholesaler inventory reports to aid in analyzing the reasonableness of the chargeback allowance. The Company assesses the reasonableness of its chargeback allowance by applying the product chargeback percentage based on historical activity to the quantities of inventory on hand per the wholesaler inventory reports and an estimate of in-transit inventory that is not reported on the wholesaler inventory reports at the end of the period. In the first quarter of 2004, the Company obtained more precise information from the wholesalers to estimate the amount of in-transit inventory, which lowered its estimate of in-transit inventory. This resulted in the Company recognizing approximately \$500,000 less in chargeback expense in the first quarter of 2004. The Company intends to use this new information on a going forward basis as a more accurate estimate of in-transit inventory. Additionally, in the second quarter of 2004, the Company, in accordance with its policy, reduced its estimate of the percentage amount of wholesaler inventory that will ultimately be sold to a third party that is subject to a contractual price agreement. This reduction was made based on an analysis of a six quarter trend of such sales being below the Company's previous estimates, thereby confirming that the reduced percentage was other than temporary.

Similarly, the Company maintains an allowance for rebates related to contract and other programs with certain customers. Rebate percentages vary by product and by volume purchased by each eligible customer. The Company tracks sales by product number for each eligible customer and then applies the applicable rebate percentage, using both historical trends and actual experience to estimate its rebate allowance. The Company reduces gross sales and increases the rebate allowance by the estimated rebate amount when the Company sells its products to its rebate-eligible customers. The Company reduces the rebate allowance when it processes a customer request for a rebate. At each balance sheet date, the Company analyzes the allowance for rebates against actual rebates processed and makes necessary adjustments as appropriate. Actual rebates processed can vary materially from period to period.

The recorded allowances reflect the Company's current estimate of the future chargeback and rebate liability to be paid or credited to each wholesaler under the various contracts and programs. For the three month periods ended March 31, 2005 and 2004, the Company recorded chargeback and rebate expense of \$4,999,000 and \$2,845,000, respectively. The allowance for chargebacks and rebates was \$5,288,000 and \$5,406,000 as of March 31, 2005 and December 31, 2004, respectively.

#### **Product Returns**

Certain of the Company's products are sold with the customer having the right to return the product within specified periods and guidelines for a variety of reasons, including but not limited to pending expiration dates. Provisions are made at the time of sale based upon tracked historical experience, by customer in some cases. In evaluating month-end allowance balances, the Company considers actual returns to date that are in process, the expected impact of any product recalls and the wholesaler's inventory information to assess the magnitude of unconsumed product that may result in a product return to the Company in the future. Actual returns processed can vary materially from period to period. For the three-month periods ended March 31, 2005 and 2004, the Company recorded a provision for product returns of \$514,000 and \$795,000, respectively. The allowance for potential product returns was \$1,067,000 and \$1,393,000 at March 31, 2005 and December 31, 2004, respectively.

#### **Doubtful Accounts**

Provisions for doubtful accounts, which reflect trade receivable balances owed to the Company that are believed to be uncollectible, are recorded as a component of selling, general and administrative expense. In estimating the allowance for doubtful accounts, the Company has:

- Identified the relevant factors that might affect the accounting estimate for allowance for doubtful accounts, including: (a) historical experience with collections and write-offs; (b) credit quality of customers; (c) the interaction of credits being taken for discounts, rebates, allowances and other adjustments; (d) balances of outstanding receivables, and partially paid receivables; and (e) economic and other exogenous factors that might affect collectibility (e.g., bankruptcies of customers, factors that affect particular distribution channels).
- Accumulated data on which to base the estimate for allowance for doubtful accounts, including: (a) collections and write-offs data; (b) information regarding current credit quality of customers; and (c) other information such as buying patterns and payment patterns, particularly with respect to major customers.



- Developed assumptions reflecting management’s judgments as to the most likely circumstances and outcomes, regarding, among other matters: (a) collectibility of outstanding balances relating to “partial payments;” (b) the ability to collect items in dispute (or subject to reconciliation) with customers; and (c) economic factors that might affect collectibility of outstanding balances — based upon information available at the time.

For the three-month periods ended March 31, 2005 and 2004, the Company recorded a net benefit for doubtful accounts of \$69,000 and \$362,000, respectively as recoveries and reduced reserve requirements exceeded write-offs and account collectibility concerns. The allowance for doubtful accounts was \$74,000 and \$435,000 as of March 31, 2005 and December 31, 2004, respectively. As of March 31, 2005, we had a total of \$46,000 of past due gross accounts receivable. We perform monthly a detailed analysis of the receivables due from our wholesaler customers and provide a specific reserve against known uncollectible items for each of the wholesaler customers. We also include in the allowance for doubtful accounts an amount that we estimate to be uncollectible for all other customers based on a percentage of the past due receivables. The percentage reserved increases as the age of the receivables increases. Of the recorded allowance for doubtful accounts of \$74,000, the portion related to major wholesaler customers is \$56,000 with the remaining \$18,000 reserve for all other customers.

#### Discounts

Cash discounts are available to certain customers based on agreed upon terms of sale. The Company evaluates the discount reserve balance against actual discounts taken. For the three-month periods ended March 31, 2005 and 2004, the Company recorded a provision for cash discounts of \$179,000 and \$192,000, respectively. The allowance for discounts was \$174,000 and \$234,000 as of March 31, 2005 and December 31, 2004, respectively.

#### NOTE F – INVENTORIES

The components of inventories are as follows (in thousands):

|                            | <u>MARCH 31,</u><br><u>2005</u> | <u>DECEMBER 31,</u><br><u>2004</u> |
|----------------------------|---------------------------------|------------------------------------|
| Finished goods             | \$ 5,354                        | \$ 5,194                           |
| Work in process            | 1,115                           | 1,380                              |
| Raw materials and supplies | 4,224                           | 3,847                              |
|                            | <u>\$ 10,693</u>                | <u>\$ 10,421</u>                   |

Inventory at March 31, 2005 and December 31, 2004 is reported net of reserves for slow-moving, unsaleable and obsolete items of \$545,000 and \$660,000, respectively, primarily related to finished goods. For the three-month periods ended March 31, 2005 and 2004, the Company recorded a provision of \$25,000 and \$303,000, respectively.

#### NOTE G — PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment consists of the following (in thousands):

|                                      | <u>MARCH 31,</u><br><u>2005</u> | <u>DECEMBER 31,</u><br><u>2004</u> |
|--------------------------------------|---------------------------------|------------------------------------|
| Land                                 | \$ 396                          | \$ 396                             |
| Buildings and leasehold improvements | 9,325                           | 9,325                              |
| Furniture and equipment              | 27,520                          | 27,516                             |
| Automobiles                          | 55                              | 55                                 |
|                                      | <u>37,296</u>                   | <u>37,292</u>                      |
| Accumulated depreciation             | <u>(24,974)</u>                 | <u>(24,337)</u>                    |
|                                      | 12,322                          | 12,955                             |
| Construction in progress             | 18,995                          | 18,938                             |
|                                      | <u>\$ 31,317</u>                | <u>\$ 31,893</u>                   |

Construction in progress primarily represents capital expenditures related to the Company's Lyophilization project that is intended to enable the Company to perform processes in-house that are currently being performed by a sub-contractor. Subject to the Company's ability to generate sufficient operating cash flow or obtain new financing for future operations and capital expenditures, the Company anticipates completing the lyophilization facility in late 2005 and being fully operational in 2006. Future costs are estimated to be \$2,000,000. The Company can make no assurances that it will be able to complete this project within its estimated timeframe, or at all, or that material impairment charges will not be required if such completion does not occur as anticipated.

#### NOTE H — FINANCING ARRANGEMENTS

The Company's long-term debt consists of (in thousands):

|                                            | March 31,<br>2005 | December 31,<br>2004 |
|--------------------------------------------|-------------------|----------------------|
| Credit Agreement with LaSalle Bank         | \$ —              | \$ —                 |
| Convertible subordinated debentures        | 5,000             | 5,000                |
| Mortgages payable                          | 1,225             | 1,307                |
| Promissory note to NeoPharm, Inc.          | 3,250             | 3,250                |
| 2003 Subordinated Notes                    | 2,767             | 2,767                |
|                                            | 12,242            | 12,324               |
| Less unamortized discount on debt          | (1,789)           | (1,944)              |
| Less current installments, debt in default | (3,596)           | (3,590)              |
| Long-term debt                             | <u>\$ 6,857</u>   | <u>\$ 6,790</u>      |

In December 1997, the Company entered into a \$45,000,000 (as amended) revolving credit agreement with The Northern Trust Company ("Northern Trust"). Borrowings under this credit agreement were secured by substantially all of the assets of the Company and bore floating interest rates that were 7.25% at September 30, 2003. The Company went into default under the Northern Trust credit agreement in 2002 and thereafter operated under an agreement under which Northern Trust would agree to forbear from exercising its remedies (the "Forbearance Agreement"). The Forbearance Agreement provided for additional borrowings and was extended on numerous occasions in 2003.

On October 7, 2003, a group of investors (the "Investors") purchased all of the Company's then outstanding senior bank debt from Northern Trust, a balance of \$37,731,000, at a discount and exchanged such debt with the Company (the "Exchange Transaction") for (i) 257,172 shares of Series A 6.0% Participating Convertible Preferred Stock ("Series A Preferred Stock"), (ii) subordinated promissory notes in the aggregate principal amount of \$2,767,139 (the "2003 Subordinated Notes"), (iii) warrants to purchase an aggregate of 8,572,400 shares of the Company's common stock with an exercise price of \$1.00 per share ("Series A Warrants"), and (iv) \$5,473,862 in cash from the proceeds of the term loan under the New Credit Facility described in a following paragraph. The 2003 Subordinated Notes and cash were issued by the Company to (a) The John N. Kapoor Trust dated 9/20/89 (the "Kapoor Trust"), the sole trustee and sole beneficiary of which is Dr. John N. Kapoor, the Company's Chairman of the Board of Directors and the holder of a significant stock position in the Company, (b) Arjun Waney, a director and the holder of a significant stock position in the Company, and (c) Argent Fund Management Ltd., for which Mr. Waney serves as Chairman and Managing Director and 52% of which is owned by Mr. Waney. The Company also issued to the holders of the 2003 Subordinated Notes warrants to purchase an aggregate of 276,714 shares of common stock with an exercise price of \$1.10 per share.

As a result of the Exchange Transaction, the Company recorded transaction costs of approximately \$3,102,000. The transaction costs consisted principally of cash and securities owed to restructuring and investment banking professionals that provided services directly related to the extinguishment of the Northern Trust debt.

In accounting for the Exchange Transaction, the Company first reduced the carrying amount of the Northern Trust debt by the cash paid to Investors. The remaining carrying value was then allocated among the three securities issued to fully extinguish the debt based on the relative fair values of those securities. Accordingly, the Series A Preferred Stock, the 2003 Subordinated Notes and the Series A Warrants were initially recorded at \$20,874,000, \$2,046,000 and \$9,337,000, respectively, before, in the case of the 2003 Subordinated Notes, the discount described below and before, in the case of the stock securities, related issuance costs of \$480,000. The fair value of the Series A Warrants was estimated by the Company using the same method and estimates as described for the warrants issued with the 2003 Subordinated Notes. All unexercised warrants expire on October 7, 2006.

Simultaneously with the consummation of the Exchange Transaction, the Company entered into a credit agreement with LaSalle Bank National Association ("LaSalle Bank") providing the Company with two Term Loans (collectively, the "Term Loans") which consisted of a \$5,500,000 term loan A, and a \$1,500,000 term loan B totaling \$7,000,000, and a revolving line of credit of up to \$5,000,000 (the "Revolver") to provide for working capital needs (collectively, the "New Credit Facility") secured by substantially all of the assets of the Company. The obligations of the Company under the New Credit Facility had been guaranteed by the Kapoor Trust and Mr. Waney. In exchange for this guaranty, the Company issued additional warrants ("Guaranty Warrants") to purchase 880,000 and 80,000 shares of common stock to the Kapoor Trust and Mr. Waney, respectively, and had agreed to issue to each of them, on each anniversary of the date of the consummation of the Exchange Transaction, warrants to purchase additional shares of common stock; however, the guarantees were terminated before the first anniversary, as described below. The warrants issued in exchange for these guarantees have an exercise price of \$1.10 per share.

The New Credit Facility matures on October 7, 2005. The Term Loans bore interest at prime plus 1.75% and were paid in full on August 23, 2004. The Revolver bears interest at prime plus 1.50% (7.25%, based on the 5.75% prime rate as of March 31, 2005). Availability under the Revolver is based on eligible accounts receivable inventory and machinery and equipment. The availability as of March 31, 2005 was \$5,000,000. The New Credit Facility contains certain restrictive covenants including but not limited to certain financial covenants such as EDITDA to interest expense and Senior Debt to EBITDA ratios. The New Credit Facility also contains subjective covenants providing that the Company would be in default if, in the judgment of the lenders, there is a material adverse change in the Company's financial condition. Because the New Credit Facility also requires the Company to maintain its deposit accounts with LaSalle Bank, the existence of these subjective covenants, pursuant to EITF Abstract No. 95-22, requires that outstanding borrowings under the Revolver be classified as a current liability. On August 13, 2004, the Company entered into the First Amendment to the New Credit Facility. Among other things, the First Amendment amended certain financial covenants and LaSalle Bank agreed to waive certain events of default arising out of noncompliance with certain obligations. Certain financial conditions in the Kapoor Trust guaranty were also amended as a result of the First Amendment. On August 26, 2004, the Company entered into the Second Amendment to the New Credit Facility, which released the Kapoor Trust guaranty and eliminated certain event of default provisions that were related to the Kapoor Trust guaranty. In addition, on August 27, 2004, LaSalle Bank cancelled each of the irrevocable standby letters of credit posted by Dr. Kapoor and Mr. Waney. On October 8, 2004, the Company entered into the Third Amendment to the New Credit Facility (the "Third Amendment"), which waived events of default, associated with the warrants issuance to AEG Partners, LLC ("AEG") and the NeoPharm Promissory Note default. In addition, the Third Amendment amended definitions of the Computation Period and EBITDA to Interest Expense Ratio for covenant calculations.

As more fully described in Note I, the Company issued additional preferred stock and warrants on August 23, 2004. A portion of the related proceeds was used to pay off the Term Loans and pay down the Revolver. The Company continues to maintain the Revolver, which, as of March 31, 2005, had an outstanding balance of zero.

In 2001, the Company entered into a \$5,000,000 convertible subordinated debt agreement (the "Convertible Note Agreement") consisting of a \$3,000,000 Tranche A note ("Tranche A Note") and a \$2,000,000 Tranche B note ("Tranche B Note") with the Kapoor Trust. Borrowing under the Convertible Note Agreement are due December 20, 2006, bear interest at prime plus 3.0% (8.75% as of March 31, 2005), and were issued with detachable warrants to purchase approximately 1,667,000 shares of common stock. Interest cannot be paid under the Convertible Note Agreement until the termination of the New Credit Facility. The convertible feature of the convertible subordinated debt, as amended, allows the Kapoor Trust to immediately convert the subordinated debt plus interest into common stock of the Company, at a price of \$2.28 per share of common stock for Tranche A Note and \$1.80 per share of common stock for Tranche B Note.

The detachable warrants and conversion feature resulted in debt discount of \$3,024,000, equivalent to the value assigned to the warrants and the "intrinsic" value of the conversion option. The discount is being amortized and charged to interest expense over the life of the subordinated debt. Additionally, as the accrued interest on the convertible subordinated debt is also convertible into common stock, it may also result in separately recordable beneficial conversion amounts. Such amounts are recorded when the price of the Company's common stock is higher than the conversion rate when the interest is accrued. The beneficial conversion feature amount related to interest was \$98,000 and \$48,000 for the three months ended March 31, 2005 and 2004, respectively, and was recorded as an increase to paid-in-capital and as additional debt discount amortizable over the remaining term of the convertible subordinated debt. Related debt discount amortization was \$165,000 and \$135,000 for the three months ended March 31, 2005 and 2004, respectively.

In December 2001, the Company entered into a \$3,250,000 five-year loan with NeoPharm, Inc. ("NeoPharm") to fund the Company's efforts to complete its Lyophilization facility located in Decatur, Illinois. This note (the "NeoPharm Promissory Note") was executed in conjunction with a processing agreement that provides NeoPharm with the option of securing at least 15% of the

capacity of the Company's Lyophilization facility each year. Dr. John N. Kapoor, the Company's chairman, is also a director of NeoPharm and holds a substantial equity position in NeoPharm as well as in the Company. On September 30, 2003, the Company defaulted under the NeoPharm Promissory Note as a result of its failure to remove all FDA warning letter sanctions related to the Company's Decatur, Illinois manufacturing facility by June 30, 2003. On September 30, 2003, the Company defaulted under the Convertible Note Agreement as a result of a cross-default to the NeoPharm Promissory Note.

In connection with the Exchange Transaction, the Kapoor Trust and NeoPharm waived all existing defaults under their respective agreements and entered into amended agreements dated October 7, 2003. Interest under the NeoPharm Promissory Note accrues at 1.75% above LaSalle Bank's prime rate (7.50%, based on the 5.75% prime rate as of March 31, 2005). Interest payments under both agreements are currently prohibited under the terms of a subordination arrangement with LaSalle Bank. The amended NeoPharm Promissory Note also requires the Company to make quarterly payments of \$150,000 beginning on the last day of the calendar quarter during which all indebtedness under the New Credit Facility has been paid and the commitment for the senior debt has been terminated. All remaining amounts owed under the amended NeoPharm Promissory Note are payable at maturity on December 20, 2006.

On October 6, 2004, the Company received a notice from NeoPharm, indicating that an event of default had occurred on the outstanding NeoPharm Promissory Note. The notice stated that an event of default was triggered when a processing agreement between NeoPharm and the Company, which was contractually obligated to go into effect on or before October 1, 2004, failed to occur. The processing agreement failed to become effective, in part, because of an inability to remove the sanctions imposed by the FDA on the Company's Decatur manufacturing facility. The event of default under the NeoPharm Promissory Note also triggered a cross-default provision under the Convertible Note Agreement and the New Credit Facility. The Kapoor Trust has waived the cross-default. On October 8, 2004, the Company entered into the Third Amendment to the New Credit Facility (the "Third Amendment"). Among other things, the Third Amendment amended certain of the financial covenants and LaSalle Bank agreed to waive certain events of default arising out of noncompliance with certain obligations, including noncompliance arising from the event of default under the NeoPharm Promissory Note. Pursuant to the subordination agreement with LaSalle Bank, the Company may not make any payments to NeoPharm and NeoPharm may not enforce any remedies against the Company under the NeoPharm Promissory Note, until the senior debt is paid in full and the commitment for the senior debt is terminated. Consequently, NeoPharm cannot take any actions that would have an adverse financial impact to the Company. However, because of its default, the Company has recorded the \$3,250,000 of debt and \$428,000 of accrued interest as current obligations as of March 31, 2005. The Company is currently trying to resolve this matter with NeoPharm.

As part of the Exchange Transaction, the Company issued the 2003 Subordinated Notes to the Kapoor Trust, Arjun Waney and Argent Fund Management, Ltd. The 2003 Subordinated Notes mature on April 7, 2006 and bear interest at prime plus 1.75% (7.50%, based on the 5.75% prime rate as of March 31, 2005), but interest payments are currently prohibited under the terms of a subordination arrangement between LaSalle and the note holders. The 2003 Subordinated Notes are subordinate to the New Credit Facility and the amended NeoPharm Promissory Note but senior to the Convertible Note Agreement. The Company also issued to the holders of the 2003 Subordinated Notes warrants (the "Note Warrants") to purchase an aggregate of 276,714 shares of common stock with an exercise price of \$1.10 per share. All unexercised Note Warrants expire on October 7, 2006. The Company assigned a value of \$336,000 to Note Warrants and recorded this amount in stockholders' equity and as a discount, along with the spread between the face value of the debt and its initial recorded value as described above, on the 2003 Subordinated Notes. Related debt discount amortization was \$88,000 and \$88,000 for the three months ended March 31, 2005 and 2004, respectively.

In June 1998, the Company entered into a \$3,000,000 mortgage agreement with Standard Mortgage Investors, LLC of which there were outstanding borrowings of \$1,225,000 and \$1,546,000 at March 31, 2005 and 2004, respectively. The principal balance is payable over 10 years, with the final payment due in June 2008. The mortgage note bears a fixed interest rate of 7.375% and is secured by the real property located in Decatur, Illinois.

As part of the Exchange Transaction, the Company recorded \$1,627,000 as deferred financing costs, including the value of the Guaranty Warrants. This amount was being amortized as a component of interest expense over the life of the related debt or guarantee. With the retirement of the Term Loans and related guarantee terminations in the third quarter of 2004, the remaining guarantee warrant amortization and deferred financing costs not related to the Revolver were charged to interest expense, resulting in \$245,000 of additional amortization. Deferred financing costs relating to the Revolver continue to be amortized. Including these adjustments, amortization for the three months ended March 31, 2005 and 2004 was \$24,000 and \$349,000, respectively.

#### **NOTE I — PREFERRED STOCK**

The Series A Preferred Stock accrues dividends at a rate of 6.0% per annum, which rate is fully cumulative, accrues daily and compounds quarterly. While the dividends could be paid in cash at the Company's option, such dividends are currently being deferred and added to the Series A Preferred Stock balance. All shares of Series A Preferred Stock have liquidation rights in preference over junior securities, including the common stock, and have certain anti-dilution protections. The Series A Preferred Stock and unpaid dividends are convertible at any time into shares of common stock at an exercise price of \$0.75 per share. All shares of Series A Preferred Stock shall convert to shares of common stock on the earlier to occur of (i) October 8, 2006 and (ii) the date on which the closing price per share of common stock for at least 20 consecutive trading days immediately preceding such date exceeds \$4.00 per share. Until the Company's stockholders approved certain provisions regarding the Series A Preferred Stock (the "Stockholders Approval"), which occurred in July 2004, the Series A Preferred Stock had a mandatory redeemable feature in October 2011.

The initially recorded amount of the Series A Preferred Stock, as described in Note H, was \$5,174,000 below its stated value. The Company, up through the Stockholders Approval date, had been accreting this difference over the time period from issuance to the mandatory redemption date in October 2011. Accretion in 2004 and 2003 was \$267,000 and \$220,000, respectively.

Pursuant to FASB No. 150, "Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity", as amended, the Series A Preferred Stock was originally reflected as a liability because of its mandatory redemption feature. That characterization remained through July 8, 2004 and as such, dividends have been reflected as interest expense in the statement of operations through July 8, 2004. As a result of the Stockholders Approval on July 8, 2004, the carrying value of the Series A Preferred Stock was reclassified into stockholders' equity and future accretion and dividends are reflected as adjustments to accumulated deficit and are shown in the financial statements as impacting income (loss) available to common stockholders. Additionally, and in accordance with EITF Abstract No. 00-27, the Company also recorded in July 2004 the value of the conversion option imbedded at issuance in each share of Series A Preferred Stock, subject to limitations described in the EITF abstract. That value, approximately \$20,874,000, reduced the carrying value of the Series A Preferred Stock to near zero with an offsetting credit to common stock. The carrying value of the Series A Preferred Stock was then adjusted to its full aggregated stated value, plus unpaid dividends (approximately \$26,552,000) with a charge directly to accumulated deficit. That charge did not impact net earnings for the third quarter, but substantially reduced earnings available to common stockholders and earnings per share for that period.

On August 23, 2004, the Company issued an aggregate of 141,000 shares of Series B 6.0% Participating Preferred Stock ("Series B Preferred Stock") at a price of \$100 per share, convertible into common stock at a price of \$2.70 per share, to certain investors, with warrants to purchase 1,566,667 additional shares of common stock exercisable until August 23, 2009, with an exercise price of \$3.50 per share ("the "Series B Warrants") The net proceeds to the Company after payment of investment banker fees and expenses and other transaction costs of approximately \$1,056,000 were approximately \$13,044,000. A portion of these proceeds were used to pay off the Term Loans and reduce the Revolver to zero. Remaining proceeds are available for working capital and other general corporate purposes, including validation testing of the Company's lyophilization facility. In accounting for the issuance of the Series B Preferred Stock and Series B Warrants, the Company recorded additional charges directly to accumulated deficit of \$5,998,000. That charge did not impact net earnings for the third quarter, but substantially reduced earnings available to common stockholders and earnings per share for that period.

Series B Preferred Stock accrues dividends at a rate of 6.0% per annum, which rate is fully cumulative, accrues daily and compounds quarterly. While the dividends could be paid in cash at the Company's option, such dividends are currently being deferred and added to the Series B Preferred Stock balance. Each share of Series B Preferred Stock, and accrued and unpaid dividends with respect to each such share, is convertible by the holder thereof at any time into shares of common stock at an exercise price of \$2.70 per share. The Company has the option of converting all shares of Series B Preferred Stock into shares of the Company's common stock on any date after August 23, 2005 as to which the closing price per share of the common stock for at least 20 consecutive trading days immediately preceding such date exceeds \$5.00 per share.

As required under the terms of the Series B Preferred Stock, the Company, in October 2004, completed a registration with the Securities and Exchange Commission of the common shares into which the Series B Preferred Stock is convertible. Due to that registration, the holders of the Series B Preferred Stock can no longer put their shares back to the Company. Accordingly, the Series B Preferred Stock was reclassified into equity from debt in October 2004.

Immediately after the private placement, the purchasers of Series B Preferred Stock held approximately 31% of the aggregate voting rights represented by outstanding shares of common stock and Preferred Stock. After the private placement and assuming the exercise of all outstanding conversion rights, warrants and options to acquire common stock, the purchasers of Series B Preferred Stock would hold approximately 9% of the common stock, on a fully-diluted basis. Prior to the private placement, the purchasers of

Series B Preferred Stock held approximately 5% of the outstanding voting securities and would have held approximately 18% of the common stock on a fully-diluted basis.

**NOTE J — EARNINGS PER COMMON SHARE**

Basic net income (loss) per common share is based upon weighted average common shares outstanding. Diluted net income (loss) per common share is based upon the weighted average number of common shares outstanding, including the dilutive effect of stock options, warrants and convertible debt using the treasury stock and if converted methods. However, for the three-month periods ended March 31, 2005 and 2004, the assumed exercise or conversion of any of these securities would be anti-dilutive; and, accordingly, diluted loss per share equals basic loss per share for each period.

The number of such shares as of March 31, 2005 and March 31, 2004 subject to warrants, convertible debt, and convertible preferred stock was 55,445,000 and 12,726,000, respectively, and subject to stock options was 4,046,000 and 3,115,000, respectively.

**NOTE K — INDUSTRY SEGMENT INFORMATION**

The Company classifies its operations into three business segments, ophthalmic, injectable and contract services. The ophthalmic segment manufactures, markets and distributes diagnostic and therapeutic pharmaceuticals. The injectable segment manufactures, markets and distributes injectable pharmaceuticals, primarily in niche markets. The contract services segment manufactures products for third party pharmaceutical and biotechnology customers based on their specifications. Selected financial information by industry segment is presented below (in thousands).

|                          | <b>THREE MONTHS ENDED MARCH 31,</b> |                   |
|--------------------------|-------------------------------------|-------------------|
|                          | <b>2005</b>                         | <b>2004</b>       |
| <b>REVENUES</b>          |                                     |                   |
| Ophthalmic               | \$ 5,096                            | \$ 7,435          |
| Injectable               | 2,901                               | 2,319             |
| Contract Services        | 2,184                               | 1,906             |
| Total revenues           | <u>\$ 10,181</u>                    | <u>\$ 11,660</u>  |
| <b>GROSS PROFIT</b>      |                                     |                   |
| Ophthalmic               | \$ 1,802                            | \$ 3,456          |
| Injectable               | 1,224                               | 406               |
| Contract Services        | 317                                 | 156               |
| Total gross profit       | 3,343                               | 4,018             |
| Operating expenses       | <u>5,089</u>                        | <u>3,908</u>      |
| Operating income (loss)  | (1,746)                             | 110               |
| Interest expense         | <u>(526)</u>                        | <u>(1,327)</u>    |
| Loss before income taxes | <u>\$ (2,272)</u>                   | <u>\$ (1,217)</u> |

The Company manages its business segments to the gross profit level and manages its operating and other costs on a company-wide basis. Intersegment activity at the gross profit level is minimal. The Company does not identify assets by segment for internal purposes, as certain manufacturing and warehouse facilities support more than one segment.

**NOTE L – COMMITMENTS AND CONTINGENCIES**

The FDA issued a warning letter to us in October 2000 following a routine inspection of our Decatur manufacturing facility. An FDA warning letter is intended to provide notice to a company of violations of the laws administered by the FDA and to elicit voluntary corrective action. Until the violations identified in the warning letter are corrected, the FDA frequently will withhold approval of any marketing applications (ANDAs, NDAs) submitted by the company and will share contents of the warning letter with other government agencies (for example, the Veterans Administration or Department of Defense) that may contract to purchase

products from the company. Failure to take effective corrective actions can result in the FDA enforcement action such as monetary fines, seizure of products, or injunction that could suspend manufacturing and compel recall of product.

The warning letter addressed several deviations from regulatory requirements identified during the inspection and requested that we take corrective actions. Since then, additional FDA inspections in 2002 and 2003 found that certain deviations continued unresolved and identified additional deviations. We have invested approximately \$2,000,000 in improved cleaning validation and enhanced process controls and have developed a comprehensive corrective action plan. We have been in regular communications with the FDA and have provided periodic reports of our progress in making corrections. In 2004, the FDA conducted two additional inspections of our Decatur manufacturing facility. The first, concluded on April 7, 2004, identified several deviations for which we provided the FDA with proposed corrective actions. The FDA initiated no enforcement action. Rather, the FDA notified us that another "confirmatory" inspection would be made to determine whether the deviations identified have been corrected. The confirmatory inspection concluded November 19, 2004. It identified deviations and we have responded to the FDA with corrective actions. We have met with the FDA and provided the status of our corrective actions. The FDA has advised us that the findings of the latest inspection are under review and a final agency decision on our regulatory status has not been made. The FDA may conclude that the findings of the latest inspection do not represent significant deviations and our voluntary corrective actions are sufficient, in which case, we can expect the FDA to remove the sanctions of the warning letter. If, however, the FDA concludes that the deviations are significant and our voluntary actions have not been adequate, it may initiate enforcement action including the following: (1) maintain the warning letter sanctions or issue a new warning letter with sanctions; (2) seek a court-ordered injunction which may include suspension of some or all operations at the Decatur manufacturing facility until compliance is achieved, recall of certain products, potential monetary penalties or other sanctions; or (3) seize our products produced at the Decatur manufacturing facility. Any of these actions could significantly impair our ability to continue to manufacture and distribute products, generate cash from our operations and may result in a covenant violation under our senior debt.

To date, the noncompliance of our Decatur manufacturing facility has prevented us from developing additional products at Decatur, some of which cannot be developed at our other facility. The inability to fully use our Decatur manufacturing facility has had a material adverse effect on our business, financial condition and results of operations.

Unless and until we correct the FDA deviations at our Decatur manufacturing facility, it is doubtful that the FDA will approve any applications that may be submitted by us for products to be manufactured in Decatur. This has adversely impacted, and is likely to continue to adversely impact our ability to grow sales. See Part II. Other Information Item 1. "Legal Proceedings".

On March 6, 2002, we received a letter from the United States Attorney's Office, Central District of Illinois, Springfield, Illinois, advising us that the DEA had referred a matter to that office for a possible civil legal action for alleged violations of the Comprehensive Drug Abuse Prevention Control Act of 1970, 21 U.S.C. § 801 et. seq. ("Comprehensive Drug Act") and regulations promulgated thereunder. The alleged violations relate to record keeping and controls surrounding the storage and distribution of controlled substances. On November 6, 2002, we entered into a Civil Consent Decree with the DEA (the "Civil Consent Decree"). Under terms of the Civil Consent Decree, without admitting any of the allegations in the complaint from the DEA, we agreed to pay a fine of \$100,000, upgrade our security system and to remain in substantial compliance with the Comprehensive Drug Act. If we failed to remain in substantial compliance during the two-year period following the entry of the Civil Consent Decree, we, in addition to other possible sanctions, might have been held in contempt of court and ordered to pay an additional \$300,000 fine. We completed the upgrades to our security system in 2003 and have received no further notice from the DEA in connection with the Civil Consent Decree. The two-year compliance period lapsed on November 6, 2004. We were inspected by the DEA in February 2005 and the DEA has not informed us of any further violations.

On August 9, 2003, Novadaq notified the Company that it had requested arbitration related to a dispute between the Company and Novadaq regarding the issuance of a Right of Reference. The Company would have been obligated to provide a Right of Reference under the January 4, 2002 Supply Agreement between the two companies. The Company did not believe it was obligated to provide the Right of Reference which, if provided, would likely reduce the required amount of time for clinical trials and reduce Novadaq's cost of developing a product for macular degeneration. The Company was also contemplating the possible development of a separate product for macular degeneration, which, if developed, could face competition from any product developed by Novadaq. On June 4, 2004, an agreement was reached between the Company and Novadaq, whereby the Company would provide the requested Right of Reference to Novadaq in exchange for Novadaq's repurchase of the Company's holdings in Novadaq at a purchase price of \$2,000,000. Proceeds were received in July 2004, used to reduce outstanding debt obligations, and a gain of approximately \$1,287,000 was reported during the third quarter of 2004.

On September 25, 2003, the Company consented to the entry of an administrative cease and desist order to resolve the issues arising from the Securities and Exchange Commission ("SEC") staff's investigation related to its allegations that internal control and books and records deficiencies prevented the Company from accurately recording, reconciling and aging its accounts receivable which had resulted in a 2003 restatement of the Company's financial statements for 2000 and 2001 to record a \$7,500,000 increase to the allowance for doubtful accounts as of December 31, 2000, which it had originally recorded as of March 31, 2001. Without the Company admitting or denying the findings set forth therein, the consent order finds that the Company failed to keep accurate books and records and failed to devise and maintain a system of adequate internal accounting controls with respect to its accounts receivable in violation of Sections 13(b)(2)(A) and 13(b)(2)(B) of the Exchange Act. The consent order did not impose a monetary penalty against the Company or require any additional restatement of the Company's financial statements. The consent order contained additional commitments by the Company related to certain corporate governance actions and reporting. The Company has met each commitment.

On October 8, 2003, the Company, pursuant to the terms of the Letter Agreement dated September 26, 2002 between the Company and AEG Partners LLC ("AEG"), terminated AEG. On August 2 and 3, 2004, the Company and AEG participated in a mandatory and binding arbitration hearing. The arbitrator took the matter under submission and rendered his decision dated August 19, 2004, which was received on August 23, 2004. The arbitrator's decision directed the following: (1) payment to AEG for the sum of \$300,000, plus interest of 5% per annum from October 7, 2003 (approximately \$13,479), (2) issuance of warrants to AEG to purchase 1,250,000 shares of our common stock at an exercise price of \$0.75 per share, and (3) denial of AEG's request that the Company pay AEG's attorneys' fees and costs. As a result of the arbitrator's decision, the Company reported a one-time net gain of approximately \$295,000 in the third quarter of 2004. If AEG decides to exercise all of the AEG Warrants, the Company will receive \$937,500 at the above-noted exercise price of \$0.75 per share. It was determined none of the anti-dilution provisions in our outstanding securities were triggered by the issuance of the AEG Warrants.

On February 23, 2004, we were sued in the United States District Court for the District of Arizona for damages resulting from the death of an Arabian show horse allegedly injected with the drug Sarapin in the summer of 2003. The case was dismissed with prejudice on January 7, 2005.

The Company is a party in other legal proceedings and potential claims arising in the ordinary course of its business. The amount, if any, of ultimate liability with respect to such matters cannot be determined. Despite the inherent uncertainties of litigation, management of the Company at this time does not believe that such proceedings will have a material adverse impact on the financial condition, results of operations, or cash flows of the Company.

#### **NOTE M — BUSINESS ALLIANCES**

On April 21, 2004, the Company announced the signing of a memo of understanding with Strides Arcolab Limited ("Strides"), a pharmaceutical manufacturer based in India. As a result of negotiations following the execution of the memo of understanding, on September 22, 2004, the Company entered agreements with Strides for the development, manufacturing and marketing of grandfathered products, patent-challenging products and ANDA products for the U.S. hospital and retail markets. The Joint Venture Company formed by Strides and us is a Delaware limited liability company. Strides will be responsible for developing, manufacturing and supplying products under an OEM Agreement between it and the Joint Venture Company. The Company will be responsible for sales and marketing of the products under an exclusive Sales and Marketing Agreement with the Joint Venture Company. The Company and Strides each own 50% of the Joint Venture Company with equal management representation. Each partner was to contribute \$1,250,000 in capital, to be used to finance the preparation of ANDAs by Strides. As of December 31, 2004, the Company had funded its \$1,250,000 capital contribution to the Joint Venture Company. An additional contribution of \$250,000 for ANDA preparation by Strides was advanced in January 2005. In February 2005, the Company loaned an additional \$1,250,000 to the Joint Venture Company that was advanced to Strides to finance its capital contribution. Under the OEM Agreement, the respective contributions were advanced to Strides to finance the preparation, development and filing with the FDA of ANDAs for generic drugs based on a mutually agreed development schedule. The Joint Venture Company will have exclusive rights to FDA approved generic drugs within the United States hospital, medical clinic, physician group and other wholesale drug markets. If within a mutually agreed time period, Strides' manufacturing facilities in India have not received a satisfactory cGMP inspection by the FDA, which remains current, and twelve ANDAs for products developed by Strides at its manufacturing facilities in India have not been submitted to the FDA, among other things, the Company will become the sole owner of the Joint Venture Company and the Joint Venture Company will be entitled to draw on a \$1,250,000 letter of credit that was established by Strides from an Indian bank that is confirmed by a U.S. bank. On the other hand, if these conditions are met, and if both managers agree, the Company and Strides may make additional equivalent capital contributions to finance subsequent ANDA preparation costs under a similar arrangement to its initial capital



contributions, including an additional loan by the Company to the Joint Venture Company to finance Strides' capital contribution. Pursuant to the requirements of FIN 46(R), because the Company funded Strides' capital contribution (even though that funding is supported by a letter of credit ultimately in favor of the Company), the Company is required to consolidate the Joint Venture Company until such time as the Company's loan is collected. Those collections are expected to occur when the Joint Venture Company begins to sell the products that Strides is currently contracted to develop into ANDAs. Accordingly, in the consolidated financial statements of the Company, its contributions to the Joint Venture Company are eliminated. The total advance of the \$2,750,000 from the Joint Venture Company to Strides is reflected as another long-term asset and is being amortized over the mutually agreed upon development schedule period. Amortization expense in the fourth quarter of 2004 was \$375,000. The first quarter 2005 amortization expense (reflected in Research & Development expense) was \$688,000. The Company has not and will not record a minority interest receivable to recognize Strides' 50% portion of the Joint Venture Company losses until such time as Strides has contributed capital at risk. Because of this, the Company has recorded 100% of the Joint Venture Company losses in the Company's results of operations.

On October 15, 2004, the Company entered into an agreement with Serum Institute of India, Ltd. ("Serum"), in an exclusive drug development and distribution agreement for oncology and other injectable drug products for the United States and Canada. Under the terms of the five-year agreement Serum will develop and manufacture certain drug products and the Company will be responsible for all regulatory submissions, will own the ANDAs and will buy the products from Serum under a negotiated transfer price arrangement, which guarantees minimum annual purchases of \$1,000,000 per product in order to maintain exclusivity. Additionally, the Company will market and sell the products in the United States and Canada under the Company's label.

On November 16, 2004, the Company entered into an agreement with Hameln Pharmaceuticals ("Hameln"), a private German pharmaceuticals company, to license and supply to the Company two Orphan Drug NDA's: Calcium-DTPA and Zinc-DTPA. The two drugs were approved on August 11, 2004 by the FDA, and are indicated as antidotes for the treatment of radioactive poisoning. Sales for the two drugs commenced in the fourth quarter of 2004. Under the agreement, Hameln provided the Company an exclusive license for an initial term of five years with automatic successive two-year extensions. The Company has paid a one-time 1,550,000 Euro (\$2,095,000) license fee, which is reflected as an intangible asset being amortized over a seven year period. The Company is responsible for marketing and distributing both drugs in the U.S. and Canada. The Company will pay Hameln the greater of 50% of its gross revenues or a minimum transfer price for the product. Hameln will be responsible for the manufacturing of both drugs for the Company. The Company will be responsible for the payment of any annual FDA establishment fees and for the cost of any post approval studies.

#### **NOTE N — CUSTOMER CONCENTRATION**

AmeriSourceBergen Health Corporation ("AmeriSource"), Cardinal Health, Inc. ("Cardinal") and McKesson Drug Company ("McKesson") are all distributors of the Company's products, as well as suppliers of a broad range of health care products. These three customers accounted for 54% and 43% of Akorn's gross revenues and 40% and 29% of net revenues for the three months ended March 31, 2005 and 2004, respectively. They accounted for approximately 58% and 49% of the gross accounts receivable balances as of March 31, 2005 and 2004, respectively.

No other customer accounted for more than 10% of gross sales, net revenues or gross trade receivables for the indicated dates and periods.

If sales to any of AmeriSource, Cardinal or McKesson were to diminish or cease, the Company believes that the end users of its products would find little difficulty obtaining the Company's products either directly from the Company or from another distributor.

**Item 2.**

**AKORN, INC.  
MANAGEMENT'S DISCUSSION AND ANALYSIS  
OF FINANCIAL CONDITION AND  
RESULTS OF OPERATIONS**

**FORWARD-LOOKING STATEMENTS AND FACTORS AFFECTING FUTURE RESULTS**

Certain statements in this Form 10-Q constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act. When used in this document, the words "anticipate," "believe," "estimate" and "expect" and similar expressions are generally intended to identify forward-looking statements. Any forward-looking statements, including statements regarding the intent, belief or expectations of Akorn or its management are not guarantees of future performance. These statements involve risks and uncertainties and actual results may differ materially from those in the forward-looking statements as a result of various factors, including but not limited to:

- Our ability to resolve our FDA compliance issues at our Decatur, Illinois manufacturing facility;
- Our ability to avoid defaults under debt covenants;
- Our ability to generate cash from operations sufficient to meet our working capital requirements;
- Our ability to obtain additional funding to operate and grow our business;
- The effects of federal, state and other governmental regulation of our business;
- Our success in developing, manufacturing and acquiring new products;
- Our success in developing, manufacturing and distributing new products through our joint venture and licensing agreements;
- Our ability to bring new products to market and the effects of sales of such products on our financial results;
- The effects of competition from generic pharmaceuticals and from other pharmaceutical companies;
- Availability of raw materials needed to produce our products; and
- Other factors referred to in this Form 10-Q, our Form 10-K and our other Securities and Exchange Commission filings.

**RESULTS OF OPERATIONS**

**THREE MONTHS ENDED MARCH 31, 2005 COMPARED TO 2004**

The following table sets forth, for the periods indicated, revenues by segment, excluding intersegment sales (in thousands):

|                           | <b>THREE MONTHS ENDED MARCH 31,</b> |                  |
|---------------------------|-------------------------------------|------------------|
|                           | <b>2005</b>                         | <b>2004</b>      |
| Ophthalmic segment        | \$ 5,096                            | \$ 7,435         |
| Injectable segment        | 2,901                               | 2,319            |
| Contract Services segment | 2,184                               | 1,906            |
| Total revenues            | <u>\$ 10,181</u>                    | <u>\$ 11,660</u> |

Consolidated revenues decreased 12.7% in the quarter ended March 31, 2005 compared to the same period in 2004.

Ophthalmic segment revenues decreased 31.5%, primarily due to the stronger sales of our diagnostic and therapeutic products early in 2004. The Injectable segment increase of 25.1% for the quarter compared with the same period in 2004 was due to significantly higher volumes associated with our anesthesia and analgesics products, as well as the re-introduction of our Indigo Carmine product. Contract Services revenues increased by 14.6% reflecting a steady, but moderate recovery towards pre-2001 revenue levels which, we believe, have not been experienced due to continued customer concerns about the status of the ongoing FDA compliance matters at our Decatur facility.

Unless and until we correct the FDA deviations at our Decatur manufacturing facility, it is doubtful the FDA will approve any applications that may be submitted by us for products to be manufactured in Decatur. This has adversely impacted, and is likely to continue to adversely impact our ability to grow sales. See Item 1. Financial Statements, Note L – “Commitments and Contingencies” and Part II. Other Information – Item 1. – “Legal Proceedings.”

Consolidated gross margin was 32.8% for the first quarter of 2005 as compared to a gross margin of 34.5% in the same period a year ago due to lower sales in the higher margin diagnostic segment during the first quarter 2005, as well as a lower margin in our Therapeutic product segment due to product sales mix. We continue to seek margin enhancement opportunities through our product offerings as well as through cost reductions at our operating facilities.

Selling, general and administrative (“SG&A”) expenses increased 16.3%, to \$3,368,000 from \$2,896,000, during the quarter ended March 31, 2005 as compared to the same period in 2004. The key components of this increase in 2005 were significant bad debt recoveries (\$362,000 benefit) in 2004.

Amortization and write-down of intangible assets decreased to \$379,000 from \$683,000 or 44.5% during the quarter ended March 31, 2005 as compared to the same period in 2004, due to \$325,000 in impairment charges taken in 2004.

Research and development (“R&D”) expense increased 307.9% in the quarter, to \$1,342,000 from \$329,000 for the same period in 2004 mainly due to the \$688,000 expense amortization for the Joint Venture Company and \$185,000 of lyophilization development/validation expenses in 2005.

Interest expense for the first quarter of 2005 was \$526,000 versus \$1,327,000, a 60.4% decrease compared to the same period in the prior year. The majority of this decrease is due to Series A dividends being classified as interest in 2004, but not in 2005, as well as interest for bank debt and higher refinancing cost amortization incurred in 2004.

For the three-month period ended March 31, 2005, we recorded federal tax expense of \$15,000 in 2005. No provision was required in the first quarter of 2004.

We reported a net loss of \$2,287,000 for the three months ended March 31, 2005, versus a net loss of \$1,217,000 for the same period in 2004.

## **FINANCIAL CONDITION AND LIQUIDITY**

### **Overview**

As of March 31, 2005, we had net working capital of \$11,503,000 versus net working capital of \$11,233,000 at December 31, 2004.

During the three-month period ended March 31, 2005, we used \$1,075,000 in cash from operations, primarily due to the net loss, a decrease in accounts payable and a \$1,500,000 advance to our joint venture partner (Strides Arcolab) to develop ANDAs, offset by non-cash adjustments for amortization and depreciation, and by a decrease in accounts receivable. Investing activities during the three-month period ended March 31, 2005 include a \$75,000 licensing fee, as well as \$83,000 of capital expenditures primarily related to the lyophilized (freeze-dried) pharmaceuticals manufacturing line expansion. Financing activities added \$342,000 in cash, due to the proceeds from stock option and warrant exercises.

During the period ended March 31, 2004, we used \$837,000 in cash from operations, primarily due to an increase in accounts receivables and inventories, offset in part by an increase in accounts payable. Investing activities during the period ended March 31, 2004 include \$228,000 primarily related to the lyophilized (freeze-dried) pharmaceuticals manufacturing line expansion. Financing activities added \$1,070,000 in cash during the period ended March 31, 2004 primarily through the increase of our new revolving credit line.

On October 7, 2003, a group of investors (the “Investors”) purchased all of our then outstanding senior bank debt at a discount and exchanged such debt with us (the “Exchange Transaction”) for (i) 257,172 shares of our Series A Preferred Stock, (ii) subordinated promissory notes in the aggregate principal amount of approximately \$2,767,000 (the “2003 Subordinated Notes”), (iii) warrants to

purchase an aggregate of 8,572,400 shares of our common stock with an exercise price of \$1.00 per share (“Series A Warrants”), and (iv) \$5,473,862 in cash from the proceeds of the term loan under the New Credit Facility described in a following paragraph. The 2003 Subordinated Notes and cash were issued by us to (a) The John N. Kapoor Trust dated 9/20/89 (the “Kapoor Trust”), the sole trustee and sole beneficiary of which is Dr. John N. Kapoor, our Chairman of the Board of Directors and the holder of a significant stock position in Akom, (b) Arjun Waney, a director and the holder of a significant stock position in Akom, and (c) Argent Fund Management Ltd., for which Mr. Waney serves as Chairman and Managing Director and 52% of which is owned by Mr. Waney. We also issued to the holders of the 2003 Subordinated Notes (the “Note Warrants”) warrants to purchase an aggregate of 276,714 shares of common stock with an exercise price of \$1.10 per share and paid a portion of the legal fees of the Investors.

Simultaneously with the consummation of the Exchange Transaction, we entered into a credit agreement with LaSalle Bank National Association (“LaSalle Bank”) providing us with two Term Loans (collectively, the “Term Loans”) which consisted of a \$5,500,000 term loan A, and a \$1,500,000 term loan B, totaling \$7,000,000, and a revolving line of credit of up to \$5,000,000 (the “Revolver”) to provide for working capital needs (the “New Credit Facility”) secured by substantially all of our assets. Our obligations under the New Credit Facility were guaranteed by the Kapoor Trust and Mr. Waney. In exchange for this guaranty, we issued additional warrants (the “Guaranty Warrants”) to purchase 880,000 and 80,000 shares of common stock to the Kapoor Trust and Mr. Waney, respectively, with an exercise price of \$1.10 per share, and agreed to issue to each of them, on each anniversary of the date of the consummation of the Exchange Transaction, warrants to purchase an additional number of shares of common stock equal to 0.08 multiplied by the principal dollar amount of the our indebtedness then guaranteed by them under the New Credit Facility.

The primary impact of the Exchange Transaction and New Credit Facility on our liquidity and capital resources was as follows:

- The then-existing default on our senior bank debt with Northern Trust was eliminated, as the associated debt was retired;
- The then-existing defaults on our subordinated loans from NeoPharm, Inc. and the Kapoor Trust were waived;
- The total amount of our senior bank debt was reduced from \$37,731,000 as of September 30, 2003 to \$7,000,000 as of the closing of those transactions;
- The interest rate on our senior bank debt was reduced from prime plus 3.0% to prime plus 1.75% for the new term loans and prime plus 1.50% for the new revolving line of credit;
- We obtained a revolving line of credit of up to \$5,000,000 and an additional \$1,000,000 pursuant to the term loan under the New Credit Facility to meet working capital needs and fund future operations;
- We issued additional subordinated debt with an aggregate principal amount of approximately \$2,767,000, which accrues interest at a rate of prime plus 1.75% per annum;
- We issued Series A Preferred Stock with an aggregate initial stated value of \$25,717,200, which accrues dividends at a rate of 6.0% per annum (“Series A Preferred Stock”); and
- The Investors acquired the Series A Preferred Stock and Series A Warrants that, as of the closing, had the right to acquire approximately 44,000,000 shares of our common stock, or more than 220% of the outstanding shares of common stock prior to the closing.

On August 23, 2004, we completed a private placement to certain investors of 141,000 shares of our Series B Preferred Stock at a price of \$100 per share, convertible into common stock at a price of \$2.70 per share (“Series B Preferred Stock”), with warrants to purchase 1,566,667 additional shares of our common stock exercisable until August 23, 2009, with an exercise price of \$3.50 per share (“Series B Warrants”). The net proceeds to us after payment of investment banker fees and expenses and other transaction costs of approximately \$1,056,000 were approximately \$13,044,000.

A portion of the net proceeds of the private placement paid off the outstanding debt from LaSalle Bank. The remainder of the net proceeds is being used for working capital and general corporate purposes. Among other things, the proceeds will pay for the validation testing of our new lyophilization facility. Validation and approval of the lyophilization facility by the FDA are anticipated in late 2005, and manufacturing capabilities for lyophilized products are projected to be in place by mid-2006. On August 26, 2004, in connection with the payoff of our outstanding debt under the New Credit Facility, we and LaSalle Bank amended the New Credit Facility to release the guaranty of the Kapoor Trust and Mr. Waney effective as of such date provided that if prior to November 24,

2004 there is then pending a petition in bankruptcy court against us or our subsidiary and there is then existing a claim that all or any portion of the payoff amount is a fraudulent transfer or a preferential payment, or should otherwise be set aside, then the guaranty shall be reinstated. As a result of the release of the guaranty, we did not issue additional warrants to the Kapoor Trust or Mr. Waney on the anniversary date of the Exchange Transaction.

The Exchange Transaction, coupled with the private placement of The Series A Preferred Stock and Series B Preferred Stock, have substantially reduced our overall debt from \$45,755,000 as of September 30, 2003 to \$10,453,000 as of March 31, 2005, and positioned us to improve our operating results.

As of March 31, 2005, we had \$3,219,000 in cash and \$5,000,000 of undrawn availability under the New Credit Facility with LaSalle Bank. We believe that our realigned balance sheet, access to our line of credit and cash flows from operations will be sufficient to operate our business for the next twelve months.

If our cash flow from operations and current line of credit are not sufficient to fund the operation of our business, we may be required to seek additional financing. Such additional financing may not be available when needed or on terms favorable to us and our stockholders. Any such additional financing, if obtained, will likely require the granting of rights, preferences or privileges senior to those of the common stock and result in additional dilution of the existing ownership interests of the common stockholders.

#### **FDA Compliance Matters**

As described in more detail in Item I. Financial Statements, Note L — “Commitment and Contingencies,” we continue to be subject to potential claims by the FDA. We have submitted to the FDA and have implemented a plan for comprehensive corrective actions at our Decatur, Illinois manufacturing facility and are seeking to resolve our ongoing compliance matters. However, an unfavorable outcome may have a material impact on our operations and our financial condition, results of operations and/or cash flows and may constitute a covenant violation under the New Credit Facility, any or all of which could have an adverse effect on our liquidity.

#### **Facility Expansion**

We are in the process of completing an expansion of our Decatur, Illinois manufacturing facility to add capacity to provide lyophilization manufacturing services, a manufacturing capability we currently do not have. Subject to, among other things, our ability to generate operating cash flow or to obtain new financing for future operations, validation and approval of the lyophilization facility by the FDA is anticipated in late 2005. Manufacturing capabilities for lyophilized products are projected to be in place by mid-2006.

As of March 31, 2005, we had spent approximately \$18,564,000 on the lyophilization expansion and anticipate the need to spend approximately \$2,000,000 of additional funds (excluding capitalized interest) to complete the expansion. The majority of the additional spending will be focused on validation testing of the lyophilization facility as the major capital equipment items are currently in place. To this end, we expect to use a portion of the proceeds we obtained from the recent sale of our Series B Preferred Stock to help fund validation efforts for the lyophilization facility and to fund the development of an internal ANDA lyophilized product pipeline.

#### **Strategic Business Alliances**

On January 10, 2005 we and Apotex Corporation (“Apotex”), the largest Canadian-owned pharmaceutical manufacturer, entered into an agreement for the purchase, supply, and marketing of select ophthalmic pharmaceutical products in the United States health care market. Under the terms of the agreement, Apotex will manufacture ophthalmic products in finished dosage forms for us, and we will market these products under our label. The agreement includes ophthalmic products currently available from Apotex, as well as select products in Apotex’s ophthalmic research and development pipeline.

On February 17, 2005 we announced that we entered into an agreement to license a patent entitled “M-EDTA Pharmaceutical Preparations of Uses Thereof” (the “Invention”) and related technology rights invented by Issam I. Raad and Robert Sheretz. The license grants us the exclusive rights to develop and market the Invention. Previously, on August 24, 2004 we announced that we had entered into an Option Agreement to license the patent. The Invention is targeted at the prevention of intravascular catheter-related infections and occlusions. We paid a license fee of \$100,000 to M.D. Anderson and will fund all expenses necessary to commercialize the product. We are obligated to pay a milestone license fee upon FDA approval and royalties for the life of the patent.

On April 13, 2005 we announced the signing of a purchase and supply agreement with a company that will provide seventeen anti-infective pharmaceutical products. Under the terms of the agreement, we will market these products under our label.

### **New Credit Facility**

As described in Item 1. Financial Statements, in Note H – “Financing Arrangements”, we entered into a New Credit Facility with LaSalle Bank in 2003. The New Credit Facility consists of the Term Loans, as well as the Revolver secured by substantially all of our assets. The New Credit Facility matures on October 7, 2005. The Term Loans carried interest at prime plus 1.75% and required principal payments of \$195,000 per month commencing October 31, 2003, with the payments first to be applied to term loan B. The Revolver bears interest at prime plus 1.50%. The Term Loans and the Revolver were paid off with the proceeds from our Series B Preferred Stock and we had a zero balance on the Revolver at March 31, 2005.

Availability under the Revolver is based on eligible accounts receivable inventory and machinery and equipment. The New Credit Facility contains certain restrictive covenants including but not limited to certain financial covenants such as EBITDA to interest expense and Senior Debt to EBITDA ratios. If we are not in compliance with the covenants of the New Credit Facility, LaSalle Bank has the right to declare an event of default and all of the outstanding balances owed under the New Credit Facility would become immediately due and payable. The New Credit Facility also contains subjective covenants providing that we would be in default if, in the judgment of the lenders, there is a material adverse change in our financial condition. We negotiated an amendment to the New Credit Facility effective December 31, 2003 that clarified certain covenant computations and waived certain technical violations. Because the New Credit Facility also requires us to maintain our deposit accounts with LaSalle, the existence of these subjective covenants, pursuant to EITF Abstract No. 95-22, require that we classify outstanding borrowings under the Revolver as a current liability (zero as of March 31, 2005).

On August 13, 2004, we entered into the First Amendment to the New Credit Facility (the “First Amendment”). Among other things, the First Amendment amended certain of our financial covenants and LaSalle Bank agreed to waive certain events of default arising out of our noncompliance with certain of our obligations. Certain financial conditions in the Kapoor Trust guaranty were also amended as a result of the First Amendment.

On August 26, 2004, we entered into the Second Amendment to the New Credit Facility (the “Second Amendment”), which released the Kapoor Trust guaranty and eliminated certain event of default provisions that were related to the Kapoor Trust guaranty. In addition, on August 27, 2004, LaSalle Bank cancelled each of the irrevocable standby letters of credit posted by Dr. Kapoor and Mr. Waney.

On October 8, 2004, we entered into the Third Amendment to the New Credit Facility (the “Third Amendment”) which waived events of default associated with the warrants issuance to AEG Partners, LLC and the NeoPharm Promissory Note default (discussed below). In addition, the Third Amendment amended definitions of the Computation Period and EBITDA to Interest Expense Ratio for covenant calculations.

### **Subordinated Debt**

In 2001, we entered into a \$5,000,000 convertible subordinated debt agreement, including a \$3,000,000 Tranche A note (“Tranche A Note”) and a \$2,000,000 Tranche B note (“Tranche B Note”) with the Kapoor Trust (collectively, the “Convertible Note Agreement”). Under the terms of the Convertible Note Agreement, both Tranche A Note and Tranche B Note, which are due December 20, 2006, bear interest at prime plus 3% and were issued with detachable warrants (the “Tranche A Warrants” and the “Tranche B Warrants”) to purchase shares of common stock. Interest payments are currently prohibited under the terms of a subordination arrangement. The convertible feature of the Convertible Note Agreement, as amended, allows for conversion of the subordinated debt plus interest into our common stock, at a price of \$2.28 per share of common stock for Tranche A and \$1.80 per share of common stock for Tranche B.

In December 2001, we entered into a \$3,250,000 five-year loan with NeoPharm, Inc. (“NeoPharm”) to fund our efforts to complete our lyophilization facility located in Decatur, Illinois. The promissory note (“NeoPharm Promissory Note”) was executed in conjunction with a processing agreement that provides NeoPharm with the option of securing at least 15% of the capacity of our lyophilization facility each year. Dr. John N. Kapoor, our chairman, is also a director of NeoPharm and holds a substantial stock position in NeoPharm as well as in us.

In connection with the Exchange Transaction, the Kapoor Trust and NeoPharm waived all existing defaults under their respective agreements and entered into amended agreements dated October 7, 2003. Interest under the NeoPharm Promissory Note accrues at 1.75% above LaSalle Bank's prime rate (7.50%, based on the 5.75% prime rate as of March 31, 2005). Interest payments under both agreements are currently prohibited under the terms of a subordination arrangement with LaSalle Bank. The NeoPharm Promissory Note also requires us to make quarterly payments of \$150,000 beginning on the last day of the calendar quarter during which all indebtedness under the New Credit Facility has been paid and the commitment for the senior debt has been terminated.

All remaining amounts owed under the NeoPharm Promissory Note are payable at maturity on December 20, 2006. The Kapoor Trust amendment did not change the interest rate or the maturity date of the Tranche A Note or Tranche B Note under the Convertible Note Agreement.

On October 6, 2004, we received a notice from NeoPharm indicating that an event of default had occurred on the outstanding NeoPharm Promissory Note. The notice stated that an event of default was triggered when a processing agreement between NeoPharm and us, which was contractually obligated to go into effect on or before October 1, 2004, failed to occur. The processing agreement failed to become effective, in part, because of an inability to remove the sanctions imposed by the FDA on our Decatur manufacturing facility. The event of default under the NeoPharm Promissory Note also triggered a cross-default provision under the Convertible Note Agreement and the New Credit Facility. The Kapoor Trust has waived the cross-default. On October 8, 2004, we entered into the Third Amendment to the New Credit Facility. Among other things, the Third Amendment amended certain of the financial covenants and LaSalle Bank agreed to waive certain events of default arising out of noncompliance with certain obligations, including noncompliance arising from the event of default under the NeoPharm Promissory Note. Pursuant to our subordination agreement with LaSalle Bank, we may not make any payments to NeoPharm and NeoPharm may not enforce any remedies against us under the NeoPharm Promissory Note, until the senior debt is paid in full and the commitment for the senior debt is terminated. Consequently, NeoPharm cannot take any actions that would have an adverse financial impact to us. However, because of this default, we recorded the \$3,250,000 of debt and \$428,000 of accrued interest as current obligations as of March 31, 2005. We are currently trying to resolve this matter with NeoPharm.

As part of the Exchange Transaction, we issued the 2003 Subordinated Notes to the Kapoor Trust, Arjun Waney and Argent Fund Management, Ltd. The 2003 Subordinated Notes mature on April 7, 2006 and bear interest at prime plus 1.75%, but interest payments are currently prohibited under the terms of our subordination agreement. The 2003 Subordinated Notes are subordinated to the New Credit Facility and the NeoPharm Promissory Note but senior to the Convertible Note Agreement.

#### **Other Indebtedness**

In June 1998, we entered into a \$3,000,000 mortgage agreement with Standard Mortgage Investors, LLC of which there were outstanding borrowings of \$1,225,000 and \$1,546,000 at March 31, 2005 and 2004, respectively. The principal balance is payable over 10 years, with the final payment due in June 2008. The mortgage note bears a fixed interest rate of 7.375% and is secured by the real property located in Decatur, Illinois.

The fair value of the debt obligations approximated the recorded value as of March 31, 2005.

#### **Preferred Stock and Warrants**

##### **Series A Preferred Stock**

The Series A Preferred Stock accrues dividends at a rate of 6.0% per annum, which rate is fully cumulative, accrues daily and compounds quarterly. While the dividends could be paid in cash at our option, such dividends are currently being deferred and will be convertible into our common stock. All shares of Series A Preferred Stock have liquidation rights in preference over junior securities, including the common stock, and have certain anti-dilution protections. The Series A Preferred Stock and unpaid dividends are convertible at any time into shares of common stock at an exercise price of \$0.75 per share. All shares of Series A Preferred Stock shall convert to shares of common stock on the earlier to occur of (i) October 8, 2006 and (ii) the date on which the closing price per share of common stock for at least 20 consecutive trading days immediately preceding such date exceeds \$4.00 per share. Until our stockholders approved certain provisions regarding the Series A Preferred Stock (the "Stockholders Approval"), which occurred in July 2004, the Series A Preferred Stock was also redeemable in October 2011.

The initial amount recorded for the Series A Preferred Stock, as described in Item 1. Financial Statements, Note I – Preferred Stock, was \$5,174,000 below its stated value. Until the July 8, 2004 Stockholders Approval date we had been accreting this difference over the time period from issuance to the mandatory redemption date in October 2011. Accretion was \$267,000 in 2004 and \$220,000 in 2003.

Pursuant to FASB No. 150 — “Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity,” as amended, the Series A Preferred Stock was originally reflected as a liability because of its mandatory redemption feature. That characterization remained through July 8, 2004 and as such, dividends have been reflected as interest expense in the statement of operations through July 8, 2004. As a result of the Stockholders Approval on July 8, 2004, the carrying value of the Series A Preferred Stock was reclassified into stockholders’ equity and future dividends are reflected as adjustments to accumulated deficit and are shown in the financial statements as impacting income (loss) available to common stockholders. Additionally, and in accordance with EITF Abstract No. 00-27, we also recorded in July 2004 the value of the conversion option imbedded at issuance in each share of Series A Preferred Stock, subject to limitations described in the EITF. That value, approximately \$20,874,000, reduced the carrying value of the Series A Preferred Stock to near zero with the offsetting excess to common stock. The carrying value of the Series A Preferred Stock was then adjusted to its full aggregated stated value, plus unpaid dividends (approximately \$26,552,000) with a charge directly to accumulated deficit. That charge did not impact net earnings for the third quarter of 2004, but substantially reduced earnings available to common stockholders and generated a loss per share for that period.

#### **Series B Preferred Stock**

On August 23, 2004, we issued an aggregate of 141,000 shares of Series B Preferred Stock at a price of \$100 per share, convertible into common stock at a price of \$2.70 per share, to certain investors, with Series B Warrants to purchase 1,566,667 additional shares of common stock exercisable until August 23, 2009, with an exercise price of \$3.50 per share. The net proceeds to us after payment of investment banker fees and expenses and other transaction costs of approximately \$1,056,000 were approximately \$13,044,000. A portion of these proceeds were used to pay off the Term Loans and reduce the Revolver to zero. That early pay down and resulting elimination of certain personal guarantees of that debt, resulted in the write-off of \$245,000 of unamortized deferred financing fees. Remaining proceeds will be used for working capital and other general corporate purposes, including validation testing of our Lyophilization facility. In accounting for the issuance of the Series B Preferred Stock and Series B Warrants, we recorded additional charges directly to accumulated deficit of \$5,998,000. That charge did not impact net earnings for the third quarter, but substantially reduced earnings available to common stockholders and earnings per share for that period.

Series B Preferred Stock accrues dividends at a rate of 6.0% per annum, which rate is fully cumulative, accrues daily and compounds quarterly. While the dividends could be paid in cash at our option, such dividends are currently being deferred and added to the Series B Preferred Stock balance. Each share of our Series B Preferred Stock, and accrued and unpaid dividends with respect to each such share, is convertible by the holder thereof at any time into shares of our common stock at an exercise price of \$2.70 per share. We have the option of converting all shares of Series B Preferred Stock into shares of our common stock on any date after August 23, 2005 as to which the closing price per share of the common stock for at least 20 consecutive trading days immediately preceding such date exceeds \$5.00 per share.

As required under the terms of the Series B Preferred Stock transaction, we completed, in October 2004, the registration with the SEC of the common shares into which the Series B Preferred Stock is convertible, among others. Had the registration statement not become effective within 270 days from August 23, 2004, each holder would have had the right to compel us to purchase its shares of Series B Preferred Stock for cash in an amount equal to \$115 per share (the “Put Option”). As a result of the Put Option, and pursuant to SEC rules and regulations, our Series B Preferred Stock was reflected outside of the shareholder’s equity section of our consolidated balance sheet until the registration statement became effective. Due to that registration, the holders of the Series B Preferred Stock can no longer put their shares back to us, and accordingly, the Series B Preferred Stock was reclassified into equity in October 2004.

Immediately after the private placement, the purchasers of Series B Preferred Stock held approximately 31% of the aggregate voting rights represented by outstanding shares of common stock and Series B Preferred Stock. After the private placement and assuming the exercise of all outstanding conversion rights, warrants and options to acquire common stock, the purchasers of Series B Preferred Stock would hold approximately 9% of the common stock, on a fully-diluted basis. Prior to the private placement, the purchasers of Series B Preferred Stock held approximately 5% of the outstanding voting securities and would have held approximately 18% of the common stock on a fully-diluted basis.



## **Warrants**

The Series A Warrants issued in connection with the Exchange Transaction are exercisable at any time prior to expiration on October 7, 2006. These outstanding warrants for 5,986,400 shares of common stock have an exercise price of \$1.00 per share. The Guaranty Warrants for 960,000 shares of common stock at an exercise price of \$1.10 per share were issued in consideration of the debt guaranty as part of the Exchange Transaction. Also, as part of the Exchange Transaction, the Note Warrants for 276,714 shares of common stock were issued with the Subordinated Notes at an exercise price of \$1.10 per share. In addition, there are Tranche A Warrants and Tranche B Warrants that were outstanding prior to the Exchange Transaction for 1,000,000 and 667,000 shares of common stock with per share exercise prices of \$2.85 and \$2.25, respectively.

The Series B Warrants are exercisable at any time prior to expiration on August 23, 2009. The warrants are for 1,566,667 shares of common stock and have an exercise price of \$3.50 per share.

As further described in Item 1. Financial Statements, Note H – “Financing Arrangements”, we have issued to AEG warrants (the “AEG Warrants”) to purchase 1,250,000 shares of our common stock at an exercise price of \$0.75 per share. As of March 31, 2005, AEG has exercised AEG Warrants with cash to purchase 50,000 shares of our common stock.

## **CRITICAL ACCOUNTING POLICIES**

### **Revenue Recognition**

We recognize product sales for our ophthalmic and injectable business segments upon the shipment of goods. The contract services segment, which produces products for third party customers based upon their specification and at a pre-determined price, also recognizes sales upon the shipment of goods or upon delivery of the product as appropriate. Revenue is recognized when all of our obligations have been fulfilled and collection of the related receivable is probable. Provision for estimated doubtful accounts, chargebacks, rebates, discounts and product returns is made at the time of sale and is analyzed and adjusted, if necessary, at each balance sheet date.

### **Allowance for Chargebacks and Rebates**

We maintain allowances for chargebacks and rebates. These allowances are reflected as a reduction of accounts receivable.

We enter into contractual agreements with certain third parties such as hospitals and group-purchasing organizations to sell certain products at predetermined prices. The parties have elected to have these contracts administered through wholesalers that buy the products from us. When a wholesaler sells products to one of the third parties that are subject to a contractual price agreement, the difference between the price paid to us by the wholesaler and the price under contract is charged back to us by the wholesaler. We track sales and submitted chargebacks by product number for each wholesaler. Utilizing this information, we estimate a chargeback percentage for each product. We reduce gross sales and increase the chargeback allowance by the estimated chargeback amount for each product sold to a wholesaler. We reduce the chargeback allowance when we process a request for a chargeback from a wholesaler. Actual chargebacks processed can vary materially from period to period.

Management obtains wholesaler inventory reports to aid in analyzing the reasonableness of the chargeback allowance. We assess the reasonableness of our chargeback allowance by applying the product chargeback percentage based on historical activity to the quantities of inventory on hand per the wholesaler inventory reports and an estimate of in-transit inventory that is not reported on the wholesaler inventory reports at the end of the period. We intend to use this revised estimate on a going forward basis until historical trends indicate that additional revisions should be made.

Similarly, we maintain an allowance for rebates related to contract and other programs with certain customers. The rebate allowance also reduces gross sales and accounts receivable by the amount of the estimated rebate amount when we sell our products to our rebate-eligible customers. Rebate percentages vary by product and by volume purchased by each eligible customer. We track sales by product number for each eligible customer and then apply the applicable rebate percentage, using both historical trends and actual experience to estimate its rebate allowance. We reduce gross sales and increase the rebate allowance by the estimated rebate amount for each product sold to an eligible customer. We reduce the rebate allowance when we process a customer request for a rebate. At each balance sheet date, we evaluate the allowance against actual rebates processed and such amount can vary materially from period to period.

The recorded allowances reflect our current estimate of the future chargeback and rebate liability to be paid or credited to the wholesaler under the various contracts and programs. For the three month periods ended March 31, 2005 and 2004, we recorded chargeback and rebate expense of \$4,999,000 and \$2,845,000, respectively. The allowance for chargebacks and rebates was \$5,288,000 and \$5,406,000 as of March 31, 2005 and December 31, 2004, respectively.

#### **Allowance for Product Returns**

We also maintain an allowance for estimated product returns. Certain of our products are sold with the customer having the right to return the product within specified periods and guidelines for a variety of reasons, including but not limited to pending expiration dates. Provisions are made at the time of sale based upon tracked historical experience, by customer in some cases. In evaluating month end allowance balances, we consider actual returns to date that are in process, the expected impact of any product recalls and the wholesaler's inventory information to assess the magnitude of unconsumed product that may result in a product return to us in the future. Actual returns processed can vary materially from period to period. For the three-month periods ended March 31, 2005 and 2004, we recorded a provision for product returns of \$514,000 and \$795,000, respectively. The allowance for potential product returns was \$1,067,000 and \$1,393,000 at March 31, 2005 and December 31, 2004, respectively.

#### **Allowance for Doubtful Accounts**

We maintain an allowance for doubtful accounts, which reflects trade receivable balances owed to us that are believed to be uncollectible. This allowance is reflected as a reduction of accounts receivable balances. In estimating the allowance for doubtful accounts, we have:

- Identified the relevant factors that might affect the accounting estimate for allowance for doubtful accounts, including: (a) historical experience with collections and write-offs; (b) credit quality of customers; (c) the interaction of credits being taken for discounts, rebates, allowances and other adjustments; (d) balances of outstanding receivables, and partially paid receivables; and (e) economic and other exogenous factors that might affect collectibility (e.g., bankruptcies of customers, factors that affect particular distribution channels).
- Accumulated data on which to base the estimate for allowance for doubtful accounts, including: (a) collections and write-offs data; (b) information regarding current credit quality of customers; and (c) other information such as buying patterns and payment patterns, particularly with respect to major customers.
- Developed assumptions reflecting management's judgments as to the most likely circumstances and outcomes, regarding, among other matters: (a) collectibility of outstanding balances relating to "partial payments;" (b) the ability to collect items in dispute (or subject to reconciliation) with customers; and (c) economic factors that might affect collectibility of outstanding balances — based upon information available at the time.

For the three-month periods ended March 31, 2005 and 2004, we recorded a net benefit for doubtful accounts of \$69,000 and \$362,000, respectively as recoveries and reduced reserve requirements exceeded write-offs and account collectibility concerns. The allowance for doubtful accounts was \$74,000 and \$435,000 as of March 31, 2005 and December 31, 2004, respectively. As of March 31, 2005, we had a total of \$46,000 of past due gross accounts receivable. We perform monthly a detailed analysis of the receivables due from our wholesaler customers and provide a specific reserve against known uncollectible items for each of the wholesaler customers. We also include in the allowance for doubtful accounts an amount that we estimate to be uncollectible for all other customers based on a percentage of the past due receivables. The percentage reserved increases as the age of the receivables increases. Of the recorded allowance for doubtful accounts of \$74,000, the portion related to major wholesaler customers is \$56,000 with the remaining \$18,000 reserve for all other customers.

#### **Allowance for Discounts**

We maintain an allowance for discounts, which reflects discounts available to certain customers based on agreed upon terms of sale. This allowance is reflected as a reduction of accounts receivable. We evaluate the allowance balance against actual discounts taken. For the three-month periods ended March 31, 2005 and 2004, we recorded a provision for cash discounts of \$179,000 and

\$192,000, respectively. The allowance for discounts was \$174,000 and \$234,000 as of March 31, 2005 and December 31, 2004, respectively.

#### **Allowance for Slow-Moving Inventory**

We maintain an allowance for slow-moving and obsolete inventory. For finished goods inventory, we estimate the amount of inventory that may not be sold prior to its expiration or is slow moving based upon recent sales activity by unit and wholesaler inventory information. We also analyze our raw material and component inventory for slow moving items. For the three-month periods ended March 31, 2005 and 2004, we recorded a provision of \$25,000 and \$303,000, respectively. The allowance for slow-moving inventory at March 31, 2005 and December 31, 2004 was \$545,000 and \$660,000, respectively.

#### **Income Taxes**

Deferred income tax assets and liabilities are determined based on differences between financial reporting and tax bases of assets and liabilities, and net operating loss and other tax credit carryforwards. These items are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. We record a valuation allowance to reduce the deferred income tax assets to the amount that is more likely than not to be realized.

#### **Intangibles**

Intangibles assets consist primarily of product licensing and other such costs that are capitalized and amortized on the straight-line method over the lives of the related license periods or the estimated life of the acquired product, which range from 3 years to 18 years. Accumulated amortization at March 31, 2005 and December 31, 2004 was \$13,746,000 and \$13,367,000, respectively. We periodically assess potential impairment of intangible assets based on several factors, including estimated fair market value and anticipated cash flows. Management continues to evaluate the value of our remaining licenses with an aggregate value of \$11,239,000 at March 31, 2005.

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

We are subject to market risk associated with changes in interest rates. Our interest rate exposure currently involves three debt instruments. Debt under the amended NeoPharm Note and the 2003 Subordinated Promissory Notes bears interest at prime plus 1.75%. Revolver debt under the New Credit Agreement bears interest at prime plus 1.50%. The subordinated convertible debentures issued to the Kapoor Trust under the Convertible Note Agreement bear interest at prime plus 3.0%. All of our remaining long-term debt is at fixed interest rates. We estimate that a change of 1.0% in our variable rate debt from the interest rates in effect at March 31, 2005 would result in a \$133,000 pre-tax change in annual interest expense.

Our financial instruments consist mainly of cash, accounts receivable, accounts payable and debt. The carrying amounts of these instruments, except debt, approximate fair value due to their short-term nature. The carrying amounts of our bank borrowings under our debt instruments approximate fair value because the interest rates are reset periodically to reflect current market rates.

The fair value of the debt obligations approximated the recorded value as of March 31, 2005.

Our exposure to foreign currency risks is immaterial as we do not transact any sales in foreign currencies and we have limited purchases activity in foreign currencies.

### **ITEM 4. CONTROLS AND PROCEDURES**

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Securities Exchange Act of 1934, as amended ("Exchange Act") reports is recorded, processed, summarized and reported within the periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management including its Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. As of the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Based on that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures are effective in timely communicating to them the material information relating to us required to be included in our periodic SEC filings.

There were no changes to our internal controls over financial reporting that occurred during our most recently completed fiscal quarter that materially affected, or is reasonably likely to materially affect our internal control over financial reporting.

## **PART II. OTHER INFORMATION**

### **ITEM 1. LEGAL PROCEEDINGS**

On February 23, 2004, we were sued in the United States District Court for the District of Arizona for damages resulting from the death of an Arabian show horse allegedly injected with the drug Sarapin in the summer of 2003. The case was dismissed with prejudice on January 7, 2005.

The FDA issued a warning letter to us in October 2000 following a routine inspection of our Decatur manufacturing facility. An FDA warning letter is intended to provide notice to a company of violations of the laws administered by the FDA and to elicit voluntary corrective action. Until the violations identified in the warning letter are corrected, the FDA frequently will withhold approval of any marketing applications (ANDAs, NDAs) submitted by the company and will share contents of the warning letter with other government agencies (for example, the Veterans Administration or Department of Defense) that may contract to purchase products from the company. Failure to take effective corrective actions can result in the FDA enforcement action such as monetary fines, seizure of products, or injunction that could suspend manufacturing and compel recall of product.

The warning letter addressed several deviations from regulatory requirements identified during the inspection and requested that we take corrective actions. Since then, additional FDA inspections in 2002 and 2003 found that certain deviations continued unresolved and identified additional deviations. We have invested approximately \$2,000,000 in improved cleaning validation and enhanced process controls and have developed a comprehensive corrective action plan. We have been in regular communications with the FDA and have provided periodic reports of our progress in making corrections. In 2004, the FDA conducted two additional inspections of our Decatur manufacturing facility. The first, concluded on April 7, 2004, identified several deviations for which we provided the FDA with proposed corrective actions. The FDA initiated no enforcement action. Rather, the FDA notified us that another "confirmatory" inspection would be made to determine whether the deviations identified have been corrected. The confirmatory inspection concluded November 19, 2004. It identified deviations and we have responded to the FDA with corrective actions. We have met with the FDA and provided the status of our corrective actions. The FDA has advised us that the findings of the latest inspection are under review and a final agency decision on our regulatory status has not been made. The FDA may conclude that the findings of the latest inspection do not represent significant deviations and our voluntary corrective actions are sufficient, in which case, we can expect the FDA to remove the sanctions of the warning letter. If, however, the FDA concludes that the deviations are significant and our voluntary actions have not been adequate, it may initiate enforcement action including the following: (1) maintain the warning letter sanctions or issue a new warning letter with sanctions; (2) seek a court-ordered injunction which may include suspension of some or all operations at the Decatur manufacturing facility until compliance is achieved, recall of certain products, potential monetary penalties or other sanctions; or (3) seize our products produced at the Decatur manufacturing facility. Any of these actions could significantly impair our ability to continue to manufacture and distribute products, generate cash from our operations and may result in a covenant violation under our senior debt.

To date, the noncompliance of our Decatur manufacturing facility has prevented us from developing additional products at Decatur, some of which cannot be developed at our other facility. The inability to fully use our Decatur manufacturing facility has had a material adverse effect on our business, financial condition and results of operations.

Unless and until we correct the FDA deviations at our Decatur manufacturing facility, it is doubtful that the FDA will approve any applications that may be submitted by us for products to be manufactured in Decatur. This has adversely impacted, and is likely to continue to adversely impact our ability to grow sales.

We are party to legal proceedings and potential claims arising in the ordinary course of our business. The amount, if any, of ultimate liability with respect to such matters cannot be determined. Despite the inherent uncertainties of litigation, we at this time do not believe that such proceedings will have a material adverse impact on our financial condition, results of operations, or cash flows.

## ITEM 2. CHANGES IN SECURITIES AND USE OF PROCEEDS

We filed a Registration Statement on Form S-1 (File No. 333-119168)(the "Registration Statement") with SEC relating to the resale of 61,778,323 shares of our common stock, no par value per share, by the selling stockholders identified therein (the "Selling Stockholders"). The shares of common stock registered by the Registration Statement represent the number of shares that have been issued or are issuable upon the conversion or exercise of the Series A Preferred Stock, Series B Preferred Stock, warrants and convertible notes described in therein, including shares estimated to be issuable in satisfaction of dividends accrued and unpaid through June 30, 2005 and interest accrued and unpaid through August 31, 2005 on such securities. We estimated the aggregate price of the offering of the amount registered to be \$182,246,053. This amount was estimated solely for the purpose of calculating the amount of the registration fee pursuant to Rule 457(h) under the Securities Act of 1933. The aggregate offering price was derived from the average of the bid and asked prices of our common stock on September 17, 2004, as reported on the OTC Bulletin Board(R). We do not know how many shares of common stock will be purchased under the Registration Statement or at what price such shares will be purchased. As of May 10, 2005, we are aware of the sale of 381,719 shares of common stock by Selling Stockholders under the Registration Statement. We will not receive any of the proceeds from the sale of the shares by the Selling Stockholders. The Selling Stockholders will receive all of the proceeds from the sale of the shares and will pay all underwriting discounts and selling commissions, if any, applicable to the sale of the shares. We will, in the ordinary course of business, receive proceeds from the issuance of shares upon exercise of the warrants described in this prospectus. The proceeds we will receive will be used for working capital and other general corporate purposes.

The Registration Statement was declared effective by the SEC on October 29, 2004, at 1:00 p.m. PDT. On May 10, 2005, we filed Post-Effective Amendment No. 1 to the Registration Statement (the "Post-Effective Amendment"). No sales may be made by the Selling Stockholders until the SEC declares the Post-Effective Amendment effective.

## ITEM 3. DEFAULT UPON SENIOR SECURITIES

On October 6, 2004, we received notice that an event of default had occurred on our outstanding promissory note with NeoPharm, Inc. The notice stated that the event of default was triggered when a processing agreement between the two companies, which was contractually obligated to go into effect on or before October 1, 2004, failed to occur. The processing agreement failed to become effective, in part, because of an inability to remove the sanctions imposed by the FDA on our Decatur manufacturing facility. The amount of principal due under the note is \$3,250,000 and as of March 31, 2005, an additional \$428,000 of accrued interest is also due. Pursuant to our subordination agreement with LaSalle Bank, we may not make any payments to NeoPharm and NeoPharm may not enforce any remedies against us under the NeoPharm Promissory Note, until the debt owed to LaSalle Bank is paid in full and the commitment for the debt to LaSalle Bank is terminated. Consequently, NeoPharm cannot take any actions that would have an adverse financial impact to us. We are currently trying to resolve this matter with NeoPharm.

## ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

No matters were submitted to a vote of security holders during the quarter ended March 31, 2005.

## ITEM 5. OTHER INFORMATION

None

## ITEM 6. EXHIBITS

Those exhibits marked with an asterisk (\*) refer to exhibits filed herewith. The other exhibits are incorporated herein by reference, as indicated in the following list.

| Exhibit No. | Description                                                                                                                                                                                                                         |
|-------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| (3.1)       | Restated Articles of Incorporation of the Company dated September 16, 2004, incorporated by reference to Exhibit 3.1 to the Company's Registration Statement on Form S-1 filed on September 21, 2004.                               |
| (3.2)       | Amended and Restated By-laws of the Company, incorporated by reference to Exhibit 3.2 to the Company's report on Form 8-K filed on October 24, 2003 and to Exhibit 3.1 to the Company's report on Form 8-K filed on April 19, 2005. |
| (10.1)      | Amended and Restated Akom, Inc. 2003 Stock Option Plan, incorporated by reference to Exhibit 10.59 to the Company's report on Form 10-K for the fiscal year ended December 31, 2004, filed on March 31, 2005.                       |
| (31.1)*     | Certification of Chief Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934                                                                                                                       |
| (31.2)*     | Certification of Chief Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934                                                                                                                       |

(32.1)\* Certification of Chief Executive Officer pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to ss. 906 of the Sarbanes-Oxley Act of 2002

(32.2)\* Certification of Chief Financial Officer pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to ss. 906 of the Sarbanes-Oxley Act of 2002

**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.

AKORN, INC.

/s/ JEFFREY A. WHITNELL

Jeffrey A. Whitnell  
Vice President, Chief Financial Officer  
(Duly Authorized and Principal Financial Officer)

Date: May 16, 2005

## CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER

I, Arthur S. Przybyl, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Akom, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report.
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - A) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be defined under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - B) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report, based on such evaluation; and
  - C) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and to the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - A) All significant deficiencies and material weaknesses in the design or operation of internal financial control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - B) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

/s/ ARTHUR S. PRZYBYL

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Arthur S. Przybyl  
*Chief Executive Officer*

Date: May 16, 2005



## CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

I, Jeffrey A. Whitnell, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Akom, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report.
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - A) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be defined under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - B) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report, based on such evaluation; and
  - C) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and to the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - A) All significant deficiencies and material weaknesses in the design or operation of internal financial control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - B) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

/s/ JEFFREY A. WHITNELL

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Jeffrey A. Whitnell  
*Chief Financial Officer*

Date: May 16, 2005

CERTIFICATION PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Akorn, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2005, as filed with the Securities and Exchange Commission and to which this Certification is an exhibit (the "Report"), the undersigned officer of Akorn, Inc. does hereby certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 16, 2005

/s/ ARTHUR S. PRZYBYL

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Arthur S. Przybyl  
Chief Executive Officer

CERTIFICATION PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Akorn, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2005, as filed with the Securities and Exchange Commission and to which this Certification is an exhibit (the "Report"), the undersigned officer of Akorn, Inc. does hereby certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 16, 2005

/s/ JEFFREY A. WHITNELL

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Jeffrey A. Whitnell  
Chief Financial Officer