MYLAN LABORATORIES INC Form 10-Q July 28, 2006

Large Accelerated Filer b

YES o NO b

## 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 þ **EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2006

| C  | OK .  |
|--|---|
| o TRANSITION REPORT PURSUANT TO EXCHANGE ACT OF 1934   | SECTION 13 OR 15(d) OF THE SECURITIES   |
| For the transition period from to  |   |
| Commission file  | e number 1-9114   |
| MYLAN LABO   | RATORIES INC.   |
| (Exact name of registrant  | as specified in its charter)  |
| Pennsylvania   | 25-1211621  |
| (State of incorporation)   | (I.R.S. Employer Identification No.)  |
| 1500 Corp  | orate Drive   |
| Canonsburg, Per  | nnsylvania 15317  |
| (Address of princip  | al executive offices)   |
| (Zip   | Code)   |
| (724) 5  | 14-1800   |
| (Registrant s telephone n  | umber, including area code)   |
|  | all reports required to be filed by Section 13 or 15(d) of the  |
| Securities Exchange Act of 1934 during the preceding twe was required to file such reports), and (2) has been subject        | lve months (or for such shorter period that the registrant to such filing requirements for the past 90 days. YES b NO |
| 0  |   |
| Indicate by check mark whether the registrant is a large acc<br>See definition of accelerated filer and large accelerated fi | celerated filer, an accelerated filer or a non-accelerated filer. ler in Rule 12b-2 of the Exchange Act.              |

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

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

Non-Accelerated Filer o

Class of **Outstanding at Common Stock** July 21, 2006

\$0.50 par value 210,811,102

# MYLAN LABORATORIES INC. AND SUBSIDIARIES FORM 10-Q

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# MYLAN LABORATORIES INC. AND SUBSIDIARIES

# **Condensed Consolidated Statements of Earnings**

(unaudited; in thousands, except per share amounts)

| Three Months Ended June 30,                          | 2006              | 2005       |
|--|-------------------|------------|
| Revenues:  | <b># 2.40.700</b> | ¢ 221 010  |
| Net revenues Other revenues                          | \$ 348,789        | \$ 321,010 |
| Other revenues                                       | 7,351             | 2,368      |
| Total revenues                                       | 356,140           | 323,378    |
| Cost of sales  | 167,940           | 155,544    |
| Gross profit   | 188,200           | 167,834    |
| Operating expenses:                                  |                   |            |
| Research and development                             | 21,225            | 25,180     |
| Selling, general and administrative                  | 49,826            | 71,089     |
| Litigation settlements, net                          |                   | 12,000     |
| Total operating expenses                             | 71,051            | 108,269    |
| Earnings from operations                             | 117,149           | 59,565     |
| Interest expense                                     | 10,359            | 39,303     |
| Other income, net                                    | 9,584             | 5,556      |
| Earnings before income taxes                         | 116,374           | 65,121     |
| Provision for income taxes                           | 40,787            | 22,206     |
| Net earnings   | \$ 75,587         | \$ 42,915  |
|  |                   |            |
| Earnings per common share: Basic                     | \$ 0.36           | \$ 0.16    |
| Diluted  | \$ 0.35           | \$ 0.16    |
|  |                   |            |
| Weighted average common shares outstanding:<br>Basic | 209,955           | 269,445    |
| Diluted  | 214,791           | 273,262    |
| Cash dividend declared per common share              | \$ 0.06           | \$ 0.06    |
| Cash dividend declared per common share              | φ U.UU            | φ U.UO     |

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See Notes to Condensed Consolidated Financial Statements

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## MYLAN LABORATORIES INC. AND SUBSIDIARIES

## **Condensed Consolidated Balance Sheets**

(unaudited; in thousands)

|  | June 30,<br>2006   | March 31,<br>2006  |
|--|--------------------|--------------------|
| Assets   |                    |                    |
| Current assets:  |                    |                    |
| Cash and cash equivalents  | \$ 153,923         | \$ 150,124         |
| Marketable securities  | 414,001            | 368,003            |
| Accounts receivable, net   | 269,473            | 242,193            |
| Inventories  | 289,755            | 279,008            |
| Deferred income tax benefit  | 152,097            | 137,672            |
| Prepaid expenses and other current assets                            | 13,533             | 14,900             |
| Total current assets   | 1,292,782          | 1,191,900          |
| Property, plant and equipment, net                                   | 426,185            | 406,875            |
| Intangible assets, net   | 99,486             | 105,595            |
| Goodwill   | 102,579            | 102,579            |
| Other assets   | 63,228             | 63,577             |
| Total assets   | \$ 1,984,260       | \$1,870,526        |
| Liabilities and shareholders equity Liabilities Current liabilities: |                    |                    |
| Trade accounts payable   | \$ 61,162          | \$ 76,859          |
| Income taxes payable   | 55,849             | 12,963             |
| Current portion of long-term obligations                             | 2,050              | 4,336              |
| Cash dividends payable   | 12,648             | 12,605             |
| Other current liabilities  | 161,182            | 158,487            |
| Total current liabilities  | 292,891            | 265,250            |
| Deferred revenue   | 91,514             | 89,417             |
| Long-term debt   | 687,000            | 685,188            |
| Other long-term obligations  | 22,724             | 22,435             |
| Deferred income tax liability  | 19,578             | 20,585             |
| Total liabilities  | 1,113,707          | 1,082,875          |
| Shareholders equity  |                    |                    |
| Preferred stock  | 15/1 02/           | 151575             |
| Common stock Additional paid-in capital                              | 154,834<br>436,470 | 154,575<br>418,954 |
|  |                    |                    |

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| Retained earnings Accumulated other comprehensive earnings | 2,001,984<br>2,287 | 1,939,045<br>2,450 |
|--|--------------------|--------------------|
|  | 2,595,575          | 2,515,024          |
| Less treasury stock at cost                                | 1,725,022          | 1,727,373          |
| Total shareholders equity                                  | 870,553            | 787,651            |
| Total liabilities and shareholders equity                  | \$ 1,984,260       | \$ 1,870,526       |
| See Notes to Condensed Consolidated Finan 4                | icial Statements   |                    |

# MYLAN LABORATORIES INC. AND SUBSIDIARIES

# **Condensed Consolidated Statements of Cash Flows**

(unaudited; in thousands)

| Three Months Ended June 30,  | 2006      | 2005      |
|--|-----------|-----------|
| Cash flows from operating activities:  | \$ 75,587 | \$ 42,915 |
| Net earnings Adjustments to reconcile net earnings to net cash provided from operating | \$ 13,301 | \$ 42,915 |
| activities:  |           |           |
| Depreciation and amortization  | 11,787    | 11,505    |
| Stock-based compensation expense   | 6,806     | 11,505    |
| Net (income) loss from equity method investees   | (5,038)   | 270       |
| Change in estimated sales allowances   | 15,738    | 6,934     |
| Restructuring provision  | 13,730    | 10,203    |
| Deferred income tax benefit  | (15,346)  | (17,281)  |
| Other non-cash items   | (624)     | 2,975     |
| Loss from litigation   | (024)     | 12,000    |
| Receipts from litigation settlements   | 2,000     | 2,000     |
| Cash received from Somerset  | 5,740     | 2,000     |
| Changes in operating assets and liabilities:   | 3,740     |           |
| Accounts receivable  | (41,925)  | 28,559    |
| Inventories  | (10,747)  | 24,325    |
| Trade accounts payable   | (8,094)   | (27,136)  |
| Income taxes   | 49,204    | 3,226     |
| Deferred revenue   | (1,793)   | 3,220     |
|  | 9,594     | 5,941     |
| Other operating assets and liabilities, net  | 9,394     | 3,941     |
| Net cash provided by operating activities  | 92,889    | 106,436   |
| Cash flows from investing activities:  |           |           |
| Capital expenditures   | (27,717)  | (25,142)  |
| Purchase of marketable securities  | (192,053) | (250,462) |
| Proceeds from sale of marketable securities  | 144,680   | 379,183   |
| Other investing items, net   | (159)     | (1,842)   |
| Net cash (used in) provided by investing activities                                    | (75,249)  | 101,737   |
| Cash flows from financing activities:  |           |           |
| Cash dividends paid  | (12,605)  | (8,078)   |
| Decrease in outstanding checks in excess of cash in disbursement accounts              | (7,605)   |           |
| Tax benefit of stock-based incentives  | 700       |           |
| Proceeds from exercise of stock options  | 6,301     | 5,005     |
| Other financing  | (632)     |           |
| Net cash used in financing activities  | (13,841)  | (3,073)   |

| Net increase in cash and cash equivalents Cash and cash equivalents beginning of period                |    | 3,799<br>150,124 | 205,100<br>137,733 |
|--|----|------------------|--------------------|
| Cash and cash equivalents end of period  | \$ | 153,923          | \$<br>342,833      |
| Supplemental disclosures of cash flow information:<br>Cash paid during the period for:<br>Income taxes | \$ | 6,227            | \$<br>36,260       |
| Interest   | \$ | 3,363            | \$                 |
| See Notes to Condensed Consolidated Financial Statement 5  | ts |                  |                    |

#### MYLAN LABORATORIES INC. AND SUBSIDIARIES

**Notes to Condensed Consolidated Financial Statements** 

(unaudited; dollars in thousands, except per share amounts)

#### 1. General

In the opinion of management, the accompanying unaudited condensed consolidated financial statements (interim financial statements) of Mylan Laboratories Inc. and subsidiaries (Mylan or the Company) were prepared in accordance with accounting principles generally accepted in the United States of America and the rules and regulations of the Securities and Exchange Commission for reporting on Form 10-Q; therefore, as permitted under these rules, certain footnotes and other financial information included in audited financial statements were condensed or omitted. The interim financial statements contain all adjustments (consisting of only normal recurring adjustments) necessary to present fairly the interim results of operations, financial position and cash flows for the periods presented.

These interim financial statements should be read in conjunction with the Consolidated Financial Statements and Notes thereto in the Company s Annual Report on Form 10-K for the fiscal year ended March 31, 2006.

The interim results of operations and interim cash flows for the three months ended June 30, 2006, are not necessarily indicative of the results to be expected for the full fiscal year or any other future period.

Certain prior year amounts were reclassified to conform to the current year presentation. Such reclassifications had no impact on reported net earnings, earnings per share or shareholders equity.

## 2. Revenue Recognition and Accounts Receivable

Revenue is recognized for product sales upon shipment when title and risk of loss transfer to the Company's customers and when provisions for estimates, including discounts, rebates, price adjustments, returns, chargebacks and other promotional programs are reasonably determinable. No revisions were made to the methodology used in determining these provisions during the three month period ended June 30, 2006. Accounts receivable are presented net of allowances relating to these provisions. Such allowances were \$398,455 and \$381,800 as of June 30, 2006, and March 31, 2006. Other current liabilities include \$59,457 and \$60,374 at June 30, 2006, and March 31, 2006, for certain rebates and other adjustments that are payable to indirect customers.

## 3. Recent Accounting Pronouncements

In July 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes an Interpretation of FASB Statement 109* (FIN 48), which clarifies the accounting for uncertain tax positions. This Interpretation provides that the tax effects from an uncertain tax position be recognized in the Company s financial statements, only if the position is more likely than not of being sustained on audit, based on the technical merits of the position. The provisions of FIN 48 will be effective for Mylan as of the beginning of fiscal 2008. The Company is currently evaluating the impact of adopting FIN 48 on our consolidated financial statements.

## 4. Stock Based Incentive Plan

Mylan s shareholders approved the *Mylan Laboratories Inc. 2003 Long-Term Incentive Plan* on July 25, 2003, and approved certain amendments on July 28, 2006 (as amended, the 2003 Plan ). Under the 2003 Plan, 22,500,000 shares of common stock are reserved for issuance to key employees, consultants, independent contractors and non-employee directors of Mylan through a variety of incentive awards, including: stock options, stock appreciation rights, restricted shares and units, performance awards, other stock-based awards and short-term cash awards. Awards are granted at the fair value of the shares underlying the options at the date of the grant and generally become exercisable over periods ranging from three to four years and generally expire in ten years.

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The Company adopted Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment* (SFAS 123R), effective April 1, 2006. SFAS 123R requires the recognition of the fair value of stock-based compensation in net earnings. Prior to April 1, 2006, the Company accounted for its stock options using the intrinsic value method of accounting provided under Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25), and related Interpretations, as permitted by Financial Accounting Standards Board (FASB) SFAS No. 123, *Accounting for Share Based Compensation*, (SFAS 123).

Mylan adopted the provisions of SFAS 123R, using the modified prospective transition method. Under this method, compensation cost recognized in the first quarter of fiscal 2007 includes: (a) compensation cost for all share-based payments granted prior to April 1, 2006, but for which the requisite service period had not been completed as of April 1, 2006, based on the grant date fair value, estimated in accordance with the original provisions of SFAS 123, and (b) compensation cost for all share-based payments granted subsequent to April 1, 2006, based on the grant date fair value estimated in accordance with the provisions of SFAS 123R. Results for prior periods have not been restated.

The previously disclosed pro forma effects of recognizing the estimated fair value of stock-based employee compensation for the three months ended June 30, 2005 were as follows:

| Three Months Ended June 30, (in thousands)   | 2   | 2005         |
|--|-----|--------------|
| Net earnings as reported Add: Stock-based compensation expense included in reported net income, net of related tax effects       | \$4 | 2,915<br>636 |
| Deduct: Total compensation expense determined under the fair value based method for all stock awards, net of related tax effects |     | (928)        |
| Pro forma net earnings   | \$4 | 2,623        |
| Earnings per share: Basic as reported  | \$  | 0.16         |
| Basic pro forma  | \$  | 0.16         |
| Diluted as reported  | \$  | 0.16         |
| Diluted pro forma  | \$  | 0.16         |
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Upon approval of the 2003 Plan, the *Mylan Laboratories Inc. 1997 Incentive Stock Option Plan* (the 1997 Plan ) was frozen, and no further grants of stock options will be made under that plan. However, there are stock options outstanding from the 1997 Plan, expired plans and other plans assumed through acquisitions.

The following table summarizes stock option activity:

|  |   | W  | eighted                          | Weighted                 |     |           |
|--|---|----|----------------------------------|--------------------------|-----|-----------|
|  | Number of                                       | A  | verage<br>xercise                | Average                  | Ag  | gregate   |
|  | Shares  |    | Price                            | Remaining<br>Contractual | Iı  | ntrinsic  |
|  | <b>Under Option</b>                             | pe | r Share                          | Term                     |     | Value (in |
| Outstanding at March 31, 2006<br>Options granted<br>Options exercised<br>Options forfeited | 21,358,670<br>348,400<br>(517,469)<br>(331,405) | \$ | 15.16<br>22.64<br>12.18<br>17.52 |                          | inc | ousands)  |
| Outstanding at June 30, 2006   | 20,858,196                                      | \$ | 15.32                            | 6.55                     | \$  | 99,540    |
| Vested and expected to vest at June 30, 2006   | 20,495,528                                      | \$ | 15.27                            | 6.52                     | \$  | 98,857    |
| Options exercisable at June 30, 2006   | 12,952,614                                      | \$ | 13.50                            | 5.38                     | \$  | 84,824    |

A summary of the status of the Company s nonvested restricted stock and restricted stock unit awards as of June 30, 2006 and the changes during the three month period ended June 30, 2006, is presented below:

|   |   | eighted<br>verage    |
|---|---|----------------------|
| Restricted<br>Stock Awards                                      | Number of<br>Restricted<br>Stock Awards | ant-Date<br>ir Value |
| Nonvested at March 31, 2006<br>Granted<br>Released<br>Forfeited | 507,962<br>199,161                      | \$<br>24.69<br>23.27 |
| Nonvested at June 30, 2006                                      | 707,123                                 | \$<br>24.22          |

Of the 199,161 awards granted in the first quarter, approximately 135,000 are performance based. The remaining awards vest ratably over three years.

As of June 30, 2006, the Company had \$30,500 of total unrecognized compensation expense, net of estimated forfeitures, related to all of its stock based awards, which will be recognized over the remaining weighted average period of 1.5 years. The total intrinsic value of stock based awards exercised during the quarter ended June 30, 2006 was \$3,750. The total fair value of all shares which vested during the quarter ended June 30, 2006, was \$6,000.

As a result of the adoption of SFAS 123R, the Company recognized stock-based compensation expense of \$6,800, pre-tax, for the three months ended June 30, 2006. The impact of recognizing the compensation expense related to SFAS 123R on basic and diluted earnings per share for the three months ended June 30, 2006, was \$0.02.

With respect to options granted under the Company's stock-based compensation plan, the fair value of each option grant was estimated at the date of grant using the Black-Scholes option pricing model. Black-Scholes utilizes assumptions related to volatility, the risk-free interest rate, the dividend yield and employee exercise behavior. Expected volatilities utilized in the model are based mainly on the historical volatility of the Company's stock price and other factors. The risk-free interest rate is derived from the U.S. Treasury yield curve in effect at the time of grant. The model incorporates exercise and post-vesting forfeiture assumptions based on an analysis of historical

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data. The expected lives of the grants are derived from historical and other factors. The assumptions used are as follows:

| Three months ended June 30,                       | 2006   |
|---|--------|
| Volatility  | 36.1%  |
| Risk-free interest rate                           | 4.9%   |
| Dividend yield                                    | 1.1%   |
| Expected term of options (in years)               | 4.4    |
| Forfeiture rate                                   | 3.0%   |
| Weighted average grant date fair value per option | \$7.58 |

## 5. Restructuring

On June 14, 2005, the Company announced that it was closing its branded subsidiary, Mylan Bertek Pharmaceuticals, Inc. (Mylan Bertek), and transferring the responsibility for marketing Mylan Bertek s products to other Mylan subsidiaries. In conjunction with this restructuring, the Company incurred restructuring charges of \$10,203, pre-tax, during the quarter ended June 30, 2005. Of this, \$231 is included in research and development expense, with the remainder in selling, general and administrative expense. As of March 31, 2006, the Company s restructuring was substantially complete.

## **6. Balance Sheet Components**

Selected balance sheet components consist of the following:

| Raw materials         \$114,637         \$98,259           Work in process         37,816         36,073           Finished goods         137,302         144,676           Property, plant and equipment:           Land and improvements         \$10,639         \$10,639           Buildings and improvements         178,096         175,343           Machinery and equipment         297,495         287,202           Construction in progress         158,648         617,613           Less: accumulated depreciation         218,693         210,738           Other current liabilities:         \$26,389         \$43,233           Accrued rebates         59,457         60,374           Royalties and product license fees         5,789         9,320           Deferred revenue         13,335         17,225           Legal and professional         31,607         30,074           Accrued interest         11,765         3,989           Other         12,840         13,182  | (in thousands) Inventories:    | June 30,<br>2006 | March 31,<br>2006 |
|--|--------------------------------|------------------|-------------------|
| Work in process         37,816         36,073           Finished goods         137,302         144,676           Property, plant and equipment:           Land and improvements         \$10,639         \$10,639           Buildings and improvements         178,096         175,343           Machinery and equipment         297,495         287,202           Construction in progress         158,648         144,429           Less: accumulated depreciation         218,693         210,738           Other current liabilities:           Payroll and employee benefit plan accruals         \$26,389         \$24,323           Accrued rebates         5,789         9,320           Deferred revenue         13,335         17,225           Legal and professional         31,607         30,074           Accrued interest         11,765         3,989   |                                | \$ 114.637       | \$ 98,259         |
| Finished goods         137,302         144,676           \$ 289,755         \$ 279,008           Property, plant and equipment:           Land and improvements         \$ 10,639         \$ 10,639           Buildings and improvements         178,096         175,343           Machinery and equipment         297,495         287,202           Construction in progress         158,648         144,429           Less: accumulated depreciation         218,693         210,738           Other current liabilities:           Payroll and employee benefit plan accruals         \$ 26,389         \$ 24,323           Accrued rebates         59,457         60,374           Royalties and product license fees         5,789         9,320           Deferred revenue         13,335         17,225           Legal and professional         31,607         30,074           Accrued interest         11,765         3,989  |                                | ·                | ' '               |
| Property, plant and equipment:           Land and improvements         \$ 10,639         \$ 10,639           Buildings and improvements         178,096         175,343           Machinery and equipment         297,495         287,202           Construction in progress         158,648         144,429           Less: accumulated depreciation         218,693         210,738           Other current liabilities:         \$ 426,185         \$ 406,875           Payroll and employee benefit plan accruals         \$ 26,389         \$ 24,323           Accrued rebates         59,457         60,374           Royalties and product license fees         5,789         9,320           Deferred revenue         13,335         17,225           Legal and professional         31,607         30,074           Accrued interest         11,765         3,989   | -                              | ,                |                   |
| Land and improvements       \$ 10,639       \$ 10,639         Buildings and improvements       178,096       175,343         Machinery and equipment       297,495       287,202         Construction in progress       158,648       144,429         Less: accumulated depreciation       644,878       617,613         Less: accumulated depreciation       218,693       210,738         Other current liabilities:         Payroll and employee benefit plan accruals       \$ 26,389       \$ 24,323         Accrued rebates       59,457       60,374         Royalties and product license fees       5,789       9,320         Deferred revenue       13,335       17,225         Legal and professional       31,607       30,074         Accrued interest       11,765       3,989   |                                | \$ 289,755       | \$ 279,008        |
| Buildings and improvements       178,096       175,343         Machinery and equipment       297,495       287,202         Construction in progress       158,648       144,429         Less: accumulated depreciation       218,693       210,738         Other current liabilities:         Payroll and employee benefit plan accruals       \$ 26,389       \$ 24,323         Accrued rebates       59,457       60,374         Royalties and product license fees       5,789       9,320         Deferred revenue       13,335       17,225         Legal and professional       31,607       30,074         Accrued interest       11,765       3,989  | Property, plant and equipment: |                  |                   |
| Machinery and equipment       297,495       287,202         Construction in progress       158,648       144,429         Less: accumulated depreciation       644,878       617,613         Less: accumulated depreciation       218,693       210,738         Other current liabilities:         Payroll and employee benefit plan accruals       \$ 26,389       \$ 24,323         Accrued rebates       59,457       60,374         Royalties and product license fees       5,789       9,320         Deferred revenue       13,335       17,225         Legal and professional       31,607       30,074         Accrued interest       11,765       3,989  | Land and improvements          | \$ 10,639        | \$ 10,639         |
| Construction in progress         158,648         144,429           Less: accumulated depreciation         644,878         617,613           Less: accumulated depreciation         218,693         210,738           Other current liabilities:           Payroll and employee benefit plan accruals         \$ 26,389         \$ 24,323           Accrued rebates         59,457         60,374           Royalties and product license fees         5,789         9,320           Deferred revenue         13,335         17,225           Legal and professional         31,607         30,074           Accrued interest         11,765         3,989  | Buildings and improvements     | 178,096          | 175,343           |
| Less: accumulated depreciation       644,878 (617,613) (218,693) (210,738) ( | Machinery and equipment        | 297,495          | 287,202           |
| Less: accumulated depreciation       218,693       210,738         \$ 426,185       \$ 406,875         Other current liabilities:         Payroll and employee benefit plan accruals       \$ 26,389       \$ 24,323         Accrued rebates       59,457       60,374         Royalties and product license fees       5,789       9,320         Deferred revenue       13,335       17,225         Legal and professional       31,607       30,074         Accrued interest       11,765       3,989  | Construction in progress       | 158,648          | 144,429           |
| Less: accumulated depreciation       218,693       210,738         \$ 426,185       \$ 406,875         Other current liabilities:         Payroll and employee benefit plan accruals       \$ 26,389       \$ 24,323         Accrued rebates       59,457       60,374         Royalties and product license fees       5,789       9,320         Deferred revenue       13,335       17,225         Legal and professional       31,607       30,074         Accrued interest       11,765       3,989  |                                | 644.878          | 617.613           |
| Other current liabilities:         Payroll and employee benefit plan accruals       \$ 26,389       \$ 24,323         Accrued rebates       59,457       60,374         Royalties and product license fees       5,789       9,320         Deferred revenue       13,335       17,225         Legal and professional       31,607       30,074         Accrued interest       11,765       3,989   | Less: accumulated depreciation | ,                | •                 |
| Payroll and employee benefit plan accruals       \$ 26,389       \$ 24,323         Accrued rebates       59,457       60,374         Royalties and product license fees       5,789       9,320         Deferred revenue       13,335       17,225         Legal and professional       31,607       30,074         Accrued interest       11,765       3,989  |                                | \$ 426,185       | \$ 406,875        |
| Payroll and employee benefit plan accruals       \$ 26,389       \$ 24,323         Accrued rebates       59,457       60,374         Royalties and product license fees       5,789       9,320         Deferred revenue       13,335       17,225         Legal and professional       31,607       30,074         Accrued interest       11,765       3,989  | Other current liabilities:     |                  |                   |
| Accrued rebates       59,457       60,374         Royalties and product license fees       5,789       9,320         Deferred revenue       13,335       17,225         Legal and professional       31,607       30,074         Accrued interest       11,765       3,989   |                                | \$ 26.389        | \$ 24.323         |
| Royalties and product license fees       5,789       9,320         Deferred revenue       13,335       17,225         Legal and professional       31,607       30,074         Accrued interest       11,765       3,989   | • • • •                        | •                | ' '               |
| Deferred revenue       13,335       17,225         Legal and professional       31,607       30,074         Accrued interest       11,765       3,989  |                                | ·                | ·                 |
| Legal and professional       31,607       30,074         Accrued interest       11,765       3,989   | · ·                            | ,                |                   |
| Accrued interest 11,765 3,989  | Legal and professional         | ,                |                   |
| ,  |                                | •                |                   |
|  | Other                          | ·                |                   |

\$ 161,182 \$ 158,487

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#### 7. Earnings per Common Share

Basic earnings per common share is computed by dividing net earnings by the weighted average number of common shares outstanding during the period. Diluted earnings per common share is computed by dividing net earnings by the weighted average number of common shares outstanding during the period adjusted for the dilutive effect of stock options and restricted stock outstanding. The effect of dilutive stock options on the weighted average number of common shares outstanding was 4,837,000 and 3,817,000 for the three months ended June 30, 2006 and 2005.

Stock options or restricted stock units representing 1,511,000 and 6,178,000 shares of common stock were outstanding as of June 30, 2006 and 2005, but were not included in the computation of diluted earnings per share for the three months then ended because to do so would have been antidilutive.

## 8. Intangible Assets

Intangible assets consist of the following components:

| (in thousands) June 30, 2006  | Weighted<br>Average<br>Life<br>(years) | Original<br>Cost                              |    | cumulated<br>nortization             |              | Book<br>alue                        |
|---|--|---|----|--------------------------------------|--------------|-------------------------------------|
| Amortized intangible assets: Patents and technologies Product rights and licenses Other | 20<br>12<br>20                         | \$ 118,935<br>102,006<br>14,267<br>\$ 235,208 | \$ | 56,408<br>72,669<br>7,428<br>136,505 | 2            | 62,527<br>29,337<br>6,839<br>98,703 |
| Intengible assets no longer subject to amortization:                                    |  | \$ 233,206                                    | φ  | 130,303                              | 7            | 96,703                              |
| Intangible assets no longer subject to amortization:<br>Trademarks                      |  |   |    |                                      |              | 783                                 |
|   |  |   |    |                                      | \$ 9         | 99,486                              |
| March 31, 2006  |  |   |    |                                      |              |                                     |
| Amortized intangible assets:  |  |   |    |                                      |              |                                     |
| Patents and technologies Product rights and licenses Other                              | 20<br>12<br>20                         | \$ 118,935<br>111,135<br>14,267               | \$ | 54,836<br>77,444<br>7,245            | \$ 3         | 64,099<br>33,691<br>7,022           |
|   |  | \$ 244,337                                    | \$ | 139,525                              | 10           | 04,812                              |
| Intangible assets no longer subject to amortization:<br>Trademarks                      |  |   |    |                                      |              | 783                                 |
|   |  |   |    |                                      | <b>.</b> 4.0 |                                     |

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\$ 105,595

Amortization expense for the three months ended June 30, 2006, and 2005 was \$3,370 and \$3,698 and is expected to be \$14,407, \$13,637, \$13,460, \$12,411, and \$11,259 for fiscal years 2007 through 2011, respectively.

## 9. Long-Term Debt

A summary of long-term debt is as follows:

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In thousands

|                            | June 30,<br>2006 |         |    | March 31,<br>2006 |  |  |
|----------------------------|------------------|---------|----|-------------------|--|--|
| Senior Notes (A)           | \$               | 500,000 | \$ | 500,000           |  |  |
| Senior credit facility (B) |                  | 187,464 |    | 187,938           |  |  |
|                            |                  | 687,464 |    | 687,938           |  |  |
| Less: Current portion      |                  | 464     |    | 2,750             |  |  |
| Total long-term debt       | \$               | 687,000 | \$ | 685,188           |  |  |

(A) On July 21, 2005, the Company issued \$500,000 in Senior Notes, which consisted of \$150,000 of Senior Notes due August 15, 2010, and bearing interest at 5 3/4% per annum (the 2010 Restricted Notes ) and \$350,000 of Senior Notes due August 15, 2015, and bearing interest at 6 3/8% per annum (the 2015 Restricted Notes , and collectively the Restricted Notes ). The proceeds from the Restricted Notes were used to finance a portion of the Dutch Auction self-tender described in Note 11.

Prior to maturity, the Company may, under certain circumstances, redeem the Notes in whole or in part at prices specified in the bond indenture governing the Notes. Upon a change of control (as defined in the indenture governing the Notes) of the Company, each holder of the Notes may require the Company to purchase all or a portion of such holder s Notes at 101% of the principal amount of such Notes, plus accrued and unpaid interest.

The Notes are senior unsecured obligations of the Company and rank junior to all of the Company s secured obligations. The Notes are guaranteed jointly and severally on a full and unconditional senior unsecured basis by all of the Company s wholly owned domestic subsidiaries except a captive insurance company, which is considered to be a minor subsidiary. Also, the assets and operations of Mylan Laboratories Inc. (Mylan Labs), the parent company, are not material, and, as such, condensed consolidating financial information for the parent and subsidiaries is not provided.

The Notes indenture contains covenants that, among other things, limit the ability of the Company to (a) incur additional secured indebtedness, (b) make investments or other restricted payments, (c) pay dividends on, redeem or repurchase the Company s capital stock, (d) engage in sale-leaseback transactions and (e) consolidate, merge or transfer all or substantially all of its assets. Certain of the covenants contained in the indenture will no longer be applicable or will be less restrictive if the Company achieves investment grade ratings as outlined in the indenture.

(B) On July 21, 2005, the Company entered into a \$500,000 senior secured credit facility (the Credit Facility ). The Credit Facility consisted of a \$225,000 five-year revolving credit facility (the Revolving Credit Facility ), and a \$275,000 five-year term loan (the Term Loan ), the proceeds of which were used to fund a portion of the Dutch Auction self-tender described in Note 11. Loans under the Revolving Credit Facility bore interest at a rate equal to either LIBOR plus 1.25% per annum or prime plus 0.25% per annum, at the Company s option, and the Term Loan bore interest at a rate equal to LIBOR plus 1.50% per annum or prime plus 0.50% per annum also at the Company s option.

The Term Loan interest rate in effect at June 30, 2006 was 6.85% and at March 31, 2006 was 6.33%. The Company was required to pay a fee on the unused portion of the Revolving Credit Facility of 0.50% per annum. At June 30, 2006 and March 31, 2006, no borrowings were outstanding under the Revolving Credit Facility. The Term Loan amortized at a rate of 1% per year for the first four years, with the balance paid in four equal quarterly installments thereafter. Subject to exceptions, the Credit Facility had mandatory prepayments with respect to certain proceeds of asset sales, debt issuances and equity issuances and with respect to the Company s excess cash flows. In March 2006, the Company elected to make a principal payment of \$85,000. Because the amount of mandatory prepayment would vary from quarter to quarter and could not be reasonably estimated, only the 1% per year amortization was included on the balance sheet as a current liability.

The Company s obligations under the Credit Facility were guaranteed jointly and severally on a full and unconditional senior secured basis by all of the Company s wholly owned domestic subsidiaries except a captive insurance company, which is considered to be a minor subsidiary. The obligations under the Credit Facility were also

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collateralized by a first priority lien on, and pledge of, 100% of the equity interests of certain of the Company s wholly owned domestic subsidiaries and 65% of the equity interests of each of the Company s foreign subsidiaries.

The Credit Facility included covenants that (a) required the Company to maintain a minimum interest coverage ratio and a maximum total leverage ratio, (b) placed limitations on the Company s ability to incur debt; grant liens; carry out mergers, acquisitions and asset sales; and make investments and (c) placed limitations on the Company s ability to pay dividends or make other restricted payments.

All financing fees associated with the Notes and the Credit Facility are being amortized over the life of the related debt. The total unamortized amounts of \$12,309 and \$12,813 are included in other assets in the Condensed Consolidated Balance Sheets at June 30, 2006 and March 31, 2006.

At June 30, 2006 the fair value of the Notes was approximately \$473,000. The Credit Facility s fair value approximated carrying value at June 30, 2006. At March 31, 2006, the carrying value of the Company s long-term debt approximated fair value.

Principal maturities of the Notes and Credit Facility for the next five years and thereafter, as of June 30, 2006, are as follows:

### (in thousands)

| Year 1     | \$ 464  |
|------------|---------|
| Year 2     |         |
| Year 3     |         |
| Year 4     |         |
| Year 5     | 337,000 |
| Thereafter | 350,000 |
|            |         |

\$687,464

On July 24, 2006, the Company borrowed \$187,000 under its new credit facility (see Note 13) and used the proceeds to repay the aggregate principal amount outstanding under the Term Loan.

#### 10. Comprehensive Earnings

Comprehensive earnings consist of the following:

| Three Months Ended June 30,                                  | 2006      | 2005      |
|--|-----------|-----------|
| (in thousands)   |           |           |
| Net earnings   | \$75,587  | \$42,915  |
| Other comprehensive earnings net of tax:                     |           |           |
| Net unrealized (loss) gain on marketable securities          | (898)     | 1,495     |
| Reclassification for losses (gains) included in net earnings | 735       | (14)      |
|  | (163)     | 1,481     |
| Comprehensive earnings                                       | \$ 75,424 | \$ 44,396 |

Accumulated other comprehensive earnings, as reflected on the balance sheet, is comprised solely of the net unrealized gain on marketable securities, net of deferred income taxes.

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#### 11. Common Stock

As of June 30, 2006 and March 31, 2006, there were 600,000,000 shares of common stock authorized with 309,667,720 and 309,150,251 shares issued. Treasury shares held as of June 30, 2006 and March 31,2006, were 98,836,731, and 98,971,431.

On June 14, 2005, the Company announced a \$1,250,000 share buyback, comprised of a modified Dutch Auction self-tender for up to \$1,000,000 (which commenced on June 16, 2005) and a \$250,000 follow-on share repurchase program. In the tender offer, shareholders were given the opportunity to tender some or all of their shares at a price not less than \$18.00 per share or more than \$20.50 per share. Based on the number of shares tendered and the prices specified by the tendering shareholders, the Company determined the lowest per share price within the range that would enable it to buy up to 48,780,487 shares, or such lesser number of shares as were properly tendered. Additionally, in the event the final purchase price was less than the maximum price of \$20.50 per share and more than 48,780,487 shares were tendered, the Company had the right to purchase up to an additional 2% of its outstanding common stock without extending the tender offer so that the Company could repurchase up to \$1,000,000 of its common stock.

The tender offer expired on July 15, 2005 and closed on July 21, 2005, at which time the Company announced that it accepted for payment an aggregate of 51,282,051 shares of its common stock at a purchase price of \$19.50 per share. The 51,282,051 shares are comprised of the 48,780,487 shares the Company offered to purchase and 2,501,564 shares purchased pursuant to the Company s right to purchase up to an additional 2%.

Additionally, during fiscal 2006, the Company purchased 12,595,200 shares for approximately \$250,000 on the open market under the follow-on repurchase program. The follow-on repurchase program was completed on February 14, 2006.

## 12. Contingencies

Dollar amounts in this Note 12 are as stated.

## Legal Proceedings

While it is not possible to determine with any degree of certainty the ultimate outcome of the following legal proceedings, the Company believes that it has meritorious defenses with respect to the claims asserted against it and intends to vigorously defend its position. An adverse outcome in any of these proceedings could have a material adverse effect on the Company s financial position and results of operations.

Omeprazole

In fiscal 2001, Mylan Pharmaceuticals Inc. (MPI), a wholly-owned subsidiary of Mylan Labs, filed an Abbreviated New Drug Application (ANDA) seeking approval from the FDA to manufacture, market and sell omeprazole delayed-release capsules and made Paragraph IV certifications to several patents owned by AstraZeneca PLC (AstraZeneca) that were listed in the FDA s. Orange Book. On September 8, 2000, AstraZeneca filed suit against MPI and Mylan Labs in the U.S. District Court for the Southern District of New York alleging infringement of several of AstraZeneca s patents. On May 29, 2003, the FDA approved MPI s ANDA for the 10 mg and 20 mg strengths of omeprazole delayed-release capsules, and, on August 4, 2003, Mylan Labs announced that MPI had commenced the sale of omeprazole 10 mg and 20 mg delayed-release capsules. AstraZeneca then amended the pending lawsuit to assert claims against Mylan Labs and MPI and filed a separate lawsuit against MPI s supplier, Esteve Quimica S.A. (Esteve), for unspecified money damages and a finding of willful infringement, which could result in treble damages, injunctive relief, attorneys fees, costs of litigation and such further relief as the court deems just and proper. MPI has certain indemnity obligations to Esteve in connection with this litigation. MPI, Esteve and the other generic manufacturers who are co-defendants in the case filed motions for summary judgment of non-infringement and patent invalidity. On January 12, 2006, those motions were denied, and a non-jury trial regarding liability only commenced on April 3, 2006, and was completed on June 14, 2006.

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Lorazepam and Clorazepate

On June 1, 2005, a jury verdict was rendered against Mylan Labs and MPI in the U.S. District Court for the District of Columbia (D.C.) in the amount of approximately \$12.0 million, which has been accrued for by the Company. The jury found Mylan willfully violated Massachusetts, Minnesota and Illinois state antitrust laws, meaning the amount of the verdict could be trebled and an award of attorneys fees and litigation costs could be made to the plaintiffs. The case was brought by four health insurers who opted out of earlier class action settlements agreed to by the Company in 2001 and represents the last remaining claims relating to Mylan s 1998 price increases for lorazepam and clorazepate. The Company filed a motion for judgment as a matter of law, a motion for a new trial and a motion to reduce verdict, all of which remain pending before the court. If the Company s post-verdict motions are denied, the Company intends to appeal to the U.S. Court of Appeals for the D.C. Circuit.

Pricing and Medicaid Litigation

On June 26, 2003, MPI and UDL Laboratories Inc. (UDL), a subsidiary of Mylan Labs, received requests from the U.S. House of Representatives Energy and Commerce Committee (the Committee) seeking information about certain products sold by MPI and UDL in connection with the Committee s investigation into pharmaceutical reimbursement and rebates under Medicaid. MPI and UDL are cooperating with this inquiry and provided information in response to the Committee s requests in 2003. Several states attorneys general (AG) have also sent letters to MPI, UDL and Mylan Bertek, demanding that those companies retain documents relating to Medicaid reimbursement and rebate calculations pending the outcome of unspecified investigations by those AGs into such matters. In addition, in July 2004, Mylan Labs received subpoenas from the AGs of California and Florida in connection with civil investigations purportedly related to price reporting and marketing practices regarding various drugs. As noted below, both California and Florida subsequently filed suits against Mylan, and the Company believes any further requests for information and disclosures will be made as part of that litigation.

Beginning in September 2003, Mylan Labs, MPI and/or UDL, together with many other pharmaceutical companies, have been named in a series of civil lawsuits filed by state AGs and municipal bodies within the state of New York alleging generally that the defendants defrauded the state Medicaid systems by allegedly reporting Average Wholesale Prices (AWP) and/or Wholesale Acquisition Costs that exceeded the actual selling price of the defendants prescription drugs. To date, Mylan Labs, MPI and UDL have been named as defendants in substantially similar civil lawsuits filed by the AGs of Alabama, California, Florida, Illinois, Kentucky, Massachusetts, Mississippi, Missouri and Wisconsin and also by the city of New York and approximately 40 counties across New York State. Several of these cases have been transferred to the AWP multi-district litigation proceedings pending in the U.S. District Court for the District of Massachusetts for pretrial proceedings. Others of these cases will likely be litigated in the state courts in which they were filed. Each of the cases seeks an unspecified amount in money damages, civil penalties and/or treble damages, counsel fees and costs, and injunctive relief. In each of these matters, with the exception of the Massachusetts, Alabama and Kentucky AG actions discussed below, Mylan Labs and its subsidiaries either have not yet been required to respond to the complaints or have motions to dismiss pending. The Company previously reported that the U.S. District Court for the District of Massachusetts had dismissed the complaint filed by the Massachusetts AG without prejudice and with leave to amend. The Massachusetts AG since filed an amended complaint which survived motions to dismiss, and Mylan Labs answered on November 14, 2005, denying liability. In addition, the Alabama AG filed a second amended complaint which has survived motions to dismiss, and Mylan Labs, MPI and UDL answered on January 30, 2006, denying liability. The Kentucky AG s first amended complaint has survived motions to dismiss, and Mylan Labs and MPI answered on July 19, 2006, denying liability. Lastly, we have been advised that Mylan Labs and MPI have been included as defendants in an AWP complaint filed by the state of Hawaii. Neither entity, however, has been served with a complaint in that action. Mylan Labs and its subsidiaries intend to defend each of these actions vigorously.

In addition by letter dated January 12, 2005, MPI was notified by the U.S. Department of Justice of an investigation concerning MPI s calculations of Medicaid drug rebates. To the best of MPI s information, the investigation is in its early stages. MPI is collecting information requested by the government and is cooperating fully with the government s investigation.

Modafanil Antitrust Litigation and FTC Inquiry

Beginning in April 2006, Mylan Labs, along with 4 other drug manufacturers, has been named in a series of civil lawsuits filed in the Eastern District of Pennsylvania by a variety of plaintiffs purportedly representing direct and indirect purchasers of the drug modafanil

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and one action brought by Apotex, Inc., a manufacturer of generic drugs seeking approval to market a generic modafanil product. These actions allege violations of federal and state laws in connection with the defendants settlement of patent litigation relating to modafanil. These actions are in their preliminary stages, and Mylan Labs has not yet been required to respond to any complaint. Mylan Labs intends to defend each of these actions vigorously. In addition, by letter dated July 11, 2006, Mylan was notified by the U.S. Federal Trade Commission (FTC) of an investigation relating to the settlement of the modafanil patent litigation. In its letter, the FTC requested certain information from Mylan Labs, MPI and Mylan Technologies, Inc. (Mylan Tech) pertaining to the patent litigation and the settlement thereof.

#### Other Litigation

The Company is involved in various other legal proceedings that are considered normal to its business. While it is not feasible to predict the ultimate outcome of such other proceedings, the Company believes that the ultimate outcome of such other proceedings will not have a material adverse effect on its financial position or results of operations.

## 13. Subsequent Event

On July 24, 2006, the Company completed the refinancing of its Credit Facility by entering into a credit agreement for a new five-year \$700,000 senior unsecured revolving credit facility (the New Facility). Borrowings totaling \$187,000 were made under the New Facility and were used to repay the Term Loan. These borrowings bear interest at a rate equal to LIBOR plus 0.60% per annum. The remaining unused portion of the New Facility is available for working capital and general corporate purposes, including acquisitions.

At the Company s option, loans under the New Facility will bear interest at either a rate equal to LIBOR plus an applicable margin of 0.60% or at a base rate, as defined in the agreement. In addition, the Company is required to pay a facility fee on average daily amount of the commitments (whether used or unused) of the New Facility at a rate, which ranges from 0.10% to 0.175%, based on the Company s total leverage ratio.

The Company s obligations under the New Facility are guaranteed on a senior unsecured basis by all of the Company s direct and indirect domestic subsidiaries, except a captive insurance company.

The New Facility includes covenants that (a) require the Company to maintain a minimum interest coverage ratio and a maximum total leverage ratio, (b) place limitations on the Company s subsidiaries ability to incur debt, (c) place limitations on the Company s and the Company s subsidiaries ability to grant liens, carry out mergers, consolidations and sales of all or substantially all of its assets and (d) place limitations on the Company s and the Company s subsidiaries ability to pay dividends or make other restricted payments. The New Facility contains customary events of default, including nonpayment, misrepresentation, breach of covenants and bankruptcy.

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

The following discussion and analysis addresses material changes in the results of operations and financial condition of Mylan Laboratories Inc. and Subsidiaries ( the Company , Mylan or we ) for the periods presented. This discussion and analysis should be read in conjunction with the Consolidated Financial Statements, the related Notes to Consolidated Financial Statements and Management s Discussion and Analysis of Results of Operations and Financial Condition included in the Company s Annual Report on Form 10-K for the fiscal year ended March 31, 2006, the unaudited interim Condensed Consolidated Financial Statements and related Notes included in Item 1 of this Report on Form 10-Q ( Form 10-Q ) and the Company s other SEC filings and public disclosures.

This Form 10-Q may contain forward-looking statements . These statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements may include, without limitation, statements about the Company s market opportunities, strategies, competition and expected activities and expenditures, and at times may be identified by the use of words such as may , will , could , should , would , project , believe , anticipate , expect , plan , estimate , forecast , potential ,

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intend, continue and variations of these words or comparable words. Forward-looking statements inherently involve risks and uncertainties. Accordingly, actual results may differ materially from those expressed or implied by these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, the risks described below under Risk Factors in Part II, Item 1A. The Company undertakes no obligation to update any forward-looking statements for revisions or changes after the date of this Form 10-Q.

#### Overview

Mylan s financial results for the three months ended June 30, 2006, included total revenues of \$356.1 million, net earnings of \$75.6 million and earnings per diluted share of \$0.35. Comparatively, the three months ended June 30, 2005, included total revenues of \$323.4 million, net earnings of \$42.9 million and earnings per diluted share of \$0.16. This represents an increase of 10% in total revenues, 76% in net earnings and 119% in earnings per diluted share when compared to the same prior year period. Included in earnings per share for the first quarter of fiscal 2007 are stock based compensation costs totaling \$0.02 per share as a result of the Company s adoption of Statement of Financial Accounting Standards (SFAS) No. 123 (revised 2004), *Share-Based Payment* (SFAS 123R). Included in earnings per share for the first quarter of fiscal 2006 was a charge of \$0.03 per diluted share with respect to a contingent legal liability related to previously-disclosed litigation in connection with the Company s lorazepam and clorazepate products and \$0.02 per share related to the closure of Mylan s subsidiary, Mylan Bertek Pharmaceuticals Inc. (Mylan Bertek).

## **Results of Operations**

## Quarter Ended June 30, 2006, Compared to Quarter Ended June 30, 2005

Total Revenues and Gross Profit

Total revenues for the current quarter increased 10% or \$32.8 million to \$356.1 million compared to \$323.4 million in the first quarter of fiscal 2006.

The increase in net revenues in the first quarter of fiscal 2007 was primarily volume driven, with fentanyl being the most significant product in terms of increased sales. Fentanyl, which accounts for approximately 20% of the Company s net revenues, continues to be the only AB-rated generic alternative to Duragesie. Fentanyl revenues benefited from Mylan s ability to meet market shortages during the first quarter as well as a rise in overall prescription trends for Mylan s fentanyl product. In total for the quarter, doses shipped increased by over 15% to 3.5 billion from 3.0 billion in the first quarter of Mylan s prior fiscal year.

Overall, pricing on the Company s product portfolio remained stable when compared to the prior year. As is the case in the generic industry, the entrance into the market of additional competition generally has a negative impact on the volume and pricing of the affected products.

Other revenue for the quarter ended June 30, 2006, consisted primarily of amounts recognized with respect to Apokyn<sup>®</sup> which was sold in the prior year, with the remainder primarily attributable to royalties.

Gross profit increased 12% or \$20.4 million to \$188.2 million and gross margins increased to 52.8% from 51.9%. A significant portion of gross profit was comprised of fentanyl which contributes margins well in excess of most other products in our portfolio. Absent any changes to market dynamics or the current competitive landscape for fentanyl, the Company expects the product to continue to be a significant contributor to sales and gross profit. *Operating Expenses* 

Research and development (R&D) expenses for the current quarter decreased 16% or \$4.0 million to \$21.2 million from \$25.2 million in the same prior year period. This decrease was primarily due to a decline in the number of ongoing R&D studies, primarily with respect to nebivolol which was outlicensed in the fourth quarter of 2006.

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Selling, general and administrative (SG&A) expenses decreased by 30% or \$21.3 million to \$49.8 million from \$71.1 million. This decrease is the direct result of the closure of Mylan Bertek in the first quarter of 2006. Charges of \$10.0 million were incurred within SG&A during the first quarter of fiscal 2006 related to employee termination and severance costs, lease termination costs and asset write-downs.

#### Interest Expense

During the second quarter of fiscal 2006, Mylan completed the financing of \$500.0 million in Senior Notes and a \$500.0 million senior secured credit facility. Interest expense related to this financing was \$10.4 million for the first quarter of fiscal 2007. Included in interest expense is a commitment fee on the unused portion of the revolving credit facility and the amortization of financing fees.

## Litigation, net

The first quarter of fiscal 2006 included a charge of \$12.0 million for a contingent liability with respect to the Company s previously disclosed lorazepam and clorazepate product litigation.

#### Other Income, net

Other income, net of non-operating expenses, was \$9.6 million in the first quarter of fiscal 2007 compared to \$5.6 million in the same prior year period. The increase is primarily the result of income related to our investment in Somerset Pharmaceuticals, Inc. (Somerset).

We own a 50% equity interest in Somerset and account for this investment using the equity method of accounting. During the quarter ended June 30, 2006, Mylan received a cash payment from Somerset of approximately \$5.5 million. The amount in excess of the carrying value of our investment in Somerset, approximately \$5.0 million, was recorded as equity income.

## Liquidity and Capital Resources

The Company s primary source of liquidity continues to be cash flows from operating activities, which were \$92.9 million. Working capital as of June 30, 2006, was \$999.9 million, an increase of \$73.2 million from the balance at March 31, 2006. The majority of this increase was the result of higher marketable securities and accounts receivable, net, partially offset by higher income taxes payable.

The increase in accounts receivable is primarily due to the timing of cash collections and increased shipments during the quarter. Income taxes payable increased primarily as a result of the timing of tax payments.

Cash used in investing activities for the three months ended June 30, 2006, was \$75.2 million. Of the Company s \$2.0 billion of total assets at June 30, 2006, \$568.0 million was held in cash, cash equivalents and marketable securities. Investments in marketable securities consist primarily of a variety of high credit quality debt securities, including U.S. government, state and local government and corporate obligations. These investments are highly liquid and available for working capital needs. As these instruments mature, the funds are generally reinvested in instruments with similar characteristics.

Capital expenditures during the three months ended June 30, 2006, were \$27.7 million. These expenditures were incurred primarily with respect to the Company s previously announced planned expansions and the implementation of an integrated ERP system. The Company expects capital expenditures for fiscal 2007 to approximate \$135.0 million as a result of the timing and scope of certain previously announced capital projects.

Cash used in financing activities was \$13.8 million for the three months ended June 30, 2006, and was comprised primarily of cash dividends paid. In the first quarter of fiscal 2006, the Board voted to double the amount of the quarterly dividend to \$0.06 per share, effective with the dividend paid for the first quarter of fiscal 2006.

The Company is involved in various legal proceedings that are considered normal to its business (see Note 12 to Condensed Consolidated Financial Statements). While it is not feasible to predict the outcome of such proceedings,

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an adverse outcome in any of these proceedings could materially affect the Company s financial position and results of operations.

The Company is actively pursuing, and is currently involved in, joint projects related to the development, distribution and marketing of both generic and brand products. Many of these arrangements provide for payments by the Company upon the attainment of specified milestones. While these arrangements help to reduce the financial risk for unsuccessful projects, fulfillment of specified milestones or the occurrence of other obligations may result in fluctuations in cash flows.

The Company is continuously evaluating the potential acquisition of products, as well as companies, as a strategic part of its future growth. Consequently, the Company may utilize current cash reserves or incur additional indebtedness to finance any such acquisitions, which could impact future liquidity.

## **Recent Accounting Pronouncements**

In July 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes an Interpretation of FASB Statement 109* (FIN 48), which clarifies the accounting for uncertain tax positions. This Interpretation provides that the tax effects from an uncertain tax position be recognized in the Company's financial statements, only if the position is more likely than not of being sustained on audit, based on the technical merits of the position. The provisions of FIN 48 will be effective for Mylan as of the beginning of fiscal 2008. The Company is currently evaluating the impact of adopting FIN 48 on our consolidated financial statements.

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

The Company is subject to market risk primarily from changes in the market values of investments in its marketable debt securities and interest rate risk from changes in interest rates associated with its long-term debt. In addition to marketable debt and equity securities, investments are made in overnight deposits, money market funds and marketable securities with maturities of less than three months. These instruments are classified as cash equivalents for financial reporting purposes and have minimal or no interest rate risk due to their short-term nature.

The following table summarizes the investments in marketable debt and equity securities which subject the Company to market risk at June 30, 2006 and March 31, 2006:

|                   | June 30,  | March 31,  |
|-------------------|-----------|------------|
| (in thousands)    | 2006      | 2006       |
| Debt securities   | \$409,006 | \$ 362,458 |
| Equity securities | 4,995     | 5,545      |
|                   |           |            |
|                   | \$414,001 | \$ 368,003 |

#### Marketable Debt Securities

The primary objectives for the marketable debt securities investment portfolio are liquidity and safety of principal. Investments are made to achieve the highest rate of return while retaining principal. Our investment policy limits investments to certain types of instruments issued by institutions and government agencies with investment-grade credit ratings. At June 30, 2006, the Company had invested \$409.0 million in marketable debt securities, of which \$72.1 million will mature within one year and \$336.9 million will mature after one year. The short duration to maturity creates minimal exposure to fluctuations in market values for investments that will mature within one year. However, a significant change in current interest rates could affect the market value of the remaining \$336.9 million of marketable debt securities that mature after one year would result in a \$16.8 million change in marketable debt securities.

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Long-Term Debt

On July 21, 2005, the Company issued \$500.0 million in Senior Notes with fixed interest rates (which were exchanged for registered notes, as described previously) and, on July 24, 2006, entered into a five-year \$700.0 million senior unsecured revolving credit facility (the 2006 Credit Facility ). Loans under the 2006 Credit Facility bear interest at a rate equal to either LIBOR plus an applicable margin of 0.60% or at a base rate, which is defined as the higher of the rate announced publicly by the administrative agent, from time to time, as its prime rate or 0.5% above the federal funds rate. In the case of the applicable margin for advances based on LIBOR, after the delivery by the Company to the administrative agent of its financial statements for the third fiscal quarter of 2006, the applicable margin may increase or decrease, within a range from 0.40% to 0.70%, based on the Company s total leverage ratio. In addition, the Company is required to pay a facility fee on average daily amount of the commitments (whether used or unused) of the Credit Facility at a rate, which ranges from 0.10% to 0.175%, based on the Company s total leverage ratio. On July 24, 2006, the Company borrowed \$187.0 million under the 2006 Credit Facility and used the proceeds to repay the aggregate principal amount outstanding under the Company s previous credit agreement, dated as of July 21, 2005 (the Previous Credit Agreement ), among the Company, the lenders and other financial institutions party thereto and Merrill Lynch Capital Corporation, as administrative agent.

Generally, the fair market value of fixed interest rate debt will decrease as interest rates rise and increase as interest rates fall. At June 30, 2006 the fair value of the Notes were approximately \$473.0 million, respectively. The Credit Facility s fair value approximated carrying value at June 30, 2006. At March 31, 2006, the carrying value of our long-term debt approximated fair value. A 10% change in interest rates on the term loan would result in a change in interest expense of approximately \$1.3 million per year.

## ITEM 4. CONTROLS AND PROCEDURES

An evaluation was performed under the supervision and with the participation of the Company s management, including the Chief Executive Officer and the Chief Financial Officer, of the effectiveness of the design and operation of the Company s disclosure controls and procedures as of June 30, 2006. Based upon that evaluation, the Chief Executive Officer and the Chief Financial Officer concluded that the Company s disclosure controls and procedures were effective. During the three months ended June 30, 2006, the Company implemented the payroll, benefits and personnel administration modules associated with our new enterprise resource planning (ERP) system. We will continue to implement other modules of this ERP system in a phased approach. No other change in the Company s internal control over financial reporting occurred during the last fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company s internal control over financial reporting.

# PART II. OTHER INFORMATION ITEM 1. LEGAL PROCEEDINGS

For a description of the material pending legal proceedings to which the Company is a party, please see our Annual Report on Form 10-K for the year ended March 31, 2006. During the quarter ended June 30, 2006, there were no new material legal proceedings or material developments with respect to pending proceedings other than as described below. While it is not possible to determine with any degree of certainty the ultimate outcome of the following legal proceedings, the Company believes that it has meritorious defenses with respect to the claims asserted against it and intends to vigorously defend its position. An adverse outcome in any of these proceedings could have a material adverse effect on the Company s financial position and results of operations. *Omeprazole* 

In fiscal 2001, Mylan Pharmaceuticals Inc. (MPI), a wholly-owned subsidiary of Mylan Labs, filed an Abbreviated New Drug Application (ANDA) seeking approval from the FDA to manufacture, market and sell omeprazole delayed-release capsules and made Paragraph IV certifications to several patents owned by AstraZeneca PLC (AstraZeneca) that were listed in the FDA s Orange Book. On September 8, 2000, AstraZeneca filed suit

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against MPI and Mylan Labs in the U.S. District Court for the Southern District of New York alleging infringement of several of AstraZeneca s patents. On May 29, 2003, the FDA approved MPI s ANDA for the 10 mg and 20 mg strengths of omeprazole delayed-release capsules, and, on August 4, 2003, Mylan Labs announced that MPI had commenced the sale of omeprazole 10 mg and 20 mg delayed-release capsules. AstraZeneca then amended the pending lawsuit to assert claims against Mylan Labs and MPI and filed a separate lawsuit against MPI s supplier, Esteve Quimica S.A. (Esteve), for unspecified money damages and a finding of willful infringement, which could result in treble damages, injunctive relief, attorneys fees, costs of litigation and such further relief as the court deems just and proper. MPI has certain indemnity obligations to Esteve in connection with this litigation. MPI, Esteve and the other generic manufacturers who are co-defendants in the case filed motions for summary judgment of non-infringement and patent invalidity. On January 12, 2006, those motions were denied, and a non-jury trial regarding liability only commenced on April 3, 2006, and was completed on June 14, 2006. *Pricing and Medicaid Litigation* 

On June 26, 2003, MPI and UDL Laboratories Inc. (UDL), a subsidiary of Mylan Labs, received requests from the U.S. House of Representatives Energy and Commerce Committee (the Committee) seeking information about certain products sold by MPI and UDL in connection with the Committee s investigation into pharmaceutical reimbursement and rebates under Medicaid. MPI and UDL are cooperating with this inquiry and provided information in response to the Committee s requests in 2003. Several states attorneys general (AG) have also sent letters to MPI, UDL and Mylan Bertek, demanding that those companies retain documents relating to Medicaid reimbursement and rebate calculations pending the outcome of unspecified investigations by those AGs into such matters. In addition, in July 2004, Mylan Labs received subpoenas from the AGs of California and Florida in connection with civil investigations purportedly related to price reporting and marketing practices regarding various drugs. As noted below, both California and Florida subsequently filed suits against Mylan, and the Company believes any further requests for information and disclosures will be made as part of that litigation.

Beginning in September 2003, Mylan Labs, MPI and/or UDL, together with many other pharmaceutical companies, have been named in a series of civil lawsuits filed by state AGs and municipal bodies within the state of New York alleging generally that the defendants defrauded the state Medicaid systems by allegedly reporting Average Wholesale Prices (AWP) and/or Wholesale Acquisition Costs that exceeded the actual selling price of the defendants prescription drugs. To date, Mylan Labs, MPI and UDL have been named as defendants in substantially similar civil lawsuits filed by the AGs of Alabama, California, Florida, Illinois, Kentucky, Massachusetts, Mississippi, Missouri and Wisconsin and also by the city of New York and approximately 40 counties across New York State. Several of these cases have been transferred to the AWP multi-district litigation proceedings pending in the U.S. District Court for the District of Massachusetts for pretrial proceedings. Others of these cases will likely be litigated in the state courts in which they were filed. Each of the cases seeks an unspecified amount in money damages, civil penalties and/or treble damages, counsel fees and costs, and injunctive relief. In each of these matters, with the exception of the Massachusetts, Alabama and Kentucky AG actions discussed below, Mylan Labs and its subsidiaries either have not yet been required to respond to the complaints or have motions to dismiss pending. The Company previously reported that the U.S. District Court for the District of Massachusetts had dismissed the complaint filed by the Massachusetts AG without prejudice and with leave to amend. The Massachusetts AG since filed an amended complaint which survived motions to dismiss, and Mylan Labs answered on November 14, 2005, denying liability. In addition, the Alabama AG filed a second amended complaint which has survived motions to dismiss, and Mylan Labs, MPI and UDL answered on January 30, 2006, denying liability. The Kentucky AG s first amended complaint has survived motions to dismiss, and Mylan Labs and MPI answered on July 19, 2006, denying liability. Lastly, we have been advised that Mylan Labs and MPI have been included as defendants in an AWP complaint filed by the state of Hawaii. Neither entity, however, has been served with a complaint in that action. Mylan Labs and its subsidiaries intend to defend each of these actions vigorously.

In addition by letter dated January 12, 2005, MPI was notified by the U.S. Department of Justice of an investigation concerning MPI s calculations of Medicaid drug rebates. To the best of MPI s information, the investigation is in its early stages. MPI is collecting information requested by the government and is cooperating fully with the government s investigation.

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Modafanil Antitrust Litigation and FTC Inquiry

Beginning in April 2006, Mylan Labs, along with 4 other drug manufacturers, has been named in a series of civil lawsuits filed in the Eastern District of Pennsylvania by a variety of plaintiffs purportedly representing direct and indirect purchasers of the drug modafanil and one action brought by Apotex, Inc., a manufacturer of generic drugs seeking approval to market a generic modafanil product. These actions allege violations of federal and state laws in connection with the defendants—settlement of patent litigation relating to modafanil. These actions are in their preliminary stages, and Mylan Labs has not yet been required to respond to any complaint. Mylan Labs intends to defend each of these actions vigorously. In addition, by letter dated July 11, 2006, Mylan was notified by the U.S. Federal Trade Commission (FTC) of an investigation relating to the settlement of the modafanil patent litigation. In its letter, the FTC requested certain information from Mylan Labs, MPI and Mylan Technologies, Inc. pertaining to the patent litigation and the settlement thereof.

Other Litigation

The Company is involved in various other legal proceedings that are considered normal to its business. While it is not feasible to predict the ultimate outcome of such other proceedings, the Company believes that the ultimate outcome of such other proceedings will not have a material adverse effect on its financial position or results of operations.

#### ITEM 1A. RISK FACTORS

The following risk factors could have a material adverse effect on our business, financial position or results of operations and could cause the market value of our common stock to decline. These risk factors may not include all of the important factors that could affect our business or our industry or that could cause our future financial results to differ materially from historic or expected results or cause the market price of our common stock to fluctuate or decline.

OUR FUTURE REVENUE GROWTH AND PROFITABILITY ARE DEPENDENT UPON OUR ABILITY TO DEVELOP AND/OR LICENSE, OR OTHERWISE ACQUIRE, AND INTRODUCE NEW PRODUCTS ON A TIMELY BASIS IN RELATION TO OUR COMPETITORS PRODUCT INTRODUCTIONS. OUR FAILURE TO DO SO SUCCESSFULLY COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

Our future revenues and profitability will depend, to a significant extent, upon our ability to successfully develop and/or license, or otherwise acquire and commercialize new generic and patent or statutorily protected (usually brand) pharmaceutical products in a timely manner. Product development is inherently risky, especially for new drugs for which safety and efficacy have not been established, and the market is not yet proven. Likewise, product licensing involves inherent risks including uncertainties due to matters that may affect the achievement of milestones, as well as the possibility of contractual disagreements with regard to terms such as license scope or termination rights. The development and commercialization process, particularly with regard to new drugs, also requires substantial time, effort and financial resources. We, or a partner, may not be successful in commercializing any of the products that we are developing or licensing (including, without limitation, nebivolol) on a timely basis, if at all, which could adversely affect our product introduction plans, financial position and results of operations and could cause the market value of our common stock to decline.

FDA approval is required before any prescription drug product, including generic drug products, can be marketed. The process of obtaining FDA approval to manufacture and market new and generic pharmaceutical products is rigorous, time-consuming, costly and largely unpredictable. We, or a partner, may be unable to obtain requisite FDA approvals on a timely basis for new generic or brand products that we may develop, license or otherwise acquire. Also, for products pending approval, we may obtain raw materials or produce batches of inventory to be used in efficacy and bioequivalence testing, as well as in anticipation of the product s launch. In the event that FDA approval is denied or delayed we could be exposed to the risk of this inventory becoming obsolete. The timing and cost of obtaining FDA approvals could adversely affect our product introduction plans, financial position and results of operations and could cause the market value of our common stock to decline.

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The ANDA approval process often results in the FDA granting final approval to a number of ANDAs for a given product at the time a patent claim for a corresponding brand product or other market exclusivity expires. This often forces us to face immediate competition when we introduce a generic product into the market. Additionally, ANDA approvals often continue to be granted for a given product subsequent to the initial launch of the generic product. These circumstances generally result in significantly lower prices, as well as reduced margins, for generic products compared to brand products. New generic market entrants generally cause continued price and margin erosion over the generic product life cycle.

The Waxman-Hatch Act provides for a period of 180 days of generic marketing exclusivity for each ANDA applicant that is first to file an ANDA containing a certification of invalidity, non-infringement or unenforceability related to a patent listed with respect to a reference drug product, commonly referred to as a Paragraph IV certification. During this exclusivity period, which under certain circumstances may be required to be shared with other applicable ANDA sponsors with Paragraph IV certifications, the FDA cannot grant final approval to other ANDA sponsors holding applications for the same generic equivalent. If an ANDA containing a Paragraph IV certification is successful and the applicant is awarded exclusivity, it generally results in higher market share, net revenues and gross margin for that applicant. Even if we obtain FDA approval for our generic drug products, if we are not the first ANDA applicant to challenge a listed patent for such a product, we may lose significant advantages to a competitor that filed its ANDA containing such a challenge. The same would be true in situations where we are required to share our exclusivity period with other ANDA sponsors with Paragraph IV certifications. Such situations could have a material adverse effect on our ability to market that product profitably and on our financial position and results of operations, and the market value of our common stock could decline.

OUR APPROVED PRODUCTS MAY NOT ACHIEVE EXPECTED LEVELS OF MARKET ACCEPTANCE, WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR PROFITABILITY, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

Even if we are able to obtain regulatory approvals for our new pharmaceutical products, generic or brand, the success of those products is dependent upon market acceptance. Levels of market acceptance for our new products could be impacted by several factors, including:

the availability of alternative products from our competitors;

the price of our products relative to that of our competitors;

the timing of our market entry;

the ability to market our products effectively to the retail level; and

the acceptance of our products by government and private formularies.

Some of these factors are not within our control. Our new products may not achieve expected levels of market acceptance. Additionally, continuing studies of the proper utilization, safety and efficacy of pharmaceutical products are being conducted by the industry, government agencies and others. Such studies, which increasingly employ sophisticated methods and techniques, can call into question the utilization, safety and efficacy of previously marketed products. For example, on July 15, 2005, the FDA issued a Public Health Advisory regarding the safe use of transdermal fentanyl patches, a product we currently market, the loss of revenues of which could have a significant impact on our business. In some cases, studies have resulted, and may in the future result, in the discontinuance of product marketing or other risk management programs such as the need for a patient registry. These situations, should they occur, could have a material adverse effect on our profitability, financial position and results of operations, and the market value of our common stock could decline.

A RELATIVELY SMALL GROUP OF PRODUCTS MAY REPRESENT A SIGNIFICANT PORTION OF OUR NET REVENUES, GROSS PROFIT OR NET EARNINGS FROM TIME TO TIME. IF THE VOLUME OR PRICING OF ANY OF THESE PRODUCTS DECLINES, IT COULD HAVE A MATERIAL

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# ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

Sales of a limited number of our products often represent a significant portion of our net revenues, gross profit and net earnings. If the volume or pricing of our largest selling products declines in the future, our business, financial position and results of operations could be materially adversely affected, and the market value of our common stock could decline.

WE FACE VIGOROUS COMPETITION FROM OTHER PHARMACEUTICAL MANUFACTURERS THAT THREATENS THE COMMERCIAL ACCEPTANCE AND PRICING OF OUR PRODUCTS, WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

Our competitors may be able to develop products and processes competitive with or superior to our own for many reasons, including that they may have:

proprietary processes or delivery systems;

larger research and development and marketing staffs;

larger production capabilities in a particular therapeutic area;

more experience in preclinical testing and human clinical trials;

more products; or

more experience in developing new drugs and financial resources, particularly with regard to brand manufacturers.

Any of these factors and others could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

BECAUSE THE PHARMACEUTICAL INDUSTRY IS HEAVILY REGULATED, WE FACE SIGNIFICANT COSTS AND UNCERTAINTIES ASSOCIATED WITH OUR EFFORTS TO COMPLY WITH APPLICABLE REGULATIONS. SHOULD WE FAIL TO COMPLY WE COULD EXPERIENCE MATERIAL ADVERSE EFFECTS ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS, AND THE MARKET VALUE OF OUR COMMON STOCK COULD DECLINE.

The pharmaceutical industry is subject to regulation by various federal and state governmental authorities. For instance, we must comply with FDA requirements with respect to the manufacture, labeling, sale, distribution, marketing, advertising, promotion and development of pharmaceutical products. Failure to comply with FDA and other governmental regulations can result in fines, disgorgement, unanticipated compliance expenditures, recall or seizure of products, total or partial suspension of production and/or distribution, suspension of the FDA s review of NDAs or ANDAs, enforcement actions, injunctions and criminal prosecution. Under certain circumstances, the FDA also has the authority to revoke previously granted drug approvals. Although we have internal regulatory compliance programs and policies and have had a favorable compliance history, there is no guarantee that these programs, as currently designed, will meet regulatory agency standards in the future. Additionally, despite our efforts at compliance, there is no guarantee that we may not be deemed to be deficient in some manner in the future. If we were deemed to be deficient in any significant way, our business, financial position and results of operations could be materially affected and the market value of our common stock could decline.

In addition to the new drug approval process, the FDA also regulates the facilities and operational procedures that we use to manufacture our products. We must register our facilities with the FDA. All products manufactured in those facilities must be made in a manner consistent with current good manufacturing practices ( cGMP ). Compliance with cGMP regulations requires substantial expenditures of time, money and effort in such areas as

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production and quality control to ensure full technical compliance. The FDA periodically inspects our manufacturing facilities for compliance. FDA approval to manufacture a drug is site-specific. Failure to comply with cGMP regulations at one of our manufacturing facilities could result in an enforcement action brought by the FDA which could include withholding the approval of NDAs, ANDAs or other product applications of that facility. If the FDA were to require one of our manufacturing facilities to cease or limit production, our business could be adversely affected. Delay and cost in obtaining FDA approval to manufacture at a different facility also could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

We are subject, as are generally all manufacturers, to various federal, state and local laws regulating working conditions, as well as environmental protection laws and regulations, including those governing the discharge of materials into the environment. Although we have not incurred significant costs associated with complying with environmental provisions in the past, if changes to such environmental laws and regulations are made in the future that require significant changes in our operations or if we engage in the development and manufacturing of new products requiring new or different environmental controls, we may be required to expend significant funds. Such changes could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

OUR REPORTING AND PAYMENT OBLIGATIONS UNDER THE MEDICAID REBATE PROGRAM AND OTHER GOVERNMENTAL PURCHASING AND REBATE PROGRAMS ARE COMPLEX AND MAY INVOLVE SUBJECTIVE DECISIONS. ANY DETERMINATION OF FAILURE TO COMPLY WITH THOSE OBLIGATIONS COULD SUBJECT US TO PENALTIES AND SANCTIONS WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS, AND THE MARKET VALUE OF OUR COMMON STOCK COULD DECLINE.

The regulations regarding reporting and payment obligations with respect to Medicaid reimbursement and rebates and other governmental programs are complex, and as discussed elsewhere in this Form 10-Q, we and other pharmaceutical companies are defendants in a number of suits filed by state attorneys general and have been notified of an investigation by the U.S. Department of Justice with respect to Medicaid reimbursement and rebates. Our calculations and methodologies are currently being reviewed internally and likewise are subject to review and challenge by the applicable governmental agencies, and it is possible that such reviews could result in material changes. In addition, because our processes for these calculations and the judgments involved in making these calculations involve, and will continue to involve, subjective decisions and complex methodologies, these calculations are subject to the risk of errors.

In addition, as also disclosed in this Form 10-Q, a number of state and federal government agencies are conducting investigations of manufacturers—reporting practices with respect to Average Wholesale Prices (AWP), in which they have suggested that reporting of inflated AWP has led to excessive payments for prescription drugs. We and numerous other pharmaceutical companies have been named as defendants in various actions relating to pharmaceutical pricing issues and whether allegedly improper actions by pharmaceutical manufacturers led to excessive payments by Medicare and/or Medicaid.

Any governmental agencies that have commenced, or may commence, an investigation of the Company could impose, based on a claim of violation of fraud and false claims laws or otherwise, civil and/or criminal sanctions, including fines, penalties and possible exclusion from federal health care programs (including Medicaid and Medicare). Some of the applicable laws may impose liability even in the absence of specific intent to defraud. Furthermore, should there be ambiguity with regard to how to properly calculate and report payments-and even in the absence of any such ambiguity-a governmental authority may take a position contrary to a position we have taken, and may impose civil and/or criminal sanctions. Any such penalties or sanctions could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

WE EXPEND A SIGNIFICANT AMOUNT OF RESOURCES ON RESEARCH AND DEVELOPMENT EFFORTS THAT MAY NOT LEAD TO SUCCESSFUL PRODUCT INTRODUCTIONS. FAILURE TO SUCCESSFULLY INTRODUCE PRODUCTS INTO THE MARKET COULD HAVE A MATERIAL

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# ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS, AND THE MARKET VALUE OF OUR COMMON STOCK COULD DECLINE.

Much of our development effort is focused on technically difficult-to-formulate products and/or products that require advanced manufacturing technology. We conduct research and development primarily to enable us to manufacture and market FDA-approved pharmaceuticals in accordance with FDA regulations. Typically, research expenses related to the development of innovative compounds and the filing of NDAs are significantly greater than those expenses associated with ANDAs. As we continue to develop new products, our research expenses will likely increase. Because of the inherent risk associated with research and development efforts in our industry, particularly with respect to new drugs (including, without limitation, nebivolol), our, or a partner s, research and development expenditures may not result in the successful introduction of FDA approved new pharmaceutical products. Also, after we submit an NDA or ANDA, the FDA may request that we conduct additional studies and as a result, we may be unable to reasonably determine the total research and development costs to develop a particular product. Finally, we cannot be certain that any investment made in developing products will be recovered, even if we are successful in commercialization. To the extent that we expend significant resources on research and development efforts and are not able, ultimately, to introduce successful new products as a result of those efforts, our business, financial position and results of operations may be materially adversely affected, and the market value of our common stock could decline. A SIGNIFICANT PORTION OF OUR NET REVENUES ARE DERIVED FROM SALES TO A LIMITED NUMBER OF CUSTOMERS. ANY SIGNIFICANT REDUCTION OF BUSINESS WITH ANY OF THESE CUSTOMERS COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS, AND THE MARKET VALUE OF OUR COMMON STOCK COULD DECLINE.

A significant portion of our net revenues are derived from sales to a limited number of customers. As such, a reduction in or loss of business with one customer, or if one customer were to experience difficulty in paying us on a timely basis, our business, financial position and results of operations could be materially adversely affected, and the market value of our common stock could decline.

THE USE OF LEGAL, REGULATORY AND LEGISLATIVE STRATEGIES BY COMPETITORS, BOTH BRAND AND GENERIC, INCLUDING AUTHORIZED GENERICS AND CITIZEN S PETITIONS, AS WELL AS THE POTENTIAL IMPACT OF PROPOSED LEGISLATION, MAY INCREASE OUR COSTS ASSOCIATED WITH THE INTRODUCTION OR MARKETING OF OUR GENERIC PRODUCTS, COULD DELAY OR PREVENT SUCH INTRODUCTION AND/OR SIGNIFICANTLY REDUCE OUR PROFIT POTENTIAL. THESE FACTORS COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

Our competitors, both brand and generic, often pursue strategies to prevent or delay competition from generic alternatives to brand products. These strategies include, but are not limited to:

entering into agreements whereby other generic companies will begin to market an authorized generic , a generic equivalent of a branded product, at the same time generic competition initially enters the market;

filing citizen s petitions with the FDA, including timing the filings so as to thwart generic competition by causing delays of our product approvals;

seeking to establish regulatory and legal obstacles that would make it more difficult to demonstrate bioequivalence;

initiating legislative efforts in various states to limit the substitution of generic versions of brand pharmaceuticals;

filing suits for patent infringement that automatically delay FDA approval of many generic products;

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introducing next-generation products prior to the expiration of market exclusivity for the reference product, which often materially reduces the demand for the first generic product for which we seek FDA approval;

obtaining extensions of market exclusivity by conducting clinical trials of brand drugs in pediatric populations or by other potential methods as discussed below;

persuading the FDA to withdraw the approval of brand name drugs for which the patents are about to expire, thus allowing the brand name company to obtain new patented products serving as substitutes for the products withdrawn; and

seeking to obtain new patents on drugs for which patent protection is about to expire.

The Food and Drug Modernization Act of 1997 includes a pediatric exclusivity provision that may provide an additional six months of market exclusivity for indications of new or currently marketed drugs if certain agreed upon pediatric studies are completed by the applicant. Brand companies are utilizing this provision to extend periods of market exclusivity.

Some companies have lobbied Congress for amendments to the Waxman-Hatch legislation that would give them additional advantages over generic competitors. For example, although the term of a company s drug patent can be extended to reflect a portion of the time an NDA is under regulatory review, some companies have proposed extending the patent term by a full year for each year spent in clinical trials rather than the one-half year that is currently permitted.

If proposals like these were to become effective, our entry into the market and our ability to generate revenues associated with new products may be delayed, reduced or eliminated, which could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline

THE INDENTURE FOR OUR SENIOR NOTES AND OUR SENIOR CREDIT FACILITY IMPOSE SIGNIFICANT OPERATING AND FINANCIAL RESTRICTIONS, WHICH MAY PREVENT US FROM CAPITALIZING ON BUSINESS OPPORTUNITIES AND TAKING SOME ACTIONS. THESE FACTORS COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

The indenture for our Senior Notes and senior credit facility impose significant operating and financial restrictions on us. These restrictions will limit the ability of us and our subsidiaries to, among other things, incur additional indebtedness at our subsidiaries, make investments, sell assets, incur certain liens, enter into agreements restricting our subsidiaries—ability to pay dividends, or merge or consolidate. In addition, our senior credit facility requires us to maintain specified financial ratios. We cannot assure you that these covenants will not adversely affect our ability to finance our future operations or capital needs or to pursue available business opportunities. A breach of any of these covenants or our inability to maintain the required financial ratios could result in a default under the related indebtedness. If a default occurs, the relevant lenders could elect to declare the indebtedness at our subsidiaries together with accrued interest and other fees, to be immediately due and payable. These factors could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

OUR ABILITY TO SERVICE OUR DEBT AND MEET OUR CASH REQUIREMENTS DEPENDS ON MANY FACTORS, SOME OF WHICH ARE BEYOND OUR CONTROL. THESE FACTORS COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

Our ability to satisfy our obligations, including our Senior Notes and our senior credit facility, will depend on our future operating performance and financial results, which will be subject, in part, to factors beyond our control, including interest rates and general economic, financial and business conditions. If we are unable to

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generate sufficient cash flow, we may be required to: refinance all or a portion of our debt, including the notes and our senior credit facility; obtain additional financing in the future for acquisitions, working capital, capital expenditures and general corporate or other purposes; redirect a substantial portion of our cash flow to debt service, which as a result, might not be available for our operations or other purposes; sell some of our assets or operations; reduce or delay capital expenditures; or revise or delay our operations or strategic plans. If we are required to take any of these actions, it could have a material adverse effect on our business, financial condition or results of operations. In addition, we cannot assure you that we would be able to take any of these actions, that these actions would enable us to continue to satisfy our capital requirements or that these actions would be permitted under the terms of our senior credit facility and the indenture governing the notes. The leverage resulting from our notes offering and our senior credit facility could have certain material adverse effects on us, including limiting our ability to obtain additional financing and reducing cash available for our operations and acquisitions. As a result, our ability to withstand competitive pressures may be decreased and, we may be more vulnerable to economic downturns, which in turn could reduce our flexibility in responding to changing business, regulatory and economic conditions. These factors could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

WE DEPEND ON THIRD-PARTY SUPPLIERS AND DISTRIBUTORS FOR THE RAW MATERIALS, PARTICULARLY THE CHEMICAL COMPOUND(S) COMPRISING THE ACTIVE PHARMACEUTICAL INGREDIENT, THAT WE USE TO MANUFACTURE OUR PRODUCTS, AS WELL AS CERTAIN FINISHED GOODS. A PROLONGED INTERRUPTION IN THE SUPPLY OF SUCH PRODUCTS COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS, AND THE MARKET VALUE OF OUR COMMON STOCK COULD DECLINE.

We typically purchase the active pharmaceutical ingredient (i.e. the chemical compounds that produce the desired therapeutic effect in our products) and other materials and supplies that we use in our manufacturing operations, as well as certain finished products, from many different foreign and domestic suppliers.

Additionally, we maintain safety stocks in our raw materials inventory, and in certain cases where we have listed only one supplier in our applications with the FDA, have received FDA approval to use alternative suppliers should the need arise. However, there is no guarantee that we will always have timely and sufficient access to a critical raw material or finished product. A prolonged interruption in the supply of a single-sourced raw material, including the active ingredient, or finished product could cause our financial position and results of operations to be materially adversely affected, and the market value of our common stock could decline. In addition, our manufacturing capabilities could be impacted by quality deficiencies in the products which our suppliers provide, which could have a material adverse effect on our business, financial position and results of operations, and the market value of our common stock could decline.

The Company utilizes controlled substances in certain of its current products and products in development and therefore must meet the requirements of the Controlled Substances Act of 1970 and the related regulations administered by the Drug Enforcement Administration (DEA). These regulations relate to the manufacture, shipment, storage, sale and use of controlled substances. The DEA limits the availability of the active ingredients used in certain of our current products and products in development and, as a result, our procurement quota of these active ingredients may not be sufficient to meet commercial demand or complete clinical trials. We must annually apply to the DEA for procurement quota in order to obtain these substances. Any delay or refusal by the DEA in establishing our procurement quota for controlled substances could delay or stop our clinical trials or product launches, or could cause trade inventory disruptions for those products that have already been launched, which could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

WE USE SEVERAL MANUFACTURING FACILITIES TO MANUFACTURE OUR PRODUCTS. HOWEVER, A SIGNIFICANT NUMBER OF OUR PRODUCTS ARE PRODUCED AT ONE LOCATION. PRODUCTION AT THIS FACILITY COULD BE INTERRUPTED, WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

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Although we have other facilities, we produce a significant number of our products at our largest manufacturing facility. A significant disruption at that facility, even on a short-term basis, could impair our ability to produce and ship products to the market on a timely basis, which could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

WE MAY EXPERIENCE DECLINES IN THE SALES VOLUME AND PRICES OF OUR PRODUCTS AS THE RESULT OF THE CONTINUING TREND TOWARD CONSOLIDATION OF CERTAIN CUSTOMER GROUPS, SUCH AS THE WHOLESALE DRUG DISTRIBUTION AND RETAIL PHARMACY INDUSTRIES, AS WELL AS THE EMERGENCE OF LARGE BUYING GROUPS. THE RESULT OF SUCH DEVELOPMENTS COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

We make a significant amount of our sales to a relatively small number of drug wholesalers and retail drug chains. These customers represent an essential part of the distribution chain of generic pharmaceutical products. Drug wholesalers and retail drug chains have undergone, and are continuing to undergo, significant consolidation. This consolidation may result in these groups gaining additional purchasing leverage and consequently increasing the product pricing pressures facing our business. Additionally, the emergence of large buying groups representing independent retail pharmacies and the prevalence and influence of managed care organizations and similar institutions potentially enable those groups to attempt to extract price discounts on our products. The result of these developments may have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

WE MAY BE UNABLE TO PROTECT OUR INTELLECTUAL AND OTHER PROPRIETARY PROPERTY IN AN EFFECTIVE MANNER, WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

Although our brand products may have patent protection, this may not prevent other companies from developing functionally equivalent products or from challenging the validity or enforceability of our patents. If any patents we use in our business are found or even alleged to be non-infringed, invalid or not enforceable, we could experience an adverse effect on our ability to commercially promote our patented products. We could be required to enforce our patent or other intellectual property rights through litigation, which can be protracted and involve significant expense and an inherently uncertain outcome. Any negative outcome could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

OUR COMPETITORS INCLUDING BRAND COMPANIES OR OTHER THIRD PARTIES MAY ALLEGE THAT WE ARE INFRINGING THEIR INTELLECTUAL PROPERTY, FORCING US TO EXPEND SUBSTANTIAL RESOURCES IN RESULTING LITIGATION, THE OUTCOME OF WHICH IS UNCERTAIN. ANY UNFAVORABLE OUTCOME OF SUCH LITIGATION COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

Companies that produce brand pharmaceutical products routinely bring litigation against ANDA applicants that seek FDA approval to manufacture and market generic forms of their branded products. These companies allege patent infringement or other violations of intellectual property rights as the basis for filing suit against an ANDA applicant. Likewise, patent holders may bring patent infringement suits against companies that are currently marketing and selling their approved generic products. Litigation often involves significant expense and can delay or prevent introduction or sale of our generic products.

There may also be situations where the Company uses its business judgment and decides to market and sell products, notwithstanding the fact that allegations of patent infringement(s) have not been finally resolved by the courts. The risk involved in doing so can be substantial because the remedies available to the owner of a patent for

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infringement include, among other things, damages measured by the profits lost by the patent owner and not by the profits earned by the infringer. In the case of a willful infringement, the definition of which is subjective, such damages may be trebled. Moreover, because of the discount pricing typically involved with bioequivalent products, patented brand products generally realize a substantially higher profit margin than bioequivalent products. An adverse decision in a case such as this or in other similar litigation could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

WE MAY EXPERIENCE REDUCTIONS IN THE LEVELS OF REIMBURSEMENT FOR PHARMACEUTICAL PRODUCTS BY GOVERNMENTAL AUTHORITIES, HMOs OR OTHER THIRD-PARTY PAYERS. ANY SUCH REDUCTIONS COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

Various governmental authorities and private health insurers and other organizations, such as HMOs, provide reimbursement to consumers for the cost of certain pharmaceutical products. Demand for our products depends in part on the extent to which such reimbursement is available. Third-party payers increasingly challenge the pricing of pharmaceutical products. This trend and other trends toward the growth of HMOs, managed health care and legislative health care reform create significant uncertainties regarding the future levels of reimbursement for pharmaceutical products. Further, any reimbursement may be reduced in the future, perhaps to the point that market demand for our products declines. Such a decline could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

LEGISLATIVE OR REGULATORY PROGRAMS THAT MAY INFLUENCE PRICES OF PRESCRIPTION DRUGS COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

Current or future federal or state laws and regulations may influence the prices of drugs and, therefore, could adversely affect the prices that we receive for our products. Programs in existence in certain states seek to set prices of all drugs sold within those states through the regulation and administration of the sale of prescription drugs. Expansion of these programs, in particular, state Medicaid programs, or changes required in the way in which Medicaid rebates are calculated under such programs, could adversely affect the price we receive for our products and could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

WE ARE INVOLVED IN VARIOUS LEGAL PROCEEDINGS AND CERTAIN GOVERNMENT INQUIRIES AND MAY EXPERIENCE UNFAVORABLE OUTCOMES OF SUCH PROCEEDINGS OR INQUIRIES, WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

We are involved in various legal proceedings and certain government inquiries, including, but not limited to, patent infringement, product liability, breach of contract and claims involving Medicaid and Medicare reimbursements, some of which are described in our periodic reports and involve claims for, or the possibility of fines and penalties involving, substantial amounts of money or for other relief. If any of these legal proceedings or inquiries were to result in an adverse outcome, the impact could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

With respect to product liability, the Company maintains commercial insurance to protect against and manage a portion of the risks involved in conducting its business. Although we carry insurance, we believe that no reasonable amount of insurance can fully protect against all such risks because of the potential liability inherent in the business of producing pharmaceuticals for human consumption. To the extent that a loss occurs, depending on the nature of the loss and the level of insurance coverage maintained, it could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

WE ENTER INTO VARIOUS AGREEMENTS IN THE NORMAL COURSE OF BUSINESS WHICH PERIODICALLY INCORPORATE PROVISIONS WHEREBY WE INDEMNIFY THE OTHER PARTY TO THE AGREEMENT. IN THE EVENT THAT WE WOULD HAVE TO PERFORM UNDER THESE INDEMNIFICATION PROVISIONS, IT COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE THE MARKET VALUE OF OUR COMMON STOCK TO DECLINE.

In the normal course of business, we periodically enter into employment, legal settlement, and other agreements which incorporate indemnification provisions. We maintain insurance coverage which we believe will effectively mitigate our obligations under these indemnification provisions. However, should our obligation under an indemnification provision exceed our coverage or should coverage be denied, our business, financial position and results of operations could be materially affected and the market value of our common stock could decline.

OUR ACQUISITION STRATEGIES IN GENERAL INVOLVE A NUMBER OF INHERENT RISKS. THESE RISKS COULD CAUSE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL POSITION AND RESULTS OF OPERATIONS AND COULD CAUSE A DECLINE IN THE MARKET VALUE OF OUR COMMON STOCK.

We continually seek to expand our product line through complementary or strategic acquisitions of other companies, products and assets, and through joint ventures, licensing agreements or other arrangements. Acquisitions, joint ventures and other business combinations involve various inherent risks, such as assessing accurately the values, strengths, weaknesses, contingent and other liabilities, regulatory compliance and potential profitability of acquisition or other transaction candidates. Other inherent risks include the potential loss of key personnel of an acquired business, our inability to achieve identified financial and operating synergies anticipated to result from an acquisition or other transaction and unanticipated changes in business and economic conditions affecting an acquisition or other transaction. International acquisitions, and other transactions, could also be affected by export controls, exchange rate fluctuations, domestic and foreign political conditions and the deterioration in domestic and foreign economic conditions.

We may be unable to realize synergies or other benefits expected to result from acquisitions, joint ventures and other transactions or investments we may undertake, or be unable to generate additional revenue to offset any unanticipated inability to realize these expected synergies or benefits. Realization of the anticipated benefits of acquisitions or other transactions could take longer than expected, and implementation difficulties, market factors and the deteriorati