Mylan Reports Second Quarter Earnings and Issues Fiscal 2005 Guidance; Comments on King's Earnings Release

PITTSBURGH, Oct. 28 /PRNewswire-FirstCall/ -- Mylan Laboratories Inc. (NYSE: MYL) today announced its financial results for the second quarter ended September 30, 2004.

Mylan also reported that it is currently assessing certain disclosures in King Pharmaceuticals' earnings release relating to returns reserves, which King indicated could lead to a restatement of its financial statements. Although a restatement would result in a failure to satisfy a condition to close the pending Mylan-King transaction, the Company has made no decisions and intends to evaluate the issue as additional information becomes available.

In light of King's disclosures, however, Mylan has postponed its previously announced investor presentation and webcast scheduled for November 1st, and will update investors when appropriate.

Second Quarter 2005 Results; Fiscal Year 2005 Guidance

Net revenues for the quarter were $307.0 million, a decrease of $53.1 million from the same prior year period. Net earnings were $48.7 million, a decrease of $42.6 million from the second quarter of fiscal 2004, while earnings per diluted share were $0.18 compared to $0.33 in the same prior year period.

"As we pre-announced on October 21, 2004, our second quarter results were negatively impacted by numerous factors, including additional entrants into the omeprazole market since the time of our launch, the emergence of competition in the carbidopa/levodopa market, the launch of an 'authorized generic' for nitrofurantoin during our 180-day exclusivity period, the delay in the launch of our fentanyl product and regulatory action surrounding levothyroxine sodium," commented Robert J. Coury, Vice Chairman and Chief Executive Officer. "The quarter was also negatively impacted by a lack of new significant product launches. However, we are continuing to invest heavily in R&D as evidenced by the growing number of ANDA filings that we have or will have before the FDA."

Mylan also today issued revised earnings guidance for fiscal 2005 of $0.80 to $0.90 per diluted share, including net gains on legal settlements in the first quarter of fiscal 2005 which amounted, net of tax, to approximately $0.06 per diluted share. This guidance assumes a January 24, 2005 launch of fentanyl with at least one competitor in the market. Mylan had previously suspended its earnings guidance in June 2004 in response to certain FDA rulings, including its fentanyl decision, and issues facing the generic pharmaceutical industry, such as the practice of "authorized generics".

Generic Segment net revenues for the second quarter decreased $52.0 million to $247.5 million, while Brand Segment net revenues of $59.4 million declined $1.1 million from the same prior year period.

For the first six months of fiscal 2005, Mylan reported net revenues of $646.0 million, a decrease of $45.5 million from the same prior year period. Net earnings and earnings per diluted share decreased to $130.7 million and $0.48 per share, respectively, from $175.1 million and $0.63 per share, respectively, in the prior year. The first six months of fiscal 2005 included net gains on legal settlements which amounted, net of tax, to approximately $0.06 per diluted share. This compares to $0.05 per diluted share attributed to gains on legal settlements in the first six months of fiscal 2004.

Segment Information

	Three Months Ended September 30,			Six Months Ended September 30,		
	2005	2004	Change	2005	2004	Change
Net Revenues (in millions)						
Generic Segment	$247.5	$299.5	-17%	$515.2	$554.7	-7%
Brand Segment	59.4	60.6	-2%	130.8	136.8	-4%
Total	$307.0	$360.1	-15%	$646.0	$691.5	-7%

Generic Segment

Net revenues for the quarter decreased $52.0 million to $247.5 million from $299.5 million for the same prior year period. This decrease is primarily the result of lower sales of omeprazole and carbidopa/levodopa, both of which decreased as a result of additional generic competition. The prior year results included net revenues of $68.6 million from the launch of new products, largely due to omeprazole, which was launched in August 2003. New products contributed net revenues of $9.9 million in the current quarter.

Gross profit for the quarter decreased $48.1 million to $121.1 million, while gross margins decreased to 48.9% from 56.5%. The impact of competition on the pricing of omeprazole and carbidopa/levodopa was primarily responsible for the decrease in margins. Earnings from operations decreased $51.6 million to $95.5 million primarily as a result of the decrease in gross profit. Additionally, the Generic Segment's operating expenses increased $3.5 million, primarily as a result of additional research and development (R&D) expenses.

For the six-month period, net revenues decreased by $39.5 million to $515.2 million from $554.7 million in the same prior year period. The decreases discussed above with respect to omeprazole and carbidopa/levodopa were primarily responsible for the year-to-date decline in sales. New products in the current fiscal year contributed net revenues of $26.1 million compared to $74.4 million in fiscal 2004.

Gross profit for the first six months of fiscal 2005 was $259.9 million, a decrease of $47.8 million from the first six months of fiscal 2004. Gross margins decreased to 50.4% in the current year compared to 55.5% in the prior year. Unfavorable pricing on several products, including omeprazole and carbidopa/levodopa as a result of the competition discussed above, contributed to the lower margins.

Operating income decreased $55.4 million to $209.2 million for the six months ended September 30, 2004. This decrease was the result of lower gross profit as well as higher R&D and general and administrative (G&A) expenses. R&D expenses increased as a result of the continued investment in our generic development platform.

Brand Segment

Brand Segment net revenues for the second quarter were $59.4 million, a decrease of $1.1 million from $60.6 million in the same prior year period. Brand Segment gross profit decreased $4.3 million to $34.2 million in the second quarter of fiscal 2005, while gross margins decreased to 57.5% from 63.5% in the same prior year period. The decrease in margin is primarily the result of increased competition on certain brand products, primarily Digitek® and Acticin®.

Earnings from operations were $8.4 million compared to $11.7 million in the same quarter of the prior year, a decrease of $3.4 million. This decrease was the result of the lower gross profit, partially offset by lower operating expenses.

For the six months ended September 30, 2004, Brand Segment net revenues decreased $6.0 million to $130.8 million from $136.8 million in the prior year. Increased generic competition on certain branded products, such as Amnesteem®, Digitek and Acticin, contributed to the decline in sales. These decreases were partially offset by higher net revenues from phenytoin and Phenytek™.

Gross profit for the Brand Segment decreased $2.4 million to $75.1 million in the first half of fiscal 2005. Despite the decrease in net revenues and gross profit, gross margins actually increased to 57.5% in the current period from 56.6% in the prior year. This increase is primarily the result of favorable product mix, with phenytoin comprising a higher percentage of sales, and Amnesteem, which contributes lower gross margins as a result of royalties paid under a supply and distribution agreement, comprising a smaller percentage.

Operating income for the six months ended September 30, 2004 was $24.6 million, an increase of $3.2 million from the same prior year period. This increase was the result of lower overall operating expenses which offset the impact of the decrease in gross profit.

Corporate/Other

G&A expenses for the second quarter of fiscal 2005 were $30.4 million compared to $24.7 million in the same prior year period. The increase was primarily the result of certain costs associated with the planned acquisition and integration of King and the implementation of an Enterprise Resource Planning (ERP) system. Other income for the second quarter was $1.9 million compared to $7.4 million in the same prior year period. Included in the prior year was a gain of $5.0 million on the sale of an office building.

For the six months ended September 30, 2004, G&A expenses increased $13.1 million to $59.8 million. This increase was the result of higher payroll and payroll related costs, as well as increased legal and professional fees. Other income for the period was $2.6 million compared to $10.5 million in the same prior year period.

Conference Call and Live Webcast

Mylan will host a conference call and live webcast to discuss its second quarter 2005 earnings on Thursday, October 28, 2004, at 10:00 am ET. The dial-in number to access the live call is (719) 457-2629. In addition to the live call, a replay will be available from approximately 12:00 pm ET on October 28, 2004, through 12:00 pm ET on November 4, 2004, and can be accessed by dialing (719) 457-0820 using conference code 837489. To access the live webcast, go to Mylan's website at http://www.mylan.com and click on the webcast icon at least 15 minutes before the call is to begin to register and download or install any necessary audio software. If you are unable to listen to the live webcast, please access http://www.mylan.com at any time within seven days to listen to a replay of the webcast.

Forward-Looking Statements

This press release includes statements that constitute "forward-looking statements", including with regard to the Company's anticipated ANDA filings, its earnings guidance, the fentanyl launch and the pending King acquisition. These statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Because such statements inherently involve risks and uncertainties, actual future results may differ materially from those expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to:

-- the Company's ability to successfully develop, license or otherwise acquire and introduce new products on a timely basis in relation to competing product introductions;

-- the Company's ability to obtain required FDA approvals for new products on a timely basis;

-- uncertainties regarding continued market acceptance of and demand for the Company's products;

-- the Company's periodic dependence on a relatively small group of products as a significant source of its net revenue or net income;

-- the effects of vigorous competition on commercial acceptance of the Company's products and their pricing;

-- the high cost and uncertainty associated with compliance with extensive regulation of the pharmaceutical industry;

-- the possibility that our calculation and reporting of amounts owed in respect of Medicaid and other governmental pricing programs could be reviewed and challenged;

-- the significant research and development expenditures the Company makes to develop products, the commercial success of which is uncertain;

-- the possible loss of business from the Company's concentrated customer base;

-- the potential costs and product introduction delays that may result from use of legal, regulatory and legislative strategies by the Company's competitors, including the practice of so-called "authorized generics";

-- the Company's dependence on third party suppliers and distributors for the raw materials, particularly the chemical compound(s) which produces the desired therapeutic effect, the active ingredient the Company uses to manufacture its products;

-- the possible negative effects of any interruption of manufacturing of products at the Company's principal facilities;

-- the effects of consolidation of the Company's customer base;

-- uncertainties regarding patent, intellectual and other proprietary property protections;

-- the expending of substantial resources associated with litigation involving patent or other intellectual property protection of products;

-- possible reductions in reimbursement rates for pharmaceutical products;

-- possible negative effects on product pricing of current or future legislative or regulatory programs, including state Medicaid programs;

-- the Company's exposure to lawsuits and contingencies associated with its business;

-- uncertainties regarding the Company's performance under indemnification clauses in certain material agreements;

-- the Company's exposure to risks inherent in acquisitions or joint ventures, including our planned acquisition of King Pharmaceuticals, Inc.;

-- risks relating to the King acquisition such as obtaining requisite shareholder approvals, and challenges and costs relating to integration of the two businesses;

-- the Company's ability to attract and retain key personnel;

-- recent decisions by the FDA, current brand tactics and other factors beyond our control which have placed our generics business under increasing pressure;

-- our implementation of an Enterprise Resource Planning system;

-- uncertainties and matters beyond the control of management, which could affect the Company's earnings guidance, as well as the subjectivity inherent in any probability weighted analysis underlying the Company's assumptions and estimates with respect to the future; and

-- inherent uncertainties involved in the estimates and judgments used in the preparation of financial statements in accordance with GAAP and related standards.

The cautionary statements referred to above should be considered in connection with any subsequent written or oral forward-looking statements that may be made by the Company or by persons acting on its behalf and in conjunction with its periodic SEC filings. In addition, please refer to the cautionary statements and risk factors in Item I of the Company's Form 10-K for the year ended March 31, 2004, and in our other filings with the SEC. The Company undertakes no duty to update its forward-looking statements, even though its situation may change in the future.

Mylan Laboratories Inc. is a leading pharmaceutical company with four subsidiaries, Mylan Pharmaceuticals Inc., Mylan Technologies Inc., UDL Laboratories, Inc. and Mylan Bertek Pharmaceuticals Inc., that develop, manufacture and market an extensive line of generic and proprietary products. For more information about Mylan, visit http://www.mylan.com .

Mylan Laboratories Inc. and Subsidiaries
Condensed Consolidated Statements of Earnings
(unaudited; in thousands, except per share amounts)

	Three Months Ended		Six Months Ended	
	September 30, 2004	September 30, 2003	September 30, 2004	September 30, 2003
Net revenues	$306,955	$360,060	$645,967	$691,468
Cost of sales	151,702	152,352	310,961	306,331
Gross profit	155,253	207,708	335,006	385,137
Operating expenses:				
Research and development	22,042	23,946	43,537	48,685
Selling and marketing	20,457	17,274	39,891	35,110
General and administrative	39,231	32,312	77,543	61,920
Litigation settlements, net	-	-	(25,985)	(21,669)
Total operating expenses	81,730	73,532	134,986	124,046
Earnings from operations	73,523	134,176	200,020	261,091
Other income, net	1,910	7,428	2,596	10,533
Earnings before income taxes	75,433	141,604	202,616	271,624
Provision for income taxes	26,779	50,326	71,929	96,483
Net earnings	$48,654	$91,278	$130,687	$175,141
Earnings per common share:				
Basic	$0.18	$0.34	$0.49	$0.65
Diluted	$0.18	$0.33	$0.48	$0.63
Weighted average common shares:				
Basic	268,945	268,644	268,749	269,432
Diluted	272,930	276,424	274,170	276,276

Mylan Laboratories Inc. and Subsidiaries
Condensed Consolidated Balance Sheets

(unaudited; in thousands)

Assets:	September 30, 2004	March 31, 2004
Current assets:		
Cash and cash equivalents	$128,112	$101,713
Marketable securities	671,360	585,445
Accounts receivable, net	210,695	191,094
Inventories	296,604	320,797
Other current assets	113,281	118,792
Total current assets	1,420,052	1,317,841
Non-current assets	573,577	557,449
Total assets	$1,993,629	$1,875,290
Liabilities:		
Current liabilities	$168,043	$173,768
Non-current liabilities	41,531	41,734
Total liabilities	209,574	215,502
Total shareholders' equity	1,784,055	1,659,788
Total liabilities and shareholders' equity	$1,993,629	$1,875,290

Mylan Laboratories Inc. and Subsidiaries
Segment Results
(unaudited; in thousands)

	Three Months Ended		Six Months Ended	
	September 30, 2004	September 30, 2003	September 30, 2004	September 30, 2003
Consolidated:				
Net revenues	$306,955	$360,060	$645,967	$691,468
Cost of sales	151,702	152,352	310,961	306,331
Gross profit	155,253	207,708	335,006	385,137
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Selling and marketing	20,457	17,274	39,891	35,110
General and administrative	39,231	32,312	77,543	61,920
Litigation settlements, net	-	-	(25,985)	(21,669)
Earnings from operations	$73,523	$134,176	$200,020	$261,091
Generic Segment:				
Net revenues	$247,511	$299,483	$515,215	$554,711
Cost of sales	126,429	130,271	255,328	247,044
Gross profit	121,082	169,212	259,887	307,667
Research and development	16,517	14,154	32,809	27,641
Selling and marketing	2,971	2,761	5,871	5,517
General and administrative	6,052	5,164	11,990	9,855
Earnings from operations	$95,542	$147,133	$209,217	$264,654
Brand Segment:				

Net revenues	$59,444	$60,577	$130,752	$136,757
Cost of sales	25,273	22,081	55,633	59,287
Gross profit	34,171	38,496	75,119	77,470
Research and development	5,525	9,792	10,728	21,044
Selling and marketing	17,486	14,513	34,020	29,593
General and administrative	2,794	2,468	5,740	5,371
Earnings from operations	$8,366	$11,723	$24,631	$21,462
Corporate/Other:				
General and administrative	$30,385	$24,680	$59,813	$46,694
Litigation settlements, net	-	-	(25,985)	(21,669)
Loss from operations	$(30,385)	$(24,680)	$(33,828)	$(25,025)

SOURCE Mylan Laboratories Inc.
10/28/2004
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