Mylan Reports Fiscal 2005 Earnings Per Diluted Share of $0.74 -- Announces Investor Presentation and Non-Deal Roadshow Scheduled for June 14, 2005

PITTSBURGH, May 12 /PRNewswire-FirstCall/ -- Mylan Laboratories Inc. (NYSE: MYL) today announced that it will host a strategic business update and investor presentation on Tuesday, June 14, 2005, to review the Company's fiscal 2005 financial results and recent operational highlights and discuss the outlook and strategies for fiscal 2006, including an update on nebivolol, Mylan's proprietary hypertension product. The timing of the strategic business update is the result of nebivolol's Prescription Drug User Fee Act ("PDUFA") date, which is currently scheduled for May 31, 2005. Mylan is also scheduling a non-deal investor roadshow following the strategic business update.

"We are pleased that we were able to achieve the high end of our earnings guidance. With the launch of our fentanyl transdermal system in January 2005, we once again demonstrated our leadership capabilities in manufacturing and the strength of our distribution network, by capturing over 41% of the fentanyl market despite the presence of an authorized generic," commented Robert J. Coury, Vice Chairman and Chief Executive Officer. "Mylan remains strongly positioned for the future despite the challenges faced by our company and our industry over the past year." Mr. Coury further stated, "We are looking forward to discussing our plans and outlining the opportunities that lie ahead at our upcoming investor presentation on June 14."

Mylan also today announced its financial results for the fourth quarter and fiscal year ended March 31, 2005. Net earnings for fiscal 2005 decreased to $203.6 million from $334.6 million in the prior year period, and earnings per diluted share decreased to $0.74 from $1.21. Fiscal 2005 earnings per diluted share included approximately $0.06 per share, net of tax, of net gains on legal settlements and approximately $0.06 per share of costs, net of tax, associated with the terminated acquisition of King Pharmaceuticals, Inc. ("King"), the termination of which was announced on February 27, 2005. The results for fiscal 2004 included net gains on legal settlements which amounted, net of tax, to approximately $0.08 per diluted share.

Generic Product Opportunities

Mylan currently has 44 generic drug applications pending before the U.S. Food and Drug Administration ("FDA"), representing approximately $35.1 billion in brand sales, including 18 applications that have received tentative approval and 12 potential first-to-file opportunities that represent approximately $8.9 billion in brand sales.

In fiscal 2005, the Company submitted 17 new Abbreviated New Drug Applications ("ANDAs"), along with two supplements and two amendments for additional product strengths. During fiscal 2005, the Company received 11 final ANDA approvals, 11 tentative ANDA approvals and five supplemental ANDA approvals for new product strengths. In fiscal 2006 to date, the Company has received final ANDA approval for bromocriptine mesylate capsules and anagrelide hydrochloride capsules and tentative approval for terbinafine hydrochloride tablets. The Company has targeted approximately 20 applications for submission to the FDA in fiscal 2006.

Mylan's strategy with respect to product selection has always been to focus on products that are difficult to both develop and manufacture, which the Company believes translates into higher margins and improved opportunities for exclusivity. Mylan's focus is not just the number of ANDAs it submits, but more importantly the potential of the products it pursues. Some of the possible near-term catalysts which could further positively impact Mylan's business are topiramate, oxybutynin and levofloxacin.

Topiramate, the generic version of Ortho McNeil's Topamax, which had annual brand revenues of approximately $1.2 billion in 2004, remains a very exciting opportunity for Mylan. The Company received tentative approval for the product on April 23, 2003, and is the first and the only company to file a Paragraph IV certification. Oral argument was held in April 2005 in the patent infringement case pending in the district court in New Jersey, during which the judge granted Mylan's motion to dismiss Ortho's claims of willful infringement. The judge also ordered a Markman hearing (a hearing to assist the court in construing disputed language in patent claims), which was held on May 6.

Oxybutynin, the generic version of Alza's Ditropan XL, had 2004 brand sales of approximately $363 million. The Company received tentative approval in January 2005, and was first to file on the 5 and 10 milligram tablet strengths. Trial in the patent infringement suit in the Northern District of West Virginia was completed in April 2005.

Levofloxacin, the generic version of Ortho McNeil's Levaquin, which had 2004 annual brand sales of approximately $1.2 billion, is a third potential near-term catalyst. The Company has a tentative approval and was first to file on the 250 and 500 milligram tablet strengths. The Company is awaiting a decision from the U.S. Court of Appeals of the Federal Circuit on the pending patent infringement suit.

Brand Product Opportunities

From a Brand Segment perspective, the Company currently has a New Drug Application ("NDA") pending at the FDA for nebivolol, a unique beta blocker, for the treatment of hypertension. Nebivolol was accepted for filing by the FDA on June 29, 2004, and on February 23, 2005, the Company announced that the FDA had extended the original 10-month PDUFA deadline for the completion of its review to May 31, 2005.

As previously stated, the NDA is based on data from more than 2,000 patients enrolled in clinical trials to demonstrate the efficacy and safety of nebivolol in lowering blood pressure in hypertensive patients when administered once daily.

Data from clinical and preclinical studies on nebivolol will be presented at the American Society of Hypertension 20th Annual Scientific Meeting and Exposition in San Francisco, California, May 14 -18, 2005. The four abstracts that have been accepted for presentation include: Nebivolol in the treatment of patients with stage 1 and stage 2 hypertension: results of a randomized, double-blind, placebo-controlled study, Abstract #633, Poster # P-251; Beta1- vs. beta2- adrenergic receptor selectivity of nebivolol compared with various other beta-adrenergic antagonists in human ventricular myocardium, Abstract #322, Poster # P-121; Membrane location of nebivolol contributes to antioxidant activity and endothelial nitric oxide release in stroke-prone hypertensive rats, Abstract #389, Poster # P-481; and Nebivolol improves eNOS function and nitric oxide bioavailability in endothelial cells from African Americans, Abstract #388, Poster # P-482.

Financial Summary

Net revenues for the fiscal year were $1.25 billion, marking the fourth consecutive year in which revenues exceeded $1.0 billion. In fiscal 2004, Mylan reported net revenues of $1.37 billion. Fiscal 2005 revenues included $87.3 million from the sale of new products, primarily fentanyl. Mylan launched its fentanyl transdermal system ("fentanyl"), the generic equivalent of Alza Corporation's Duragesic®, in January 2005.

For the fourth quarter ended March 31, 2005, net revenues were $316.4 million, a decrease of $16.9 million from the same prior year period. Net earnings for the three months ended March 31, 2005, decreased $36.7 million to $38.1 million from $74.9 million in the same prior year period. Diluted earnings per share were $0.14 for the fourth quarter of fiscal 2005 compared to $0.27 in the fourth quarter of fiscal 2004, a decrease of $0.13. Of the $0.06 per share of costs incurred in fiscal 2005 with respect to the terminated King acquisition, approximately $0.05 per share was expensed in the fourth quarter. The fourth quarter of fiscal 2004 included $0.02 per diluted share related to gains on legal settlements.

Segment Information

	Three Months Ended March 31,			Fiscal Year Ended March 31,		
	2005	2004	Change	2005	2004	Change
Net Revenues (in millions)						
Generic Segment	$258.9	$264.0	-2%	$1,012.5	$1,096.1	-8%
Brand Segment	57.5	69.4	-17%	240.9	278.5	-14%
Total	$316.4	$333.4	-5%	$1,253.4	$1,374.6	-9%

Generic Segment

Net revenues for the quarter decreased $5.0 million to $258.9 million from $264.0 million in the fourth quarter of fiscal 2004. Overall unfavorable pricing, including price erosion as a result of increased competition, negatively impacted the Company's product portfolio, with omeprazole being the product most affected. Increased volume, including higher volume on omeprazole, partially offset the impact of the unfavorable pricing, as did new products which contributed net revenues of $64.1 million during the fourth quarter of fiscal 2005, largely due to fentanyl. Generic volume shipped for the fourth quarter increased nearly 6% to 2.8 billion doses.

Gross profit for the quarter decreased 12% to $122.6 million, resulting in a gross margin of 47%, compared to gross profit of $139.0 million and gross margin of 53% in the same prior year period. The impact of competition on the pricing of omeprazole and carbidopa/levodopa, as well as other products in the Company's portfolio, was primarily responsible for the decrease in margins. Earnings from operations decreased 16% to $97.0 million, primarily as a result of the decrease in gross profit.

For fiscal 2005, net revenues decreased to $1.01 billion from $1.10 billion in the prior year. As was the case in the fourth quarter, favorable volume and new products, which contributed net revenues of $84.8 million, partially offset the impact of

overall unfavorable pricing. On an overall basis, generic volume shipped for the year increased nearly 6% to 11.4 billion doses. Fiscal 2005 was the first year in which revenue and earnings were significantly impacted by the presence of an authorized generic, specifically as it related to nitrofurantoin monohydrate/macrocrystals capsules and fentanyl. Additionally, net revenues in fiscal 2005 were impacted by certain customers who decreased their level of purchases in order to reduce the amount of the Company's inventory that they maintain on their shelves.

Gross profit for fiscal 2005 decreased $110.5 million to $489.8 million, compared to $600.3 million in fiscal 2004, and gross margins decreased from 55% to 48% of net revenues. Operating income for fiscal 2005 decreased 24% or $124.6 million to $386.2 million from $510.8 million. The decrease in operating income was driven by the lower gross profit, as well as increased research and development (R&D) and general and administrative (G&A) expenses. R&D expenses increased by 17% or $9.8 million as the Company continues to selectively invest in targeted opportunities for its pipeline.

Brand Segment

The Brand Segment net revenues for the fourth quarter of fiscal 2005 were $57.5 million, a decrease of $11.9 million from $69.4 million for the same prior year period. Unfavorable pricing on Amnesteem™ was primarily responsible for the decrease in revenues.

Gross profit for the Brand Segment decreased $8.5 million to $30.6 million in the fourth quarter of fiscal 2005 from $39.1 million in the fourth quarter of fiscal 2004, while gross margins decreased to 53% from 56%. The unfavorable pricing on Amnesteem, as well as unfavorable pricing on Digitek®, also as a result of increased competition, were the main reasons for the decrease in margin. Earnings from operations were $7.4 million in the fourth quarter of fiscal 2005 compared to $8.0 million in the same quarter of the prior year. Lower operating expenses, both R&D and selling and marketing, offset the impact of the lower gross profit. The decrease in R&D expenses is the result of the completion in the prior year of the pivotal clinical studies in support of the nebivolol hypertension NDA which was filed on April 30, 2004.

For the fiscal year, Brand Segment net revenues decreased $37.6 million to $240.9 million also as a result of pricing pressures due to additional competition, with Amnesteem and Digitek the two products most affected. Additionally, fiscal 2004 Brand Segment revenues included $13.9 million from the sale of the U.S. and Canadian rights for sertaconazole nitrate 2% cream ("sertaconazole").

Gross profit for fiscal 2005 decreased $28.4 million to $133.8 million from $162.2 million, and gross margins decreased to 56% from 58% of net revenues. Excluding the sertaconazole sale, Brand Segment gross margins were essentially unchanged. Earnings from operations were $35.4 million in fiscal 2005 compared to $46.5 million in fiscal 2004. The decrease in earnings from operations was the result of lower gross profit and increased selling and marketing expenses, partially offset by lower R&D expenses. As discussed above, the decrease in R&D expenses is primarily due to the completion in the prior year of the clinical studies in support of the nebivolol hypertension NDA. The increase in selling and marketing was primarily the result of expenses incurred with respect to nebivolol and costs associated with the current year launch of Apokyn™.

Corporate/Other

G&A expenses for the fourth quarter of fiscal 2005 were $51.2 million compared to $25.9 million in the same prior year period, an increase of $25.3 million. The majority of this increase is the result of direct costs incurred with respect to the terminated acquisition of King. For the fiscal year ended March 31, 2005, G&A expenses were $145.4 million compared to $97.3 million, an increase of $48.1 million. In addition to the direct costs incurred with respect to the terminated acquisition of King, Mylan incurred other costs related to the planned integration of the two companies. The remainder of the increase during fiscal 2005 is the result of higher legal expenses, predominately the result of an increase in the number of first to file opportunities and the associated litigation, consulting costs related to the implementation of an Enterprise Resource Planning ("ERP") system and compliance with the requirements of Sarbanes Oxley, and higher payroll and payroll related costs.

Other income, net, for the fourth quarter and fiscal year was $3.8 million and $10.1 million, respectively. For the year, other income decreased by $7.7 million primarily as a result of lower gains on the sale of marketable securities, partially offset by lower losses realized by Somerset Pharmaceuticals, Inc., a company in which Mylan maintains an equity investment. Additionally, included in other income for fiscal 2004 was a gain of $5.0 million on the sale of an office building.

Forward-Looking Statements

This press release includes statements that constitute "forward-looking statements", including with regard to the Company's future position including the continued strength of its distribution network; the success of the Company's product selection strategy; the Company's anticipated submissions to the FDA; the planned investor presentation and roadshow; and the Company's generic and brand product opportunities. 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;
- unexpected delays in the Company's ability to submit applications to the FDA;
- risks inherent in legal proceedings, including those pending for topiramate, oxybutynin and levofloxacin;

- the effects of vigorous competition on commercial acceptance of the Company's products and their pricing, including, without limitation, the impact of the entry of generic competition for the Company's fentanyl product;
- a change in the PDUFA date for nebivolol, or any other regulatory delay impacting the launch of nebivolol;
- the high cost and uncertainty associated with compliance with extensive regulation of the pharmaceutical industry;
- unexpected constraints or delays that may impact the scheduling of the investor presentation or the investor roadshow;
- the possibility that the calculation and reporting of amounts owed in respect of Medicaid and other governmental pricing programs could be challenged, and that sanctions or penalties could be assessed;
- 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 and other third parties, including the practice of so-called "authorized generics" and the use of citizen's petitions to delay or prevent product introductions;
- 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;

- the Company's ability to attract and retain key personnel;
- recent decisions by the FDA, current brand tactics and other factors beyond the Company's control which have placed its generics business under increasing pressure;
- the Company's implementation of an Enterprise Resource Planning system; 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 its 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 www.mylan.com .

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

	Three Months Ended		Fiscal Year Ended	
	March 31, 2005	March 31, 2004	March 31, 2005	March 31, 2004
Net revenues	$316,435	$333,363	$1,253,374	$1,374,617
Cost of sales	163,248	155,216	629,834	612,149
Gross profit	153,187	178,147	623,540	762,468
Operating expenses:				
Research and development	21,177	26,880	87,881	100,813
Selling and marketing	20,286	21,488	79,838	74,625
General and administrative	58,555	31,971	179,640	126,987
Litigation settlements, net	-	(10,413)	(25,990)	(34,758)
Total operating expenses	100,018	69,926	321,369	267,667
Earnings from operations	53,169	108,221	302,171	494,801
Other income, net	3,781	3,080	10,076	17,807
Earnings before income taxes	56,950	111,301	312,247	512,608
Provision for income taxes	18,815	36,451	108,655	177,999
Net earnings	$38,135	$74,850	$203,592	$334,609
Earnings per common share:				
Basic	$0.14	$0.28	$0.76	$1.24
Diluted	$0.14	$0.27	$0.74	$1.21
Weighted average common shares:				
Basic	269,276	268,301	268,985	268,931
Diluted	273,003	275,838	273,621	276,318

Mylan Laboratories Inc. and Subsidiaries
Condensed Consolidated Balance Sheets
(unaudited; in thousands)

	March 31, 2005	March 31, 2004
Assets:		
Current assets:		
Cash and cash equivalents	$137,733	$111,484
Marketable securities	670,348	585,445
Accounts receivable, net	297,334	191,094
Inventories	286,267	320,797
Other current assets	136,770	118,792
Total current assets	1,528,452	1,327,612
Non-current assets	607,221	557,449
Total assets	$2,135,673	$1,885,061

Liabilities:		
Current liabilities	$245,507	$183,539
Non-current liabilities	44,230	41,734
Total liabilities	289,737	225,273
Total shareholders' equity	1,845,936	1,659,788
Total liabilities and shareholders' equity	$2,135,673	$1,885,061

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

	Three Months Ended		Fiscal Year Ended	
	March 31, 2005	March 31, 2004	March 31, 2005	March 31, 2004
Consolidated:				
Net revenues	$316,435	$333,363	$1,253,374	$1,374,617
Cost of sales	163,248	155,216	629,834	612,149
Gross profit	153,187	178,147	623,540	762,468
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Selling and marketing	20,286	21,488	79,838	74,625
General and administrative	58,555	31,971	179,640	126,987
Litigation settlements, net	-	(10,413)	(25,990)	(34,758)
Earnings from operations	$53,169	$108,221	$302,171	$494,801
Generic Segment:				
Net revenues	$258,931	$263,971	$1,012,503	$1,096,128
Cost of sales	136,312	124,940	522,748	495,848
Gross profit	122,619	139,031	489,755	600,280
Research and development	17,978	16,989	68,858	59,066
Selling and marketing	3,374	3,447	12,353	11,707
General and administrative	4,252	2,877	22,345	18,686
Earnings from operations	$97,015	$115,718	$386,199	$510,821
Brand Segment:				
Net revenues	$57,504	$69,392	$240,871	$278,489
Cost of sales	26,936	30,276	107,086	116,301
Gross profit	30,568	39,116	133,785	162,188
Research and development	3,199	9,891	19,023	41,747
Selling and marketing	16,912	18,041	67,485	62,918
General and administrative	3,101	3,177	11,898	11,002
Earnings from operations	$7,356	$8,007	$35,379	$46,521
Corporate/Other:				
General and administrative	$51,202	$25,917	$145,397	$97,299
Litigation settlements, net	-	(10,413)	(25,990)	(34,758)
Loss from operations	$(51,202)	$(15,504)	$(119,407)	$(62,541)

SOURCE Mylan Laboratories Inc.
05/12/2005
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