MYLAN LABORATORIES INC
Form 8-K
July 19, 2005

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15 (d) OF
THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): **July 19, 2005**

MYLAN LABORATORIES INC.

(Exact name of registrant as specified in its charter)

Pennsylvania	**1-9114**	**25-1211621**
(State or other jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

1500 Corporate Drive
Canonsburg, PA 15317
(Address of principal executive offices)

(724) 514-1800
(Registrant s telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2 (b))
- o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4 (c))

Item 8.01. Other Events.

On July 15, 2005, the U.S. Food and Drug Administration (the FDA) issued a Public Health Advisory regarding the safe use of transdermal fentanyl patches and its investigation regarding these patches. During a conference call held July 19, 2005, Mylan Laboratories Inc., a Pennsylvania corporation (Mylan or the Company), provided the information below regarding its fentanyl product.

> The Company s net revenues for the quarter ended June 30, 2005 were $323.4 million, a decrease of $15.6 million from the prior year first quarter. The decrease in net revenues is attributable to unfavorable pricing, partially offset by revenues from new products launched since July 1, 2004. During the first quarter, new products contributed net revenues of $55.0 million substantially all of which was due to fentanyl, which was launched during the Company s fourth quarter of fiscal 2005. New products contributed net revenues of $64.1 million in the fourth quarter of fiscal 2005, also largely due to fentanyl. On a sequential quarter basis, gross margins for the quarter ended June 30, 2005, increased to 52% from 48% for the quarter ended March 31, 2005. This increase reflects a full quarter of fentanyl sales without the impact of costs incurred in conjunction with the product s launch.

In addition, during the conference call on July 19, 2005, Robert J. Coury, Vice Chairman and Chief Executive Officer of Mylan, said:

> We are especially proud of the performance of our fentanyl transdermal system, which continues to command significant market share and remains the only FDA approved generic alternative to J&J s Duragesic.

In emphasizing that there have been no new developments brought to the Company s attention as to the safety of these products, Mr. Coury continued:

> Fentanyl represents a significant clinical contribution as a potent Schedule II opioid agonist. In the treatment and control of pain, Fentanyl s opioid abuse properties are significantly less when compared to other products in this scheduled class such as morphine, oxycodone, methadone and others. In early February 2005, Health and Human Services at a meeting with the industry discussed issues such as drug abuse, patient compliance with labeling and instructions, and the development of risk management programs for the Schedule II opioid agonists. The risks of this class of drugs with their serious adverse events have long been understood. The FDA has implemented and enhanced labeling instructions and last Friday communicated directly to physicians and consumers through a public health advisory. While Mylan believes it has experienced a very small number of adverse events with our product, we are confident the adverse events are not associated with the quality of our product. It is Mylan s understanding that the recent statements reported by the FDA regarding the 120 deaths come from a review of the FDA s existing Adverse Events database pertaining to J&J s Duragesic. Mylan has been and will continue to work with the FDA on this issue. Mylan strongly supports the FDA s efforts to appropriately educate physicians, health care professionals, and patients on the safe utilization of these Schedule II drugs. In this vitally important category, the longstanding efforts of the FDA s policy have been to improve or enhance the safe use of these drugs. In light of their continued work on this issue, our ability to respond to questions concerning fentanyl is limited.

The FDA s investigation regarding the safe use of transdermal fentanyl patches is continuing and has not been completed. See Risk Factors in the Company s Form 10-K for the fiscal year ended March 31, 2005 for a discussion of the risks and uncertainties regarding the Company s business, including the potential risks inherent in any regulatory investigation such as the FDA investigation referred to above.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

MYLAN LABORATORIES INC.

Date: July 19, 2005

By: /s/ Edward J. Borkowski
Edward J. Borkowski
Chief Financial Officer