

IMPAX LABORATORIES INC

FORM 8-K (Current report filing)

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Address	30831 HUNTWOOD AVENUE HAYWARD, CA 94544
Telephone	510-240-6000
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SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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): November 9, 2004

Impax Laboratories, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	0-27354	65-0403311

(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

30831 Huntwood Ave., Hayward, CA 94544

(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code (510) 476-2000

Not Applicable

(Former name or former address, if changed since last report)

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 (see General Instruction A.2. below):

Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

ITEM 2.02. RESULTS OF OPERATIONS AND FINANCIAL CONDITION

On November 9, 2004, Impax Laboratories, Inc. (the "Company") issued a press release reporting its financial results for the third quarter of 2004 and announcing that it intends to restate its financial results for the first and second quarters of 2004. A copy of the press release is furnished as Exhibit 99.1 to this report.

ITEM 4.02(a). NON-RELIANCE ON PREVIOUSLY ISSUED FINANCIAL STATEMENTS OR A RELATED AUDIT REPORT OR COMPLETED INTERIM REVIEW

On November 8, 2004, management of the Company concluded that the Company's previously issued financial statements for the first and second quarter of 2004 should (i) no longer be relied upon because of errors in those financial statements and (ii) be restated to reflect the accounting adjustments necessary to cure such errors. Accordingly, the Company will restate its financial results for the first and second quarter of 2004, and intends to file as practicable amendments to its Quarterly Reports on Form 10-Q for the first and second quarters of 2004 to reflect the restatement.

The restatement is required as a result of customer credits granted by one of the Company's strategic partners on sales of the Company's bupropion products made by the strategic partner during March 2004. The strategic partner notified the Company of the customer credits when reporting sales of the Company's products for the quarter ended September 30, 2004. Under the terms of the Strategic Alliance Agreement, the Company's strategic partner has sole and exclusive right to determine all terms and conditions of sale to its customers including pricing, discounts, allowances, price adjustments, returns and rebates.

The restatement will include an adjustment to the Company's reported total revenues for the first quarter of 2004, reducing them by \$4,308,000, from \$38,853,000 to \$34,545,000. As a result of the restatement, the Company's reported net income for the first quarter of 2004 is expected to decrease by \$3,832,000, from \$9,048,000 to \$5,216,000, and the Company's reported earnings per share for the first quarter of 2004 is expected to decrease by \$0.07 per share (\$0.07 per share on a fully diluted basis) from \$0.16 per share to \$0.09 per share (\$0.08 per share on a fully diluted basis).

The restatement will include an adjustment to the Company's reported total revenues for the second quarter of 2004, reducing them by \$281,000 from \$30,845,000 to \$30,564,000. As a result of the restatement, the Company's reported net income for the second quarter of 2004 is expected to decrease by \$251,000, from \$572,000 to \$321,000. The Company's reported earnings per share for the second quarter of 2004 will remain \$0.01 per share (\$0.01 per share on a fully diluted basis).

The restatement will also result in corresponding changes to accounts receivable, accrued expenses and deferred revenues, and accumulated deficit line items in the balance sheets for those periods.

The Company's Audit Committee and senior management discussed the matters disclosed in this report with the Company's independent registered public accountants, Deloitte & Touche LLP. On November 8, 2004, the Company decided to restate its financial statements as described above.

ITEM 9.01. FINANCIAL STATEMENTS AND EXHIBITS

(c) Exhibits.

99.1 - Press release dated November 9, 2004 (Furnished)

SIGNATURES

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

IMPAX LABORATORIES, INC.

Date: November 9, 2004

By: /s/ Cornel C. Spiegler

Name: Cornel C. Spiegler
Title: Chief Financial Officer

EXHIBIT INDEX

Exhibit No.

99.1

Description

Press Release dated November 9, 2004.

[GRAPHIC IMPAX

OMITTED] LABORATORIES, INC.

COMPANY CONTACTS: INVESTOR RELATIONS CONTACTS:

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**IMPAX REPORTS THIRD QUARTER 2004 FINANCIAL RESULTS; COMPANY TO
RESTATE FIRST AND SECOND QUARTER 2004 RESULTS DUE TO REPORTING
ADJUSTMENTS ON BUPROPION REVENUES BY STRATEGIC PARTNER**

HAYWARD, CALIF (NOVEMBER 9, 2004) - IMPAX LABORATORIES, INC. (NASDAQ NM: IPXL) today reported financial results for the three and nine months ended September 30, 2004. IMPAX also announced that it has determined to restate its financial results for the first and second quarters of 2004. The restatement is required as the result of an adjustment due to recently reported customer credits granted by our strategic partner on sales of the Company's bupropion products made by our strategic partner during March 2004.

THIRD QUARTER AND NINE MONTHS RESULTS

Total revenues for the third quarter of 2004 were \$30.7 million, or approximately 86% higher than the total revenues of \$16.5 million in the prior year's third quarter. The year-over-year increase was primarily due to shipments of generic versions of Wellbutrin(R) SR (Bupropion Hydrochloride) 100 mg and 150 mg Controlled Release Tablets, and Declomycin(R) (Demeclocycline Hydrochloride) 150 mg and 300 mg Tablets, which commenced during the first quarter of 2004; and Zyban(R) (Bupropion Hydrochloride) and Sinemet(R) CR (Carbidopa/Levodopa) Extended Release Tablets, which commenced during the second quarter of 2004. During the 2004 third quarter, IMPAX's revenues from product shipments through our strategic alliance agreements with Teva and Andrx were approximately \$10.8 million compared with \$8.3 million in the 2004 second quarter.

Net income for the 2004 third quarter was \$735,000 or \$0.01 per share, compared with a net loss of \$3,608,000 or \$(0.07) per share, in the prior year's third quarter.

Gross margin for the 2004 third quarter was \$13.1 million, or approximately 43% of total revenues, compared with gross margin of \$3.5 million, or approximately 21% of total revenues, in the prior year's third quarter. The year-over-year increase in the gross margin percentage was primarily due to the introduction of new products since last year with higher margins, such as Bupropion Hydrochloride, Demeclocycline Hydrochloride, Flavoxate, and Carbidopa/Levodopa. Research and development expense for the 2004 third quarter of \$4.9 million was approximately \$1.6 million higher than the 2003 third quarter due primarily to higher personnel costs, biostudies, clinical studies, and new product introduction costs. The patent litigation expenses for the 2004 third quarter of \$3.3 million were approximately \$2.5 million higher than the 2003 third quarter due to the increase in the activity level of patent litigation.

For the nine months ended September 30, 2004, the Company reported total revenues of \$95.8 million, or approximately 128% higher than total revenues of \$42.0 million in the comparable period of the previous year. Net income for the first nine months of 2004 was \$6.3 million, or \$0.10 per fully diluted share, compared with a net loss of \$9.1 million, or \$(0.18) per share, for the first nine months of 2003.

Unrestricted cash, cash equivalents and short-term investments were \$89.6 million at September 30, 2004, compared to \$15.5 million at December 31, 2003. The increase in cash balance was primarily due to a private placement of \$95 million aggregate principal amount of 1.250% convertible senior subordinated debentures that closed during the second quarter of 2004.

RESTATEMENT OF FIRST AND SECOND QUARTER FINANCIAL STATEMENTS

The Company is restating its financial statements for the first and second quarters of 2004 as the result of customer credits granted by our strategic partner on sales of the Company's bupropion products made by our strategic partner during March 2004. The strategic partner notified the Company of the adjustment when reporting sales of the Company's products for the quarter ended September 30, 2004. Under the terms of the Strategic Alliance Agreement, the Company's strategic partner has sole and exclusive right to determine all terms and conditions of sale to its customers, including pricing, discounts, allowances, price adjustments, returns and rebates. The Company is endeavoring to take steps under the Strategic Alliance Agreement to ensure that all such adjustments granted by its strategic partner in the future are reported to the Company on a timely basis.

The restatement will include an adjustment to the Company's reported total revenues for the first quarter of 2004, reducing them by \$4,308,000, from \$38,853,000 to \$34,545,000. As a result of the restatement, the Company's reported net income for the first quarter of 2004 is expected to decrease by \$3,832,000, from \$9,048,000 to \$5,216,000, and the Company's reported earnings per share for the first quarter of 2004 is expected to decrease by \$0.07 per share (\$0.07 per share on a fully diluted basis) from \$0.16 per share to \$0.09 per share (\$0.08 per share on a fully diluted basis).

The restatement will include an adjustment to the Company's reported total revenues for the second quarter of 2004, reducing them by \$281,000 from \$30,845,000 to \$30,564,000. As a result of the restatement, the Company's reported net income for the second quarter of 2004 is expected to decrease by \$251,000, from \$572,000 to \$321,000. The Company's reported earnings per share for the second quarter of 2004 will remain \$0.01 per share (\$0.01 per share on a fully diluted basis).

The restatement will also result in corresponding changes to accounts receivable, accrued expenses and deferred revenues, and accumulated deficit line items in the balance sheets for those periods.

IMPAX intends to file amendments to its Quarterly Reports on Form 10-Q for the first quarter of 2004 and second quarter of 2004 to reflect the restatement as soon as practicable. The Company will be filing a Form 12b-25 to extend the deadline for the filing of its Form 10-Q for the quarter ended September 30, 2004.

IMPAX Laboratories, Inc. is a technology based specialty pharmaceutical company applying its formulation expertise and drug delivery technology to the development of controlled-release and specialty generics in addition to the development of branded products. IMPAX markets its generic products through its Global Pharmaceuticals division and intends to market its branded products through the IMPAX Pharmaceuticals division. Additionally, where strategically appropriate, IMPAX has developed marketing partnerships to fully leverage its technology platform. IMPAX Laboratories is headquartered in Hayward, California, and has a full range of capabilities in its Hayward and Philadelphia facilities. For more information, please visit the Company's Web site at: www.impaxlabs.com.

"Safe Harbor" statement under the Private Securities Litigation Reform Act of 1995:

To the extent any statements made in this news release contain information that is not historical, these statements are forward-looking in nature and express the beliefs and expectations of management. Such statements are based on current expectations and involve a number of known and unknown risks and uncertainties that could cause IMPAX's future results, performance or achievements to differ significantly from the results, performance or achievements expressed or implied by such forward-looking statements. Such risks and uncertainties include, but are not limited to, IMPAX's ability to obtain sufficient capital to fund its operations, the difficulty of predicting FDA filings and approvals, consumer acceptance and demand for new pharmaceutical products, the impact of competitive products and pricing, IMPAX's ability to successfully develop and commercialize pharmaceutical products, IMPAX's reliance on key strategic alliances, the uncertainty of patent litigation, the availability of raw materials, the regulatory environment, dependence on patent and other protection for innovative products, exposure to product liability claims, fluctuations in operating results and other risks detailed from time to time in IMPAX's filings with the Securities and Exchange Commission. Forward-looking statements speak only as to the date on which they are made, and IMPAX undertakes no obligation to update publicly or revise any forward-looking statement, regardless of whether new information becomes available, future developments occur or otherwise.

(Tables to follow)

IMPAX LABORATORIES, INC.
CONDENSED STATEMENTS OF INCOME (UNAUDITED)
(DOLLARS IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2004	2003	2004	2003
Net sales	\$ 30,261	\$ 15,908	\$ 91,798	\$ 40,434
Revenue from reversal of refundable deposit from Teva	--	--	2,500	--
Other revenues	443	589	1,515	1,555
Total revenues	30,704	16,497	95,813	41,989
Cost of sales	17,592	12,976	54,679	30,444
Gross margin	13,112	3,521	41,134	11,545
Research and development	4,942	3,358	15,266	10,463
Reimbursements from Teva	(217)	(93)	(306)	(247)
Research and development, net	4,725	3,265	14,960	10,216
Patent litigation expenses	3,299	845	7,146	1,842
Selling expenses	908	546	2,345	1,552
General and administrative expenses	3,289	2,321	9,757	6,526
Other operating income (expense), net	4	4	15	25
Net Income (loss) from operations	895	(3,452)	6,941	(8,566)
Interest income	387	87	714	199
Interest expense	(547)	(243)	(1,383)	(738)
Net income (loss) before provision for income taxes	\$ 735	\$ (3,608)	\$ 6,272	\$ (9,105)
Provision for income taxes	--	--	--	--
Net income (loss)	\$ 735	\$ (3,608)	\$ 6,272	\$ (9,105)
Earnings per share				
Basic	\$ 0.01	\$ (0.07)	\$ 0.11	\$ (0.18)
Diluted	\$ 0.01	\$ (0.07)	\$ 0.10	\$ (0.18)
Weighted average common shares outstanding				
Basic	58,469,272	52,610,356	57,855,637	50,382,455
Diluted	62,137,376	52,610,356	61,352,899	50,382,455

IMPAX LABORATORIES, INC.
CONDENSED BALANCE SHEETS
(IN THOUSANDS)

	SEPTEMBER 30, 2004 (UNAUDITED) -----	DECEMBER 31, 2003 (UNAUDITED) -----
ASSETS		
Cash, cash equivalents and short-term investments	\$ 89,603	\$ 15,505
Restricted cash (a)	--	10,000
Accounts receivable, net	19,730	9,885
Inventory	38,232	28,479
Property, plant and equipment, net	43,849	38,132
Goodwill and intangibles, net	27,665	27,953
Other assets	6,408	2,752
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Total assets	\$ 225,487	\$ 132,706
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LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities	\$ 33,889	\$ 42,365
Long-term debt, net of current portion	7,284	8,854
Refundable deposit from Teva	--	5,000
Convertible debentures	95,000	--
Deferred revenues and other liabilities	2,978	2,879
Mandatorily redeemable convertible preferred stock	--	7,500
Stockholders' equity	86,336	66,108
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Total liabilities and stockholders' equity	\$ 225,487	\$ 132,706
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(a) Represents cash held as collateral for the \$25 million revolving credit facility and term loan with Wachovia Bank N.A. The restriction was removed by Wachovia Bank N.A. in the 2004 second quarter.

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