

IMPAX LABORATORIES INC

FORM 8-K (Current report filing)

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Address	30831 HUNTWOOD AVENUE HAYWARD, CA 94544
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**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): May 4, 2010

Impax Laboratories, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other Jurisdiction of
Incorporation)

001-34263

(Commission File Number)

65-0403311

(IRS Employer Identification No.)

30831 Huntwood Avenue, Hayward, CA

(Address of Principal Executive Offices)

94544

(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:

- ☐ 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))
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Item 2.02 Results of Operations and Financial Condition.

On May 4, 2010, Impax Laboratories, Inc. issued a press release announcing its results for the quarter ended March 31, 2010. A copy of this press release is attached hereto as Exhibit 99.1 and incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit is furnished herewith.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued May 4, 2010.

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.

Dated: May 4, 2010

IMPAX LABORATORIES, INC .

By: /s/ Arthur A. Koch, Jr. _____

Name: Arthur A. Koch, Jr.

Title: Senior Vice President, Finance, and
Chief Financial Officer

EXHIBIT INDEX

Exhibit No.
99.1

Description
Press release issued May 4, 2010.

**Company Contact:**

Impax Laboratories, Inc.

Mark Donohue

Sr. Director

Investor Relations and Corporate Communications

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Impax Laboratories Reports Significant Growth for the First Quarter 2010

First-Quarter Highlights (versus the prior year period)

The Company set multiple Financial Records in the First-Quarter

- Record total revenue of \$323.3 million — up \$264.4 million
- Generic Flomax[®] launched on March 2 added \$176.2 million of revenue and \$167.9 million of gross profit
- Record total gross profit of \$243.8 million — up \$211.1 million
- Gross profit margin increased to 75.4% — up from 55.4%
- Record income from operations of \$211.0 million — up \$206.8 million
- Record net income of \$131.5 million — up \$129.3 million
- Record earnings per diluted share of \$2.06 — up \$2.02

HAYWARD, Calif. (May 4, 2010) — Impax Laboratories, Inc. (NASDAQ: IPXL) today reported significant growth in the first quarter of 2010 due to an increase in sales from its Global product sales channel. Total revenue increased \$264.4 million to \$323.3 million driven by the successful March 2 exclusive launch of generic Flomax[®] (\$176.2 million of revenue and \$167.9 million of gross profit) and continued strong sales of generic Adderall XR[®] for which there were no comparable amounts in the first quarter 2009, as well as increased sales of the Company's fenofibrate products. Net income increased to \$131.5 million, or \$2.06 per diluted share, compared to \$2.2 million, or \$0.04 per diluted share in the prior year period.

Larry Hsu, Ph.D., president and chief executive officer of Impax Laboratories, said: "This has been a truly gratifying quarter as the investments we've been making across our organization are producing dramatic and record-breaking returns. A major contributor to our impressive first quarter was the launch of generic Flomax[®], the largest product launch in our history under the Global Pharmaceuticals label. Our efforts to prepare for the launch were well-rewarded as we achieved significant penetration of the market during our eight-week exclusivity period. As anticipated, we do not expect our future sales of generic Flomax[®] to remain at first quarter 2010 levels as competing generic versions of the product entered the market in late April and are likely to result in both price erosion and reduction of our market share."

Dr. Hsu continued, "The recent increase in cash flow generated from our operations, including our strong generic Flomax[®] and generic Adderall XR[®] product sales, will contribute significantly to our ongoing business development activities. We will continue our fundamental investments in internal research and development to take full advantage of our core competency in drug delivery formulation technology, as well as our experience in product development. In addition, we are aggressively looking at generic and brand opportunities to acquire products, technologies or companies with strategic value to create long-term growth opportunities. The range of these strategic opportunities we can consider is expanding as our resources increase significantly and our resolve to complete a transaction that meets our focused objectives remains very high. These are exciting times for Impax as we embark on another chapter in our long-term growth strategy."

First Quarter 2010 Segment Information

The Company has two reportable segments, the Global Pharmaceuticals Division (generic products) and the Impax Pharmaceuticals Division (brand products) and does not allocate general corporate services to either segment.

Global Pharmaceuticals Division Information

(amounts in thousands)	Three Months Ended March 31,	
	2010 (unaudited)	2009 (unaudited)
Revenues:		
Global product sales, net	\$ 309,105	\$ 39,121
Private Label	672	1,297
Rx Partner	4,903	10,736
OTC Partner	1,765	1,858
Research Partner	3,385	2,611
Other	—	6
Total Revenues	319,830	55,629
Cost of revenues	76,432	23,233
Gross profit	243,398	32,396
Operating expenses:		
Research and development	9,435	10,275
Patent litigation	1,984	1,017
Selling, general and administrative	3,334	2,594
Total operating expenses	14,753	13,886
Income from operations	\$ 228,645	\$ 18,510

First Quarter 2010

Global Pharmaceuticals Division revenues in the first quarter 2010 increased \$264.2 million to \$319.8 million, driven by a significant increase in Global product net sales, as discussed below.

During the first quarter of 2010, Global product net sales increased \$270.0 million to \$309.1 million over the same period in 2009 primarily due to strong sales of generic Flomax[®], generic Adderall XR[®], and to a lesser extent, increased sales of the Company's fenofibrate products. On March 2, 2010, the Company successfully launched generic Flomax[®] which contributed \$176.2 million to first quarter 2010 sales. The Company was the only supplier of generic Flomax[®] during the period ending April 27, 2010, after which competitors entered the market. Partially offsetting these gains was a \$5.8 million decline in Rx Partner revenues primarily attributable to reduced sales of generic Wellbutrin[®] products as competition continues to erode the Company's market share.

Cost of revenues was \$76.4 million for the first quarter 2010, an increase of \$53.2 million primarily related to the increase in Global product net sales offset by lower Rx Partner sales.

Gross profit for the first quarter 2010 increased \$211.0 million to \$243.4 million primarily due to sales of generic Flomax[®] (\$167.9 million in the first quarter 2010), generic Adderall XR[®] and an increase in fenofibrate sales. Gross profit margin of 76% for the first quarter 2010 increased significantly over the 58% margin for the prior year period primarily due to higher margin sales of generic Flomax[®] and, to a lesser extent, fenofibrate.

Total research and development expenses for the first quarter 2010 decreased slightly by \$0.8 million to \$9.4 million, compared to the prior year primarily due to lower spending on biostudies.

Total selling, general and administrative expenses for the first quarter 2010 increased \$0.7 million to \$3.3 million due to increased customer freight and higher sales force incentive compensation, both related to higher sales levels as noted above.

Generic division income from operations in the first quarter 2010 increased \$210.1 million to \$228.6 million, compared to \$18.5 million in the prior year, due to the increase in sales as noted above.

The Company's generic business development activities are primarily focused on acquiring products/technologies/businesses in complementary dosage forms where the Company's core competency in drug delivery and formulation expertise can be combined to produce above-average growth in high-value products. The Company has a number of opportunities under consideration and has expanded the field of opportunities as the Company's resources have increased. It is not possible to predict when any such transaction will occur, if at all, but these activities are a critical element of the Company's planned growth and management is devoting significant time and attention to these activities.

Impax Pharmaceuticals Division Information

<i>(amounts in thousands)</i>	Three Months Ended March 31,	
	2010 (unaudited)	2009 (unaudited)
Promotional Partner revenues	\$ 3,503	\$ 3,284
Cost of revenues	3,144	3,017
Gross profit	359	267
Operating expenses:		
Research and development	8,874	5,514
Selling, general and administrative	809	1,040
Total operating expenses	9,683	6,554
Loss from operations	(\$9,324)	(\$6,287)

First Quarter 2010

Promotional Partner revenues in the first quarter 2010 were \$3.5 million, a slight increase over the prior year as the Company continues to meet its detailing objectives.

Cost of revenues for the first quarter 2010 were \$3.1 million, up slightly from the prior year.

The Company is currently investing in research and development to develop brand products which provide longer product life cycles and the potential for significantly higher profit margins than generic products. In the first quarter of 2010, research and development increased \$3.4 million to \$8.9 million, due to planned increased spending on clinical studies and to a lesser extent, staffing costs and incentives associated with the management of these studies and the division.

The Company's planned increase in investment in research and development during the first quarter of 2010 contributed to a brand division loss from operations of \$9.3 million compared to a loss from operations of \$6.3 million in the first quarter of 2009.

The Company's brand business development activities are focused on (1) obtaining strategic partners for promotion and marketing the Company's products outside the United States and (2) co-development agreements with co-marketing rights where the Company's contribution to the venture is its commercial capabilities in its current markets. The Company has a number of opportunities under consideration and has expanded the field of opportunities as the Company's resources have increased. It is not possible to predict when any such transaction will occur, if at all, but these activities are a critical element of the Company's planned growth and management is devoting significant time and attention to these activities.

Corporate and Other Information

	Three Months Ended March 31,	
	2010 (unaudited)	2009 (unaudited)
<i>(amounts in thousands)</i>		
Litigation settlement	—	\$ 237
General and administrative	8,342	7,851
Total operating expenses	8,342	8,088
Loss from operations	(\$8,342)	(\$8,088)

Total corporate operating expenses for the first quarter 2010 increased slightly by \$0.3 million to \$8.3 million.

Cash and Cash Equivalents

Cash and short-term investments was \$130.4 million as of March 31, 2010, as compared to \$90.4 million as of December 31, 2009. The change in cash and short-term investments from year-end 2009 is due to strong product sales as noted above.

Cash flows from operating activities, before changes in working capital, less capital expenditures (Free Cash Flow) were a positive \$112.6 million in the first quarter 2010.

2010 Financial Outlook

The Company previously disclosed its 2010 financial outlook on January 11, 2010. As of May 4, 2010, the Company has updated its full year 2010 forecast as noted below.

- Cash flows from operating activities, before changes in working capital, less capital expenditures (Free Cash Flow), planned to be positive.
- Updated — gross margins as a percent of total revenues to approximate 50% for the balance of the year.
- Total research and development expenses across the generic and brand divisions to approximate \$77 million with generic R&D to approximate \$41 million and brand R&D to approximate \$36 million.
- Patent litigation expenses of approximately \$11 million.

- Selling, general and administrative expenses of approximately \$50 million.
- Updated — estimated consolidated effective tax rate of approximately 40% (without renewal in 2010 of the federal R&D tax credit).
- Capital expenditures expected to be approximately \$20 million.

Conference Call Information

The Company will host a conference call today at 11:00 a.m. EDT to discuss its results. The number to call from within the United States is (877) 356-3814 and (706) 758-0033 internationally. The call can also be accessed via a live Webcast through the Investor Relations section of the Company's Web site, www.impaxlabs.com. A replay of the conference call will be available shortly after the call for a period of seven days. To access the replay, dial (800) 642-1687 (in the U.S.) and (706) 645-9291 (international callers). The access conference code is 67229487.

About Impax Laboratories, Inc.

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 markets 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, Philadelphia and Taiwan 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 the Company'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, the effect of current economic conditions on the Company's industry, business, financial position, results of operations and market value of its common stock, the ability to maintain an effective system of internal control over financial reporting, fluctuations in revenues and operating income, reductions or loss of business with any significant customer, the impact of competitive pricing and products and regulatory actions on the Company's products, the ability to sustain profitability and positive cash flows, the ability to maintain sufficient capital to fund operations, any delays or unanticipated expenses in connection with the operation of the Taiwan facility, the ability to successfully develop and commercialize pharmaceutical products, the uncertainty of patent litigation, consumer acceptance and demand for new pharmaceutical products, the difficulty of predicting Food and Drug Administration filings and approvals, the inexperience of the Company in conducting clinical trials and submitting new drug applications, reliance on key alliance and collaboration agreements, the availability of raw materials, the ability to comply with legal and regulatory requirements governing the healthcare industry, the regulatory environment, exposure to product liability claims and other risks described in the Company's periodic reports filed 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.
Consolidated Statements of Operations
(amounts in thousands, except share and per share data)

	Three Months Ended March 31, 2010 (unaudited)	2009 (unaudited)
Revenues:		
Global Pharmaceuticals Division	\$ 319,830	\$ 55,629
Impax Pharmaceuticals Division	3,503	3,284
Total Revenues	<u>323,333</u>	<u>58,913</u>
Cost of revenues	<u>79,576</u>	<u>26,250</u>
Gross profit	<u>243,757</u>	<u>32,663</u>
Operating expenses:		
Research and development	18,309	15,789
Patent litigation	1,984	1,017
Litigation settlement	—	237
Selling, general and administrative	<u>12,485</u>	<u>11,485</u>
Total operating expenses	<u>32,778</u>	<u>28,528</u>
Income from operations	<u>210,979</u>	<u>4,135</u>
Other income (expense), net	(18)	55
Interest income	82	149
Interest expense	<u>(46)</u>	<u>(294)</u>
Income before income taxes	210,997	4,045
Provision for income taxes	<u>79,484</u>	<u>1,836</u>
Net income before noncontrolling interest	131,513	2,209
Add back (profit) loss attributable to noncontrolling interest	<u>(28)</u>	<u>10</u>
Net Income	<u><u>\$ 131,485</u></u>	<u><u>\$ 2,219</u></u>
Net Income per share:		
Basic	<u><u>\$ 2.16</u></u>	<u><u>\$ 0.04</u></u>
Diluted	<u><u>\$ 2.06</u></u>	<u><u>\$ 0.04</u></u>
Weighted average common shares outstanding:		
Basic	61,008,015	59,711,133
Diluted	63,865,678	60,222,215

Impax Laboratories, Inc.
Condensed Consolidated Balance Sheets
(amounts in thousands)

	March 31, 2010 <u>(unaudited)</u>	December 31, 2009 <u></u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 83,747	\$ 31,770
Short-term investments	46,615	58,599
Accounts receivable, net	324,692	185,854
Inventory, net	52,015	49,130
Current portion of deferred product manufacturing costs-alliance agreements	11,435	11,624
Current portion of deferred income taxes	35,109	32,286
Prepaid expenses and other current assets	3,963	4,748
Total current assets	<u>557,576</u>	<u>374,011</u>
Property, plant and equipment, net	102,330	101,650
Deferred product manufacturing costs-alliance agreements	95,986	96,619
Deferred income taxes, net	44,570	48,544
Other assets	16,993	12,358
Goodwill	27,574	27,574
Total assets	<u>\$ 845,029</u>	<u>\$ 660,756</u>
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	33,249	23,295
Accrued expenses	64,758	62,055
Accrued income taxes payable	78,582	31,627
Accrued profit sharing and royalty expenses	41,307	53,695
Current portion of deferred revenue-alliance agreements	33,433	33,196
Total current liabilities	<u>251,329</u>	<u>203,868</u>
Deferred revenue-alliance agreements	219,727	224,522
Other liabilities	12,212	10,139
Total liabilities	<u>483,268</u>	<u>438,529</u>
Stockholders equity	361,761	222,227
Total liabilities and stockholders equity	<u>\$ 845,029</u>	<u>\$ 660,756</u>

Impax Laboratories, Inc.
Condensed Consolidated Statement of Cash Flows
(amounts in thousands)

	Three Months Ended March 31, 2010 (unaudited)	2009 (unaudited)
Cash flows from operating activities:		
Net income	\$ 131,485	\$ 2,219
Adjustments to reconcile net income to net cash (used in) provided by operating activities:		
Depreciation	2,946	2,544
Amortization of 3.5% Debentures discount and deferred financing costs	—	150
Amortization of Wachovia Credit Agreement deferred financing costs	25	—
Bad debt expense	91	23
Deferred income taxes (benefit)	1,151	(3,027)
Provision for uncertain tax positions	12	218
Tax benefit related to the exercise of employee stock options	(738)	—
Deferred revenue-Alliance Agreements	5,495	19,723
Deferred product manufacturing costs-Alliance Agreements	(3,427)	(9,919)
Deferred revenue recognized-Alliance Agreements	(10,053)	(15,205)
Amortization deferred product manufacturing costs-Alliance Agreements	4,249	7,666
Accrued profit sharing and royalty expense	41,307	72
Profit sharing and royalty payments	(53,695)	(252)
Payments on exclusivity period fee	—	(3,000)
Payments on accrued litigation settlements	(5,865)	(4,007)
Share-based compensation expense	2,785	1,437
Accretion of interest income on short-term investments	(64)	(36)
Changes in assets and liabilities:		
Accounts receivable	(138,929)	(18,530)
Inventory	(2,885)	2,546
Prepaid expenses and other assets	(3,870)	2,042
Accounts payable and accrued expenses	64,678	(3,481)
Other liabilities	2,089	734
Net cash provided (used in) by operating activities	<u>\$ 36,787</u>	<u>(\$18,083)</u>
Cash flows from investing activities:		
Purchase of short-term investments	(23,055)	(27,810)
Maturities of short-term investments	35,103	18,245
Purchases of property, plant and equipment	(3,116)	(3,881)
Net cash provided by (used in) investing activities	<u>\$ 8,932</u>	<u>(\$13,446)</u>
Cash flows from financing activities:		
Repayment of long-term debt	—	(36)
Tax benefit related to the exercise of employee stock options	738	—
Proceeds from exercise of stock options and purchases under the ESPP	5,520	334
Net cash provided by financing activities	<u>\$ 6,258</u>	<u>\$ 298</u>
Net increase (decrease) in cash and cash equivalents	\$ 51,977	(\$31,231)
Cash and cash equivalents, beginning of period	\$ 31,770	\$ 69,275
Cash and cash equivalents, end of period	\$ 83,747	\$ 38,044