

IMPAX LABORATORIES INC

FORM 8-K

(Current report filing)

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Address	30831 HUNTWOOD AVENUE HAYWARD, CA 94544
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Sector	Healthcare
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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 1, 2012

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) 240-6000

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))
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Item 2.02 Results of Operations and Financial Condition.

On May 1, 2012, Impax Laboratories, Inc. issued a press release announcing its results for the quarter ended March 31, 2012. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated by reference herein.

The information in this report furnished pursuant to Item 2.02, including Exhibit 99.1 attached hereto, shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section. It may only be incorporated by reference in another filing under the Exchange Act or the Securities Act of 1933, as amended, if such subsequent filing specifically references the information furnished pursuant to Item 2.02 of this report.

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 1, 2012.

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 1, 2012

IMPAX LABORATORIES, INC .

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

Name: Arthur A. Koch, Jr.

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

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued May 1, 2012.

**Company Contact:**

Mark Donohue
 Sr. Director
 Investor Relations and Corporate Communications
 (215) 558-4526
www.impaxlabs.com

**Impax Laboratories Reports Adjusted First Quarter 2012 EPS of \$0.52;
 GAAP EPS of \$0.18
 —Provides update on FDA inspection of Hayward facility—**

HAYWARD, Calif. (May 1, 2012) – Impax Laboratories, Inc. (NASDAQ: IPXL) today reported first quarter ended March 31, 2012 financial results.

First Quarter 2012 Results

- Adjusted net income increased to \$35.1 million, or \$0.52 per diluted share, compared to \$13.9 million, or \$0.21 per diluted share, in the prior year period, primarily attributable to the benefit of the gross profit of \$30.0 million (\$0.29 per diluted share) earned from United States (U.S.) Zomig[®] sales pursuant to the previously disclosed License Agreement with AstraZeneca UK Limited.
- GAAP net income decreased to \$12.4 million, or \$0.18 per diluted share, compared to \$13.9 million, or \$0.21 per diluted share, primarily due to higher expenses and an inventory adjustment as a result of a change in the strategic direction of certain generic products.
- Total revenues increased to \$128.6 million, compared to \$108.7 million in the prior year period, primarily due to higher sales of generic Adderall XR[®]. First quarter 2012 revenues exclude U.S. Zomig[®] sales by AstraZeneca, although the Company will receive the benefit of the gross profit from these sales during the specified transition period pursuant to the License Agreement.
- Adjusted earnings before interest, taxes, depreciation and amortization (Adjusted EBITDA), increased to \$61.1 million compared to \$27.1 million in the prior year period, primarily attributable to the benefit of the gross profit earned from U.S. Zomig[®] sales by AstraZeneca.

Please refer to “Non-GAAP Financial Measures” below for a reconciliation of GAAP to non-GAAP items.

“Our improved first quarter performance was primarily driven by increased deliveries of generic Adderall XR[®] from our third-party supplier,” said Larry Hsu, Ph.D., president and CEO, Impax Laboratories, Inc. “We continue to pursue every available means to acquire sufficient product to meet strong demand.”

“During the first quarter of 2012, we established the infrastructure to successfully transition the U.S. commercial opportunity for Zomig[®] from AstraZeneca to our brand division. The transaction was accretive to our first quarter non-GAAP earnings per diluted share as we received the benefit of the gross profit of \$30.0 million from first quarter U.S. sales, partially offset by our \$25.0 million payment under the terms of the agreement. We also expect this transaction to be accretive to our non-GAAP earnings for the full year 2012. On April 1, our expanded neurology focused sales force began promotion efforts. This product will support the growth of our commercial organization, as we prepare for the potential launch of IPX066, our leading brand product candidate for Parkinson’s Disease, and thereafter. The Zomig[®] license is the latest effort in our active pursuit of additional long term growth opportunities for our generic and brand businesses.”

Separately, the U.S. Food and Drug Administration (FDA) completed its re-inspection of the Company's Hayward manufacturing facility in connection with the previously disclosed warning letter. In addition to the re-inspection relating to the warning letter, the FDA conducted a general GMP inspection of the Company's Hayward operations. At the conclusion of this additional inspection, the FDA issued a new Form 483 with observations primarily relating to the Company's Quality Control Laboratory. There were no repeat deficiencies or observations set forth in the Form 483 and the observations described therein are different from the observations raised in the warning letter. The Company has timely submitted its response to the Form 483 to the FDA.

Currently, the Company has not been informed by the FDA of the impact this latest Form 483 will have on the resolution or timing of resolving the warning letter or whether any further regulatory action may be taken as to its manufacturing operations. The Company has no control over the Agency's timing to review its response or to evaluate its corrective actions. In the interim, the Company continues to manufacture products and is working diligently to address the observations raised by the FDA in the Form 483.

Dr. Hsu said "While we believe we have addressed the observations raised in the warning letter and have instituted appropriate corrective actions, we are disappointed to have received a Form 483 on these new observations. We believe we have submitted a complete response to the Form 483 and are working diligently to enhance our quality control procedures. We have already taken decisive action, including a change in the testing laboratory leadership, as well as strengthened and clarified laboratory testing standard operating procedures."

Segment Information

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

Global Pharmaceuticals Division Information

<i>(unaudited, amounts in thousands)</i>	Three Months Ended	
	March 31,	
	2012	2011
Revenues:		
Global Product sales, net	\$116,211	\$ 92,338
Rx Partner	2,978	2,682
OTC Partner	691	1,943
Research Partner	3,385	6,385
Total Revenues	123,265	103,348
Cost of revenues	63,106	47,174
Gross profit	60,159	56,174
Operating expenses:		
Research and development	10,662	9,776
Patent litigation	4,038	1,774
Selling, general and administrative	4,766	2,931
Total operating expenses	19,466	14,481
Income from operations	\$ 40,693	\$ 41,693

Global Pharmaceuticals Division revenues increased \$19.9 million to \$123.3 million in the first quarter 2012, compared to \$103.3 million in the prior year, due to higher Global Product sales, net.

For the first quarter 2012, Global Product sales, net, were \$116.2 million, up \$23.9 million from the prior year primarily due to higher sales of authorized generic Adderall XR[®] products (\$53.6 million in the first quarter 2012 compared to \$36.1 million in the prior year), as well as higher sales of other Global label products. Partially offsetting this increase were declines in Research Partner and OTC Partner revenues. Research Partner revenues declined \$3.0 million due to a milestone payment achieved during the first quarter of 2011 under the Medicis joint development agreement originally entered into in the fourth quarter of 2008. OTC Partner revenues declined due to lower sales of product marketed under the Company's alliance agreement with Pfizer.

Gross profit of \$60.2 million represented a 49% gross margin in the first quarter 2012, and was lower than the gross margin of 54% for the prior year period. The decline was primarily due to a \$5.2 million inventory adjustment as a result of a change in the strategic direction of certain generic products. Additionally, gross profit in the first quarter 2011 includes the \$3.0 million payment from Medicis described above.

Total generic operating expenses in the first quarter 2012 increased \$5.0 million to \$19.5 million, compared to the prior year, due to higher planned investments in research and development (R&D), as well as patent litigation and selling, general and administrative expenses (SG&A).

Impax Pharmaceuticals Division Information

<i>(unaudited, amounts in thousands)</i>	Three Months Ended March 31,	
	2012	2011
Revenues:		
Rx Partner	\$ 1,438	\$ 1,438
Promotional Partner	3,535	3,535
Research Partner	330	330
Total revenues	5,303	5,303
Cost of revenues	2,909	2,940
Gross profit	2,394	2,363
Operating expenses:		
Research and development	8,154	9,714
Selling, general and administrative	3,061	1,107
Total operating expenses	11,215	10,821
Loss from operations	<u>\$ (8,821)</u>	<u>\$ (8,458)</u>

Impax Pharmaceuticals Division revenues in the first quarter 2012 were flat compared to the prior year.

Total brand operating expenses in the first quarter 2012 increased slightly compared to the prior year due to higher SG&A expenses, partially offset by lower R&D expenses.

On February 1, 2012, the Company announced that it had entered into the Distribution, License, Development and Supply Agreement with AstraZeneca UK Limited. As part of the License Agreement, AstraZeneca granted to the Company an exclusive license to commercialize the tablet, orally disintegrating and nasal spray formulations of Zomig[®] (zolmitriptan) products for the treatment of migraine headaches in the United States and in certain U.S. territories. Under the terms of the agreement, the Company agreed to pay AstraZeneca quarterly payments totaling \$130.0 million during 2012 of which \$25.0 million was paid in the first quarter. During the specified product transition period pursuant to the agreement, the Company will receive the benefit of the gross profit (\$30.0 million for the three months ended March 31, 2012) from U.S. Zomig[®] sales commencing from January 1, 2012 and ending when the Company commences commercialization of the Zomig[®] products. The benefit of the gross profit received from AstraZeneca is recorded as a reduction of the \$130.0 million to be paid by the Company to AstraZeneca during 2012 and is not reflected within the Company's income.

Corporate and Other

<i>(unaudited, amounts in thousands)</i>	Three Months Ended	
	March 31,	
	2012	2011
General and administrative expenses	\$ 13,406	\$ 12,541
Loss from operations	\$(13,406)	\$(12,541)

General and administrative expenses in the first quarter 2012 increased \$0.9 million compared to the prior year primarily due to higher corporate legal fees.

Cash and Short-term Investments

Cash and short-term investments were \$343.3 million as of March 31, 2012, as compared to \$346.4 million as of December 31, 2011.

2012 Financial Outlook

The Company's 2012 financial outlook which was last updated on February 1, 2012 is noted below.

- Gross margins as a percent of total revenues of approximately 60%.
- Total R&D expenses across the generic and brand divisions to approximate \$89.0 million with generic R&D of approximately \$48.0 million and brand R&D of approximately \$41.0 million.
- Patent litigation expenses of approximately \$10.0 million.
- SG&A expenses of approximately \$113.0 million.
- Effective tax rate of approximately 36%.
- Capital expenditures of approximately \$78.0 million.

Conference Call Information

The Company will host a conference call on May 1, 2012 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 (855) 859-2056 (in the U.S.) and (404) 537-3406 (international callers). The access conference code is 69137467.

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 third-party 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 and results of operations, fluctuations in the Company’s revenues and operating income, the Company’s ability to successfully develop and commercialize pharmaceutical products, reductions or loss of business with any significant customer, the impact of consolidation of the Company’s customer base, the impact of competition, the Company’s ability to sustain profitability and positive cash flows, any delays or unanticipated expenses in connection with the operation of the Company’s Taiwan facility, the effect of foreign economic, political, legal and other risks on the Company’s operations abroad, the uncertainty of patent litigation, increased government scrutiny on the Company’s agreements with brand pharmaceutical companies, consumer acceptance and demand for new pharmaceutical products, the difficulty of predicting Food and Drug Administration filings and approvals, the Company’s inexperience in conducting clinical trials and submitting new drug applications, the Company’s ability to successfully conduct clinical trials, the Company’s reliance on third parties to conduct clinical trials and testing, the availability of raw materials and impact of interruptions in the Company’s supply chain, the use of controlled substances in the Company’s products, disruptions or failures in the Company’s information technology systems and network infrastructure, the Company’s reliance on alliance and collaboration agreements, the Company’s dependence on certain employees, the Company’s ability to comply with legal and regulatory requirements governing the healthcare industry, the regulatory environment, the Company’s ability to protect the Company’s intellectual property, exposure to product liability claims, changes in tax regulations, the Company’s ability to manage the Company’s growth, including through potential acquisitions, the restrictions imposed by the Company’s credit facility, uncertainties involved in the preparation of the Company’s financial statements, the Company’s ability to maintain an effective system of internal control over financial reporting, any manufacturing difficulties or delays, the effect of terrorist attacks on the Company’s business, the location of the Company’s manufacturing and research and development facilities near earthquake fault lines 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.

Impax Laboratories, Inc.
Consolidated Statements of Operations
(unaudited, amounts in thousands, except share and per share data)

	Three Months Ended March 31,	
	2012	2011
Revenues:		
Global Pharmaceuticals Division	\$ 123,265	\$ 103,348
Impax Pharmaceuticals Division	5,303	5,303
Total Revenues	128,568	108,651
Cost of revenues	66,015	50,114
Gross profit	62,553	58,537
Operating expenses:		
Research and development	18,816	19,490
Patent litigation	4,038	1,774
Selling, general and administrative	21,233	16,579
Total operating expenses	44,087	37,843
Income from operations	18,466	20,694
Other income (expense), net	(80)	3
Interest income	255	321
Interest expense	(39)	(16)
Income before income taxes	18,602	21,002
Provision for income taxes	6,269	7,144
Net income before noncontrolling interest	12,333	13,858
Add back loss attributable to noncontrolling interest	32	5
Net Income	<u>\$ 12,365</u>	<u>\$ 13,863</u>
Net Income per share:		
Basic	<u>\$ 0.19</u>	<u>\$ 0.22</u>
Diluted	<u>\$ 0.18</u>	<u>\$ 0.21</u>
Weighted average common shares outstanding:		
Basic	<u>65,122,240</u>	<u>63,390,527</u>
Diluted	<u>67,907,263</u>	<u>67,044,266</u>

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

	March 31,	December 31,
	2012	2011
Assets		
Current assets:		
Cash and cash equivalents	\$192,048	\$ 104,419
Short-term investments	151,202	241,995
Accounts receivable, net	119,183	153,773
Inventory, net	57,938	54,177
Deferred product manufacturing costs	1,444	1,413
Deferred income taxes	38,586	37,853
Prepaid expenses and other current assets	89,295	6,305
Total current assets	<u>649,696</u>	<u>599,935</u>
Property, plant and equipment, net	126,886	118,158
Deferred product manufacturing costs	7,236	7,433
Other assets	44,909	38,509
Intangible assets, net	46,997	2,250
Goodwill	27,574	27,574
Total assets	<u>\$903,298</u>	<u>\$ 793,859</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 18,568	\$ 22,955
Accrued expenses	73,950	70,116
Accrued profit sharing and royalty expenses	25,567	40,766
Accrued product licensing payments	105,000	—
Deferred revenue	17,926	23,024
Total current liabilities	<u>241,011</u>	<u>156,861</u>
Deferred revenue	16,189	17,131
Other liabilities	19,768	16,861
Total liabilities	<u>276,968</u>	<u>190,853</u>
Total stockholders' equity	<u>626,330</u>	<u>603,006</u>
Total liabilities and stockholders' equity	<u>\$903,298</u>	<u>\$ 793,859</u>

Impax Laboratories, Inc.
Consolidated Statements of Cash Flows
(unaudited, amounts in thousands)

	Three Months Ended March 31,	
	2012	2011
Cash flows from operating activities:		
Net income	\$ 12,365	\$ 13,863
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	3,722	3,457
Amortization of Credit Agreement deferred financing costs	8	5
Accretion of interest income on short-term investments	(171)	(245)
Deferred income taxes	801	(1,106)
Provision for uncertain tax positions	16	40
Tax benefit related to the exercise of employee stock options	(1,632)	(2,353)
Deferred revenue	315	910
Deferred product manufacturing costs	(495)	(478)
Recognition of deferred revenue	(6,061)	(7,384)
Amortization of deferred product manufacturing costs	661	1,357
Accrued profit sharing and royalty expense	25,555	17,090
Payments of profit sharing and royalty expense	(40,755)	(14,139)
Share-based compensation expense	3,809	2,887
Bad debt expense	—	62
Changes in assets and liabilities:		
Accounts receivable	34,590	(12,288)
Inventory	(3,761)	(4,291)
Prepaid expenses and other assets	(3,745)	(949)
Accounts payable and accrued expenses	(4,153)	2,518
Other liabilities	2,661	2,055
Net cash provided by operating activities	<u>23,730</u>	<u>1,011</u>
Cash flows from investing activities:		
Purchase of short-term investments	(35,585)	(87,783)
Maturities of short-term investments	126,549	135,408
Purchases of property, plant and equipment	(8,165)	(8,723)
Payment for product licensing rights	(25,000)	—
Net cash provided by investing activities	<u>57,799</u>	<u>38,902</u>
Cash flows from financing activities:		
Tax benefit related to the exercise of employee stock options and restricted stock	1,632	2,353
Proceeds from exercise of stock options and ESPP	4,468	6,669
Net cash provided by financing activities	<u>6,100</u>	<u>9,022</u>
Net increase in cash and cash equivalents	87,629	48,935
Cash and cash equivalents, beginning of period	104,419	91,796
Cash and cash equivalents, end of period	<u>\$192,048</u>	<u>\$140,731</u>

Impax Laboratories, Inc.
Non-GAAP Financial Measures

Total adjusted net income, adjusted net income per diluted share and adjusted EBITDA are not measures of financial performance under generally accepted accounting principles (GAAP) and should not be construed as substitutes for, or superior to, GAAP net income, and net income per diluted share as a measure of financial performance. However, management uses both GAAP financial measures and the disclosed non-GAAP financial measures internally to evaluate and manage the Company's operations and to better understand its business. Further, management believes the inclusion of non-GAAP financial measures provides meaningful supplementary information to and facilitates analysis by investors in evaluating the Company's financial performance, results of operations and trends. The Company's calculation of adjusted net income, adjusted net income per diluted share and adjusted EBITDA, may not be comparable to similarly designated measures reported by other companies, since companies and investors may differ as to what type of events warrant adjustment.

The following table reconciles reported net income to adjusted net income.

<i>(Unaudited, amounts in millions, except per share data)</i>	Three months ended March 31,	
	2012	2011
Net income	\$ 12.4	\$ 13.9
Adjusted to add (deduct):		
Gross profit earned on Zomig [®] Agreement ^(a)	30.0	—
Strategic inventory adjustment	5.2	—
Income tax effect	(12.5)	—
Adjusted net income	<u>\$ 35.1</u>	<u>\$ 13.9</u>
Adjusted net income per diluted share	<u>\$ 0.52</u>	<u>\$ 0.21</u>
Net income per diluted share	\$ 0.18	\$ 0.21

Impax Laboratories, Inc.
Non-GAAP Financial Measures

The following table reconciles reported net income to adjusted EBITDA.

<i>(Unaudited, amounts in millions)</i>	Three months ended March 31,	
	2012	2011
Net income	\$ 12.4	\$ 13.9
Adjusted to add (deduct):		
Interest income	(0.3)	(0.3)
Depreciation, amortization and other	3.7	3.5
Income taxes	6.3	7.1
EBITDA	<u>22.1</u>	<u>24.2</u>
Adjusted to add:		
Gross profit earned on Zomig [®] Agreement ^(a)	30.0	—
Strategic inventory adjustment	5.2	—
Share-based compensation	3.8	2.9
Adjusted EBITDA	<u>\$ 61.1</u>	<u>\$ 27.1</u>

^(a) During the specified product transition period pursuant to the agreement, the Company will receive the benefit of the gross profit (\$30.0 million for the three months ended March 31, 2012) from U.S. Zomig[®] sales commencing from January 1, 2012 and ending when the Company commences commercialization of the Zomig[®] products. The benefit of the gross profit received from AstraZeneca is recorded as a reduction of the \$130.0 million to be paid by the Company to AstraZeneca during 2012 and is not reflected within the Company's income but included in the Company's adjusted net income. This reduction in the \$130 million to be paid to AstraZeneca will result in lower future amortization expense in the GAAP results and will be excluded from future adjusted results.