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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Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

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): February 25, 2013

Impax Laboratories, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-34263**	**65-0403311**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

30831 Huntwood Avenue, Hayward, CA	**94544**
(Address of principal executive offices)	(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))

Item 2.02 Results of Operations and Financial Condition.

On February 25, 2013, Impax Laboratories, Inc. issued a press release announcing its results for the fourth quarter and the fiscal year ended December 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.

Exhibit No.	**Description**
99.1	Press release issued February 25, 2013.

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 .

Dated: February 25, 2013

By: /s/ Bryan M. Reasons

Name: Bryan M. Reasons
Title: Senior VP, Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release issued February 25, 2013.

Exhibit 99.1

Company Contact:
Mark Donohue
Investor Relations and Corporate Communications
(215) 558-4526
www.impaxlabs.com

Impax Laboratories Reports Fourth Quarter and Full Year 2012 Results

- Company Updates 2013 Financial Guidance
- Provides Update on IPX159 Phase IIb Trial in Restless Legs Syndrome

HAYWARD, Calif. (February 25, 2013) – Impax Laboratories, Inc. (NASDAQ: IPXL) today reported fourth quarter 2012 adjusted net income of $20.5 million or $0.30 per diluted share, compared to $21.9 million or $0.33 per diluted share in the fourth quarter 2011. Adjusted net income for the fourth quarter 2012 excludes $15.7 million or $0.23 per diluted share, primarily related to amortization and acquisition costs from third-party business development transactions in 2012. GAAP net income for the fourth quarter 2012 was $4.8 million or $0.07 per diluted share, compared to $21.9 million or $0.33 per diluted share in the prior year period.

For the fourth quarter 2012, total revenues were $141.1 million, a decrease of 11%, compared to $158.6 million in the prior year period, primarily due to lower sales of the Company's authorized generic Adderall XR® products as a result of additional competition, partially offset by United States (U.S.) sales of Zomig®. Total revenues for the fourth quarter 2012 included the recognition of $9.0 million of previously deferred revenue related to a product marketed under the generic OTC Partner alliance agreement with Pfizer (Pfizer Agreement).

Adjusted earnings before interest, taxes, depreciation and amortization (Adjusted EBITDA), was $38.3 million in the fourth quarter 2012, compared to $40.4 million in the fourth quarter 2011. Cash and short-term investments were $298.9 million as of December 31, 2012. Please refer to the attached "Non-GAAP Financial Measures" for a reconciliation of GAAP to non-GAAP items.

Full Year 2012 results

For the full year 2012, adjusted net income was $130.8 million or $1.91 per diluted share, compared to $66.0 million or $0.98 per diluted share for the full year 2011. The increase was primarily driven by U.S. sales of Zomig under the AstraZeneca License Agreement. Adjusted results exclude acquisition-related costs, as well as other items noted in the attached reconciliation table. GAAP net income for the full year 2012 was $55.9 million or $0.82 per diluted share, compared to $65.5 million or $0.97 per diluted share in 2011.

Total revenues for the full year 2012 increased 13% to $581.7 million, compared to $512.9 million for the full year 2011, primarily due to U.S. sales of Zomig and higher sales of fenofibrate products, partially offset by lower sales of authorized generic Adderall XR. Adjusted EBITDA was $228.5 million for the full year 2012, compared to $126.4 million in the prior year.

"While our adjusted full year 2012 financial results improved over last year, it was still a challenging year for Impax. We faced a few obstacles on two of our key objectives for 2012 - successfully resolving the warning letter at our Hayward facility and obtaining approval of our first internally developed branded product candidate RYTARY ™," said Larry Hsu, Ph.D., president and CEO, Impax Laboratories, Inc. "The resolution of the quality issues in Hayward continues to be a top priority throughout the company."

The Company recently completed its Phase IIb trial of its investigational drug candidate IPX159 in primary Restless Legs Syndrome (RLS). Analysis of the study data indicated that although the results showed a modest improvement in addressing RLS symptoms, such results did not achieve the statistical criteria for its primary efficacy endpoints compared to placebo and does not support advancement of the program in RLS.

Dr. Hsu continued, “These obstacles, however, are not preventing us from continuing to invest in developing future generic and branded product opportunities or moving forward with our long-term growth strategy. In 2012 we made significant progress in diversifying our generics business by expanding our alternative dosage form portfolio from 9 products in 2011 to 33 currently marketed and pipeline products. We also focused on building a brand pipeline through both internal R&D and external business development activities.”

“We ended 2012 with almost $300 million in cash and short-term investments, and no debt. In addition, we expect the pre-tax receipt of approximately $150 million from Endo Health Solutions and Shire under previously announced agreements. These resources combined with our strong balance sheet will help to support our business objectives,” concluded Dr. Hsu.

The Company also announced that the United States Patent Office had granted a second formulation patent for IPX066 (RYTARY ™), an extended-release capsule formulation of carbidopa and levodopa. The patent (No. 8,377,474), titled “Controlled Release Formulations of Levodopa and Uses Thereof” extends through 2028.

Fourth Quarter and Full Year 2012 Business 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

(unaudited, amounts in thousands)	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2012	**2011**	**2012**	**2011**
Revenues:				
Global Product sales, net	$ 79,771	$ 142,694	$ 421,875	$ 443,818
Rx Partner	1,793	6,164	6,445	26,333
OTC Partner	9,365	1,015	11,602	5,021
Research Partner	995	3,384	8,760	16,538
Total revenues	91,924	153,257	448,682	491,710
Cost of revenues	51,665	78,086	229,355	242,713
Gross profit	40,259	75,171	219,327	248,997
Operating expenses:				
Research and development	13,350	11,441	48,540	46,169
Patent litigation	3,191	1,409	9,772	7,506
Selling, general and administrative	4,065	2,578	15,377	11,313
Total operating expenses	20,606	15,428	73,689	64,988
Income from operations	$ 19,653	$ 59,743	$ 145,638	$ 184,009

Fourth Quarter 2012

Global Pharmaceuticals Division revenues in the fourth quarter 2012 declined to $91.9 million, compared to $153.3 million in the prior year period. The decline was primarily due to lower sales of authorized generic Adderall XR products as a result of additional generic competition and lower sales of Rx Partner products through the Company's Strategic Alliance Agreement with Teva Pharmaceutical Industries Ltd. (Teva Agreement).

OTC Partner revenues in the fourth quarter 2012 increased to $9.4 million, compared to $1.0 million in the prior year period, due to the recognition of $9.0 million of previously deferred revenue under the Pfizer Agreement. The Global Division's OTC Partner Sales Channel is no longer considered a core area of the Company's generic business.

Research Partner revenues in the fourth quarter 2012 declined to $1.0 million, compared to $3.4 million in the prior year period, resulting from the extension of the revenue recognition period for the Joint Development Agreement with Valeant Pharmaceuticals International, Inc., formerly Medicis Pharmaceutical Corporation (Valeant Agreement) from November 2012 to November 2013 due to changes in the estimated timing of completion of certain research and development activities.

Gross profit in the fourth quarter 2012 was $40.3 million, compared to $75.2 million in the prior year period, primarily due to lower sales of authorized generic Adderall XR products. Gross margin in the fourth quarter 2012 decreased to 44%, compared to 49% in the prior year period, primarily due to the recognition of $8.6 million of previously deferred OTC Partner manufacturing costs under the Pfizer Agreement as described above.

Total generic operating expenses in the fourth quarter 2012 increased to $20.6 million, compared to $15.4 million in the prior year period, primarily due to higher patent litigation expenses and a one-time back-log fee required under the Generic Drug Fee User Amendments of 2012 for pending Abbreviated New Drug Applications.

Full Year 2012

Global Pharmaceuticals Division revenues for the full year 2012 declined to $448.7 million, compared to $491.7 million for the full year 2011, principally resulting from a decrease in Global Product sales, net and Rx Partner revenues.

Global Product sales, net, for the full year 2012 declined to $421.9 million, compared to $443.8 million in the prior year, primarily as a result of lower sales of authorized generic Adderall XR partially offset by higher sales of fenofibrate products.

Rx Partner revenues for the full year 2012 declined to $6.4 million, compared to $26.3 million in the prior year, primarily due to a profit-share adjustment from Teva under the Teva Agreement realized in 2011 for which there was no similar amount realized in 2012, as well as lower sales of products marketed through the Teva Agreement.

Research Partner revenues for the full year 2012 declined to $8.8 million, compared to $16.5 million in the prior year. The decline was due to the extension of the revenue recognition period for the Valeant Agreement as described above, and the recognition of a $3.0 million milestone payment in 2011 under the same agreement for which there was no such milestone payment recognized in 2012.

OTC Partner revenues for the full year 2012 increased to $11.6 million, compared to $5.0 million in the prior year, due to the recognition of $9.0 million of previously deferred revenue under the Pfizer Agreement as described above.

Gross profit for the full year 2012 declined to $219.3 million, compared to $249.0 million in the prior year. Gross margin for the full year 2012 decreased to 49%, compared to 51% in the prior year. The decline in both gross profit and gross profit margin were primarily due to lower sales of authorized generic Adderall XR products and lower profit share recognized under the Teva Agreement as described above.

Total generic operating expenses for the full year 2012 increased to $73.7 million, compared to $65.0 million in the prior year, due to increased patent litigation activity related to several cases which were not present in the prior year, higher executive-level compensation costs as a result of vacancies during the prior year period, higher marketing expenses and business development activities. Partially offsetting the increase was the reimbursement of $5.0 million for legal fees received in 2012 pursuant to the settlement of a lawsuit.

Impax Pharmaceuticals Division Information

(unaudited, amounts in thousands)	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2012	**2011**	**2012**	**2011**
Revenues:				
Impax Product sales, net	$ 46,698	$ -	$ 118,121	$ -
Rx Partner	2,125	1,437	6,500	5,750
Research Partner	330	330	1,319	1,319
Promotional Partner	-	3,535	7,070	14,140
Total revenues	49,153	5,302	133,010	21,209
Cost of revenues	25,261	3,071	69,783	11,911
Gross profit	23,892	2,231	63,227	9,298
Operating expenses:				
Research and development	9,273	8,952	32,780	36,532
Selling, general and administrative	15,630	3,319	37,896	7,435
Total operating expenses	24,903	12,271	70,676	43,967
Loss from operations	$ (1,011)	$ (10,040)	$ (7,449)	$ (34,669)

Fourth Quarter 2012

Impax Pharmaceuticals Division revenues in the fourth quarter 2012 increased $43.9 million to $49.2 million, compared to the prior year period, due to U.S. sales of Zomig for which there was no comparable amount in the prior year period. This increase was partially offset by a $3.5 million decline in Promotional Partner revenues as the Company's detailing for Pfizer's product Lyrica ® ended on June 30, 2012.

Gross profit in the fourth quarter 2012 increased $21.7 million to $23.9 million, compared to the prior year period, due to U.S. Zomig sales. Gross margin in the fourth quarter 2012 increased to 49%, compared to 42% in the prior year period. The fourth quarter 2012 gross margin was, however, negatively impacted by the inclusion of $23.4 million in cost of revenues for amortization and acquisition-related costs from the Zomig transaction.

Total brand operating expenses in the fourth quarter 2012 increased to $24.9 million, compared to $12.3 million in the prior year period, due to the expansion of the sales and marketing group, pre-launch planning costs for RYTARY ™ and higher selling, general and administration expenses related to Zomig.

Full Year 2012

Impax Pharmaceuticals Division revenues for the full year 2012 increased $111.8 million to $133.0 million, compared to the full year 2011, due to U.S. sales of Zomig for which there was no comparable amount in the prior year. This increase was partially offset by a $7.1 million decline in Promotional Partner revenues as detailing for Pfizer's product Lyrica ended on June 30, 2012.

For the full year 2012, gross profit increased $53.9 million to $63.2 million over the prior year, due to the addition of U.S. Zomig sales. Gross margin for the full year 2012 increased to 48%, compared to 44% for the prior year. The full year 2012 gross margin was, however, negatively impacted by the inclusion of $59.3 million in cost of revenues for amortization and acquisition-related costs due to the Zomig transaction.

Total brand operating expenses for the full year 2012 increased to $70.7 million, compared to $44.0 million in the prior year, primarily due to higher sales and marketing expenses related to Zomig, pre-launch marketing expenses related to RYTARY™, and higher compensation costs related to the expansion of the sales and marketing group. In addition, the Company incurred $8.9 million in 2012 for charges related to its branded products sales force which had been included as a component of cost of revenues in the prior year period as the sales force was previously engaged in providing co-promotion services for Pfizer's product Lyrica, as described above.

Corporate and Other

(unaudited, amounts in thousands)	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2012	**2011**	**2012**	**2011**
General and administrative expenses	$ 13,745	$ 14,174	$ 55,197	$ 49,729
Loss from operations	$ (13,745)	$ (14,174)	$ (55,197)	$ (49,729)

Fourth Quarter 2012

General and administrative expenses of $13.7 million in the fourth quarter 2012 were slightly lower as compared to $14.2 million in the prior year period.

Full Year 2012

General and administrative expenses for the full year 2012 increased to $55.2 million, compared to $49.7 million for the prior year, primarily due to increased headcount, severance-related charges, higher professional fees and IT initiatives in support of strategic growth, partially reduced by lower litigation expenses.

Cash and Short-term Investments

Cash and short-term investments were $298.9 million as of December 31, 2012, compared to $346.4 million as of December 31, 2011. The decline was primarily due to the Zomig and TOLMAR, Inc. transactions and investments in property, plant and equipment.

2013 Financial Guidance

The Company provided its 2013 financial guidance on January 7, 2013, which included estimated launch expenses related to the anticipated approval of RYTARY ™ and product launch in the first quarter 2013 as the Prescription Drug User Fee Act date for a review of the New Drug Application (NDA) by the U.S. Food and Drug Administration (FDA) was January 21, 2013. On January 18, 2013, the Company received a complete response letter from the FDA indicating that the FDA requires a satisfactory re-inspection of the Company's Hayward facility as a result of the warning letter issued in May 2011 before the NDA may be approved due to the facility's involvement in the development of RYTARY ™ , and supportive manufacturing and distribution activities. Since the timing for resolution of the warning letter and further review of the NDA by the FDA is currently unknown, estimated launch expenses have been removed from the 2013 selling, general and administrative (SG&A) guidance. However, the Company is continuing pre-launch planning for RYTARY ™ and expenses associated with such pre-launch activities are included within the updated SG&A guidance set forth below.

- Gross margins as a percent of total revenues in the low to mid 50% range.
- UPDATED - Total R&D expenses, excluding patent litigation expenses, across the generic and brand divisions of approximately $87.0 million to $95.0 million; generic R&D expenses of approximately $49.0 million to $53.0 million and brand R&D expenses of approximately $38.0 million to $42.0 million.
- UPDATED - Patent litigation expenses of approximately $10.0 million to $12.0 million.
- UPDATED - SG&A expenses of approximately $115.0 million to $120.0 million.
- Amortization expense of approximately $14.0 million. Approximate 2013 quarterly impact on cost of goods sold: first quarter $7.0 million, second quarter $5.0 million, third quarter $1.0 million and fourth quarter $1.0 million.
- UPDATED - Effective tax rate of approximately 32% to 34%.

Conference Call Information

The Company will host a conference call on February 25, 2013 at 4:30 p.m. EDT to discuss its results. The call can also be accessed via a live Webcast through the Investor Relations section of the Company's Web site, www.impaxlabs.com . The number to call from within the United States is (877) 356-3814 and (706) 758-0033 internationally. The conference ID is 90423980. 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).

About Impax Laboratories, Inc.

Impax Laboratories, Inc. (Impax) 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 central nervous system disorder 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 develops marketing partnerships to fully leverage its technology platform and pursues partnership opportunities that offer alternative dosage form technologies, such as injectables, nasal sprays, inhalers, patches, creams and ointments. 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 December 31,		Twelve Months Ended December 31,	
	2012	**2011**	**2012**	**2011**
Revenues:				
Global Pharmaceuticals Division	$ 91,924	$ 153,257	$ 448,682	$ 491,710
Impax Pharmaceuticals Division	49,153	5,302	133,010	21,209
Total revenues	141,077	158,559	581,692	512,919
Cost of revenues	76,926	81,157	299,138	254,624
Gross profit	64,151	77,402	282,554	258,295
Operating expenses:				
Research and development	22,623	20,393	81,320	82,701
Patent litigation	3,191	1,409	9,772	7,506
Selling, general and administrative	33,440	20,071	108,470	68,477
Total operating expenses	59,254	41,873	199,562	158,684
Income from operations	4,897	35,529	82,992	99,611
Other expense, net	(119)	(2,089)	(138)	(2,492)
Interest income	318	270	1,089	1,149
Interest expense	(25)	(76)	(632)	(157)
Income before income taxes	5,071	33,634	83,311	98,111
Provision for income taxes	272	11,772	27,438	32,616
Net income	$ 4,799	$ 21,862	$ 55,873	$ 65,495
Net Income per share:				
Basic	$ 0.07	$ 0.34	$ 0.85	$ 1.02
Diluted	$ 0.07	$ 0.33	$ 0.82	$ 0.97
Weighted average common shares outstanding:				
Basic	66,217,421	64,687,753	65,660,271	64,126,855
Diluted	68,419,888	67,029,407	68,404,551	67,319,989

Impax Laboratories, Inc .

Condensed Consolidated Balance Sheets

(unaudited, amounts in thousands)

	December 31, 2012	December 31, 2011
Assets		
Current assets:		
Cash and cash equivalents	$ 142,162	$ 104,419
Short-term investments	156,756	241,995
Accounts receivable, net	92,249	153,773
Inventory, net	89,764	54,177
Deferred income taxes	42,529	37,853
Prepaid expenses and other assets	22,083	7,718
Total current assets	545,543	599,935
Property, plant and equipment, net	180,758	118,158
Other assets	62,145	45,942
Intangible assets, net	47,950	2,250
Goodwill	27,574	27,574
Total assets	$ 863,970	$ 793,859
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 134,082	$ 93,071
Accrued profit sharing and royalty expenses	4,936	40,766
Deferred revenue	6,277	23,024
Total current liabilities	145,295	156,861
Deferred revenue	6,362	17,131
Other liabilities	21,210	16,926
Total liabilities	172,867	190,918
Total stockholders' equity	691,103	602,941
Total liabilities and stockholders' equity	$ 863,970	$ 793,859

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

	Twelve Months Ended December 31, 2012	2011
Cash flows from operating activities:		
Net income	$ 55,873	$ 65,495
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	77,934	15,710
Accretion of interest income on short-term investments	(639)	(870)
In-process research and development charge	1,550	-
Deferred income taxes (benefit)	(18,861)	13,641
Tax benefit related to the exercise of employee stock options	(4,702)	(6,535)
Deferred revenue	2,278	2,568
Deferred product manufacturing costs	(2,823)	(1,721)
Recognition of deferred revenue	(29,099)	(25,579)
Amortization of deferred product manufacturing costs	11,669	3,111
Accrued profit sharing and royalty expense	72,106	107,760
Payments of profit sharing and royalty expense	(107,935)	(81,145)
Share-based compensation expense	16,303	12,685
Bad debt expense	-	163
Changes in assets and liabilities:		
Accounts receivable	61,524	(71,882)
Inventory	(35,587)	(9,628)
Prepaid expenses and other assets	(20,753)	(17,627)
Accounts payable and accrued expenses	24,117	(2,042)
Other liabilities	3,254	2,254
Net cash provided by operating activities	106,209	6,358
Cash flows from investing activities:		
Purchase of short-term investments	(210,688)	(359,646)
Maturities of short-term investments	296,566	375,126
Purchases of property, plant and equipment	(66,900)	(30,524)
Payment for product licensing rights, net	(104,760)	-
Net cash used in investing activities	(85,782)	(15,044)
Cash flows from financing activities:		
Proceeds from exercise of stock options and ESPP	12,614	14,774
Tax benefit related to the exercise of employee stock options and restricted stock	4,702	6,535
Net cash provided by financing activities	17,316	21,309
Net increase in cash and cash equivalents	37,743	12,623
Cash and cash equivalents, beginning of year	104,419	91,796
Cash and cash equivalents, end of year	$ 142,162	$ 104,419

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.

(Unaudited, amounts in millions, except per share data)	**Three months ended December 31,**		**Twelve months ended December 31,**	
	2012	**2011**	**2012**	**2011**
Net income	$ 4.8	$ 21.9	$ 55.9	$ 65.5
Adjusted to add (deduct):				
Amortization and acquisition-related costs [(a)]	23.8	-	60.2	-
Change in OTC Partner deferred revenue recognition, net [(b)]	(0.4)	-	(0.4)	-
Generic product withdraw costs	-	-	2.0	-
Patent litigation settlement	-	-	(5.0)	-
Gross profit earned on Zomig® Agreement [(c)]	-	-	46.2	-
Acquisition related in process R&D [(d)]	-	-	1.6	-
Employee severance	-	-	1.9	0.8
Inventory adjustment	-	-	3.5	-
Lower of cost or market charge	-	-	1.7	-
Income tax effect	(7.7)	-	(36.8)	(0.3)
Adjusted net income	$ 20.5	$ 21.9	$ 130.8	$ 66.0
Adjusted net income per diluted share	$ 0.30	$ 0.33	$ 1.91	$ 0.98
Net income per diluted share	$ 0.07	$ 0.33	$ 0.82	$ 0.97

Impax Laboratories, Inc .
Non-GAAP Financial Measures

The following table reconciles reported net income to adjusted EBITDA.

(Unaudited, amounts in millions)	Three months ended December 31,		Twelve months ended December 31,	
	2012	**2011**	**2012**	**2011**
Net income	$ 4.8	$ 21.9	$ 55.9	$ 65.5
Adjusted to add (deduct):				
Interest income	(0.3)	(0.3)	(1.1)	(1.1)
Interest expense	0.0	0.1	0.6	0.2
Depreciation and other	5.9	3.8	17.7	15.7
Income taxes	0.3	11.8	27.4	32.6
EBITDA	10.7	37.3	100.5	112.9
Adjusted to add:				
Amortization and acquisition-related costs [(a)]	23.8	-	60.2	-
Change in OTC Partner deferred revenue recognition, net [(b)]	(0.4)	-	(0.4)	-
Generic product withdraw costs	-	-	2.0	-
Patent litigation settlement	-	-	(5.0)	-
Gross profit earned on Zomig® Agreement [(c)]	-	-	46.2	-
Acquisition related in process R&D [(d)]	-	-	1.6	-
Employee severance	-	-	1.9	0.8
Inventory adjustment	-	-	3.5	-
Lower of cost or market charge	-	-	1.7	-
Share-based compensation	4.2	3.1	16.3	12.7
Adjusted EBITDA	$ 38.3	$ 40.4	$ 228.5	$ 126.4

(a) Amortization and acquisition-related costs from the January 2012 Distribution, License, Development and Supply Agreement with AstraZeneca UK Limited and the June 2012 Development, Distribution and Supply Agreement with TOLMAR, Inc.

(b) The net effect of $9.0 million of previously deferred revenue and $8.6 million of deferred manufacturing costs under the Pfizer Agreement.

(c) On February 1, 2012, the Company announced that it had entered into the AstraZeneca License Agreement. As part of the AstraZeneca 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 AstraZeneca License Agreement, the Company agreed to pay AstraZeneca quarterly payments totaling $130.0 million during 2012. During the specified product transition period pursuant to the AstraZeneca License Agreement, the Company received the benefit of the gross profit ($46.2 million) from U.S. Zomig sales by AstraZeneca commencing from January 1, 2012 and ending when the Company commenced commercialization of the Zomig products. The benefit of the gross profit received from AstraZeneca is recorded as a reduction of the $130.0 million paid by the Company to AstraZeneca during 2012 and is not reflected within the Company's income.

(d) Acquisition related in-process R&D from the June 2012 Development, Distribution and Supply Agreement with TOLMAR, Inc.