

IMPAX LABORATORIES INC

FORM 8-K (Current report filing)

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Address	30831 HUNTWOOD AVENUE HAYWARD, CA 94544
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Industry	Biotechnology & Drugs
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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, 2013

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))

Item 2.02 Results of Operations and Financial Condition.

On May 1, 2013, Impax Laboratories, Inc. issued a press release announcing its results for the quarter ended March 31, 2013. 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 May 1, 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.

Dated: May 1, 2013

IMPAX LABORATORIES, INC .

By: /s/ Bryan M. Reasons

Name: Bryan M. Reasons
Title: Senior Vice President, Finance, and Chief
Financial Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release issued May 1, 2013.

**Company Contact:**

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

Impax Laboratories Reports First Quarter 2013 Results

(May 1, 2013) – Impax Laboratories, Inc. (NASDAQ: IPXL) today reported first quarter 2013 adjusted net income of \$25.3 million or \$0.37 per diluted share, compared to \$35.8 million or \$0.53 per diluted share in the first quarter 2012. GAAP net income for the first quarter 2013 was \$105.4 million or \$1.55 per diluted share, compared to \$12.4 million or \$0.18 per diluted share in the prior year period.

For the first quarter 2013, total revenues were \$148.5 million, an increase of 15%, compared to \$128.6 million in the prior year period. The increase was due to United States (U.S.) sales of Zomig® and sales from the January 4, 2013, launch of generic oxymorphone hydrochloride extended-release tablets, for which there was no comparable amount for either product in the prior year period, partially offset by lower sales of the Company's authorized generic Adderall XR® products as a result of additional generic competition.

Cash and short-term investments increased \$50.1 million to \$349.0 million as of March 31, 2013, compared to \$298.9 million as of December 31, 2012, primarily due to the receipt of a one-time pre-tax payment of \$48.0 million in connection with the settlement of litigation as described below. On April 18, 2013, the Company received a one-time pre-tax payment of \$102.0 million from Endo Pharmaceuticals, Inc. (Endo) under a previously announced agreement. The payment is recorded as a receivable as of March 31, 2013 and is not reflected in the first quarter 2013 cash and cash equivalents balance.

Adjusted earnings before interest, taxes, depreciation and amortization (Adjusted EBITDA), was \$43.4 million in the first quarter 2013, compared to \$62.1 million in the first quarter 2012.

The adjusted results in the first quarter 2013 primarily reflect the removal of the following pre-tax items:

- The receipt of \$102.0 million from Endo in connection with a previously announced settlement and license agreement.
- The receipt of \$48.0 million from Shire LLC (Shire) in connection with the settlement of litigation relating to supply of authorized generic Adderall XR products to the Company under the terms of the License and Supply Agreement with Shire (Shire Agreement).
- Total charges of \$18.1 million, including an inventory reserve on discontinued products (\$6.7 million), as further described below, and a reserve of pre-launch inventory for RYTARY™ (\$5.0 million) and other generic products (\$6.4 million) as a result of the delay in the anticipated regulatory approvals.
- A charge of \$7.1 million for amortization and acquisition costs from third-party business development transactions.

The adjusted results in the first quarter 2012 primarily reflect the removal of the following pre-tax items:

- The receipt of the gross profit of \$30.0 million earned from U.S. Zomig sales pursuant to the License Agreement with AstraZeneca UK Limited (AstraZeneca Agreement).
- A charge of \$5.2 million relating to an inventory adjustment as a result of a change in the strategic direction of certain generic products.

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

In the first quarter 2013, the Company recorded an inventory reserve of \$6.7 million as stated above. This charge was the result of a strategic review conducted by the Company with a third party consulting firm of the Company’s currently manufactured generic product portfolio. This review was completed during the first quarter 2013 and the Company decided to discontinue manufacturing a number of low-sales/low-margin mature products. The total net sales of these products in 2012 were less than 3% of the total Company product revenues, with minimal impact on net income. The Company is currently reviewing manufacturing costs and expects that the discontinuation of these products and other efficiencies will result in cost savings of approximately \$10.0 million for the full year 2013, which has been reflected in the revised full year gross margin guidance.

“We expect that this decision will improve operating efficiencies and ensures that resources are allocated and aligned with our strategic growth priorities,” said Larry Hsu, Ph.D., president and CEO, Impax Laboratories, Inc. “We will continue to look for opportunities to free up resources that can be invested to best position Impax for a strong future.”

“On March 21, 2013, we submitted our responses to the recent Form 483 to the FDA and have requested a meeting with the San Francisco District Office to ensure that our plan and actions are in alignment with the FDA’s expectations. We expect to incur \$10.0 million to \$15.0 million in remediation costs during fiscal year 2013. While we have implemented numerous improvements across our manufacturing and quality operations over the past two years, we remain committed to resolving all observations and exceeding current Good Manufacturing Practices,” concluded Dr. Hsu.

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 March 31,	
	2013	2012
Revenues:		
Global Product sales, net	\$ 97,785	\$ 116,211
Rx Partner	3,114	2,978
Other revenues	737	4,076
Total revenues	101,636	123,265
Cost of revenues	61,444	63,106
Gross profit	40,192	60,159
Operating expenses:		
Research and development	11,711	10,673
Patent litigation	4,278	4,038
Selling, general and administrative	5,043	4,317
Total operating expenses	21,032	19,028
Income from operations	\$ 19,160	\$ 41,131

In the first quarter 2013, Global Product sales, net, were \$97.8 million, compared to \$116.2 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, partially offset by the January 4, 2013, launch of oxymorphone hydrochloride extended-release tablets.

Other revenues in the first quarter 2013 were \$0.7 million, compared to \$4.1 million in the prior year period. The decline is primarily the result of the extension of the revenue recognition period for the Joint Development Agreement with Valeant Pharmaceuticals International, Inc. (formerly Medicis Pharmaceutical Corporation) from November 2013 to December 2014 due to changes in the estimated timing of completion of certain research and development activities.

Gross profit in the first quarter 2013 decreased to \$40.2 million, compared to \$60.2 million in the prior year period. This decrease is primarily due to lower sales of authorized generic Adderall XR products and a \$13.1 million inventory reserve for discontinued products and other generic products as a result of the delay in the anticipated regulatory approvals as described above. Gross margin in the first quarter 2013 decreased to 40%, compared to 49% in the prior year period, primarily due to the inclusion of the \$13.1 million inventory charge in cost of revenues as described above.

Total Global Pharmaceuticals operating expenses in the first quarter 2013 increased to \$21.0 million, compared to \$19.0 million in the prior year period, with such difference primarily due to a \$2.0 million milestone payment to a research and development partner.

Impax Pharmaceuticals Division Information*(unaudited, amounts in thousands)*

	Three Months Ended March 31,	
	2013	2012
Revenues:		
Impax Product sales, net	\$ 46,521	\$ -
Other revenues	332	5,303
Total revenues	46,853	5,303
Cost of revenues	29,174	2,909
Gross profit	17,679	2,394
Operating expenses:		
Research and development	7,894	8,143
Selling, general and administrative	12,764	3,061
Total operating expenses	20,658	11,204
Loss from operations	\$ (2,979)	\$ (8,810)

In the first quarter 2013, Impax Product sales, net, were \$46.5 million as a result of U.S. sales of Zomig for which there was no comparable amount in the prior year period. The U.S. patents on Zomig tablets and orally disintegrating tablets expire on May 14, 2013. These two dosage forms represent approximately 90% of the Company's quarterly sales of Zomig. As a result of the patent expiration, the Company expects generic competition that will significantly impact future sales of these two dosage forms. The Company is planning to launch authorized generic versions of both products upon patent expiration. Impax Pharmaceuticals will continue to commercialize the Zomig nasal spray which has U.S. patents expiring as late as May 2021.

Other revenues in the first quarter 2013 declined to \$0.3 million, compared to \$5.3 million in the prior year period. This decrease was due to a \$3.5 million decline in promotional partner revenues as the Company's detailing for Pfizer's product Lyrica[®] ended on June 30, 2012 and a \$1.4 million decline related to the December 31, 2012 completion of the 24 month amortization period of the \$11.5 million up-front payment received under the License, Development and Commercialization Agreement with Glaxo Group Limited.

Gross profit in the first quarter 2013 increased to \$17.7 million, compared to \$2.4 million in the prior year period, primarily due to U.S. Zomig sales. Gross margin in the first quarter 2013 decreased to 38%, compared to 45% in the prior year period. The first quarter 2013 gross margin was, however, negatively impacted by the inclusion in cost of revenues of \$6.7 million for amortization and acquisition-related costs from the Zomig transaction and a \$5.0 million charge for the reserve of RYTARY[™] pre-launch inventory as a result of the delay in the anticipated regulatory approval. In addition, beginning January 1, 2013, the Company paid AstraZeneca royalties on sales of Zomig under the terms of the AstraZeneca Agreement.

Total Impax Pharmaceuticals operating expenses in the first quarter 2013 increased to \$20.7 million, compared to \$11.2 million in the prior year period, primarily due to the expansion of the sales and marketing group during the third and fourth quarters of 2012 to support the anticipated launch of RYTARY[™].

Corporate and Other

(unaudited, amounts in thousands)

	Three Months Ended March 31,	
	2013	2012
General and administrative expenses	\$ 11,910	\$ 13,855
Loss from operations	\$ (11,910)	\$ (13,855)

General and administrative expenses in the first quarter 2013 decreased to \$11.9 million, compared to \$13.9 million in the prior year period primarily due to lower corporate legal fees.

2013 Financial Guidance

The Company updated its 2013 financial guidance as noted below.

- UPDATED - Gross margins as a percent of total revenues are expected to be in the mid 40% range.
- Total R&D 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.
- Patent litigation expenses of approximately \$10.0 million to \$12.0 million.
- 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.
- Effective tax rate of approximately 32% to 34%.

Conference Call Information

The Company will host a conference call on May 1, 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 32064217. 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. 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 revenues and operating income, the Company's ability to promptly correct the issues raised in the warning letter and Form 483 observations received from the FDA, the Company's ability to successfully develop and commercialize pharmaceutical products in a timely manner, 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, the increased government scrutiny on the Company's agreements with brand pharmaceutical companies, consumer acceptance and demand for new pharmaceutical products, the impact of market perceptions of the Company and the safety and quality of the Company's products, the difficulty of predicting FDA filings and approvals, the Company's ability to achieve returns on its investments in research and development activities, 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, impact of illegal distribution and sale by third parties of counterfeits or stolen products, 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 its intellectual property, exposure to product liability claims, changes in tax regulations, the Company's ability to manage 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, 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 the Company 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,	
	2013	2012
Revenues:		
Global Pharmaceuticals Division	\$ 101,636	\$ 123,265
Impax Pharmaceuticals Division	46,853	5,303
Total revenues	148,489	128,568
Cost of revenues	90,618	66,015
Gross profit	57,871	62,553
Operating expenses:		
Research and development	19,605	18,816
Patent litigation	4,278	4,038
Selling, general and administrative	29,717	21,233
Total operating expenses	53,600	44,087
Income from operations	4,271	18,466
Other income (expense), net	149,456	(48)
Interest income	276	255
Interest expense	(283)	(39)
Income before income taxes	153,720	18,634
Provision for income taxes	48,278	6,269
Net income	<u>\$ 105,442</u>	<u>\$ 12,365</u>
Net Income per share:		
Basic	<u>\$ 1.59</u>	<u>\$ 0.19</u>
Diluted	<u>\$ 1.55</u>	<u>\$ 0.18</u>
Weighted average common shares outstanding:		
Basic	66,487,470	65,122,240
Diluted	68,178,355	67,907,263

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

	March 31, 2013	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	\$ 197,577	\$ 142,162
Short-term investments	151,436	156,756
Accounts receivable, net	113,606	92,249
Other receivable	102,049	-
Inventory, net	82,090	89,764
Deferred income taxes	44,365	42,529
Prepaid expenses and other assets	7,804	22,083
Total current assets	<u>698,927</u>	<u>545,543</u>
Property, plant and equipment, net	176,963	180,758
Other assets	64,500	62,145
Intangible assets, net	40,809	47,950
Goodwill	27,574	27,574
Total assets	<u>\$ 1,008,773</u>	<u>\$ 863,970</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 151,199	\$ 134,082
Accrued profit sharing and royalty expenses	22,553	4,936
Deferred revenue	4,452	6,277
Total current liabilities	<u>178,204</u>	<u>145,295</u>
Deferred revenue	7,074	6,362
Other liabilities	25,038	21,210
Total liabilities	<u>210,316</u>	<u>172,867</u>
Total stockholders' equity	798,457	691,103
Total liabilities and stockholders' equity	<u>\$ 1,008,773</u>	<u>\$ 863,970</u>

Consolidated Statements of Cash Flows
(unaudited, amounts in thousands)

	Three Months Ended	
	March 31,	
	2013	2012
Cash flows from operating activities:		
Net income	\$ 105,442	\$ 12,365
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	12,397	3,730
Provision for inventory reserves	22,804	4,094
Accretion of interest income on short-term investments	(158)	(171)
Deferred income taxes (benefit)	(2,800)	817
Tax impact related to the exercise of employee stock options	3	(1,632)
Deferred revenue	-	315
Deferred product manufacturing costs	-	(495)
Recognition of deferred revenue	(1,113)	(6,061)
Amortization of deferred product manufacturing costs	-	661
Accrued profit sharing and royalty expense	22,541	25,555
Payments of profit sharing and royalty expense	(4,925)	(40,755)
Share-based compensation expense	4,359	3,809
Other receivable	(102,049)	-
Changes in assets and liabilities:		
Accounts receivable	(21,357)	34,590
Inventory	(15,130)	(7,855)
Prepaid expenses and other assets	12,561	(3,745)
Accounts payable and accrued expenses	22,645	(4,153)
Other liabilities	2,527	2,661
Net cash provided by operating activities	<u>57,747</u>	<u>23,730</u>
Cash flows from investing activities:		
Purchase of short-term investments	(60,515)	(35,585)
Maturities of short-term investments	65,993	126,549
Purchases of property, plant and equipment	(9,361)	(8,165)
Payment for product licensing rights	-	(25,000)
Net cash (used in) provided by investing activities	<u>(3,883)</u>	<u>57,799</u>
Cash flows from financing activities:		
Proceeds from exercise of stock options and ESPP	1,554	4,468
Tax impact related to the exercise of employee stock options and restricted stock	(3)	1,632
Net cash provided by financing activities	<u>1,551</u>	<u>6,100</u>
Net increase in cash and cash equivalents	55,415	87,629
Cash and cash equivalents, beginning of period	142,162	104,419
Cash and cash equivalents, end of period	<u>\$ 197,577</u>	<u>\$ 192,048</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.

(Unaudited, amounts in millions, except per share data)

	Three Months Ended March 31,	
	2013	2012
Net income	\$ 105.4	\$ 12.4
Adjusted to add (deduct):		
Payments received from litigation settlements ^(a)	(150.0)	-
Provision for inventory reserves ^(b)	18.1	5.2
Amortization and acquisition-related costs ^(c)	7.1	-
R&D partner milestone payment ^(d)	2.0	-
Hayward facility remediation costs ^(e)	1.9	1.0
Loss on asset disposal ^(f)	0.9	-
Gross profit earned on Zomig® Agreement	-	30.0
Income tax effect	39.9	(12.8)
Adjusted net income	<u>\$ 25.3</u>	<u>\$ 35.8</u>
Adjusted net income per diluted share	\$ 0.37	\$ 0.53
Net income per diluted share	\$ 1.55	\$ 0.18

Impax Laboratories, Inc .
Non-GAAP Financial Measures

The following table reconciles reported net income to adjusted EBITDA.

(Unaudited, amounts in millions)

	Three Months Ended March 31,	
	2013	2012
Net income	\$ 105.4	\$ 12.4
Adjusted to add (deduct):		
Interest income	(0.3)	(0.3)
Interest expense	0.3	0.0
Depreciation and other	5.3	3.7
Income taxes	48.3	6.3
EBITDA	<u>159.0</u>	<u>22.1</u>
Adjusted to add (deduct):		
Payments received from litigation settlements ^(a)	(150.0)	-
Provision for inventory reserves ^(b)	18.1	5.2
Amortization and acquisition-related costs ^(c)	7.1	-
R&D partner milestone payment ^(d)	2.0	-
Hayward facility remediation costs ^(e)	1.9	1.0
Loss on asset disposal ^(f)	0.9	-
Gross profit earned on Zomig® Agreement	-	30.0
Share-based compensation	4.4	3.8
Adjusted EBITDA	<u>\$ 43.4</u>	<u>\$ 62.1</u>

- (a) As of March 31, 2013, the Company had a \$102.0 million receivable in connection with a previously announced settlement and license agreement with Endo Pharmaceuticals, Inc., which was recorded as other income in the first quarter 2013. The \$102.0 million receivable was received by the Company in April 2013. In addition, in connection with the settlement of litigation relating to supply of authorized generic Adderall XR® products to the Company under the terms of the Shire Agreement, the Company received a one-time payment of \$48.0 million from Shire LLC in the first quarter 2013.
- (b) In the first quarter 2013, the Company recorded an inventory reserve charge relating to discontinued products (\$6.7 million), and a reserve of pre-launch inventory for RYTARY™ (\$5.0 million) and other generic products (\$6.4 million) as a result of the delay in the anticipated regulatory approvals.
- (c) Amortization and acquisition-related costs from the January 2012 AstraZeneca Agreement and the June 2012 Development, Distribution and Supply Agreement with TOLMAR, Inc.
- (d) In the first quarter 2013, the Company recorded a \$2.0 million milestone payment under the terms of a research and development partnership agreement.
- (e) Remediation costs relating to the Hayward, CA. manufacturing facility.
- (f) In the first quarter 2013, the Company recorded a loss of \$0.9 million on the disposal of an asset.