

# IMPAX LABORATORIES INC

## FORM 10-Q (Quarterly Report)

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the quarterly period ended **March 31, 2013**

OR

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: 001-34263

**Impax Laboratories, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation or organization)

**65-0403311**

(I.R.S. Employer Identification No.)

**30831 Huntwood Avenue, Hayward, CA**

(Address of principal executive offices)

**94544**

(Zip Code)

**(510) 240-6000**

(Registrant's telephone number, including area code)

**Not Applicable**

(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company)

Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes  No

As of April 26, 2013, there were 68,477,096 shares of the registrant's common stock outstanding.

**Impax Laboratories, Inc.**

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**PART I: FINANCIAL INFORMATION**

**ITEM 1: FINANCIAL STATEMENTS**

**Impax Laboratories, Inc.**  
**CONSOLIDATED BALANCE SHEETS**  
(amounts in thousands, except share and per share data)

	<u>March 31,</u> <u>2013</u>	<u>December 31,</u> <u>2012</u>
	(unaudited)	
<b>ASSETS</b>		
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 current 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	43,128	42,751
Deferred income taxes	21,372	19,394
Intangible assets, net	40,809	47,950
Goodwill	27,574	27,574
Total assets	<u>\$ 1,008,773</u>	<u>\$ 863,970</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 30,587	\$ 41,340
Accrued expenses	120,612	92,742
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>
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, \$0.01 par value, 2,000,000 shares authorized, 0 shares outstanding at March 31, 2013 and December 31, 2012	---	---
Common stock, \$0.01 par value, 90,000,000 shares authorized and 68,735,134 and 68,516,251 shares issued at March 31, 2013 and December 31, 2012, respectively	687	685
Additional paid-in capital	320,124	314,717
Treasury stock - 243,729 shares	(2,157)	(2,157)
Accumulated other comprehensive income	1,747	5,244
Retained earnings	478,056	372,614
Total stockholders' equity	<u>798,457</u>	<u>691,103</u>
Total liabilities and stockholders' equity	<u>\$ 1,008,773</u>	<u>\$ 863,970</u>

The accompanying notes are an integral part of these interim consolidated financial statements.



**Impax Laboratories, Inc.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
(amounts in thousands, except share and per share data)  
(unaudited)

	<b>Three Months Ended</b>	
	<b>March 31, 2013</b>	<b>March 31, 2012</b>
<b>Revenues:</b>		
Global Division revenues, net	\$ 101,636	\$ 123,265
Impax Division revenues, net	46,853	5,303
Total revenues	<u>148,489</u>	<u>128,568</u>
Cost of revenues	<u>90,618</u>	<u>66,015</u>
Gross profit	<u>57,871</u>	<u>62,553</u>
<b>Operating expenses:</b>		
Research and development	19,605	18,816
Patent litigation expense	4,278	4,038
Selling, general and administrative	29,717	21,233
Total operating expenses	<u>53,600</u>	<u>44,087</u>
Income from operations	<u>4,271</u>	<u>18,466</u>
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>
<b>Net Income per share:</b>		
Basic	<u>\$ 1.59</u>	<u>\$ 0.19</u>
Diluted	<u>\$ 1.55</u>	<u>\$ 0.18</u>
<b>Weighted average common shares outstanding:</b>		
Basic	<u>66,487,470</u>	<u>65,122,240</u>
Diluted	<u>68,178,355</u>	<u>67,907,263</u>

The accompanying notes are an integral part of these unaudited interim consolidated financial statements.

**Impax Laboratories, Inc.**  
**CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME**  
**(amounts in thousands)**  
**(unaudited)**

	<b>Three Months Ended</b>	
	<b>March 31, 2013</b>	<b>March 31, 2012</b>
Net income	\$ 105,442	\$ 12,365
Currency translation adjustments	(3,497)	1,608
Comprehensive income	<u>\$ 101,945</u>	<u>\$ 13,973</u>

The accompanying notes are an integral part of these unaudited interim consolidated financial statements.

**Impax Laboratories, Inc.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(amounts in thousands)  
(unaudited)

	<b>Three Months Ended</b>	
	<b>March 31, 2013</b>	<b>March 31, 2012</b>
<b>Cash flows from operating activities:</b>		
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 (benefits)	(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 certain 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	57,747	23,730
<b>Cash flows from investing activities:</b>		
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 for) provided by investing activities	(3,883)	57,799
<b>Cash flows from financing activities:</b>		
Tax impact related to the exercise of employee stock options and restricted stock	(3)	1,632
Proceeds from exercise of stock options and ESPP	1,554	4,468
Net cash provided by financing activities	1,551	6,100
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	\$ 197,577	\$ 192,048

Supplemental disclosure of non-cash investing and financing activities:

(in \$000's)	<b>Three Months Ended</b>	
	<b>March 31, 2013</b>	<b>March 31, 2012</b>
Cash paid for interest	\$ 87	\$ 10
Cash paid for income taxes	\$ 222	\$ 1,065

Accrued vendor invoices of approximately \$4,273,000 and \$3,872,000 at March 31, 2013 and 2012, respectively, are excluded from the purchase of property, plant, and equipment and the change in accounts payable and accrued expenses. Depreciation expense was \$4,760,000 and \$3,356,000 for the three months ended March 31, 2013 and 2012, respectively.

The accompanying notes are an integral part of these unaudited interim consolidated financial statements.

## NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS (unaudited)

### 1. THE COMPANY & BASIS OF PRESENTATION

Impax Laboratories, Inc. (“Impax” or “Company”) is a technology-based, specialty pharmaceutical company. The Company has two reportable segments, referred to as the “Global Pharmaceuticals Division” (“Global Division”) and the “Impax Pharmaceuticals Division” (“Impax Division”).

The Global Division develops, manufactures, sells, and distributes generic pharmaceutical products primarily through four sales channels: the “Global products” sales channel, for generic pharmaceutical prescription products the Company sells directly to wholesalers, large retail drug chains, and others; the “Private Label” sales channel, for generic pharmaceutical over-the-counter (“OTC”) and prescription products the Company sells to unrelated third-party customers who in-turn sell the product to third parties under their own label; the “Rx Partner” sales channel, for generic prescription products sold through unrelated third-party pharmaceutical entities under their own label pursuant to alliance agreements; and the “OTC Partner” sales channel, for generic pharmaceutical OTC products sold through an unrelated third-party pharmaceutical entity under its own label pursuant to an alliance agreement. Revenues from the “Global Products” sales channel and the “Private Label” sales channel are reported under the caption “Global Product sales, net” in “Note 18 – Supplementary Financial Information.” The Company also generates revenue from research and development services provided under a joint development agreement with an unrelated third party pharmaceutical company, and reports such revenue under the caption “Other Revenues” in “Note 18 – Supplementary Financial Information.” The Company provides these services through the research and development group in the Global Division. Revenues from the “OTC Partner” sales channel are also reported under the caption “Other Revenues” in “Note 18 – Supplementary Financial Information.”

The Impax Division is engaged in the development of proprietary brand pharmaceutical products that the Company believes represent improvements to already-approved pharmaceutical products addressing central nervous system (“CNS”) disorders. The Impax Division currently has one internally developed late stage branded pharmaceutical product candidate, RYTARY™ (IPX066), an extended release capsule formulation of carbidopa-levodopa for the symptomatic treatment of Parkinson’s disease, for which the New Drug Application (“NDA”) was accepted for filing by the U.S. Food and Drug Administration (“FDA”) in February 2012 and for which the Company received a Complete Response Letter from the FDA in January 2013. The Company is currently working with the FDA on the appropriate next steps for the RYTARY™ NDA. In addition to RYTARY™, the Impax Division has a number of other product candidates that are in varying stages of development. The Impax Division is also engaged in the sale and distribution of Zomig® (zolmitriptan) products, indicated for the treatment of migraine headaches, under the terms of a Distribution, License, Development and Supply Agreement (“AZ Agreement”) with AstraZeneca UK Limited (“AstraZeneca”) in the United States and in certain U.S. territories. Revenues from Impax-labeled Zomig® products are reported under the caption “Impax Product sales, net” in “Note 18 – Supplementary Financial Information.” Finally, the Company generates revenue in the Impax Division from research and development services provided under a development and license agreement with another unrelated third-party pharmaceutical company, and reports such revenue under the caption “Other Revenues” in “Note 18 – Supplementary Financial Information.”

In California, the Company utilizes a combination of owned and leased facilities mainly located in Hayward. The Company’s primary properties in California consist of a leased office building used as the Company’s corporate headquarters, in addition to five properties it owns, including a research and development center facility and a manufacturing facility. Additionally, the Company leases two facilities in Hayward, utilized for additional research and development, administrative services, and equipment storage. In Pennsylvania, the Company owns a packaging, warehousing, and distribution center located in Philadelphia and leases a facility in New Britain used for sales and marketing, finance, and administrative personnel, as well as providing additional warehouse space. Outside the United States, in Taiwan, Republic of China (“R.O.C.”), the Company owns a manufacturing facility.

The accompanying unaudited interim consolidated financial statements of the Company, have been prepared based upon United States Securities and Exchange Commission (“SEC”) rules permitting reduced disclosure for interim periods, and include all adjustments necessary for a fair presentation of statements of operations, statements of comprehensive income, statements of cash flows, and financial condition for the interim periods shown, including normal recurring accruals and other items. While certain information and disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”) have been condensed or omitted pursuant to SEC rules and regulations, the Company believes the disclosures are adequate to make the information presented not misleading. The unaudited interim consolidated financial statements of the Company include the accounts of the operating parent company, Impax Laboratories, Inc., its wholly-owned subsidiaries, including Impax Laboratories (Taiwan) Inc., Impax Laboratories USA, LLC and Impax Laboratories (Netherlands) BV, and an equity investment in Prohealth Biotech, Inc. (“Prohealth”), in which the Company held a 57.54% majority ownership interest at March 31, 2013. All significant intercompany accounts and transactions have been eliminated.

The unaudited results of operations and cash flows for the interim period are not necessarily indicative of the expected results of the Company's operations for any other interim period or for the full year ending December 31, 2013. The unaudited interim consolidated financial statements and footnotes should be read in conjunction with the consolidated financial statements and footnotes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2012 as filed with the SEC, wherein a more complete discussion of significant accounting policies and certain other information can be found.

The preparation of financial statements in conformity with GAAP and the rules and regulations of the SEC requires the use of estimates and assumptions, based on complex judgments considered reasonable, which affect the reported amounts of assets and liabilities and disclosure of contingent assets and contingent liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. The most significant judgments are employed in estimates used in determining values of tangible and intangible assets, legal contingencies, tax assets and tax liabilities, fair value of share-based compensation related to equity incentive awards issued to employees and directors, and estimates used in applying the Company's revenue recognition policy including those related to accrued chargebacks, rebates, product returns, Medicare, Medicaid, and other government rebate programs, shelf-stock adjustments, and the timing and amount of deferred and recognized revenue and deferred and amortized product manufacturing costs related to alliance and collaboration agreements. Actual results may differ from estimated results. Certain prior year amounts have been reclassified to conform to the current year presentation.

In the normal course of business, the Company is subject to loss contingencies, such as legal proceedings and claims arising out of its business, covering a wide range of matters, including, among others, patent litigation, and product and clinical trial liability. In accordance with Financial Accounting Standards Board ("FASB") Accounting Standard Codification ("ASC") Topic 450, "Contingencies", the Company records accrued loss contingencies when it is probable a liability has been incurred and the amount of loss can be reasonably estimated. The Company, in accordance with FASB ASC Topic 450, does not recognize gain contingencies until realized.

## 2. REVENUE RECOGNITION

The Company recognizes revenue when the earnings process is complete, which under SEC Staff Accounting Bulletin No. 104, Topic No. 13, "Revenue Recognition" ("SAB 104"), is when revenue is realized or realizable and earned, there is persuasive evidence a revenue arrangement exists, delivery of goods or services has occurred, the sales price is fixed or determinable, and collectability is reasonably assured.

The Company accounts for revenue arrangements with multiple deliverables in accordance with FASB ASC Topic 605-25, revenue recognition for arrangements with multiple elements, which addresses the determination of whether an arrangement involving multiple deliverables contains more than one unit of accounting. A delivered item within an arrangement is considered a separate unit of accounting only if both of the following criteria are met:

- the delivered item has value to the customer on a stand-alone basis; and
- if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item is considered probable and substantially in the control of the vendor.

Under FASB ASC Topic 605-25, if both of the criteria above are not met, then separate accounting for the individual deliverables is not appropriate. Revenue recognition for arrangements with multiple deliverables constituting a single unit of accounting is recognized generally over the greater of the term of the arrangement or the expected period of performance, either on a straight-line basis or on a modified proportional performance basis.

The Company accounts for milestones related to research and development activities in accordance with FASB ASC Topic 605-28, milestone method of revenue recognition. FASB ASC Topic 605-28 allows for the recognition of consideration, which is contingent on the achievement of a substantive milestone, in its entirety in the period the milestone is achieved. A milestone is considered to be substantive if all of the following criteria are met: the milestone is commensurate with either: (1) the performance required to achieve the milestone, or (2) the enhancement of the value of the delivered items resulting from the performance required to achieve the milestone; the milestone relates solely to past performance; and, the milestone is reasonable relative to all of the deliverables and payment terms within the agreement.

### Global Product sales, net, and Impax Product sales, net:

Global Product sales, net and Impax Product sales, net include revenue recognized related to shipments of generic and branded pharmaceutical products to the Company's customers, primarily drug wholesalers and retail chains. Gross sales revenue is recognized at the time title and risk of loss passes to the customer, which is generally when product is received by the customer. Global and Impax Product revenue, net may include deductions from the gross sales price related to estimates for chargebacks, rebates, distribution service fees, returns, shelf-stock, and other pricing adjustments. The Company records an estimate for these deductions in the same period when the revenue is recognized. A summary of each of these deductions is as follows:

### Chargebacks

The Company has agreements establishing contract prices for certain products with certain indirect customers, such as managed care organizations, hospitals and government agencies who purchase products from drug wholesalers. The contract prices are lower than the prices the customer would otherwise pay to the wholesaler, and the price difference is referred to as a chargeback, which generally takes the form of a credit memo issued by the Company to reduce the invoiced gross selling price charged to the wholesaler. An estimated accrued provision for chargeback deductions is recognized at the time of product shipment. The primary factors considered when estimating the provision for chargebacks are the average historical chargeback credits given, the mix of products shipped, and the amount of inventory on hand at the major drug wholesalers with whom the Company does business. The Company also monitors actual chargebacks granted and compares them to the estimated provision for chargebacks to assess the reasonableness of the chargeback reserve at each quarterly balance sheet date.

## 2. REVENUE RECOGNITION (continued)

### Rebates

The Company maintains various rebate programs with its customers in an effort to maintain a competitive position in the marketplace and to promote sales and customer loyalty. The rebates generally take the form of a credit memo to reduce the invoiced gross selling price charged to a customer for products shipped. An estimated accrued provision for rebate deductions is recognized at the time of product shipment. The primary factors the Company considers when estimating the provision for rebates are the average historical experience of aggregate credits issued, the mix of products shipped and the historical relationship of rebates as a percentage of total gross product sales, the contract terms and conditions of the various rebate programs in effect at the time of shipment, and the amount of inventory on hand at the major drug wholesalers with whom the Company does business. The Company also monitors actual rebates granted and compares them to the estimated provision for rebates to assess the reasonableness of the rebate reserve at each quarterly balance sheet date.

### Distribution Service Fees

The Company pays distribution service fees to several of its wholesaler customers related to sales of its Impax Products. The wholesalers are generally obligated to provide the Company with periodic outbound sales information as well as inventory levels of the Company's Impax Products held in their warehouses. Additionally, the wholesalers have agreed to manage the variability of their purchases and inventory levels within specified days on hand limits. An accrued provision for distribution service fees is recognized at the time products are shipped to wholesalers.

### Returns

The Company allows its customers to return product if approved by authorized personnel in writing or by telephone with the lot number and expiration date accompanying any request and if such products are returned within six months prior to or until twelve months following, the products' expiration date. The Company estimates and recognizes an accrued provision for product returns as a percentage of gross sales based upon historical experience. The product return reserve is estimated using a historical lag period, which is the time between when the product is sold and when it is ultimately returned and estimated return rates which may be adjusted based on various assumptions including changes to internal policies and procedures, changes in business practices, and commercial terms with customers, competitive position of each product, amount of inventory in the wholesaler supply chain, the introduction of new products, and changes in market sales information. The Company also considers other factors, including significant market changes which may impact future expected returns, and actual product returns. The Company monitors actual returns on a quarterly basis and may record specific provisions for returns it believes are not covered by historical percentages.

### Shelf-Stock Adjustments

Based upon competitive market conditions, the Company may reduce the selling price of certain Global Division products. The Company may issue a credit against the sales amount to a customer based upon their remaining inventory of the product in question, provided the customer agrees to continue to make future purchases of product from the Company. This type of customer credit is referred to as a shelf-stock adjustment, which is the difference between the original selling price and the revised lower sales price, multiplied by an estimate of the number of product units on hand at a given date. Decreases in selling prices are discretionary decisions made by the Company in response to market conditions, including estimated launch dates of competing products and declines in market price. The Company records an estimate for shelf-stock adjustments in the period it agrees to grant such a credit memo to a customer.

### Medicaid and Other Government Pricing Programs

As required by law, the Company provides a rebate on drugs dispensed under the Medicaid program, Medicare Part D, TRICARE, and other U.S. government pricing programs. The Company determines its estimated government rebate accrual primarily based on historical experience of claims submitted by the various states and other jurisdictions and any new information regarding changes in the various programs which may impact the Company's estimate of government rebates. In determining the appropriate accrual amount, the Company considers historical payment rates and processing lag for outstanding claims and payments. The Company records estimates for government rebates as a deduction from gross sales, with corresponding adjustment to accrued liabilities.

## 2. REVENUE RECOGNITION (continued)

### Cash Discounts

The Company offers cash discounts to its customers, generally 2% of the gross selling price, as an incentive for paying within invoice terms, which generally range from 30 to 90 days. An estimate of cash discounts is recorded in the same period when revenue is recognized.

### Rx Partner and OTC Partner:

The Rx Partner and OTC Partner contracts include revenue recognized under alliance and collaboration agreements between the Company and unrelated third-party pharmaceutical companies. The Company has entered into these alliance agreements to develop marketing and/or distribution relationships with its partners to fully leverage its technology platform.

The Rx Partners and OTC Partners alliance agreements obligate the Company to deliver multiple goods and/or services over extended periods. Such deliverables include manufactured pharmaceutical products, exclusive and semi-exclusive marketing rights, distribution licenses, and research and development services. In exchange for these deliverables, the Company receives payments from its agreement partners for product shipments and research and development services, and may also receive other payments including royalty, profit sharing, upfront, and periodic milestone payments. Revenue received from the alliance agreement partners for product shipments under these agreements is not subject to deductions for chargebacks, rebates, product returns, and other pricing adjustments. Royalty and profit sharing amounts the Company receives under these agreements are calculated by the respective agreement partner, with such royalty and profit share amounts generally based upon estimates of net product sales or gross profit which include estimates of deductions for chargebacks, rebates, product returns, and other adjustments the alliance agreement partners may negotiate with their respective customers. The Company records the alliance agreement partner's adjustments to such estimated amounts in the period the agreement partner reports the amounts to the Company.

The Company applies the updated guidance of ASC 605-25 "Multiple Element Arrangements" to the Strategic Alliance Agreement with Teva Pharmaceuticals Curacao N.V., a subsidiary of Teva Pharmaceutical Industries Limited ("Teva Agreement"). The Company looks to the underlying delivery of goods and/or services which give rise to the payment of consideration under the Teva Agreement to determine the appropriate revenue recognition. The Company initially defers consideration received as a result of research and development-related activities performed under the Teva Agreement. The Company recognizes deferred revenue on a straight-line basis over the Company's expected period of performance of such services. Consideration received as a result of the manufacture and delivery of products under the Teva Agreement is recognized at the time title and risk of loss passes to the customer which is generally when product is received by Teva. The Company recognizes profit share revenue in the period earned.

OTC Partner revenue is related to an agreement with Pfizer Inc. (formerly Wyeth) with respect to the supply of over-the-counter pharmaceutical products. The OTC Partner sales channel is no longer a core area of the business, and the over-the-counter pharmaceutical products the Company sells through this sales channel are older products which are only sold to Pfizer, and which are currently sold at a loss. The manufacturing of the over-the-counter pharmaceutical products is the Company's only continuing obligation under this agreement with Pfizer. In order to avoid deferring the losses incurred upon shipment of these products to Pfizer, Inc., the Company recognizes revenue, and the associated manufacturing costs, at the time title and risk of loss passes to Pfizer which is generally when the product is shipped. The Company recognizes profit share revenue in the period earned.

## 2. REVENUE RECOGNITION (continued)

### Research Partner:

The Research Partner contracts include revenue recognized under development agreements with unrelated third-party pharmaceutical companies. The development agreements generally obligate the Company to provide research and development services over multiple periods. In exchange for this service, the Company received upfront payments upon signing of each development agreement and is eligible to receive contingent milestone payments, based upon the achievement of contractually specified events. Additionally, the Company may also receive royalty payments from the sale, if any, of a successfully developed and commercialized product under one of these development agreements. The Company recognizes revenue received from the provision of research and development services, including the upfront payment and the milestone payments received before January 1, 2011 on a straight line basis over the expected period of performance of the research and development services. The Company recognizes revenue received from the achievement of contingent research and development milestones after January 1, 2011 in the period such payment is earned. Royalty fee income, if any, will be recognized by the Company in the period when the revenue is earned.

### Promotional Partner:

The Promotional Partner contract includes revenue recognized under a promotional services agreement with an unrelated third-party pharmaceutical company. The promotional services agreement obligated the Company to provide physician detailing sales calls services to promote certain of the unrelated third-party company's branded drug products. The Company received service fee revenue in exchange for providing this service. The Company recognized revenue from providing physician detailing sales calls services as the services were provided. The Company's obligation to provide physician detailing sales calls under the promotional services agreement ended on June 30, 2012.

### Shipping and Handling Fees and Costs

Shipping and handling fees related to sales transactions are recorded as selling expense.

### 3. RECENT ACCOUNTING PRONOUNCEMENTS

In December 2011, the FASB issued its updated guidance on balance sheet offsetting. This new standard provides guidance to determine when offsetting in the balance sheet is appropriate. The guidance is designed to enhance disclosures by requiring improved information about financial instruments and derivative instruments. The goal is to provide users of the financial statements the ability to evaluate the effect or potential effect of netting arrangements on an entity's statement of financial position. This guidance will only impact the disclosures within an entity's financial statements and notes to the financial statements and does not result in a change to the accounting treatment of financial instruments and derivative instruments. The Company adopted this guidance on January 1, 2013, and it did not have a material impact on the Company's consolidated financial statements.

In March 2013, the FASB issued updated guidance on foreign currency matters. The update applies to the release of the cumulative translation adjustment into net income when a parent either sells a part or all of its investment in a foreign entity or no longer holds a controlling financial interest in a subsidiary or group of assets within a foreign entity. The Company is required to adopt this guidance on January 1, 2014 and does not expect the adoption to have a material effect on its consolidated financial statements.

### 4. INVESTMENTS

Investments consist of commercial paper, corporate bonds and government sponsored enterprise obligations. The Company's policy is to invest in only high quality "AAA-rated" or investment-grade securities. Investments in debt securities are accounted for as 'held-to-maturity' and are recorded at amortized cost, which approximates fair value, generally based upon observable market values of similar securities. The Company has historically held all investments in debt securities until maturity, and has the ability and intent to continue to do so. All of the Company's investments have remaining contractual maturities of less than 12 months and are classified as short-term. Upon maturity, the Company uses a specific identification method.

A summary of short-term investments as of March 31, 2013 and December 31, 2012 is as follows:

(in \$000's)	<u>Amortized Cost</u>	<u>Gross Unrecognized Gains</u>	<u>Gross Unrecognized Losses</u>	<u>Fair Value</u>
<b><u>March 31, 2013</u></b>				
Commercial paper	\$ 49,937	\$ 19	\$ --	\$ 49,956
Government sponsored enterprise obligations	9,996	4	--	10,000
Corporate bonds	91,503	12	(19)	91,496
Total short-term investments	<u>\$ 151,436</u>	<u>\$ 35</u>	<u>\$ (19)</u>	<u>\$ 151,452</u>

(in \$000's)	<u>Amortized Cost</u>	<u>Gross Unrecognized Gains</u>	<u>Gross Unrecognized Losses</u>	<u>Fair Value</u>
<b><u>December 31, 2012</u></b>				
Commercial paper	\$ 70,140	\$ 28	\$ --	\$ 70,168
Government sponsored enterprise obligations	9,994	4	--	9,998
Corporate bonds	76,622	23	(12)	76,633
Total short-term investments	<u>\$ 156,756</u>	<u>\$ 55</u>	<u>\$ (12)</u>	<u>\$ 156,799</u>

## 5. ACCOUNTS RECEIVABLE AND OTHER RECEIVABLES

The composition of accounts receivable, net is as follows:

(in \$000's)	<b>March 31, 2013</b>	<b>December 31, 2012</b>
Gross accounts receivable	\$ 190,816	\$ 167,696
Less: Rebate reserve	(48,267)	(46,011)
Less: Chargeback reserve	(17,001)	(18,410)
Less: Other deductions	(11,942)	(11,026)
Accounts receivable, net	<u>\$ 113,606</u>	<u>\$ 92,249</u>

A roll forward of the rebate and chargeback reserves activity for the three months ended March 31, 2013 and the year ended December 31, 2012 is as follows:

(in \$000's)	<b>March 31, 2013</b>	<b>December 31, 2012</b>
<b><u>Rebate reserve</u></b>		
Beginning balance	\$ 46,011	\$ 29,164
Provision recorded during the period	36,808	111,099
Credits issued during the period	(34,552)	(94,252)
Ending balance	<u>\$ 48,267</u>	<u>\$ 46,011</u>

(in \$000's)	<b>March 31, 2013</b>	<b>December 31, 2012</b>
<b><u>Chargeback reserve</u></b>		
Beginning balance	\$ 18,410	\$ 22,161
Provision recorded during the period	72,135	209,452
Credits issued during the period	(73,544)	(213,203)
Ending balance	<u>\$ 17,001</u>	<u>\$ 18,410</u>

Other deductions include allowance for uncollectible amounts and cash discounts. The Company maintains an allowance for doubtful accounts for estimated losses resulting from amounts deemed to be uncollectible from its customers, with such allowances for specific amounts on certain accounts. The Company had an allowance for uncollectible amounts of \$575,000 and \$553,000 at March 31, 2013 and December 31, 2012, respectively.

As of March 31, 2013, the Company had a \$102,049,000 receivable in connection with the settlement of litigation under the June 2010 settlement and license agreement with Endo Pharmaceuticals, Inc. during the three months ended March 31, 2013. The receivable was collected in April 2013. For more information, see "Note 12 – Alliance and Collaboration Agreements."

## 6. INVENTORY

Inventory is stated at the lower of cost or market. Cost is determined using a standard cost method, and the cost flow assumption is first in, first out (“FIFO”) flow of goods. Standard costs are revised annually, and significant variances between actual costs and standard costs are apportioned to inventory and cost of goods sold based upon inventory turnover. Costs include materials, labor, quality control, and production overhead. Inventory is adjusted for short-dated, unmarketable inventory equal to the difference between the cost of inventory and the estimated value based upon assumptions about future demand and market conditions. If actual market conditions are less favorable than those projected by the Company, additional inventory write-downs may be required. Consistent with industry practice, the Company may build pre-launch inventories of certain products which are pending required approval from the FDA and/or resolution of patent infringement litigation, when, in the Company’s assessment, such action is appropriate to increase the commercial opportunity and FDA approval is expected in the near term and/or the litigation will be resolved in the Company’s favor. The Company accounts for all costs of idle facilities, excess freight and handling costs, and wasted materials (spoilage) as a current period charge in accordance with GAAP.

Inventory, net of carrying value reserves at March 31, 2013 and December 31, 2012 consisted of the following:

(in \$000’s)	March 31, 2013	December 31, 2012
Raw materials	\$ 31,242	\$ 31,884
Work in process	2,367	4,005
Finished goods	56,251	60,956
Total inventory	89,860	96,845
Less: Non-current inventory	7,770	7,081
Total inventory-current	\$ 82,090	\$ 89,764

Inventory carrying value reserves were \$28,035,000 and \$5,231,000 at March 31, 2013 and December 31, 2012, respectively. During the three month period ended March 31, 2013, the Company decided to discontinue the manufacture and distribution of certain unprofitable products after the Company conducted a strategic review of its currently manufactured generic product portfolio. As a result of this decision, the Company recorded an inventory reserve of \$6.7 million related to the discontinued products. In addition, upon receipt of the Complete Response Letter for RYTARY™, the Company evaluated the impact of the expected delay of FDA approval on its ability to sell the associated inventory. The Company determined that a reserve of \$5.0 million was appropriate and recorded this amount in the three month period ended March 31, 2013. The Company also recorded a \$6.4 million reserve for pre-launch inventory of a product manufactured for another third-party pharmaceutical company, due to the anticipated delayed launch of such product as a result of the warning letter related to our Hayward, California manufacturing facility. The carrying value of unapproved inventory less reserves, was \$6,212,000 and \$12,106,000 at March 31, 2013 and December 31, 2012, respectively.

The Company recognizes pre-launch inventories at the lower of its cost or the expected net selling price. Cost is determined using a standard cost method, which approximates actual cost, and assumes a FIFO flow of goods. Costs of unapproved products are the same as approved products and include materials, labor, quality control, and production overhead. When the Company concludes that FDA approval is expected within approximately six months for a drug product candidate, the Company may begin to schedule manufacturing process validation studies as required by the FDA to demonstrate the production process can be scaled up to manufacture commercial batches. Consistent with industry practice, the Company may build quantities of unapproved product inventory pending final FDA approval and/or resolution of patent infringement litigation, when, in the Company’s assessment, such action is appropriate to increase its commercial product opportunity, and FDA approval is expected in the near term, and/or the litigation will be resolved in the Company’s favor. The capitalization of unapproved pre-launch inventory involves risks, including, among other items, FDA approval may not occur; approvals may require additional or different testing and/or specifications than used for unapproved inventory, and in cases where the unapproved inventory is for a product subject to litigation, the litigation may not be resolved or settled in the Company’s favor. If any of these risks materialize and the launch of the unapproved product inventory is delayed or prevented, then the net carrying value of unapproved inventory may be partially or fully reserved. Generally, the selling price of a generic pharmaceutical product is at discount from the corresponding brand product selling price. Typically, a generic drug is easily substituted for the corresponding brand product, and once a generic product is approved, the pre-launch inventory is typically sold within the next three months. If the market prices become lower than the product inventory carrying costs, then the pre-launch inventory value is reduced to such lower market value. If the inventory produced exceeds the estimated market acceptance of the generic product and becomes short-dated, a carrying value reserve will be recorded. In all cases, the carrying value of the Company’s pre-launch product inventory is lower than the respective estimated net selling prices.

To the extent inventory is not scheduled to be utilized in the manufacturing process and/or sold within twelve months of the balance sheet date, it is included as a component of other non-current assets. Amounts classified as non-current inventory consist of raw materials, net of valuation reserves. Raw materials generally have a shelf life of approximately three to five years, while finished goods generally have a shelf life of approximately two years.

## 7. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment, net consisted of the following:

(in \$000's)	<u>March 31,</u> <u>2013</u>	<u>December 31,</u> <u>2012</u>
Land	\$ 5,773	\$ 5,773
Buildings and improvements	130,450	130,995
Equipment	110,355	110,353
Office furniture and equipment	11,492	10,558
Construction-in-progress	9,921	9,843
Property, plant and equipment, gross	\$ 267,991	\$ 267,522
Less: Accumulated depreciation	(91,028)	(86,764)
Property, plant and equipment, net	<u>\$ 176,963</u>	<u>\$ 180,758</u>

## 8. GOODWILL AND INTANGIBLE ASSETS

Goodwill was \$27,574,000 at March 31, 2013 and December 31, 2012, and the Company attributes the entire carrying amount of goodwill to the Global Division. Goodwill is tested at least annually for impairment or whenever events or changes in circumstances have occurred which could have a material adverse effect on the estimated fair value of the reporting unit, and thus indicate a potential impairment of the goodwill carrying value. The Company concluded the carrying value of goodwill was not impaired as of December 31, 2012.

Intangible assets consisted of the following:

(in \$000's)	<u>Initial Cost</u>	<u>Accumulated Amortization</u>	<u>Carrying Value</u>
<b>March 31, 2013</b>			
Amortized intangible assets:			
Zomig <sup>®</sup> product rights	\$ 45,096	\$ (24,698)	\$ 20,398
Tolmar product rights	19,450	(1,289)	18,161
Other product rights	2,250	---	2,250
Total intangible assets	<u>\$ 66,796</u>	<u>\$ (25,987)</u>	<u>\$ 40,809</u>

(in \$000's)	<u>Initial Cost</u>	<u>Accumulated Amortization</u>	<u>Carrying Value</u>
<b>December 31, 2012</b>			
Amortized intangible assets:			
Zomig <sup>®</sup> product rights	\$ 45,096	\$ (17,987)	\$ 27,109
Tolmar product rights	19,450	(859)	18,591
Other product rights	2,250	---	2,250
Total intangible assets	<u>\$ 66,796</u>	<u>\$ (18,846)</u>	<u>\$ 47,950</u>

The Zomig<sup>®</sup> product rights under the Distribution, License, Development and Supply Agreement (“AZ Agreement”) with AstraZeneca UK Limited (“AstraZeneca”) are being amortized on a straight-line basis over a period of 14 months starting in April 2012 and ending upon the expiration of the underlying patent for the tablet, over a period of 11 months starting in July 2012 and ending upon the expiration of the underlying patent for the orally disintegrating tablet, and over a period of 72 months starting in July 2012 for the nasal spray. In June 2012, the Company entered into a Development, Supply and Distribution Agreement (the “Tolmar Agreement”) with TOLMAR, Inc. (“Tolmar”). Under the terms of the Tolmar Agreement, Tolmar granted to the Company an exclusive license to commercialize up to 11 generic topical prescription drug products, including nine currently approved products and two products pending approval at the FDA, in the United States and its territories. Under the terms of the Tolmar Agreement, Tolmar is responsible for developing and manufacturing the products, and the Company is responsible for the marketing and sale of the products. The Tolmar product rights are being amortized over the remaining estimated useful lives of the underlying products over a period ranging from five to 12 years, starting upon commencement of commercialization activities by the Company during the year ended December 31, 2012. Information concerning the AZ Agreement and the Tolmar Agreement can be found in “Note 12 - Alliance and Collaboration Agreements.” Other product rights consist of Abbreviated New Drug Applications (“ANDAs”) which have been filed with the FDA. The Company will either commence amortization of the cost of these product rights over their estimated useful life upon FDA approval and commercialization, or will expense the related costs immediately upon failure to obtain FDA approval. Amortization expense is included as a component of cost of revenues on the consolidated statement of operations and was \$7,142,000 for the three month period ended March 31, 2013.

The following schedule shows the expected amortization of the Zomig<sup>®</sup> and Tolmar product rights for the next five years and thereafter:

(in \$000s)	<u>Amortization Expense</u>
2013	\$ 14,732
2014	4,851
2015	4,851
2016	4,851
2017	4,776
Thereafter	11,639
Totals	<u>\$ 45,700</u>



## 9. ACCRUED EXPENSES, COMMITMENTS AND CONTINGENCIES

The following table sets forth the Company's accrued expenses:

(in \$000's)	March 31, 2013	December 31, 2012
Payroll-related expenses	\$ 14,708	\$ 22,553
Product returns	23,951	23,440
Government rebates	25,097	33,794
Legal and professional fees	8,016	3,993
Clinical trial costs	400	1,610
Income taxes payable	39,346	1,541
Physician detailing sales force fees	2,888	1,471
Other	6,206	4,340
Total accrued expenses	<u>\$ 120,612</u>	<u>\$ 92,742</u>

### *Product Returns*

The Company maintains a return policy to allow customers to return product within specified guidelines. At the time of sale, the Company estimates a provision for product returns based upon historical experience for sales made through its Global Products and Impax Products sales channels. Sales of product under the Private Label, Rx Partner and OTC Partner alliance and collaboration agreements are generally not subject to returns. A roll forward of the product return reserve for the three month period ended March 31, 2013 and the year ended December 31, 2012 is as follows:

(in \$000's)	March 31, 2013	December 31, 2012
<b>Returns Reserve</b>		
Beginning balance	\$ 23,440	\$ 24,101
Provision related to sales recorded in the period	1,584	3,003
Credits issued during the period	(1,073)	(3,664)
Ending balance	<u>\$ 23,951</u>	<u>\$ 23,440</u>

### *Taiwan Facility Construction*

The Company has entered into several contracts relating to ongoing construction at its manufacturing facility located in Jhunan, Taiwan, R.O.C. As of March 31, 2013, the Company had remaining obligations under these contracts of approximately \$7,758,000.

### *Purchase Order Commitments*

As of March 31, 2013, the Company had \$40,807,000 of open purchase order commitments, primarily for raw materials. The terms of these purchase order commitments are less than one year in duration.

## 10. INCOME TAXES

The Company calculates its interim income tax provision in accordance with FASB ASC Topics 270 and 740. At the end of each interim period, the Company makes an estimate of the annual United States domestic and foreign jurisdictions' expected effective tax rates and applies these rates to its respective year-to-date taxable income or loss. The computation of the annual estimated effective tax rates at each interim period requires certain estimates and assumptions including, but not limited to, the expected operating income for the year, projections of the proportion of income (or loss) earned and taxed in the United States, and the various state and local tax jurisdictions, as well as tax jurisdictions outside the United States, along with permanent differences, and the likelihood of deferred tax asset utilization. The accounting estimates used to compute the provision for income taxes may change as new events occur, more experience is acquired or additional information is obtained. The computation of the annual estimated effective tax rate includes modifications, which were projected for the year, for share-based compensation and federal and state research and development credits, among others. In addition, the effect of changes in enacted tax laws, rates, or tax status is recognized in the interim period in which the respective change occurs.

During the three month period ended March 31, 2013, the Company recognized an aggregate consolidated tax provision of \$48,278,000 for United States domestic and foreign income taxes. In the three month period ended March 31, 2012, the Company recognized an aggregate consolidated tax provision of \$6,269,000 for United States domestic and foreign income taxes. The increase in the tax provision resulted from higher consolidated income before taxes in the three month period ended March 31, 2013, as compared to the same period in the prior year. The effective tax rate of 31% for the three month period ended March 31, 2013 was lower than the effective tax rate of 34% for the prior year period primarily as a result of recording the estimated 2012 federal research and development credit, which was enacted retroactively in January 2013, in the three month period ended March 31, 2013, as well as the partial year 2013 estimated federal research and development credit recorded in the three month period ended March 31, 2013, which was not available for the same period last year due to the expiration of the credit.

## 11. REVOLVING LINE OF CREDIT

The Company has a Credit Agreement, as amended (the "Credit Agreement") with Wells Fargo Bank, N.A., as a lender and as administrative agent (the "Administrative Agent"). The Credit Agreement provides the Company with a revolving line of credit in the aggregate principal amount of up to \$50,000,000 (the "Revolving Credit Facility"). Under the Revolving Credit Facility, up to \$10,000,000 is available for letters of credit, the outstanding face amounts of which reduce availability under the Revolving Credit Facility on a dollar for dollar basis. Proceeds under the Credit Agreement may be used for working capital, general corporate and other lawful purposes. The Company has not yet borrowed any amounts under the Revolving Credit Facility.

The Company's borrowings under the Credit Agreement are secured by substantially all of the personal property assets of the Company pursuant to a Security Agreement (the "Security Agreement") entered into by the Company and the Administrative Agent. As further security, the Company also pledged to the Administrative Agent, 65% of the Company's equity interest in its wholly-owned subsidiary Impax Laboratories (Taiwan), Inc., all of the Company's equity interests in its wholly owned domestic subsidiaries and must similarly pledge all or a portion of its equity interest in future subsidiaries. Under the Credit Agreement, among other things:

- The outstanding principal amount of all revolving credit loans, together with accrued and unpaid interest thereon, will be due and payable on the maturity date, which will occur four years following the February 11, 2011 closing date.
- Borrowings under the Revolving Credit Facility will bear interest, at the Company's option, at either an Alternate Base Rate (as defined in the Credit Agreement) plus the applicable margin in effect from time to time ranging from 0.5% to 1.5%, or a LIBOR Rate (as defined in the Credit Agreement) plus the applicable margin in effect from time to time ranging from 1.5% to 2.5%. The Company is also required to pay an unused commitment fee ranging from 0.25% to 0.45% per annum based on the daily average undrawn portion of the Revolving Credit Facility. The applicable margin described above and the unused commitment fee in effect at any given time will be determined based on the Company's Total Net Leverage Ratio (as defined in the Credit Agreement), which is based upon the Company's consolidated total debt, net of unrestricted cash in excess of \$100 million, compared to Consolidated EBITDA (as defined in the Credit Agreement) for the immediately preceding four quarters.
- The Company may prepay any outstanding loan under the Revolving Credit Facility without premium or penalty.
- The Company is required under the Credit Agreement and the Security Agreement to comply with a number of affirmative, negative and financial covenants. Among other things, these covenants (i) require the Company to provide periodic reports, notices of material events and information regarding collateral, (ii) restrict the Company's ability, subject to certain exceptions and baskets, to incur additional indebtedness, grant liens on assets, undergo fundamental changes, change the nature of its business, make investments, undertake acquisitions, sell assets, make restricted payments (including the ability to pay dividends and repurchase stock) or engage in affiliate transactions, and (iii) require the Company to maintain a Total Net Leverage Ratio (which is, generally, total funded debt, net of unrestricted cash in excess of \$100 million, over EBITDA for the preceding four quarters) of less than 3.75 to 1.00, a Senior Secured Leverage Ratio (which is, generally, total senior secured debt over EBITDA for the preceding four quarters) of less than 2.50 to 1.00 and a Fixed Charge Coverage Ratio (which is, generally, EBITDA for the preceding four quarters over the sum of cash interest expense, cash tax payments, scheduled funded debt payments and capital expenditures during such four quarter period, subject to certain specified exceptions) of at least 2.00 to 1.00 (with each such ratio as more particularly defined as set forth in the Credit Agreement). As of March 31, 2013, the Company was in compliance with the various covenants contained in the Credit Agreement and the Security Agreement.
- The Credit Agreement contains customary events of default (subject to customary grace periods, cure rights and materiality thresholds), including, among others, failure to pay principal, interest or fees, violation of covenants, material inaccuracy of representations and warranties, cross-default and cross-acceleration of material indebtedness and other obligations, certain bankruptcy and insolvency events, certain judgments, certain events related to the Employee Retirement Income Security Act of 1974, as amended, and a change of control.

## 11. REVOLVING LINE OF CREDIT (continued)

- Following an event of default under the Credit Agreement, the Administrative Agent would be entitled to take various actions, including the acceleration of amounts due under the Credit Agreement and seek other remedies that may be taken by secured creditors.

During the three month periods ended March 31, 2013 and 2012, unused line fees incurred under the Credit Agreement were \$30,000 and \$32,000, respectively.

## 12. ALLIANCE AND COLLABORATION AGREEMENTS

The Company has entered into several alliance, collaboration, license and distribution agreements, and similar agreements with respect to certain of its products and services, with unrelated third-party pharmaceutical companies. The consolidated statement of operations includes revenue recognized under agreements the Company has entered into to develop marketing and/or distribution relationships with its partners to fully leverage its technology platform, revenue recognized under development agreements which generally obligate the Company to provide research and development services over multiple periods, and revenue recognized under a promotional services agreement which obligates the Company to provide physician detailing sales calls services to promote its promotional partner's branded drug products over multiple periods.

The Company's alliance and collaboration agreements often include milestones and provide for milestone payments upon achievement of these milestones. Generally, the milestone events contained in the Company's alliance and collaboration agreements coincide with the progression of the Company's products and technologies from pre-commercialization to commercialization.

The Company groups pre-commercialization milestones in its alliance and collaboration agreements into clinical and regulatory categories, each of which may include the following types of events:

### Clinical Milestone Events:

- *Designation of a development candidate* . Following the designation of a development candidate, generally, IND-enabling animal studies for a new development candidate take 12 to 18 months to complete.
- *Initiation of a Phase I clinical trial* . Generally, Phase I clinical trials take one to two years to complete.
- *Initiation or completion of a Phase II clinical trial* . Generally, Phase II clinical trials take one to three years to complete.
- *Initiation or completion of a Phase III clinical trial* . Generally, Phase III clinical trials take two to four years to complete.
- *Completion of a bioequivalence study* . Generally, bioequivalence studies take three months to one year to complete.

### Regulatory Milestone Events:

- *Filing or acceptance of regulatory applications for marketing approval such as a New Drug Application in the United States or Marketing Authorization Application in Europe* . Generally, it takes six to twelve months to prepare and submit regulatory filings and approximately two months for a regulatory filing to be accepted for substantive review.
- *Marketing approval in a major market, such as the United States or Europe* . Generally it takes one to three years after an application is submitted to obtain approval from the applicable regulatory agency.
- *Marketing approval in a major market, such as the United States or Europe for a new indication of an already-approved product* . Generally it takes one to three years after an application for a new indication is submitted to obtain approval from the applicable regulatory agency.

Commercialization milestones in the Company's alliance and collaboration agreements may include the following types of events:

- *First commercial sale in a particular market , such as in the United States or Europe* .
- *Product sales in excess of a pre-specified threshold, such as annual sales exceeding \$100 million* . The amount of time to achieve this type of milestone depends on several factors including but not limited to the dollar amount of the threshold, the pricing of the product and the pace at which customers begin using the product.

## 12. ALLIANCE AND COLLABORATION AGREEMENTS (continued)

### *License and Distribution Agreement with Shire*

In January 2006, the Company entered into a License and Distribution Agreement with an affiliate of Shire Laboratories, Inc. (“Prior Shire Agreement”), under which the Company received a non-exclusive license to market and sell an authorized generic of Shire’s Adderall XR<sup>®</sup> product (“AG Product”) subject to certain conditions, but in any event by no later than January 1, 2010. The Company commenced sales of the AG Product in October 2009. On February 7, 2013, the Company entered into an Amended and Restated License and Distribution Agreement with Shire (the “Amended and Restated Shire Agreement”), which amended and restated the Prior Shire Agreement. The Amended and Restated Shire Agreement was entered into by the parties in connection with the settlement of the Company’s litigation with Shire relating to Shire’s supply of the AG Product to the Company under the Prior Shire Agreement. During the three month period ended March 31, 2013, the Company received a payment in the amount of \$48,000,000 from Shire in connection with such litigation settlement, which was recorded as other income on the consolidated statement of operations. For more information about the litigation with Shire, see “Note 17 - Legal and Regulatory Matters.” The Amended and Restated Shire Agreement provides for Shire to supply the AG Product and for the Company to market and sell the AG Product subject to the terms and conditions thereof until the earlier of (i) the first commercial sale of the Company’s generic equivalent product to Adderall XR<sup>®</sup> and (ii) September 30, 2014 (the “Supply Term”), subject to certain continuing obligations of the parties upon expiration or early termination of the Supply Term, including Shire’s obligation to deliver AG Products still owed to the Company as of the end of the Supply Term. The Company is required to pay a profit share to Shire on sales of the AG Product, of which the Company owed a profit share payable to Shire of \$5,640,000 and \$25,348,000 on sales of the AG Product during the three month periods ended March 31, 2013 and 2012, respectively, with a corresponding charge included in the cost of revenues line on the consolidated statement of operations.

### *Development, Supply and Distribution Agreement with TOLMAR, Inc.*

In June 2012, the Company entered into the Tolmar Agreement with Tolmar. Under the terms of the Tolmar Agreement, Tolmar granted to the Company an exclusive license to commercialize up to 11 generic topical prescription drug products, including nine currently approved products and two products pending approval at the FDA, in the United States and its territories. Under the terms of the Tolmar Agreement, Tolmar is responsible for developing and manufacturing the products, and the Company is responsible for marketing and sale of the products. The Company is required to pay a profit share to Tolmar on sales of each product commercialized pursuant to the terms of the Tolmar Agreement. The Company paid Tolmar a \$21,000,000 up-front payment upon signing of the agreement and a \$1,000,000 milestone payment in the year ended December 31, 2012. The Company has the potential to pay up to \$24,000,000 in additional contingent milestone payments if certain commercialization and regulatory events occur. The up-front payment for the Tolmar product rights has been allocated to the underlying topical products based upon the relative fair value of each product and is being amortized over the remaining estimated useful life of each underlying product, ranging from five to 12 years, starting upon commencement of commercialization activities by the Company during the second half of 2012. The amortization of the Tolmar product rights is included as a component of cost of revenues on the consolidated statement of operations. The Company initially allocated \$1,550,000 of the up-front payment to two products which are still in development and recorded such amount as in-process research and development expense in its results of operations for the year ended December 31, 2012. The Company similarly recorded the \$1,000,000 milestone paid in the year ended December 31, 2012 as a research and development expense. Contingent milestone payments will be initially recognized in the period the triggering event occurs. Milestone payments which are contingent upon commercialization events will be accounted for as an additional cost of acquiring the product license rights. Milestone payments that are contingent upon regulatory approval events will be capitalized and amortized over the remaining estimated useful life of the approved product.

## 12. ALLIANCE AND COLLABORATION AGREEMENTS (continued)

### *Strategic Alliance Agreement with Teva*

The Company entered into a Strategic Alliance Agreement with Teva in June 2001 (“Teva Agreement”). The Teva Agreement commits the Company to develop and manufacture, and Teva to distribute, a specified number of controlled release generic pharmaceutical products (“generic products”), each for a 10-year period. The Company identified the following deliverables under the Teva Agreement: (i) the manufacture and delivery of generic products; (ii) the provision of research and development activities (including regulatory services) related to each product; and (iii) market exclusivity associated with the products. In July 2010, the Teva Agreement was amended to terminate the provisions of the Teva Agreement with respect to the Omeprazole (generic to Prilosec®) 10mg, 20mg and 40mg products. Additionally, in exchange for the return of product rights, the Company agreed to pay to Teva a profit share on future sales of the fexofenadine HCl/pseudoephedrine (generic to Allegra-D®) product, if any, but in no event will such profit share payments exceed an aggregate amount of \$3,000,000. The Company recognized previously deferred revenue related to the Teva Agreement of \$327,000 in the three month periods ended March 31, 2013 and 2012. No additional amounts were deferred during the three month periods ended March 31, 2013 and 2012.

### *OTC Partners Alliance Agreement*

In June 2002, the Company entered into a Development, License and Supply Agreement with Pfizer Inc. (formerly Wyeth) (the “Pfizer Agreement”), for a term of approximately 15 years, relating to the Company’s Loratadine and Pseudoephedrine Sulfate 5 mg/120 mg 12-hour Extended Release Tablets and Loratadine and Pseudoephedrine Sulfate 10 mg/240 mg 24-hour Extended Release Tablets for the OTC market. The Company previously developed the products, and is currently only responsible for manufacturing the products, and Pfizer is responsible for marketing and sale. The agreement included payments to the Company upon achievement of development milestones, as well as royalties paid to the Company by Pfizer on its sales of the product. Pfizer launched this product in May 2003 as Alavert® D-12 Hour. In February 2005, the agreement was partially cancelled with respect to the 24-hour Extended Release Product due to lower than planned sales volume. The Pfizer Agreement is no longer a core area of the Company’s business, and the over-the-counter pharmaceutical products the Company sells to Pfizer under the Pfizer Agreement are older products which are only sold to Pfizer, and which are sold at a loss. In order to avoid deferring the losses incurred upon shipment of these products to Pfizer, the Company recognizes revenue, and the associated manufacturing costs, at the time title and risk of loss passes to Pfizer which is generally when the product is shipped. The Company recognizes profit share revenue in the period earned. The Company recognized revenue of \$271,000 and product manufacturing costs of \$459,000 under the Pfizer Agreement in the three month period ended March 31, 2013. The Company deferred revenue of \$315,000 and recognized previously deferred revenue of \$581,000 in the three month period ended March 31, 2012, related to the Pfizer Agreement. The Company deferred product manufacturing costs of \$495,000 and recognized previously deferred product manufacturing costs of \$661,000 in the three month period ended March 31, 2012, related to the Pfizer Agreement.

### *Joint Development Agreement with Valeant Pharmaceuticals International, Inc.*

In November 2008, the Company and Valeant Pharmaceuticals International, Inc., formerly Medicis Pharmaceutical Corporation (“Valeant”), entered into a Joint Development Agreement and a License and Settlement Agreement (“Joint Development Agreement”). The Joint Development Agreement provides for the Company and Valeant to collaborate in the development of a total of five dermatology products, including four of the Company’s generic products and one branded advanced form of Valeant’s SOLODYN® product. Under the provisions of the Joint Development Agreement the Company received a \$40,000,000 upfront payment, paid by Valeant in December 2008. The Company has also received an aggregate of \$15,000,000 in milestone payments composed of two \$5,000,000 milestone payments, paid by Valeant in March 2009 and September 2009, a \$2,000,000 milestone payment paid by Valeant in December 2009, and a \$3,000,000 milestone payment paid by Valeant in March 2011. The Company has the potential to receive up to an additional \$8,000,000 of contingent regulatory milestone payments each of which the Company believes to be substantive, as well as the potential to receive royalty payments from sales, if any, by Valeant of its advanced form SOLODYN® brand product. Finally, to the extent the Company commercializes any of its four generic dermatology products covered by the Joint Development Agreement, the Company will pay to Valeant a gross profit share on sales of such products. The Company began selling one of the four dermatology products during the year ended December 31, 2011. During the three month period ended March 31, 2013, the Company extended the revenue recognition period for the Joint Development Agreement from the previous recognition period ending in November 2013 to December 2014, due to changes in the estimated timing of completion of certain research and development activities. This change was made on a prospective basis, and resulted in a reduced amount of revenue recognized in the three month period ended March 31, 2013, as compared to preceding quarters, and a reduced periodic amount of revenue to be recognized in future periods.

## 12. ALLIANCE AND COLLABORATION AGREEMENTS (continued)

### *License, Development and Commercialization Agreement & Supply Agreement with Glaxo Group Limited*

In December 2010, the Company entered into a License, Development and Commercialization Agreement with Glaxo Group Limited (“GSK”). Under the terms of the agreement with GSK, GSK received an exclusive license to develop and commercialize IPX066 (brand name RYTARY™ in the United States) throughout the world, except in the U.S. and Taiwan, and certain follow-on products at the option of GSK. Under the terms of the agreement, GSK paid an \$11,500,000 upfront payment in December 2010, and the Company had the potential to receive up to \$169,000,000 of contingent milestone payments. The upfront payment was recognized as revenue on a straight-line basis over the Company’s expected period of performance to provide research and development services which ended on December 31, 2012. In April 2013, the Company and GSK announced that they were terminating their collaboration for the development and commercialization of IPX066 outside the United States and Taiwan as a result of delays in the anticipated regulatory approval and launch dates in countries in which GSK has rights to commercialize the product and terminated the License, Development and Commercialization Agreement. At the end of July 2013, GSK’s right to develop and commercialize IPX066 outside the United States and Taiwan will transfer back to the Company. For more information, refer to “Note 19 – Subsequent Events.”

### *Distribution, License, Development and Supply Agreement with AstraZeneca UK Limited*

In January 2012, the Company entered into the AZ Agreement with AstraZeneca. Under the terms of the AZ Agreement, AstraZeneca granted to the Company an exclusive license to commercialize the tablet, orally disintegrating tablet and nasal spray formulations of Zomig® (zolmitriptan) products for the treatment of migraine headaches in the United States and in certain U.S. territories, except during an initial transition period when AstraZeneca fulfilled all orders of Zomig® products on the Company’s behalf and AstraZeneca paid to the Company the gross profit on such Zomig® products. The Company is obligated to fulfill certain minimum requirements with respect to the promotion of currently approved Zomig® products as well as other dosage strengths of such products approved by the FDA in the future. The Company may, but has no obligation to, develop and commercialize additional products containing zolmitriptan and additional indications for Zomig®, subject to certain restrictions as set forth in the AZ Agreement. The Company will be responsible for conducting clinical studies and preparing regulatory filings related to the development of any such additional products and would bear all related costs. During the term of the AZ Agreement, AstraZeneca will continue to be the holder of the NDA for existing Zomig® products, as well as any future dosage strengths thereof approved by the FDA, and will be responsible for certain regulatory and quality-related activities for such Zomig® products. AstraZeneca will manufacture and supply Zomig® products to the Company and the Company will purchase its requirements of Zomig® products from AstraZeneca until a date determined in the AZ Agreement. Thereafter, AstraZeneca may terminate its supply obligations upon certain advance notice to the Company, in which case the Company would have the right to manufacture or have manufactured its own requirements for the applicable Zomig® product.

Under the terms of the AZ Agreement, AstraZeneca was required to make payments to the Company representing 100% of the gross profit on sales of AstraZeneca-labeled Zomig® products during the specified transition period. The Company received transition payments from AstraZeneca aggregating \$43,564,000 during 2012, and accounted for these payments as a reduction of the aggregate \$130,000,000 in quarterly payments made to AstraZeneca during 2012. The Company allocated \$45,096,000 of the \$86,436,000 net payments made to AstraZeneca to an intangible asset, and the remaining \$41,340,000 to prepaid royalty expense related to sales of Impax-labeled Zomig® products during 2012, with such royalty expense included in cost of revenues on the consolidated statement of operations. Beginning in January 2013, the Company is obligated to pay AstraZeneca tiered royalties on net sales of Zomig® products, depending on brand exclusivity and subject to customary reductions and other terms and conditions set forth in the AZ Agreement. The Company is also obligated to pay AstraZeneca royalties after a certain specified date based on gross profit from sales of authorized generic versions of the Zomig products subject to certain terms and conditions set forth in the AZ Agreement.

## 12. ALLIANCE AND COLLABORATION AGREEMENTS (continued)

### *Development and Co-Promotion Agreement with Endo Pharmaceuticals, Inc.*

In June 2010, the Company and Endo Pharmaceuticals, Inc. ("Endo") entered into a Development and Co-Promotion Agreement ("Endo Agreement") under which the Company and Endo have agreed to collaborate in the development and commercialization of a next-generation advanced form of the Company's lead brand product candidate ("Endo Agreement Product"). Under the provisions of the Endo Agreement, in June 2010, Endo paid to the Company a \$10,000,000 up-front payment. The Company has the potential to receive up to an additional \$30,000,000 of contingent milestone payments, which includes \$15,000,000 contingent upon the achievement of clinical events, \$5,000,000 contingent upon the achievement of regulatory events, and \$10,000,000 contingent upon the achievement of commercialization events. The Company believes all milestones under the Endo Agreement are substantive. Upon commercialization of the Endo Agreement Product in the United States, Endo will have the right to co-promote such product to non-neurologists, which will require the Company to pay Endo a co-promotion service fee of up to 100% of the gross profits attributable to prescriptions for the Endo Agreement Product which are written by the non-neurologists.

The Company is recognizing the \$10,000,000 upfront payment as revenue on a straight-line basis over a period of 91 months, which is the estimated expected period of performance of research and development activities under the Endo Agreement, commencing with the June 2010 effective date of the Endo Agreement and ending in December 2017, the estimated date of FDA approval of the Company's NDA. The FDA approval of the Endo Agreement Product NDA represents the end of the Company's expected period of performance, as the Company will have no further contractual obligation to perform research and development activities under the Endo Agreement, and therefore the earnings process will be completed. Deferred revenue is recorded as a liability captioned "Deferred revenue" on the consolidated balance sheet and deferred revenue under the Endo Agreement was \$6,264,000 as of March 31, 2013. Revenue recognized under the Endo Agreement is reported in the line item captioned Research Partner. The Company determined the straight-line method aligns revenue recognition with performance as the level of research and development activities performed under the Endo Agreement are expected to be performed on a ratable basis over the Company's estimated expected period of performance. Upon FDA approval of the Company's Endo Agreement Product NDA, the Company will have the right (but not the obligation) to begin manufacture and sale of such product. The Company will sell its manufactured branded product to customers in the ordinary course of business through its Impax Pharmaceuticals Division. The Company will account for any sale of the product covered by the Endo Agreement as current period revenue. The co-promotion service fee paid to Endo, as described above, if any, will be accounted for as a current period selling expense as incurred.

The Company and Endo also entered into a Settlement and License Agreement in June 2010 (the "Endo Settlement Agreement") pursuant to which Endo agreed to make a payment to the Company should Prescription Sales of Opana® ER (as defined in the Endo Settlement Agreement) fall below a predetermined contractual threshold in the quarter immediately prior to the Company launching a generic version of Opana® ER. As a result of the Company's launch of its generic version of Opana ER in January 2013 and Endo's Prescription Sales of Opana ER during the fourth quarter of 2012, the Company recorded a \$102,049,000 settlement gain during the three month period ended March 31, 2013 which is included in "Other Income" in the consolidated statement of operations. Payment of the \$102,049,000 settlement was received from Endo in April 2013.

### *Co-Promotion Agreement with Pfizer*

In March 2010, the Company and Pfizer, Inc. ("Pfizer") entered into the First Amendment to the Co-Promotion Agreement (originally entered into with Wyeth, now a wholly owned subsidiary of Pfizer) ("Pfizer Co-Promotion Agreement"). The Company's obligation to provide physician detailing sales calls under the Pfizer Co-Promotion Agreement ended on June 30, 2012. Prior to such time, the Company had received a fixed fee, effective January 1, 2010, for providing such physician detailing sales calls within a contractually defined range of an aggregate number of physician detailing sales calls rendered, determined on a quarterly basis. The Company recognized the physician detailing sales force fee revenue as the related services were performed and the performance obligations were met. The Company recognized \$3,535,000 in the three month period ended March 31, 2012 under the Pfizer Co-Promotion Agreement, which is included in the line item "Other Revenues" in "Note 18 - Supplementary Financial Information." As the Company's obligation under the Pfizer Co-Promotion Agreement ended on June 30, 2012, no amounts were recognized under this agreement during the three month period ended March 31, 2013.

### 13. SHARE-BASED COMPENSATION

The Company recognizes the grant date fair value of each stock option and restricted stock award over its vesting period. Stock options and restricted stock awards are granted under the Company's Amended and Restated 2002 Equity Incentive Plan ("2002 Plan") and generally vest over a three or four year period and have a term of ten years. Total share-based compensation expense recognized in the consolidated statement of operations during the three month periods ended March 31, 2013 and 2012 was as follows:

(in \$000's)	Three Months Ended March 31,	
	2013	2012
Manufacturing expenses	\$ 673	\$ 637
Research and development	1,376	1,213
Selling, general and administrative	2,310	1,959
Total	<u>\$ 4,359</u>	<u>\$ 3,809</u>

The following table summarizes stock option activity during the three month period ended March 31, 2013:

	Number of Shares Under Option	Weighted Average Exercise Price per Share
Outstanding at December 31, 2012	4,177,221	\$ 12.72
Options granted	--	\$ --
Options exercised	(212,115)	\$ 6.37
Options forfeited	(7,880)	\$ 14.40
Outstanding at March 31, 2013	<u>3,957,226</u>	\$ 13.06
Options exercisable at March 31, 2013	<u>3,028,925</u>	\$ 11.43

The Company estimated the fair value of each stock option award on the grant date using the Black-Scholes option pricing model, wherein: expected volatility is based solely on historical volatility of the Company's common stock over the period commensurate with the expected term of the stock options. The expected term calculation is based on the "simplified" method described in SAB No. 107, Share-Based Payment and SAB No. 110, Share-Based Payment, as the result of the simplified method provides a reasonable estimate in comparison to the Company's actual experience. The risk-free interest rate is based on the U.S. Treasury yield at the date of grant for an instrument with a maturity that is commensurate with the expected term of the stock options. The dividend yield of zero is based on the fact that the Company has never paid cash dividends on its common stock, and has no present intention to pay cash dividends.

A summary of the Company's non-vested restricted stock awards activity during the three month period ended March 31, 2013 is presented below:

<b>Restricted Stock Awards</b>	<b>Number of Restricted Stock Awards</b>	<b>Weighted Average Grant-Date Fair Value</b>
Non-vested at December 31, 2012	1,954,570	\$ 20.97
Granted	41,675	\$ 21.23
Vested	(58,429)	\$ 10.49
Forfeited	(22,201)	\$ 20.56
Non-vested at March 31, 2013	<u>1,915,615</u>	\$ 21.31

The Company grants restricted stock awards to certain eligible employees and directors as a component of its long-term incentive compensation program. The restricted stock award grants are made in accordance with the Company's 2002 Plan, and typically specify that the shares of common stock underlying the restricted stock awards are not issued until they vest. The restricted stock awards generally vest ratably over a three or four year period from the date of grant.

### **13. SHARE-BASED COMPENSATION (continued)**

As of March 31, 2013, the Company had total unrecognized share-based compensation expense, net of estimated forfeitures, of \$38,799,000 related to all of its share-based awards, which will be recognized over a weighted average period of 2.17 years. As of March 31, 2013, the Company estimated 3,503,300 stock options and 1,695,900 shares of restricted stock awards granted to employees which were vested or expected to vest. The intrinsic value of stock options exercised during the three month periods ended March 31, 2013 and 2012 was \$2,933,000 and \$6,266,000, respectively. The total fair value of restricted stock awards which vested during the three month periods ended March 31, 2013 and 2012 was \$613,000 and \$435,000, respectively. As of March 31, 2013, the Company had 1,164,834 shares of common stock available for issuance of stock options, restricted stock awards, and/or stock appreciation rights.

### **14. STOCKHOLDERS' EQUITY**

#### ***Preferred Stock***

Pursuant to its certificate of incorporation, the Company is authorized to issue 2,000,000 shares, \$0.01 par value per share, "blank check" preferred stock, which enables the Board of Directors, from time to time, to create one or more new series of preferred stock. Each series of preferred stock issued can have the rights, preferences, privileges and restrictions designated by the Board of Directors. The issuance of any new series of preferred stock could affect, among other things, the dividend, voting, and liquidation rights of the Company's common stock. During the three month periods ended March 31, 2013 and 2012, the Company did not issue any preferred stock.

#### ***Common Stock***

The Company's certificate of incorporation, as amended, authorizes the Company to issue 90,000,000 shares of common stock with \$0.01 par value.

## 15. EARNINGS PER SHARE

The Company's earnings per share (EPS) includes basic net income per share, computed by dividing net income (as presented on the consolidated statement of operations), by the weighted-average number of shares of common stock outstanding for the period, along with diluted net income per share, computed by dividing net income by the weighted-average number of shares of common stock adjusted for the dilutive effect of common stock equivalents outstanding during the period. A reconciliation of basic and diluted net income per share of common stock for the three month periods ended March 31, 2013 and 2012 was as follows:

(in \$000's except per share amounts)	Three Months Ended	
	March 31,	
	2013	2012
<b>Numerator:</b>		
Net income	\$ 105,442	\$ 12,365
<b>Denominator:</b>		
Weighted average common shares outstanding	66,487,470	65,122,240
Effect of dilutive stock options and restricted stock awards	1,690,885	2,785,023
Diluted weighted average common shares outstanding	68,178,355	67,907,263
Basic net income per share	\$ 1.59	\$ 0.19
Diluted net income per share	\$ 1.55	\$ 0.18

For the three month periods ended March 31, 2013 and 2012, the Company excluded 1,276,394 and 698,955, respectively, of shares issuable upon the exercise of stock options and unvested restricted stock awards from the computation of diluted net income per common share as the effect of these options and unvested restricted stock awards would have been anti-dilutive. Quarterly computations of net income per share amounts are made independently for each quarterly reporting period, and the sum of the per share amounts for the quarterly reporting periods may not equal the per share amounts for the year-to-date reporting period.

## 16. SEGMENT INFORMATION

The Company has two reportable segments, the Global Division and the Impax Division. The Global Division develops, manufactures, sells, and distributes generic pharmaceutical products, primarily through the following sales channels: the Global Products sales channel for sales of generic prescription products directly to wholesalers, large retail drug chains, and others; the Private Label Product sales channel for generic over-the-counter and prescription products sold to unrelated third-party customers who, in-turn, sell the products under their own label; the Rx Partner sales channel for generic prescription products sold through unrelated third-party pharmaceutical entities under their own label pursuant to alliance agreements; and the OTC Partner sales channel for over-the-counter products sold through an unrelated third-party pharmaceutical entity under its own label pursuant to an alliance agreement. Revenues from the “Global Products” sales channel and the “Private Label” sales channel are reported under the caption “Global Product sales, net” in “Note 18 – Supplementary Financial Information.” The Company also generates revenue in its Global Division from research and development services provided under a joint development agreement with another unrelated third-party pharmaceutical company, and reports such revenue under the caption “Other Revenues” revenue in “Note 18 – Supplementary Financial Information.” Revenues from the “OTC Partner” sales channel are also reported under the caption “Other Revenues” in “Note 18 – Supplementary Financial Information.”

The Impax Division is engaged in the development of proprietary brand pharmaceutical products that the Company believes represent improvements to already-approved pharmaceutical products addressing CNS disorders. The Impax Division currently has one internally developed late stage branded pharmaceutical product candidate, RYTARY™, an extended release capsule formulation of carbidopa-levodopa for the symptomatic treatment of Parkinson’s disease, for which the NDA was accepted for filing by the FDA in February 2012 and which the Company received a Complete Response Letter from the FDA in January 2013. The Company is currently working with the FDA on the appropriate next steps for the RYTARY™ NDA. In addition to RYTARY™, the Impax Division has a number of other product candidates that are in varying stages of development. The Impax Division is also engaged in the sale and distribution of Zomig® (zolmitriptan) products, indicated for the treatment of migraine headaches, under the terms of the AZ Agreement with AstraZeneca in the United States and in certain U.S. territories. Revenues from Impax-labeled Zomig® products are reported under the caption “Impax Product sales, net” in “Note 18 – Supplementary Financial Information.” Finally, the Company generates revenue in the Impax Division from research and development services provided under a development and license agreement with another unrelated third-party pharmaceutical company, and reports such revenue under the caption “Other Revenues” revenue in “Note 18 – Supplementary Financial Information.”

The Company’s chief operating decision maker evaluates the financial performance of the Company’s segments based upon segment income (loss) before income taxes. Items below income (loss) from operations are not reported by segment, except litigation settlements, since they are excluded from the measure of segment profitability reviewed by the Company’s chief operating decision maker. Additionally, general and administrative expenses, certain selling expenses, certain litigation settlements, and non-operating income and expenses are included in “Corporate and Other.” The Company does not report balance sheet information by segment since it is not reviewed by the Company’s chief operating decision maker. The accounting policies for the Company’s segments are the same as those described above in the discussion of “Revenue Recognition” and in the “Summary of Significant Accounting Policies” in the Company’s Form 10-K for the year ended December 31, 2012. The Company has no inter-segment revenue.

## 16. SEGMENT INFORMATION (continued)

The tables below present segment information reconciled to total Company consolidated financial results, with segment operating income or loss including gross profit less direct research and development expenses, and direct selling expenses as well as any litigation settlements, to the extent specifically identified by segment:

(in \$000's)	<b>Global Division</b>	<b>Impax Division</b>	<b>Corporate and Other</b>	<b>Total Company</b>
<b>Three Months Ended March 31, 2013</b>				
Revenues, net	\$ 101,636	\$ 46,853	\$ ---	\$ 148,489
Cost of revenues	61,444	29,174	---	90,618
Research and development	11,711	7,894	---	19,605
Patent litigation expense	4,278	---	---	4,278
Income (loss) before provision for income taxes	\$ 19,160	\$ (2,979)	\$ 137,539	\$ 153,720

(in \$000's)	<b>Global Division</b>	<b>Impax Division</b>	<b>Corporate and Other</b>	<b>Total Company</b>
<b>Three Months Ended March 31, 2012</b>				
Revenues, net	\$ 123,265	\$ 5,303	\$ ---	\$ 128,568
Cost of revenues	63,106	2,909	---	66,015
Research and development	10,673	8,143	---	18,816
Patent litigation	4,038	---	---	4,038
Income (loss) before provision for income taxes	\$ 41,131	\$ (8,810)	\$ (13,687)	\$ 18,634

### *Foreign Operations*

The Company's wholly-owned subsidiary, Impax Laboratories (Taiwan) Inc., is constructing a manufacturing facility in Jhunan, Taiwan R.O.C. which is utilized for manufacturing, research and development, warehouse, and administrative functions, with approximately \$134,095,000 of net carrying value of assets, composed principally of a building and equipment, included in the Company's consolidated balance sheet at March 31, 2013.

## 17. LEGAL AND REGULATORY MATTERS

### *Patent Litigation*

There is substantial litigation in the pharmaceutical, biological, and biotechnology industries with respect to the manufacture, use, and sale of new products which are the subject of conflicting patent and intellectual property claims. One or more patents typically cover most of the brand name controlled release products for which the Company is developing generic versions.

Under federal law, when a drug developer files an ANDA for a generic drug seeking approval before expiration of a patent, which has been listed with the FDA as covering the brand name product, the developer must certify its product will not infringe the listed patent(s) and/or the listed patent is invalid or unenforceable (commonly referred to as a “Paragraph IV” certification). Notices of such certification must be provided to the patent holder, who may file a suit for patent infringement within 45 days of the patent holder’s receipt of such notice. If the patent holder files suit within the 45 day period, the FDA can review and approve the ANDA, but is prevented from granting final marketing approval of the product until a final judgment in the action has been rendered in favor of the generic drug developer, or 30 months from the date the notice was received, whichever is sooner. Lawsuits have been filed against the Company in connection with the Company’s Paragraph IV certifications seeking an order delaying the approval of the Company’s ANDA until expiration of the patent(s) at issue in the litigation.

Should a patent holder commence a lawsuit with respect to an alleged patent infringement by the Company, the uncertainties inherent in patent litigation make the outcome of such litigation difficult to predict. The delay in obtaining FDA approval to market the Company’s product candidates as a result of litigation, as well as the expense of such litigation, whether or not the Company is ultimately successful, could have a material adverse effect on the Company’s results of operations and financial position. In addition, there can be no assurance that any patent litigation will be resolved prior to the end of the 30-month period. As a result, even if the FDA were to approve a product upon expiration of the 30-month period, the Company may elect to not commence marketing the product if patent litigation is still pending.

The Company is generally responsible for all of the patent litigation fees and costs associated with current and future products not covered by its alliance and collaboration agreements. The Company has agreed to share legal expenses with respect to third-party and Company products under the terms of certain of the alliance and collaboration agreements. For instance, under the Teva Agreement, the Company and Teva have agreed to share in fees and costs related to patent infringement litigation associated with the products covered by the Teva Agreement and the Company is currently sharing litigation costs with respect to three products under the terms of two other separate agreements. The Company records the costs of patent litigation as expense in the period when incurred for products it has developed, as well as for products which are the subject of an alliance or collaboration agreement with a third-party.

Although the outcome and costs of the asserted and unasserted claims is difficult to predict, the Company does not expect the ultimate liability, if any, for such matters to have a material adverse effect on its financial condition, results of operations, or cash flows.

## 17. LEGAL AND REGULATORY MATTERS (continued)

### *Patent Infringement Litigation*

#### *Eurand, Inc., et al. v. Impax Laboratories, Inc. (Cyclobenzaprine)*

In January 2009, Eurand, Inc., Cephalon, Inc., and Anesta AG (collectively, “Cephalon”) filed suit against the Company in the U.S. District Court for the District of Delaware (“District Court”), alleging patent infringement for the filing of the Company’s ANDA relating to Cyclobenzaprine Hydrochloride Extended Release Capsules, 15 mg and 30 mg, generic to Amrix<sup>®</sup>. This matter was settled and dismissed on October 11, 2010.

On November 8, 2011, the District Court expressly named the Company in an order enjoining it from engaging in the commercial use, offer for sale, or sale within the United States of any generic Amrix<sup>®</sup>. On November 22, 2011, the Company filed a motion to reargue and modify the injunction. Plaintiffs responded on December 9, 2011, with a motion for declaratory judgment, seeking a declaration that the Company does not have the right to sell generic Amrix<sup>®</sup>. The Company responded on December 20, 2011, and moved to enforce the terms of a settlement agreement entered into with plaintiffs that it claims grants the Company the right to sell generic Amrix<sup>®</sup>. On March 15, 2012, the District Court denied the Company’s motion and refused to modify the injunction. The Company appealed the order. The United States Court of Appeals for the Federal Circuit affirmed the District Court’s decision to enjoin the Company on February 1, 2013. On April 4, 2013, the District Court granted a stipulated injunction against the Company prohibiting it from making, using, offering to sell, or selling the cyclobenzaprine ANDA products in the United States or importing such products into the United States except as permitted under the terms of the parties’ settlement agreement.

#### *The Research Foundation of State University of New York et al. v. Impax Laboratories, Inc.; Galderma Laboratories Inc., et al. v. Impax Laboratories, Inc. (Doxycycline Monohydrate)*

In September 2009, The Research Foundation of State University of New York; New York University; Galderma Laboratories Inc.; and Galderma Laboratories, L.P. (collectively, “Galderma”) filed suit against the Company in the U.S. District Court for the District of Delaware alleging patent infringement for the filing of the Company’s ANDA relating to Doxycycline Monohydrate Delayed-Release Capsules, 40 mg, generic to Oracea<sup>®</sup>. In May 2011, Galderma Laboratories Inc., Galderma Laboratories, L.P. and Supernus Pharmaceuticals, Inc. filed a second lawsuit in Delaware alleging infringement of an additional patent related to Oracea<sup>®</sup>. The Company filed an answer and counterclaims in both matters. In October 2009 for the first lawsuit and in July 2011 for the second lawsuit, the parties agreed to be bound by the final judgment concerning infringement, validity and enforceability of the patents at issue in an earlier-filed case brought by Galderma and Supernus against another generic drug manufacturer. Proceedings in the lawsuits involving the Company were stayed pending resolution of the related matter. In July 2011, a four-day trial was held in the case involving the other generic manufacturer in the U.S. District Court for the District of Delaware on the issues of patent infringement and validity. In August 2011, the Court issued its decision finding four of the five patents invalid and/or not infringed, and the fifth patent, which expires in December 2027, infringed and not invalid. After proceedings related to the remedy, on June 8, 2012, the Court entered final judgment with respect to that litigation. On June 22, 2012, the Court entered its final judgment with respect to the Company. All parties filed notices of appeal and/or cross-appeal in July 2012. The briefing at the United States Court of Appeals for the Federal Circuit was completed for all parties on January 28, 2013. The decision of the District Court will be binding on the Company unless reversed or modified on appeal or in subsequent litigation.

#### *Schering Corporation, et al. v. Impax Laboratories, Inc. (Ezetimibe/Simvastatin)*

In August 2010, Schering Corporation and MSP Singapore Company LLC (together, “Schering”) filed suit against the Company in the U.S. District Court for the District of New Jersey (“District Court”) alleging patent infringement for the filing of the Company’s ANDA relating to Ezetimibe/Simvastatin Tablets, 10/80 mg, generic to Vytarin<sup>®</sup>. The Company filed an answer and counterclaim. In December 2010, the parties agreed to be bound by the final judgment concerning validity and enforceability of the patents at issue in cases brought by Schering against other generic drug manufacturers that have filed ANDAs relating to this product, and proceedings in the Company’s case were stayed. In April 2012, the District Court issued a decision, finding the latest-expiring patent (U.S. Patent No. RE 42,461) to be valid and enforceable. The District Court’s decision was subsequently affirmed by the Federal Circuit on appeal on February 7, 2013, and the mandate issued on April 18, 2013. The parties thereafter entered into a stipulated judgment, and the case was dismissed.

## 17. LEGAL AND REGULATORY MATTERS (continued)

### *Shire LLC, et al. v. Impax Laboratories, Inc., et al. (Guanfacine)*

In December 2010, Shire LLC, Supernus Pharmaceuticals, Inc., Amy F.T. Arnsten, Ph.D., Pasko Rakic, M.D., and Robert D. Hunt, M.D. (together, “Shire”) filed suit against the Company in the U.S. District Court for the Northern District of California alleging patent infringement for the filing of the Company’s ANDA relating to Guanfacine Hydrochloride Tablets, 4 mg, generic to Intuniv<sup>®</sup>. In January, 2011 Shire amended its complaint to add the 1 mg, 2 mg, and 3 mg strengths, based on the Company amending its ANDA to include those additional strengths. The Company filed its answer and counterclaims. The Court issued a claim construction ruling on June 1, 2012. Trial is scheduled for February 10, 2014.

### *Takeda Pharmaceutical Co., Ltd, et al. v. Impax Laboratories, Inc. (Dexlansoprazole)*

In April 2011, Takeda Pharmaceutical Co., Ltd., Takeda Pharmaceuticals North America, Inc., Takeda Pharmaceuticals LLC, and Takeda Pharmaceuticals America, Inc. (collectively, “Takeda”) filed suit against the Company in the U.S. District Court for the Northern District of California alleging patent infringement based on the filing of the Company’s ANDA relating to Dexlansoprazole Delayed Release Capsules, 30 and 60 mg, generic to Dexilant<sup>®</sup>. The Company filed an answer and counterclaims. The trial court issued a claim construction ruling on April 11, 2012. In November 2012, the Company and Takeda filed cross motions for summary judgment regarding infringement and validity of the patents at issue. On April 8, 2013, the District Court ruled on the summary judgment motions as follows: (a) granted the Company’s motion for non-infringement of U.S. Patent No. 7,790,755, (b) granted Takeda’s motion of infringement of U.S. Patent Nos. 6,664,276 and 6,462,058, and (c) denied the Company’s motion of invalidity for U.S. Patent No. 6,939,971. Trial is scheduled for June 3, 2013.

### *Purdue Pharma L.P., The P.F. Laboratories, Inc., Purdue Pharmaceuticals L.P., Rhodes Technologies, Board of Regents of the University of Texas System, and Grunenthal GmbH v. Impax Laboratories, Inc. (Oxycodone)*

In April 2011, Purdue Pharma L.P., The P.F. Laboratories, Inc., Purdue Pharmaceuticals L.P., Rhodes Technologies, Board of Regents of the University of Texas System, and Grunenthal GmbH (collectively “Purdue”) filed suit against the Company in the U.S. District Court for the Southern District of New York alleging patent infringement based on the filing of the Company’s ANDA relating to Oxycodone Hydrochloride, Controlled Release tablets, 10, 15, 20, 30, 40, 60 and 80 mg, generic to Oxycontin<sup>®</sup> (related to NDA 022272). The Company filed an answer and counterclaims. Discovery is proceeding. No trial date has been scheduled. In February 2013, Purdue Pharma L.P. and Grunenthal GmbH filed a separate lawsuit against the Company involving the same product and ANDA, asserting infringement of two recently issued patents. The Company filed an answer and counterclaims in February 2013. No trial date has been scheduled.

### *Avanir Pharmaceuticals, Inc. et al. v. Impax Laboratories, Inc. (Dextromethorphan/Quinidine)*

In August 2011, Avanir Pharmaceuticals, Inc., Avanir Holding Co., and Center for Neurological Study filed suit against the Company in the U.S. District Court for the District of Delaware alleging patent infringement based on the filing of the Company’s ANDA relating to Dextromethorphan/Quinidine Capsules, 20 mg/10 mg, generic of Nuedexta<sup>®</sup>. The Company filed an answer and counterclaims. On October 8, 2012, Avanir Pharmaceuticals, Inc. filed suit against the Company in the U.S. District Court for the District of Delaware alleging patent infringement of a new patent, US Patent 8,227,484, issued July 24, 2012, also based on the filing of the Company’s ANDA relating to Dextromethorphan/Quinidine Capsules, 20 mg/10 mg, generic of Nuedexta. The Company filed an answer and counterclaims on October 10, 2012. A claim construction hearing was conducted on October 5, 2012. Discovery is proceeding, and trial is scheduled for September 9, 2013.

### *GlaxoSmithKline LLC, et al. v. Impax Laboratories, Inc., et al. (Dutasteride/Tamsulosin)*

In September 2011, GlaxoSmithKline LLC and SmithKline Beecham Corp. filed suit against the Company in the U.S. District Court for the District of Delaware alleging patent infringement based on the filing of the Company’s ANDA relating to Dutasteride/Tamsulosin Capsules, 0.5 mg/0.4 mg, generic of Jalyn<sup>®</sup>. The Company filed an answer and counterclaim. The trial court issued a claim construction ruling on November 15, 2012. A bench trial was conducted starting on January 28, 2013, and a decision is pending.

## 17. LEGAL AND REGULATORY MATTERS (continued)

### *Cephalon, Inc. et al. v. Impax Laboratories, Inc. (Fentanyl Citrate)*

In November 2011, Cephalon, Inc. and CIMA Labs, Inc. (together “Cephalon”) filed suit against the Company in the U.S. District Court for the District of Delaware, alleging patent infringement of U.S. Patent Nos. 6,200,604, 6,974,590, 7,862,832, and 7,862,833, based on the filing of the Company’s ANDA relating to Fentanyl Citrate Buccal Tablets, 100, 200, 400, 600, and 800 mcg, generic to Fentora<sup>®</sup>. The Company filed an answer and counterclaims, as well as declaratory judgment counterclaims to include three other patents (U.S. Patent Nos. 6,264,981; 8,092,832; and 8,119,158). In response, Cephalon alleged infringement of those three patents against the Company. The Company also filed a supplemental counterclaim seeking declaratory judgment regarding U.S. Patent No. 8,119,158. The claims for infringement of U.S. Patent Nos. 6,200,604 and 6,974,590 were subsequently dismissed based on a judgment of invalidity in another case. That decision of invalidity was reversed on appeal. Discovery is ongoing, and trial is scheduled for June 24, 2013.

### *Acura Pharmaceuticals, Inc. v. Impax Laboratories, Inc. (Oxycodone HCl)*

In October 2012, Acura Pharmaceuticals, Inc., filed suit against the Company in the U.S. District Court for the District of Delaware alleging patent infringement for the filing of the Company’s ANDA relating to Oxycodone Hydrochloride Tablets, 5 mg and 7.5 mg, generic to Oxecta<sup>®</sup>. In November 2012, the Company filed its answer and counterclaims. Trial is scheduled for October 27, 2014.

### *Endo Pharmaceuticals Inc. and Grunenthal GmbH v. Impax Laboratories, Inc. and ThoRx Laboratories, Inc. (Oxymorphone hydrochloride); Endo Pharmaceuticals Inc. and Grunenthal GmbH v. Impax Laboratories, Inc. (Oxymorphone hydrochloride)*

In November 2012, Endo Pharmaceuticals, Inc. and Grunenthal GmbH (collectively, “Endo”) filed suit against ThoRx Laboratories, Inc., a wholly owned subsidiary of the Company (“ThoRx”), and the Company in the U.S. District Court for the Southern District of New York alleging patent infringement based on the filing of ThoRx’s ANDA relating to Oxymorphone Hydrochloride, Extended Release tablets, 5, 7.5, 10, 15, 20, 30 and 40 mg, generic to Opana ER<sup>®</sup>. In January 2013, Endo filed a separate suit against the Company in the U.S. District Court for the Southern District of New York alleging patent infringement based on the filing of the Company’s ANDA relating to the same products. ThoRx and the Company filed an answer and counterclaims to the November 2012 suit and the Company filed an answer and counterclaims with respect to the January 2013 suit. No trial dates have been set.

### *Purdue Pharma L.P., The P.F. Laboratories, Inc., Purdue Pharmaceuticals L.P. and Rhodes Technologies v. Impax Laboratories, Inc. (Oxycodone HCl)*

In January 2013, Purdue Pharma L.P., The P.F. Laboratories, Inc., Purdue Pharmaceuticals L.P. and Rhodes Technologies (collectively “Purdue”) filed suit against the Company in the U.S. District Court for the Southern District of New York alleging patent infringement based on the filing of the Company’s two ANDAs relating to Oxycodone Hydrochloride, extended-release tablets: one for 10, 15, 20, 30 and 40 mg, and one for 60 and 80 mg. The dosage forms are generic to OxyContin<sup>®</sup> (related to NDA 020553). The Company filed an answer and counterclaims in February 2013. No trial date has been set.

## 17. LEGAL AND REGULATORY MATTERS (continued)

### *Other Litigation Related to the Company's Business*

#### *Impax Laboratories, Inc. v. Shire LLC and Shire Laboratories, Inc. (generic Adderall XR<sup>®</sup>)*

On November 1, 2010, the Company filed suit against Shire LLC and Shire Laboratories, Inc. (collectively "Shire") in the Supreme Court of the State of New York, alleging breach of contract and other related claims due to Shire's failure to fill the Company's orders for the generic Adderall XR<sup>®</sup> product as required by the parties' Settlement Agreement and License and Distribution Agreement, each signed in January 2006. In November 2010, the case was removed to the U.S. District Court for the Southern District of New York by Shire based on diversity jurisdiction. The parties entered into a settlement agreement and the case was dismissed on February 14, 2013.

#### *Civil Investigative Demand from the FTC*

On May 2, 2012, the Company received a Civil Investigative Demand ("CID") from the United States Federal Trade Commission ("FTC") concerning its investigation into the drug SOLODYN<sup>®</sup> and its generic equivalents. According to the FTC, the investigation is to determine whether Medicis Pharmaceutical Corporation (now a wholly owned subsidiary of Valeant Pharmaceuticals International, Inc.), the Company, and six other companies have engaged or are engaged in unfair methods of competition in or affecting commerce by (i) entering into agreements regarding SOLODYN<sup>®</sup> or its generic equivalents and/or (ii) engaging in other conduct regarding the sale or marketing of SOLODYN<sup>®</sup> or its generic equivalents. The Company is cooperating with the FTC in producing documents and information in response to the CID. To the knowledge of the Company no proceedings have been initiated against the Company to date, however no assurance can be given as to the timing or outcome of this investigation.

#### *Securities and Derivative Class Actions*

On March 7, 2013 and April 8, 2013, two class action complaints were filed against the Company and certain current and former officers and directors of the Company in the United States District Court for the Northern District of California by Denis Mulligan, individually and on behalf of others similarly situated, and Haverhill Retirement System, individually and on behalf of others similarly situated, respectively, ("Securities Class Actions") alleging that the Company and those named officers and directors violated the federal securities law by making materially false and misleading statements and/or failed to disclose material adverse facts to the public in connection with manufacturing deficiencies at the Hayward, California manufacturing facility, including but not limited to the impact the deficiencies would have on the Company's ability to gain approval from the FDA for the Company's branded product candidate, RYTARY<sup>™</sup> and generic product Concerta. These two Securities Class Actions have subsequently been assigned to the same judge. On March 19, 2013, Virender Singh, derivatively on behalf of the Company, filed a state court action against certain current and former officers and board of directors for breach of fiduciary duty and unjust enrichment in the Superior Court of the State of California County of Santa Clara, asserting similar allegations as those in the Securities Class Actions. That action has been stayed pending resolution of the class action suit. In addition, the Company is aware of a letter from a stockholder demanding action by the Company's board of directors to: (i) undertake an independent internal investigation into management's alleged violations of Delaware and/or federal law; and (ii) commence a civil action against members of management to recover damages sustained as a result of alleged breaches of fiduciary duties. The letter further states that if such action is not commenced within a reasonable period of time, the stockholder will commence a shareholder's derivative action on behalf of the Company.

**18. SUPPLEMENTARY FINANCIAL INFORMATION** (unaudited)

Selected financial information for the quarterly periods noted is as follows:

(in \$000's except shares and per share amounts)	<b>Quarter Ended: March 31, 2013</b>
<b>Revenue:</b>	
Global Product sales, gross	\$ 197,956
Less:	
Chargebacks	64,345
Rebates	30,572
Product Returns	94
Other credits	5,160
Global Product sales, net	<u>97,785</u>
Rx Partner	3,114
Other Revenues	737
Global Division revenues, net	<u>101,636</u>
Impax Product sales, gross	69,292
Less:	
Chargebacks	7,790
Rebates	6,236
Product Returns	1,490
Other credits	7,255
Impax Product sales, net	<u>46,521</u>
Other Revenues	332
Impax Division revenues, net	<u>46,853</u>
Total revenues	<u>148,489</u>
Gross profit	57,871
Net income	<u>\$ 105,442</u>
Net income per share (basic)	<u>\$ 1.59</u>
Net income per share (diluted)	<u>\$ 1.55</u>
<b>Weighted Average:</b>	
common shares outstanding:	
Basic	<u>66,487,470</u>
Diluted	<u>68,178,355</u>

Quarterly computations of net income per share amounts are made independently for each quarterly reporting period, and the sum of the per share amounts for the quarterly reporting periods may not equal the per share amounts for the year-to-date reporting period.

**18. SUPPLEMENTARY FINANCIAL INFORMATION** (unaudited) (continued)

Selected financial information for the quarterly periods noted is as follows:

(in \$000's except shares and per share amounts)	<b>Quarter Ended: March 31, 2012</b>
<b>Revenue:</b>	
Global Product sales, gross	\$ 185,671
Less:	
Chargebacks	39,155
Rebates	20,589
Product Returns	(329)
Other credits	10,045
Global Product sales, net	<u>116,211</u>
Rx Partner	2,978
Other Revenues	4,076
Global Division revenues, net	<u>123,265</u>
Impax Product sales, gross	--
Less:	
Chargebacks	--
Rebates	--
Product Returns	--
Other credits	--
Impax Product sales, net	--
Other Revenues	5,303
Impax Division revenues, net	<u>5,303</u>
Total revenues	<u>128,568</u>
Gross profit	62,553
Net income	<u>\$ 12,365</u>
Net income per share (basic)	<u>\$ 0.19</u>
Net income per share (diluted)	<u>\$ 0.18</u>
<b>Weighted Average:</b>	
common shares outstanding:	
Basic	<u>65,122,240</u>
Diluted	<u>67,907,263</u>

Quarterly computations of net income per share amounts are made independently for each quarterly reporting period, and the sum of the per share amounts for the quarterly reporting periods may not equal the per share amounts for the year-to-date reporting period.

## 19. SUBSEQUENT EVENTS

In April 2013, the Company and GlaxoSmithKline plc (“GSK”) announced that they were terminating their collaboration for the development and commercialization of IPX066 outside the United States and Taiwan and terminated the License, Development and Commercialization Agreement. Under the terms of the agreement entered into in December 2010, GSK’s right to develop and commercialize IPX066 outside the United States and Taiwan will transfer back to Impax, effective at the end of July 2013. The decision was reached due to delays in the anticipated regulatory approval and launch dates in countries in which GSK has rights to commercialize the product.

## **ITEM 2. Management’s Discussion and Analysis of Results of Operations and Financial Condition**

The following discussion and analysis, as well as other sections in this Quarterly Report on Form 10-Q, should be read in conjunction with the unaudited interim consolidated financial statements and related notes to the unaudited interim consolidated financial statements included elsewhere herein.

Statements included in this Quarterly Report on Form 10-Q not related to present or historical conditions are “forward-looking statements.” Such forward-looking statements involve risks and uncertainties which could cause results or outcomes to differ materially from those expressed in the forward-looking statements. Forward-looking statements may include statements relating to our plans, strategies, objectives, expectations and intentions. Words such as “believes,” “forecasts,” “intends,” “possible,” “estimates,” “anticipates,” “plans,” “will,” “should,” “could” and similar expressions are intended to identify forward-looking statements. Our ability to predict results or the effect of events on our operating results is inherently uncertain. Forward-looking statements involve a number of risks, uncertainties and other factors that could cause actual results to differ materially from those discussed in this Quarterly Report on Form 10-Q. Such risks and uncertainties include the effect of current economic conditions on our industry, business, financial position and results of operations, fluctuations in our revenues and operating income, our ability to promptly correct the issues raised in the warning letter and Form 483 observations received from the FDA, our 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 our customer base, the impact of competition, our ability to sustain profitability and positive cash flows, any delays or unanticipated expenses in connection with the operation of our Taiwan facility, the effect of foreign economic, political, legal and other risks on our operations abroad, the uncertainty of patent litigation, the increased government scrutiny on our 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 our products, the difficulty of predicting FDA filings and approvals, our ability to achieve returns on our investments in research and development activities, our inexperience in conducting clinical trials and submitting new drug applications, our inexperience in conducting clinical trials and submitting new drug applications, our ability to successfully conduct clinical trials, our reliance on third parties to conduct clinical trials and testing, the impact of illegal distribution and sale by third parties of counterfeits or stolen products, the availability of raw materials and impact of interruptions in our supply chain, the use of controlled substances in our products, disruptions or failures in our information technology systems and network infrastructure, our reliance on alliance and collaboration agreements, our dependence on certain employees, our ability to comply with legal and regulatory requirements governing the healthcare industry, the regulatory environment, our ability to protect our intellectual property, exposure to product liability claims, changes in tax regulations, our ability to manage our growth, including through potential acquisitions, the restrictions imposed by our credit facility, uncertainties involved in the preparation of our financial statements, our ability to maintain an effective system of internal control over financial reporting, any manufacturing difficulties or delays, the effect of terrorist attacks on our business, the location of our manufacturing and research and development facilities near earthquake fault lines, and other risks described herein and in our Annual Report on Form 10-K for the year ended December 31, 2012. You should not place undue reliance on forward-looking statements. Such statements speak only as to the date on which they are made, and we undertake no obligation to update or revise any forward-looking statement, regardless of future developments or availability of new information, except to the extent required by applicable law.

RYTARY™ is a trademark of Impax Laboratories, Inc. Other names are for informational purposes only and are used to identify companies and products and may be trademarks of their respective owners.

## Overview

We are a technology based, specialty pharmaceutical company applying formulation and development expertise, as well as our drug delivery technology, to the development, manufacture and marketing of controlled-release and niche generics, in addition to the development of branded products. We operate in two segments, referred to as the “Global Pharmaceuticals Division” or “Global Division” and the “Impax Pharmaceuticals Division” or “Impax Division.” The Global Division concentrates its efforts on the development, manufacture, sale and distribution of our generic products, which are the pharmaceutical and therapeutic equivalents of brand-name drug products and are usually marketed under their established nonproprietary drug names rather than by a brand name. The Impax Division is currently focused on the development of proprietary brand pharmaceutical products that we believe represent improvements to already-approved pharmaceutical products addressing central nervous system (“CNS”) disorders. The Impax Division is also engaged in the sale and distribution of Zomig<sup>®</sup> (zolmitriptan) products, indicated for the treatment of migraine headaches, under the terms of a Distribution, License, Development and Supply Agreement (“AZ Agreement”) with AstraZeneca UK Limited (“AstraZeneca”) in the United States and in certain U.S. territories. Each of the Global Division and the Impax Division also generates revenue from research and development services provided to unrelated third-party pharmaceutical entities .

We plan to continue to expand our Global Division through targeted ANDAs and a first-to-file and first-to-market strategy and to continue to evaluate and pursue external growth initiatives, including acquisitions and partnerships. We focus our efforts on developing, manufacturing, selling and distributing controlled-release generic versions of selected brand-name pharmaceuticals covering a broad range of therapeutic areas and having technically challenging drug-delivery mechanisms or unique product formulations. We employ our technologies and formulation expertise to develop generic products that reproduce brand-name products’ physiological characteristics but do not infringe any valid patents relating to such brand-name products. Generic products contain the same active ingredient and are of the same route of administration, dosage form, strength and indication(s) as brand-name products already approved for use in the United States by the FDA. We generally focus our generic product development on brand-name products as to which the patents covering the active pharmaceutical ingredient have expired or are near expiration, and we employ our proprietary formulation expertise to develop controlled-release technologies that do not infringe patents covering the brand-name products’ controlled-release technologies. We also develop, manufacture, sell and distribute specialty generic pharmaceuticals that we believe present one or more competitive advantages, such as difficulty in raw materials sourcing, complex formulation or development characteristics or special handling requirements. Our Global Division also generates revenues from research and development services provided under a joint development agreement with an unrelated third-party pharmaceutical entity. In addition to our focus on solid oral dosage products, we have expanded our generic pharmaceutical products portfolio to include alternative dosage form products, primarily through alliance and collaboration agreements with third parties, such as our development, supply and distribution agreement with TOLMAR, Inc. (“Tolmar”) pursuant to which we received an exclusive license to commercialize up to 11 generic topical prescription drug products, including nine currently approved products and two products pending at the FDA, in the United States and its territories.

We sell and distribute generic pharmaceutical products primarily through four sales channels:

- the “*Global Product*” sales channel: generic pharmaceutical prescription products we sell directly to wholesalers, large retail drug chains, and others;
- the “*Private Label*” sales channel : generic pharmaceutical over-the-counter (“OTC”) and prescription products we sell to unrelated third parties who in-turn sell the product under their own label;
- the “*Rx Partner*” sales channel : generic prescription products sold through unrelated third-party pharmaceutical entities pursuant to alliance and collaboration agreements; and
- the “*OTC Partner*” sales channel : sales of generic pharmaceutical OTC products sold through an unrelated third-party pharmaceutical entity pursuant to an alliance and collaboration agreement.

As of April 26, 2013, we marketed 127 generic pharmaceutical products representing dosage variations of 37 different pharmaceutical compounds through our Global Division, and 14 other generic pharmaceutical products, representing dosage variations of four different pharmaceutical compounds, through our alliance and collaboration agreement partners. As of April 26, 2013, our marketed generic products included, but are not limited to, authorized generic Adderall XR<sup>®</sup>, Fenofibrate (generic to Lofibra<sup>®</sup>) and Oxymorphone HCl ER (generic to Opana<sup>®</sup> ER).

The Impax Division is focused on developing proprietary branded pharmaceutical products for the treatment of CNS disorders, which include epilepsy, migraine, multiple sclerosis and Parkinson's disease, and the promotion and sale of branded pharmaceutical products through our specialty sales force. We believe that we have the research, development and formulation expertise to develop branded products that will deliver significant improvements over existing therapies.

Our branded pharmaceutical product portfolio consists of commercial CNS products and development stage projects. In February 2012, we licensed from AstraZeneca the exclusive U.S. commercial rights to Zomig<sup>®</sup> (zolmitriptan) tablet, orally disintegrating tablet, and nasal spray formulations pursuant to the terms of the AZ Agreement, and began sales of the Zomig<sup>®</sup> products under our label during the year ended December 31, 2012 through our specialty sales force. As part of the AZ Agreement, we also have non-exclusive rights to develop new products containing zolmitriptan and to exclusively commercialize these products in the United States in connection with the Zomig<sup>®</sup> brand. With the addition of Zomig<sup>®</sup> to the promotional product portfolio, we increased our specialty sales team during 2012.

In the development of our pipeline products, we apply formulation and development expertise to develop differentiated, modified, or controlled-release versions of drug substances that are currently marketed either in the U.S. or outside the U.S. We currently have one late-stage branded pharmaceutical product candidate which we are developing internally, RYTARY<sup>™</sup> (IPX066) for the treatment of symptomatic Parkinson's disease, for which an NDA was accepted for filing by the FDA in February 2012. In January 2013, the FDA issued a Complete Response Letter regarding the NDA for RYTARY<sup>™</sup>. A Complete Response Letter is issued by the FDA's Center for Drug Evaluation and Research when the review cycle for a pharmaceutical product candidate is complete and the application is not yet ready for approval. In the Complete Response Letter, the FDA indicated that it required a satisfactory re-inspection of our Hayward manufacturing facility as a result of the warning letter issued to us in May 2011 before the NDA may be approved by the FDA due to the facility's involvement in the development of RYTARY<sup>™</sup> and supportive manufacturing and distribution activities. During the assessment of the NDA, we withdrew our Hayward site as an alternative site of commercial production at launch for RYTARY<sup>™</sup>. We are currently working with the FDA on the appropriate next steps for the RYTARY<sup>™</sup> NDA and on resolving the warning letter.

Our branded product pharmaceutical programs in our Impax Division previously included a program for IPX159, an oral controlled-release formulation for the potential treatment of moderate to severe Restless Legs Syndrome ("RLS"). After a review of the results from the Phase IIb clinical study of IPX159 in patients, we determined that although the results showed a modest improvement in addressing RLS symptoms, such results from the study did not achieve the statistical criteria for its primary efficacy endpoints compared to placebo. Give these results, in mid-February 2013, we discontinued our development program for IPX159 and redirected our resources to our other programs. We also have a number of other product candidates that are in varying stages of development. We intend to expand our portfolio of branded pharmaceutical products through internal development and through licensing and acquisition.

We have entered into several alliance and collaboration agreements with respect to certain of our products and services and may enter into similar agreements in the future. These agreements typically obligate us to deliver multiple goods and/or services over extended periods. Such deliverables include manufactured pharmaceutical products, exclusive and semi-exclusive marketing rights, distribution licenses, and research and development services. Our alliance and collaboration agreements often include milestones and provide for milestone payments upon achievement of these milestones. For more information about the types of milestone events in our agreements and how we categorize them, see "Item 1. Financial Statements — Note 12 to Interim Consolidated Financial Statements."

Pursuant to a license and distribution agreement, we are dependent on a third-party pharmaceutical company to supply us with our authorized generic Adderall XR<sup>®</sup>, which we market and sell. We experienced disruptions related to the supply of our authorized generic Adderall XR<sup>®</sup> from this third-party pharmaceutical company. In November 2010, we filed suit against the third-party supplier of our authorized generic of Adderall XR<sup>®</sup> for breach of contract and other related claims due to a failure to fill our orders as required by the license and distribution agreement. We entered into a settlement agreement and an amended and restated license and distribution agreement with the third party supplier in February 2013. If we suffer supply disruptions related to our authorized generic Adderall XR<sup>®</sup> product in the future, our revenues and relationships with our customers may be materially adversely affected. Further, we may enter into similar license and distribution agreements in the future.

## *Quality Control*

In late May 2011, we received a warning letter from the FDA related to an on-site FDA inspection of our Hayward, California manufacturing facility conducted between December 13, 2010 and January 21, 2011. In the warning letter, the FDA cited deviations from current Good Manufacturing Practices (cGMP), which are extensive regulations governing manufacturing practices for finished pharmaceutical products and which establish requirements for manufacturing processes, stability testing, record keeping and quality standards and controls. In summary, the FDA observations set forth in the warning letter related to sampling and testing of in-process materials and drug products, production record review, and our process for investigating the failure of certain manufacturing batches (or portions of batches) to meet specifications.

During the quarter ended March 31, 2012 and the quarter ended March 31, 2013, the FDA conducted inspections of our Hayward manufacturing facility and at the conclusion of each inspection, we received a Form 483. The Form 483 issued in 2012 contained observations primarily relating to our Quality Control Laboratory and the Form 483 issued during the quarter ended March 31, 2013 contained several observations pertaining to the operations of the Hayward facility, three of which were designated by the FDA as repeat observations from inspections that occurred prior to the warning letter. After the issuance of the Form 483 in 2012, we were notified by the FDA that a satisfactory re-inspection of our Hayward manufacturing facility would be required to close out the warning letter. Since our receipt of the warning letter in late May 2011 to date, we have provided the FDA with written responses and subsequent updates in connection with the warning letter and the Form 483 observations and have continued to cooperate with the FDA to resolve the warning letter and the Form 483 observations. The FDA observations do not currently place restrictions on our ability to manufacture and ship our products.

We have taken a number of steps to thoroughly review our quality control and manufacturing systems and standards and are working with several third-party experts to assist us with our review and assist in enhancing such systems and standards. This work is ongoing and we are committed to improving our quality control and manufacturing practices. We cannot be assured, however, that the FDA will be satisfied with our corrective actions and as such, we cannot be assured of when the warning letter will be closed out. Unless and until the warning letter is closed out, it is possible we may be subject to additional regulatory action by the FDA as a result of the current or future FDA observations, including, among others, monetary sanctions or penalties, product recalls or seizure, injunctions, total or partial suspension of production and/or distribution, and suspension or withdrawal of regulatory approvals. Additionally, the FDA has withheld and may continue to withhold approval of pending drug applications listing our Hayward, California facility as a manufacturing location of finished dosage forms until these FDA observations are resolved. Further, other federal agencies, our customers and partners in our alliance, development, collaboration and other partnership agreements with respect to our products and services may take the warning letter into account when considering the award of contracts or the continuation or extension of such partnership agreements. If we are unable to promptly correct the issues raised in the warning letter, our business, consolidated results of operations and consolidated financial condition could be materially adversely affected.

### *Critical Accounting Estimates*

The preparation of our consolidated financial statements in accordance with accounting principles generally accepted in the United States (“GAAP”) and the rules and regulations of the U.S. Securities & Exchange Commission (“SEC”) require the use of estimates and assumptions, based on complex judgments considered reasonable, and affect the reported amounts of assets and liabilities and disclosure of contingent assets and contingent liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. The most significant judgments are employed in estimates used in determining values of tangible and intangible assets, legal contingencies, tax assets and tax liabilities, fair value of share-based compensation related to equity incentive awards issued to employees and directors, and estimates used in applying the Company’s revenue recognition policy including those related to accrued chargebacks, rebates, distribution service fees, product returns, Medicare, Medicaid, and other government rebate programs, shelf-stock adjustments, and the timing and amount of deferred and recognized revenue and deferred and amortized manufacturing costs under the Company's several alliance and collaboration agreements. Actual results may differ from estimated results. Certain prior year amounts have been reclassified to conform to the current year presentation.

Although we believe our estimates and assumptions are reasonable when made, they are based upon information available to us at the time they are made. We periodically review the factors having an influence on our estimates and, if necessary, adjust such estimates. Although historically our estimates have generally been reasonably accurate, due to the risks and uncertainties involved in our business and evolving market conditions, and given the subjective element of the estimates made, actual results may differ from estimated results. This possibility may be greater than normal during times of pronounced economic volatility.

*Global Product sales, net, and Impax Product sales, net.* We recognize revenue from direct sales in accordance with SEC Staff Accounting Bulletin No. 104, Topic 13 "Revenue Recognition" (“SAB 104”). We recognize revenue from direct product sales at the time title and risk of loss pass to customers, which is generally when product is received by the customer. We establish accrued provisions for estimated chargebacks, rebates, distribution service fees, product returns, shelf-stock and other pricing adjustments in the period we record the related sales.

Consistent with industry practice, we record an accrued provision for estimated deductions for chargebacks, rebates, distribution service fees, product returns, Medicare, Medicaid, and other government rebate programs, shelf-stock adjustments, and other pricing adjustments, in the same period when revenue is recognized. The objective of recording provisions for these deductions at the time of sale is to provide a reasonable estimate of the aggregate amount we expect to ultimately credit our customers. Since arrangements giving rise to the various sales credits are typically time driven (i.e. particular promotions entitling customers who make purchases of our products during a specific period of time, to certain levels of rebates or chargebacks), these deductions represent important reductions of the amounts those customers would otherwise owe us for their purchases of those products. Customers typically process their claims for deductions in a reasonably timely manner, usually within the established payment terms. We monitor actual credit memos issued to our customers and compare actual amounts to the estimated provisions, in the aggregate, for each deduction category to assess the reasonableness of the various reserves at each quarterly balance sheet date. Differences between our estimated provisions and actual credits issued have not been significant, and are accounted for in the current period as a change in estimate in accordance with GAAP. We do not have the ability to specifically link any particular sales credit to an exact sales transaction and since there have been no material differences, we believe our systems and procedures are adequate for managing our business. An event such as the failure to report a particular promotion could result in a significant difference between the estimated amount accrued and the actual amount claimed by the customer, and, while there have been none to date, we would evaluate the particular events and factors giving rise to any such significant difference in determining the appropriate accounting.

*Chargebacks.* We have agreements establishing contract prices for specified products with some of our indirect customers, such as managed care organizations, hospitals, and government agencies who purchase our products from drug wholesalers. The contract prices are lower than the prices the customer would otherwise pay to the wholesaler, and the difference is referred to as a chargeback, which generally takes the form of a credit memo issued by us to reduce the gross sales amount we invoiced to our wholesaler customer. We recognize an estimated accrued provision for chargeback deductions at the time we ship the products to our wholesaler customers. The primary factors we consider when estimating the accrued provision for chargebacks are the average historical chargeback credits given, the mix of products shipped, and the amount of inventory on hand at the major drug wholesalers with whom we do business. We monitor aggregate actual chargebacks granted and compare them to the estimated accrued provision for chargebacks to assess the reasonableness of the chargeback reserve at each quarterly balance sheet date. The following table is a roll-forward of the activity in the chargeback reserve for the three months ended March 31, 2013 and the year ended December 31, 2012:

	<u>March 31,</u> <u>2013</u>	<u>December 31,</u> <u>2012</u>
	(\$ in 000's)	
<b><u>Chargeback reserve</u></b>		
Beginning balance	\$ 18,410	\$ 22,161
Provision recorded during the period	72,135	209,452
Credits issued during the period	<u>(73,544)</u>	<u>(213,203)</u>
Ending balance	<u>\$ 17,001</u>	<u>\$ 18,410</u>
Provision as a percent of gross product sales	27%	22%

As noted in the table above, the provision for chargebacks, as a percent of gross product sales, increased 5% during the three month period ended March 31, 2013 as a result of changes in the estimated provision for chargebacks related to our Impax-labeled Zomig® products which we commenced selling during 2012, based on the availability of actual historical data.

*Rebates.* In an effort to maintain a competitive position in the marketplace and to promote sales and customer loyalty, we maintain various rebate programs with our customers to whom we market our products through our Global Division Global Products sales channel. The rebates generally take the form of a credit memo to reduce the invoiced gross sales amount charged to a customer for products shipped. We recognize an estimated accrued provision for rebate deductions at the time of product shipment. The primary factors we consider when estimating the provision for rebates are the average historical experience of aggregate credits issued, the mix of products shipped and the historical relationship of rebates as a percentage of total gross product sales, the contract terms and conditions of the various rebate programs in effect at the time of shipment, and the amount of inventory on hand at the major drug wholesalers with which we do business. We also monitor aggregate actual rebates granted and compare them to the estimated aggregate provision for rebates to assess the reasonableness of the aggregate rebate reserve at each quarterly balance sheet date. The following table is a roll-forward of the activity in the rebate reserve for the three months ended March 31, 2013 and the year ended December 31, 2012:

	<u>March 31,</u> <u>2013</u>	<u>December 31,</u> <u>2012</u>
	(\$ in 000's)	
<b><u>Rebate reserve</u></b>		
Beginning balance	\$ 46,011	\$ 29,164
Provision recorded during the period	36,808	111,099
Credits issued during the period	<u>(34,552)</u>	<u>(94,252)</u>
Ending balance	<u>\$ 48,267</u>	<u>\$ 46,011</u>
Provision as a percent of gross product sales	14%	12%

As noted in the table above, the provision for rebates, as a percent of gross product sales, increased during the three month period ended March 31, 2013 as a result of product sales mix, as well as higher levels of rebates offered on our authorized generic Adderall XR® products.

*Returns.* We allow our customers to return product (i) if approved by authorized personnel in writing or by telephone with the lot number and expiration date accompanying any request and (ii) if such products are returned within six months prior to, or until twelve months following, the products' expiration date. We estimate and recognize an accrued provision for product returns as a percentage of gross sales based upon historical experience of product sales. We estimate the product return reserve using a historical lag period, which is the time between when the product is sold and when it is ultimately returned, and return rates, adjusted by estimates of the future return rates based on various assumptions, which may include changes to internal policies and procedures, changes in business practices, and commercial terms with customers, competitive position of each product, amount of inventory in the wholesaler supply chain, the introduction of new products and changes in market sales information. We also consider other factors, including significant market changes which may impact future expected returns, and actual product returns. We monitor aggregate actual product returns on a quarterly basis and we may record specific provisions for product returns we believe are not covered by historical percentages. The following table is a roll-forward of the activity in the product returns reserve for the three months ended March 31, 2013 and the year ended December 31, 2012:

	<u>March 31,</u> <u>2013</u>	<u>December 31,</u> <u>2012</u>
	(\$ in 000's)	
<b><u>Returns reserve</u></b>		
Beginning balance	\$ 23,440	\$ 24,101
Provision related to sales recorded in the period	1,584	3,003
Credits issued during the period	<u>(1,073)</u>	<u>(3,664)</u>
Ending balance	<u>\$ 23,951</u>	<u>\$ 23,440</u>
Provision as a percent of gross product sales	0.6%	0.3%

As noted in the table above, the provision for returns as a percent of gross product sales remained relatively consistent during the three month period ended March 31, 2013, as compared to the prior year period. Our historical experience for returns has continued to remain low in recent years due to low levels of returns for certain of our high volume products such as our fenofibrate products.

*Medicaid and Other Government Pricing Programs.* As required by law, we provide a rebate payment on drugs dispensed under the Medicaid, Medicare Part D, TRICARE, and other U.S. government pricing programs. We determine our estimate of the accrued rebate reserve for government programs primarily based on historical experience of claims submitted by the various states, and other jurisdictions, and any new information regarding changes in the pricing programs which may impact our estimate of rebates. In determining the appropriate accrual amount, we consider historical payment rates and processing lag for outstanding claims and payments. We record estimates for government rebate payments as a deduction from gross sales, with corresponding adjustments to accrued liabilities. The accrual for payments under government pricing programs totaled \$25,097,000 and \$33,794,000 as of March 31, 2013 and December 31, 2012, respectively. The decrease from the prior year period is primarily the result of a lower portion of our sales coming from Medicaid patients.

*Shelf-Stock Adjustments.* Based upon competitive market conditions, we may reduce the selling price of some of our products to customers for certain future product shipments. We may issue a credit against the sales amount to a customer based upon their remaining inventory of the product in question, provided the customer agrees to continue to make future purchases of product from us. This type of customer credit is referred to as a shelf-stock adjustment, which is the difference between the sales price and the revised lower sales price, multiplied by an estimate of the number of product units on hand at a given date. Decreases in selling prices are discretionary decisions made by us in response to market conditions, including estimated launch dates of competing products and estimated declines in market price. The accrued reserve for shelf-stock adjustments totaled \$413,000 and \$390,000 as of March 31, 2013 and December 31, 2012, respectively.

*Rx Partner and OTC Partner.* Each of our Rx Partner and OTC Partner agreements involves multiple deliverables in the form of products, services and/or licenses over extended periods. Financial Accounting Standards Board (“FASB”) Accounting Standards Codification™ (“ASC”) Topic 605-25 supplemented SAB 104 providing guidance for accounting for such multiple-element revenue arrangements. With respect to our multiple-element revenue arrangements, we determine whether any or all of the elements of the arrangement should be separated into individual units of accounting under FASB ASC Topic 605-25. If separation into individual units of accounting is appropriate, we recognize revenue for each deliverable when the revenue recognition criteria specified by SAB 104 are achieved for the deliverable. If separation is not appropriate, we recognize revenue and related direct manufacturing costs over the estimated life of the agreement or our estimated expected period of performance using either the straight-line method or a modified proportional performance method.

The Rx Partners and OTC Partners agreements obligate us to deliver multiple goods and/or services over extended periods. Such deliverables include manufactured pharmaceutical products, exclusive and semi-exclusive marketing rights, distribution licenses, and research and development services. In exchange for these deliverables, we receive payments from our agreement partners for product shipments and research and development services, and may also receive other payments including royalty, profit sharing, upfront payments, and periodic milestone payments. Revenue received from our partners for product shipments under these agreements is generally not subject to deductions for chargebacks, rebates, product returns, and other pricing adjustments. Royalty and profit sharing amounts we receive under these agreements are calculated by the respective agreement partner, with such royalty and profit share amounts generally based upon estimates of net product sales or gross profit which include estimates of deductions for chargebacks, rebates, product returns, and other adjustments the alliance agreement partners may negotiate with their customers. We record the agreement partner's adjustments to such estimated amounts in the period the agreement partner reports the amounts to us.

We apply the updated guidance of ASC 605-25, “Multiple Element Arrangements”, to the Strategic Alliance Agreement with Teva Pharmaceuticals Curacao N.V., a subsidiary of Teva Pharmaceutical Industries Ltd. (“Teva Agreement”). We look to the underlying delivery of goods and/or services which give rise to the payment of consideration under the Teva Agreement to determine the appropriate revenue recognition. Consideration received as a result of research and development-related activities performed under the Teva Agreement is initially deferred and recorded as a liability captioned “Deferred revenue”. We recognize the deferred revenue on a straight-line basis over our expected period of performance for such services. Consideration received as a result of the manufacture and delivery of products under the Teva Agreement is recognized at the time title and risk of loss passes to the customer which is generally when the product is received by Teva. We recognize profit share revenue in the period earned.

OTC Partner revenue is related to our alliance and collaboration agreement with Pfizer Inc. (formerly Wyeth) with respect to the supply of over-the-counter pharmaceutical products. The OTC Partner sales channel is no longer a core area of our business, and the over-the-counter pharmaceutical products we sell through this sales channel are older products which are only sold to Pfizer, and which we sell at a loss. The manufacturing of the over-the-counter pharmaceutical products is our only continuing obligation under this agreement with Pfizer. In order to avoid deferring the losses we incur upon shipment of these products to Pfizer, Inc., we recognize revenue, and the associated manufacturing costs, at the time title and risk of loss passes to Pfizer which is generally when the product is shipped by us. We recognize profit share revenue in the period earned.

*Research Partner* . We have entered into development agreements with unrelated third-party pharmaceutical companies under which we are collaborating in the development of five dermatological products, including four generic products and one branded dermatological product, and one branded CNS product. Under each of the development agreements, we received an upfront fee with the potential to receive additional milestone payments upon completion of contractually specified clinical and regulatory milestones. Additionally, we may also receive royalty payments from the sale, if any, of a successfully developed and commercialized branded product under one of the development agreements. We defer and recognize revenue received from the provision of research and development services, including the upfront payment and the milestone payments received before January 1, 2011 on a straight line basis over the expected period of performance of the research and development services. We recognize revenue received from the achievement of contingent research and development milestones after January 1, 2011 currently in the period such payment is earned. We will recognize royalty fee income, if any, as current period revenue when earned.

*Promotional Partner* . We entered into a promotional services agreement with an unrelated third-party pharmaceutical company under which we provided physician detailing sales calls services to promote certain of the unrelated third-party company's branded drug products. We received service fee revenue in exchange for providing this service. We recognized revenue from the provision of physician detailing sales calls as such services were rendered. Our obligations to provide physician detailing sales calls under the promotional services agreement ended on June 30, 2012.

*Estimated Lives of Alliance and Collaboration Agreements.* The revenue we receive under our alliance and collaboration agreements is not subject to adjustment for estimated chargebacks, rebates, product returns and other pricing adjustments as such adjustments are included in the amounts we receive from our alliance partners. However, because we may defer revenue we receive under our alliance agreements, and recognize it over the estimated life of the related agreement, or our expected period of performance, we are required to estimate the recognition period under each such agreement in order to determine the amount of revenue to be recognized in each period. Sometimes this estimate is based on the fixed term of the particular alliance agreement. In other cases the estimate may be based on more subjective factors as noted in the following paragraphs. While changes to the estimated recognition periods have been infrequent, such changes, should they occur, may have a significant impact on our consolidated financial statements.

As an illustration, the consideration received from the provision of research and development services under the Joint Development Agreement with Valeant Pharmaceuticals International, Inc. (“Valeant Agreement”), including the upfront fee and milestone payments received before January 1, 2011, have been initially deferred and are being recognized as revenue on a straight-line basis over our expected period of performance to provide research and development services under the Valeant Agreement. The completion of the final deliverable under the Valeant Agreement represents the end of our estimated expected period of performance, as we will have no further contractual obligation to perform research and development services under the Valeant Agreement, and therefore the earnings process will be complete. The expected period of performance was initially estimated to be a 48 month period, starting in December 2008, upon receipt of the \$40.0 million upfront payment, and ending in November 2012. During the year ended December 31, 2012, we extended the end of the revenue recognition period for the Valeant Agreement from November 2012 to November 2013 and during the three month period ended March 31, 2013, we further extended the end of the revenue recognition period for the agreement from November 2013 to December 2014 due to changes in the estimated timing of completion of certain research and development activities under the agreement. This change in estimate was made on a prospective basis and resulted in a reduced amount of revenue recognized in the three month period ended March 31, 2013, as compared to preceding quarters, and a reduced periodic amount of revenue to be recognized in future periods. If there are additional changes in the estimated timing of the completion of the final deliverable under the Valeant Agreement, the revenue recognition period will change on a prospective basis at such time the event occurs. If we were to further extend the revenue recognition period, the amount of revenue recognized in future periods would further reduce.

*Third-Party Research and Development Agreements.* In addition to our own research and development resources, we may use unrelated third-party vendors, including universities and independent research companies, to assist in our research and development activities. These vendors provide a range of research and development services to us, including clinical and bio-equivalency studies. We generally sign agreements with these vendors which establish the terms of each study performed by them, including, among other things, the technical specifications of the study, the payment schedule, and timing of work to be performed. Third-party researchers generally earn payments either upon the achievement of a milestone, or on a pre-determined date, as specified in each study agreement. We account for third-party research and development expenses as they are incurred according to the terms and conditions of the respective agreement for each study performed, with an accrued expense at each balance sheet date for estimated fees and charges incurred by us, but not yet billed to us. We monitor aggregate actual payments and compare them to the estimated provisions to assess the reasonableness of the accrued expense balance at each quarterly balance sheet date.

*Share-Based Compensation.* We recognize the grant date fair value of each option and restricted share over its vesting period. Options and restricted shares granted under the 2002 Plan vest over a three or four year period and have a term of ten years. We estimate the fair value of each stock option award on the grant date using the Black-Scholes-Merton option-pricing model, wherein: expected volatility is based on historical volatility of our common stock, and of a peer group for the period of time our common stock was deregistered, over the period commensurate with the expected term of the stock options. We base the expected term calculation on the “simplified” method described in SAB No. 107, Share-Based Payment and SAB No. 110, Share-Based Payment, because it provides a reasonable estimate in comparison to our actual experience. We base the risk-free interest rate on the U.S. Treasury yield in effect at the time of grant for an instrument with a maturity that is commensurate with the expected term of the stock options. The dividend yield is zero as we have never paid cash dividends on our common stock and have no present intention to pay cash dividends.

*Income Taxes.* We are subject to U.S. federal, state and local income taxes and Taiwan R.O.C. income taxes. We create a deferred tax asset, or a deferred tax liability, when we have temporary differences between the financial statement carrying values (GAAP) and the tax bases of our assets and liabilities.

We calculate our interim income tax provision in accordance with FASB ASC Topics 270 and 740. At the end of each interim period, we make an estimate of the annual U.S. domestic and foreign jurisdictions’ expected effective tax rates and apply these rates to their respective year-to-date taxable income or loss. The computation of the annual estimated effective tax rates at each interim period requires certain estimates and assumptions including, but not limited to, the expected operating income for the year, projections of the proportion of income (or loss) earned and taxed in the United States, and the various state and local tax jurisdictions, as well as tax jurisdictions outside the United States, along with permanent differences, and the likelihood of deferred tax asset utilization. The accounting estimates used to compute the provision for income taxes may change as new events occur, more experience is acquired, or additional information is obtained. The computation of the annual estimated effective tax rate includes modifications, which were projected for the year, for share-based compensation charges and federal and state research and development credits, among others. In addition, the effect of changes in enacted tax laws, rates, or tax status is recognized in the interim period in which the respective change occurs.

*Fair Value of Financial Instruments.* Our cash and cash equivalents include a portfolio of high-quality credit securities, including U.S. Government sponsored entity securities, treasury bills, corporate bonds, short-term commercial paper, and/or high rated money market funds. Our entire portfolio matures in less than one year. The carrying value of the portfolio approximated the market value at March 31, 2013. We carry our deferred compensation liability at fair value, based upon observable market values. We had no debt outstanding as of March 31, 2013. Our only remaining debt instrument at March 31, 2013 was our credit facility with Wells Fargo Bank, N.A., which would be subject to variable interest rates and principal payments should we decide to borrow under it.

*Contingencies.* In the normal course of business, we are subject to loss contingencies, such as legal proceedings and claims arising out of our business, covering a wide range of matters, including, among others, patent litigation, shareholder lawsuits, and product and clinical trial liability. In accordance with FASB ASC Topic 450 - Contingencies, we record accrued loss contingencies when it is probable a liability will be incurred and the amount of loss can be reasonably estimated and we do not recognize gain contingencies until realized.

*Goodwill.* In accordance with FASB ASC Topic 350, "Goodwill and Other Intangibles", rather than recording periodic amortization of goodwill, goodwill is subject to an annual assessment for impairment by applying a fair-value-based test. Under FASB ASC Topic 350, if the fair value of the reporting unit exceeds the reporting unit's carrying value, including goodwill, then goodwill is considered not impaired, making further analysis not required. We consider each of our Global Division and Impax Division operating segments to be a reporting unit, as this is the lowest level for each of which discrete financial information is available. We attribute the entire carrying amount of goodwill to the Global Division. We concluded the carrying value of goodwill was not impaired as of December 31, 2012, as the fair value of the Global Division exceeded its carrying value. We perform our annual goodwill impairment test in the fourth quarter of each year. We estimate the fair value of the Global Division using a discounted cash flow model for both the reporting unit and the enterprise, as well as earnings and revenue multiples per common share outstanding for enterprise fair value. In addition, on a quarterly basis, we perform a review of our business operations to determine whether events or changes in circumstances have occurred that could have a material adverse effect on the estimated fair value of the reporting unit, and thus indicate a potential impairment of the goodwill carrying value. If such events or changes in circumstances were deemed to have occurred, we would perform an interim impairment analysis, which may include the preparation of a discounted cash flow model, or consultation with one or more valuation specialists, to analyze the impact, if any, on our assessment of the reporting unit's fair value. To date, we have not deemed there to be any significant adverse changes in the legal, regulatory or business environment in which we conduct our operations.

## Results of Operations

### Three Months Ended March 31, 2013 Compared to the Three Months Ended March 31, 2012

#### Overview:

The following table sets forth our summarized, consolidated results of operations for the three month periods ended March 31, 2013 and 2012:

(in \$000's)	Three Months Ended		Increase/ (Decrease)	
	March 31, 2013	March 31, 2012		
	(unaudited)		\$	%
Total revenues	\$ 148,489	\$ 128,568	\$ 19,921	15%
Gross profit	57,871	62,553	(4,682)	(7)%
Income from operations	4,271	18,466	(14,195)	(77)%
Income before income taxes	153,720	18,634	135,086	nm
Provision for income taxes	48,278	6,269	42,009	nm
Net income	<u>\$ 105,442</u>	<u>\$ 12,365</u>	<u>\$ 93,077</u>	<u>nm</u>

*\*nm-not meaningful*

Net income for the three month period ended March 31, 2013 was \$105.4 million, an increase of \$93.1 million as compared to \$12.4 million for the three month period ended March 31, 2012. The increase was primarily attributable to a \$102 million gain in connection with the settlement of litigation under the June 2010 settlement and license agreement with Endo which we recorded as other income in the three month period ended March 31, 2013, as well as the receipt of a \$48 million payment from Shire in the three month period ended March 31, 2013, in connection with the settlement of litigation. In addition, total revenues increased as compared to the same period in 2012, primarily as a result of sales of Impax-labeled Zomig<sup>®</sup> tablets which we began selling in the three month period ended June 30, 2012, and sales of Impax-labeled Zomig<sup>®</sup> orally-disintegrating tablets and nasal spray which we began selling in the three month period ended September 30, 2012. These amounts were partially offset by decreased revenue from our Global Products and increased cost of revenues primarily as a result of inventory reserves recorded during the three month period ended March 31, 2013, both discussed below. In addition, selling, general and administrative expenses and income taxes increased in the three month period ended March 31, 2013, as compared to the prior year period. We continued to earn significant revenues and gross profit from sales of our authorized generic Adderall XR<sup>®</sup> products and fenofibrate products during the three months ended March 31, 2013, despite increased competition for such products, as discussed below. In addition, we generated significant revenues as a result of the launch of our oxymorphone hydrochloride extended-release tablets in January 2013. With respect to our authorized generic Adderall XR<sup>®</sup> products we have experienced significant declines in both market share and average net selling prices as a result of an unrelated pharmaceutical company receiving FDA approval in June 2012 for a competitor product and beginning to market their product. With respect to our fenofibrate products, in October 2012, a competitor product to our fenofibrate capsule product was approved for sale by the FDA and began being marketed. Any further diminution in the consolidated revenue and/or gross profit of our authorized generic Adderall XR<sup>®</sup> and fenofibrate products, or any of our other products, due to competition and/or product supply delays or disruptions or any other reasons in future periods may materially and adversely affect our consolidated results of operations in such future periods.

## Global Division

The following table sets forth results of operations for the Global Division for the three month periods ended March 31, 2013 and 2012:

	<b>Three Months Ended</b>		<b>Increase/ (Decrease)</b>	
	<b>March 31, 2013</b>	<b>March 31, 2012</b>	<b>\$</b>	<b>%</b>
(in \$000's)	(unaudited)			
<b>Revenues:</b>				
Global Product sales, net	\$ 97,785	\$ 116,211	\$ (18,426)	(16)%
Rx Partner	3,114	2,978	136	5%
Other Revenues	737	4,076	(3,339)	(82)%
<b>Total revenues</b>	<b>101,636</b>	<b>123,265</b>	<b>(21,629)</b>	<b>(18)%</b>
Cost of revenues	61,444	63,106	(1,662)	(3)%
<b>Gross profit</b>	<b>40,192</b>	<b>60,159</b>	<b>(19,967)</b>	<b>(33)%</b>
<b>Operating expenses:</b>				
Research and development	11,711	10,673	1,038	10%
Patent litigation expense	4,278	4,038	240	6%
Selling, general and administrative	5,043	4,317	726	17%
<b>Total operating expenses</b>	<b>21,032</b>	<b>19,028</b>	<b>2,004</b>	<b>11%</b>
<b>Income from operations</b>	<b>\$ 19,160</b>	<b>\$ 41,131</b>	<b>\$ (21,971)</b>	<b>(53)%</b>

### *Revenues*

Total revenues for the Global Division for the three month period ended March 31, 2013, were \$101.6 million, a decrease of 18% over the same period in 2012, principally resulting from the decrease in Global Product sales, net, as discussed below.

Global Product sales, net, were \$97.8 million for the three month period ended March 31, 2013, a decrease of 16% over the same period in 2012, primarily as a result of lower sales of our authorized generic Adderall XR®. With respect to such products we have experienced significant declines in both market share and average net selling prices as a result of the launch of a competitor product, as discussed above. Partially offsetting this decrease were sales of our oxymorphone hydrochloride extended-release tablets, which we launched in January 2013. Sales of our fenofibrate products remained relatively consistent period over period; however, a competitor product to our fenofibrate capsule product was approved for sale by the FDA in October 2012, and began being marketed.

Rx Partner revenues were \$3.1 million for the three month period ended March 31, 2013, a slight increase of \$0.1 million from the prior year period.

Other revenues were \$0.7 million for the three month period ended March 31, 2013, with the decrease of \$3.3 million from the prior year period primarily resulting from our extension of the revenue recognition period for the Valeant Agreement from the initial recognition period ending in November 2012, to December 2014, due to changes in the estimated timing of completion of certain research and development activities under the agreement.

### *Cost of Revenues*

Cost of revenues was \$61.4 million for the three month period ended March 31, 2013, a decrease of \$1.7 million compared to the prior year period. Cost of revenues decreased by \$1.7 million primarily as a result of a lower profit share expense related to sales of our authorized generic Adderall XR®, partially offset by inventory reserves recorded in the three month period ended March 31, 2013 for products discontinued by the Company and other reserves for pre-launch inventory due to delays caused by the warning letter.

### *Gross Profit*

Gross profit for the three month period ended March 31, 2013 was \$40.2 million, or approximately 40% of total revenues, as compared to \$60.2 million, or approximately 49% of total revenues, in the prior year period. Gross profit in the current year period decreased, on a percentage basis, when compared to gross profit in the prior year period due primarily to inventory reserves of \$6.7 million recorded in the three month period ended March 31, 2013 for products discontinued by the Company during the period.

### *Research and Development Expenses*

Total research and development expenses for the three month period ended March 31, 2013 were \$11.7 million, an increase of 10%, as compared to \$10.7 million in the prior year period. Generic research and development expenses increased \$1.0 million primarily as a result of a \$2.0 million milestone payment to a research and development partner, for which there was no similar payment made in the prior year period, partially offset by decreased expenses due to the timing of completion of other research and development projects.

### *Patent Litigation Expenses*

Patent litigation expenses for the three month period ended March 31, 2013 and 2012 were \$4.3 million and \$4.0 million, respectively. The increase in patent litigation expenses of \$0.3 million compared to the prior year period was primarily the result of legal activity related to several cases which were not present in the prior year period.

### *Selling, General and Administrative Expenses*

Selling, general and administrative expenses for the three month period ended March 31, 2013 were \$5.0 million, a 17% increase over the same period in 2012. The increase resulted primarily from increased marketing expenses.

## Impax Division

The following table sets forth results of operations for the Impax Division for the three month periods ended March 31, 2013 and 2012:

(in \$000's)	<b>Three Months Ended</b>		<b>Increase/ (Decrease)</b>	
	<b>March 31, 2013</b>	<b>March 31, 2012</b>	<b>\$</b>	<b>%</b>
	(unaudited)			
<b>Revenues:</b>				
Impax Product sales, net	\$ 46,521	\$ ---	\$ 46,521	nm
Other Revenues	332	5,303	(4,971)	(94)%
<b>Total revenues</b>	<b>46,853</b>	<b>5,303</b>	<b>41,550</b>	<b>nm</b>
<b>Cost of revenues</b>	<b>29,174</b>	<b>2,909</b>	<b>26,265</b>	<b>nm</b>
<b>Gross profit</b>	<b>17,679</b>	<b>2,394</b>	<b>15,285</b>	<b>nm</b>
<b>Operating expenses:</b>				
Research and development	7,894	8,143	(249)	(3)%
Selling, general and administrative	12,764	3,061	9,703	317%
<b>Total operating expenses</b>	<b>20,658</b>	<b>11,204</b>	<b>9,454</b>	<b>84%</b>
<b>Income (loss) from operations</b>	<b>\$ (2,979)</b>	<b>\$ (8,810)</b>	<b>\$ 5,831</b>	<b>(66)%</b>

\*nm-not meaningful

### Revenues

Total revenues for the Impax Division were \$46.9 million for the three month period ended March 31, 2013, an increase of \$41.6 million over the same period in the prior year due to sales of our Impax-labeled Zomig<sup>®</sup> tablets which we began selling during the three month period ended June 30, 2012, and our Impax-labeled Zomig<sup>®</sup> orally disintegrating tablets and nasal spray which we began selling during the three month period ended September 30, 2012. This increase was partially offset by a \$5.0 million decrease in Other Revenues. Other Revenues during the three month periods ended March 31, 2013 and 2012 included an initial \$10.0 million up-front payment we received in June 2010 under a Development and Co-Promotion Agreement with Endo Pharmaceuticals, Inc. which we are recognizing as revenue on a straight-line basis over our expected period of performance during the development period, which we currently estimate to be the 91 month period ending December 2017. Also included in other revenues for the three month period ended March 31, 2012, is an \$11.5 million up-front payment received under our License, Development and Commercialization Agreement with GSK in December 2010 which we recognized as revenue on a straight-line basis over the 24 month development period that ended in December 2012, and for which there was no similar amount recognized during the current year period. Finally, Other Revenues for the three month period ended March 31, 2012 included \$3.5 million under our Co-Promotion Agreement with Pfizer which ended on June 30, 2012.

### Cost of Revenues

Cost of revenues was \$29.2 million for the three month period ended March 31, 2013, an increase of \$26.3 million over the prior year period primarily as a result of \$24.2 million in costs related to our Impax-labeled Zomig<sup>®</sup> products which we commenced selling during 2012. In addition, as a result of the Complete Response Letter received during the current period, we recorded a \$5.0 million reserve in the three month period ended March 31, 2013 for pre-launch inventory related to RYTARY<sup>™</sup>. Partially offsetting these increases was \$2.9 million in charges related to our branded products sales force that we incurred during the three month period ended March 31, 2012, for which there were no similar amounts included in cost of revenues in the current year period. Charges for our branded products sales force 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 to Pfizer under an agreement which ended on June 30, 2012.

### Gross Profit

Gross profit for the three month period ended March 31, 2013 was \$17.7 million, an increase of \$15.3 million over the prior year period primarily resulting from the commencement of sales of our Impax-labeled Zomig<sup>®</sup> products during 2012.

*Research and Development Expenses*

Total research and development expenses for the three month period ended March 31, 2013 were \$7.9 million, a decrease of 3%, as compared to \$8.1 million in the prior year period. The decrease was principally driven by decreased expenses as a result of the completion of the Phase III studies for RYTARY™ during the year ended December 31, 2012.

*Selling, General and Administrative Expenses*

Selling, general and administrative expenses were \$12.8 million for the three month period ended March 31, 2013, an increase of \$9.7 million as compared to \$3.1 million in the prior period. The increase is primarily related to higher compensation costs of \$2.4 million related to the expansion of the sales and marketing group, \$1.8 million of higher expenses necessary to support the Zomig® launch as well as \$1.0 million in pre-launch spending for RYTARY™. In addition, we incurred \$4.1 million in charges related to our branded products sales force during the three month period ended March 31, 2013. Charges for our branded products sales force 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 to Pfizer under an agreement which ended on June 30, 2012.

## Corporate and Other

The following table sets forth corporate general and administrative expenses, as well as other items of income and expense presented below income or loss from operations for the three month periods ended March 31, 2013 and 2012:

(in \$000's)	<b>Three Months Ended</b>		<b>Increase/ (Decrease)</b>	
	<b>March 31, 2013</b>	<b>March 31, 2012</b>		
	(unaudited)		<b>\$</b>	<b>%</b>
General and administrative expenses	\$ 11,910	\$ 13,855	\$ (1,945)	(14)%
Loss from operations	(11,910)	(13,855)	1,945	14%
Other income (expense), net	149,456	(48)	149,504	nm
Interest income	276	255	21	8%
Interest expense	(283)	(39)		nm
Income (loss) before income taxes	137,539	(13,687)	151,226	nm
Provision for income taxes	\$ 48,278	\$ 6,269	\$ 42,009	nm

\*nm-not meaningful

### *General and Administrative Expenses*

General and administrative expenses for the three month period ended March 31, 2013 were \$11.9 million, a 14% decrease over the same period in 2012. The decrease was principally driven by legal expenses related to the Shire litigation in the prior period, of which there were decreased expenses in the current period, partially offset by increased personnel costs of \$1.0 million.

### *Other Income (Expense), net*

Other income, net of \$149.5 million during the three month period ended March 31, 2013 primarily resulted from a \$102 million gain in connection with the settlement of litigation under the June 2010 settlement and license agreement with Endo which we recorded as other income in the three month period ended March 31, 2013, as well as a \$48 million payment received from Shire in connection with the settlement of litigation in the three month period ended March 31, 2013. Partially offsetting this income was a \$0.9 million loss on disposal of software. In addition, we had realized exchange rate net losses of \$0.3 million on foreign currency denominated transactions during the three month period ended March 31, 2013, which were relatively consistent with the same period in 2012.

### *Interest Income*

Interest income in the three month period ended March 31, 2013 was \$0.3 million, and was relatively consistent with the same period in 2012.

### *Interest Expense*

Interest expense was \$0.3 million in the three month period ended March 31, 2013, increasing from the same period in 2012 as a result of an accrual for estimated interest related to our provision for uncertain tax positions.

### *Income Taxes*

During the three month period ended March 31, 2013, we recorded an aggregate tax provision of \$48.3 million for U.S. domestic income taxes and for foreign income taxes. In the three month period ended March 31, 2012, we recorded an aggregate tax provision of \$6.3 million for U.S. domestic income taxes and for foreign income taxes. The increase in the tax provision resulted from higher income before taxes in the three month period ended March 31, 2013 as compared to the same period in the prior year. The effective tax rate was 31% for the three month period ended March 31, 2013 and 34% for the three month period ended March 31, 2012. The decrease in the effective tax rate was primarily as a result of recording the estimated 2012 federal research and development credit, which was enacted retroactively in January 2013, in the three month period ended March 31, 2013, as well as the partial year 2013 estimated federal research and development credit recorded in the three month period ended March 31, 2013, which was not available for the same period last year due to the expiration of the credit.

## Liquidity and Capital Resources

We have historically funded our operations with the proceeds from the sale of debt and equity securities, and more recently, with cash from operations. Currently, our principal source of liquidity is cash from operations, consisting of the proceeds from the sales of our products and the provision of services.

We expect to incur significant operating expenses, including research and development activities and patent litigation expenses, for the foreseeable future. In addition, we are generally required to make cash expenditures to manufacture and/or acquire finished product inventory in advance of selling the finished product to our customers and collecting payment for such product sales, which may result in a significant use of cash. We believe our existing cash and cash equivalents and short-term investment balances, together with cash expected to be generated from operations, and our bank revolving line of credit, will be sufficient to meet our cash requirements through the next 12 months. We may seek additional financing through alliance, collaboration, and licensing agreements, as well as from the debt or equity capital markets to fund the planned capital expenditures, our research and development plans, potential acquisitions, and potential revenue shortfalls due to delays in new product introductions.

### *Cash and Cash Equivalents*

At March 31, 2013, we had \$197.6 million in cash and cash equivalents, an increase of \$55.4 million as compared to December 31, 2012. As more fully discussed below, the increase in cash and cash equivalents during the three month period ended March 31, 2013 was primarily driven by \$57.7 million of net cash provided by operating activities, partially offset by \$3.9 million of cash used in investing activities.

### *Cash Flows*

#### *Three Month Period Ended March 31, 2013 Compared to the Three Month Period Ended March 31, 2012*

Net cash provided by operating activities for the three month period ended March 31, 2013 was \$57.7 million, an increase of \$34.0 million as compared to the prior year period \$23.7 million net cash provided by operating activities. The period over period increase in net cash provided by operating activities principally resulted from the receipt of a \$48 million payment from Shire in connection with the settlement of litigation during the three month period ended March 31, 2013. The balance of accounts receivable was \$113.6 million as of March 31, 2013, resulting in a \$21.4 million use of cash for the three month period ended March 31, 2013, compared to the same period in the prior year when accounts receivable resulted in a \$34.6 million source of cash.

Net cash used in investing activities for the three month period ended March 31, 2013, was \$3.9 million, compared to the prior year period of \$57.8 million of net cash provided by investing activities. The change was due primarily to a period over period \$85.5 million decrease in cash provided by net maturities of short-term investments, partially offset by a \$25.0 million payment to AstraZeneca in the three month period ended March 31, 2012, for which there was no corresponding payment in the current period. Net maturities of short-term investments during the three month period ended March 31, 2013 resulted in a \$5.5 million source of cash, as compared to a \$91.0 million source of cash from net maturities of short-term investments during the same period in the prior year. Purchases of property, plant and equipment for the three month period ended March 31, 2013 were \$9.4 million as compared to \$8.2 million for the prior year period.

Net cash provided by financing activities for the three month period ended March 31, 2013 was \$1.6 million, representing a decrease of \$4.5 million as compared to the prior year period \$6.1 million of net cash provided by financing activities. The period over period decrease in net cash provided by financing activities was due to a \$2.9 million decrease in cash proceeds received from the exercise of stock options and contributions to the employee stock purchase plan, as well as a \$1.6 million decrease in the tax benefit related to the exercise of employee stock options and restricted stock as a result of the lower level of exercise activity in the current year period.

## Outstanding Debt Obligations

*Senior Lenders; Wells Fargo Bank, N.A.*

We have a Credit Agreement, as amended (the “Credit Agreement”) with Wells Fargo Bank, N. A., as a lender and as administrative agent (the “Administrative Agent”). The Credit Agreement provides us with a revolving line of credit in the aggregate principal amount of up to \$50.0 million (the “Revolving Credit Facility”). Under the Revolving Credit Facility, up to \$10.0 million is available for letters of credit, the outstanding face amounts of which reduce availability under the Revolving Credit Facility on a dollar for dollar basis. Proceeds under the Credit Agreement may be used for working capital, general corporate and other lawful purposes. We have not yet borrowed any amounts under the Revolving Credit Facility.

Borrowings under the Credit Agreement are secured by substantially all of our personal property assets pursuant to a Security Agreement (the “Security Agreement”) entered into by us and the Administrative Agent. As further security, we also pledged to the Administrative Agent, 65% of our equity interest in Impax Laboratories (Taiwan), Inc., all of our equity interests in our wholly owned domestic subsidiaries and must similarly pledge all or a portion of our equity interest in future subsidiaries. Under the Credit Agreement, among other things:

- The outstanding principal amount of all revolving credit loans, together with accrued and unpaid interest thereon, will be due and payable on the maturity date, which will occur four years following the February 11, 2011 closing date.
- Borrowings under the Revolving Credit Facility will bear interest, at our option, at either an Alternate Base Rate (as defined in the Credit Agreement) plus the applicable margin in effect from time to time ranging from 0.5% to 1.5%, or a LIBOR Rate (as defined in the Credit Agreement) plus the applicable margin in effect from time to time ranging from 1.5% to 2.5%. We are also required to pay an unused commitment fee ranging from 0.25% to 0.45% per annum based on the daily average undrawn portion of the Revolving Credit Facility. The applicable margin described above and the unused commitment fee in effect at any given time will be determined based on the Company’s Total Net Leverage Ratio (as defined in the Credit Agreement), which is based upon our consolidated total debt, net of unrestricted cash in excess of \$100 million, compared to Consolidated EBITDA (as defined in the Credit Agreement) for the immediately preceding four quarters.
- We may prepay any outstanding loan under the Revolving Credit Facility without premium or penalty.
- We are required under the Credit Agreement and the Security Agreement to comply with a number of affirmative, negative and financial covenants. Among other things, these covenants (i) require us to provide periodic reports, notices of material events and information regarding collateral, (ii) restrict our ability, subject to certain exceptions and baskets, to incur additional indebtedness, grant liens on assets, undergo fundamental changes, change the nature of its business, make investments, undertake acquisitions, sell assets, make restricted payments (including the ability to pay dividends and repurchase stock) or engage in affiliate transactions, and (iii) require us to maintain a Total Net Leverage Ratio (which is, generally, our total funded debt, net of unrestricted cash in excess of \$100 million, over our EBITDA for the preceding four quarters) of less than 3.75 to 1.00, a Senior Secured Leverage Ratio (which is, generally, our total senior secured debt over our EBITDA for the preceding four quarters) of less than 2.50 to 1.00 and a Fixed Charge Coverage Ratio (which is, generally, our EBITDA for the preceding four quarters over the sum of cash interest expense, cash tax payments, scheduled funded debt payments and capital expenditures during such four quarter period, subject to certain specified exceptions) of at least 2.00 to 1.00 (with each such ratio as more particularly defined as set forth in the Credit Agreement). As of March 31, 2013, we were in compliance with the various covenants contained in the Credit Agreement and the Security Agreement.
- The Credit Agreement contains customary events of default (subject to customary grace periods, cure rights and materiality thresholds), including, among others, failure to pay principal, interest or fees, violation of covenants, material inaccuracy of representations and warranties, cross-default and cross-acceleration of material indebtedness and other obligations, certain bankruptcy and insolvency events, certain judgments, certain events related to the Employee Retirement Income Security Act of 1974, as amended, and a change of control.

- Following an event of default under the Credit Agreement, the Administrative Agent would be entitled to take various actions, including the acceleration of amounts due under the Credit Agreement and seek other remedies that may be taken by secured creditors.

During the three month periods ended March 31, 2013 and 2012, unused line fees incurred under the Credit Agreement were \$30,000 and \$32,000, respectively.

### **Off-Balance Sheet Arrangements**

We did not have any off-balance sheet arrangements as of March 31, 2013.

### **Contractual Obligations**

As of March 31, 2013, there were no significant changes to our contractual obligations as set forth in our Annual Report on Form 10-K for the year ended December 31, 2012.

### **Recent Accounting Pronouncements**

In December 2011, the FASB issued its updated guidance on balance sheet offsetting. This new standard provides guidance to determine when offsetting in the balance sheet is appropriate. The guidance is designed to enhance disclosures by requiring improved information about financial instruments and derivative instruments. The goal is to provide users of the financial statements the ability to evaluate the effect or potential effect of netting arrangements on an entity's statement of financial position. This guidance will only impact the disclosures within an entity's financial statements and notes to the financial statements and does not result in a change to the accounting treatment of financial instruments and derivative instruments. We were required to adopt this guidance on January 1, 2013, and it did not have a material impact on our consolidated financial statements.

In March 2013, the FASB issued updated guidance on foreign currency matters. The update applies to the release of the cumulative translation adjustment into net income when a parent either sells a part or all of its investment in a foreign entity or no longer holds a controlling financial interest in a subsidiary or group of assets within a foreign entity. The Company is required to adopt this guidance on January 1, 2014 and does not expect the adoption to have a material effect on its consolidated financial statements.

**ITEM 3. Quantitative and Qualitative Disclosures About Market Risk**

There were no material changes to the quantitative and qualitative disclosures about market risk set forth in our Annual Report on Form 10-K for the year ended December 31, 2012.

**ITEM 4. Controls and Procedures****Disclosure Controls and Procedures**

We maintain disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) that are designed to ensure that information required to be disclosed by us in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including its principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures, as defined in Rule 13a-15(e) of the Exchange Act, were effective as of March 31, 2013 at the reasonable assurance level.

**Changes in Internal Control over Financial Reporting**

During the quarter ended March 31, 2013, there were no changes in the Company's internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) which materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

**Limitations on the Effectiveness of Controls**

Systems of disclosure controls and internal controls over financial reporting and their associated policies and procedures, no matter how well conceived and operated, are designed to provide a reasonable, but not an absolute, level of assurance the objectives of the system of control are achieved. Further, the design of a control system must be balanced against resource constraints, and therefore the benefits of controls must be considered relative to their costs. Given the inherent limitations in all systems of controls, no evaluation of controls can provide absolute assurance all control issues and instances of fraud, if any, within a company have been detected. These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Accordingly, given the inherent limitations in a cost-effective system of internal control, financial statement misstatements due to error or fraud may occur and may not be detected. Our disclosure controls and procedures are designed to provide a reasonable assurance of achieving their objectives. We conduct periodic evaluations of our systems of controls to enhance, where necessary, our control policies and procedures.

## **PART II. Other Information**

### **Item 1. Legal Proceedings**

Information pertaining to legal proceedings can be found in “Item 1. Financial Statements – Note 17. Legal and Regulatory Matters” and is incorporated by reference herein.

### **Item 1A. Risk Factors**

During the quarter ended March 31, 2013, except as set forth below, there were no material changes to the risk factors included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2012. Please carefully consider the information set forth in this Quarterly Report on Form 10-Q and the risk factors discussed in Part I, “Item 1A. Risk Factors” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2012, which could materially affect our business, consolidated financial condition or consolidated results of operations. The risks described herein, and in our Annual Report on Form 10-K for the fiscal year ended December 31, 2012 are not the only risks we face. Additional risks and uncertainties not currently known to us or which we currently deem to be immaterial may also materially adversely affect our business, consolidated financial condition and/or consolidated results of operations.

***We have received a warning letter from the FDA. If we are unable to promptly correct the issues raised in the warning letter, our business, results of operations and financial condition could be materially adversely affected.***

In late May 2011, we received a warning letter from the FDA related to an on-site FDA inspection of our Hayward, California manufacturing facility conducted between December 13, 2010 and January 21, 2011. In the warning letter, the FDA cited deviations from current Good Manufacturing Practices (cGMP), which are extensive regulations governing manufacturing practices for finished pharmaceutical products and which establish requirements for manufacturing processes, stability testing, record keeping and quality standards and controls. In summary, the FDA observations set forth in the warning letter related to sampling and testing of in-process materials and drug products, production record review, and our process for investigating the failure of certain manufacturing batches (or portions of batches) to meet specifications. During the quarter ended March 31, 2012 and the quarter ended March 31, 2013, the FDA conducted inspections of our Hayward manufacturing facility and at the conclusion of each inspection, we received a Form 483. The Form 483 issued in 2012 contained observations primarily relating to our Quality Control Laboratory and the Form 483 issued during the quarter ended March 31, 2013 contained several observations pertaining to the operations of the Hayward facility, three of which were designated by the FDA as repeat observations from inspections that occurred prior to the warning letter. After the issuance of the Form 483 in 2012, we were notified by the FDA that a satisfactory re-inspection of our Hayward manufacturing facility would be required to close out the warning letter. Since our receipt of the warning letter in late May 2011 to date, we have provided the FDA with written responses and subsequent updates in connection with the warning letter and the Form 483 observations and have continued to cooperate with the FDA to resolve the warning letter and the Form 483 observations. The FDA observations do not currently place restrictions on our ability to manufacture and ship our products. We have taken a number of steps to thoroughly review our quality control and manufacturing systems and standards and are working with several third-party experts to assist us with our review and assist in enhancing such systems and standards. This work is ongoing and we are committed to improving our quality control and manufacturing practices. We cannot be assured, however, that the FDA will be satisfied with our corrective actions and as such, we cannot be assured of when the warning letter will be closed out. Unless and until the warning letter is closed out, it is possible we may be subject to additional regulatory action by the FDA as a result of the current or future FDA observations, including, among others, monetary sanctions or penalties, product recalls or seizure, injunctions, total or partial suspension of production and/or distribution, and suspension or withdrawal of regulatory approvals. Additionally, the FDA has withheld and may continue to withhold approval of pending drug applications currently or previously listing our Hayward, California facility as a manufacturing location of finished dosage forms until these FDA observations are resolved. For instance, in January 2013, the FDA issued a Complete Response Letter regarding our NDA for our late stage branded pharmaceutical product candidate, RYTARY™, which we are developing internally, for the symptomatic treatment of Parkinson’s disease. In the Complete Response Letter, the FDA indicated that it required a satisfactory re-inspection of our Hayward manufacturing facility as a result of the warning letter issued to us in May 2011 before the NDA may be approved by the FDA due to the facility’s involvement in the development of RYTARY™ and supportive manufacturing and distribution activities. During the assessment of the NDA, we had amended the NDA to withdraw the Hayward site as an alternative site of commercial production in the launch of RYTARY™. We are currently working with the FDA on the appropriate next steps for the RYTARY™ NDA and, as noted above, on closing out the warning letter, however we cannot be assured of when that will occur. Further, other federal agencies, our customers and partners in our alliance, development, collaboration and other partnership agreements with respect to our products and services may take the warning letter into account when considering the award of contracts or the continuation or extension of such partnership agreements. Any such actions could significantly disrupt our business and harm our reputation, resulting in a material adverse effect on our business, business, results of operations and financial condition.

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**

The following table provides information regarding the purchases of our equity securities by us during the three months ended March 31, 2013.

<u>Period</u>	<u>Total Number of Shares (or Units) Purchased(1)</u>	<u>Average Price Paid Per Share (or Unit)</u>	<u>Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs</u>	<u>Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs</u>
January 1, 2013 to January 31, 2013	9,350 shares of common stock	\$21.25	—	—
February 1, 2013 to February 28, 2013	15,324 shares of common stock	\$19.99	—	—
March 1, 2013 to March 31, 2013	---	---	—	—

(1) Represents shares of our common stock that we accepted during the indicated periods as a tax withholding from certain of our employees in connection with the vesting of shares of restricted stock pursuant to the terms of our 2002 Plan.

**ITEM 3. Defaults Upon Senior Securities.**

Not Applicable.

**ITEM 4. Mine Safety Disclosures.**

Not Applicable.

**ITEM 5. Other Information.**

Not Applicable.

**ITEM 6. Exhibits**

<b>Exhibit No.</b>	<b>Description of Document</b>
10.1	Second Amendment to Credit Agreement dated as of January 10, 2013 to the Credit Agreement, dated as of February 11, 2011, as amended, by and among Impax Laboratories, Inc., the Guarantors named therein, the Lenders named therein and Wells Fargo Bank, National Association, as Administrative Agent.(1)
10.2	Amended and Restated License and Distribution Agreement dated as of February 7, 2013 by and between Shire LLC and Impax Laboratories, Inc.*
11.1	Statement re computation of per share earnings (incorporated by reference to Note 15 in the Notes to the unaudited interim Consolidated Financial Statements in this Quarterly Report on Form 10-Q).
31.1	Certification of the Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of the Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of the Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2013, formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets as of March 31, 2013 and December 31, 2012, (ii) Consolidated Statements of Operations for each of the three months ended March 31, 2013 and March 31, 2012, (iii) Consolidated Statements of Comprehensive Income for each of the three months ended March 31, 2013 and March 31, 2012, (iv) Consolidated Statements of Cash Flows for each of the three months ended March 31, 2013 and March 31, 2012 and (v) Notes to Interim Consolidated Financial Statements.**

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(1) Incorporated by reference to the Company's Current Report on Form 8-K filed on January 10, 2013.

\* Confidential treatment requested for certain portions of this exhibit pursuant to Rule 24b-2 under the Exchange Act, which portions are omitted and filed separately with the SEC.

\*\* Pursuant to Rule 406T of Regulation S-T, the Interactive Data Files in Exhibit 101 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Exchange Act and otherwise are not subject to liability under those sections.

## 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, thereunto duly authorized.

Date: May 3, 2013

**Impax Laboratories, Inc .**

By: /s/ Larry Hsu, Ph.D .

Name: Larry Hsu, Ph.D

Title: President and Chief Executive Officer  
(Principal Executive Officer)

By: /s/ Bryan M. Reasons

Name: Bryan M. Reasons

Title: Chief Financial Officer and  
Sr. Vice President, Finance  
(Principal Financial and Accounting Officer)

## EXHIBIT INDEX

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\*\*\* Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

**AMENDED AND RESTATED  
LICENSE AND DISTRIBUTION AGREEMENT**

**BY AND BETWEEN**

**SHIRE LLC**

**AND**

**IMPAX LABORATORIES, INC.**

**DATED FEBRUARY 7, 2013**

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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

**AMENDED AND RESTATED  
LICENSE AND DISTRIBUTION AGREEMENT**

**THIS AMENDED AND RESTATED LICENSE AND DISTRIBUTION AGREEMENT** (this “Agreement”) dated February 7, 2013 (the “Effective Date”) is hereby entered into by and between Shire LLC, a Kentucky limited liability company with offices located at 9200 Brookfield Court, Florence, KY 41042 (“Shire”), and Impax Laboratories, Inc. , a Delaware corporation with offices located at 30831 Huntwood Ave., Hayward, CA 94544 (“Impax”).

R E C I T A L S:

**WHEREAS** , Shire and Impax settled certain claims pursuant to a certain Settlement Agreement by and between Shire Laboratories, Inc. and Impax dated January 19, 2006 (the “Patent Litigation Settlement Agreement”);

**WHEREAS** , in connection therewith, Shire and Impax entered into a certain License and Distribution Agreement dated January 19, 2006 (the “Original Effective Date”), as amended on March 1, 2010 (the “Original License and Distribution Agreement”);

**WHEREAS** , the Parties are now entering into another Settlement Agreement contemporaneously herewith (the “Supply Litigation Settlement Agreement”) which settles the Pending Litigation (as defined in the Settlement Agreement); and

**WHEREAS** , in connection therewith, the Parties are modifying their current relationship as of the Effective Date and have agreed to amend and restate the Original License and Distribution Agreement as set forth herein.

**NOW THEREFORE** , in consideration of the foregoing premises, mutual covenants, the terms and conditions hereof and in the Supply Litigation Settlement Agreement, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereby agree as follows.

**1.        Definitions**

**1.1**        “[ \*\*\* ] **QA Period**” shall have the meaning assigned to such term in Section 5. 3(h).

**1.2**        “**Act**” shall mean the United States Federal Food, Drug and Cosmetic Act, as amended from time to time, and the rules, regulations and guidelines promulgated thereunder.

**1.3**        “**ADR Procedure**” shall have the meaning assigned to such term in Section 16. 13(d).

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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

- 1.4** “**Adderall XR**” shall mean the pharmaceutical product that contains the Compound as its sole active ingredient which is approved for Marketing in the Territory pursuant to Shire’s NDA and sold under the trade name Adderall XR.
- 1.5** “**Adderall XR ANDA**” shall mean an ANDA seeking approval of a Generic Equivalent.
- 1.6** “**Adderall XR Intellectual Property**” shall mean (i) U. S. Patent Nos. 6,322,819, 6,605,300, and 6,913,768 and any patent that issues as a result of a reexamination or reissue thereof; (ii) any patent that issues from, or from any continuation, continuation-in-part or divisional application relating to, U. S. Patent Application Serial Nos. 09/176,542, 10/353,073, 10/758,417, 10/774,697, and 11/030,174; and (iii) any other present or future U. S. patent owned or controlled by Shire which may read upon the making, using, selling or importing of a Generic Product.
- 1.7** “**Adderall XR License**” shall mean a license under the Adderall XR Intellectual Property.
- 1.8** “**Adverse Drug Experience**” shall mean an adverse event associated with the use of Generic Product in humans, whether or not considered drug related, including the following: an adverse event occurring in the course of the use of a drug product in professional practice; an adverse event occurring from drug overdose whether accidental or intentional; an adverse event occurring from drug abuse; an adverse event occurring from drug withdrawal; and any failure of expected pharmacological action. The above definition of “Adverse Drug Experience” is defined by 21 C. F. R. § 314. 80(a), and will be deemed to be changed to reflect any changes to that section of 21 C. F. R. § 314. 80.
- 1.9** “**Affiliate**” shall mean a Person that controls, is controlled by or is under common control with a Party. For the purposes of this definition, the word “control” (including, with correlative meaning, the terms “controlled by” or “under common control with”) means the actual power, either directly or indirectly through one or more intermediaries, to direct the management and policies of such Person, whether by the ownership of at least fifty percent (50%) of the voting interest of such Person (it being understood that the direct or indirect ownership of a lesser percentage of such interest shall not necessarily preclude the existence of control), or by contract or otherwise.
- 1.10** “**AG Product**” shall mean generically Labeled Adderall XR, commonly called an authorized generic product, approved for sale by the FDA pursuant to a labeling supplement to Shire’s NDA.
- 1.11** “**Agreement**” shall have the meaning assigned to such term in the introduction, as may be amended by a signed written agreement pursuant to Section 16. 4.
- 1.12** “**Allocated Quota**” shall have the meaning assigned to such term in Section 5. 3(b).
- 1.13** “**Allocation Deadline**” shall have the meaning assigned to such term in Section 5. 3(c).
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

- 1.14** “**Allocation Period**” shall mean, except as modified herein pursuant to Section 5. 3(f), the [\*\*\*] period immediately preceding the calendar month in which a DEA Quota Grant Letter is dated for which [\*\*\*] at such date.
- 1.15** “**Allocation Plan**” shall have the meaning assigned to such term in Section 5. 3(c).
- 1.16** “**ANDA**” shall mean an Abbreviated New Drug Application to the FDA for approval to Manufacture and/or Market a pharmaceutical product in the Territory.
- 1.17** “**Annual DEA Quota Grant**” shall mean the initial DEA Quota Grant permitting the procurement of Compound beginning in a calendar year for the Manufacture of AG Product and Adderall XR.
- 1.18** “**Applicable Law**” shall mean the applicable Laws, rules, regulations, guidelines and requirements of any Governmental Authority related to the development, registration, Manufacture and Marketing of the Generic Product in the Territory or the performance of either Party’s obligations under this Agreement.
- 1.19** “**Authorization and License**” shall have the meaning assigned to such term in Section 2. 3.
- 1.20** “**Business Day**” shall mean any day other than a Saturday, Sunday or a day on which banks in New York, New York are closed or required by Law to close.
- 1.21** “**Cancellation Period**” shall have the meaning assigned to such term in Section 5. 13(d)(ii).
- 1.22** “**cGMP**” shall mean all applicable standards relating to manufacturing practices for fine chemicals, active pharmaceutical ingredients, intermediates, bulk products or finished pharmaceutical products, including the principles detailed in the U.S. Current Good Manufacturing Practices, 21 C. F. R. Parts 210 and 211.
- 1.23** “**Claim**” shall have the meaning assigned to such term in Section 12. 1(a).
- 1.24** “**Commercially Reasonable Efforts**” shall mean efforts and diligence in accordance with the subject Party’s reasonable and sound business, legal, medical and scientific judgment and in accordance with the efforts and resources such Party would use in other aspects of its business that have similar commercial value and market potential, taking into account the competitiveness of the marketplace, the business life-cycle, the proprietary position of the company and the profitability of the pertinent product.
- 1.25** “**Compound**” shall mean mixed amphetamine salts.
- 1.26** “**Confidential Information**” shall mean any scientific, technical, formulation, process, Manufacturing, clinical, non-clinical, regulatory, Marketing, financial or commercial information or data relating to the business, projects, employees or products of either Party and provided by one Party to the other by written, oral, electronic or other means in connection with this Agreement.
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

**1.27** “**Cost of Goods**” shall mean the [\*\*\*] to be paid by Impax to Shire for Packaged and Labeled AG Product. With respect to AG Product, the Cost of Goods shall equal the [\*\*\*].

**1.28** [\*\*\*]

**1.29** “**DEA**” shall mean the United States Drug Enforcement Administration or any successor agency thereof.

**1.30** “**DEA Quota**” shall mean an amount of Compound authorized by the DEA to be procured by Shire or Shire’s Manufacturer for the commercial Manufacture of Adderall XR and AG Product.

**1.31** “**DEA Quota Grant**” shall mean the issuance by the DEA of DEA Quota to Shire or Shire’s Manufacturer.

**1.32** “**DEA Quota Grant Letter**” shall mean the letter from DEA to Shire or Shire’s Manufacturer setting forth a DEA Grant.

**1.33** “**Deficient Lot**” shall have the meaning assigned to such term in Section 5. 2.

**1.34** “**Delivery Delay**” shall have the meaning assigned to such term in Section 5. 3(f).

**1.35** “**Delivery Month**” shall have the meaning assigned to such term in Section 5. 3(h).

**1.36** “**Delivery Schedule**” shall have the meaning assigned to such term in Section 5. 3(e).

**1.37** “**Disputed Quota**” shall have the meaning assigned to such term in Section 5. 3(c).

**1.38** “**Effective Date**” shall have the meaning assigned to such term in the introduction.

**1.39** “**Exclusive**” shall mean, when used in connection with a specific grant of rights, that the granting Party (i) shall retain for itself no ability to use such granted rights and (ii) shall have no ability to authorize its Affiliates or Third Parties (other than the grantee of such specific rights) to use such granted rights, in the Territory and in the granted field of use, for the term of the grant.

**1.40** [\*\*\*]

**1.41** “**FDA**” shall mean the United States Food and Drug Administration or any successor agency thereof.

**1.42** “**Force Majeure**” shall mean any circumstances reasonably beyond a Party’s control, including, without limitation, acts of God, civil disorders or commotions, acts of aggression, fire, explosions, floods, drought, war, sabotage, embargo, unexpected safety or efficacy results obtained with the Generic Product, utility failures, [\*\*\*], [\*\*\*], labor disturbances, a national health emergency, or appropriations of property.

**1.43** “**Forecast Period**” shall have the meaning assigned to such term in Section 5. 10.

**1.44** [\*\*\*]

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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

- 1.45 “GAAP” shall mean generally-accepted accounting principles in effect in the United States from time to time, entirely applied.
- 1.46 “Generic Equivalent” shall mean a pharmaceutical product which is submitted to the FDA for Regulatory Approval pursuant to an ANDA (or equivalent regulatory mechanism) as a Therapeutic Equivalent to Adderall XR. Generic Equivalent shall also mean the AG Product.
- 1.47 “Generic Product” shall mean both Impax AG Product and Impax Product.
- 1.48 “Governmental Authority” shall mean any court, tribunal, arbitrator, agency, legislative body, commission, official or other instrumentality of (i) any government of any country, or (ii) a federal, state, province, county, city or other political subdivision thereof.
- 1.49 “Impax” shall have the meaning assigned to such term in the introduction.
- 1.50 “Impax AG Product” shall mean AG Product supplied to Impax pursuant to this Agreement.
- 1.51 “Impax ANDA” shall mean ANDA No. 76-852, and any amendment and supplement thereto.
- 1.52 “Impax Liability” shall have the meaning assigned to such term in Section 12. 2.
- 1.53 “Impax [\*\*\*] Notice” shall have the meaning assigned to such term in Section 5. 13(c).
- 1.54 [\*\*\*]
- 1.55 “Impax Party” shall have the meaning assigned to such term in Section 12. 1.
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

**1.56** “**Impax Product**” shall mean the Generic Equivalent that is the subject of the Impax ANDA.

**1.57** [\*\*\*]

**1.58** “**Impax Allocated Share**” and “**Impax’s Allocated Share**” shall mean, including as may be modified pursuant to Sections 5. 3(c), 5. 3(f), or 5. 4(b), the product (in kilograms) obtained by [\*\*\*] or [\*\*\*], as applicable.

**1.59** “**Impax’s Launch Notice**” shall have the meaning assigned to such term in Section 3. 7.

**1.60** [\*\*\*]

**1.61** [\*\*\*] shall have the meaning assigned to such term in Section 5. 13(d)(iv).

**1.62** [\*\*\*]

**1.63** [\*\*\*]

**1.64** “**JAMS Rules**” shall have the meaning assigned to such term in Schedule 16. 13(d).

**1.65** “**January – December 2013 Delivery Schedule**” shall have the meaning assigned to such term in Section 5. 3(g).

**1.66** “**January – December 2012 Period**” shall have the meaning assigned to such term in Section 5. 3(f).

**1.67** [\*\*\*]

**1.68** “**Label**” shall mean any Package (immediate container) labeling designed for use with a product, including the package insert for such product that is approved by the FDA, and “**Labeled**” or “**Labeling**” shall have the correlated meaning.

**1.69** “**Late-Supplied AG Product**” shall have the meaning assigned to such term in Section 5. 13(c).

**1.70** “**Launch**” shall mean the first commercial sale of a product to an unaffiliated Third Party.

**1.71** “**Law**” or “**Laws**” shall mean all laws, statutes, rules, codes, regulations, orders, judgments and/or ordinances of any governmental Authority.

**1.72** “**License Effective Date**” shall mean October 1, 2009.

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**1.73** “**Losses**” shall mean any liabilities, damages, costs or expenses, including reasonable attorneys’ fees and expert fees, incurred by any Party that arise from any Claim, lawsuit or other action by a Third Party.

**1.74** [ \*\*\*]

**1.75** “**Manufacture**” shall mean all activities related to the manufacturing of a pharmaceutical product, or any ingredient thereof including, but not limited to, manufacturing Compound or supplies for development, manufacturing, as the case may be, Impax Product, Impax AG Product, AG Product, and/or Adderall XR for commercial sale, Packaging, in-process and finished product testing, release of product or any component or ingredient thereof, quality assurance activities related to manufacturing and release of product, ongoing stability tests and regulatory activities related to any of the foregoing, and “**Manufactured**” or “**Manufacturing**” shall have the correlated meaning.

**1.76** “**Manufacturing Costs**” for each dosage strength of AG Product shall mean [\*\*\*], accrued in accordance with GAAP. Manufacturing Costs for each dosage strength of Impax Product shall mean [\*\*\*], accrued in accordance with GAAP.

**1.77** “**Manufacturing Failure or Delay**” shall mean a failure or delay, [\*\*\*] in (i) the Manufacturing of AG Product or Adderall XR, as applicable, or (ii) AG Product or Adderall XR, as applicable, meeting the specifications in Shire’s NDA or applicable cGMP standards, including any period of time when an investigation is being conducted into whether AG Product or Adderall XR, as applicable, meets the specifications in Shire’s NDA or applicable cGMP standards.

**1.78** “**Market**” shall mean to distribute, promote, advertise, import, market and sell, and “**Marketing**” or “**Marketed**” shall have correlated meaning.

**1.79** “**Modification**” shall have the meaning assigned to such term in Schedule 5. 3(e).

**1.80** “**Modification Date**” shall have the meaning assigned to such term in Schedule 5. 3(e).

**1.81** “**NDA**” shall mean a New Drug Application filed with the FDA pursuant to and under 21 U. S. C. § 355(b) of the Act, together with the FDA’s implementing rules and regulations.

**1.82** “**Net Profits**” shall mean the difference between Net Sales for the applicable Generic Product and the Cost of Goods for product.

**1.83** “**Net Sales**” shall mean, with respect to all sales of Generic Product sold on or after April 1, 2011 and all related calculations, the gross invoice price of sales of Generic Product in the Territory by Impax and its Affiliates to unaffiliated Third Parties, less all applicable deductions permitted by GAAP including, without limitation (i) trade discounts, (ii) promotional allowances, (iii) cash discounts, (iv) customer refunds and credits, (v) returns, (vi) repurchase charges, (vii) customer and government rebates (viii) chargebacks, (ix) retroactive price or shelf stock adjustments and price equalizations ; (x) Impax’s actual freight, storage, and insurance expense, (xi) administrative fees, (xii) fees for management and service of Third Party contracts including contract maintenance, chargeback processing, credit and collections and store level delivery, (xiii) marketing and administration fees to cover national inventory costs, contract handling, and chargeback maintenance costs, and (xiv) program fees for the administration of a private label generic program. [\*\*\*].

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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions. portions.

1.84 [\*\*\*]

1.85 [\*\*\*]

1.86 “**New Delivery Date**” shall have the meaning assigned to such term in Section 5. 13(d)(i).

1.87 “**New Delivery Date Notice**” shall have the meaning assigned to such term in Section 5. 13(d)(i).

1.88 [\*\*\*]

1.89 “**Non-binding Forecast**” shall have the meaning assigned to such term in Section 5. 10.

1.90 “**Non-Supplied AG Product**” shall have the meaning assigned to such term in Section 5. 13(d).

1.91 [ \*\*\* ] shall have the meaning assigned to such term in Section 5. 13(d)(ii).

1.92 “**Original Effective Date**” shall have the meaning assigned to such term in the whereas section.

1.93 “**Original License and Distribution Agreement**” shall have the meaning assigned to such term in the whereas section.

1.94 “**Original Schedule**” shall have the meaning assigned to such term in Schedule 5. 3(e).

1.95 “**Package**” shall mean all primary containers, including bottles, cartons, shipping cases or any other like matter used in packaging or accompanying a product, and “**Packaged**” or “**Packaging**” shall have the correlated meaning.

1.96 “**Party**” or “**Parties**” shall mean Shire and/or Impax, as applicable.

1.97 “**Patent Litigation Settlement Agreement**” shall have the meaning assigned to such term in the whereas section.

1.98 “**Payment Amount**” shall have the meaning assigned to such term in Section 9.9.

**CONFIDENTIAL TREATMENT REQUESTED  
BY IMPAX LABORATORIES, INC.**

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- 1.99** “**Person**” shall mean any individual, partnership, association, corporation, limited liability company, trust, or other legal or entity.
- 1.100** [\*\*\*]
- 1.101** “**QA Testing**” shall have the meaning assigned to such term in Section 5. 3(h).
- 1.102** “**Quality Agreement**” shall have the meaning assigned to such term in Section 7. 7.
- 1.103** “**Regulatory Approval**” shall mean final Marketing approval by the FDA for the sale and Marketing of a pharmaceutical product in the Territory.
- 1.104** “**Reporting Period**” shall have the meaning set forth in Section 9. 3.
- 1.105** “**Reserve Quota**” shall have the meaning assigned to such term in Section 5. 3(b).
- 1.106** “**Reserve Quota Event**” shall have the meaning assigned to such term in Section 5. 3(b).
- 1.107** “**Returns and Final Reconciliation Report**” shall have the meaning assigned to such term in Section 9. 8.
- 1.108** [\*\*\*]
- 1.109** “**Shire**” shall have the meaning assigned to such term in introduction.
- 1.110** “**Shire Liability**” shall have the meaning assigned to such term in Section 12. 1.
- 1.111** “**Shire Party**” shall have the meaning assigned to such term in Section 12. 2.
- 1.112** “**Shire’s Manufacturer**” shall mean a Third Party designated by Shire to conduct some or all of the Manufacturing of Adderall XR and AG Product.
- 1.113** “**Shire’s NDA**” shall mean Shire’s NDA No. 21-303, and all supplements filed pursuant to the requirements of the FDA, including all documents, data and other information concerning Adderall XR which are necessary for FDA approval to Market Adderall XR in the Territory.
- 1.114** “**Shortfall**” shall have the meaning assigned to such term in Section 5. 3(d).
- 1.115** “**SKU**” shall measure stock keeping units, which is expressed herein in dosage amounts (in mgs. ).
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

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- 1.116** “**SKU Mix**” shall mean the distribution of Impax’s Allocated Share among the different dosage strengths of Impax AG
- 1.117** [\*\*\*]
- 1.118** “**Subsequent Cancellation Period**” shall have the meaning assigned to such term in Section 5. 13(d)(iii).
- 1.119** “**Subsequent Delivery Date Notice**” shall have the meaning assigned to such term in Section 5. 13(d)(iii).
- 1.120** “**Supply Litigation Settlement Agreement**” shall have the meaning assigned to such term in the whereas section.
- 1.121** “**Supply Term**” shall have the meaning assigned to such term in Section 15. 1.
- 1.122** “**Term**” shall have the meaning assigned to such term in Section 15. 1.
- 1.123** “**Territory**” shall mean the United States of America.
- 1.124** “**Teva**” shall mean Teva Pharmaceuticals USA, Inc. and its Affiliates, successor to Barr Laboratories, Inc. as a result of Teva’s acquisition of Barr Laboratories, Inc. in 2008.
- 1.125** [\*\*\*]
- 1.126** “**Therapeutic Equivalent**” shall have the meaning given to it by the FDA in the current edition of the “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”) as may be amended from time to time during the Term.
- 1.127** “**Third Party**” or “**Third Parties**” shall mean any Person or entity other than a Party or its Affiliates.
- 1.128** “**Undelivered Product**” shall have the meaning assigned to such term in Section 5. 4(c).
- 1.129** “**Valid Claim**” shall mean an issued and unexpired patent claim which has not been held to be invalid or unenforceable by a court of competent jurisdiction in a final unappealable decision.

## **2. Authorization and License**

**2.1** Subject to the terms, conditions and limitations hereof, including the conditions set forth in Section 3 [\*\*\*], Shire hereby grants to Impax a limited license, under the Adderall XR Intellectual Property and under any and all statutory and regulatory exclusivities to Manufacture, have Manufactured and Market Impax Product in the Territory on and after the License Effective Date.

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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

**2.2** Subject to the terms, conditions and limitations hereof, including the conditions set forth in Section 3, Shire hereby authorizes Impax to Market Impax AG Product in the Territory from and after the License Effective Date. In connection with and solely for purposes of such authorization, Shire hereby grants to Impax a limited license under the Adderall XR Intellectual Property and under any and all statutory and regulatory exclusivities to Market such Impax AG Product in the Territory from and after the License Effective Date.

**2.3** The authorizations and licenses granted by this Section 2. 1 and 2. 2 are referred to herein as the “ Authorization and License .” Except to the extent of the assignment permitted pursuant to Section 16. 3, or pursuant to any extension of licenses under Section 3. 8, Impax shall not have the right to sublicense or assign any of its rights under the Authorization and License.

### **3. Conditions**

**3.1** Impax shall not Market or authorize or knowingly facilitate the Marketing of Impax AG Product outside the Territory and agrees to take all appropriate and legal steps as may be required to ensure that its Affiliates or customers do not sell or distribute Impax AG Product outside the Territory including, without limitation, by limiting or terminating the supply of Impax AG Product to customers which, to Impax’s knowledge, are distributing or selling Impax AG Product outside the Territory.

**3.2** Subject to the provisions of Sections 3. 3 and 3. 4 below, the Authorization and License shall be on an Exclusive basis.

**3.3** Shire reserves the right to license and authorize Barr Laboratories, Inc. to Manufacture, have Manufactured and Market a Generic Equivalent in the Territory and supply AG Product to Teva (originally Barr Laboratories, Inc.) in full and complete settlement of the original litigation between Shire and Barr Laboratories, Inc. involving the Adderall XR Intellectual Property.

**3.4** Shire reserves the right to grant licenses under the Adderall XR Intellectual Property and any and all statutory and regulatory exclusivities to any Third Party to Manufacture, have Manufactured and Market a Generic Equivalent, but only under its applicable ANDA, in settlement of any then-pending or then-threatened litigation involving the Adderall XR Intellectual Property; provided, however, that such licenses shall be on terms no more favorable to such Third Party than those set forth in this Agreement.

**3.5** Except to the extent permitted under the Authorization and License, neither Impax nor any of its Affiliates shall under any circumstances: (a) Market any Generic Equivalent that infringes or misappropriates the Adderall XR Intellectual Property or (b) aid, abet, enable or contract with any Third Party regarding the Marketing of any Generic Equivalent that infringes or misappropriates the Adderall XR Intellectual Property.

**3.6** Nothing set forth herein shall be deemed to prevent or restrict Impax or its Affiliates from Marketing any product which would not infringe or misappropriate the Adderall XR Intellectual Property. In addition, nothing shall prohibit Impax from entering into any agreement with a Third Party related to any Generic Equivalent that does not infringe or misappropriate the Adderall XR Intellectual Property; provided, however, that if Impax so enters into any such agreement (except an agreement that is reasonably required for Impax to Market the Generic Product and is approved by Shire pursuant to Section 8. 1), Impax shall promptly notify Shire, and Shire shall be free to terminate the Authorization and License and any supply obligations to Impax immediately upon notice to Impax.

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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions. portions.

**3.7 Impax's Right to Launch Impax Product.** During the Supply Term, Impax agrees and covenants not to Manufacture, have Manufactured or Market any Impax Product in the Territory, or otherwise license, authorize or allow a Third Party to Manufacture, have Manufactured or Market any Generic Equivalent in the Territory under the Impax ANDA; provided, however, notwithstanding anything to the contrary, Impax has the right to develop Impax Product; Manufacture development, validation or commercial batches of Impax Product; seek and obtain approval of the Impax ANDA; and engage in any supporting activities relating thereto, and such activities will not affect Shire's obligation to supply Impax AG Product to Impax under the terms and conditions of this Agreement. During the Supply Term, upon Launch of the Impax Product, Impax shall give Shire written notice of the Launch within [\*\*\*] thereafter (" Impax's Launch Notice "). Upon Impax Launch of an Impax Product, all outstanding allocations and purchase orders for Impax AG Product shall be automatically cancelled and Shire shall have no further obligation to supply Impax AG Product to Impax other than AG Product that would have been otherwise delivered to Impax prior to the Impax Product Launch, but which AG Product has not been delivered including, without limitation, Undelivered Product; provided, further that with respect to any finished Impax AG Product including Impax AG Product that has been encapsulated, that Shire has not supplied to Impax prior to receipt of Impax's Launch Notice, Impax shall accept supply of all such Impax AG Product under the terms of this Agreement. For clarity, notwithstanding any other provision of this Agreement, an Impax Product Launch shall not release Shire from its obligation to [\*\*\*] to Impax under Section 5. 13(c) or 5. 13(d) for Late-Supplied AG Product or Non-Supplied AG Product, or to deliver to Impax Late-Supplied AG Product, Non-Supplied AG Product, or Undelivered Product as required thereunder.

**3.8 Impax's Right to [\*\*\*]** The license granted to Impax under the Adderall XR Intellectual Property includes [\*\*\*].

#### **4. Authorized Generic**

The Parties hereby confirm that Impax elected, under the Original License and Distribution Agreement, by providing written notice to Shire, to have Shire supply Impax AG Product to Impax for sale in the Territory from and after the License Effective Date.

#### **5. Supply; Delivery Schedule; SKU Mix; and [\*\*\*] for Delay and Nondelivery**

**5.1** All AG Product supplied will be released for sale under a generic Label in Packaged form which complies with Shire's NDA. Subject to compliance with Shire's NDA, Impax will provide Shire with appropriate and customary generic Package and Label design which will be utilized by Shire in Manufacturing AG Product. Any costs incurred by Shire in utilizing such Packaging or Labeling, or in performing other Manufacturing specifications (such as tablet imprints) requested by Impax and to which Shire agrees (such agreement not to be unreasonably withheld, delayed or conditioned), including related capital expenditures, shall be included in Manufacturing Costs.

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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions. portions.

**5.2 Shire's Supply Obligations** . Subject to the terms, conditions and limitations of this Agreement, Shire agrees to supply AG Product to Impax for Marketing pursuant to Section 4 and in accordance with the terms of this Agreement. Consistent with the Delivery Schedule, (i) Impax shall submit purchase orders for each Delivery Month specifying the amount of Impax AG Product by SKU Mix and in full lot increments of [\*\*\*] bottles, and (ii) Shire shall deliver Impax AG Product. The Parties agree that the amount of [\*\*\*] bottles represents an approximation of the average size of a lot of Impax AG Product that will be Manufactured to satisfy each SKU lot ordered by Impax and that Shire shall deliver, and Impax will accept, the actual number of bottles for such SKU lot that is Manufactured to fill Impax's ordered SKU lot, whether greater or less than [\*\*\*] bottles. Shire's delivery of such actual Manufactured bottles shall be in full satisfaction of Impax's order for a SKU lot provided that the actual number of bottles for such SKU lot delivered to Impax is at least [\*\*\*] bottles. In the event a SKU lot delivered to Impax is less than [\*\*\*] bottles (a "Deficient Lot"), Shire shall Manufacture and deliver to Impax the difference between [\*\*\*] bottles and the amount actually delivered to Impax from such Deficient Lot as promptly as practicable. With respect to all DEA Quota Grants issued prior to the Effective Date, Shire's obligation to supply Impax AG Product under this Agreement shall be limited to the delivery of Impax AG Product as set forth in the Delivery Schedule in Section 5. 3(g) below and in accordance with all the terms and conditions of this Agreement.

**5.3 Allocation of DEA Quota Grants to Impax** . With respect to all DEA Quota Grants issued after the Effective Date, the amount and timing of Impax's ordering and Shire's delivery of Impax AG Product to Impax will be determined in accordance with the procedures set forth in this Section 5. 3. Except as required to meet its supply obligations to Impax under this Agreement, nothing in this Agreement shall be interpreted or construed as in anyway limiting Shire's right or ability to allocate any DEA Quota Grant for use in the Manufacture of Adderall XR or AG Product. The Parties agree that the provisions of this Agreement are intended to set forth, among other things, the terms and conditions for Impax's ordering of Impax AG Product, and the supply and delivery of Impax AG Product by Shire to Impax; certain rights and obligations of Impax relating to Impax AG Product; and Shire's supply obligations for Impax AG Product.

(a) **Notification to Impax of DEA Quota Grants** . Shire will notify Impax of receipt of each DEA Quota Grant and provide Impax with a copy of the DEA Quota Grant Letter as soon as possible, but in any event no later than [\*\*\*] after Shire receives such DEA Quota Grant Letter. To the extent a DEA Quota Grant Letter contains information not related to Adderall XR or any AG Product (for example, relating to another Shire product), such information will be redacted before transmission to Impax.

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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions. portions.

(b) **Allocation to Impax of DEA Quota Grants** . In determining the total amount of any DEA Quota that will be subject to the allocation methodology set forth herein (the “Allocated Quota”), the following amounts will be excluded: (i) [\*\*\*] percent ([\*\*\*]%) of the DEA Quota shall be designated for use in [\*\*\*]; and (ii) [\*\*\*] percent ([\*\*\*]%) of such grant shall be designated as reserve quota (the “Reserve Quota”) to be used for Manufacturing replacement product for any of Impax, Shire and/or Teva due to product loss caused by [\*\*\*] (each one, a “Reserve Quota Event”). To the extent any or all of the Adderall XR Manufactured [\*\*\*] is not [\*\*\*], Shire shall be free to use such Adderall XR at its discretion. To the extent that the Reserve Quota is not used to replace AG Product for Teva and/or Impax or Adderall XR for Shire that was not delivered due to a Reserve Quota Event that occurs prior to the next DEA Quota Grant, such unused Reserve Quota will be added to the quota available for allocation with the next succeeding DEA Quota allocation that occurs and Impax’s share of such unused Reserve Quota shall be allocated in accordance with the Allocation Plan applicable to such next succeeding DEA Quota allocation set forth in Section 5. 3(c). However, with respect to unused Reserve Quota remaining from the last DEA Quota Grant granted on or prior to [\*\*\*], based on a SKU Mix provided by Impax, Shire shall deliver to Impax its share of such unused Reserve Quota which will be based on [\*\*\*]. Shire shall deliver to Impax such unused Reserve Quota remaining from [\*\*\*] within [\*\*\*] which utilizes any of the DEA Quota Grant immediately following [\*\*\*]. With respect to any Reserve Quota Event, Shire shall provide Impax with the information and documentation in its possession reasonably needed to confirm the cause of the relevant Reserve Quota Event. In addition, within thirty (30) days of each DEA Quota Grant, Shire shall provide to Impax an accounting of Reserve Quota reserved from the preceding DEA Quota Grant including documentation detailing, by Reserve Quota Event, use of any quantities of the Reserve Quota for Reserve Quota Events and the amount of Reserve Quota remaining for allocation.

(c) **Allocation Plan** . Within [\*\*\*] after the date Shire receives a DEA Quota Grant Letter, Shire will prepare and deliver to Impax, for its review, a proposed “Allocation Plan” that calculates [\*\*\*] and Impax’s Allocated Share [\*\*\*] for the Allocation Period. At the time of delivery of the proposed Allocation Plan, Shire will also provide Impax with justification documents in support of its calculation of [\*\*\*], [\*\*\*], and Impax’s Allocated Share, which documents shall include copies of all data and information used in the calculations, as well as a detailed description of the related calculations. Within [\*\*\*] of receipt of Shire’s proposed Allocation Plan and justification documents, Impax will either agree to the proposed Allocation Plan, or provide to Shire any proposed adjustments to the Allocation Plan based upon what Impax believes are errors or miscalculations of [\*\*\*], [\*\*\*] and/or Impax’s Allocated Share. At the time of delivery of the proposed adjustments, Impax will also provide Shire with justification documents in support of its belief that there were such errors or miscalculations, which documents shall include copies of all data and information used to confirm the errors or miscalculations, as well as a detailed description of the related calculations. The Parties shall use their best efforts to agree upon a final Allocation Plan not less than [\*\*\*] thereafter (the “Allocation Deadline”). In the event the Parties do not agree on Impax’s Allocated Share by the Allocation Deadline, the dispute resolution procedure set forth in Section 16. 13 (d) hereof shall be immediately implemented in order to definitively resolve all disputes related to the calculation of Impax’s Allocated Share. In addition, Shire shall: (i) place an amount of kilograms equal to the difference between Shire’s proposed Impax’s Allocated Share and Impax’s proposed Impax’s Allocated Share (the “Disputed Quota”) into reserve pending resolution of the dispute in accordance with the terms herein; and (ii) make and deliver Impax AG Product not in dispute in accordance with the Delivery Schedule contemplated in Section 5. 3(e). To the extent the dispute is resolved in Impax’s favor, the Allocation Plan shall immediately be recalculated to include the relevant amount of Disputed Quota, and Impax’s Allocated Share and [\*\*\*] shall be increased accordingly [\*\*\*]. With respect to the delivery of Impax AG Product representing any Disputed Quota allocated to Impax following resolution of the relevant dispute, Shire will use its best efforts to deliver such batches to Impax as soon as practicable.

[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions. portions.

(d) **SKU Mix** . Within [\*\*\*] of the earlier of: (i) the Allocation Deadline, or (ii) the Parties' agreement on an Allocation Plan, Impax will provide to Shire its SKU Mix and Impax's preferred delivery sequence for the SKU Mix; provided, however, that the SKU Mix shall not exceed the total kilograms of Impax's Allocated Share. To the extent that the total kilograms of DEA Quota used in Impax's SKU Mix is less than Impax's Allocated Share, then Shire shall place the balance of Impax's Allocated Share (the "Shortfall") into reserve and Impax shall have the right to have the Shortfall added to Impax's Allocated Share as part of the next DEA Quota allocation or to any Disputed Quota that is ultimately allocated to Impax in accordance with Section 5. 3(c). If there is a dispute as to Impax's Allocated Share, the SKU Mix submitted by Impax shall not include the Disputed Quota. If any Disputed Quota is ultimately allocated to Impax, then within [\*\*\*] after such allocation, Impax shall provide the SKU Mix and Impax's preferred delivery sequence for the SKU Mix and Shire shall reserve, without limitation, any Shortfall from the Disputed Quota for future use by Impax. After the resolution of outstanding disputes related to the Disputed Quota, the aggregate reserve amount of Shortfall shall neither exceed [\*\*\*] nor be less than [\*\*\*]. To the extent the aggregate reserve amount of Shortfall is greater than [\*\*\*], Shire shall be free to allocate the excess above [\*\*\*] at its sole discretion. In the event the Shortfall is less than [\*\*\*], Shire shall be free to allocate such amount at its sole discretion.

(e) **Delivery Schedule** . Within [\*\*\*] of receiving any SKU Mix and preferred delivery sequence from Impax, Shire will provide to Impax an estimated monthly delivery schedule, based on the form of the delivery schedule set out in Section 5. 3 (g), setting out the number of lots by month, and specifying SKU, of Impax AG Product Shire expects to deliver to Impax, consistent with the Allocation Plan and the SKU Mix and which takes into account all of the requirements set forth in this Subsection (e) ("Delivery Schedule"). In preparing the Delivery Schedule, Shire shall take into account [\*\*\*], and Manufacturing-related issues. The Delivery Schedule shall provide that:

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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions. portions.

(i) for any Annual DEA Quota Grant, Impax will receive at a minimum: (a) within [\*\*\*] which utilizes any such DEA Quota Grant, [\*\*\*] percent ([\*\*\*]%) of Impax's Allocated Share of such DEA Quota Grant and, (b) in each Delivery Month thereafter, Impax AG Product constituting [\*\*\*] percent ([\*\*\*]%) of Impax's Allocated Share of such DEA Quota Grant until all of Impax's Allocated Share is delivered; and

(ii) for any supplemental DEA Quota Grant, Impax will receive at a minimum: (y) within [\*\*\*] which utilizes any such DEA Quota Grant, [\*\*\*] percent ([\*\*\*]%) of Impax's Allocated Share of such DEA Quota Grant, and (z) in each Delivery Month [\*\*\*] percent ([\*\*\*]%) of Impax's Allocated Share of such DEA Quota Grant.

Shire shall use its best efforts to schedule the Manufacturing of Adderall XR and AG Product in order to ensure that [\*\*\*]. Within [\*\*\*] of receiving Shire's proposed Delivery Schedule, Impax may propose modifications to Shire's proposed Delivery Schedule, including the SKU Mix for a Delivery Month, and Shire will use its best efforts to accommodate Impax's requests, and within [\*\*\*] deliver to Impax an updated Delivery Schedule reflecting the same. With respect to any Disputed Quota, the Parties shall also update the Delivery Schedule to reflect the resolution of the dispute and such AG Product shall be delivered as soon as practicable in accordance with the last sentence of Subsection (c) above. The Delivery Schedule may only be modified as follows: (i) to add to the Delivery Schedule for Disputed Quota allocated to Impax; (ii) to revise the Delivery Schedule as required in Section 5. 3(i) due to delays; and (iii) by the Parties as part of a Delivery Schedule Modification in the form annexed as Schedule 5. 3(e) hereto, executed on behalf of Impax by one of its Senior Vice Presidents (or a more senior Impax officer) and Shire.

(f) **Additional Considerations for Allocation to Impax of DEA Quota Grants** . If either Party has verifiable evidence that, [\*\*\*], such Party may provide evidence to the other Party of the same, and upon the other Party's consent, not to be unreasonably withheld, [\*\*\*]. In the event that in any Allocation Period, [\*\*\*] as permitted in this Section [\*\*\*], such that [\*\*\*] remain a part of the calculation of [\*\*\*], then the [\*\*\*] shall be replaced with [\*\*\*]. With respect to [\*\*\*] applicable to the period beginning on January 1, 2012 and ending on December 31, 2012 (the "January-December 2012 Period"), each Party acknowledges and agrees that [\*\*\*] for the January-December 2012 Period has been calculated utilizing an acceptable method, and accurately reflects [\*\*\*] for the January-December 2012 Period. Further, if at any time, whether due to [\*\*\*], Impax AG Product not delivered to Impax according to the Delivery Schedule is: (i) more than [\*\*\*], or (ii) more than [\*\*\*] in any [\*\*\*] period (either being a "Delivery Delay"), at Impax's sole option [\*\*\*] shall for the next Allocation Period, subject to the following sentence, be deemed to be the greater of: [\*\*\*] or [\*\*\*]; provided, however, the foregoing option shall not be available to Impax if Shire can reasonably demonstrate that the difference between [\*\*\*] and [\*\*\*] resulted solely from factors other than a Delivery Delay (e. g. , [\*\*\*]). In the event of a Shire failure to supply resulting from [\*\*\*], and such Shire failure to supply [\*\*\*] due to such [\*\*\*], then [\*\*\*] for the next Allocation Period shall be that of the [\*\*\*] beginning immediately prior to the month of the first delayed or missed product delivery resulting from such [\*\*\*].

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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

(g) **Supply of Impax AG Product January-December 2013.** The Delivery Schedule with respect to any DEA Quota Grant issued prior to the Effective Date (the “January-December 2013 Delivery Schedule”) shall be as follows:

SKU	Jan 2013 (lots)	Feb 2013 (lots)	March 2013 (lots)	April 2013 (lots)	May 2013 (lots)	June 2013 (lots)	July 2013 (lots)	Aug 2013 (lots)	Sept 2013 (lots)	Oct 2013 (lots)	Nov 2013 (lots)	Dec 2013 (lots)	Total Lots
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
Total lots per month	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]

The Parties acknowledge and agree that as of the Effective Date: (i) Shire has supplied the Impax AG Product ordered by Impax for delivery before the Effective Date; and (ii) all purchase orders and forecasts issued by Impax before the Effective Date are cancelled.

(h) **Manufacture and Delivery of Impax AG Product .** The Parties agree and acknowledge that all or some of the Manufacturing of Impax AG Product may be conducted by Shire’s Manufacturer, including [\*\*\*], provided that Impax AG Product [\*\*\*]. Should Shire desire to [\*\*\*] then Shire shall give Impax not less than [\*\*\*]’ prior written notice of the same, along with a complete explanation as to the [\*\*\*]. [\*\*\*]. In addition, Shire shall [\*\*\*] of AG Product to Impax in accordance with the Delivery Schedule. Impax AG Product shall only be delivered to Impax following Shire’s completion of the testing and inspections of the applicable Product as set forth in Section 6. 4 (the “QA Testing”). Subject to any extensions for the [\*\*\*] QA Period, the delivery due date for each month of the Delivery Schedule (a “Delivery Month”) shall be the last Business Day of the month, provided that Shire shall make Impax AG Product available for pickup by Impax earlier in a Delivery Month when Impax AG Product has completed QA Testing. If Impax AG Product is received by Shire from Shire’s Manufacturer in the last several days of a Delivery Month, it will be supplied to Impax within [\*\*\*] after receipt thereafter in order to allow for Shire to complete QA Testing (the “[\*\*\*] QA Period”).

[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions. portions.

(i) **Delays in Delivery** . In the event that any Impax delivery will be delayed, in whole or in part, including without limitation, due to [\*\*\*], Shire will notify Impax of such late delivery as soon as possible and promptly thereafter agree with Impax, such agreement not to be unreasonably withheld, on a later date for delivery that is intended to accommodate the delay, taking into consideration [\*\*\*]. Except as provided in Section 5. 13(d), in no event shall a delay in delivery alter Shire's obligation to supply Impax's Allocated Share according to the Delivery Schedule. If a delay in delivery is unique to batches for Impax, Shire will use its best efforts including, without limitation, utilizing available Reserve Quota, to deliver such batches to Impax as soon as practicable but not later than within [\*\*\*] after the delivery date set forth in the Delivery Schedule. If a delay in delivery is caused by [\*\*\*], then Shire will, in consultation with Impax, set a later date for delivery intended to deliver Impax AG Product to Impax as close to the Delivery Schedule as possible, [\*\*\*], as the case may be. In connection with any [\*\*\*] related to Impax AG Product in addition to notices required by Section 16. 1 hereof, Shire shall provide Impax with the information in its possession reasonably needed to confirm [\*\*\*].

#### **5.4 Allocation of DEA Quota to Impax in 2014**

(a) [\*\*\*]. Shire shall allocate Impax AG Product in an amount not less than Impax's Allocated Share and provide a Delivery Schedule for Impax AG Product with respect to: (i) any quota granted by DEA pursuant to [\*\*\*]; and (ii) any supplemental quota granted by DEA [\*\*\*].

(b) With respect to the Allocation Plan for the Annual DEA Quota Grant for 2014, Impax shall be allocated Impax's Allocated Share, [\*\*\*]; provided, however, that Impax will never receive less than the [\*\*\*] Impax Allocated Share for such DEA Quota Grant. [\*\*\*]. For all DEA Quota Grants received [\*\*\*] but after [\*\*\*], [\*\*\*] shall be utilized to determine Impax's Allocated Share. [\*\*\*].

(c) Except for DEA Quota allocated to Impax during the Supply Term, including without limitation any replacement for such DEA Quota, the Parties agree that Shire shall have no obligation to allocate to Impax any Impax AG Product from any DEA Quota Grant that is granted after [\*\*\*]. Notwithstanding anything to the contrary in this Agreement, Shire is obligated to deliver to Impax all Impax AG Product to be Manufactured from Impax's Allocated Share which Impax was entitled to receive under this Agreement, but which was undelivered as of the end of the Supply Term including, without limitation, AG Product owed from a Deficient Lot, AG Product to be reallocated to Impax pursuant to Section 5. 3(b), Disputed Quota allocated to Impax pursuant to Section 5. 3(c), Shortfall, delayed Impax AG Product, and all undelivered replacement product (“Undelivered Product”). It is understood that the Delivery Schedule may extend beyond expiration of the Supply Term and all Undelivered Product shall be delivered to Impax in accordance with the Delivery Schedule. Impax has the right to Market its inventory after the Supply Term until the inventory is depleted.

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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions. portions.

(d) Notwithstanding anything to the contrary in this Agreement, [\*\*\*]; provided, however, that Shire may request a [\*\*\*] to replace any Adderall XR or AG Product subject to a recall, market withdrawal or seizure. In the event of any discussion or correspondence with DEA concerning a [\*\*\*], or if any DEA Quota Grant actually grants a [\*\*\*], Shire shall notify Impax within five (5) days of such discussion, correspondence or grant in writing with full details including, without limitation, an explanation of any basis for such a [\*\*\*] or discussion thereof, of which Shire has knowledge. Shire shall be solely responsible for compliance with any [\*\*\*] and Impax shall have no liability therefor, provided that such [\*\*\*], further provided, however, that if there is a [\*\*\*].

**5.5 Payment for Impax AG Product.** Shire shall invoice Impax at the time of each shipment of AG Product at the [\*\*\*] for such shipment. Impax shall pay each such invoice within thirty (30) days of receipt.

**5.6 Deliveries.** All deliveries to Impax of Impax AG Product shall be [\*\*\*] facility to a carrier designated by [\*\*\*]. The terms and conditions of this Agreement shall be controlling over any conflicting terms and conditions stated in Impax's purchase order or Shire's invoice or confirmation. Any other document which shall conflict with or be in addition to the terms and conditions of this Agreement is hereby rejected (unless the Parties shall have mutually agreed to the contrary in writing in respect of a particular instance).

**5.7 Records.** During the Term, and for a period of three (3) years thereafter, Shire shall, and shall ensure that its Affiliates shall, keep at either its normal place of business, or at an off-site storage facility, detailed, accurate and up to date:

- (a) records and books of account sufficient to confirm the calculation of the Cost of Goods; and
  - (b) information and data contained in any invoices provided to Impax in connection with this Agreement.
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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

**5.8 Impax Audit of Shire.** On no less than five (5) Business Days' notice from Impax, Shire shall make all (i) records, books of account, information and data concerning the Manufacturing Costs of Impax AG Product and (ii) documentation to verify first receipt by Shire of Adderall XR and AG Product from Shire's manufacturer from each Quota Grant (with any other product information redacted), available for inspection during normal business hours by Impax or its nominee for the purpose of general review or audit, provided that Impax may not request such inspection more than twice in any calendar year. In the event Impax's auditors believe there is a discrepancy in the calculation of Manufacturing Costs or the dates of first receipt, Impax's auditors shall be entitled to take copies or extracts from such records, books of account, information and data (but only to the extent related to the calculation of Manufacturing Costs or to verify dates of receipt) during any review or audit provided the auditor signs a confidentiality agreement with Shire providing that such records, books of account, information and data shall be treated as Confidential Information which may only be disclosed to Impax, its auditors, its legal and other advisors, and as otherwise required by Applicable Laws. If Impax's external auditor's results shows an overpayment by Impax, Shire shall pay the amount of such overpayment, plus simple, non-compounded interest at an annual rate of [\*\*\*] percent ([\*\*\*]%) beginning on the date such overpayment occurred. If Impax's external auditor's results shows an underpayment to Shire, Impax shall pay the amount of such underpayment to Shire. Any underpayment or overpayment of amounts due hereunder due to a discrepancy in the calculation of Manufacturing Costs shall be paid or refunded by the applicable Party within thirty (30) days of the earlier of: (i) the Parties' agreement in writing as to the appropriate overpayment or underpayment; or (ii) the resolution of any disputes related thereto if a dispute is referred for resolution pursuant to Section 16.13(d). For clarity, all disputes related to Impax's, or Shire's or their auditor's conclusions, shall be resolved by the dispute resolution process in Schedule 16.13(d).

**5.9 Audit Costs.** Impax shall be solely responsible for its costs in making any such review and audit, unless Impax identifies a discrepancy in Manufacturing Cost paid to Shire hereunder of five percent (5%) or greater in which event Shire shall be solely responsible for the cost of such review and audit and refund Impax any overpayment. All information disclosed by Shire or its Affiliates pursuant to this Section 5.9 shall be deemed Confidential Information.

**5.10 Rolling Twelve (12) Month Non-Binding Forecasts .** Within fourteen (14) Business Days of the Effective Date and on or before the fifth (5th) Business Day of every calendar quarter thereafter, Impax will deliver a non-binding forecast ("Non-binding Forecast") to Shire, for planning purposes only, of the quantities of Impax AG Product, by SKU, which Impax anticipates it will require for Marketing during the twelve (12) month period ("Forecast Period") beginning three (3) months following the date of such Non-binding Forecast and will include delivery quantities for each month of the Forecast Period.

**5.11 No Other Agreements; [\*\*\*] .** Other than Teva, Shire shall not grant to any Third Party the right to take delivery of or sell AG Product prior to the end of the Supply Term. In addition, Shire agrees to give Impax not less than five (5) Business Days' written notice of [\*\*\*].

**5.12 Communication .** Personnel from Shire and Impax with the requisite decision-making authority will conduct conference calls every two (2) weeks to discuss all issues related to the supply of Impax AG Product to Impax including, all information relating to Shire's DEA Quota Grant requests and DEA Quota Grants, Impax's Allocated Share, [\*\*\*], Allocation Plans for Impax AG Product, SKU Mix, Delivery Schedules, Purchase Orders, Non-binding Forecasts, increased Impax business, timing and quantity estimates for delivery of Impax AG Product, relevant quality assurance issues and relevant batch issues for Impax AG Product. To facilitate increased communication, [\*\*\*] and [\*\*\*] will make themselves available to participate on such calls (or in person) for at least the first two (2) months following the Effective Date.

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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions. portions.

**5.13** [\*\*\*] **for Late Deliveries and Non-Delivery.** Notwithstanding anything to the contrary in this Agreement, if Shire fails to provide supply of Impax AG Product in accordance with the terms of this Agreement, then the following shall apply.

(a) If the Impax AG Product is delivered within [\*\*\*] days of the delivery date set forth in the Delivery Schedule for such AG Product (including only modifications expressly permitted under Section 5. 3(e)), Impax shall have [\*\*\*] due to the delay in delivery. In the event Shire believes that it will be unable to deliver a particular SKU lot within [\*\*\*] days of the delivery date set forth in the Delivery Schedule for such SKU lot, Shire shall provide Impax prompt written notice of the same and may offer Impax timely delivery of a different SKU lot in lieu thereof. If Impax notifies Shire within [\*\*\*] Business Days thereafter that Impax will accept the delivery of the different SKU lot offered by Shire, then (i) the Delivery Schedule will be deemed amended to include, as a replacement for the original SKU lot, the different SKU lot (with the same delivery date as the original) and (ii) Shire shall deliver such different SKU lot on or prior to such delivery date.

(b) Provided that replacement or delayed Impax AG Product is provided to Impax as contemplated herein (including, without limitation, in accordance with Sections 5. 3(b) and 5. 3(i)) such that Impax receives Impax AG Product representing all of Impax's Allocated Share, Impax will [\*\*\*] due to any delay in supplying Impax AG Product later than [\*\*\*] days from the delivery date set forth in the Delivery Schedule if the delay is caused by [\*\*\*]. For any delay in delivery caused by [\*\*\*], Impax's sole remedy for such delay will be [\*\*\*].

(c) If Shire supplies Impax AG Product not covered by an event described in Section 5. 13(b) above, later than [\*\*\*] days but before [\*\*\*] days after the delivery date set forth in the Delivery Schedule (“Late-Supplied AG Product”), Impax's sole and exclusive remedy for such delay will be [\*\*\*]. The Parties shall fully cooperate in the prompt calculation [\*\*\*] under this Section, which calculation shall be completed not later than thirty (30) days after Impax has determined [\*\*\*]. In connection with such calculation, Impax shall provide Shire with written notice of Impax's calculation (the “Impax [\*\*\*] Notice”), along with all the information, documentation, and calculations reasonably needed for Shire to confirm Impax's calculation.

(d) If Shire has failed to supply Impax AG Product not covered by an event described in Section 5. 13(b) above, within [\*\*\*] days of the delivery date set forth in the Delivery Schedule (“Non-Supplied AG Product”):

(i) Shire shall deliver to Impax written notice (the “New Delivery Date Notice”) of a new firm delivery date (the “New Delivery Date”) for the Non-Supplied AG Product.

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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions. portions.

(ii) Beginning on the date the Impax AG Product becomes Non-Supplied AG Product and ending [\*\*\*] days after Impax's receipt of the New Delivery Date Notice from Shire (the "Cancellation Period"), Impax will have the option to cancel its order for the Non-Supplied AG Product, in whole or in part, but only in whole lot increments, and, subject to [\*\*\*] adjustments set forth in Section 5. 3(f), Impax's sole and exclusive remedy for such amount of cancelled Non-Supplied AG Product will be [\*\*\*]. In the event Impax cancels its order for the Non-Supplied AG Product, the amount of DEA Quota that Shire or Shire's Manufacturer would have used to produce the Non-Supplied AG Product shall revert to Shire for its use at its sole discretion. With respect to any amount of Non-Supplied AG Product not cancelled by Impax by the end of the Cancellation Period, Shire shall deliver all such uncanceled Non-Supplied AG Product on or before the New Delivery Date set forth in the New Delivery Date Notice. Subject to [\*\*\*] adjustments set forth in Section 5. 3(f), Impax's sole and exclusive remedy for the amount of Non-Supplied AG Product that is not cancelled by Impax as permitted hereunder and is delivered by the New Delivery Date will be [\*\*\*]. For clarity, in connection with such calculation, [\*\*\*] will be calculated based on the delivery date as originally set forth in the Delivery Schedule, and not based on any New Delivery Date.

(iii) If Shire does not deliver to Impax all of the uncanceled Non-Supplied AG Product subject to a New Delivery Date Notice on or before the New Delivery Date, with respect such Non-Supplied AG Product, Shire shall deliver to Impax another New Delivery Date Notice (a "Subsequent Delivery Date Notice") and, beginning on the first day after the New Delivery Date and ending [\*\*\*] days after Impax's receipt of such Subsequent Delivery Date Notice (a "Subsequent Cancellation Period"), Impax will have the option to cancel its order for the Non-Supplied AG Product, in whole or in part, but only in whole lot increments, and, subject to [\*\*\*] adjustments set forth in Section 5. 3(f), Impax's sole and exclusive remedy for such amount of cancelled Non-Supplied AG Product will be [\*\*\*]. With respect to the amount of Non-Supplied AG Product not cancelled by Impax by the end of the Subsequent Cancellation Period, Shire shall deliver all such uncanceled Non-Supplied AG Product on or before the New Delivery Date set forth in the Subsequent Delivery Date Notice. Subject to [\*\*\*] adjustments set forth in Section 5. 3(f), Impax's sole and exclusive remedy for the amount of Non-Supplied AG Product that is not cancelled by Impax as permitted hereunder and is delivered by the New Delivery Date set forth in the Subsequent Delivery Date Notice will be [\*\*\*]. For clarity, in connection with such calculation, [\*\*\*] will be calculated based on the delivery date as originally set forth in the Delivery Schedule, and not based on any New Delivery Date. The foregoing process shall be repeated until all remaining Non-Supplied AG Product is either (i) cancelled by Impax and Shire [\*\*\*] for such cancelled Non-Supplied AG Product or (ii) delivered to Impax by Shire by or before the then-applicable New Delivery Date.

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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

(iv) The Parties shall fully cooperate in the prompt calculation of [\*\*\*] which calculation shall be completed no later than thirty (30) days after Impax's delivery of notice of cancellation of any Non-Supplied AG Product. In connection with such calculation, Impax shall provide Shire with written notice of Impax's [\*\*\*] along with all the information, documentation, and calculations reasonably needed for Shire to confirm Impax's calculation.

(e) If Shire believes there is an error or miscalculation in Impax's calculation under Sections 5. 13(c) or (d), then (i) Shire shall provide Impax with an explanation of the reasons why it believes there has been an error or miscalculation and Shire shall pay all undisputed amounts within ten (10) days of receipt of the Impax [\*\*\*] Notice or the [\*\*\*] (as applicable) and (ii) Impax shall provide Shire any additional documents that it believes may assist in understanding the calculations in dispute. With respect to any disputed amounts, upon request from Shire, Impax shall permit reasonable access to its records in order for Shire to verify Impax's relevant calculations. In addition, the Parties shall have the right to seek a resolution pursuant to the dispute resolution procedure required by Section 16. 13(d). Disputed amounts shall be paid within ten (10) Business Days of agreement between the Parties or resolution of dispute resolution. If any dispute is resolved in favor of Impax, interest [\*\*\*] at the rate set forth in Section 5. 13(h).

(f) In the event that Shire has failed to supply Impax AG Product to Impax as contemplated by Section 5. 13(d), [\*\*\*].

(g) During any period when any Impax AG Product has not been delivered by its delivery date set forth in the Delivery Schedule, all incoming Impax AG Product shall be credited as follows: (i) first, against any deliveries of Impax AG Product scheduled for the Delivery Month in which the delayed Impax AG Product is delivered, and (ii) second, against delayed Impax AG Product originally scheduled for delivery in each prior Delivery Month, beginning with the most recent Delivery Month preceding the Delivery Month referred to in clause (i) of this subsection and continuing to the next most recent Delivery Month until all Impax AG Product deliveries are up to date. Except as provided for in Section 5. 13(f), nothing in this Agreement shall be interpreted or construed to allow or permit a Party to delay, withhold, deduct, or cancel any amounts due and payable to the Party under this Agreement, including, without limitation, royalties due and payable by Impax under Section 9 and payment for Impax AG Product under Section 5. 5.

(h) All [\*\*\*] to be made pursuant to Section 5. 13(d) shall be subject to simple, non-compounded interest at an annual rate of [\*\*\*] percent ([\*\*\*]%) beginning on the delivery date in the Delivery Schedule until such [\*\*\*].

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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

**6. Quality Assurance; Acceptance**

**6.1** Shire represents, covenants and warrants to Impax that:

(a) all AG Product hereunder shall be produced in accordance with cGMP and other Applicable Laws, rules and regulations and that none of the AG Product supplied hereunder shall be adulterated or misbranded as defined by the Act;

(b) all shipments of AG Product supplied hereunder shall meet the specifications and quality control standards set forth in Shire's NDA;

(c) Shire or a Shire Affiliate will use Commercially Reasonable Efforts to maintain throughout the term of this Agreement all permits, licenses, registrations and other forms of governmental authorization and approval required in order for Shire to perform its obligations hereunder in accordance with all Applicable Laws;

(d) to Shire's knowledge upon due investigation, as of the Original Effective Date, the Manufacture or Marketing of the AG Products in the Territory pursuant to this Agreement does not infringe, misappropriate or otherwise conflict with any intellectual property rights of any Third Party;

(e) Shire or a Shire Affiliate owns and possesses all right, title and interest in the Shire NDA; and

(f) Shire has the right to grant all of the rights and licenses granted herein to Impax under the Adderall XR Intellectual Property, and it is not under any obligation to any Third Party that conflicts with the terms of this Agreement.

**6.2** Impax AG Products shall (i) have a shelf life of at least [\*\*\*] months from the date of Manufacture and (ii) conform to ; NDA.

**6.3** All AG Products will be in finished dosage form, filled, Packaged and Labeled for commercial sale in accordance with the terms and conditions of this Agreement, the Quality Agreement, and Applicable Laws.

**6.4** Shire shall perform all quality control tests and other inspections required by applicable cGMP standards and Shire's NDA and shall furnish to Impax a certificate of analysis together with each lot of AG Product shipped to Impax. Shire will also provide Impax with Material Safety Data Sheets as required by Law for the AG Products, and updates of same as necessary.

**6.5** Shire will promptly notify Impax of any request from the FDA to change AG Product specifications or Labeling and will notify Impax of any changes in specifications. No such change which requires FDA approval will be implemented prior to obtaining such Impax approval.

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**6.6** Impax shall conduct, at its own expense, such tests as it deems necessary to determine the compliance of the AG Product with the requirements of Sections 6. 1(a-b), 6. 2 and 6. 3. Impax shall notify Shire within thirty (30) days of its receipt of each shipment of the AG Product of any non-compliance of the AG Product with the requirements of Sections 6. 1(a-b), 6. 2 or 6. 3 revealed by such testing. If no notice of non-compliance is delivered to Shire within such thirty (30) day period, the AG Product so delivered shall be deemed to comply with Sections 6. 1(a-b), 6. 2 or 6. 3.

**6.7** Subject to the provisions of Section 6. 8, Shire shall replace, at its own expense including, without limitation, all freight costs, any AG Product that does not meet the requirements of Sections 6. 1, 6. 2 and 6. 3. Subject only to the indemnification obligations set forth in Section 12. 1, Shire shall have no other obligation with respect to Losses in respect of such AG Product or the representations set forth in Sections 6. 1, 6. 2 and 6. 3.

**6.8** If, following the timely delivery of a notice by Impax pursuant to the provisions of Section 6. 6, Impax and Shire do not agree that any lot or lots of the AG Product referred to in the notice meets the requirements of Sections 6. 1(a-b), 6. 2 or 6. 3, that lot or those lots of the AG Product shall be tested for such compliance, within thirty (30) days after notice of the defect is delivered to Shire, by a disinterested Third Party expert selected by the mutual agreement of Impax and Shire. The decision of such Third Party expert with respect to the question of compliance shall be binding upon Impax and Shire for the purposes of Sections 6. 1(a-b), 6. 2 or 6. 3 of this Agreement only. The costs of such testing shall be borne by Shire if such lot or lots are found not to meet the requirements of Sections 6. 1(a-b), 6. 2 or 6. 3 and by Impax if those lot or lots are found to meet the requirements of Sections 6. 1(a-b), 6. 2 or 6. 3.

**6.9** At least once per calendar year following the License Effective Date, Impax will provide Shire with a certificate of a duly authorized officer with regulatory responsibilities to the effect that Impax stores and ships AG Product in accordance with all Applicable Laws and regulations, including cGMP standards.

**6.10** Impax represents, covenants and warrants to Shire that all Generic Product Marketed by Impax will be stored, shipped and handled in accordance with cGMP and all Applicable Laws, rules and regulations and all Impax Product Manufactured by Impax, or for Impax by a Third Party, shall be Manufactured, shipped and handled in accordance with cGMP and all Applicable Laws, rules and regulations and the Impax ANDA.

**7. Regulatory Responsibilities; Adverse Event Reporting; Recalls**

**7.1** As the holder of Shire's NDA, Shire will have sole authority to deal with regulatory matters relating to Shire's NDA or AG Product. During the term hereof, Shire shall maintain Shire's NDA in accordance with all applicable requirements of the FDA and other Governmental Authorities, including, without limitation, the filing of all annual and other reports or filings required by the FDA.

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**7.2** Impax shall submit to Shire all reports of Adverse Drug Experiences, together with all relevant information possessed by it, in time for Shire to meet all periodic and annual safety regulatory obligations to the FDA. Impax shall also promptly submit to Shire all AG Product inquiries or complaints for handling by Shire. Each Party shall cooperate with the other and provide information in its possession to the extent necessary for the other Party to comply with all legal requirements relating to the Manufacture or Marketing of Generic Product and the Parties will use diligent efforts to agree upon a customary pharmacovigilance protocol as promptly as practicable after the date hereof to provide for the necessary exchange of adverse event and related information to permit Shire to comply with Applicable Laws and regulations on a timely basis.

**7.3** Each of Shire and Impax will immediately inform the other in writing if it believes one or more lots of any AG Product should be subject to recall from distribution, setting forth the reasons therefore with reasonable specificity. To the extent permitted by legal and public safety requirements, the Parties will confer before initiating any recall. If the Parties do not reach agreement on the need for a recall, either Party may initiate a recall. The Party initiating the recall shall initially bear the cost thereof and shall carry out the recall in accordance with best industry practices. In the event it is determined that a recall resulted from a breach by a Party of any of its representations or warranties hereunder, such Party shall be responsible for the costs of the recall and the cost of any unnecessary or groundless recall or other recall which is not the result of a breach by the other Party or any of its representations and warranties hereunder, shall be borne by the Party initiating or requesting such recall. In no event shall a Party's liability to the other hereunder exceed the actual out-of-pocket costs incurred or the cost of replacement of AG Product at a price equal to the Manufacturing Costs, as the case may be, and neither Party shall be liable for lost profits or other consequential damages.

**7.4** As the holder of the Impax ANDA, Impax will have sole authority and responsibility to deal with regulatory matters relating to the Impax ANDA or Impax Product including maintaining the Impax ANDA as applicable in accordance with all applicable requirements of the FDA, including, without limitation, the filing of all annual and other reports or filings required by the FDA.

**7.5** Shire shall keep, or cause its Affiliates to keep, as required, such samples and such records (or copies thereof) in respect of the AG Products as are required by Applicable Law for such period of time as may be required thereunder.

**7.6** Each of Shire and Impax shall promptly inform the other of any correspondence from the FDA regarding the Generic Products that would materially affect its ability to meet its obligations under this Agreement. Each of Shire and Impax shall notify the other promptly, but in no event later than ten (10) Business Days following the occurrence thereof, of any materially adverse inspections by the FDA or other regulatory authorities which pertain to the Generic Products or to the facilities of such Party or its Affiliate where the Generic Products are being Manufactured or stored.

**7.7** Impax and Shire have entered into a Quality Agreement in form and content reasonably acceptable to Impax and Shire ("Quality Agreement"). The Quality Agreement includes protocols and specific responsibilities for handling AG Products quality complaints, ADE reports, and professional medical service inquiries in accordance with Shire's standard operating procedures and in conformity with Applicable Laws.

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## **8. Marketing of Generic Product**

**8.1** Impax shall, at its sole cost and expense, utilize all Commercially Reasonable Efforts in Marketing the Generic Product in the Territory to maximize sales and profits of Generic Product. During the Term Impax shall not enter into any arrangements or agreements with any other Person to Market or promote Generic Product in the Territory without Shire's prior written consent, except that Impax shall not be restricted in entering into customary agreements with its ordinary trade customers including, without limitation, distributors and retailers.

**8.2** It is the intent of the Parties that Impax will seek to sell Generic Product for its full market value. Impax will have sole discretion, however, in setting the price for the sale of the Generic Product in the Territory. Impax will also agree that if it prices Generic Product in order to gain or maintain sales of other products, then for purposes of calculating the payments due hereunder, the Net Sales of such Generic Product shall be adjusted to reverse any discount which was given to a customer that was in excess of customary discounts for the Generic Product (or, in the absence of relevant data for this Generic Product, other similar products under similar market conditions).

## **9. Shire Profit Share**

**9.1** During the Term, Impax shall pay to Shire a royalty of [\*\*\*] percent ([\*\*\*]%) of the Net Profits of Impax Product.

**9.2** Impax shall pay a royalty to Shire equal to:

(a) [\*\*\*] percent ([\*\*\*]%) of the Net Profits on sales of Impax AG Product made by Impax during any period when the Impax AG Product is the only Generic Equivalent being Marketed in the Territory other than a Generic Equivalent marketed by or on behalf of Barr Laboratories, Inc. or any successor in interest to Barr Laboratories, Inc.'s ANDA that is the subject of the past litigation between Shire and Barr Laboratories, Inc.

(b) [\*\*\*] percent ([\*\*\*]%) of the Net Profits on sales of Impax AG Product made by Impax during any time period other than as described in Section 9. 2(a).

**9.3** Payments due under this Section 9 shall be made within forty-five (45) days from the end of each calendar quarter in which Generic Product is sold (" Reporting Period "). All such payments shall include an invoice detailing the calculation of Net Sales and Net Profits, including itemized calculations for each of (i) through (xiv) set forth in Sections 1. 82 and 1. 83, as each may be applicable and the royalties payable hereunder. In the event of two occurrences where payment by Impax is delayed beyond the relevant Reporting Period, the Reporting Period shall be changed to thirty (30) days from the end of each calendar quarter at Shire's election and upon ten (10) days advance written notice from Shire to Impax. For clarity, the definition of Net Sales set forth in Section 1. 83 of this Agreement shall be applied to all sales of Generic Product sold on or after April 1, 2011 and shall be used for all related calculations.

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**9.4** In the event that Net Profits is a negative amount for any Reporting Period, no payment or refund shall be due from Impax to Shire or from Shire to Impax, in respect thereof and the Net Profits with respect to the subsequent Reporting Period, shall be reduced by such negative amount for purposes of determining Shire's share of the Net Profits for such subsequent Reporting Period.

**9.5 Maintenance of Records** . During the Term, and for a period of three (3) years thereafter, Impax shall, and shall insure that its Affiliates shall, keep at either its normal place of business, or at an off-site storage facility, detailed, accurate and up to date:

- (a) records and books of account sufficient to confirm the calculation of the Net Sales and Net Profits; and
- (b) information and data contained in any invoices or reports accompanying any payment to Shire provided to Shire in connection with this Agreement.

**9.6 Inspection.** On no less than five (5) Business Days' notice from Shire, Impax shall make all such records, books of account, information and data concerning this Agreement available for inspection during normal business hours by Shire or its nominee for the purpose of general review or audit, provided that Shire may not request such inspection more than twice in any calendar year. In the event Shire's external auditors believe there is a discrepancy in the calculation of Net Sales or Net Profits paid to Shire (including in the Returns and Final Reconciliation Report) or [\*\*\*] paid, or to be paid, by Shire pursuant to Section 5. 13, Shire's external auditors shall be entitled to take copies or extracts from such records, books of account, information and data (but only to the extent related to the contractual obligations set out in this Agreement) during any review or audit provided the external auditor signs a confidentiality agreement with Impax providing that such records, books of account, information and data shall be treated as Confidential Information which may be disclosed to Shire, its auditors, its legal and other advisors, and as otherwise required by Applicable Laws. If Shire's external auditor's results shows an underpayment to Shire, subject to the rights and remedies available to Impax including a right to seek dispute resolution, Impax shall pay the amount of such underpayment, plus simple, non-compounded interest at an annual rate of [\*\*\*] percent ([\*\*\*]%) beginning on the date of such underpayment. If Shire's external auditor's results shows an overpayment to Shire, Shire shall pay the amount of such overpayment to Impax. Any underpayment or overpayment of amounts due hereunder shall be paid or refunded by the applicable Party within thirty (30) days of the earlier of (i) the Parties' agreement in writing as to the appropriate overpayment or underpayment or (ii) the resolution of any disputes related thereto if a dispute is referred for resolution pursuant to Section 16. 13(d). For clarity all disputes related to Impax's, or Shire's or their auditor's conclusions, shall be resolved by the dispute resolution process in Schedule 16. 13(d).

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**9.7 Inspection Costs** . Shire shall be solely responsible for its costs in making any such review and audit, unless Shire identifies a discrepancy in the calculation of Net Sales or Net Profits paid to Shire under this Agreement in any calendar year from those properly payable for that calendar year of five percent (5%) or greater, in which event Impax shall be solely responsible for the cost of such review and audit and refund Shire any overpayment. All information disclosed by Impax or its Affiliates pursuant to this Section 9 shall be deemed Confidential Information.

**9.8 12-Month True Up.** Twelve (12) months after the end of the Supply Term, Impax shall perform a “true-up” reconciliation of the items comprising deductions from Net Sales and thereafter shall provide Shire with a written report of such reconciliation (the “Returns and Final Reconciliation Report”). The reconciliation shall be based on actual cash paid or credits issued through the end of the Supply Term, and during the [\*\*\*] month setoff period that follows the Supply Term. In determining whether and to the extent an underpayment or overpayment to Shire has been made, the reconciliation shall calculate the payments due Shire based on the royalty rate due Shire under Section 9. 1 or 9. 2 applicable at the time the deduction was originally accrued. If the Returns and Final Reconciliation Report shows an underpayment to Shire, subject to the rights and remedies available to Impax including a right to seek dispute resolution, Impax shall pay the amount of such underpayment plus simple, non-compounded interest at an annual rate of [\*\*\*] percent ([\*\*\*]%) beginning on the date such deduction was accrued, to Shire within thirty (30) days of the date of delivery of such report. If the Returns and Final Reconciliation Report shows an overpayment to Shire, Shire shall pay the amount of such overpayment, to Impax within thirty (30) days of the date of delivery of such report. Shire shall be entitled to conduct an audit of Impax within thirty (30) days of Shire’s receipt of the Returns and Final Reconciliation Report, in accordance with the procedures set forth in Sections 9. 6 and 9. 7.

**9.9 Shire Payment.** As part of the consideration set forth herein, Shire agrees to pay Impax Forty-Eight Million Dollars (\$48,000,000) (the “Payment Amount”). Within [\*\*\*] after the Court’s entry of a Stipulation of Dismissal or Order of Dismissal (each as defined in the Supply Litigation Settlement Agreement) as applicable, Shire shall pay Impax the Payment Amount in a single cash payment via wire transfer to an account designated by Impax at least [\*\*\*] prior to the date the Payment Amount is due.

## **10. Confidentiality**

**10.1 Confidentiality Obligation** . The Parties, their Affiliates and their respective employees, directors, officers, consultants and contractors shall keep and maintain as confidential any Confidential Information supplied by the other Party during the Term. The confidentiality and non-disclosure obligations contained in this Agreement shall not apply to the extent that such Confidential Information is:

- (a) at the time of disclosure by one Party to the other, in the public domain or otherwise publicly known;
  - (b) after disclosure by one Party to the other becomes part of the public domain, other than by breach of any obligation of confidentiality;
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(c) information which the receiving Party can establish by competent evidence was already in its possession at the time of receipt or was independently developed by the receiving Party; or

(d) received from a Third Party who was lawfully entitled to disclose such information free of an obligation of confidentiality.

**10.2 Exceptions** . Notwithstanding Section 10. 1, the Party receiving Confidential Information may disclose such Confidential Information to the extent that such disclosure has been ordered by a court of law or directed by a Governmental Authority, provided that, the disclosure is limited to the extent ordered or directed and wherever practicable, the Party that owns the Confidential Information has been given sufficient written notice in advance to enable it to seek protection or confidential treatment of such Confidential Information.

**10.3 Expiration of Confidentiality** . The confidentiality obligation contained in this Section 10 shall survive the termination of this Agreement for so long as such information remains confidential.

**10.4 Disclosure** . If a Party is subpoenaed or otherwise requested by any Person including, without limitation, any Governmental Authority to give testimony or provide information which in any way relates to this Agreement, the Generic Product or practices associated with the Generic Product, such Party shall give the other Party prompt notice of such request, and unless otherwise required by Law, shall make no disclosure until such other Party has had a reasonable opportunity to contest the right of the requesting Person to such disclosure. The Parties shall provide each other with all reasonable cooperation and generally make its employees available to give testimony or to provide reasonable assistance in connection with any lawsuits, claims, proceedings and investigations relating to this Agreement, the Generic Product or practices associated with the Generic Product.

**10.5** The Parties agree that equitable relief, including injunctive relief and specific performance, is appropriate in enforcing the confidentiality provisions of this Agreement. In the event of any such action to construe this provision, the prevailing Party will be entitled to recover, in addition to any charges fixed by the court, its costs and expenses of suit, including reasonable attorney's fees. Such remedies shall not be deemed to be the exclusive remedies for a breach of this provision, but shall be in addition to all other remedies available at law or equity.

## **11. Representations and Warranties of Both Parties**

With respect to Sections 11. 1 and 11. 2 below, each of Shire and Impax represents, warrants, and covenants, to the other Party that:

**11.1 Organization and Authority** . Such Party is a corporation duly organized, validly existing and in good standing under the Laws of its jurisdiction of incorporation. Such Party has the requisite corporate power and authority to enter into this Agreement. Such Party has the requisite corporate power and authority to execute and deliver this Agreement and to perform all of its obligations hereunder. The execution and delivery of this Agreement and the performance by such Party of its obligations hereunder have been authorized by all requisite corporate action on its part. This Agreement has been validly executed and delivered by such Party, and, assuming that such documents have been duly authorized, executed and delivered by the other Party, constitutes a valid and binding obligation of such Party, enforceable against such Party in accordance with its terms.

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## 11.2 Consents and Approvals; No Violations

(a) Except as otherwise set forth in this Agreement or the Supply Litigation Settlement Agreement, no material filing with, and no material permit, authorization, consent such Party of the transactions contemplated by this Agreement, except for those filings, permits, authorizations, consents or approvals, the failure of which to be made or obtained would not materially impair such Party's ability to consummate the transactions contemplated hereby or materially delay the consummation of the transactions contemplated hereby.

(b) Neither the execution nor the delivery of this Agreement by such Party, nor the performance by such Party of its obligations hereunder, will (i) violate the certificate of incorporation, by-laws or other organizational document of such Party; (ii) conflict in any material respect with or result in a material violation or breach of, or constitute a material default under, any material contract, agreement or instrument to which such Party is a party; or (iii) violate or conflict in any material respect with any material Law, rule, regulation, judgment, order or decree of any court or Governmental Authority applicable to such Party, except in the case of clause (ii) or (iii) for violations, breaches or defaults which would not have a material adverse effect on such Party's ability to consummate the transactions contemplated hereby.

(c) The Parties shall submit this Agreement together with the Supply Litigation Settlement Agreement (as part of the Settlement Documents, as defined in the Supply Litigation Settlement Agreement) to the Federal Trade Commission Bureau of Competition and the Assistant Attorney General in charge of the Antitrust Division of the Department of Justice as soon as practicable following its execution and in no event later than ten (10) Business Days following its execution.

## 12. Indemnities; Product Liability; Insurance

**12.1 Indemnity by Shire** . Shire shall defend, indemnify and hold harmless each of Impax and its Affiliates and its and their directors, officers, employees and contractors (“Impax Party”) from and against any and all Losses, (“Shire Liability”) arising from or in connection with:

(a) any Third Party claim, lawsuit, investigation, proceeding, regulatory action, or other cause of action (“Claim”) resulting from any negligent acts or acts of willful misconduct of any Shire Party in connection with the performance of its obligations under this Agreement;

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- (b) Shire's failure to Manufacture, store or release the AG Product for shipment in accordance with Applicable Laws, regulations or Shire's NDA;
- (c) the breach by Shire of any of its representations or warranties contained in this Agreement; or
- (d) any misuse by a Shire Party of Impax's company name or logo or other trademark;

except, in each case, to the extent that the Shire Liability is caused by the negligence, breach of the terms of this Agreement, or willful misconduct of an Impax Party.

**12.2 Indemnity by Impax** . Impax shall defend, indemnify and hold harmless each of Shire and its Affiliates and its and their directors, officers, employees and contractors (" Shire Party ") from and against any and all Losses (" Impax Liability ") arising from or in connection with:

- (a) any Claim resulting from any negligent acts or acts of willful misconduct of any Impax Party in connection with the performance of its obligations under this Agreement;
- (b) any Claim based on or arising out of the use, Manufacturing or Marketing of Impax Product, including, without limitation, any investigation by a Governmental Authority or any Claim for personal injury or property damage asserted by any user of Impax Product;
- (c) any Claim based on or arising out of the use or Marketing of AG Product by Impax, including, without limitation, any investigation by a Governmental Authority or any Claim for personal injury or property damage asserted by any user of AG Product in each case to the extent that such liability is a result of the acts or failure to act of Impax or its employees, agents, partners, contractors or the like;
- (d) the breach by Impax of any of its representations or warranties contained in this Agreement; or
- (e) any misuse by the Impax Parties of Shire's company name or logo or other trademark;

except, in each case, to the extent that the Impax Liability is caused by the negligence, breach of the terms of this Agreement, or willful misconduct of a Shire Party.

**12.3 Control of Proceedings** . A Party seeking indemnification hereunder shall provide prompt written notice to the other Party (and, in any event, within five (5) Business Days) of the assertion of any Claim against such Party as to which indemnity is to be requested hereunder. The indemnifying Party shall have the sole control over the defense of any Claim, provided that, the indemnifying Party shall obtain the written consent of the indemnified Party prior to settling or otherwise disposing of such Claim if as a result of the settlement or Claim disposal the indemnified Party's interests are in any way adversely affected.

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**12.4 No Admissions** . The indemnified Party shall not make any payment or incur any expenses in connection with any Impax Liability or Shire Liability (as the case may be), or make any admissions or do anything that may compromise or prejudice the defense of any Claim without the prior written consent of the indemnifying Party.

**12.5 Claim Information** . Each Party shall promptly:

- (a) inform the other by written notice of any actual or threatened Claim to which Sections 12. 1 or 12. 2 apply;
- (b) provide to the other Party copies of all papers and official documents received in respect of any such Claim;

and

- (c) cooperate as reasonably requested by the other Party in the defense of any such Claim.

**12.6 Contributory Negligence** . If any Shire Liability or Impax Liability is caused by the negligence of both Shire and Impax, the apportionment of liability shall be shared between Shire and Impax based upon the comparative degree of each Party's negligence and each Party shall be responsible for its own defense and its own costs including, but not limited to, the cost of defense attorneys' fees and witnesses' fees and expenses incident thereto.

**12.7 Limitation of Liability**. Except (i) as may be included in a Claim under Section 12. 1 or 12. 2, or (ii) as provided in Section 5. 13, in no event shall either Party or their respective Affiliates be liable for special, punitive, indirect, incidental or consequential loss or damage, or for any lost profits, business or revenue, based on contract, tort or any other legal theory arising out of this Agreement, including as caused by Shire's failure to deliver Impax AG Product as required under this Agreement; even if the remedies provided for in this Agreement fail of their essential purpose and even if either Party has been advised of the possibility or probability of such damages.

**12.8 Product Liability Insurance** . Each Party shall maintain, at its own cost, general commercial liability insurance (including comprehensive product liability) in such amount as Shire and Impax respectively, customarily maintain with respect to its other products and which is reasonable and customary in the U. S. pharmaceutical industry for companies of comparable size and activities but in any event not less than \$[\*\*\*] per occurrence and \$[\*\*\*] in the aggregate. In the event the insurance policy obtained by a Party is a "claims made" policy (as opposed to an "occurrence" policy), such Party shall obtain comparable insurance for not less than six (6) years following the expiry or termination of this Agreement. Impax will cause Shire to be named as an additional insured under Impax's product liability insurance.

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**12.9 Limitation on Representations, Warranties and Indemnification. NEITHER PARTY SHALL BE DEEMED TO MAKE ANY REPRESENTATIONS OR WARRANTIES, WHETHER EXPRESS OR IMPLIED, EXCEPT AS SPECIFICALLY SET FORTH HEREIN. ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, WITH REGARD TO THE AG PRODUCT TO BE SUPPLIED BY SHIRE HEREUNDER, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, ARE HEREBY DISCLAIMED BY EACH PARTY.**

**13. Force Majeure**

**13.1 Force Majeure .** Neither Party shall be entitled to terminate this Agreement or shall be liable to the other under this Agreement for loss or damages attributable to any Force Majeure, provided the Party affected shall give prompt notice thereof to the other Party. Subject to Section 13. 2, except as provided in Sections 5. 3(i) and 5. 13(b), the Party giving such notice shall be excused from such of its obligations hereunder for so long as it continues to be affected by Force Majeure.

**13.2 Continued Force Majeure.** If any Force Majeure continues unabated for a period of at least ninety (90) days, the Parties shall meet to discuss in good faith what actions to take or what modifications should be made to this Agreement as a consequence of such Force Majeure in order to alleviate its consequences on the affected Party.

**14. Trademarks and Trade Names**

Except for the identification of Shire as manufacturer of AG Product on Packaging or Labeling to the extent required by Law, Impax shall have no right to use any trademark or tradeness of Shire and shall have no rights to any other intellectual property of Shire or its Affiliates (including patents or other intellectual property relating to the shape, consistency, formulation or Manufacturing process for the AG Product) other than to the extent of the Authorization and License.

**15. Term and Termination**

**15.1** Unless sooner terminated in accordance with the terms hereof, the term of this Agreement shall extend from the date hereof until the expiration of the last Valid Claim within the Adderall XR Intellectual Property (the “Term”). The foregoing notwithstanding, the obligations of Shire regarding supply of AG Product under this Agreement shall extend from the date hereof only until the earlier of: (i) September 30, 2014, or (ii) Impax’s Launch of an Impax Product (the “Supply Term”), subject to Section 15. 3(c).

**15.2 Termination .** Either Party shall be entitled to terminate this Agreement by written notice to the other if:

(a) the other Party commits a material breach of this Agreement, and fails to remedy it within sixty (60) days of receipt of notice from the first Party of such breach and of its intention to exercise its rights under this Section 15. 2; or

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(b) an order is made or a resolution is passed for the winding up of the other Party (other than voluntarily for the purposes of solvent amalgamation or reconstruction) or an order is made for the appointment of an administrator to manage the other Party's affairs, business and property or if a receiver (which expression shall include an administrative receiver) is appointed over any of the other Party's assets or undertaking or if circumstances arise which entitle the court or a creditor to appoint a receiver or manager or which entitle the court to make a winding-up order or if a voluntary arrangement is proposed in respect of the other Party or if the other Party takes or suffers any similar or analogous action in consequence of debt, and such order, appointment or similar action is not removed within ninety (90) days.

### **15.3 Effect of Expiration or Termination .**

(a) In the event of early termination of this Agreement for any reason, Impax shall no longer have the right to Market Impax Product under the Authorization and License; provided that Impax may continue to Market inventory then on hand for an additional six (6) month period as to which Impax shall pay Shire the applicable royalty under Section 9 above.

(b) In the event of expiry or early termination of this Agreement for any reason, Impax shall promptly return to Shire all Confidential Information of Shire provided to Impax during the Term.

(c) In the event of the expiry or early termination of the Supply Term for any reason, Impax shall no longer have the right to Market Impax AG Product, provided that Impax may continue to Market inventory of Impax AG Product then on hand until such inventory is depleted; and Impax shall have the right to Market any Impax AG Product that would have been otherwise delivered to Impax prior to termination, but which AG Product had not been delivered including without limitation Undelivered Product and any AG Product to be delivered post-Launch pursuant to Section 3. 7; provided, however, that Impax shall pay Shire the applicable royalty under Section 9 above for all such Impax AG Product Marketed.

**15.4 Liability on Termination .** The termination or expiry of this Agreement shall not release either of the Parties from any liability which at the time of termination or expiry has already accrued to the other Party, nor affect in any way the survival of any other right, duty or obligation of the Parties which is expressly stated elsewhere in this Agreement to survive such termination or expiry.

**15.5 Surviving Sections.** The provisions of Sections 1, 3. 7, 3. 8, 5. 4(c), 5. 6, 5. 7, 5. 8, 5. 9, 5. 13, 6, 7, 9. 4, 9. 5, 9. 6, 9. 7, 9. 8, 10, 12, 14, 15 and 16, and any other provisions necessary and proper to give effect to the intention of the Parties as to the effect of the Agreement after termination, shall continue in force in accordance with their respective terms notwithstanding expiry or termination of this Agreement for any reason.

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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions. portions.

**16. Miscellaneous**

**16.1 Notice.**

(a) Any notice or other document given under this Agreement shall be in writing in the English language and shall be given by hand or sent by prepaid airmail, by fax transmission or e-mail to the address of the receiving Party as set out in Section 16. 2 below unless a different address or fax number has been notified to the other in writing for this purpose.

(b) Each such notice or document shall:

(i) if sent by hand, be deemed to have been given when delivered at the relevant address;

(ii) if sent by prepaid mail, be deemed to have been given five (5) days after posting; or

(iii) if sent by fax or email transmission be deemed to have been given when transmitted, provided that, a confirmatory copy of such fax or email transmission shall have been sent by prepaid mail within twenty-four (24) hours of such transmission.

**16.2 Address for Notice .** The address for services of notices and other documents on the Parties shall be:

**If to Shire :** Shire LLC  
9200 Brookfield Court  
Florence, KY 41042  
United States of America  
Fax: (484) 595-8674  
Attn: Associate General Counsel

**If to Impax:** Impax Laboratories, Inc.  
30831 Huntwood Avenue  
Hayward, CA 94544  
United States of America  
Fax: (510) 240-6000  
Attn: Chief Executive Officer

**With a copy to :** Impax Laboratories, Inc.  
31047 Genstar Road  
Hayward, CA 94544  
Fax: (510) 240-6096  
Attn: Mark A. Schlossberg, Esq. ,  
Senior Vice President and General Counsel

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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions. portions.

### **16.3 Assignment.**

(a) Subject to Section 16.3(b), Impax shall not assign or transfer any of its rights or obligations under this Agreement without the prior written consent of Shire, such consent not to be unreasonably withheld or delayed.

(b) Subject to Section 16.3(c) in the case of Impax, each Party shall be entitled to assign all or any of its rights or obligations under this Agreement to an Affiliate or to a successor entity by way of merger or acquisition of substantially all of the assets of Impax; provided the Affiliate or other successor entity expressly assumes in writing those rights, duties and obligations under this Agreement and this Agreement itself and the Affiliate or other successor is a financially capable business entity.

(c) Anything to the contrary in this Agreement notwithstanding, to the extent that Impax assigns or transfers any of its rights or obligations under this Agreement to any [\*\*\*].

(d) Subject to the foregoing this Agreement shall be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns. Any assignment or transfer in contravention of the terms of this Agreement shall be null and void.

**16.4 Amendment .** Subject to the procedure for the modification of Delivery Schedules required by Section 5.3(e), this Agreement may not be varied, changed, waived, discharged or terminated, except by an instrument in writing signed by the Party against which enforcement of such variation, change, waiver, discharge or termination is sought.

**16.5 Public Announcements .** Except as expressly provided for in the Supply Litigation Settlement Agreement, neither Party shall make any publicity releases, interviews or other dissemination of information concerning this Agreement or its terms, or either Party's performance hereunder, to communication media, financial analysts or others without the prior written approval of the other Party, which approval shall not be unreasonably withheld, delayed or conditioned. Notwithstanding anything to the contrary in this Agreement, the Parties understand and agree that either Party, may, if so required, disclose some or all of the information included in this Agreement or other Confidential Information of the other Party(a) in order to comply with its obligations under the Law, including the United States Securities Act of 1933, the United States Securities Exchange Act of 1934, (b) the listing standards or agreements of any national or international securities exchange or The NASDAQ Stock Market or other similar Laws of a Governmental Authority, (c) to respond to an inquiry of a Governmental Authority or regulatory authority as required by Law, or (d) in a judicial, administrative or arbitration proceeding. In any such event the Party making such disclosure shall (x) provide the other Party with as much advance notice as reasonably practicable of the required disclosure, (y) cooperate with the other Party in any attempt to prevent or limit the disclosure, and (z) limit any disclosure to the specific purpose at issue.

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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions. portions.

**16.6 Superiority of Agreement** . The Parties agree that the provisions of this Agreement, together with any amendments hereto, supersede the Original License and Distribution Agreement and shall prevail over any inconsistent statements or provisions contained in any prior discussions, arrangements or comments between the Parties and in any documents passing between the Parties, including, but not limited to, any forecast, purchase order, purchase order revision, acknowledgment, confirmation or notice. It is agreed that:

(a) neither Party has entered into this Agreement in reliance upon any representation, warranty or undertaking of the other Party which is not expressly set out in this Agreement, the Patent Litigation Settlement Agreement or the Supply Litigation Settlement Agreement;

(b) neither Party shall have any remedy in respect of misrepresentation or untrue statement made by the other Party or for any breach of warranty which is not contained in this Agreement;

(c) this Section 16. 6 shall not exclude or limit any liability for, or remedy in respect of, fraudulent misrepresentation; and

(d) notwithstanding the foregoing, the Patent Litigation Settlement Agreement and the Supply Litigation Settlement Agreement shall be deemed of equal dignity to this Agreement and this Agreement shall be construed together with the Patent Litigation Settlement Agreement and the Supply Litigation Settlement Agreement in a consistent manner as reflecting a single intent and purpose.

**16.7 Governing Law** . This Agreement shall be governed by the laws of the State of New York without regard to the conflicts of law provisions thereof. The Parties irrevocably agree that the federal district courts in the State of New York shall have exclusive jurisdiction to deal with any disputes arising out of or in connection with this Agreement and that, accordingly, any proceedings arising out of or in connection with this Agreement shall be brought in the United States District Court for the Southern District of New York. Notwithstanding the foregoing, if there is any dispute for which the federal district courts in the Southern District of New York do not have subject matter jurisdiction, the state courts in New York, shall have jurisdiction. In connection with any dispute arising out of it in connection with this Agreement, each Party hereby expressly consents and submits to the personal jurisdiction of the federal and state courts in County, City, and State of New York.

**16.8 Agreement Costs**. Each Party shall pay its own costs, charges and expenses incurred in connection with the negotiation, preparation and completion of this Agreement.

**16.9 Counterparts** . This Agreement may be executed in any number of counterparts (including facsimile counterparts), each of which shall be an original as against a Party whose signature appears thereon, but all of which taken together shall constitute one and the same instrument.

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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions. portions.

**16.10 Severability** . In the event that any of the provisions of this Agreement shall be held by a court or other tribunal of competent jurisdiction to be illegal, invalid or unenforceable, such provisions shall be limited or eliminated to the minimum extent necessary so that this Agreement shall otherwise remain in full force and effect.

**16.11 Relationship of the Parties** . In making and performing this Agreement, the Parties are acting and shall act as independent contractors. Nothing in this Agreement shall be deemed to create an agency, joint venture or partnership relationship between the Parties hereto. This Agreement shall become binding when any one or more counterparts hereof, individually or taken together, bears the signatures of each of the Parties hereto.

**16.12 Construction** . The language in all parts of this Agreement shall be construed, in all cases, according to its fair meaning. Shire and Impax acknowledge that each Party and its counsel have reviewed and revised this Agreement and that any rule of construction to the effect that any ambiguities are to be resolved against the drafting Party shall not be employed in the interpretation of this Agreement. The words “hereof,” “herein,” “hereto” and “hereunder” and words of similar import, when used in this Agreement, shall refer to this Agreement as a whole and not to any particular provision of this Agreement. The terms defined in the singular shall have a comparable meaning when used in the plural, and vice versa. Whenever used herein, the words “include,” “includes” and “including” shall mean “include, without limitation,” “includes, without limitation” and “including, without limitation,” respectively. The masculine, feminine or neuter gender and the singular or plural number shall each be deemed to include the others whenever the context so indicates. With respect to any particular action or agreement, the use of the words “Shire shall” or “Shire will” herein shall also mean “Shire shall cause” the particular action to be performed. Similarly, with respect to any particular action or agreement, the use of the words “Impax shall” or “Impax will” herein shall also mean “Impax shall cause” the particular action to be performed. Nothing in this Agreement shall operate to exclude any provision implied into this Agreement by Law and which may not be excluded by Law or limit or exclude any liability, right or remedy to a greater extent than is permissible under Law.

**16.13 Dispute Resolution.**

(a) **Preliminary Process** . Except as to a dispute arising out of Section 5, 6, 7, or 9 if there is a disagreement between the Parties as to the interpretation of this Agreement or in relation to any aspect of the performance by either Party of its obligations under this Agreement, the Parties shall, within ten (10) Business Days of receipt of a written request from either Party, meet in good faith and try to resolve the disagreement without recourse to legal proceedings.

(b) **Escalation of Dispute** . If resolution of the disagreement does not occur within five (5) Business Days after such meeting, the matter shall be escalated for determination by the President of Impax and Shire’s President of Specialty Pharmaceuticals for resolution, who may resolve the matter themselves or jointly appoint a mediator or independent expert to do so.

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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

(c) **Equitable Relief** . Nothing in this Section 16. 13 restricts either Party’s freedom to seek urgent relief to preserve a legal right or remedy, or to protect a proprietary or trade secret right, or to otherwise seek legal remedies through any available channel if resolution is not otherwise achieved under this Section 16. 13.

(d) **ADR For Certain Disputes**. Notwithstanding Section 16. 7, in the event there is a dispute arising out of Sections 5, 6, 7 or 9 the Alternate Dispute Resolution procedure (the “ ADR Procedure ”) set forth in Schedule 16. 13(d) will apply. For the avoidance of doubt, it is the Parties’ intent that the ADR Procedure will apply solely to any disputes arising out of Sections 5, 6, 7 and 9; provided that either Party shall be free to raise defenses and counter-claims in such ADR Procedure based on any Section of this Agreement.

**16.14 Cumulative Rights**. The rights and remedies of each of the Parties under or pursuant to this Agreement are cumulative, may be exercised as often as such Party considers appropriate and are in addition to its rights and remedies under general law.

**16.15 No Third Party Benefit** . This Agreement shall be binding upon and inure solely to the benefit of the Parties hereto, their successors and permitted assigns, and nothing in this Agreement, express or implied, is intended to or shall confer upon any other Person or Persons any right, benefits or remedies of any nature whatsoever under or by reason of this Agreement.

**16.16 Further Assurance** . Each of the Parties shall do, execute and perform and shall procure to be done and perform all such further acts deeds documents and things as the other Party may reasonably require from time to time to give full effect to the terms of this Agreement.

**16.17 Waiver** . No failure or delay by either Party in exercising any right or remedy provided by law under or pursuant to this Agreement shall impair such right or remedy or operate or be construed as a waiver or variation of it or preclude its exercise at any subsequent time and no single or partial exercise of any such right or remedy shall preclude any other or further exercise of it or the exercise of any other right or remedy.

*[Signature Page Follows]*

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\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

*[Signature Page to Amended and Restated License and Distribution Agreement]*

**IN WITNESS WHEREOF**, the undersigned have executed this Amended and Restated License and Distribution Agreement as of the date and year first above written.

**SHIRE LLC**

By: /s/ Mike Chapman  
Name: Mike Chapman  
Title: President

**IMPAX LABORATORIES, INC.**

By: /s/ Larry Hsu  
Name: Larry Hsu  
Title: President and CEO

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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions. portions.

**Schedule 5. 3(e)**

**DELIVERY SCHEDULE MODIFICATION FORM**

**THIS DELIVERY SCHEDULE MODIFICATION** (this “ Modification ”) dated \_\_\_\_\_, 201\_ (the “ Modification Date ”) is hereby entered into by and between Impax Laboratories, Inc. and Shire LLC in connection with the Amended and Restated License and Distribution Agreement dated as of [\_\_\_\_\_, \_\_\_\_]. All capitalized terms used herein not otherwise defined shall have the meaning given to them in such Amended and Restated License and Distribution Agreement.

The Parties hereby agree, as of the Modification Date, as follows:

1. The Delivery Schedule dated \_\_\_\_\_ and annexed hereto as Exhibit A hereto (the “ Original Schedule ”) is hereby amended and replaced as of [the Modification Date][OTHER SPECIFIC DATE] by the modified Delivery Schedule annexed as Exhibit B hereto (the “ Modified Delivery Schedule ”). [The changes in the Delivery Schedule reflect the following agreements of the Parties: \_\_\_\_\_.]

2. **FOR THE PURPOSES OF CALCULATING [ \*\*\* ] IN CONNECTION WITH THE LATE DELIVERY OF AG PRODUCT TO IMPAX UNDER THE AMENDED AND RESTATED LICENSE AND DISTRIBUTION AGREEMENT INCLUDING, WITHOUT LIMITATION, UNDER SECTION 5. 13, THE DELIVERY DATES SET FORTH IN THE MODIFIED SCHEDULE SHALL BE USED TO CALCULATE SUCH [ \*\*\* ].**

3. Once executed by the Parties, this Modification shall be deemed incorporated as part of the Amended and Restated License and Distribution Agreement.

Accepted and agreed to this \_\_\_ day of \_\_\_\_\_, 201\_.

**SHIRE LLC**

By: \_\_\_\_\_  
Name:  
Title:

**ONLY TO BE EXECUTED ON BEHALF OF  
IMPAX BY THE FOLLOWING PERSONS:**

1. CFO
2. PRESIDENT OF GLOBAL  
PHARMACEUTICALS
3. GC
4. A SENIOR VICE PRESIDENT  
OR MORE SENIOR OFFICER

**IMPAX LABORATORIES, INC.**

By: \_\_\_\_\_  
Name:  
Title:

[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions. portions.

### **Schedule 16. 13(d)**

The Parties agree that any dispute arising out of Sections 5, 6, 7 or 9 will be elevated in the first instance to [\*\*\*] and [\*\*\*], or their designated successors, for resolution.

In the event of a dispute as to any Allocation Plan or Delivery Schedule, [\*\*\*] and [\*\*\*], or their designated successors, shall be available for an expedited meet and confer meeting, at the request of either Party, within [\*\*\*] of the request to discuss and resolve in good faith the Parties' differences regarding such Allocation Plan or Delivery Schedule.

If [\*\*\*] and [\*\*\*] are unable to resolve a dispute within [\*\*\*] of notice of the dispute, the dispute will be referred to a single neutral arbitrator for a binding and final resolution in the following manner.

#### **a. General Provisions**

The arbitrator will be a duly licensed attorney-at-law with expertise in the pharmaceutical industry.

The arbitration will be conducted in New York City at JAMS, currently located at 620 Eighth Ave, 34th Floor, New York, NY 10018, according to the JAMS "Streamlined Arbitration Rules of Procedure," effective July 15, 2009 (the "JAMS Rules"), as modified herein.

The arbitration will be decided in accordance with the laws of the State of New York, without reference to its conflicts of law rules.

The arbitrator's decision will be binding and conclusive upon both Parties.

The proceedings will be kept confidential and will not be disclosed to the public.

#### **b. Selection of Arbitrator**

Within [\*\*\*] of the initiation of arbitration each Party will propose up to [\*\*\*] candidates to act as arbitrator. If the Parties do not agree on any one arbitrator within [\*\*\*] of the exchange of the proposed arbitrators, they will jointly inform JAMS and JAMS will promptly send the Parties a list of [\*\*\*] arbitrator candidates. JAMS will also provide each Party with a brief description of the background and experience of each arbitrator candidate.

Within [\*\*\*] of service of the list of names by JAMS, [\*\*\*].

If this process does not yield an arbitrator (due to a tie or otherwise), JAMS will designate the arbitrator within [\*\*\*] thereafter.

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[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions. portions.

**c. Exchange of Information** . There will be limited discovery during [\*\*\*] commencing on the day the arbitrator is selected, for the purposes of requesting and obtaining documents, and asking and answering interrogatories.

**d. Hearing** . An arbitration hearing will be scheduled not later than [\*\*\*] after the arbitrator has been selected.

**e. Pre-Hearing Submissions**

Within [\*\*\*] after the completion of the exchange of information, each Party will submit concise written statements of its position, including summaries of the facts and evidence a Party intends to present, discussion of the applicable law and the basis for the requested award or denial of relief sought. The statements will be filed with JAMS and served upon the other Party. [\*\*\*].

Within [\*\*\*] after submission of the Parties' initial statements each Party may submit a rebuttal statement[\*\*\*]; and

[\*\*\*] before the arbitration hearing the Parties will (a) submit a written report for each expert they intend to present at the arbitration hearing, drafted in accord with Fed. R. Civ. P. 26(a) and (b) exchange a list and copies of each document which they intend to introduce as exhibits at the arbitration hearing and a list of all individuals who may be called upon to testify at the hearing, including all experts.

**f. Arbitration Hearing** . The arbitration hearing [\*\*\*] and will be conducted in accord with the JAMS Rules, as hereby modified.

**g. Decision** . The arbitrator will render a reasoned decision within [\*\*\*] of the last day of the hearing, which decision will be final and binding upon the Parties.

**h. Costs** . The costs and fees of the arbitrator will be shared equally by the Parties.

**i. Equitable Relief** . Nothing contained in this Section will alter the Parties' rights to seek an injunction or other equitable relief or to file a suit to enforce these arbitration provisions, including the arbitrator's award.

**CERTIFICATION PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Larry Hsu, certify:

1. I have reviewed this Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2013 of Impax Laboratories, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

May 3, 2013

By:

/s/ Larry Hsu, Ph.D.

Larry Hsu, Ph.D.

President and Chief Executive Officer

**CERTIFICATION PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Bryan M. Reasons, certify:

1. I have reviewed this Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2013 of Impax Laboratories, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

May 3, 2013

By: /s/ Bryan M. Reasons  
Bryan M. Reasons  
Chief Financial Officer and Sr. Vice President, Finance

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Impax Laboratories, Inc. (the "Company") for the fiscal quarter ended March 31, 2013 (the "Report"), Larry Hsu, President and Chief Executive Officer, hereby certifies, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Section 1350 of Chapter 63 of Title 18 of the United States Code), that:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

May 3, 2013

By: /s/ Larry Hsu, Ph.D.

Larry Hsu, Ph.D.

President and Chief Executive Officer

The foregoing certification is being furnished solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Section 1350 of Chapter 63 of Title 18 of the United States Code) and is not being filed as part of the Report or as a separate disclosure document.

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Impax Laboratories, Inc. (the "Company") for the fiscal quarter ended March 31, 2013 (the "Report"), Bryan M. Reasons, Chief Financial Officer, and Sr. Vice President, Finance hereby certifies, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Section 1350 of Chapter 63 of Title 18 of the United States Code), that:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

May 3, 2013

By: /s/ Bryan M. Reasons  
Bryan M. Reasons  
Chief Financial Officer and Sr. Vice President,  
Finance

The foregoing certification is being furnished solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Section 1350 of Chapter 63 of Title 18 of the United States Code) and is not being filed as part of the Report or as a separate disclosure document.