IMPAX LABORATORIES INC

FORM 8-K
(Current report filing)

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Address	30831 HUNTWOOD AVENUE HAYWARD, CA 94544
Telephone	510-240-6000
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): February 7, 2013

Impax Laboratories, Inc.

(Exact name of registrant as specified in its charter)

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

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

Registrant's telephone number, including area code: **(510) 240-6000**

Not Applicable

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 1.01 Entry into a Material Definitive Agreement

On February 7, 2013, Impax Laboratories, Inc. (the "Company") entered into the Amended and Restated License and Distribution Agreement (the "Amended and Restated License Agreement") with Shire LLC ("Shire"), which amended and restated that certain License and Distribution Agreement by and between the Company and Shire, dated as of January 19, 2006, as amended on March 1, 2010 (the "Prior Agreement"). The Amended and Restated License Agreement was entered into by the parties in connection with the settlement of all pending litigation between Shire and the Company relating to Shire's supply of its authorized generic Adderall XR® products (the "AG Product") to the Company under the Prior Agreement.

Among other items, the Amended and Restated License Agreement provides for Shire to supply the AG Product to the Company subject to the terms and conditions thereof until the earlier of (i) the first commercial sale by the Company of its generic equivalent product to Adderall XR® (the "Impax Product") 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 Impax as of the end of the Supply Term. The Company will be permitted to sell any AG Products in its inventory or owed to it by Shire under the Amended and Restated License Agreement until all such products are sold and the Company will continue to pay a profit share to Shire on such sales. The Amended and Restated License Agreement also provides for (A) a process for allocation of quota of the amount of the mixed amphetamine salts authorized by the United States Drug Enforcement Administration to the AG Product for the Company and (B) under certain specified circumstances, dispute resolution procedures and payments to be paid by Shire in the event of AG Product non-delivery or delays not otherwise excused under the terms thereof. Impax will continue to pursue approval of its pending Abbreviated New Drug Application for the Impax Product which was filed with the U.S. Food and Drug Administration in September 2003 (which may include, if necessary, amending the original application) and has the right to conduct further development and manufacture of the Impax Product, in each case without impacting Shire's supply of the AG Product to the Company. In the event the Company launches Impax Products, it will pay a profit share to Shire based on sales of such products.

The foregoing is a summary description of the terms and conditions of the Amended and Restated License Agreement and is qualified in its entirety by the text of the Amended and Restated License Agreement, which will be filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2013.

Item 8.01 Other Events

On February 8, 2013, the Company issued a press release announcing that it had settled all pending litigation between Shire and the Company relating to Shire's supply of its authorized generic Adderall XR® products to the Company under the Prior Agreement. As part of the settlement, Shire agreed to make a one-time cash payment to Impax of $48 million upon the court's order of dismissal.

A copy of the press release is attached hereto as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit is filed herewith.

Exhibit No.	Description
99.1	Press Release issued on February 8, 2013.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: February 13, 2013

IMPAX LABORATORIES, INC .

By: /s/ Bryan M. Reasons

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

Exhibit No.	Description
99.1	Press Release issued on February 8, 2013.

Exhibit 99.1

Impax and Shire Settle Litigation Concerning Supply of Authorized Generic Adderall XR®

Hayward, Calif. – February 8 , 2013 – Impax Laboratories, Inc. (NASDAQ: IPXL) today announced that it has settled all pending litigation with Shire LLC and Shire Laboratories, Inc. (collectively Shire) relating to supply of its authorized generic Adderall XR® under the parties' License and Distribution Agreement that was signed in January 2006. As part of the settlement, the parties will submit a stipulation of dismissal for entry by the Court. Shire has agreed to make a one-time cash payment to Impax of $48 million upon the court's order of dismissal.

Impax commenced sales of authorized generic Adderall XR in October 2009. On November 1, 2010, Impax filed suit against Shire for breach of contract and other related claims alleging that Shire failed to fill Impax's orders for the authorized generic Adderall XR. Shire filed a counterclaim against Impax relating to its ordering practices under the agreement. Under the terms of the settlement, Impax's claims and Shire's counterclaims will be dismissed.

The parties have entered into an amended License and Distribution Agreement which will govern the future supply of authorized generic Adderall XR from Shire to Impax. Following the end of the supply term on September 30, 2014, Impax will continue to have the right to sell its products on hand or owed to it under the agreement until depleted and will continue to pay a profit share to Shire on sales of such products.

Impax will continue to pursue approval of its pending Abbreviated New Drug Application for generic Adderall XR which was filed with the U.S. Food and Drug Administration in September 2003.

About Impax Laboratories, Inc.
Impax Laboratories, Inc. (Impax) is a technology based specialty pharmaceutical company applying its formulation expertise and drug delivery technology to the development of controlled-release and specialty generics in addition to the development of central nervous system disorder branded products. Impax markets its generic products through its Global Pharmaceuticals division and markets its branded products through the Impax Pharmaceuticals division. Additionally, where strategically appropriate, Impax develops marketing partnerships to fully leverage its technology platform and pursues partnership opportunities that offer alternative dosage form technologies, such as injectables, nasal sprays, inhalers, patches, creams and ointments. Impax Laboratories is headquartered in Hayward, California, and has a full range of capabilities in its Hayward, Philadelphia and Taiwan facilities. For more information, please visit the Company's Web site at: www.impaxlabs.com .

" *Safe Harbor" statement under the Private Securities Litigation Reform Act of 1995:*
To the extent any statements made in this news release contain information that is not historical, these statements are forward-looking in nature and express the beliefs and expectations of management. Such statements are based on current expectations and involve a number of known and unknown risks and uncertainties that could cause the Company's future results, performance or achievements to differ significantly from the results, performance or achievements expressed or implied by such forward-looking statements. Such risks and uncertainties include, but are not limited to, the effect of current economic conditions on the Company's industry, business, financial position and results of operations, fluctuations in the Company's revenues and operating income, the Company's ability to successfully develop and commercialize pharmaceutical products, reductions or loss of business with any significant customer, the impact of consolidation of the Company's customer base, the impact of competition, the Company's ability to sustain profitability and positive cash flows, any delays or unanticipated expenses in connection with the operation of the Company's Taiwan facility, the effect of foreign economic, political, legal and other risks on the Company's operations abroad, the uncertainty of patent litigation, increased government scrutiny on the Company's agreements with brand pharmaceutical companies, consumer acceptance and demand for new pharmaceutical products, the difficulty of predicting Food and Drug Administration filings and approvals, the Company's inexperience in conducting clinical trials and submitting new drug applications, the Company's ability to successfully conduct clinical trials, the Company's reliance on third parties to conduct clinical trials and testing, the availability of raw materials and impact of interruptions in the Company's supply chain, the use of controlled substances in the Company's products, disruptions or failures in the Company's information technology systems and network infrastructure, the Company's reliance on alliance and collaboration agreements, the Company's dependence on certain employees, the Company's ability to comply with legal and regulatory requirements governing the healthcare industry, the regulatory environment, the Company's ability to protect the Company's

intellectual property, exposure to product liability claims, changes in tax regulations, the Company's ability to manage the Company's growth, including through potential acquisitions, the restrictions imposed by the Company's credit facility, uncertainties involved in the preparation of the Company's financial statements, the Company's ability to maintain an effective system of internal control over financial reporting, any manufacturing difficulties or delays, the effect of terrorist attacks on the Company's business, the location of the Company's manufacturing and research and development facilities near earthquake fault lines and other risks described in the Company's periodic reports filed with the Securities and Exchange Commission. Forward-looking statements speak only as to the date on which they are made, and Impax undertakes no obligation to update publicly or revise any forward-looking statement, regardless of whether new information becomes available, future developments occur or otherwise.

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