IMPAX LABORATORIES INC

FORM 8-K
(Current report filing)

Filed 04/29/13 for the Period Ending 04/29/13

Address	30831 HUNTWOOD AVENUE HAYWARD, CA 94544
Telephone	510-240-6000
CIK	0001003642
Symbol	IPXL
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

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

Date of Report (Date of earliest event reported): April 29, 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 1.02 Termination of a Material Definitive Agreement

On April 29, 2013, Impax Laboratories, Inc. ("Impax") announced its receipt of a notice of termination from Glaxo Group Limited ("GSK") with respect to that certain License, Development and Commercialization Agreement dated as of December 15, 2010 by and between Impax and GSK, as amended (the "License Agreement"), with such termination effective at the end of July 2013. Impax and GSK are also parties to a related Supply Agreement dated as of December 15, 2010 (the "Supply Agreement") and pursuant to the terms thereof, the Supply Agreement will automatically terminate upon termination of the License Agreement. A description of the terms of the License Agreement and Supply Agreement was included in Item 1.01 of the Current Report on Form 8-K filed by Impax with the Securities and Exchange Commission on December 21, 2010, and to the extent required by Item 1.02 of this Form 8-K, such description is incorporated by reference in this Item 1.02 pursuant to General Instruction B.3 of Form 8-K.

Impax issued a press release on April 29, 2013, a copy of which is filed 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, dated April 29, 2013, issued by Impax Laboratories, Inc.

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: April 29, 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, dated April 29, 2013, issued by Impax Laboratories, Inc.

Exhibit 99.1

Impax Pharmaceuticals and GlaxoSmithKline terminate their collaboration on IPX066 (RYTARY ™)

Hayward, Calif. – April 29, 2013 – Impax Pharmaceuticals, the brand products division of Impax Laboratories, Inc. (NASDAQ: IPXL) today announced that Impax and GlaxoSmithKline (GSK) are terminating their collaboration for the development and commercialization of IPX066 outside the United States (U.S.) and Taiwan. IPX066 (known as RYTARY™ in the U.S.) is an investigational extended-release capsule formulation of carbidopa-levodopa being developed for the symptomatic treatment of adult patients with idiopathic Parkinson's disease and is not approved anywhere in the world.

Under the terms of the agreement entered into in December 2010, GSK's right to develop and commercialize IPX066 outside the U.S. and Taiwan will transfer back to Impax effective at the end of July 2013. The decision has been reached because of delays in the anticipated regulatory approval and launch dates in countries in which GSK has rights to commercialize the product.

Impax intends to initiate activities to find a partner or partners for markets outside the U.S. looking to grow their non-US neurology franchise.

About RYTARY (IPX066)
RYTARY is an investigational extended-release capsule formulation of carbidopa-levodopa being developed for the symptomatic treatment of adult patients with idiopathic Parkinson's disease. It is not approved or licensed anywhere in the world. Results from the phase III studies of RYTARY, APEX-PD (early PD patients), ADVANCE-PD (advanced PD patients) and ASCEND-PD (advanced PD patients) have previously been announced.

About Impax Pharmaceuticals
Impax Pharmaceuticals is the branded products division of Impax Laboratories, Inc. Impax Pharmaceuticals is focused on targeting significant unmet needs, with a primary focus on developing treatments for central nervous system disorders. For more information, please visit its Web site at: www.impaxpharma.com.

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

" Safe Harbor" statement under the Private Securities Litigation Reform Act of 1995:

To the extent any statements made in this news release contain information that is not historical, these statements are forward-looking in nature and express the beliefs and expectations of management. Such statements are based on current expectations and involve a number of known and unknown risks and uncertainties that could cause the Company's future results, performance or achievements to differ significantly from the results, performance or achievements expressed or implied by such forward-looking statements. Such risks and uncertainties include, but are not limited to, the effect of current economic conditions on the Company's industry, business, financial position and results of operations, fluctuations in revenues and operating income, the Company's ability to promptly correct the issues raised in the warning letter and Form 483 observations received from the FDA, the Company's ability to successfully develop and commercialize pharmaceutical products in a timely manner, reductions or loss of business with any significant customer, the impact of consolidation of the Company's customer base, the impact of competition, the Company's ability to sustain profitability and positive cash flows, any delays or unanticipated expenses in connection with the operation of the Company's Taiwan facility, the effect of foreign economic, political, legal and other risks on the Company's operations abroad, the uncertainty of patent litigation, the increased government scrutiny on the Company's agreements with brand pharmaceutical companies, consumer acceptance and demand for new pharmaceutical products, the impact of market perceptions of the Company and the safety and quality of the Company's products, the difficulty of predicting FDA filings and approvals, the Company's ability to achieve returns on its investments in research and development activities, the Company's inexperience in conducting clinical trials and submitting new drug applications, the Company's ability to successfully conduct clinical trials, the Company's reliance on third parties to conduct clinical trials and testing, impact of illegal distribution and sale by third parties of counterfeits or stolen products, the availability of raw materials and impact of interruptions in the Company's supply chain, the use of controlled substances in the Company's products, disruptions or failures in the Company's information technology systems and network infrastructure, the Company's reliance on alliance and collaboration agreements, the Company's dependence on certain employees, the Company's ability to comply with legal and regulatory requirements governing the healthcare industry, the regulatory environment, the Company's ability to protect its intellectual property, exposure to product liability claims, changes in tax regulations, the Company's ability to manage growth, including through potential acquisitions, the restrictions imposed by the Company's credit facility, uncertainties involved in the preparation of the Company's financial statements, the Company's ability to maintain an effective system of internal control over financial reporting, the effect of terrorist attacks on the Company's business, the location of the Company's manufacturing and research and development facilities near earthquake fault lines and other risks described in the Company's periodic reports filed with the Securities and Exchange Commission. Forward-looking statements speak only as to the date on which they are made, and the Company undertakes no obligation to update publicly or revise any forward-looking statement, regardless of whether new information becomes available, future developments occur or otherwise.

Company Contact:
Mark Donohue
Investor Relations and Corporate Communications
215-558-4526
