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): January 21, 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 8.01 Other Events.

On January 21, 2013, Impax Laboratories, Inc. (the "Company") issued a press release announcing that it received complete response letter regarding the Company's New Drug Application ("NDA") for RYTARY™ (IPX066), an extended-release capsule formulation of carbidopa-levodopa, a potential treatment for the symptomatic treatment of Parkinson's disease currently under review in the United States. The complete response letter indicates that the FDA requires a satisfactory re-inspection of the Company's Hayward facility as a result of the warning letter issued in May 2011 before the Company's NDA may be approved due to the facility's involvement in the development of RYTARY™, and supportive manufacturing and distribution activities. During the assessment of the NDA, the Company withdrew the Hayward site as an alternative site of commercial production at launch.

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 furnished herewith.

Exhibit No.	Description
99.1	Press Release issued on January 21, 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: January 22, 2013

IMPAX LABORATORIES, INC .

By:/s/ Bryan M. Reasons

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

Exhibit No.	Description
99.1	Press Release issued on January 21, 2013.

Exhibit 99.1

Company Contact:
Mark Donohue
Sr. Director, Investor Relations and Corporate Communications
215-558-4526
www.impaxlabs.com

FDA Issues Complete Response Letter for RYTARY™ (Carbidopa and Levodopa) Extended-Release Capsules (IPX066) New Drug Application

Hayward, Calif. – January 21 , 2013 – Impax Pharmaceuticals, a division of Impax Laboratories, Inc. (NASDAQ: IPXL), announced today that the U.S. Food and Drug Administration (FDA) issued a complete response letter regarding the New Drug Application (NDA) for RYTARY™ (IPX066), an extended-release capsule formulation of carbidopa-levodopa, a potential treatment for the symptomatic treatment of Parkinson's disease currently under review in the United States.

The complete response letter indicates that the FDA requires a satisfactory re-inspection of the company's Hayward facility as a result of the warning letter issued in May 2011 before the company's NDA may be approved due to the facility's involvement in the development of RYTARY, and supportive manufacturing and distribution activities. During the assessment of the NDA the company withdrew the Hayward site as an alternative site of commercial production at launch.

"We will work with the FDA on the appropriate next steps for the RYTARY application," said Larry Hsu, Ph.D., president and CEO, Impax Laboratories, Inc. "We remain committed to resolving the warning letter and bringing this new treatment option to patients who are suffering from Parkinson's disease."

A complete response letter is issued by the FDA's Center for Drug Evaluation and Research when the review cycle for a drug is complete and the application is not yet ready for approval.

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

RYTARY has been licensed to GlaxoSmithKline (GSK) for countries outside the U.S. and Taiwan for development and marketing.

A **bout the Impax GSK collaboration**
Impax Pharmaceuticals and GSK announced an agreement for the development and commercialization of IPX066 in December 2010. Under the terms of the agreement, GSK received an exclusive license to register and commercialize IPX066 throughout the world except in the U.S. and Taiwan.

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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