IMPAX LABORATORIES INC

FORM 8-K
(Current report filing)

Filed 10/31/14 for the Period Ending 10/30/14

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): October 30, 2014

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 2.05 Costs Associated with Exit or Disposal Activities

On October 30, 2014, the management of Impax Laboratories, Inc. (the "Company") committed to a reduction in the Company's workforce, eliminating approximately 49 positions, including about 42 positions in the Company's research and development ("R&D") organization. The reduction in workforce is part of the Company's reorganization of its R&D organizations by consolidating the product development and analytical functions of the generic and brand R&D organizations. After the reorganization, the generic R&D organization will be responsible for early stage product development and analytical functions for all Company products, while the brand R&D organization will focus on phase II, III and IV clinical activities, drug safety and pharmacovigilance for all Company products. The Company notified the majority of the impacted employees on October 30, 2014.

The Company expects this workforce reduction to result in charges of approximately $2.0 million for severance and related one-time termination costs, all of which represent cash expenditures. The Company anticipates that these charges will be recorded in the fourth quarter of its 2014 fiscal year. The Company also expects to realize approximately $8.0 million of annual cost savings beginning in 2015 and approximately $1.5 million of cost savings in the fourth quarter of 2014.

A copy of the Company's press release, dated October 30, 2014, announcing the workforce reduction is attached to this Current Report on Form 8-K as Exhibit 99.1 and is incorporated herein by reference.

Cautionary Statement Regarding Forward-Looking Statements

To the extent any statements made in this Current Report on Form 8-K 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 dependence on certain employees 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.

Item 9.01 Fi nancial Statements and Exhibits .

(d) Exhibits.

The following exhibit is filed herewith.

Exhibit No.	Description
99.1	Press release issued October 30, 2014.

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: October 30, 2014

IMPAX LABORATORIES, INC .

By: /s/ Bryan M. Reasons

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release issued October 30, 2014.

Exhibit 99.1

Impax Announces R&D Reorganization Designed to Yield Process Improvements and Efficiencies

—Optimizes resources by leveraging shared-services —
—Refocuses Brand R&D on late stage projects with near term value —
—R&D re-aligned toward continued successful implement ation of Quality Improvement Programs —

HAYWARD, Calif., October 30, 2014 – Impax Laboratories, Inc. (NASDAQ: IPXL) today announced a reorganization of its research and development (R&D) organizations and a prioritization of the project portfolios within the generic and brand businesses. As a result of the reorganization, the generic R&D organization will be responsible for early stage product development and analytical functions for all Impax products, while the brand R&D organization will focus on phase II, III and IV clinical activities, drug safety and pharmacovigilance for all Impax products. This realignment of the R&D organization and reallocation of responsibilities between these teams is intended to better optimize Impax's core technologies and scientific expertise, increase efficiencies and process improvements in key areas and allow Impax to maximize its investment in product development.

"Our brand R&D team will now focus on existing late-stage opportunities, while the generic R&D team will continue to focus on a concentrated portfolio of high value generic products," said Fred Wilkinson, president and CEO of Impax. "This structure also aligns the entire scientific team on the successful implementation of our quality improvement initiatives. We believe this organizational realignment allows us to take advantage of the internal strengths within R&D to the benefit of both the brand and generic businesses."

"By leveraging our resources in this manner, we improve our R&D efficiency and effectiveness," Wilkinson continued. "This change is also designed to ensure we are investing in internal projects and external opportunities that enhance our pipelines, support our growth, and offer the greatest return on investment, with the goal to create value for patients, customers and shareholders."

The Company expects to realize approximately $8.0 million of annual cost savings beginning in 2015 and approximately $1.5 million in the fourth quarter of 2014. The cost savings are the result of a net reduction of approximately 49 positions, including 42 in R&D or about 25% of the combined brand and generic R&D organizations. In the fourth quarter 2014, the Company expects to record certain charges of about $2.0 million associated with the reorganization.

Impax is committed to a more focused R&D portfolio. As a result, the Company has modified its brand and generic R&D portfolios in an effort to match resources to high-value projects.

Generic Portfolio

- 23 Abbreviated New Drug Applications pending at the U.S. Food and Drug Administration (FDA) and 23 projects under development. This includes 4 pending and 9 under development that are alternative dosage form products through external collaborations.

Branded Portfolio

- RYTARY ™ (IPX066) is a patented extended- release capsule formulation of carbidopa and levodopa, an investigational drug for the symptomatic treatment of Parkinson's disease. A New Drug Application is pending at the FDA with a Prescription Drug User Fee Act (PDUFA) review date of January 9, 2015. The Company is also planning to file a Marketing Authorization Application in Europe by the end of 2014.
- IPX239, an investigational transdermal bupivacaine patch for the treatment of pain associated with post-herpetic neuralgia (PHN) licensed from DURECT Corporation.
- IPX203, an investigational drug for the symptomatic treatment of Parkinson's disease. The Company recently filed an Investigational New Drug Application with the FDA.

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: 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 substantial portion of our total revenues derived from sales of a limited number of products; 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 manufacturing facilities; the effect of foreign economic, political, legal, and other risks on the Company’s operations abroad; the uncertainty of patent litigation and other legal proceedings; the increased government scrutiny on the Company’s agreements with brand pharmaceutical companies; product development risks and the difficulty of predicting FDA filings and approvals; 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 Company’s determinations to discontinue the manufacture and distribution of certain products; 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; the Company’s lack of a license partner for commercialization of IPX066 outside of the United States; 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 Company’s policies regarding returns, allowances and chargebacks; the use of controlled substances in the Company’s products; the effect of current economic conditions on our industry, business, results of operations and financial condition; 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 reliance on licenses to proprietary technologies; 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; risks relating to goodwill and intangibles; changes in tax regulations; the Company’s ability to manage growth, including through potential acquisitions; the Company’s ability to meet expectations regarding the timing and completion of the proposed transaction with Tower Holdings Inc. and Lineage Therapeutics Inc., the Company’s ability to consummate such proposed transaction; the conditions to the completion of such proposed transaction (including the receipt of the regulatory approvals required for the transaction not being obtained on the terms expected or on the anticipated schedule), the integration of the acquired business by the Company being more difficult, time-consuming or costly than expected, operating costs, customer loss and business disruption (including, without limitation, difficulties in maintaining relationships with employees, customers, clients or suppliers) being greater than expected following the proposed transaction, the retention of certain key employees of the acquired business being difficult, the Company’s and the acquired business’s expected or targeted future financial and operating performance and results, the combined company’s capacity to bring new products to market, and the possibility that the Company may be unable to achieve expected synergies and operating efficiencies in connection with the proposed transaction within the expected time-frames or at all and to successfully integrate the acquired business, 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; expansion of social media platforms 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
www.impaxlabs.com

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