

IMPAX LABORATORIES INC

Form 8-K

March 04, 2013

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): March 4, 2013

Impax Laboratories, Inc.

(Exact name of registrant as specified in its charter)

Delaware

001-34263 65-0403311

(State or other jurisdiction (Commission (IRS Employer

of incorporation)

File Number) 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 7.01 Regulation FD Disclosure.

On March 4, 2013, Impax Laboratories, Inc. (the Company) issued a press release announcing its receipt of a Form 483 from the U.S. Food and Drug Administration (the FDA) related to the FDA 's inspection of the Company 's Hayward, California manufacturing facility. A copy of the press release is attached hereto as Exhibit 99.1 and a redacted copy of the Form 483 issued by the FDA is attached hereto as Exhibit 99.2, each of which is incorporated by reference herein.

This Current Report on Form 8-K and the information in this Item 7.01 hereof, including the exhibits attached hereto, will not be deemed to be filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act), nor will it be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act unless expressly identified therein as being specifically incorporated therein by reference.

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

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 actual developments and results to differ significantly from those that are 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 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 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 comply with legal and regulatory requirements governing the healthcare industry, the regulatory environment 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, except to the extent required by applicable law.

Item 9.01 Financial Statements and Exhibits.

(d)Exhibits.

The following exhibits are furnished herewith.

Exhibit No. Description

99.1	Press release issued March 4, 2013
99.2	FDA Form 483

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: March 4, 2013

IMPAX LABORATORIES, INC.

By: /s/ Bryan M. Reasons

Name:

Title:

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

EXHIBIT INDEX

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