IMPAX LABORATORIES INC

FORM 8-K
(Current report filing)

Filed 01/08/13 for the Period Ending 01/07/13

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): January 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 7.01 Regulation FD Disclosure.

On Monday, January 7, 2013, Impax Laboratories, Inc. (the "Company") is scheduled to present at the 31st Annual J.P. Morgan Healthcare Conference. A copy of the materials that the Company will present at the conference is attached hereto as Exhibit 99.1 and incorporated herein by reference.

This Current Report on Form 8-K and the information in this Item 7.01 hereof 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit is furnished herewith.

Exhibit No.	Description
99.1	31st Annual J.P. Morgan Healthcare Conference Presentation dated as of January 7, 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 7, 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	31st Annual J.P. Morgan Healthcare Conference Presentation dated as of January 7, 2013.

Exhibit 99.1

IMPAX LABORATORIES, INC.

IPXL
NASDAQ
LISTED

J.P. Morgan Healthcare Conference

January 7, 2013

Safe Harbor Statement

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

To the extent any statements made in this presentation 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.

Note: All product sales data included herein are derived from data published by Wolters Kluwer Health for the 12 months ended October 2012.

Well-Positioned for Future Growth

Investment Considerations

Targeting Sustainable Generic and Specialized Brand Markets	▪ Generic pipeline targeting $26B U.S. sales ▪ Brand pipeline focused on Central Nervous System (CNS) ▪ Solid platform on which to build long-term growth
Established Core Competencies	▪ Track record of complex formulation and development ▪ Established drug delivery capabilities ▪ Hatch-Waxman expertise and Paragraph IV successes
Strong and Flexible Financial Profile	▪ Diversifying Generic business product mix ▪ Building a Branded business pipeline ▪ Financial resources and flexibility to support growth

Note: All brand/generic product sales data included herein are derived from data published by Wolters Kluwer Health for the 12 months ended October 2012.

Two Platforms for Growth

Generic Platform

- Unique targeted ANDAs
  - Solid Oral Dosage (SOD)
  - Alternative Dosage Form (ADF)
- First-to-File/First-to-Market emphasis
- Focusing on sustainable products
- Partnerships/M&A primarily on ADFs
- 75 products pending at FDA or under development

Branded Platform

- Creating highly valued CNS products
- RYTARY™ PDUFA - Jan. 21, 2013
- Commercializing Zomig® in the U.S.
- Partnerships/M&A areas
  - Neurology
  - Psychiatry
- Building a strong product pipeline
- Developing strong IP positions

Note: Data as of January 7, 2013

Strategy to Create Long Term Growth

Revenue Growth Opportunities

- Diversifying Generic Business product mix
- Focusing on building a strong Brand pipeline
- Executing business development and M&A activities

Operational Improvements

- Right-sizing manufacturing costs and capacity
- Driving global quality and compliance
- Enhancing management team across the company

Supported by financial resources and strong balance sheet: approximately $340M+ cash/cash equivalents and NO DEBT!

Note: Data as of September 30, 2012

Strategic Initiatives for Generic Growth

GLOBAL PHARMACEUTICALS

Focusing on…

- Organic Growth Both Solid Oral & Alternative Dosage Forms (ADF)
- Strategic Partnerships Primarily in ADFs
- Strategic M & A Primarily in ADFs

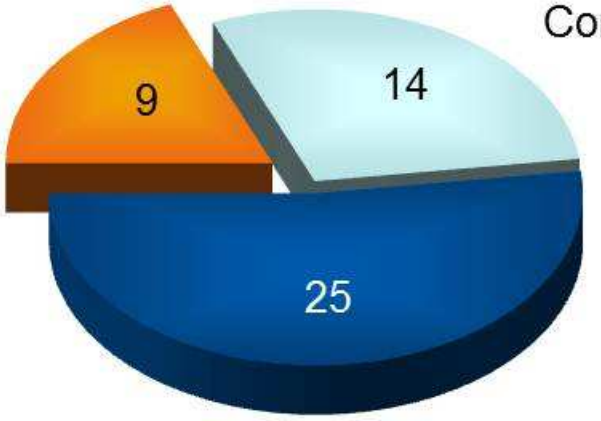
IMPAX LABORATORIES, INC.

Diversifying Currently Marketed Portfolio

48 Currently Marketed Products

Alternative Dosage Form 19%

Controlled-Release Solid Oral 29%



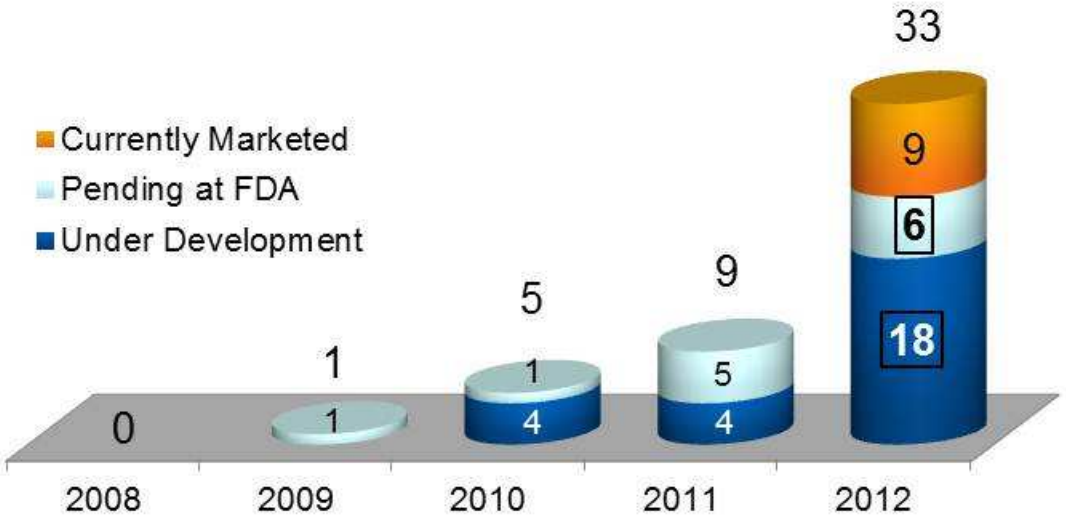
Other Solid Oral 52%

Note: Data as of January 7, 2013. Percentages reflect individual share of the number of products in currently marketed portfolio.

Growing Alternative Dosage Form Portfolio

ADF Products Offer Potential Market Sustainability

24 Future Opportunities are ADFs
A number of them still FTF/FTM opportunities
$5B Current U.S. Brand/Generic Sales

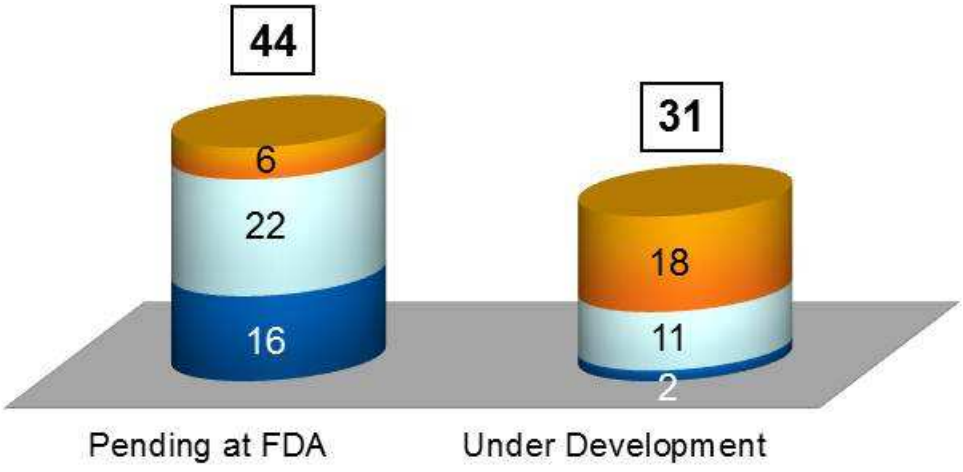


Cumulative Growth of Partnership and Internal/Hybrid ADF Projects

Note: All product sales data included herein are derived from data published by Wolters Kluwer Health for the 12 months ended October 2012.

Diversifying Generic Product Pipeline

75 Future Opportunities Pending at FDA or Under Development
$26B Current U.S. Brand/Generic Sales



18 Total Other SO 24% of Pipeline	33 Total C-R SO 44% of Pipeline	24 Total ADF 32% of Pipeline

Note: All product sales data included herein are derived from data published by Wolters Kluwer Health for the 12 months ended October 2012.

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Numerous Potential Near-Term Opportunities

Generic Pipeline Designed to Drive Future Growth

A Highlight of Some of the Near-Term Potential Generic Launches

2013

- gConcerta®
  - $1.2B brand & generic sales
- gSolaraze® Gel (FTF)
  - 6 months exclusivity expected
  - $123M brand sales
  - Potential approval in 2013

2014

- gTrilipix®
  - $551M brand sales
- gRenvela® tablets (FTF)
  - 6 months exclusivity expected
  - $634M brand sales

2015

- gWelchol® tablets (FTF)
  - 3 months exclusivity expected
  - $364M brand sales

Plus 39 Additional Pending ANDA Opportunities With the Potential to Drive Future Growth

(FTF) = First-to-File
g = Generic form of brand name product
Note: All product sales data included herein are derived from data published by Wolters Kluwer Health for the 12 months ended October 2012.

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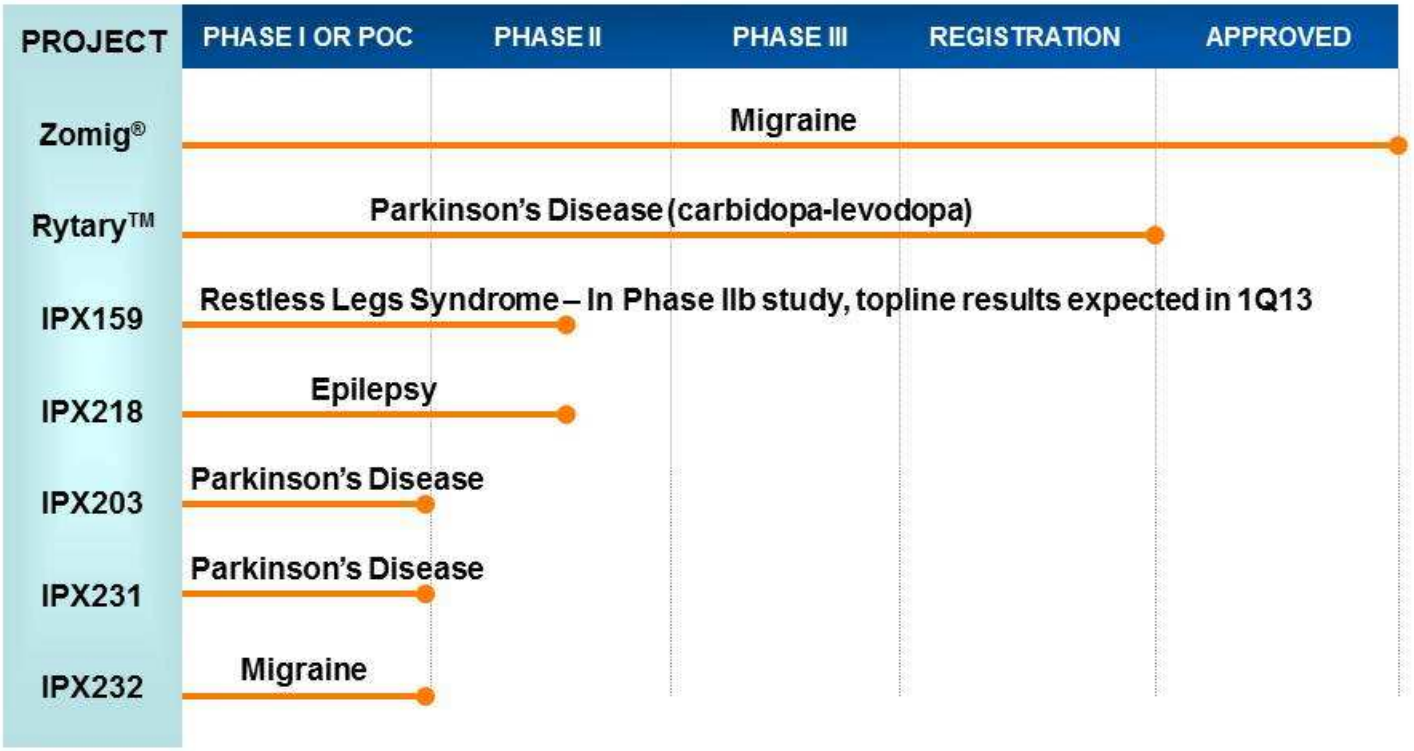
Strategic Initiatives for Brand Growth

Building a Brand Product Pipeline

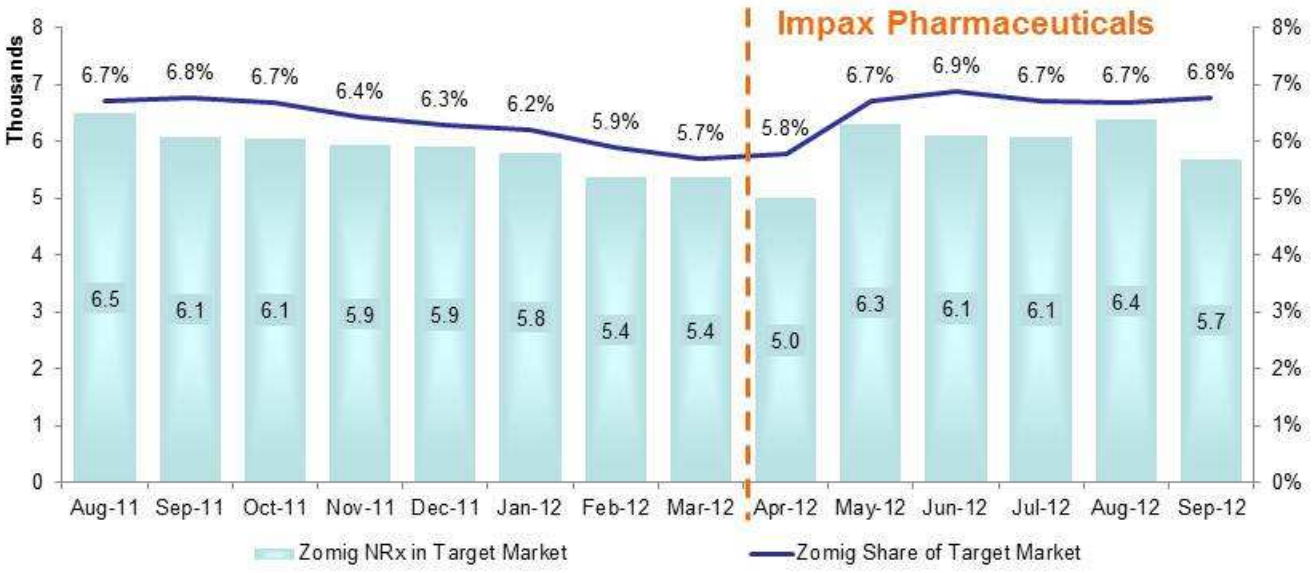


IMPAX LABORATORIES, INC.

Continuing Our Commercial Success

Building relationships with neurologists since July 2006

- Licensed exclusive U.S. commercialization rights to Zomig®
- Began commercializing Zomig® in April 2012
- Increased NRx sales since April 2012



Source: inVentiv and IMS Exponent

IMPAX LABORATORIES, INC.

RYTARY™ (IPX066): Preparing for Launch

Carbidopa and Levodopa Extended-release Capsule

PATENT INFORMATION	DEC. 2011	FEB. 2012	JAN. 21, 2013[a]	THROUGHOUT 2012/1Q13
Rytary™ (IPX066) for the Symptomatic Treatment of Parkinson's Disease				
1st Patent Granted ▪ Aug. 2006 ▪ Expires May 2022 2nd Patent Submission ▪ Dec. 2008 ▪ Expires Dec. 2028	NDA Filed	FDA Acceptance of NDA Filing	PDUFA Date	Pre-launch planning ▪ Building sales & marketing team ▪ Conducting pre-launch activities ▪ Prepare for launch in 1Q13

More than one million people in the U.S., with 50,000-60,000 new cases diagnosed each year in the U.S. alone

(a) The Company announced on Oct. 12, 2012 that the FDA extended the PDUFA date by three months to review additional requested information. The initial PDUFA date was Oct. 21, 2012.

Source: National Parkinson's Foundation. Parkinson's Disease Overview

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Investments Drove Revenue Growth

Created Significant Resources to Fund Business Development and M&A
Financial Flexibility = $340M+ in cash/cash equivalents and NO DEBT

$ millions

Note: $340M+ cash and cash equivalents as of September 30, 2012. Annual revenues as reported (GAAP) except 2010 which excludes $196M due to a change in revenue recognition under the Teva Agreement.

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2013 Objectives

- Resolve Warning Letter (WL) in Hayward
- Potential 2013 generic product launches, including:
  - gConcerta® and many undisclosed pending ANDAs *(all requiring resolution of WL)*
  - gSolaraze® Gel *(Tolmar partnership – resolution of WL not required)*
- RYTARY™ approved and launched
  - PDUFA date of January 21
  - Launch First Quarter
- January launch of Oxymorphone Hydrochloride ER Tablets
  - Therapeutically equivalent to original formulation of Opana ER®
  - Six months of exclusivity 5 mg, 10 mg, 20 mg, 30 mg and 40 mg
- Significant efforts in business development and M&A
- Complete Taiwan facility expansion
  - Footprint provides space for installation of additional equipment as needed
  - Capable of supporting annual production of 2B doses
- Continue transfer of generic products from Hayward to Taiwan
  - Improves product economics by utilizing more efficient facility

Note: As of January 7, 2013. Contains forward looking statements; actual results may vary materially.

2013 Financial Forecast

Item	2013 Forecast ($ in millions)
Gross margin	Low to mid 50% range
Total R&D	$101 - $109
Generic R&D (includes patent litigation)	$63 - $67
Brand R&D	$38 - $42
SG & A	$154 - $162
Amortization expense(1)	Approximately $14
Tax rate	34% - 36%

Note: As of January 7, 2013. Contains forward looking statements; actual results may vary materially. Existing business only. No projected business development or M&A initiatives included in forecast.
(1) Amortization expense from 2012 deal related activity. Approximate 2013 quarterly impact on cost of goods sold: 1Q13 = $7M, 2Q13 = $5M, 3Q13 = $1, 4Q13 = $1M

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