

LILLY ELI & CO

FORM 10-K (Annual Report)

Filed 02/19/16 for the Period Ending 12/31/15

Address	LILLY CORPORATE CTR DROP CODE 1112 INDIANAPOLIS, IN 46285
Telephone	3172762000
CIK	0000059478
Symbol	LLY
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 10-K

Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
for the fiscal year ended December 31, 2015

Commission file number 001-06351

Eli Lilly and Company

An Indiana corporation

I.R.S. employer identification no. 35-0470950

Lilly Corporate Center, Indianapolis, Indiana 46285

(317) 276-2000

Securities registered pursuant to Section 12(b) of the Exchange Act:

<u>Title of Each Class</u>	<u>Name of Each Exchange On Which Registered</u>
Common Stock (no par value)	New York Stock Exchange
7 1/8% Notes Due June 1, 2025	New York Stock Exchange
6.77% Notes Due January 1, 2036	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Exchange Act: None

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 under the Securities Act. Yes No

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act. Yes No

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the preceding 12 months, and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the Registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the Registrant was required to submit and post such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant's knowledge, in the definitive proxy statement incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 under the Exchange Act. (Check one):

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company

Indicate by check mark whether the Registrant is a shell company as defined in Rule 12b-2 under the Exchange Act: Yes No

Aggregate market value of the common equity held by non-affiliates computed by reference to the price at which the common equity was last sold as of the last business day of the Registrant's most recently completed second fiscal quarter (Common Stock): approximately \$81,473,000,000

Number of shares of common stock outstanding as of February 12, 2016 : 1,106,093,485

Portions of the Registrant's Proxy Statement to be filed on or about March 21, 2016 have been incorporated by reference into Part III of this report.

Eli Lilly and Company
Form 10-K
For the Year Ended December 31, 2015
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Forward-Looking Statements

This Annual Report on Form 10-K includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 (Exchange Act). Forward-looking statements include all statements that do not relate solely to historical or current facts, and can generally be identified by the use of words such as “may,” “believe,” “will,” “expect,” “project,” “estimate,” “intend,” “anticipate,” “plan,” “continue,” or similar expressions.

In particular, information appearing under “Business,” “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” includes forward-looking statements. Forward-looking statements inherently involve many risks and uncertainties that could cause actual results to differ materially from those projected in these statements. Where, in any forward-looking statement, we express an expectation or belief as to future results or events, it is based on management’s current plans and expectations, expressed in good faith and believed to have a reasonable basis. However, we can give no assurance that any such expectation or belief will result or will be achieved or accomplished. The following include some but not all of the factors that could cause actual results or events to differ materially from those anticipated:

- the timing of anticipated regulatory approvals and launches of new products;
- market uptake of recently launched products;
- competitive developments affecting current products;
- the expiration of intellectual property protection for certain of our products;
- our ability to protect and enforce patents and other intellectual property;
- the impact of actions of governmental and private payers affecting pricing of, reimbursement for, and access to pharmaceuticals;
- regulatory compliance problems or government investigations;
- regulatory actions regarding currently marketed products;
- unexpected safety or efficacy concerns associated with our products;
- issues with product supply stemming from manufacturing difficulties or disruptions;
- regulatory changes or other developments;
- changes in patent law or regulations related to data-package exclusivity;
- litigation involving past, current or future products as we are largely self-insured;
- unauthorized disclosure or misappropriation of trade secrets or other confidential data stored in our information systems, networks, and facilities, or those of third parties with whom we share our data;
- changes in tax law;
- changes in foreign currency exchange rates, interest rates, and inflation;
- asset impairments and restructuring charges;
- changes in accounting standards promulgated by the Financial Accounting Standards Board and the Securities and Exchange Commission;
- acquisitions and business development transactions and related integration costs;
- information technology system inadequacies or operating failures;
- reliance on third-party relationships and outsourcing arrangements; and
- the impact of global macroeconomic conditions.

Investors should not place undue reliance on forward-looking statements. You should carefully read the factors described in the “Risk Factors” section of this Annual Report on Form 10-K for a description of certain risks that could, among other things, cause our actual results to differ from these forward-looking statements.

All forward-looking statements speak only as of the date of this report and are expressly qualified in their entirety by the cautionary statements included in this report. Except as is required by law, we expressly disclaim any obligation to publicly release any revisions to forward-looking statements to reflect events after the date of this report.

Part I

Item 1. Business

Eli Lilly and Company (the “company” or “registrant” or “Lilly”) was incorporated in 1901 in Indiana to succeed to the drug manufacturing business founded in Indianapolis, Indiana, in 1876 by Colonel Eli Lilly. We discover, develop, manufacture, and market products in two business segments—human pharmaceutical products and animal health products.

The mission of our human pharmaceutical business is to make medicines that help people live longer, healthier, more active lives. Our vision is to make a significant contribution to humanity by improving global health in the 21st century. Most of the products we sell today were discovered or developed by our own scientists, and our success depends to a great extent on our ability to continue to discover, develop, and bring to market innovative new medicines.

Our animal health business, operating through our Elanco division, develops, manufactures, and markets products for both food animals and companion animals. Elanco food animal products help the food industry produce an abundant supply of safe, nutritious and affordable food. Elanco companion animal products help pets live longer, healthier, happier lives.

We manufacture and distribute our products through facilities in the United States (U.S.), Puerto Rico, and 14 other countries. Our products are sold in approximately 125 countries.

Human Pharmaceutical Products

Our human pharmaceutical products include:

Endocrinology products, including:

- *Humalog*®, *Humalog Mix 75/25*™, and *Humalog Mix 50/50*™, insulin analogs for the treatment of diabetes
- *Humulin*®, human insulin of recombinant DNA origin for the treatment of diabetes
- *Trajenta*®, for the treatment of type 2 diabetes
- *Jentadueto*®, a combination tablet of linagliptin (Trajenta) and metformin hydrochloride for use in the treatment of type 2 diabetes
- *Jardiance*®, for the treatment of type 2 diabetes (approved in the U.S., Europe, and Japan in 2014)
- *Trulicity*®, for the treatment of type 2 diabetes (approved in the U.S. and Europe in 2014 and Japan in 2015)
- *Glyxambi*®, a combination tablet of linagliptin and empagliflozin (Jardiance) for the treatment of type 2 diabetes (approved in the U.S. in 2015)
- *Synjardy*®, a combination tablet of empagliflozin and metformin hydrochloride for the treatment of type 2 diabetes (approved in the U.S. and Europe in 2015)
- *Basaglar*® (insulin glargine injection), a long-acting human insulin analog for the treatment of diabetes (launched in Japan in 2015 and in Europe in 2015 under the trade name Abasaglar®). Basaglar was also approved in the U.S. in 2015; under an agreement settling patent litigation with Sanofi-Aventis U.S. LLC (Sanofi) regarding Sanofi's insulin glargine product, we will have the ability to launch Basaglar in the U.S. on December 15, 2016. Under the terms of the agreement, Sanofi has granted us a royalty-bearing license so we can manufacture and sell Basaglar in the Kwikpen™ device globally.
- *Forteo*®, for the treatment of osteoporosis in postmenopausal women and men at high risk for fracture and for glucocorticoid-induced osteoporosis in men and postmenopausal women

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.