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, 2022

Commission file number 001-06351

ELI LILLY AND COMPANY

(Exact name of Registrant as specified in its charter)

Indiana	35-0470950
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

Lilly Corporate Center, Indianapolis, Indiana 46285
(Address and zip code of principal executive offices)

Registrant's telephone number, including area code (317) 276-2000

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

Title of Each Class	Trading Symbol(s)	Name of Each Exchange On Which Registered
Common Stock (no par value)	LLY	New York Stock Exchange
7 1/8% Notes due 2025	LLY25	New York Stock Exchange
1.625% Notes due 2026	LLY26	New York Stock Exchange
2.125% Notes due 2030	LLY30	New York Stock Exchange
0.625% Notes due 2031	LLY31	New York Stock Exchange
0.500% Notes due 2033	LLY33	New York Stock Exchange
6.77% Notes due 2036	LLY36	New York Stock Exchange
1.625% Notes due 2043	LLY43	New York Stock Exchange
1.700% Notes due 2049	LLY49A	New York Stock Exchange
1.125% Notes due 2051	LLY51	New York Stock Exchange
1.375% Notes due 2061	LLY61	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 of 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 (or for such shorter period that the Registrant was required to file such reports) 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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files).

Yes ☒ No ☐

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

Large accelerated filer ☒	Accelerated filer ☐
Non-accelerated filer ☐	Smaller reporting company ☐
	Emerging growth company ☐

If an emerging growth company, indicate by check mark if the Registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the Registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b). ☐

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of 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: approximately $274,342,000,000.

Number of shares of common stock outstanding as of February 17, 2023: 950,296,118

Portions of the Registrant's Proxy Statement for the 2023 Annual Meeting of Shareholders have been incorporated by reference into Part III of this report.

Eli Lilly and Company

Form 10-K
For the Year Ended December 31, 2022

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Forward-Looking Statements

This Annual Report on Form 10-K and our other publicly available documents include 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), and are subject to the safe harbor created thereby under the Private Securities Litigation Reform Act of 1995. In particular, information appearing under "Business," "Risk Factors," and "Management's Discussion and Analysis of Results of Operations and Financial Condition" includes forward-looking statements. Forward-looking statements include all statements that do not relate solely to historical or current facts, and generally can be identified by the use of words such as "may," "believe," "will," "expect," "project," "estimate," "intend," "anticipate," "plan," "continue," or similar expressions or future or conditional verbs.

Forward-looking statements inherently involve many risks and uncertainties that could cause actual results to differ materially from those expressed in forward-looking 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. Investors therefore should not place undue reliance on forward-looking statements. The following include some but not all of the factors that could cause actual results or events to differ materially from those anticipated:

- the significant costs and uncertainties in the pharmaceutical research and development process, including with respect to the timing and process of obtaining regulatory approvals;
- the impact and outcome of acquisitions and business development transactions and related integration costs;
- the expiration of intellectual property protection for certain of our products and competition from generic and/or biosimilar products;
- our ability to protect and enforce patents and other intellectual property;
- changes in patent law or regulations related to data package exclusivity;
- competitive developments affecting current products and our pipeline;
- market uptake of recently launched products;
- information technology system inadequacies, breaches, or operating failures;
- unauthorized access, disclosure, misappropriation, or compromise of confidential information or other data stored in our information technology systems, networks, and facilities, or those of third parties with whom we share our data;
- the impact of global macroeconomic conditions, trade disruptions, disputes, unrest, war, regional dependencies, or other costs, uncertainties and risks related to engaging in business globally;
- unexpected safety or efficacy concerns associated with our products;
- litigation, investigations, or other similar proceedings involving past, current, or future products or commercial activities as we are largely self-insured;
- issues with product supply and regulatory approvals stemming from manufacturing difficulties, disruptions, or shortages, including as a result of unpredictability and variability in demand, labor shortages, third-party performance, quality, or regulatory actions related to our facilities;
- dependence on certain products for a significant percentage of our total revenue and an increasingly consolidated supply chain;
- reliance on third-party relationships and outsourcing arrangements;
- the impact of public health outbreaks, epidemics, or pandemics, such as the COVID-19 pandemic;
- regulatory changes or other developments;
- regulatory actions regarding operations and products;
- continued pricing pressures and the impact of actions of governmental and private payers affecting pricing of, reimbursement for, and access to pharmaceuticals;
- devaluations in foreign currency exchange rates or changes in interest rates and inflation;
- changes in tax law, tax rates, or events that differ from our assumptions related to tax positions;
- asset impairments and restructuring charges;

- changes in accounting and reporting standards promulgated by the Financial Accounting Standards Board and the Securities and Exchange Commission (SEC);
- regulatory compliance problems or government investigations; and
- actual or perceived deviation from environmental-, social-, or governance-related requirements or expectations.

Investors should also carefully read the factors described under Item 1A, "Risk Factors" in 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 those expressed in forward-looking statements. Investors should understand that it is not possible to predict or identify all such factors and should not consider the risks described above and under Item 1A, "Risk Factors" to be a complete statement of all potential risks and uncertainties.

All forward-looking statements speak only as of the date of this Annual Report and are expressly qualified in their entirety by the risk factors and cautionary statements included in this Annual 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 Annual Report.

Part I

Item 1. Business

Eli Lilly and Company (referred to as the company, Lilly, we, or us) 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 a single business segment—human pharmaceutical products.

Our purpose is to unite caring with discovery to create medicines that make life better for people around the world. Most of the products that we sell today were discovered or developed by our own scientists, and our long-term success depends on our ability to continually discover or acquire, develop, and commercialize innovative medicines.

We manufacture and distribute our products through facilities in the United States (U.S.), including Puerto Rico, and 7 other countries. Our products are sold in approximately 110 countries.

Products

Our products include:

Diabetes products, including:

- *Basaglar*®, in collaboration with Boehringer Ingelheim, a long-acting human insulin analog for the treatment of diabetes.
- *Humalog*®, *Humalog Mix 75/25, Humalog U-100, Humalog U-200, Humalog Mix 50/50*, *insulin lispro, insulin lispro protamine*, and *insulin lispro mix 75/25,* human insulin analogs for the treatment of diabetes.
- *Humulin*®, *Humulin 70/30, Humulin N, Humulin R,* and *Humulin U-500*, human insulins of recombinant DNA origin for the treatment of diabetes.
- *Jardiance*®, in collaboration with Boehringer Ingelheim, for the treatment of type 2 diabetes; to reduce the risk of cardiovascular death in adult patients with type 2 diabetes and established cardiovascular disease; and to reduce the risk of cardiovascular death and hospitalizations for heart failure in adults.
- *Mounjaro*®, a glucose-dependent insulinotropic polypeptide and glucagon-like peptide-1 receptor agonist, for the treatment of adults with type 2 diabetes in combination with diet and exercise to improve glycemic control.
- *Trulicity*®, for the treatment of type 2 diabetes in adults and pediatric patients 10 years of age and older, and to reduce the risk of major adverse cardiovascular events in adult patients with type 2 diabetes and established cardiovascular disease or multiple cardiovascular risk factors.

Oncology products, including:

- *Alimta*®, for the first-line treatment, in combination with two other agents, of advanced non-small cell lung cancer (NSCLC) for patients with non-squamous cell histology and no epidermal growth factor receptor or anaplastic lymphoma kinase genomic tumor aberrations; for the first-line treatment, in combination with another agent, of advanced non-squamous NSCLC; for the second-line treatment of advanced non-squamous NSCLC; as monotherapy for the maintenance treatment of advanced non-squamous NSCLC in patients whose disease has not progressed immediately following chemotherapy treatment; and in combination with another agent for the treatment of malignant pleural mesothelioma.
- *Cyramza*®, for use as monotherapy or in combination with another agent as a second-line treatment of advanced or metastatic gastric cancer or gastro-esophageal junction adenocarcinoma; in combination with another agent as a second-line treatment of metastatic NSCLC; in combination with another agent as a second-line treatment of metastatic colorectal cancer; as a monotherapy as a second-line treatment of hepatocellular carcinoma; and in combination with another agent as a first-line treatment of adult patients with metastatic NSCLC with activating epidermal growth factor receptor mutations.
- *Erbitux*®, indicated both as monotherapy and in combination with another agent for the treatment of certain types of colorectal cancers; and as monotherapy, in combination with chemotherapy, or in combination with radiation therapy for the treatment of certain types of head and neck cancers.

DOCKET ALARM

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.