
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 21, 2009

ELI LILLY AND COMPANY

(Exact name of registrant as specified in its charter)

Indiana
(State or Other Jurisdiction
of Incorporation)

001-06351
(Commission
File Number)

35-0470950
(I.R.S. Employer
Identification No.)

Lilly Corporate Center
Indianapolis, Indiana
(Address of Principal
Executive Offices)

46285
(Zip Code)

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

No Change
(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:

- 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))
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Item 2.02. Results of Operations and Financial Condition

On October 21, 2009, we issued a press release announcing our results of operations for the quarter and nine months ended September 30, 2009, including, among other things, an income statement for those periods. In addition, on the same day we held a teleconference for analysts and media to discuss those results. The teleconference was web cast on our web site. The press release and related financial statements are attached to this Form 8-K as [Exhibit 99.1](#).

For the third quarter 2009, the press release attached as Exhibit 99.1 includes a pro forma non-GAAP presentation of our results. We use non-GAAP financial measures, such as pro forma non-GAAP net income and pro forma non-GAAP earnings per share, that differ from financial statements reported in conformity to U.S. generally accepted accounting principles (“GAAP”). In the press release attached as Exhibit 99.1, we used non-GAAP financial measures in comparing the financial results for the third quarter and first nine months of 2009 with the same periods of 2008. Those measures include total revenue, operating income, income before taxes, income taxes, effective tax rate, net income, and earnings per share adjusted to exclude the effect of the following items (described in more detail in the press release attached as Exhibit 99.1):

- The following item in the third quarter of 2009:
 - Asset impairments and restructuring primarily related to the sale of our Tippecanoe, Indiana site.
 - A charge related to settlements and potential settlements with the attorneys general of several states of claims related to Zyprexa.
- The following item in the second quarter of 2009:
 - A charge related to the potential settlement with the attorneys general of several states of claims related to Zyprexa.
- The following items in the third quarter of 2008:
 - Charges related to Zyprexa investigations with the U.S. Attorney for the Eastern District of Pennsylvania, as well as the resolution of a multi-state investigation regarding Zyprexa involving 32 states and the District of Columbia.
 - Asset impairments and restructuring primarily driven by the sale of our Greenfield, Indiana site.
 - Acquired in-process research and development associated with the SGX acquisition.
- The following items in the second quarter of 2008:
 - Restructuring and other special charges primarily related to the termination of the company’s AIR Insulin program.

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- Asset impairments associated with certain manufacturing operations (included in cost of sales).
- In-process research and development (IPR&D) charges associated with a licensing arrangement with TransPharma Medical Ltd.
- The following items in the first quarter of 2008:
 - A tax benefit from resolution of a substantial portion of an IRS audit of the company's federal income tax returns for the years 2001 to 2004.
 - Asset impairments, restructuring, and other special charges primarily related to the termination of the company's AIR Insulin program.
 - In-process research and development charges associated with an in-licensing transaction with BioMS Medical.

In addition, the pro forma non-GAAP presentation assumes that the acquisition of ImClone Systems Incorporated ("ImClone") was completed on January 1, 2008, and includes adjustments to the first three quarters of 2008 for the ImClone acquisition. We also provide certain operating results, including earnings-per-share growth, without the impact of changes in foreign exchange rates for the third quarter and first nine months of 2009 compared to the same periods in 2008.

In the press release attached as Exhibit 99.1, we provided financial expectations for 2009. We provided earnings per share, revenue, research and development expenses, and our effective tax rate expectations on both a GAAP basis and a pro forma non-GAAP basis. In order to provide additional insight into the earnings-per-share growth comparison between 2008 results and expected 2009 results, we adjusted 2008 earnings per share for the 2008 items described above and for the items described below for the balance of 2008. We presented 2008 as if the ImClone acquisition were completed on January 1, 2008.

- In the fourth quarter of 2008:
 - Charges related to the acquisition of ImClone Systems, including in-process research and development, as well as ImClone operating results subsequent to the acquisition, incremental interest costs and amortization of the intangible asset associated with Erbitux®.
 - Asset impairments, restructuring and other special charges.
 - A tax benefit based upon the determination at final resolution of the agreement that a portion of the EDPA settlement charge, taken in the third quarter of 2008, is tax deductible.

The items that we exclude when we provide adjusted results or adjusted expectations are typically highly variable, difficult to predict, and of a size that could have a substantial impact on our reported operations for a period. We believe that these non-GAAP measures provide useful

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information to investors. Among other things, they may help investors evaluate our ongoing operations. They can assist in making meaningful period-over-period comparisons and in identifying operating trends that would otherwise be masked or distorted by the items subject to the adjustments. Management uses these non-GAAP measures internally to evaluate the performance of the business, including to allocate resources and to evaluate results relative to incentive compensation targets.

Investors should consider these non-GAAP measures in addition to, not as a substitute for or superior to, measures of financial performance prepared in accordance with GAAP. For the reasons described above for use of non-GAAP measures, our prospective earnings guidance is subject to adjustment for certain future matters, similar to those identified above, as to which prospective quantification generally is not feasible.

In accordance with GAAP, we have provided pro forma results in order to help investors make meaningful comparisons of 2009 results and expectations to 2008 results and identify underlying operating trends that might otherwise be masked by the inclusion of ImClone results in a part of 2008.

The information in this Item 2.02 and the press release attached as Exhibit 99.1 are considered furnished to the Commission and are not deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

Item 9.01. Financial Statements and Exhibits

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press release dated October 21, 2009, together with related attachments

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 thereunto duly authorized.

ELI LILLY AND COMPANY
(Registrant)

By: /s/ Arnold C. Hanish

Name: Arnold C. Hanish

Title: Vice President and
Chief Accounting Officer

Dated: October 21, 2009

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Exhibit</u>
99.1	Press release dated October 21, 2009, together with related attachments.



Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana 46285
U.S.A.

www.lilly.com

Date: October 21, 2009

For Release: Immediately

Refer to: (317) 276-5795 — Mark E. Taylor (Media)

(317) 655-6874 — Philip Johnson (Investors)

Lilly Reports Solid Third-Quarter 2009 Results; Revises Full-Year 2009 EPS Guidance

- Higher volume drives revenue growth
- Stronger dollar results in improved gross margin
- Earnings per share increase to \$.86 (reported) or \$1.20 (pro forma non-GAAP)
- Full-year 2009 EPS guidance range revised to \$3.90 — \$4.00 (reported) or \$4.30 — \$4.40 (pro forma non-GAAP)

Eli Lilly and Company (NYSE: LLY) today announced financial results for the third quarter of 2009.

\$ in millions, except per share data	Third Quarter		% Growth
	2009	2008	
Total Revenue — Reported	\$5,562.0	\$5,209.5	7%
Net Income (loss) — Reported	941.8	(465.6)	NM
EPS (Loss per share) — Reported	.86	(.43)	NM
Total Revenue — Pro forma	5,562.0	5,308.7	5%
Net Income — Pro forma non-GAAP	1,311.8	1,075.4	22%
EPS — Pro forma non-GAAP	1.20	.98	22%

NM — not meaningful

Due to significant strategic actions taken by the company, financial results for 2009 and 2008 are presented on both a reported and a pro forma non-GAAP basis. Reported results were prepared in accordance with generally accepted accounting principles (GAAP) and include all revenue and expenses recognized during the period. Pro forma non-GAAP results exclude significant items described in the reconciliation tables and also assume the ImClone acquisition was completed January 1, 2008. The pro forma non-GAAP results are presented in order to provide additional insights into the underlying trends in the company's business. The company's 2009 financial guidance is also being provided on both a reported and a pro forma non-GAAP basis.

“Lilly continues to deliver very solid financial results,” said John C. Lechleiter Ph.D., Lilly’s chairman and chief executive officer. “Our performance in the third quarter once again was driven by volume-based sales growth, improving gross margins and tight control of operating expenses, allowing us to deliver very attractive earnings growth. These results are evidence of the strength of our current operations as we implement our new operating model, streamline our organization and take measures to accelerate the flow of new medicines through our pipeline.”

Significant Events Over the Last Three Months

- The company unveiled a new operating model and announced a series of changes to speed medicines from its pipeline to patients. To help achieve this goal, the company will establish a Development Center of Excellence to streamline and accelerate late-stage development of new medicines, and will reorganize its pharmaceutical business into four business units (oncology, diabetes, established markets and emerging markets) that will operate alongside the Elanco animal health business unit. In addition, the company has set a goal to significantly reduce its cost structure by \$1.0 billion and lower global headcount to 35,000 by the end of 2011, excluding strategic sales force additions in high-growth emerging markets and Japan.
- The company announced an agreement to sell its Tippecanoe Laboratories manufacturing site to an affiliate of Evonik Industries AG, one of the world’s largest chemical companies. The site, located in Lafayette, Indiana, will remain in operation with a focus on producing high-quality active pharmaceutical ingredients (API) and specialty chemical and animal health products. In connection with the sale of the site, the two companies will also enter into a nine-year supply and services agreement, whereby Evonik will manufacture final and intermediate step API for certain Lilly human and animal health products.
- The U.S. District Court for the Southern District of Indiana upheld the company’s method-of-use patents on Evista®. These patents provide protection for Evista in the United States through March of 2014.
- The U.S. District Court for the Eastern District of Michigan granted a motion by Sun Pharmaceuticals for partial summary judgment, invalidating Lilly’s method-of-use patent for Gemzar®, which had been set to expire in 2013. The ruling has no bearing on Gemzar’s

compound patent, which remains valid until November 2010. The company intends to pursue an appeal of this decision with the Court of Appeals for the Federal Circuit.

- The company announced that results from its pivotal, five-year, Phase III "GENERATIONS" trial for arzoxifene met its primary endpoints of significantly reducing the risk of vertebral fracture and invasive breast cancer in postmenopausal women. However, the study failed to demonstrate a statistically significant difference in key secondary efficacy endpoints, such as non-vertebral fractures, clinical vertebral fractures, cardiovascular events and cognitive function, compared to placebo. In addition, certain adverse events, including venous thromboembolic events, hot flushes and gynecological-related events, were reported more frequently in the arzoxifene group compared with placebo. After reviewing the overall clinical profile of arzoxifene in light of currently available treatments, including Lilly's own osteoporosis products, the company decided not to submit the compound for regulatory review.
- The company and its partner, BioMS Medical Corp., announced that dirucotide did not meet the primary endpoint of delaying disease progression, as measured by the Expanded Disability Status Scale, during the two-year MAESTRO-01 Phase III trial in patients with secondary progressive multiple sclerosis. In addition, there were no statistically significant differences between dirucotide and placebo on the secondary endpoints of the study. Lilly and BioMS also announced they would discontinue ongoing clinical trials - including MAESTRO-02 and MAESTRO-03.
- The U.S. Food and Drug Administration approved a new use for Forteo® to treat osteoporosis associated with sustained, systemic glucocorticoid therapy in men and women at high risk of fracture.

Third-Quarter Reported Results

In the third quarter of 2009, worldwide total revenue was \$5.562 billion, an increase of 7 percent compared with the third quarter of 2008. This 7 percent revenue growth was comprised of an 8 percent increase due to higher volume and a 2 percent increase due to higher prices, partially offset by a 3 percent decline due to the impact of foreign exchange rates. Worldwide total revenue of \$5.562 billion was comprised of product sales of \$5.385 billion, an increase of 6 percent, and collaboration and other revenue of \$176.5 million, an increase of 51 percent, primarily due to the inclusion of Erbitux® revenue as a result of the ImClone acquisition. U.S. total revenue increased 14

percent to \$3.146 billion due to higher volume, higher prices, and the inclusion of Erbitux revenue. Total revenue outside the U.S. decreased 1 percent to \$2.416 billion due to the negative impact of foreign exchange rates and, to a lesser extent, lower prices, partially offset by increased demand.

Gross margin as a percent of total revenue increased by 3.3 percentage points, to 81.1 percent. This increase was primarily due to the impact of the decline in foreign currencies compared to the U.S. dollar on international inventories sold during the quarter, resulting in a benefit to cost of sales as compared to the third quarter of 2008.

Marketing, selling and administrative expenses increased 3 percent compared with the third quarter of 2008, to \$1.702 billion. The increase was driven by the impact of the ImClone acquisition and higher incentive compensation, partially offset by the movement of foreign exchange rates and a reduction in advertising expenses in the U.S. market. Research and development expenses were \$1.122 billion, or 20 percent of total revenue. Compared with the third quarter of 2008, research and development expenses grew 18 percent due primarily to the ImClone acquisition, increased late-stage clinical trial costs, and estimated costs to terminate arzoxifene clinical trials. Total operating expenses, defined as the sum of research and development, marketing, selling and administrative expenses, increased 9 percent compared with the third quarter of 2008.

In the third quarter of 2008, the company recognized a charge of \$28.0 million for acquired in-process research and development associated with the SGX Corporation acquisition.

In the third quarter of 2009, the company recognized asset impairments, restructuring and other special charges of \$549.8 million. Of this charge, \$424.8 million was for asset impairments and restructuring primarily related to the company's sale of its Tippecanoe, Indiana manufacturing site to Evonik Industries. In addition, the company is in advanced discussions or has settled with the attorneys general of the twelve states that were not part of the Eastern District of Pennsylvania settlement and filed separate Zyprexa-related claims against the company. In the third quarter of 2009, the company incurred a special pretax charge of \$125.0 million related to these settlements and the currently probable and estimable exposures in connection with the remaining states' claims.

In the third quarter of 2008, the company recognized asset impairments, restructuring and other special charges totaling \$1.659 billion. These charges included \$1.477 billion related to the

Zyprexa® investigations led by the U.S. Attorney for the Eastern District of Pennsylvania, as well as the resolution of a multi-state investigation regarding Zyprexa involving 32 states and the District of Columbia. In addition, the company recognized a charge of \$182.4 million for asset impairments and restructuring primarily driven by the sale of its Greenfield, Indiana site.

Operating income in the third quarter of 2009 rose to \$1.136 billion. In the third quarter of 2008, the company had reported an operating loss of \$235.3 million, due to the charges associated with the EDPA settlement.

Other income (expense) decreased \$69.4 million, to a net expense of \$66.9 million, primarily due to lower interest income and higher interest expense associated with the ImClone acquisition.

The effective tax rate was 11.9 percent in the third quarter of 2009, primarily due to the tax benefit of the asset impairment and restructuring charges associated with the sale of the Tippecanoe site.

Net income and earnings per share increased to \$941.8 million and \$.86, respectively, compared with third-quarter 2008 net loss of \$465.6 million and loss per share of \$.43.

Third-Quarter Pro Forma non-GAAP Results

Worldwide pro forma total revenue for the third quarter of 2009 was \$5.562 billion, an increase of 5 percent compared with the third quarter of 2008. This 5 percent revenue growth was comprised of a 6 percent increase due to higher volume and a 2 percent increase due to higher prices, partially offset by a 3 percent decline due to the impact of foreign exchange rates. Gross margin as a percent of total revenue increased by 3.7 percentage points to 81.1 percent. Marketing, selling and administrative expenses increased 2 percent, while research and development expenses increased 13 percent. Total operating expenses, defined as the sum of research and development, marketing, selling and administrative expenses, grew 6 percent compared with the third quarter of 2008. Operating income increased 17 percent to \$1.686 billion, due to improved gross margins. Excluding the impact of changes in foreign exchange rates, operating income would have increased approximately 8 percent. Other income (expense) increased \$9.4 million to a net expense of \$66.9 million. The effective tax rate was 19.0 percent, down from 21.1 percent in the third quarter of 2008, reflecting a benefit for a cumulative adjustment in the forecasted effective tax rate for the year. Net income and earnings per share both increased 22 percent to \$1.312 billion and \$1.20 per

share, respectively, primarily due to volume-driven sales growth, improved gross margins and a lower tax rate. Excluding the impact of changes in foreign exchange rates, earnings per share would have increased approximately 11 percent.

Third-Quarter Significant Items Affecting Reported Net Income

The reported results for the third quarters of 2009 and 2008 were affected by significant items totaling \$.33 and \$1.47 per share, respectively. To reflect the impact of the ImClone acquisition as if the acquisition occurred on January 1, 2008, third quarter 2008 pro forma earnings per share have been reduced by \$.06 per share. For further detail, see the reconciliation below as well as the footnotes to the pro forma non-GAAP income statement later in this press release.

	Third Quarter		% Growth
	2009	2008	
Earnings per share (reported)	\$.86	\$ (.43)	NM
Charges related to Zyprexa litigation	.07	1.33	
Asset impairments and restructuring charges	.26	.11	
In-process research and development charge associated with SGX acquisition	—	.03	
Pro forma as if the ImClone acquisition was completed on January 1, 2008	—	(.06)	
Earnings per share (pro forma non-GAAP)	\$ 1.20	\$.98	22%

NM — not meaningful; numbers in the 2009 third quarter column do not add due to rounding.

Revenue Highlights — Reported

(Dollars in millions)	Third Quarter		% Change Over/(Under) 2008	Year-to-Date		% Change Over/(Under) 2008
	2009	2008		2009	2008	
Zyprexa	\$ 1,223.0	\$ 1,189.5	3%	\$ 3,549.2	\$ 3,549.5	0%
Cymbalta®	790.2	716.4	10%	2,243.9	1,975.9	14%
Humalog®	500.2	432.6	16%	1,428.2	1,277.8	12%
Alimta®	461.9	313.9	47%	1,182.5	836.0	41%
Cialis®	397.2	376.6	5%	1,119.6	1,075.7	4%
Gemzar	331.8	440.2	(25)%	1,052.8	1,306.5	(19)%
Evista	259.5	265.7	(2)%	767.7	806.6	(5)%
Humulin®	260.4	271.6	(4)%	749.1	800.8	(6)%
Forteo	213.1	192.7	11%	603.9	584.3	3%
Strattera®	145.5	149.5	(3)%	447.2	432.7	3%
Total Product Sales	5,385.5	5,092.4	6%	15,390.6	14,835.6	4%
Collaboration and Other Revenue ¹	176.5	117.1	51%	511.2	331.9	54%
Total Revenue ²	\$ 5,562.0	\$ 5,209.5	7%	\$ 15,901.8	\$ 15,167.5	5%

¹ Collaboration and other revenue is primarily comprised of Erbitux royalties and 50 percent of Byetta's gross margin in the U.S.

² Total revenue for the third quarter of 2009 includes \$115.8 million of Byetta revenue and \$101.9 million of Erbitux revenue.

Zyprexa

In the third quarter of 2009, Zyprexa sales totaled \$1.223 billion, an increase of 3 percent compared with the third quarter of 2008. U.S. sales of Zyprexa increased 3 percent to \$569.6 million, driven by higher net effective selling prices, offset in part by lower demand. Zyprexa sales in international markets increased 3 percent, to \$653.4 million, driven by the higher demand, partially offset by the unfavorable impact of foreign exchange rates. Demand outside the U.S. was favorably impacted by the withdrawal of generic competition in Germany.

Cymbalta

For the third quarter of 2009, Cymbalta generated \$790.2 million in sales, an increase of 10 percent compared with the third quarter of 2008. U.S. sales of Cymbalta increased 9 percent, to \$652.7 million, driven by higher demand and higher net effective selling prices. Sales outside the U.S. were \$137.5 million, an increase of 15 percent, driven primarily by higher demand, partially offset by the unfavorable impact of foreign exchange rates and lower prices.

Humalog

For the third quarter of 2009, worldwide Humalog sales increased 16 percent, to \$500.2 million. Sales in the U.S. increased 27 percent to \$310.6 million, driven by higher prices and higher demand. Sales outside the U.S. increased 1 percent to \$189.6 million, driven by higher demand partially offset by the unfavorable impact of foreign exchange rates.

Alimta

For the third quarter of 2009, Alimta generated sales of \$461.9 million, an increase of 47 percent compared with the third quarter of 2008. U.S. sales of Alimta increased 44 percent, to \$215.5 million, due to increased demand. Sales outside the U.S. increased 50 percent, to \$246.4 million, due to increased demand, partially offset by the unfavorable impact of foreign exchange rates. Demand outside the U.S. was favorably impacted by the addition of the non-small cell lung cancer indication in Japan.

Cialis

Cialis sales for the third quarter of 2009 increased 5 percent compared with third-quarter 2008 to \$397.2 million. U.S. sales of Cialis were \$158.7 million in the third quarter, a 13 percent increase compared with the third quarter of 2008, driven by higher demand and, to a lesser extent, increased net effective selling prices. Sales of Cialis outside the U.S. increased 1 percent, to \$238.5 million, driven primarily by increased demand and higher prices, partially offset by the unfavorable impact of foreign exchange rates.

Gemzar

Gemzar sales totaled \$331.8 million in the third quarter of 2009, a decrease of 25 percent from the third quarter of 2008. Sales in the U.S. increased 1 percent, to \$191.0 million, due primarily to higher net effective selling prices, partially offset by lower demand. Sales outside the U.S.

decreased 44 percent, to \$140.8 million, due to reduced demand and lower prices as a result of the entry of generic competition in most major markets.

Evista

Evista sales were \$259.5 million in the third quarter of 2009, a 2 percent decrease compared with the third quarter of 2008. U.S. sales of Evista increased 2 percent to \$174.4 million, as a result of higher net effective selling prices, partially offset by lower demand. Sales outside the U.S. decreased 10 percent to \$85.1 million, driven by the outlicensing of Evista in most European markets.

Humulin

Worldwide Humulin sales decreased 4 percent in the third quarter of 2009, to \$260.4 million. U.S. sales increased 11 percent to \$105.8 million, due primarily to higher net effective selling prices. Product demand in the U.S. continues to decline. Sales outside the U.S. decreased 12 percent, to \$154.6 million, driven by the unfavorable impact of foreign exchange rates and lower prices, partially offset by increased demand.

Forteo

Third-quarter sales of Forteo were \$213.1 million, an 11 percent increase compared with the third quarter of 2008. U.S. sales of Forteo increased 15 percent, to \$135.1 million, driven by higher prices and the impact of wholesaler buying patterns. Sales outside the U.S. increased 3 percent, to \$78.0 million, due to higher demand and increased prices, partially offset by the unfavorable impact of foreign exchange rates.

Strattera

During the third quarter of 2009, Strattera generated \$145.5 million of sales, a decrease of 3 percent compared with the third quarter of 2008. U.S. sales decreased 2 percent to \$106.9 million, due to lower volume, partially offset by higher net effective selling prices. Sales outside the U.S. decreased 3 percent, to \$38.7 million, driven by lower prices and the unfavorable impact of foreign exchange rates, partially offset by increased demand. (numbers do not add due to rounding)

Byetta®

Lilly reports in collaboration revenue its 50 percent share of Byetta's gross margin in the U.S., and in product sales 100 percent of Byetta sales outside the U.S., and its sales of Byetta pen delivery devices to its partner, Amylin Pharmaceuticals. For the third quarter, Lilly recognized total revenue of \$115.8 million for Byetta, an increase of 6 percent, comprised of collaboration revenue of \$77.8 million and product sales of \$38.0 million.

Worldwide sales of Byetta were \$205.7 million in the third quarter of 2009, a 2 percent increase compared with the third quarter of 2008, driven by growth in international markets. U.S. sales of Byetta declined 5 percent to \$171.1 million compared with the third quarter of 2008, while sales of Byetta outside the U.S. were \$34.6 million.

Erbitux®

Lilly reports in collaboration revenue the net royalties received from its Erbitux collaboration partners, and in product sales the revenue from manufactured product sold to these partners. For the third quarter, Lilly recognized total revenue of \$101.9 million for Erbitux, comprised of collaboration revenue of \$79.6 million and product sales of \$22.3 million.

Effient™

Worldwide Effient sales were \$22.6 million in the third quarter of 2009. U.S. Effient sales were \$21.1 million, driven by wholesaler stocking and initial demand. Sales outside the U.S. were \$1.5 million. The product is in the early phases of launch in both the U.S. and Europe. Lilly and its partner, Daiichi Sankyo, continue to make good progress in gaining reimbursement and access for the product.

Animal Health

Worldwide sales of animal health products in the third quarter of 2009 were \$314.6 million, an increase of 14 percent compared with the third quarter of 2008. U.S. sales grew 38 percent, to \$176.8 million, primarily due to the inclusion of sales from the Posilac® acquisition completed in October, 2008. Sales outside the U.S. decreased 8 percent, to \$137.8 million, driven primarily by the unfavorable impact of foreign exchange rates and lower volume.

Year-to-Date Results

For the first nine months of 2009, worldwide total revenue increased 5 percent on a reported basis and 3 percent on a pro forma basis, to \$15.902 billion, compared with sales for the same period in 2008. Reported net income and earnings per share were \$3.413 billion and \$3.11, respectively. Net income and earnings per share, on a pro forma non-GAAP basis, were \$3.852 billion and \$3.51, respectively.

Year-to-Date Significant Items Affecting Net Income

In addition to the significant items previously mentioned, net income for the first nine months of 2008 and 2009 was also affected by significant items occurring in the first half of 2008 and 2009. To reflect the impact of the ImClone acquisition as if the acquisition occurred on January 1, 2008, year-to-date 2008 pro forma earnings per share have been reduced by \$.15 per share. For further detail, see the reconciliation below as well as the footnotes to the pro forma non-GAAP income statement later in this press release.

	Year-to-date		% Growth
	2009	2008	
Earnings per share (reported)	\$ 3.11	\$ 1.42	NM
Charges related to Zyprexa litigation	.13	1.33	
Asset impairments and restructuring charges (included in asset impairments, restructuring and other special charges)	.26	.25	
Asset impairments (included in cost of sales)	—	.04	
In-process research and development charges associated with SGX acquisition and in-licensing transactions with BioMS and TransPharma (2008)	—	.10	
Benefit from resolution of IRS audit in first quarter of 2008	—	(.19)	
Pro forma as if the ImClone acquisition was completed on January 1, 2008	—	(.15)	
Earnings per share (pro forma non-GAAP)	\$ 3.51	\$ 2.80	25%

NM – not meaningful; numbers in the 2009 year-to-date column do not add due to rounding.

2009 Financial Guidance

The company revised certain aspects of its 2009 financial guidance. The company now expects its full-year 2009 earnings per share to be in the range of \$3.90 to \$4.00 on a reported basis, or \$4.30 to \$4.40 on a pro forma non-GAAP basis.

	2009 Expectations	2008 Results	% Growth
Earnings (Loss) per share (reported)	\$3.90 to \$4.00	(\$1.89)	NM
Financial impact of ImClone acquisition, including in-process research and development and other charges	—	4.46	
Charges related to Zyprexa litigation	.13	1.20	
Asset impairments and restructuring charges (included in asset impairments, restructuring and other special charges)	.26	.30	
Asset impairments (included in cost of sales)	—	.04	
In-process research and development charges associated with SGX acquisition and in-licensing transactions with BioMS and TransPharma	—	.10	
Benefit from resolution of IRS audit in the first quarter of 2008	—	(.19)	
Pro forma as if the ImClone acquisition was completed on January 1, 2008	—	(.20)	
Earnings per share (pro forma non-GAAP)	\$4.30 to \$4.40	\$ 3.82	13% to 15%

NM – not meaningful

Numbers in the 2009 Expectations column do not add due to rounding

The company now expects low- to mid-single digit total revenue growth on a pro-forma basis and mid-single digit revenue growth on a reported basis.

The company continues to expect gross margin as a percent of total revenue to increase for the full year, driven primarily by the beneficial foreign exchange impact in the first nine months of 2009 compared to the first nine months of 2008. For the fourth quarter of 2009, the company expects a decrease in gross margin as a percent of total revenue compared to the fourth quarter of 2008.

Marketing, selling, and administrative expenses are still projected to show flat to low-single digit growth. Research and development expenses are still projected to grow in the high-single digits on a pro forma non-GAAP basis and in the low-double digits on a reported basis.

Other income is still expected to be a net loss of between \$200 million and \$250 million.

The effective tax rate is now expected to be approximately 21 percent on a pro forma non-GAAP basis and approximately 20 percent on a reported basis. Capital expenditures are now expected to be less than \$1.0 billion. The company still expects continued strong operating cash flow.

Webcast of Conference Call

As previously announced, investors and the general public can access a live webcast of the third-quarter 2009 financial results conference call through a link on Lilly's website at www.lilly.com. The conference call will be held today from 9:00 a.m. to 10:00 a.m. Eastern Daylight Time (EDT) and will be available for replay via the website through November 20, 2009.

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of pharmaceutical products by applying the latest research from its own worldwide laboratories and from collaborations with eminent scientific organizations. Headquartered in Indianapolis, Ind., Lilly provides answers – through medicines and information – for some of the world's most urgent medical needs. Additional information about Lilly is available at www.lilly.com; Lilly's clinical trial registry is available at www.lillytrials.com.

F-LLY

This press release contains forward-looking statements that are based on management's current expectations, but actual results may differ materially due to various factors. There are significant risks and uncertainties in pharmaceutical research and development. There can be no guarantees with respect to pipeline products that the products will receive the necessary clinical and manufacturing regulatory approvals or that they will prove to be commercially successful. The company's results may also be affected by such factors as competitive developments affecting current products; rate of sales growth of recently launched products; the timing of anticipated regulatory approvals and launches of new products; regulatory actions regarding currently marketed products; other regulatory developments and government investigations; patent disputes and other litigation involving current and future products; the impact of governmental actions regarding pricing, importation, and reimbursement for pharmaceuticals; changes in tax law; asset impairments and restructuring charges; acquisitions and business development transactions; and the impact of exchange rates and global macroeconomic conditions. For additional information about the factors that affect the company's business, please see the company's latest Form 10-Q filed July 2009 and Form 10-K filed February 2009. The company undertakes no duty to update forward-looking statements.

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Alimta® (pemetrexed, Lilly)
Byetta® (exenatide injection, Amylin Pharmaceuticals)
Cialis® (tadalafil, Lilly)
Cymbalta® (duloxetine hydrochloride, Lilly)
Effient™ (prasugrel, Lilly)
Erbitux® (cetuximab, ImClone Systems, Lilly)
Evista® (raloxifene hydrochloride, Lilly)
Forteo® (teriparatide of recombinant DNA origin injection, Lilly)
Gemzar® (gemcitabine hydrochloride, Lilly)
Humalog® (insulin lispro injection of recombinant DNA origin, Lilly)
Humulin® (human insulin of recombinant DNA origin, Lilly)
Posilac® (recombinant bovine somatotropin, Lilly)
Strattera® (atomoxetine hydrochloride, Lilly)
Zyprexa® (olanzapine, Lilly)

Eli Lilly and Company Employment Information

	<u>September 30, 2009</u>	<u>December 31, 2008</u>
Worldwide Employees	40,800	40,450

Eli Lilly and Company
Operating Results (Unaudited) — REPORTED
(Dollars in millions, except per share data)

	Three Months Ended September 30			Nine Months Ended September 30		
	2009	2008	% Chg.	2009	2008	% Chg.
Net product sales	\$ 5,385.5	\$ 5,092.4	6%	\$ 15,390.6	\$ 14,835.6	4%
Collaboration and other revenue	176.5	117.1	51%	511.2	331.9	54%
Total Revenue	5,562.0	5,209.5	7%	15,901.8	15,167.5	5%
Cost of sales	1,051.9	1,155.2	(9)%	2,815.7	3,467.4	(19)%
Research and development	1,122.1	953.0	18%	3,109.8	2,781.6	12%
Marketing, selling and administrative	1,701.8	1,649.2	3%	4,939.2	4,899.8	1%
Acquired in-process research and development	—	28.0		—	150.0	
Asset impairments, restructuring and other special charges	549.8	1,659.4		654.8	1,894.0	
Operating income	1,136.4	(235.3)	NM	4,382.3	1,974.7	NM
Net interest income (expense)	(44.0)	9.2		(149.7)	10.4	
Net other income (expense)	(22.9)	(6.7)		(12.0)	44.7	
Other income (expense)	(66.9)	2.5		(161.7)	55.1	
Income (loss) before income taxes	1,069.5	(232.8)	NM	4,220.6	2,029.8	NM
Income taxes	127.7	232.8	NM	807.2	472.3	NM
Net income (loss)	\$ 941.8	\$ (465.6)	NM	\$ 3,413.4	\$ 1,557.5	NM
Earnings (loss) per share — basic	\$.86	\$ (0.43)	NM	\$ 3.11	\$ 1.42	NM
Earnings (loss) per share — diluted	\$.86	\$ (0.43)	NM	\$ 3.11	\$ 1.42	NM
Dividends paid per share	\$.49	\$.47	4%	\$ 1.47	\$ 1.41	4%
Weighted-average shares outstanding (thousands) — basic	1,097,673	1,093,977		1,097,352	1,093,872	
Weighted-average shares outstanding (thousands) — diluted	1,097,700	1,093,977		1,097,382	1,093,927	

NM — not meaningful

Eli Lilly and Company

Operating Results (Unaudited) — Pro forma Non-GAAP

(Dollars in millions, except per share data)

	Three Months Ended September 30			Nine Months Ended September 30		
	2009(a)	2008(c)	% Chg.	2009 (a)(b)	2008(c)(d)	% Chg.
Net product sales	\$ 5,385.5	\$ 5,118.4	5%	\$ 15,390.6	\$ 14,908.4	3%
Collaboration and other revenue	176.5	190.3	(7)%	511.2	562.0	(9)%
Total Revenue	5,562.0	5,308.7	5%	15,901.8	15,470.4	3%
Cost of sales	1,051.9	1,199.2	(12)%	2,815.7	3,537.6	(20)%
Research and development	1,122.1	996.4	13%	3,109.8	2,903.8	7%
Marketing, selling and administrative	1,701.8	1,673.2	2%	4,939.2	4,987.8	(1)%
Operating income	1,686.2	1,439.9	17%	5,037.1	4,041.2	25%
Net interest income (expense)	(44.0)	(57.3)		(149.7)	(179.4)	
Net other income (expense)	(22.9)	(19.0)		(12.0)	20.8	
Other income (expense)	(66.9)	(76.3)		(161.7)	(158.6)	
Income before income taxes	1,619.3	1,363.6	19%	4,875.4	3,882.6	26%
Income taxes	307.5	288.2	7%	1,023.8	821.9	25%
Net income	\$ 1,311.8	\$ 1,075.4	22%	\$ 3,851.6	\$ 3,060.7	26%
Earnings per share — basic	\$ 1.20	\$ 0.98	22%	\$ 3.51	\$ 2.80	25%
Earnings per share — diluted	\$ 1.20	\$ 0.98	22%	\$ 3.51	\$ 2.80	25%
Dividends paid per share	\$.49	\$.47	4%	\$ 1.47	\$ 1.41	4%
Weighted-average shares outstanding (thousands) — basic	1,097,673	1,093,977		1,097,352	1,093,872	
Weighted-average shares outstanding (thousands) — diluted	1,097,700	1,094,024		1,097,382	1,093,927	

NM — not meaningful

- (a) The third quarter and year-to-date 2009 financial statements have been adjusted to eliminate an asset impairment and restructuring charge of \$424.8 million (pretax), or \$0.26 (after-tax). This charge is primarily related to the sale of the company's Tippecanoe manufacturing site and the severance costs associated with the sale. In addition, the third quarter and year-to-date 2009 financial statements have been adjusted to eliminate a special charge of \$125.0 million (pretax), or \$0.07 per share (after-tax), related to the currently probable and estimable exposures in connection with several states' litigation claims involving Zyprexa.

- (b) The 2009 year-to-date financial statements have also been adjusted to eliminate an additional special pretax charge of \$105.0 million, or \$0.06 per share (after-tax), representing the currently probable and estimable exposures in connection with several states' litigation claims involving Zyprexa.
- (c) The third-quarter and year-to-date 2008 financial statements have been adjusted to reflect the acquisition of ImClone as if it was completed by Lilly effective January 1, 2008. The 2008 third-quarter and year-to-date amounts have also been adjusted to eliminate a charge of \$28.0 million (no tax benefit), or \$0.03 per share, for acquired in-process research and development related to the SGX acquisition; a charge of \$182.4 million (pre-tax), or \$0.11 per share (after-tax), for asset impairments and restructuring primarily associated with the sale of the Greenfield site; and charges totaling \$1.477 billion (pre-tax), or \$1.33 per share (after-tax), related to pending and resolved Zyprexa investigations.
- (d) The 2008 year-to-date financial statements have also been adjusted to eliminate charges totaling \$122.0 million (pre-tax), or \$0.07 per share (after-tax), for acquired in-process research and development associated with the in-licensing of compounds from BioMS, and TransPharma; a charge of \$291.7 million (pre-tax), or \$0.18 per share (after-tax), for asset impairments, restructuring, and other special charges; and a discrete income tax benefit of \$210.3 million, or \$(0.19) per share related to the resolution of a substantial portion of an IRS audit.