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Date: April 18, 2011

For Release: Immediately

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Lilly Reports First-Quarter 2011 Results

- *First quarter 2011 revenue grew 6 percent to \$5.8 billion, driven by increased demand in international markets.*
- *Company delivered first quarter earnings per share of \$.95 (reported), or \$1.24 (non-GAAP).*
- *2011 non-GAAP earnings per share guidance range unchanged at \$4.15 - \$4.30; reported earnings per share guidance range of \$3.86 - \$4.01 now reflects Q1 restructuring charge.*

Eli Lilly and Company (NYSE: LLY) today announced financial results for the first quarter of 2011.

\$ in millions, except per share data	<u>First Quarter</u>		<u>%</u>
	<u>2011</u>	<u>2010</u>	<u>Growth</u>
Total Revenue – Reported	\$5,839.2	\$5,485.5	6%
Net Income – Reported	1,055.9	1,248.1	(15)%
EPS – Reported	0.95	1.13	(16)%
Net Income – non-GAAP	1,374.9	1,297.6	6%
EPS – non-GAAP	1.24	1.18	5%

Financial results for 2011 and 2010 are presented on both a reported and a 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. Non-GAAP results exclude the items described in the reconciliation tables. The non-GAAP results are presented in order to provide additional insights into the underlying trends in the company's business. The company's 2011 financial guidance is also being provided on both a reported and a non-GAAP basis.

“Lilly started the year by delivering solid financial results as we continue to advance the next wave of potential new medicines in our pipeline,” said John C. Lechleiter, Ph.D., Lilly’s chairman, president and chief executive officer. “Growth in international markets and the strong performance of Cymbalta, Alimta and our animal health business drove volume-based revenue growth of six percent, despite a significant decline in Gemzar sales due to generic competition. This revenue growth allowed us to make necessary investments in research and development to address the challenges of upcoming patent expirations. We are on track to deliver on our 2011 headcount and expense reduction targets, as well as our goal of having at least ten potential new medicines in Phase 3 clinical development by the end of this year.”

Key Events Over the Last Three Months

- The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) issued a positive opinion recommending approval of exenatide 2 mg powder and solvent for prolonged release suspension for injection (proposed trade name Bydureon™) in the European Union for the treatment of type 2 diabetes in combination with certain oral therapies. The CHMP's positive opinion is now referred for final action by the European Commission, which has the authority to approve medicines for the European Union. The Commission usually makes a decision on CHMP recommendations within two to three months.
- Late last week, the company received a complete response letter from the U.S. Food and Drug Administration (FDA) for its New Drug Application (NDA) for liprotamase, a non-porcine pancreatic enzyme replacement therapy (PERT), under investigation for the treatment of exocrine pancreatic insufficiency (EPI). The complete response letter communicated the need for Lilly to conduct an additional clinical trial prior to a re-submission. The company will be working diligently to address the agency’s questions.
- The company announced that Axiron® (testosterone) topical solution is available in pharmacies throughout the U.S.
- The company received a complete response letter from the FDA for the NDA for Amyvid™ (florbetapir F 18 injection), a Positron Emission Tomography (PET) imaging agent under investigation for the detection of beta-amyloid plaque in the brains of living patients. The company is working to address the FDA’s questions.

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- The company made an irrevocable, unconditional offer to acquire the animal health business of Janssen Pharmaceutica NV, a Johnson & Johnson Company. The two companies have notified the appropriate European works councils of their intentions. Upon deal closing, Lilly's animal health division, Elanco, would obtain a portfolio of about 50 marketed animal health products.

First-Quarter Reported Results

In the first quarter of 2011, worldwide total revenue was \$5.839 billion, an increase of 6 percent compared with the first quarter of 2010. This 6 percent revenue growth was comprised of an increase of 5 percent in volume and 1 percent due to the impact of foreign exchange rates. Pricing changes had a negligible impact on revenue growth. Total revenue in the U.S. increased 1 percent to \$3.076 billion primarily due to higher prices, partially offset by lower volume. Total revenue outside the U.S. increased 13 percent to \$2.763 billion due to increased volume and, to a lesser extent, the positive impact of foreign exchange rates, partially offset by lower prices. First-quarter 2011 total revenue was reduced by approximately \$90 million due to the impact of U.S. health care reform.

Gross margin increased 7 percent in the first quarter of 2011. Gross margin as a percent of total revenue was 79.8 percent, reflecting an increase of 0.3 percentage points compared with the first quarter of 2010.

Total operating expense, defined as the sum of research and development, marketing, selling and administrative expenses, increased 10 percent compared with the first quarter of 2010 and included additional expenses related to the diabetes collaboration with Boehringer Ingelheim. Marketing, selling and administrative expenses increased 11 percent to \$1.786 billion, driven by increased administrative expenses in the U.S., as well as higher marketing and selling expenses outside the U.S. Higher administrative expenses in the U.S. included approximately \$45 million related to the mandatory pharmaceutical manufacturers fee associated with U.S. health care reform, as well as higher litigation expenses. Research and development expenses were \$1.124 billion, or 19.2 percent of total revenue. Compared with the first quarter of 2010, research and development expenses grew 8 percent due primarily to increased late-stage clinical trial costs.

In the first quarter of 2011, the company recognized a charge of \$76.3 million for restructuring related to severance costs from previously announced strategic actions that the company is taking to reduce its cost structure and global workforce, as well as a \$388.0 million in-process research and development charge associated with the diabetes collaboration with Boehringer Ingelheim. In the first quarter of 2010, the company recognized asset impairments, restructuring and other special charges of \$26.2 million, primarily related to the previously announced strategic actions, as well as a \$50.0 million in-process research and development charge associated with the in-licensing of Axiron from Acrux Ltd.

Operating income in the first quarter of 2011 decreased 21 percent to \$1.285 billion, compared to the first quarter of 2010, due primarily to higher in-process research and development charges, as well as higher restructuring charges and increased administrative expenses.

Other income (expense) was a net expense of \$11.2 million, compared to \$74.5 million of other income in the first quarter of 2010. The first quarter of 2010 included damages recovered from generic pharmaceutical companies following Zyprexa[®] patent litigation in Germany, as well as a gain related to the disposition of investment securities acquired in the ImClone acquisition.

The effective tax rate was 17.1 percent in the first quarter of 2011, compared with an effective tax rate of 26.9 percent in the first quarter of 2010. The effective tax rate in the first quarter of 2010 was driven upward by the one-time charge of \$85.1 million associated with the imposition of tax on the prescription drug subsidy of the company's retiree health plan as part of U.S. health care reform, as well as the lapse of the U.S. R&D tax credit. The effective tax rate for the first quarter of 2011 reflects the tax benefit of the in-process research and development charge associated with the diabetes collaboration with Boehringer Ingelheim as well as the extension of the R&D tax credit in the U.S.

Net income and earnings per share decreased to \$1.056 billion and \$0.95, respectively, compared with first-quarter 2010 net income of \$1.248 billion and earnings per share of \$1.13. The decreases in net income and earnings per share were primarily driven by lower operating income due to the restructuring and in-process research and development charges, partially offset by improved gross margin and a lower effective tax rate.

First-Quarter 2011 non-GAAP Results

Operating income increased 2 percent to \$1.749 billion, due to increased gross margin, partially offset by increased administrative expenses and research and development expenses. Net income increased 6 percent to \$1.375 billion, while earnings per share increased 5 percent to \$1.24. These increases were primarily driven by increased gross margin and a lower net effective tax rate.

Excluding the impact of changes in foreign exchange rates, operating income and earnings per share would have increased approximately 1 percent and 3 percent, respectively.

For purposes of non-GAAP reporting, items totaling \$.29 and \$.05 per share in the first quarters of 2011 and 2010, respectively, have been excluded. For further detail, see the reconciliation below as well as the footnotes to the non-GAAP income statement later in this press release.

	<u>First Quarter</u>		
	<u>2011</u>	<u>2010</u>	<u>% Growth</u>
Earnings per share (reported)	\$.95	\$1.13	(16)%
In-process research and development charges associated with Boehringer Ingelheim collaboration (2011) and Acrux licensing agreement (2010)	.23	.03	
Asset impairments and restructuring charges	.06	.02	
Earnings per share (non-GAAP)	\$.24	\$1.18	5%

U.S. Health Care Reform Impact

U.S. health care reform reduced first-quarters 2011 and 2010 earnings per share by approximately \$.10 and \$.12 per share, respectively, on both a reported and non-GAAP basis. For the first quarter of 2011, U.S. health care reform reduced revenue by approximately \$90 million due to higher rebates and subsidies, and increased administrative expenses by approximately \$45 million related to the mandatory pharmaceutical manufacturers fee. For the first quarter of 2010, U.S. health care reform reduced revenue by approximately \$60 million due to higher rebates, and increased tax expense by \$85.1 million due to the imposition of tax on the prescription drug subsidy of the company's retiree health plan.

(Dollars in millions)	<u>First Quarter</u>		<u>% Change</u>
	<u>2011</u>	<u>2010</u>	<u>Over/(Under)</u> <u>2010</u>
Zyprexa	\$1,281.9	\$1,215.0	6%
Cymbalta [®]	908.8	803.2	13%
Alimta [®]	579.9	527.4	10%
Humalog [®]	525.4	506.4	4%
Cialis [®]	434.4	408.3	6%
Humulin [®]	289.8	257.8	12%
Evista [®]	266.1	241.6	10%
Forteo [®]	216.1	194.5	11%
Gemzar [®]	156.1	287.8	(46)%
Strattera [®]	138.7	146.4	(5)%
Animal Health	369.8	289.6	28%
Total Revenue	\$5,839.2	\$5,485.5	6%

Zyprexa

In the first quarter of 2011, Zyprexa sales totaled \$1.282 billion, an increase of 6 percent compared with the first quarter of 2010. U.S. sales of Zyprexa increased 2 percent to \$597.1 million, driven by higher prices, partially offset by lower volume. Zyprexa sales in international markets increased 8 percent, to \$684.8 million, driven primarily by higher volume, and to a lesser extent the favorable impact of foreign exchange rates.

Cymbalta

For the first quarter of 2011, Cymbalta generated \$908.8 million in revenue, an increase of 13 percent compared with the first quarter of 2010. U.S. sales of Cymbalta increased 6 percent, to \$691.1 million, driven by higher prices, and to a lesser extent, increased demand. Sales outside the U.S. were \$217.6 million, an increase of 43 percent, driven primarily by higher demand resulting from recent launches in Japan and other international markets.

Alimta

For the first quarter of 2011, Alimta generated sales of \$579.9 million, an increase of 10 percent compared with the first quarter of 2010. U.S. sales of Alimta increased 5 percent, to \$233.0 million,

driven by higher prices and higher demand, partially offset by wholesaler buying patterns. Sales outside the U.S. increased 14 percent, to \$346.9 million, due to increased demand in Japan and other international markets.

Humalog

For the first quarter of 2011, worldwide Humalog sales increased 4 percent, to \$525.4 million. Sales in the U.S. decreased 2 percent to \$303.8 million, driven by lower net effective selling prices, partially offset by increased demand. Sales outside the U.S. increased 13 percent to \$221.6 million, driven by higher demand.

Cialis

Cialis sales for the first quarter of 2011 increased 6 percent to \$434.4 million. U.S. sales of Cialis were \$157.8 million in the first quarter, a 5 percent increase compared with the first quarter of 2010, driven primarily by higher prices, partially offset by decreased volume. Sales of Cialis outside the U.S. increased 7 percent, to \$276.6 million, driven by increased demand and, to a lesser extent, higher prices.

Humulin

Worldwide Humulin sales increased 12 percent in the first quarter of 2011, to \$289.8 million. U.S. sales increased 13 percent to \$129.4 million, driven by increased demand resulting from the partnership with Walmart for Humulin[®] ReliOn[®]. Sales outside the U.S. increased 12 percent, to \$160.4 million, driven by higher demand, partially offset by lower prices.

Evista

Evista sales were \$266.1 million in the first quarter of 2011, a 10 percent increase compared with the first quarter of 2010. U.S. sales of Evista increased 10 percent to \$174.2 million, as a result of higher prices, partially offset by decreased demand. Sales outside the U.S. increased 10 percent to \$92.0 million, driven by increased demand in Japan and to a lesser extent the favorable impact of foreign exchange rates, partially offset by lower prices.

Forteo

First-quarter sales of Forteo were \$216.1 million, an 11 percent increase compared with the first quarter of 2010. U.S. sales of Forteo decreased 4 percent to \$111.7 million due to decreased

demand, partially offset by higher prices. Sales outside the U.S. increased 34 percent, to \$104.4 million, due primarily to increased demand resulting from the recent launch in Japan.

Gemzar

Gemzar sales totaled \$156.1 million in the first quarter of 2011, a decrease of 46 percent from the first quarter of 2010. Sales in the U.S. decreased 66 percent, to \$59.3 million, due to the impact of generic competition. Sales outside the U.S. decreased 15 percent, to \$96.8 million, due to generic competition in most major markets.

Strattera

During the first quarter of 2011, Strattera generated \$138.7 million of sales, a decrease of 5 percent compared with the first quarter of 2010. U.S. sales decreased 16 percent to \$86.6 million, due to lower net effective selling prices and lower demand. Sales outside the U.S. increased 20 percent, to \$52.1 million, driven primarily by continued strong demand in Japan.

Erbix[®]

Lilly recognizes net royalties received from its Erbitux collaboration partners and revenue from manufactured product sold to these partners. For the first quarter of 2011, Lilly recognized total revenue of \$104.0 million for Erbitux, an increase of 12 percent from the first quarter of 2010, due primarily to the timing of the sale of manufactured product to partners for development purposes.

Byetta[®]

Lilly recognizes in revenue its 50 percent share of Byetta's gross margin in the U.S., 100 percent of Byetta sales outside the U.S., and its sales of Byetta pen delivery devices to its partner, Amylin Pharmaceuticals. For the first quarter of 2011, Lilly recognized total revenue of \$101.8 million for Byetta, a decrease of 12 percent.

Worldwide sales of Byetta were \$165.4 million in the first quarter of 2011, a 12 percent decrease compared with the first quarter of 2010, due to competitive pressures in the U.S. and European markets. U.S. sales of Byetta decreased 15 percent to \$128.0 million compared with the first quarter of 2010, while sales of Byetta outside the U.S. decreased 2 percent to \$37.4 million.

Effient[®]

Worldwide Effient sales were \$56.3 million in the first quarter of 2011, up from \$47.0 million in the fourth quarter of 2010. U.S. Effient sales were \$42.0 million. Sales outside the U.S. were \$14.3 million.

Animal Health

Worldwide sales of animal health products in the first quarter of 2011 were \$369.8 million, an increase of 28 percent compared with the first quarter of 2010. U.S. sales grew 28 percent, to \$202.4 million, due to increased demand for food animal products and the U.S. launch of Trifexis[™]. Sales outside the U.S. increased 27 percent, to \$167.4 million, driven by increased demand and the impact of the acquisition of certain Pfizer animal health assets in Europe.

2011 Financial Guidance

The company has updated certain elements of its 2011 financial guidance. The company still expects full-year 2011 earnings per share to be in the range of \$4.15 to \$4.30 on a non-GAAP basis, but now expects earnings per share on a reported basis to be in the range of \$3.86 to \$4.01, due to the restructuring charge taken in the first quarter of 2011. Earnings per share guidance excludes potential future restructuring charges.

2011 Earnings Per Share Expectations:

	2011 Expectations	2010 Results	% Growth
Earnings per share (reported)	\$3.86 to \$4.01	\$4.58	(12)% to (16)%
In-process research and development charge associated with Boehringer Ingelheim collaboration (2011) and Acrux licensing agreement (2010)	.23	.03	
Asset impairments and restructuring charges	.06	.13	
Earnings per share (non-GAAP)	\$4.15 to \$4.30	\$4.74	(9)% to (12)%

Due to the recent appreciation of several foreign currencies versus the U.S. dollar, the company now expects total revenue to grow in the low-single digits, an increase from the prior guidance of flat to slightly increasing total revenue growth. The company still anticipates that the impact of U.S. health care reform will lower 2011 revenue by \$400 million to \$500 million. 2011 revenue guidance assumes the company maintains its patent exclusivity for U.S. Strattera sales, and also assumes rapid and severe erosion of global Zyprexa sales after patent expirations in major markets, including the U.S. starting in October 2011, and the continued severe erosion of U.S. Gemzar sales. The company expects these reductions in revenue to be offset by sales growth of Alimta, Cialis, Cymbalta, Effient, Humalog and animal health products.

Due to the recent appreciation of several foreign currencies versus the U.S. dollar, the company now anticipates that gross margin as a percent of revenue will decline approximately 3 percentage points, a revision from prior guidance of an approximate 2 percentage point decline.

Marketing, selling and administrative expenses are still projected to grow in the low- to mid-single digits and include an estimated \$150 million to \$200 million in non-tax deductible expense for the

mandatory pharmaceutical manufacturers fee associated with U.S. health care reform. Research and development expense growth is still projected to be relatively flat.

Other income is still expected to be a net expense of between \$50 million and \$150 million.

The tax rate is now expected to be approximately 21 percent on a non-GAAP basis and approximately 20 percent on a reported basis. The estimated full year tax rates on both a non-GAAP and reported basis have decreased due to the benefits arising from the resolution of IRS audit matters. The estimated full year reported tax rate has also decreased from prior 2011 guidance due to the tax benefit of the in-process research and development charge associated with the Boehringer Ingelheim collaboration.

Cash flows are still expected to be sufficient to fund capital expenditures of between \$800 million and \$900 million, as well as anticipated business development activity and the company's dividend.

Webcast of Conference Call

As previously announced, investors and the general public can access a live webcast of the first-quarter 2011 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 May 20, 2011.

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. Pharmaceutical products can develop unexpected safety or efficacy concerns. The company's results may also be affected by such factors as competitive developments affecting current products; market uptake of recently-launched products; the timing of anticipated regulatory approvals and launches of new products; regulatory actions regarding

currently marketed products; issues with product supply; regulatory changes or other developments; regulatory compliance problems or government investigations; patent disputes; changes in patent law or regulations related to data-package exclusivity; other litigation involving current or future products; the impact of governmental actions regarding pricing, importation, and reimbursement for pharmaceuticals, including U.S. health care reform; 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 and Form 10-K filed with the U.S. Securities and Exchange Commission. The company undertakes no duty to update forward-looking statements.

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Alimta[®] (pemetrexed, Lilly)
 Amyvid[™] (florbetapir, Lilly),
 Axiron[®] (testosterone, Acrux Corp.)
 Byetta[®] (exenatide injection, Amylin Pharmaceuticals)
 Bydureon[™] (exenatide for extended-release injectable suspension, 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)
 Strattera[®] (atomoxetine hydrochloride, Lilly)
 Trifexis[™] (spinosad + milbemycin oxime, Lilly)
 Zyprexa[®] (olanzapine, Lilly)

Eli Lilly and Company Employment Information

	<u>March 31, 2011</u>	<u>December 31, 2010</u>
Worldwide Employees	38,165	38,350

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

	Three Months Ended		
	March 31		% Chg.
	2011	2010	
Total revenue	\$ 5,839.2	\$ 5,485.5	6%
Cost of sales	1,180.1	1,122.5	5%
Research and development	1,124.0	1,039.1	8%
Marketing, selling and administrative	1,785.7	1,614.4	11%
Acquired in-process research and development	388.0	50.0	NM
Asset impairments, restructuring and other special charges	<u>76.3</u>	<u>26.2</u>	NM
Operating income	1,285.1	1,633.3	(21)%
Net interest income (expense)	(30.3)	(37.0)	
Net other income (expense)	<u>19.1</u>	<u>111.5</u>	
Other income (expense)	(11.2)	74.5	NM
Income before income taxes	1,273.9	1,707.8	(25)%
Income taxes	<u>218.0</u>	<u>459.7</u>	(53)%
Net income	\$ <u>1,055.9</u>	\$ <u>1,248.1</u>	(15)%
Earnings per share – basic	\$ <u>0.95</u>	\$ <u>1.13</u>	(16)%
Earnings per share – diluted	\$ <u>0.95</u>	\$ <u>1.13</u>	(16)%
Dividends paid per share	\$ 0.49	\$ 0.49	NM
Weighted-average shares outstanding (thousands) – basic	1,112,003	1,103,380	
Weighted-average shares outstanding (thousands) – diluted	1,112,026	1,103,406	

Eli Lilly and Company
 Operating Results (Unaudited) – Non-GAAP
 (Dollars in millions, except per share data)

	Three Months Ended		
	March 31		% Chg.
	2011(a)	2010(b)	
Total revenue	\$ 5,839.2	\$ 5,485.5	6%
Cost of sales	1,180.1	1,122.5	5%
Research and development	1,124.0	1,039.1	8%
Marketing, selling and administrative	<u>1,785.7</u>	<u>1,614.4</u>	11%
Operating income	1,749.4	1,709.5	2%
Net interest income (expense)	(30.3)	(37.0)	
Net other income (expense)	<u>19.1</u>	<u>111.5</u>	
Other income (expense)	(11.2)	74.5	NM
Income before income taxes	1,738.2	1,784.0	(3)%
Income taxes	<u>363.3</u>	<u>486.4</u>	(25)%
Net income	\$ <u>1,374.9</u>	\$ <u>1,297.6</u>	6%
Earnings per share – basic	\$ <u>1.24</u>	\$ <u>1.18</u>	5%
Earnings per share – diluted	\$ <u>1.24</u>	\$ <u>1.18</u>	5%
Dividends paid per share	\$ 0.49	\$ 0.49	NM
Weighted-average shares outstanding (thousands) – basic	1,112,003	1,103,380	
Weighted-average shares outstanding (thousands) – diluted	1,112,026	1,103,406	

- (a) The first quarter 2011 has been adjusted to eliminate a restructuring charge of \$76.3 million (pretax), or \$0.06 (after-tax). This charge is related to severance costs from previously announced strategic actions that the company is taking to reduce its cost structure and global workforce. In addition, the first quarter 2011 financial statements have been adjusted to eliminate a charge of \$388.0 million (pretax), or \$0.23 per share (after-tax), for acquired in-process research and development associated with the collaboration with Boehringer Ingelheim.
- (b) The first quarter 2010 has been adjusted to eliminate a restructuring charge of \$26.2 million (pretax), or \$0.02 (after-tax). This charge is primarily related to severance costs from previously announced strategic actions that the company is taking to reduce its cost structure and global workforce. In addition, the first quarter 2010 financial statements have been adjusted to eliminate a charge of \$50.0 million (pretax), or

\$0.03 per share (after-tax), for acquired in-process research and development associated with the in-licensing agreement with Acrux Ltd.