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Promise

Annual Report 2001

*Lilly*

Answers That Matter.

*W. K.*

# 2001 Financial Highlights

Eli Lilly and Company and Subsidiaries (Dollars in millions, except per-share data)	Year Ended December 31	2001	2000	Change %
Net sales .....		\$11,542.5	\$10,862.2	6 <sup>1</sup>
Research and development .....		2,235.1	2,018.5	11
Net income .....		2,780.0	3,057.8	(9)
Earnings per share—basic .....		\$ 2.58	\$ 2.83	(9)
Earnings per share—diluted .....		2.55	2.79	(9)
Normalized <sup>2</sup>				
Net income .....		\$ 3,013.9	\$ 2,904.6	4
Net income as a percent of normalized sales .....		26.1%	26.5%	
Earnings per share—diluted .....		\$ 2.76	\$ 2.65	4
Dividends paid per share .....		\$ 1.12	\$ 1.04	8
Capital expenditures .....		\$ 884.0	\$ 677.9	30
Economic Value Added (EVA®) <sup>3</sup> .....		\$ 1,968	\$ 1,966	—

<sup>1</sup>Excluding Prozac®, the company's worldwide net sales increased 17 percent in 2001.

<sup>2</sup>Normalized net income reflects the results of operations adjusted for significant unusual items. In 2001, these items were the charges for acquired in-process research and development, asset impairment and other site charges, and an extraordinary charge for the repurchase of higher interest rate debt. In 2000, these items were the gain on the sale of Kinetra LLC and the net impact of year-2000-related sales made in the fourth quarter of 1999 that ordinarily would have been realized in the first quarter of 2000. Normalized earnings per share reflect net income adjusted for these same items. See notes to the consolidated financial statements.

<sup>3</sup>For comparison purposes, 2000 EVA was restated for program changes effective January 1, 2001.

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# To Our Shareholders

Our memories of 2001 will always be dominated by the terrorist attacks on September 11. The company and many employees joined with institutions and individuals worldwide in responding immediately to the tragedies with financial aid and donations of blood. We also helped several organizations to provide psychological counseling to people directly affected by the attacks.

The heartbreak of September 11 prompted many people not only to do whatever they could for victims but also to reflect on their priorities. Many have clearly felt a renewed appreciation of and responsibility for what is really important in life—family and friends, community and country.

This same spirit has moved the 41,000 people of Eli Lilly and Company to pursue with even more passion and vigor our mission of helping people live longer, fuller lives. So, we have redoubled our efforts to provide the global health care community with medicines that are better than other products or pioneer new classes of drugs.

No medicine better symbolizes our mission than Xigris™. In late November, the U.S. Food and Drug Administration (FDA) told us that we could begin marketing this biotech agent, the world's first treatment for adults with severe sepsis who have a high risk of death. We believe that Xigris—the product of two decades of Lilly research—will prove to be one of our industry's genuine break-



Sidney Taurel, Chairman of the Board, President, and Chief Executive Officer

throughs. (Please see pages 6–9 for more about Xigris.)

## **End of the Prozac Era at Lilly**

As we added Xigris to our product line, the “circle of life” in our innovation-driven business brought the role of Prozac® in the company's growth to an end. As you will recall, in August 2000, the Court of Appeals for the Federal Circuit reversed part of a federal district court decision upholding our U.S. patents for that breakthrough antidepressant. As a result, we lost our exclusive rights to Prozac in the United States on

August 2, 2001—almost three years sooner than we had expected.

We knew the competitive assault on one of the most successful medicines ever would be fierce. But the sales of this molecule dropped even faster than we had expected. Its sales declined 66 percent in the fourth quarter, bringing the total sales for the year down 23 percent, to \$2.0 billion.

Prozac stands among our company's greatest achievements. We take great pride in its benefits for tens of millions of patients and its influence on the awareness,

diagnosis, and treatment of mental illness.

### Strong product performance

Managing the patent expiration for a blockbuster product like Prozac is among the toughest challenges in our industry. But we were ready. Over several years, we had implemented a comprehensive plan to create and to capitalize on other opportunities. As part of that effort, we redoubled our support for five superb medicines that have been the primary sources of our recent growth. Last year, the sales of those products collectively rose 36 percent and accounted for 47 percent of our total revenues.

With sales of \$3.1 billion in 2001, Zyprexa® was both the first Lilly product and the first medicine for treating mental illnesses to surpass the \$3 billion mark in sales for a single year. Zyprexa provides outstanding safety and efficacy in two hard-to-treat conditions: schizophrenia and the acute mania associated with bipolar disorder. We increased its growth rate to 31 percent from 25 percent in 2000.

The cancer agent Gemzar® also did very well. With sales of \$723 million in 2001, its growth rate accelerated to 29 percent from 23 percent the previous year. Gemzar is the standard of therapy for non-small-cell lung cancer in many countries. In Europe and the United States, most patients with pancreatic cancer receive Gemzar.

Last year, our sales of the osteoporosis product Evista® climbed 27 percent, to \$665 million. This medicine generated strong growth in many countries, including Italy and Spain, and was approved for reimbursement in France. We also continued to press forward with

long-term studies to determine whether Evista reduces the risk of breast cancer and cardiovascular disease.

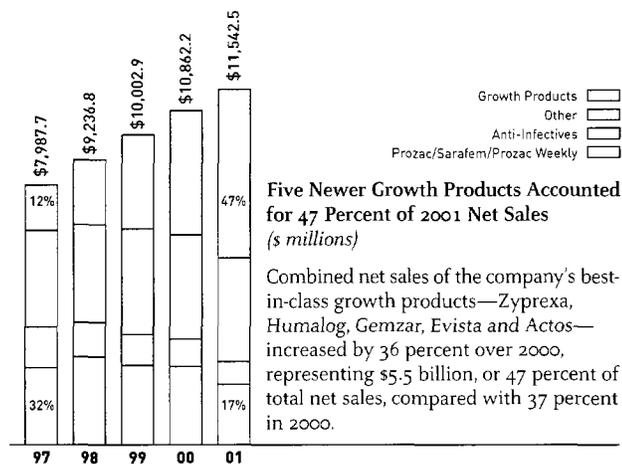
We excelled in two important diabetes categories in 2001. Led by the 79 percent increase in the sales of the human-insulin analog Humalog®, our global insulin revenues rose 16 percent. Meanwhile, Actos® performed very well in the fastest growing segment of oral medicines for type 2 diabetes and became the U.S. leader in cash share of the so-called TZD class of medicines. Our revenue from Actos, a discovery of our marketing partner, Takeda Chemical Indus-

tries, Inc., was \$361 million, up 62 percent from 2000.

Largely due to the outstanding performance of those five products, the company's sales—excluding Prozac—rose 17 percent. Including Prozac, our sales, adjusted for one-time items, rose 5 percent last year, to \$11.5 billion. Our normalized net income and earnings per share both increased 4 percent, to \$3.0 billion and \$2.76, respectively.

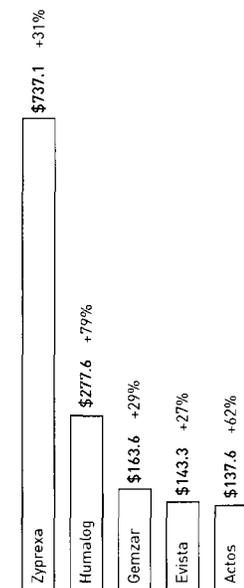
### Expanding growth opportunities

The second part of our plan for overcoming the Prozac patent expiration was to speed the development



Five Newer Growth Products Accounted for 47 Percent of 2001 Net Sales (\$ millions)

Combined net sales of the company's best-in-class growth products—Zyprexa, Humalog, Gemzar, Evista and Actos—increased by 36 percent over 2000, representing \$5.5 billion, or 47 percent of total net sales, compared with 37 percent in 2000.



Five Newer Growth Products Collectively Delivered 36 Percent Increase (\$ millions; percentages represent changes from 2000)

The company's five major growth products—Zyprexa, Humalog, Gemzar, Evista, and Actos—generated \$1.46 billion of incremental net sales and \$5.5 billion of total net sales in 2001. Combined, these products grew 36 percent for the year with Zyprexa, Humalog, and Gemzar growing at rates faster than 2000. During 2001, Zyprexa became the company's first product with net sales in excess of \$3 billion.

of high-potential Lilly molecules and add others from partners. Here, too, we made a lot of progress.

In 2001, we submitted the most New Drug Applications for novel molecules that the company has ever had in a single year. In addition to Xigris, we filed applications for three promising candidates: Lilly ICOS LLC's Cialis™, for erectile dysfunction; atomoxetine, for attention-deficit hyperactivity disorder; and duloxetine, for depression. Very importantly, we delivered each of those regulatory submissions either on or ahead of schedule.

With those applications, regulators are now evaluating four drug candidates, including the osteoporosis agent Fortéo™, that will expand our product line. Last year, we also stayed on track to file submissions for six more new medicines that we hope to launch between 2003 and 2005. (Please see pages 10–18 for more about selected drug candidates.)

In 2001, we further strengthened an already exciting pipeline of drug candidates. Our scientists advanced eight molecules into Phase II and Phase III of clinical evaluation. Thirty Lilly drug candidates and significant new indications are now in those vital stages of development.

Last year, we also expanded and upgraded our pipeline by in-licensing five molecules—another Lilly record—that are well into development. 3M Pharmaceutical's resiquimod targets genital herpes. An antisense agent from Isis Pharmaceuticals, Inc., is a potential treatment for lung cancer. The other three candidates we in-licensed are in the cardiovascular category, the largest in the pharma-

ceutical industry. They are CS-747, a molecule from Sankyo Company, Ltd., for stroke and acute coronary syndromes; bioMérieux-Pierre Fabre Group's eflucimibe, for atherosclerosis; and Bioprojet's fasidotril, for hypertension and congestive heart failure.

With all those promising molecules, we have a great opportunity to triple the size of our product line over the next five or so years. As a result, we believe Lilly has what it will take to become the pharmaceutical growth company of this first decade of the twenty-first century.

### **Growth-related challenges**

In our high-risk business where many compounds fail, we have been delighted that our pipeline has continued to look better and better. Consequently, we faced the welcome problem of supporting more new-product candidates than we had anticipated. But those opportunities came at the very time our resources were squeezed by our declining Prozac sales.

So, we faced a choice. We could reduce the support for our expanding product line and deliver higher near-term earnings. Or we could pull back a bit on our earnings for late 2001 and for 2002—and increase our investments to fully capitalize on our many product opportunities, thereby generating strong growth in 2003 and beyond.

To create more value for our shareholders, we opted for the second alternative. Last year, we increased the investments in our growing product line and our robust pipeline. In 2002, we are continuing to invest aggressively in our many long-term growth opportunities.

### **A deep disappointment**

Although 2001 was generally a good year, it had one major blemish. As part of inspections related to the regulatory reviews of Fortéo and a new formulation called Zyprexa IntraMuscular, the FDA found quality issues at two of our production facilities in Indianapolis. The agency's reinspection resulted in additional critical observations about our quality unit.

To address those concerns, we have strengthened the leadership of our global quality and manufacturing groups and enlisted help from outside experts and from people in many parts of the company. Employees at the Indianapolis facilities and other production sites have labored heroically for months to raise the quality at their operations to the highest standards. We have worked closely with the FDA throughout this effort.

But progress has been slower than we had hoped. So, we have put more resources behind those efforts. Although the safety and efficacy of our current products are not at issue, the resolution of our quality issues is a key part of getting the FDA's go-ahead to market Fortéo, Zyprexa IntraMuscular, and other new products. Needless to say, this is our number-one task in 2002.

### **Strategic implementation**

The overall progress we made in 2001 was guided by a simple strategy for serving our customers and delivering strong, sustainable growth. First, we discover or collaborate on drug candidates with best-in-class, often first-in-class, potential. And, second, we make sure that those molecules, supported by useful information

and services, fulfill the unmet needs of our customers worldwide.

Under the first part of our strategy, our global R&D organization further strengthened the capabilities that have already made the company an R&D powerhouse. For example, we selected 15 new-drug candidates to begin formal development last year—the most ever at Lilly. By doing certain key experiments earlier in the research process, our scientists have, in the past few years, doubled the probability that our molecules will survive to begin clinical testing.

In addition, we are pushing harder than ever to find opportunities to collaborate with other companies and research groups that can help us get access to new R&D technologies, high-potential biological targets, and promising drug candidates. We are taking advantage of our three-year-old Office of Alliance Management to help our partners and us succeed with our cooperative efforts.

Because we have to manage so many opportunities, we have improved our ability to set priorities and make choices among some 60 drug candidates we are working on. We moved decisively in 2001 to stop our least promising projects, to in-license high-potential molecules, and to out-license compounds that other firms could better support while we focused on opportunities most consistent with our growth goals. With those decisions, we increased the value of our research portfolio by 40 percent last year and expedited work on our most promising projects.

Guided by the second part of our strategy, we took a hard look at our sales-and-marketing capabilities a

few years ago. We found we were neither good enough nor big enough to communicate persuasively with our customers about how our medicines benefit patients and help limit total medical costs.

So, we undertook a major effort to strengthen our sales-and-marketing organization and processes. We have increased the size of the sales organizations supporting our growing product line. In the United States, the teams promoting our products grew from 2,900 sales professionals in January 2000 to 5,100 in January 2002. During that two-year period, the global organization selling Lilly medicines expanded from 9,500 people to 13,500.

In addition, we are investing far more in our products far earlier in their development. By starting early, we can ensure our clinical studies focus on product features that are important to our customers. We also get a head start with the planning for new indications and formulations that can make our medicines even more useful.

Our sales-and-marketing efforts are paying off. As noted earlier, we accelerated the growth of Zyprexa, Gemzar, and Humalog in 2001. We also increased the share of sales for Zyprexa and Actos in the face of head-to-head competition with larger companies. And we delivered strong growth in the world's major pharmaceutical markets. For instance, we were the fastest growing major drug company in the United States during the first half of 2001—before Prozac faced generic competition. Last year, we also were the fastest growing pharmaceutical company in Japan, and our growth was number three among large drug companies in Europe.

Every year, our employees do a better job of implementing our strategy. We have consistently delivered on our R&D and sales-and-marketing commitments. We are focusing the same tenacity on improving our quality assurance and control. As one of the industry's most prolific sources of exciting molecules, we must excel in the critical manufacturing phase of the innovation cycle. We will do just that.

### **Promising future**

As we come to the end of our company's 125th year of doing business, we are keenly aware that our most important asset is the trust we have earned with all the people to whom we are accountable. At a time when investors are very concerned about some firms' business decisions and accounting practices, we continue to be guided, in everything we do, by the highest standards of integrity.

With your support, we are bringing medical advances to people throughout the world. Our innovations are clearly making a difference. Our customers are using our growing line of best-in-class, often first-in-class, medicines to get the best possible results for millions of patients. Those results affirm our conviction that we have a great opportunity to become the pharmaceutical growth company of the decade.

For the board of directors,



Sidney Taurel  
*Chairman of the Board, President,  
and Chief Executive Officer*  
February 8, 2002

# Products in Late-Stage Development

## Launched in 2001

Xigris™

*Severe sepsis*

## Targeted first launch in 2002

Fortéo™

*Osteoporosis*

Cialis™

*Male erectile dysfunction*

Atomoxetine

*Attention-deficit hyperactivity disorder (ADHD)*

Duloxetine

*Depression*

## Targeted first launch in 2003

Alimta®

*Mesothelioma*

Duloxetine

*Stress urinary incontinence*

## Targeted first launch in 2004/2005

Protein Kinase C beta (PKCβ) inhibitor

*Diabetic retinopathy (in Europe)*

OFC (olanzapine-fluoxetine combination)

*Treatment-resistant depression*

LY900003 (formerly ISIS 3521)

*Non-small-cell lung cancer*

Resiquimod

*Genital herpes*

The search for new drugs is risky and uncertain. While Lilly believes each of these molecules holds great promise, there are no guarantees. Remaining scientific and regulatory hurdles may cause a late-stage compound to be delayed or even fail to reach the market at all. See "Other Matters" on pages 25-26 for more discussion of required FDA manufacturing and clinical approvals.

# Xigris

Xigris is a breakthrough drug for a killer disease. It now offers hope in the U.S. to adult victims of severe sepsis at high risk of death. And it fulfills Lilly's promise to help solve some of the world's most urgent medical problems.

At first, it might feel like the flu. Your muscles ache, and you feel feverish and dizzy.

Suddenly, you are in real trouble. Your blood pressure plummets. Then, your kidneys stop working. Your fingers bloat like sausages. Finally, your lungs fail.

This is how severe sepsis can kill. And this is the deadly puzzle that Lilly was determined to solve.

The risks were worth it. On November 21, 2001, doctors and caregivers cheered the news that Xigris had won U.S. regulatory approval. The first-in-class drug could help save one in five people who otherwise would die.

"We persevered," says one of the lead scientists, Betty Yan, Ph.D. (at left). "No one wanted to give up. We knew that, every day, people were dying."

## A grim reaper

Sepsis claims 1,400 lives every day—or one victim, on average, each minute. The complexity of the disease is daunting: sepsis is, in essence, the body turning on itself as it tries to fight an overwhelming infection, such as pneumonia. Vital organs are starved of blood, and they fail.

Early on, Lilly researchers capitalized on the company's biotechnology expertise and bet correctly that a treatment might lie in the Activated Protein C molecule, a naturally occurring protein in the body. But the protein is unusually large and complex, and it took years of painstaking research to

determine its full medical potential. The end result, Xigris, reduces inflammation and clotting.

Looking back, Yan says discovering and manufacturing Xigris was perhaps the most complex biotech challenge ever attempted by a pharmaceutical company, much like "putting a man on the moon."

"There was a steep learning curve," agrees Brian Grinnell, Ph.D., who did some of the most important early work on Xigris. Other companies tried, too; 16 firms failed after experimenting with a dozen other molecules.

Nor was it easy figuring out how to manufacture Xigris; Lilly took a risk and invested heavily in manufacturing operations long before final clinical trial results for Xigris were known. Says Danny Connor, who served as the product's manufacturing representative, "We could only hope that our time and investments would pay off for the patient."

They clearly did. And now, says Yan, "It is an awfully big relief to have it available to those who so desperately need it."



Ours was an urgent mission in uncharted territory. It took nearly 20 years, hundreds of millions of dollars, significant scientific risks, manufacturing innovations, and intricate teamwork to develop Xigris, the world's first approved treatment for adult severe sepsis patients at high risk of death.

*When Juanne Herrold fell ill with severe sepsis, her life was saved with the help of Xigris. Now fully recovered, she is enjoying her Florida home, retirement with her husband, and 10 grandchildren. She says, "I am thrilled to be alive."*



# Xigris: A mission accomplished

Two decades of perseverance and investments result in a lifesaving treatment

Early 1980s	During the 1980s	Early 1990s	Early 1990s	December 1994	June 1997
Lilly scientists began searching for a treatment for diseases such as sepsis. They focused on cloning a key molecule, Activated Protein C.	Lilly researchers discovered methods that generated this complex protein in a fully functional recombinant form. New technologies were developed that enabled the generation of a commercially viable mammalian cell line.	Betty Yan, Ph.D.; Brian Grinnell, Ph.D.; and Ralph Riggin, Ph.D., among others at Lilly Research Laboratories, continued the quest for a treatment for sepsis despite concerns throughout the pharmaceutical industry that the goal was out of reach.	Researchers made significant progress, finding new ways to scale up and culture Protein C, producing mammalian cells, and better defining the mechanism of action.	An Investigational New Drug Application was submitted, and a month later, the first human clinical trials began.	A manufacturing milestone was reached as an agreement was signed with biotechnology experts to speed production of Xigris. This was a risk; Phase III trials were just commencing.

## A life saved

Juanne Herrold (pictured on the preceding page) was slipping fast. She had survived surgery for colon cancer but developed severe sepsis. A doctor put her odds of survival at close to zero.

The 68-year-old Florida woman was far from home. She had fallen ill in tiny Maggie Valley, North Carolina, where she and her husband, Ed, have a summer home.

"Here I was, in a strange hospital, near death," she says. "But I had the fighting spirit."

Lying in intensive care, her kidneys, lungs, and circulatory system failing, she remembers "seeing a white light, the brightest light I had ever seen. I felt like I

was standing at the edge of a cliff. And then I heard a voice, asking me if I wanted to live or die.

"I was calm, not panicky. I thought, 'Wait, wait. I'm not ready to die. I've got little bitty grandchildren. I need to see those darlings grow up.'"

### 'I need that drug'

Her husband, doctors, nurses, hospital administrators—and some Lilly employees she had never met—weren't giving up either. From early morning until evening last July 13, they raced to save her life. "There are a lot of heroes in this story," she says.

She gives special thanks to Harry Lipham, M.D., a pulmonologist and critical care specialist at Haywood Regional Medical Center,

who moved quickly to help her. Though Xigris was not yet approved by the U.S. Food and Drug Administration, it was available for extraordinary "compassionate use" cases.

Lipham called his Lilly sales representative, Tate Gilchrist, and urgently said, "I need that drug for a dying patient." Gilchrist connected the doctor to Lilly offices and nearby clinicians in Tennessee.

### 'We are truly grateful'

Quickly, paperwork was faxed back and forth. Infectious disease experts were consulted. An emergency meeting of the hospital board was convened. Administrators approved Xigris's use. A supply of the then-investigational drug was located a state away. A

**March 2000**

The first production-scale batch of Xigris was manufactured as Lilly awaited clinical trial results.

**June 2000**

Cheers erupted throughout the medical and scientific communities after a panel of experts recommended that Phase III trials be stopped early due to overwhelmingly positive results.

**Fall 2000**

Lilly began recruiting and training hundreds of sales representatives to talk with physicians about sepsis and to be ready to market Xigris following approval.

**October 2000**

Lilly began converting Building 358 in Indianapolis to a Xigris manufacturing plant to provide quantities of one of the most complex drugs ever produced.

**October 2001**

A U.S. FDA advisory committee met to discuss the scientific and clinical trial data on Xigris. A few weeks later, Xigris received a "complete response letter" from the FDA.

**November 2001**

Nearly two decades of research, hundreds of millions of dollars in investments, and dozens of smart risks started to pay dividends for patients, clinicians, and Lilly as Xigris was approved for U.S. marketing.

special courier jumped in a car and delivered Xigris in just two hours.

By 4:30 p.m., the medicine had arrived and was being infused into Mrs. Herrold's system. "It was the most hectic six hours I have ever spent," says Lipham.

As Lipham anxiously watched over his patient that evening, he was amazed to see her kidneys start to function within an hour. After another hour, her vital signs had returned. "Clearly, she was getting better. I was certainly impressed. This was cutting-edge medicine."

Two days later, she came off the ventilator and her relieved husband went from wondering whether she would survive to asking when she might go home. Two months later, she had fully recovered.

Now back in her Florida home, Mrs. Herrold says she is grateful to be alive. She notes that the "scariest part of sepsis is it happens so fast. One minute you are OK and the next, you are going to die. It can kill you before you even know what's wrong."

Adds Ed Herrold, "If we hadn't had Xigris, my wife would be dead. We are truly grateful for this miracle drug."

### Searching for answers

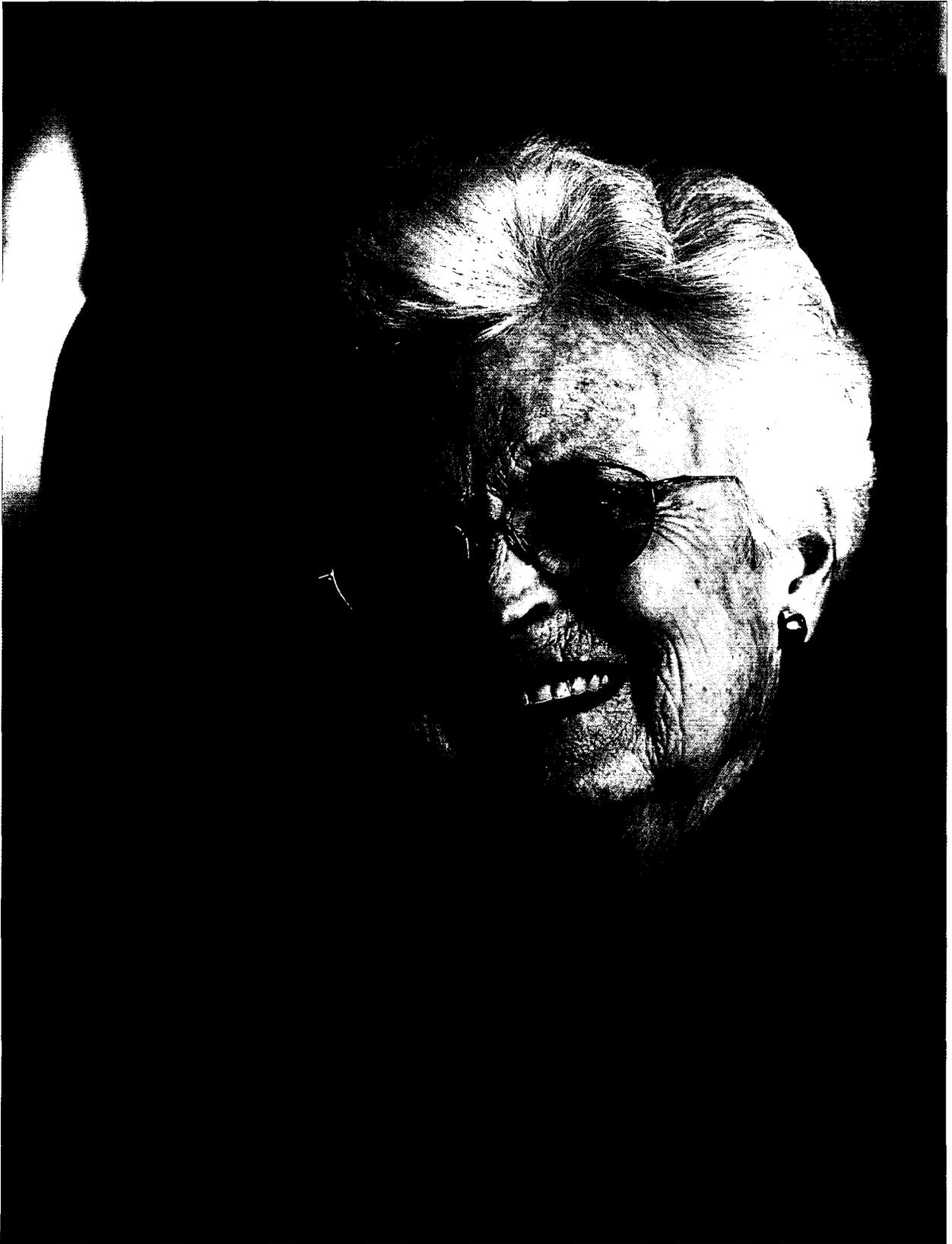
The team of scientists that discovered Xigris now closely follows such stories of patients' recoveries. In the first months after the drug's launch, they heard how Xigris helped save dozens of lives, including patients in Kentucky, Michigan, Texas, and Puerto Rico.

Countless more patients will have an increased chance for survival as Xigris is targeted for launches later this year in Australia, Canada, and the European Union.

"It's hard to put into words how it feels to have such a large impact on a devastating disease," Grinnell says. "In the face of difficult problems, we took risks and never stopped searching for answers."

For Yan, Grinnell, and their team, patients like Juanne Herrold spur them to keep hunting for the next lifesaving drug. "Every one of these cases is extremely motivating to us," Yan says. "They keep us going. They are what Lilly research is all about."

*Martha Jordan has suffered four fractures in her spine but says she won't become "a prisoner in my own home." She swims, cooks, cares for her family, and still does the grocery shopping, adding, "I just hang onto the cart."*



# Fortéo

Osteoporosis and broken bones can destroy the golden years, leaving senior citizens debilitated and in pain. A promising treatment called Fortéo may offer new hope.

Masahiko Sato, Ph.D., had good reasons to spend six years searching for an answer to severe osteoporosis.

His mother in Japan and mother-in-law in America both suffer from the disease. So do some aged friends at his church. "As we worked," he says, "they have all been on my mind."

The innovative result of his team's efforts—a novel treatment called Fortéo—promises to offer relief to patients suffering the loss of bone. Fortéo currently is awaiting marketing approval from the U.S. Food and Drug Administration. While other osteoporosis therapies only slow or stop bone loss, Fortéo would be the first and only drug that stimulates the formation of healthy, new bone.

Photographs perhaps tell the story best. Images on Sato's computer screen (at right) show a bit of animal hip bone with and without treatment with Fortéo. The "with" slide (on the left) reveals a significant increase in bone density and, consequently, in bone strength.

## Living with pain

Osteoporosis is a fast-growing health threat. In the U.S. alone, women and men suffer more than 1.5 million osteoporotic fractures each year. Too often, fractures due to osteoporosis force the elderly to end their days in bed and in pain.

Martha Jordan (at left) is determined to avoid that fate. The 81-year-old Indianapolis grandmother swims and cooks up pots of soup. But the pain is always there; her bones are so fragile that she has suffered four fractures in her spine.

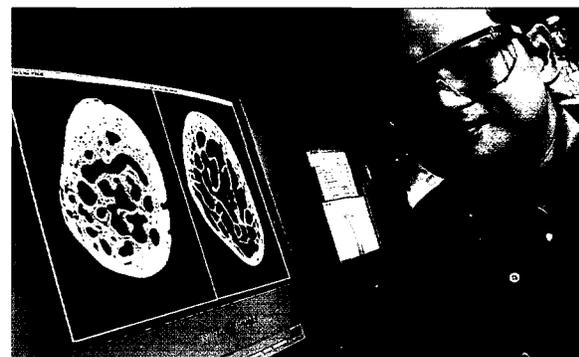
Because of those fractures, she says, "It hurts just to be up on my feet." Looking out the window at her lovely neighborhood, she adds, "My wish is that I would be able to walk around the block again."

Recently, her doctor told her about the potential future availability of Fortéo, which has been shown to significantly reduce the risk of spinal and nonspinal fractures. She is eager to see if it can help her.

## 'Time and care'

Bringing a first-in-class drug to market is never easy. After years of

work on Fortéo, Lilly voluntarily suspended clinical trials in 1998 after discovering that laboratory rats given the drug for most of their lives developed bone tumors. The drug's label is expected to include a warning noting that finding, and other measures will be recommended to ensure proper use of the product.



No tumors have been found in human clinical trial patients. And an assessment by leading external researchers concluded that the finding in rats was not likely to predict a risk for humans.

For Sato, the development process is a "roller coaster ride." But he adds that, when a drug like Fortéo has the potential to improve lives, that's the payoff. "It's worth it to take extraordinary time and care."

# Cialis

Millions of men worldwide who suffer from erectile dysfunction may soon have an important new treatment choice. It's called Cialis and it's the result of an innovative partnership.

Most men are reluctant to talk about erectile dysfunction—but not Rob Rozman. The 58-year-old retired high school math teacher in London, Ontario, isn't shy about these things. He believes in education and public discourse.

Five years ago, Rozman (at right) underwent radical prostate cancer surgery, which impaired his ability to have sexual relations with his wife, Kathie. "At first, we were worried about life-and-death issues," he says. "You feel silly asking anything else. But later, we turned to how this would affect our romantic life."

He says erectile dysfunction can destroy a man's confidence and damage relationships. That's why he goes out of his way to counsel others. Discussing the problem, which he does with 10 other prostate cancer survivors as part of a support group, provides insight.

"It's such a hush-hush subject, but if I mention it, all of a sudden others will talk about it, too," he says. "We all just need a little push."

## Promising new choice

Worldwide, at least 150 million men suffer from erectile dysfunction. Most are embarrassed to talk about the ailment, even with their doctors.

Cialis, a collaborative effort of Lilly and ICOS Corporation, of Bothell, Washington, could offer men a new option. In clinical trials, Cialis had a statistically significant effect even at 24 hours after dosing. In addition, up to 81 percent of patients treated in trials reported improved erections.

"Patients need more than one option—not every drug works for everyone," says Harin Padmanathan, M.D., a noted urologist

who cares for patients at a clinic in Beverly Hills, California. "This is a patient-driven area and some patients want and need a longer acting drug." Cialis currently is under review by U.S. and European regulatory agencies.

## Alliance that works

Cialis is an innovative product for Lilly. Our alliance with ICOS, the biotechnology firm that developed the drug, is unique; the companies have created a global team with physicians and scientists not only in Indiana and Washington but also in England, Spain, and Canada.

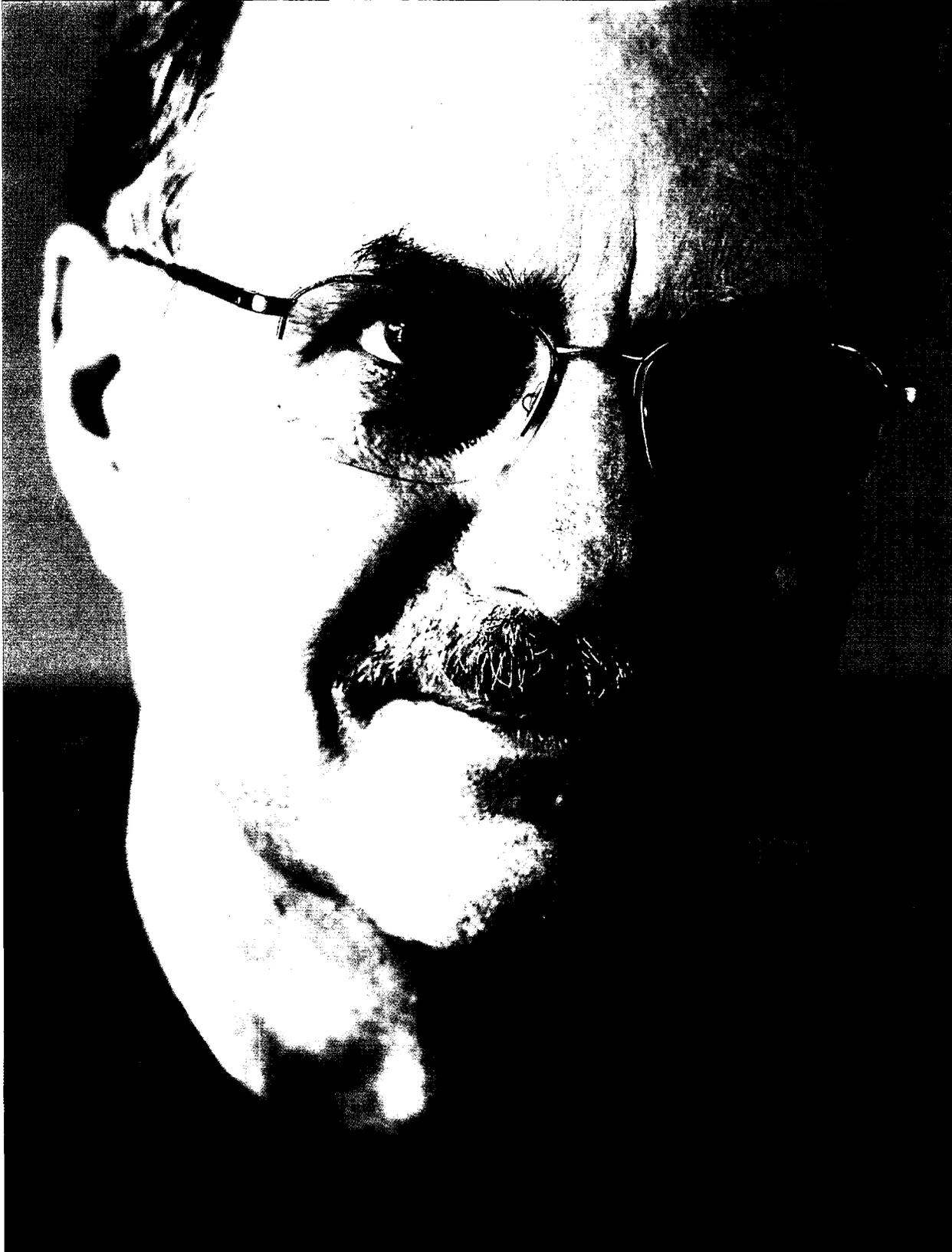
"Though we have two companies doing business across many time zones, this has been an amazingly effective alliance," says ICOS's Ken Ferguson, Ph.D. (at left), the team's chief scientific officer and chief operating officer. Rather than "slowing things down," he says, the alliance has meant a faster timetable for the drug's development.

Yet another fresh idea now is being implemented by the team: an Internet-based clinical trial. In this study, men can try Cialis and record its effectiveness in the privacy of their homes.

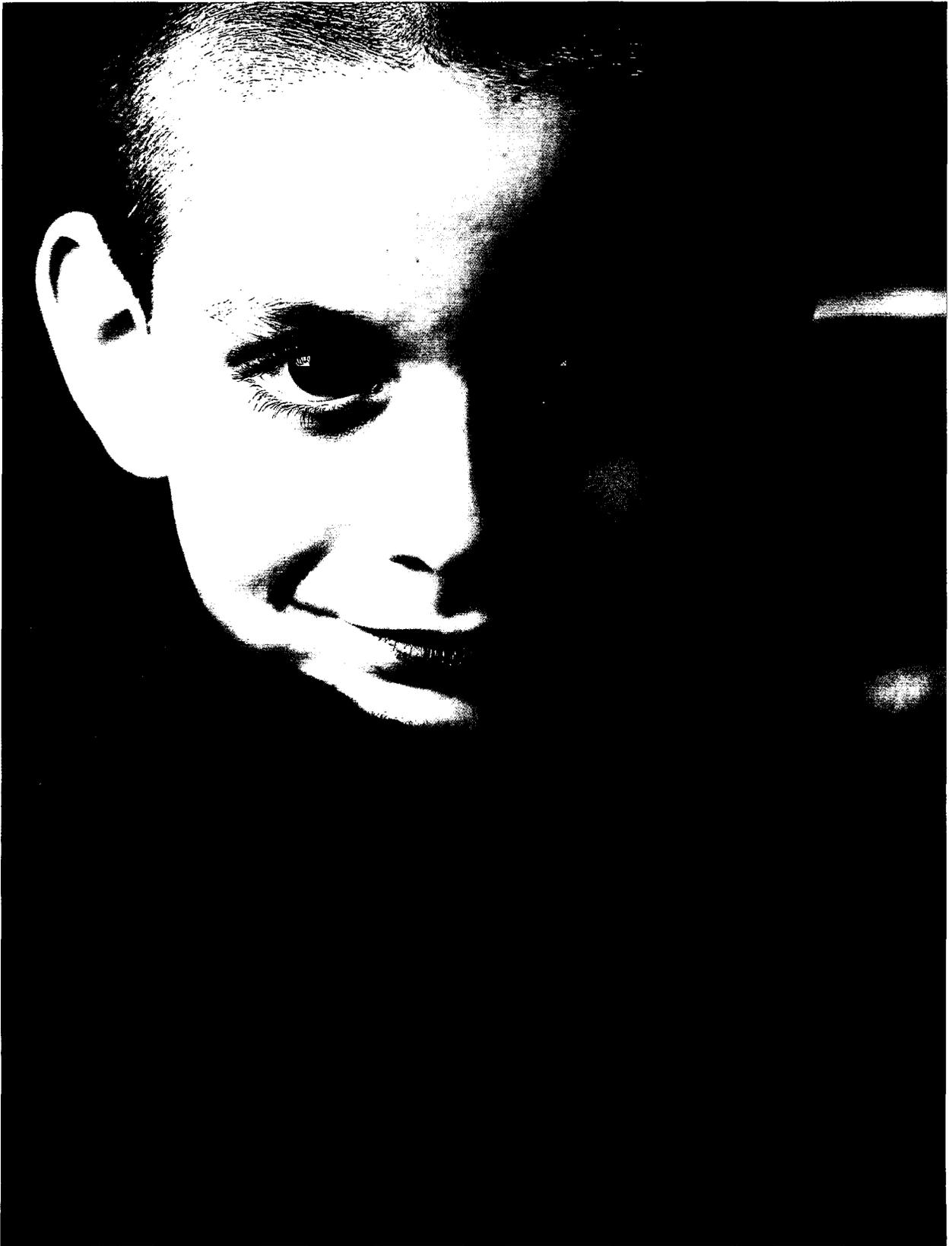


Rozman talked to his doctor and enrolled in a clinical trial for Cialis. He says there is an urgent need for more treatment choices for men with his condition. "Most of us suffer in silence," he says. "But we do need help."

*Despite having battled prostate cancer and erectile dysfunction, Rob Rozman says he is a lucky man. He has the love of a beautiful wife and doting children and the friendship of a group of cancer survivors who meet regularly to support and inspire one another.*



*Attention problems don't keep 10-year-old Michael from his favorite activities—movies, dining out on steak dinners, and, most of all, sports. He especially loves basketball, baseball, football, and swimming. In his spare time, he plans for the future: "I want to be a lawyer when I grow up."*



# Atomoxetine

For parents worried about children with attention-deficit hyperactivity disorder, we are working on a promising compound called atomoxetine. The best news is: It's not a stimulant.

Michael is only 10 years old. So he doesn't much care that atomoxetine, if approved for use, would be the first nonstimulant to treat attention-deficit hyperactivity disorder.

What he does care about is being able to pay attention at school, make friends easily, and struggle less with his homework. That frees him up for the important things in his life, like family, football, and Harry Potter books. "I'm a pretty busy kid," he says, grinning.

Michael (at left) has a mild form of ADHD. For the past three years, he has taken part in a clinical trial for atomoxetine through Riley Hospital for Children near his Indianapolis home. His mother, Kay, called the hospital early on after noticing that her young son was easily distracted.

She says Michael, for instance, would ask for a cookie and then a few minutes later forget that he wanted one. Now that he's in fourth grade, Michael has even more to remember: in the mornings, he needs to get dressed, pack his lunch, collect his gym clothes, and organize his homework.

"That is a lot for him," says his mother. "Like all parents, I don't want to medicate my son if he doesn't need it. But we do want to help him in a safe, responsible way."

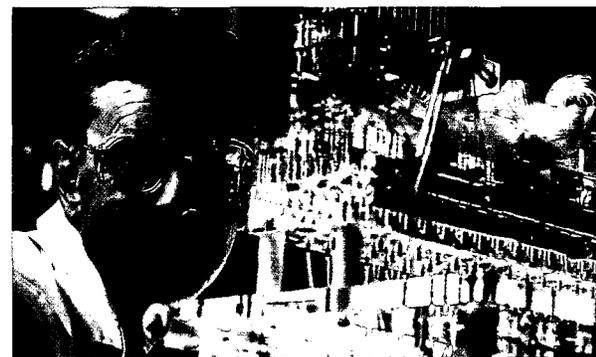
## New class of drugs

ADHD is one of the most common chronic childhood conditions, affecting 3 to 7 percent of school-age children. In clinical studies so far, atomoxetine has significantly reduced symptoms such as severe attention problems and hyperactivity in children and adolescents.

Importantly, atomoxetine is not a stimulant. In fact, it is the first of a new class of drugs and the first new treatment for this disorder in 30 years. It works by acting on norepinephrine, a neurotransmitter that helps modulate brain activity controlling attention and behavior. Many ADHD children go untreated because parents want to avoid stimulants.

Atomoxetine also appears, in clinical trials, to be long-acting. So, if the U.S. Food and Drug Administration agrees, children may be able to take a pill in the morning and avoid the stigma of going to the school nurse at lunchtime for a second dose.

"We are proud of this compound," says Frank Bymaster, (below) a senior research scientist who played a critical role in developing atomoxetine and also Prozac. "This has the potential to help a lot of children."



## Potential help for grownups

Many adults suffer, too. Atomoxetine is the first medication extensively researched for adults with ADHD. These men and women can have trouble holding jobs and sustaining relationships. Up to 60 percent of school-age children who suffer from this disorder struggle with symptoms into adulthood.

That possibility is a long way off for Michael. But his mother says that, as long as he needs help, he'll get it. She adds, "His well-being will always be important to us."

# Duloxetine

Prozac revolutionized the treatment of depression and helped millions of people live better lives. Its successor, duloxetine, could set a new standard for antidepressant care.

John Brown wakes up every day “in a gray fog.” His depression is so severe that he dreads leaving his home in Austin, Texas. Trips to the grocery store are “pure torture.”



“It’s terrible to feel as bad as I do as often as I do,” says Brown, who has suffered depression, anxiety, and accompanying headaches and back pain since childhood. Over the years, he has tried many drugs with limited or no success.

But the 40-year-old artist (at right) isn’t giving up. Brown says he wants to feel “more human.” He wants to sleep soundly, gain more confidence, socialize more, and go to work every day.

He says he has come to realize that depression is a disease that can be treated. “A lot of people still see it

as a personal weakness or character defect. But it is not.”

With the right medication, he says, “I won’t get a new wardrobe or become a millionaire. But I do want to feel better. Lord knows, I wrestle with this every day.”

## A reason to hope

Duloxetine for depression has been submitted for approval to the U.S. Food and Drug Administration—and, for many, that is reason to hope.

The World Health Organization estimates that more than 120 million people suffer from depression. Current therapies offer relief to only two in three patients. Clinical trial data indicate that duloxetine appears to offer advantages over existing therapies, particularly in improving mood and associated physical symptoms.

New treatments like duloxetine are needed, says William Privitera, M.D., who saw its results as an investigator for several Lilly clinical trials. “In my opinion, it really is an advancement,” he says.

## Pain and depression

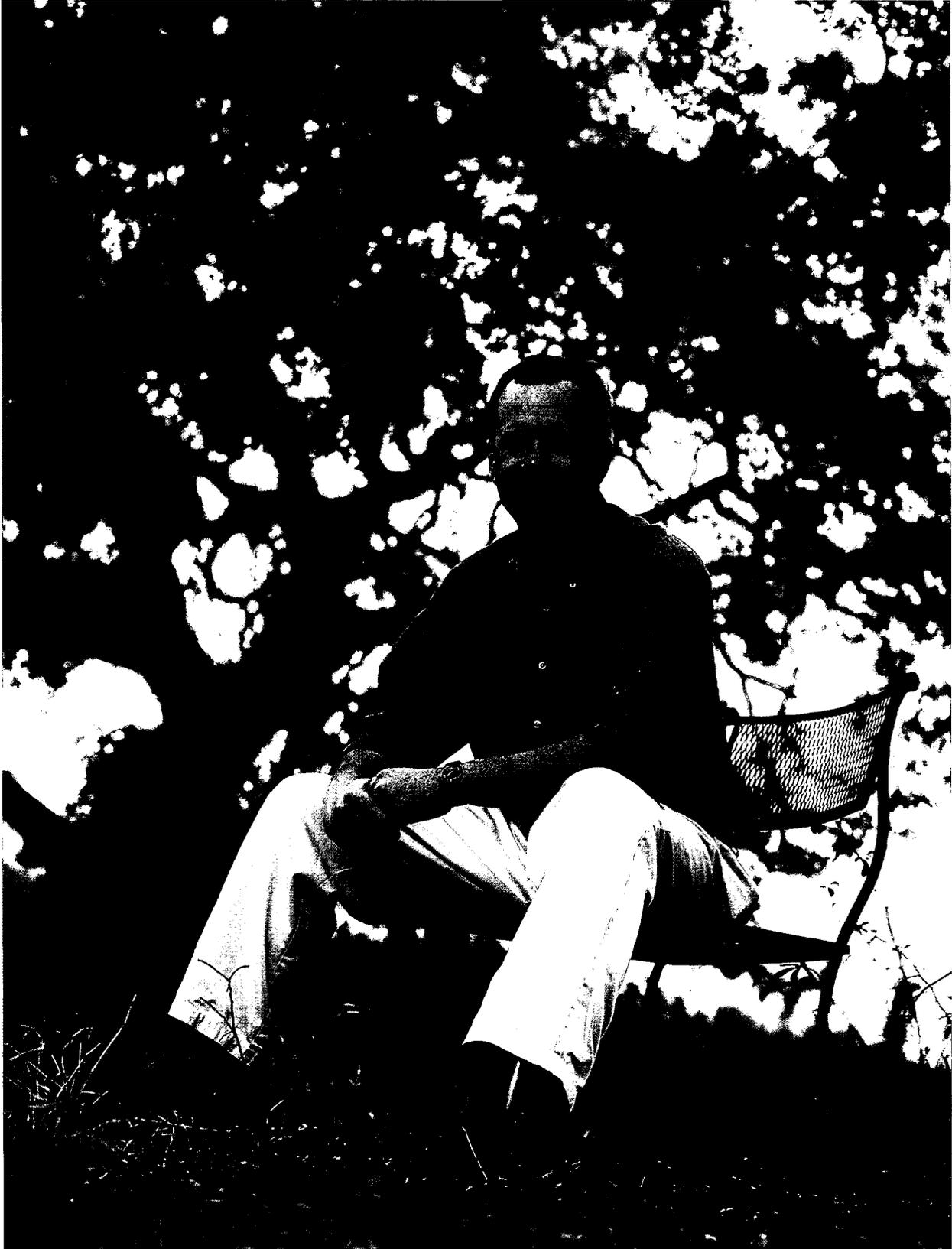
Studies show patients taking duloxetine had very high response and remission rates. Why? Scientists believe it works by elevating two key brain chemicals that affect emotional and physical symptoms. And, clinical trials indicate, it appears to combat not only depression but also painful physical symptoms that often go with it.

Just as Prozac forever changed the way depression is treated, its successor, duloxetine, may be the next important step in treating this disease.

“Prozac brought depression out of the closet. Now, with duloxetine, we are hoping to bring the treatment of depression to a new level by treating both depressed mood and painful physical symptoms associated with depression,” says Smriti Iyengar, Ph.D. (at left), a senior research scientist.

Iyengar led a team investigating duloxetine’s potential in treating chronic pain. Pain and depression, she says, share circuitry in the brain. Duloxetine’s efficacy to treat pain associated with depression now is being tested in clinical trials.

*Artist John Brown relaxes in the shade of a giant oak tree in his backyard. Though Brown has suffered from depression since he was a child, he tries to keep his spirits up. "There are so many people who suffer worse than I do."*



**Beyond 2002: Tomorrow's Promise** Is there hope for victims of a rare and deadly lung cancer? How do we combat the most stubborn forms of depression? What can be done about stress urinary incontinence and genital herpes? Read on.

### **Alimta for cancer**

Alimta shows promise against a variety of deadly cancers. With its ability to block three enzymes that speed cell replication, it may be possible to disrupt and even prevent the growth of cancer cells. Our first target likely will be mesothelioma, a cancer of the lining of the lung often associated with asbestos exposure. Alimta also has shown promise in breast, non-small-cell lung, pancreatic, colon, and gastric cancers.

### **Duloxetine for stress urinary incontinence**

We're testing duloxetine not only for depression but also for stress urinary incontinence. In the U.S. alone, 16 million women struggle with stress urinary incontinence. Sufferers experience accidental loss or leakage of urine as pressure on their bladder increases—such as when they cough, sneeze, laugh, or exercise. This can lead to embarrassment and even social isolation. Current treatment options include pelvic muscle exercises, absorbent pads, and surgery.

### **Protein Kinase C beta (PKC $\beta$ ) for diabetic retinopathy and diabetic macular edema**

Our inhibitor of the PKC beta enzyme may counteract the destructive effects of high blood sugar and slow the progression of two serious eye complications related to diabetes. Diabetic retinopathy, a disease of the retina's blood vessels, and diabetic macular edema, a swelling near the retina, can both lead to blindness. *Worldwide, about 2.5 million people are blind due to complications of diabetes.*

### **OFC (olanzapine-fluoxetine combination) for treatment-resistant depression**

This potent combination of Zyprexa and Prozac would combat a stubborn form of depression. About 20 percent of patients with major depression fail to respond to conventional treatments. Treatment-resistant depression causes untold human suffering and economic costs. Early data suggest that OFC relieves depressive and psychotic symptoms and also shows efficacy in bipolar depression.

### **LY900003 (formerly ISIS 3521) for non-small-cell lung cancer**

This molecule could represent a new and innovative approach to the treatment of non-small-cell lung cancer and other solid tumors. We are studying LY900003 in combination with Gemzar and cisplatin and in combination with Taxol<sup>®</sup> and carboplatin, two of the most common regimens used against non-small-cell lung cancer. Lilly licensed LY900003 from California-based Isis Pharmaceuticals and formed an alliance with the firm to collaborate on the discovery of antisense drugs.

### **Resiquimod for genital herpes**

Resiquimod is a potential treatment for genital herpes, a sexually transmitted disease that is increasingly pervasive. Those infected with the virus can suffer painful genital blisters and sores, as well as devastating social consequences. Data from early trials suggest that topical treatment of herpes outbreaks with resiquimod may increase the time between subsequent outbreaks. Resiquimod was licensed from and is being developed with Minnesota-based 3M Pharmaceuticals.

# Review of Operations

## Operating Results—2001

### Summary

Net income was \$2.78 billion, or \$2.55 per share, in 2001 and \$3.06 billion, or \$2.79 per share, in 2000. Comparisons between 2001 and 2000 are made difficult by the impact of several unusual items that are reflected in the company's operating results for both years. Excluding these unusual items, which are discussed further below, net income for 2001 and 2000 would have been \$3.01 billion, or \$2.76 per share, and \$2.90 billion, or \$2.65 per share, respectively. This represents an increase in net income and earnings per share of 4 percent. The 2001 increases are attributed to growth in sales, offset, in part, by operating expenses (as defined below) increasing at a rate greater than sales growth.

### Unusual Items

As noted above, several unusual items are reflected in the company's operating results for 2001 and 2000. These transactions are summarized as follows (see Notes 3, 4, and 7 to the consolidated financial statements for additional information).

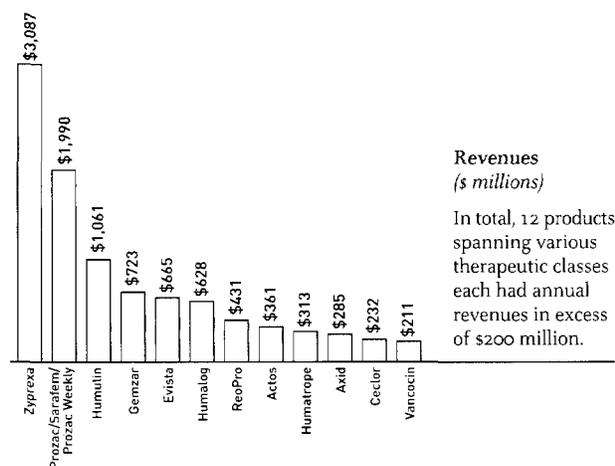
#### 2001

- Pretax charges of \$190.5 million for acquired in-process research and development related to collaboration arrangements with Isis Pharmaceuticals, Inc. (Isis); Minnesota Mining and Manufacturing Company (3M); and Bioprojet, Société Civile de Recherche (Bioprojet), in the third and fourth quarters of 2001, which decreased earnings per share by approximately \$.05 in the third quarter and \$.06 in the fourth quarter of 2001
- Pretax charges of \$121.4 million associated with asset impairments and other site charges in the third quarter of 2001 due to actions taken as a result of the recent assessment of the company's worldwide manufacturing capacity, which decreased earnings per share by approximately \$.07 in the third quarter of 2001
- An extraordinary charge of \$45.2 million (\$29.4 million net of income taxes) from the repurchase of higher interest rate debt in the third and fourth quarters of 2001, which decreased earnings per share by approximately \$.02 in the third quarter and \$.01 in the fourth quarter of 2001

#### 2000

- A gain of \$214.4 million on the sale of the company's interest in Kinetra LLC to WebMD Corporation (WebMD) and the subsequent sale of WebMD stock, which increased earnings per share

- by approximately \$.20 in the first quarter of 2000
- Approximately \$91 million in additional product sales in 1999 as a result of year-2000-related wholesaler buying that normally would have been realized during the first quarter of 2000, which increased earnings per share by approximately \$.06 in the fourth quarter of 1999 and reduced earnings per share by the same amount in the first quarter of 2000



### Sales

The company's reported worldwide sales for 2001 increased 6 percent, to \$11.54 billion. Worldwide sales for 1999 included approximately \$91 million of sales relating to year-2000 wholesaler buying that normally would have been recognized in 2000. Adjusting for the impact of year-2000 wholesaler buying, sales growth for 2001 would have been 5 percent. Sales growth was led by Zyprexa, a treatment for schizophrenia and related psychoses; diabetes and related products; Gemzar, an oncolytic product; and Evista, an osteoporosis treatment and prevention agent. Sales in the U.S. increased 5 percent, to \$7.36 billion. Sales outside the U.S. increased 8 percent, to \$4.18 billion. Both worldwide and U.S. sales growth was offset, in part, by decreased sales of Prozac, an antidepressant, and anti-infectives. The decrease in Prozac sales was primarily due to the entrance of generic fluoxetine in the U.S. market in early August 2001. Excluding Prozac, the company's worldwide and U.S. sales increased 17 percent and 22 percent, respectively. Worldwide sales reflected volume growth of 8 percent and a 1 percent increase in global selling prices, partially offset by a 2 percent decrease in exchange rates. (Percentages do not add due to rounding.)

Zyprexa had worldwide sales of \$3.09 billion in 2001, representing an increase of 31 percent. Sales

in the U.S. increased 29 percent, to \$2.18 billion. Zyprexa's sales continued to experience strong growth in the face of an additional competitive product in the U.S. Sales outside the U.S. increased 38 percent, to \$910.5 million, benefiting, in part, from the launch of Zyprexa in Japan during the second quarter of 2001.

Diabetes care products, composed primarily of Humulin<sup>®</sup>, the company's biosynthetic human insulin; Humalog, the company's insulin analog; and Actos, an oral agent for the treatment of type 2 diabetes, had worldwide revenues of \$2.13 billion in 2001, representing an increase of 21 percent. Diabetes care revenues in the U.S. increased 27 percent, to \$1.37 billion. Diabetes care revenues outside the U.S. increased 12 percent, to \$764.8 million. Humulin had worldwide sales of \$1.06 billion, representing a decrease of 5 percent due to the continued shift by patients to Humalog and Humalog mixture products and to increased competition. Humulin sales in the U.S. decreased 6 percent, to \$578.5 million. Humulin sales outside the U.S. decreased 3 percent, to \$482.2 million. Humalog had worldwide sales of \$627.8 million, representing an increase of 79 percent. The company received service revenues of \$360.6 million in 2001, an increase of 62 percent, relating to sales of Actos. Actos is manufactured and sold in the U.S. by Takeda Chemical Industries, Ltd., and is copromoted by Takeda and the company.

Prozac, Prozac Weekly, and Sarafem<sup>™</sup>, a treatment for premenstrual dysphoric disorder (collectively "fluoxetine product(s)") had combined worldwide sales of \$1.99 billion, representing a decrease of 23 percent. This full-year result included a 66 percent decline in the fourth quarter of 2001. Fluoxetine product sales in the U.S. decreased 26 percent, to \$1.66 billion, primarily due to generic competition for Prozac beginning in early August 2001. Fluoxetine product sales outside the U.S. decreased 3 percent, to \$330.1 million, primarily due to continuing generic competition. For additional information on the expected financial impact of generic competition, see the "Financial Expectations for 2002 and 2003" section.

Gemzar had worldwide sales of \$722.9 million in 2001, representing an increase of 29 percent. Sales in the U.S. increased 32 percent, to \$417.4 million. Sales outside the U.S. increased 26 percent, to \$305.5 million.

Evista had worldwide sales of \$664.8 million in 2001, representing an increase of 27 percent. Sales in the U.S. increased 21 percent, to \$526.1 million. U.S. sales growth slowed in the second half of the year primarily due to increased competition. Sales outside the U.S. increased 58 percent, to \$138.7 million, primarily due to the launch of Evista as a treatment for postmenopausal osteoporosis in a

number of European countries during the second quarter of 2000.

ReoPro<sup>®</sup> had worldwide sales of \$431.4 million in 2001, representing an increase of 3 percent. Sales in the U.S. decreased 1 percent, to \$312.3 million, due to continued competition. Sales outside the U.S. increased 16 percent, to \$119.1 million.

At the end of November 2001, the company received approval from the U.S. Food and Drug Administration (FDA) and launched Xigris, a treatment for adult severe sepsis patients at high risk of death. Initial Xigris sales were \$21.2 million in 2001.

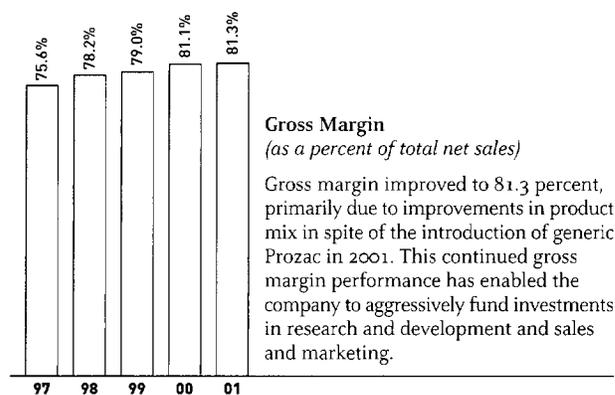
Anti-infectives had worldwide sales of \$749.5 million in 2001, representing a decrease of 16 percent, due to continuing competitive pressures. Cefaclor and Keflex<sup>®</sup> accounted for the majority of the decline. Sales in the U.S. of anti-infectives decreased 32 percent, to \$128.9 million. Sales outside the U.S. decreased 12 percent, to \$620.6 million.

Animal health products had worldwide sales of \$686.1 million in 2001, representing an increase of 3 percent. Sales in the U.S. increased 5 percent, to \$323.2 million. Sales outside the U.S. remained flat at \$362.9 million.

The company's payments under federally mandated Medicaid rebate programs reduced 2001 sales by approximately \$475.0 million compared with approximately \$464.0 million in 2000.

### Gross Margin, Costs, and Expenses

The 2001 gross margin improved to 81.3 percent of sales compared with 81.1 percent for 2000. This



increase was attributed primarily to favorable changes in product mix due to growth in sales of higher margin products, such as Zyprexa, Gemzar, Evista, and diabetes care products. The decline in sales of Prozac, also a higher margin product, partially offset these gross margin increases.

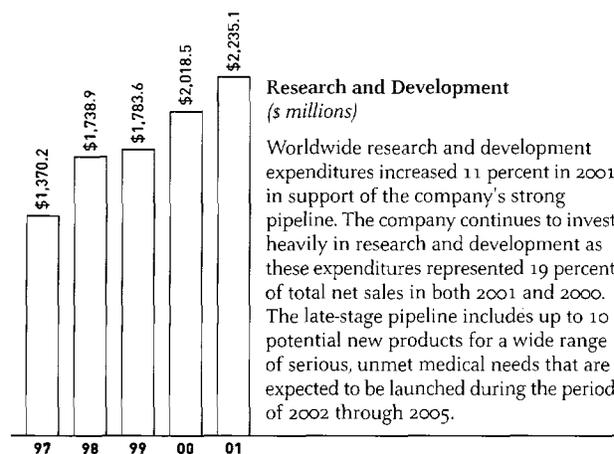
Operating expenses (the aggregate of research and development and marketing and administrative expenses) increased 8 percent in 2001. Investment in research and development expenses increased

# Consolidated Statements of Income

Eli Lilly and Company and Subsidiaries		Year Ended December 31		
(Dollars in millions, except per-share data)		2001	2000	1999
Net sales		\$11,542.5	\$10,862.2	\$10,002.9
Cost of sales		2,160.2	2,055.7	2,098.0
Research and development		2,235.1	2,018.5	1,783.6
Marketing and administrative		3,417.4	3,228.3	2,757.6
Acquired in-process research and development (Note 3)		190.5	—	—
Asset impairment and other site charges (Note 4)		121.4	—	87.4
Interest expense		146.5	182.3	183.8
Other income—net		(280.7)	(481.3)	(152.9)
		<u>7,990.4</u>	<u>7,003.5</u>	<u>6,757.5</u>
Income from continuing operations before income taxes and extraordinary item		3,552.1	3,858.7	3,245.4
Income taxes (Note 11)		<u>742.7</u>	<u>800.9</u>	<u>698.7</u>
Income from continuing operations before extraordinary item		2,809.4	3,057.8	2,546.7
Income from discontinued operations, net of tax (Note 5)		—	—	174.3
Extraordinary item, net of tax (Note 7)		<u>(29.4)</u>	<u>—</u>	<u>—</u>
Net income		<u>\$ 2,780.0</u>	<u>\$ 3,057.8</u>	<u>\$ 2,721.0</u>
Earnings per share—basic (Note 10)				
Income from continuing operations before extraordinary item		\$ 2.61	\$ 2.83	\$ 2.34
Income from discontinued operations		—	—	.16
Extraordinary item		<u>(.03)</u>	<u>—</u>	<u>—</u>
Net income		<u>\$ 2.58</u>	<u>\$ 2.83</u>	<u>\$ 2.50</u>
Earnings per share—diluted (Note 10)				
Income from continuing operations before extraordinary item		\$ 2.58	\$ 2.79	\$ 2.30
Income from discontinued operations		—	—	.16
Extraordinary item		<u>(.03)</u>	<u>—</u>	<u>—</u>
Net income		<u>\$ 2.55</u>	<u>\$ 2.79</u>	<u>\$ 2.46</u>

See notes to consolidated financial statements.

11 percent, to \$2.24 billion, as the company continued to invest in its promising product pipeline. Marketing and administrative expenses increased 6 percent. Expansion of the worldwide sales force and increased marketing efforts in support of the company's growth products and upcoming product launches offset a slight decline in administrative expenses. The growth rates of both research and development expenses and marketing and administrative expenses were diminished by reduced incentive compensation expenses resulting from lower growth in earnings.



Research and Development (\$ millions)

Worldwide research and development expenditures increased 11 percent in 2001 in support of the company's strong pipeline. The company continues to invest heavily in research and development as these expenditures represented 19 percent of total net sales in both 2001 and 2000. The late-stage pipeline includes up to 10 potential new products for a wide range of serious, unmet medical needs that are expected to be launched during the period of 2002 through 2005.

During 2001, the company recorded \$190.5 million for acquired in-process research and development charges related to collaboration arrangements with Isis, 3M, and Bioprojet. The compounds acquired in these collaboration agreements are in the development phase and no alternative future uses were identified.

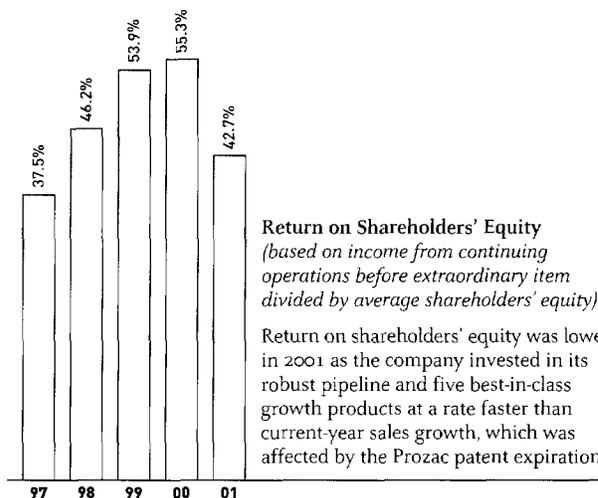
Net other income for 2001 was \$280.7 million, an increase of \$12.8 million, excluding the gain on the sale of Kinetra LLC in 2000. The increase was primarily due to an increase in interest income.

The company's effective tax rate for 2001 was 20.9 percent compared with 20.8 percent for 2000. Excluding the unusual items discussed previously, the effective tax rate was 22.0 percent for both years. See Note 11 to the consolidated financial statements for additional information.

## Operating Results—2000

### Summary

Net income was \$3.06 billion, or \$2.79 per share, in 2000 and \$2.72 billion, or \$2.46 per share, in 1999. Comparisons between 2000 and 1999 are made difficult by the impact of several unusual items that are reflected in the company's operating results for both years. Excluding these unusual items, which are discussed further below, net income for 2000 and 1999 would have been \$2.90 billion, or \$2.65 per



Return on Shareholders' Equity (based on income from continuing operations before extraordinary items divided by average shareholders' equity)

Return on shareholders' equity was lower in 2001 as the company invested in its robust pipeline and five best-in-class growth products at a rate faster than current-year sales growth, which was affected by the Prozac patent expiration.

share, and \$2.52 billion, or \$2.28 per share, respectively. This represents an increase in net income and earnings per share of 15 percent and 16 percent, respectively. The 2000 increases are attributed to growth in sales, improved gross margin, and increased interest income, offset by increases in operating expenses at a rate greater than sales growth. Earnings per share also benefited from a decrease in the number of shares outstanding as a result of the share repurchase plan.

### Unusual Items

As noted above, several unusual items are reflected in the company's operating results for 2000 and 1999. The unusual items relating to 2000 are summarized under "Operating Results—2001." The 1999 unusual items are summarized as follows (see Notes 3, 4, 5, and 13 to the consolidated financial statements for additional information).

- A pretax gain of \$110.0 million in settlement of litigation with Biochimica Opos S.p.A., which increased earnings per share by approximately \$.06 in the fourth quarter of 1999
- A pretax charge of \$26.0 million associated with the decommissioning of manufacturing facilities and other site charges, which decreased earnings per share by approximately \$.02 in the fourth quarter of 1999
- A pretax gain of \$67.8 million on the sale of U.S. and Puerto Rican Lorabid® marketing rights, which increased earnings per share by approximately \$.05 in the third quarter of 1999
- A pretax gain of \$165.6 million (\$174.3 million net of an income tax benefit) on the sale of PCS, the company's health-care-management subsidiary, which increased earnings per share by approximately \$.16 in the first quarter of 1999
- A pretax charge of \$150.0 million as the result of a contribution to Eli Lilly and Company Foundation, which decreased earnings per share by approximately \$.09 in the first quarter of 1999

- A pretax charge of \$61.4 million associated with the impairment of certain manufacturing assets, which decreased earnings per share by approximately \$.04 in the first quarter of 1999

## Sales

The company's reported worldwide sales for 2000 increased 9 percent, to \$10.86 billion. Worldwide sales for 1999 included approximately \$91 million of sales relating to year-2000 wholesaler buying that normally would have been recognized in 2000. Adjusting for the impact of year-2000 wholesaler buying, sales growth for 2000 would have been 10 percent. Sales growth was led by Zyprexa, diabetes care products, Evista, and Gemzar. Sales in the U.S. increased 12 percent, to \$7.00 billion. Sales outside the U.S. increased 2 percent, to \$3.86 billion. Worldwide sales reflected volume growth of 11 percent, partially offset by a 2 percent decrease in exchange rates while prices remained flat.

Fluoxetine products had combined worldwide sales of \$2.57 billion, representing a decrease of 2 percent. Sales in the U.S. increased 7 percent, to \$2.23 billion. The U.S. sales comparison benefited, in part, from wholesaler inventory reductions in 1999. Fluoxetine product sales outside the U.S. decreased 35 percent, to \$341.0 million, primarily due to continuing generic competition in the U.K.

Zyprexa had worldwide sales of \$2.35 billion in 2000, representing an increase of 25 percent. Sales in the U.S. increased 23 percent, to \$1.69 billion. Sales in 2000 benefited from the FDA approval of Zyprexa for the treatment of acute mania associated with bipolar disorder in the first quarter of 2000. Sales outside the U.S. increased 28 percent, to \$659.3 million.

Diabetes care products, composed primarily of Humulin, Humalog, and Actos, had worldwide revenues of \$1.76 billion in 2000, representing an increase of 22 percent. Diabetes care revenues in the U.S. increased 21 percent, to \$1.08 billion. Diabetes care revenues outside the U.S. increased 22 percent, to \$685.8 million. Humulin had worldwide sales of \$1.11 billion, representing an increase of 2 percent. Humulin sales in the U.S. decreased 6 percent, to \$617.4 million, largely as a result of patients shifting to Humalog and Humalog mixture products. Humulin sales outside the U.S. increased 15 percent, to \$497.0 million. Humalog had worldwide sales of \$350.2 million, representing an increase of 56 percent. Sales of Humalog benefited from the U.S. launch of Humalog Mix75/25™ Pen in the first quarter of 2000. The company received service revenues of \$223.0 million in 2000 relating to sales of Actos.

Gemzar had worldwide sales of \$559.3 million in 2000, representing an increase of 23 percent. Sales in the U.S. increased 20 percent, to \$315.9 million.

Sales outside the U.S. increased 27 percent, to \$243.3 million.

Evista had worldwide sales of \$521.5 million in 2000, representing an increase of 60 percent. Sales in the U.S. increased 52 percent, to \$433.8 million. Increases in sales in the U.S. were due, in part, to the FDA approval of Evista for the treatment of post-menopausal osteoporosis in the U.S., which was granted in September 1999. Sales outside the U.S. increased 115 percent, to \$87.7 million.

ReoPro had worldwide sales of \$418.1 million in 2000, representing a decrease of 7 percent. Sales in the U.S. decreased 12 percent, to \$315.1 million. Sales outside the U.S. increased 15 percent, to \$102.9 million. The decline in sales was due to increased competition in the U.S.

Anti-infectives had worldwide sales of \$894.3 million in 2000, representing a decrease of 13 percent, due to continuing competitive pressures. Cefaclor and Lorabid accounted for the majority of the decline. Sales in the U.S. decreased 12 percent, to \$189.4 million. Sales outside the U.S. decreased 13 percent, to \$704.9 million.

Animal health products had worldwide sales of \$668.5 million in 2000, representing an increase of 6 percent. Sales in the U.S. increased 8 percent, to \$307.5 million. Sales outside the U.S. increased 5 percent, to \$360.9 million. The increases were balanced across the product line.

The company's payments under federally mandated Medicaid rebate programs reduced 2000 sales by approximately \$464.0 million compared with approximately \$352.5 million in 1999.

## Gross Margin, Costs, and Expenses

The 2000 gross margin improved to 81.1 percent of sales compared with 79.0 percent for 1999. This increase was attributed primarily to favorable changes in product mix due to growth in sales of newer products and, to a lesser extent, increased production volume.

Operating expenses increased 16 percent in 2000. Research and development expenses increased 13 percent, to \$2.02 billion, as the company continued to invest in both the early and late stages of its internal product pipeline and external collaborations. Marketing and administrative expenses increased 17 percent primarily due to sales force expansions and increased marketing efforts to support the company's newer products.

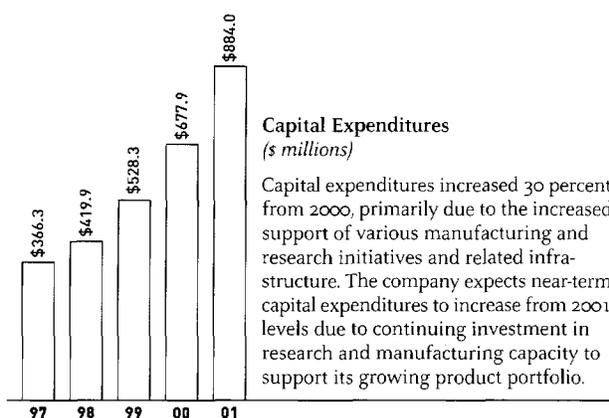
Net other income for 2000 was \$267.9 million, an increase of \$142.8 million, excluding the gain on the sale of Kinetra LLC, the gains from the litigation settlement, the sale of Lorabid marketing rights, and a charge for the contribution to Eli Lilly and Company Foundation in 1999. The increase was primarily due to an increase in interest income.

The company's effective tax rate for 2000 was 20.8 percent compared with 21.5 percent for 1999. Excluding the unusual items discussed previously, the effective tax rate for both 2000 and 1999 was 22.0 percent. See Note 11 to the consolidated financial statements for additional information.

## Financial Condition

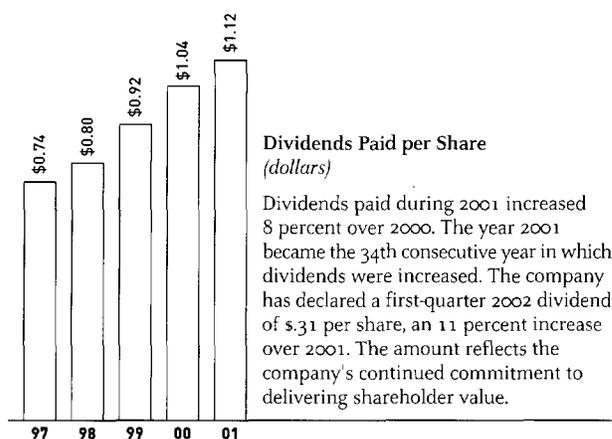
As of December 31, 2001, cash, cash equivalents, and short-term investments totaled approximately \$3.73 billion compared with \$4.62 billion at December 31, 2000. The decrease in cash was primarily due to cash generated from operations and from issuances of debt being more than offset by the purchase of investments, dividends paid, share repurchases, and capital expenditures. The company acquired approximately 7.2 million shares, for approximately \$595.8 million, during 2001 pursuant to its previously announced \$3 billion share repurchase program. The company has now completed \$1.41 billion of purchases in connection with that program.

Total debt at December 31, 2001, was \$3.42 billion, an increase of \$600.4 million, primarily due to the issuance of \$250 million of one-year resettable notes in March 2001, \$250 million of 30-year debt in May 2001, \$400 million of five-year notes in July 2001, and \$249.5 million of seven-year debt in November 2001. This issuance of debt was partially offset by the repurchase of \$401.2 million of higher interest rate debt, which resulted in an extraordinary charge of \$45.2 million (\$29.4 million net of income taxes), and additional repayment of short-term debt.



Capital expenditures of \$884.0 million during 2001 were \$206.1 million more than in 2000 as the company continued to invest in manufacturing and research and development initiatives and related infrastructure. The company expects near-term capital expenditures to increase significantly from 2001 levels.

Dividends of \$1.12 per share were paid in 2001, an increase of 8 percent from the \$1.04 per share paid in 2000. In the fourth quarter of 2001, effective



Dividends Paid per Share (dollars)

Dividends paid during 2001 increased 8 percent over 2000. The year 2001 became the 34th consecutive year in which dividends were increased. The company has declared a first-quarter 2002 dividend of \$.31 per share, an 11 percent increase over 2001. The amount reflects the company's continued commitment to delivering shareholder value.

for the first-quarter dividend in 2002, the quarterly dividend was increased to \$.31 per share (11 percent increase), resulting in an indicated annual rate for 2002 of \$1.24 per share. The year 2001 was the 117th consecutive year in which the company made dividend payments and the 34th consecutive year in which dividends have been increased.

The company believes that cash generated from operations, along with available cash and cash equivalents, will be sufficient to fund most of the company's operating needs, including debt service, share repurchases, capital expenditures, and dividends in 2002. The company will issue additional debt in 2002 to fund the remaining cash requirements. The company believes that, if necessary, amounts available through existing commercial paper programs should be adequate to fund maturities of short-term borrowings. The company's commercial paper program is also currently backed by \$2.03 billion of committed bank credit facilities. Various risks and uncertainties, including those discussed in the "Other Matters" and "Financial Expectations for 2002 and 2003" sections, may affect the company's operating results and cash generated from operations.

In the normal course of business, operations of the company are exposed to fluctuations in interest rates and currency values. These fluctuations can vary the costs of financing, investing, and operating. The company addresses a portion of these risks through a controlled program of risk management that includes the use of derivative financial instruments. The objective of controlling these risks is to limit the impact on earnings of fluctuations in interest and currency exchange rates. All derivative activities are for purposes other than trading.

The company's primary interest rate risk exposure results from changes in short-term U.S. dollar interest rates. In an effort to manage interest rate exposures, the company strives to achieve an acceptable balance between fixed and floating rate debt positions and may enter into interest rate derivatives to help maintain that balance. Based on the com-

pany's overall interest rate exposure at December 31, 2001 and 2000, including derivatives and other interest rate risk-sensitive instruments, a hypothetical 10 percent change in interest rates applied to the fair value of the instruments as of December 31, 2001 and 2000, respectively, would have no material impact on earnings, cash flows, or fair values of interest rate risk-sensitive instruments over a one-year period.

The company's foreign currency risk exposure results from fluctuating currency exchange rates, primarily the strengthening of the U.S. dollar against the Japanese yen and the euro. The company faces transactional currency exposures that arise when its foreign subsidiaries (or the company itself) enter into transactions, generally on an intercompany basis, denominated in currencies other than their local currency. The company also faces currency exposure that arises from translating the results of its global operations to the U.S. dollar at exchange rates that have fluctuated from the beginning of the period. The company uses forward contracts and purchased options to manage its foreign currency exposures. Company policy outlines the minimum and maximum hedge coverage of such exposures. Gains and losses on these derivative positions offset, in part, the impact of currency fluctuations on the existing assets, liabilities, commitments, and anticipated revenues. Considering the company's derivative financial instruments outstanding at December 31, 2001 and 2000, a hypothetical 10 percent change in exchange rates (primarily against the U.S. dollar) as of December 31, 2001 and 2000, respectively, would have no material impact on earnings, cash flows, or fair values of foreign currency rate risk-sensitive instruments over a one-year period. These calculations do not reflect the impact of the exchange gains or losses on the underlying positions that would be offset, in part, by the results of the derivative instruments.

### **Critical Accounting Policies**

To understand the company's financial statements, it is important to understand its accounting policies. In preparing the financial statements in accordance with generally accepted accounting principles (GAAP), management must often make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses, and related disclosures at the date of the financial statements and during the reporting period. Some of those judgments can be subjective and complex, and consequently actual results could differ from those estimates. For any given individual estimate or assumption made by the company, there may also be other estimates or assumptions that are reasonable; however, the company believes that given current facts and circumstances, it is unlikely that applying

any such other reasonable judgment would cause a material adverse effect on the company's consolidated results of operations, financial position, or liquidity for the periods presented in this report.

The company's most critical accounting policies include sales rebates and discounts and their impact on revenue recognition; licensing arrangements, including milestone recognition and acquired in-process research and development; product litigation liabilities; pension benefit costs; recoverability of deferred tax assets; and other contingencies.

Sales rebate and discount accruals, the largest of which relates to Medicaid rebates, are established in the same period the related sales are recorded and are included in other current liabilities. The accruals are based on estimates of the proportion of sales that will be subject to rebates and discounts. A 5 percent change in the Medicaid rebate accrual assumptions would lead to an approximate \$9 million effect on the statement of operations before income taxes [Note 1].

Licensing milestone income is recorded in other income and recognized upon the occurrence of the event requiring the milestone payment (Note 1).

Acquired in-process research and development costs are recognized at the time of acquisition if the regulatory agency has not yet approved the acquired technology or compound and there is no alternative future use. Licensing milestone expense is generally recognized when the event requiring payment of the milestone occurs (Notes 1 and 3).

Product litigation liabilities and other contingencies are based upon judgments and probabilities. Due in part to the insurance coverage currently in effect, a reasonable change in product litigation liability assumptions would not have a material effect on consolidated results of operations (Note 13).

Pension benefit costs include assumptions for the discount rate, expected return on plan assets, and the health-care-cost trend rates. See Note 12 for a discussion of these assumptions and how a change in these assumptions could affect the company's results of operations.

The company has recorded valuation allowances related to deferred tax assets primarily from net operating loss carryforwards. The company has not assumed future taxable income or tax planning strategies in the jurisdictions associated with these carryforwards. Implementation of tax planning strategies in these jurisdictions could lead to additional income recognition. If it were determined that 5 percent of these carryforwards currently reserved for could be utilized, the company would recognize approximately \$17 million additional net income (Notes 1 and 11).

### **Other Matters**

In mid-2001, Lilly ICOS LLC, a joint venture between

ICOS Corporation and the company, submitted to the FDA a New Drug Application (NDA) for Cialis to treat erectile dysfunction.

In the fourth quarter of 2001, the company filed with the FDA an NDA for the use of atomoxetine, a treatment for attention-deficit hyperactivity disorder (ADHD) in children, adolescents, and adults. If approved for use, atomoxetine would be the first nonstimulant and the first new type of medication for the treatment of ADHD in more than 30 years.

Also in the fourth quarter of 2001, the company submitted to the FDA an NDA for duloxetine for the treatment of depression. Clinical trials suggest that duloxetine's clinical profile may enable it to address a number of unmet medical needs in the antidepressant market.

On March 29, 2001, the company received an approvable letter from the FDA for Zyprexa IntraMuscular for the treatment of agitation associated with schizophrenia, bipolar mania, and dementia. Approval is contingent upon successful completion of manufacturing inspections. On October 6, 2001, the company received an approvable letter from the FDA for the use of Fortéo in postmenopausal women and men with osteoporosis. Approval is contingent upon labeling negotiations, agreement on measures to ensure appropriate use of the product, and successful completion of manufacturing inspections.

As a result of preapproval plant inspections for those two products in early 2001, the FDA informed the company of a number of observations and issued the company a warning letter regarding its adherence to current Good Manufacturing Practices (cGMP) regulations. In response, the company has been implementing comprehensive, companywide improvements in its manufacturing operations. In November 2001, following a reinspection of the manufacturing facilities for Zyprexa IntraMuscular and Fortéo, the FDA noted additional observations, primarily relating to computer system validation, manufacturing process reviews, and data handling. The company has responded to the FDA relative to these observations and has met with agency officials to discuss its plans to address the issues raised. Approval of new products, including Zyprexa IntraMuscular, Fortéo, and others in the near-term pipeline, such as Cialis, atomoxetine, and duloxetine for depression, will depend on resolution of all manufacturing issues to the agency's satisfaction. The timeline for resolution of these issues is difficult to predict. A manufacturer subject to a warning letter that fails to correct cGMP deficiencies to the agency's satisfaction could be subject to interruption of production, delays in NDA approvals, recalls, seizures, fines, and other penalties.

In the U.S., many pharmaceutical products are subject to increasing pricing pressures, which could

be significantly affected by the current national debate over Medicare reform as well as by actions by individual states to reduce pharmaceutical costs for Medicaid and other programs. Many proposals now being considered at the federal and state levels and, in some cases, implemented at the state level, may result in government agencies demanding discounts from pharmaceutical companies that may expressly or implicitly create price controls on prescription drugs. In addition, managed care organizations, institutions, and other government agencies continue to seek price discounts. International operations are also generally subject to extensive price and market regulations. As a result, it is expected that pressures on pharmaceutical pricing will continue.

### **Financial Expectations for 2002 and 2003**

As noted previously, in early August 2001, generic fluoxetine was introduced in the U.S. market. As a result, sales of Prozac have experienced a very steep decline and further declines are expected beginning in February 2002 when the number of generic sellers of fluoxetine is no longer restricted under the federal Hatch-Waxman Act of 1984. Prozac sales in the U.S. have historically represented a significant portion of the company's overall sales, accounting for approximately 20 percent in 2000. While the Prozac decline is expected to significantly affect results of operations for the 12 months following August 2001, its impact on the company's consolidated financial position or liquidity is not expected to be material due to the growth of the company's newer products, including Zyprexa, Humalog, Gemzar, Evista, Actos, and Xigris.

The company currently expects low-to-mid single-digit sales growth for 2002. Several key products are expected to contribute to this growth, including Zyprexa, Gemzar, Evista, diabetes care products, and Xigris. Growth in all these products is anticipated to more than offset the decline of Prozac sales and anti-infectives. The company also plans a number of new-product approvals, including Fortéo, Cialis, atomoxetine, and duloxetine for depression, and the introduction of a new formulation, Zyprexa IntraMuscular.

Gross margins as a percent of sales are expected to decline in 2002 approximately 1 percentage point as a result of the decline in Prozac sales. The company anticipates marketing and administrative expenses will grow at least in the mid-single digits. Research and development expenses are expected to grow in the low-single digits. Nonoperating income is expected to contribute approximately \$100 million in 2002. The effective tax rate is expected to remain at approximately 22 percent for the full year, absent unusual items.

As a result of the above, excluding any unusual items, the company anticipates earnings per share for

2002 to be in the range of \$2.70 to \$2.80. The company continues to expect a decline in earnings per share for the first half of 2002 followed by a return to earnings growth for the second half. For the first quarter of 2002, excluding unusual items, the company expects earnings per share to be in the range of \$.56 to \$.58. For 2003, the company is targeting high-teen earnings-per-share growth, excluding unusual items.

Actual results could differ materially and will depend on, among other things, the timing, number of entrants, and pricing strategies of generic fluoxetine competitors; the continuing growth of the company's other currently marketed products; developments with competitive products; the timing and scope of regulatory approvals, including the necessary FDA approvals of manufacturing operations in connection with pending NDAs; the timing and success of new-product launches; foreign exchange rates; and the impact of state, federal, and foreign government pricing and reimbursement measures. The company undertakes no duty to update these forward-looking statements.

### **Legal and Environmental Matters**

In February 2001, the company was notified that Zenith Goldline Pharmaceuticals, Inc. ("Zenith"), had submitted an *Abbreviated New Drug Application* (ANDA) under the federal Hatch-Waxman Act of 1984 seeking permission to market a generic version of Zyprexa in various dosage forms prior to the expiration of the company's U.S. patents for the product, alleging that the patents are invalid or not infringed. On April 2, 2001, the company filed suit against Zenith in federal district court in Indianapolis seeking a ruling that Zenith's challenge to the U.S. compound patent (expiring in 2011) is without merit. In May 2001, the company was notified that Dr. Reddy's Laboratories Ltd. ("Reddy") had also filed an ANDA covering two dosage forms, alleging that the patents are invalid or not infringed. On June 26, 2001, the company filed suit against Reddy in federal district court in Indianapolis seeking a ruling that Reddy's patent challenge is without merit. In January 2002, the company was notified that Reddy had supplemented its ANDA to include the remaining dosage forms. The company believes that the generic manufacturers' patent claims are without merit and expects to prevail in this litigation. However, it is not possible to predict or determine the outcome of this litigation and accordingly there can be no assurance that the company will prevail. An unfavorable outcome could have a material adverse impact on the company's consolidated results of operations, liquidity, and financial position.

Several generic manufacturers filed ANDAs for generic forms of Prozac in various dosage forms, challenging the company's patents under the Hatch-

Waxman Act. On May 30, 2001, the Court of Appeals for the Federal Circuit held that the company's 2003 method of use patent was invalid. Generic fluoxetine entered the U.S. market in early August 2001. On January 14, 2002, the U.S. Supreme Court denied a petition filed by the company seeking review of the decision, bringing the litigation to a close.

The company is a defendant in numerous product liability suits involving primarily two products, diethylstilbestrol (DES) and Prozac. See Note 13 to the consolidated financial statements for further information on those matters.

The company's worldwide operations are subject to complex and changing environmental and health and safety laws and regulations, which will continue to require capital investment and operational expenses. The company has also been designated a potentially responsible party with respect to fewer than 10 sites under the federal environmental law commonly known as Superfund. For more information on those matters, see Note 13 to the consolidated financial statements.

The company is nearing completion of an examination by the Internal Revenue Service (IRS) for tax years 1996 and 1997. Discussions between the company and the IRS are currently under way related to one remaining issue.

While it is not possible to predict or determine the outcome of the patent, product liability, or other legal actions brought against the company or the ultimate cost of environmental matters or the resolution of the examination by the IRS, the company believes that, except as noted above with respect to the patent litigation, the costs associated with all such matters will not have a material adverse effect on its consolidated financial position or liquidity but could possibly be material to the consolidated results of operations in any one accounting period.

### **Private Securities Litigation Reform Act of 1995—A Caution Concerning Forward-Looking Statements**

Under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, the company cautions investors that any forward-looking statements or projections made by the company, including those made in this document, are based on management's expectations at the time they are made, but they are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Economic, competitive, governmental, technological, and other factors that may affect the company's operations and prospects are discussed above and in Exhibit 99 to the company's most recent report on Forms 10-Q and 10-K filed with the Securities and Exchange Commission.

# Consolidated Balance Sheets

Eli Lilly and Company and Subsidiaries  
(Dollars in millions)

December 31

2001

2000

## Assets

### Current Assets

Cash and cash equivalents .....	\$ 2,702.3	\$ 4,114.9
Short-term investments .....	1,028.7	503.3
Accounts receivable, net of allowances of \$88.5 (2001) and \$115.3 (2000) ..	1,406.2	1,630.7
Other receivables .....	289.0	335.4
Inventories .....	1,060.2	883.1
Deferred income taxes (Note 11) .....	223.3	269.5
Prepaid expenses .....	229.2	206.1
Total current assets .....	6,938.9	7,943.0

### Other Assets

Prepaid pension (Note 12) .....	1,102.8	1,032.5
Investments .....	2,710.9	395.7
Sundry .....	1,149.1	1,143.0
	4,962.8	2,571.2

Property and Equipment .....	4,532.4	4,176.6
	<u>\$16,434.1</u>	<u>\$14,690.8</u>

## Liabilities and Shareholders' Equity

### Current Liabilities

Short-term borrowings (Note 7) .....	\$ 286.3	\$ 184.3
Accounts payable .....	624.1	661.9
Employee compensation .....	381.9	468.3
Dividends payable .....	341.0	315.4
Income taxes payable (Note 11) .....	2,319.5	2,200.2
Other liabilities .....	1,250.2	1,130.6
Total current liabilities .....	5,203.0	4,960.7

### Other Liabilities

Long-term debt (Note 7) .....	3,132.1	2,633.7
Other noncurrent liabilities .....	995.0	1,049.5
	4,127.1	3,683.2

Commitments and contingencies (Note 13) .....	—	—
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### Shareholders' Equity (Notes 8 and 9)

Common stock—no par value		
Authorized shares: 3,200,000,000		
Issued shares: 1,124,333,530 (2001) and 1,126,567,407 (2000) .....	702.7	704.4
Additional paid-in capital .....	2,610.0	2,610.0
Retained earnings .....	7,411.2	6,223.2
Employee benefit trust .....	(2,635.0)	(2,635.0)
Deferred costs—ESOP .....	(129.1)	(135.0)
Accumulated other comprehensive loss (Note 14) .....	(748.4)	(611.2)
	7,211.4	6,156.4

### Less cost of common stock in treasury

2001—984,781 shares		
2000—1,007,235 shares .....	107.4	109.5
	<u>7,104.0</u>	<u>6,046.9</u>
	<u>\$16,434.1</u>	<u>\$14,690.8</u>

See notes to consolidated financial statements.

# Consolidated Statements of Cash Flows

Eli Lilly and Company and Subsidiaries  
 (Dollars in millions)

Year Ended December 31

2001

2000

1999

## Cash Flows From Operating Activities

Net income ..... \$2,780.0      \$3,057.8      \$2,721.0

## Adjustments To Reconcile Net Income to Cash Flows

### From Operating Activities

Depreciation and amortization .....	454.9	435.8	439.7
Change in deferred taxes .....	273.8	(442.7)	27.1
Gain on sale of Kinetra (2000) and PCS (1999), net of tax ..	—	(214.4)	(174.3)
Acquired in-process research and development, net of tax ..	123.8	—	—
Asset impairment and other site charges, net of tax .....	78.9	—	58.1
Other, net .....	27.6	117.3	96.6
	<u>3,739.0</u>	<u>2,953.8</u>	<u>3,168.2</u>

### Changes in operating assets and liabilities

Receivables—(increase) decrease .....	167.5	(165.4)	(179.0)
Inventories—(increase) decrease .....	(184.2)	9.8	16.9
Other assets—increase .....	(81.1)	(210.5)	(88.8)
Accounts payable and other liabilities— increase (decrease) .....	20.4	1,143.8	(174.9)
	<u>(77.4)</u>	<u>777.7</u>	<u>(425.8)</u>

**Net Cash Provided by Operating Activities** ..... 3,661.6      3,731.5      2,742.4

## Cash Flows From Investing Activities

Purchase of property and equipment .....	(884.0)	(677.9)	(528.3)
Disposals of property and equipment .....	31.6	5.1	78.3
Proceeds from sale of investments .....	319.0	983.9	216.1
Purchase of investments .....	(3,061.7)	(1,233.2)	(162.8)
Purchase of in-process research and development .....	(159.6)	—	—
Proceeds from sale of PCS .....	—	—	1,600.0
Other, net .....	(210.1)	(134.4)	(116.6)
	<u>(3,964.8)</u>	<u>(1,056.5)</u>	<u>1,086.7</u>

**Net Cash Provided by (Used in) Investing Activities** ..... (3,964.8)      (1,056.5)      1,086.7

## Cash Flows From Financing Activities

Dividends paid .....	(1,207.2)	(1,126.0)	(1,000.5)
Purchase of common stock and other capital transactions ...	(545.7)	(1,052.8)	(1,453.0)
Issuances under stock plans .....	109.5	178.4	187.5
Net change in short-term borrowings .....	102.0	(203.0)	(139.4)
Proceeds from issuance of long-term debt .....	901.3	1.1	843.5
Repayments of long-term debt .....	(408.6)	(27.2)	(13.5)
	<u>(1,048.7)</u>	<u>(2,229.5)</u>	<u>(1,575.4)</u>

**Net Cash Used for Financing Activities** ..... (1,048.7)      (2,229.5)      (1,575.4)

Effect of exchange rate changes on cash .....	(60.7)	(31.0)	(49.0)
Net increase (decrease) in cash and cash equivalents .....	(1,412.6)	414.5	2,204.7
Cash and cash equivalents at beginning of year .....	4,114.9	3,700.4	1,495.7
<b>Cash and cash equivalents at end of year</b> .....	<u>\$2,702.3</u>	<u>\$4,114.9</u>	<u>\$3,700.4</u>

See notes to consolidated financial statements.

# Consolidated Statements of Comprehensive Income

Eli Lilly and Company and Subsidiaries (Dollars in millions)		Year Ended December 31		
		2001	2000	1999
Net income		\$2,780.0	\$3,057.8	\$2,721.0
Other comprehensive income (loss)				
Foreign currency translation adjustments		(83.8)	(170.7)	(177.7)
Net unrealized gains (losses) on securities (Note 14)		47.7	(20.5)	27.8
Minimum pension liability adjustment		(95.6)	(33.6)	(26.7)
Effective portion of cash flow hedges		(42.0)	—	—
Other comprehensive loss before income taxes		(173.7)	(224.8)	(176.6)
Provision for income taxes related to other comprehensive loss items		36.5	20.0	—
Other comprehensive loss		(137.2)	(204.8)	(176.6)
Comprehensive income		\$2,642.8	\$2,853.0	\$2,544.4

See notes to consolidated financial statements.

## Segment Information

The company operates in one significant business segment—pharmaceutical products. Operations of the animal health business segment are not material and share many of the same economic and operating characteristics as pharmaceutical products. Therefore, they are included with pharmaceutical products for purposes of segment reporting.

Eli Lilly and Company and Subsidiaries  
(Dollars in millions)

	Year Ended December 31	2001	2000	1999
<b>Net sales—to unaffiliated customers</b>				
Neurosciences		\$ 5,328.2	\$ 5,157.6	\$ 4,729.3
Endocrinology		3,103.5	2,583.5	2,075.5
Anti-infectives		749.5	894.3	1,022.3
Oncology		739.1	580.5	486.1
Animal health		686.1	668.5	627.8
Cardiovascular		593.4	587.9	637.6
Other pharmaceutical		342.7	389.9	424.3
Net sales		<u>\$11,542.5</u>	<u>\$10,862.2</u>	<u>\$10,002.9</u>
<b>Geographic Information</b>				
Net sales—to unaffiliated customers <sup>1</sup>				
United States		\$ 7,364.3	\$ 7,002.9	\$ 6,226.4
Western Europe		1,953.1	1,773.9	1,888.0
Other foreign countries		2,225.1	2,085.4	1,888.5
		<u>\$11,542.5</u>	<u>\$10,862.2</u>	<u>\$10,002.9</u>
Long-lived assets				
United States		\$ 4,015.4	\$ 3,621.0	\$ 3,416.8
Western Europe		767.9	735.3	744.2
Other foreign countries		519.6	472.1	470.3
		<u>\$ 5,302.9</u>	<u>\$ 4,828.4</u>	<u>\$ 4,631.3</u>

<sup>1</sup>Net sales are attributed to the countries based on the location of the subsidiary making the sale.

The largest category of products is the neurosciences group, which includes Zyprexa, Prozac, Permax®, and Darvon®. Endocrinology products consist primarily of Humulin, Evista, Humalog, Actos, and Humatrope®. Anti-infectives include primarily Ceclor®, Vancocin®, Keflex, Nebcin®, and Lorabid®. Oncology products consist primarily of Gemzar. Animal health products include Tylan®, Rumensin®, Micotil®, Surmax®, Coban®, and other products for livestock and poultry. Cardiovascular products consist primarily of ReoPro, Xigris, and Dobutrex®. The other pharmaceutical product group includes primarily Axid® and other miscellaneous pharmaceutical products and services.

Most of the pharmaceutical products are distributed through wholesalers that serve physicians and other health care professionals, pharmacies, and hospitals. In 2001, the company's three largest wholesalers each accounted for between 19 percent and 23 percent of consolidated net sales. Further, they each accounted for between 11 percent and 14 percent of accounts receivable as of December 31, 2001. Animal health products are sold primarily to wholesale distributors.

The company's business segments are distinguished by the ultimate end user of the product: humans or animals. Performance is evaluated based on profit or loss from operations before income taxes. The accounting policies of the individual segments are substantially the same as those described in the summary of significant accounting policies in Note 1 to the consolidated financial statements. Income before taxes for the animal health business was approximately \$204 million, \$180 million, and \$165 million in 2001, 2000, and 1999, respectively.

The assets of the animal health business are intermixed with those of the pharmaceutical products business and are not separately determinable. Long-lived assets disclosed above consist of property and equipment and certain sundry assets.

The company is exposed to the risk of changes in social, political, and economic conditions inherent in foreign operations, and the company's results of operations and the value of its foreign assets are affected by fluctuations in foreign currency exchange rates.

## Selected Quarterly Data (unaudited)

Eli Lilly and Company and Subsidiaries  
(Dollars in millions, except per-share data)  
2001

	Fourth	Third	Second	First
Net sales	\$2,828.9	\$2,874.4	\$3,033.5	\$2,805.7
Cost of sales	566.7	549.0	522.2	522.3
Operating expenses	1,472.6	1,431.9	1,463.6	1,284.4
Acquired in-process research and development	100.0	90.5	—	—
Asset impairment and other site charges	—	121.4	—	—
Other income—net	(51.7)	(33.7)	(13.4)	(35.4)
Income before income taxes and extraordinary item	741.3	715.3	1,061.1	1,034.4
Net income	575.4 <sup>1</sup>	570.1 <sup>1</sup>	827.7	806.8
Earnings per share—basic	.53	.53	.77	.75
Earnings per share—diluted	.53	.52	.76	.74
Dividends paid per share	.28	.28	.28	.28
Common stock prices				
High	83.60	83.37	87.47	90.23
Low	74.73	73.65	73.15	71.83

	Fourth	Third	Second	First
Net sales	\$2,977.7	\$2,811.9	\$2,621.5	\$2,451.1
Cost of sales	565.2	490.1	491.7	508.7
Operating expenses	1,489.4	1,306.4	1,304.2	1,146.8
Other (income) expense—net	(60.6)	17.0	(28.5)	(226.9)
Income before income taxes	983.7	998.4	854.1	1,022.5
Net income	767.3	778.8	666.2	845.5
Earnings per share—basic	.71	.72	.62	.78
Earnings per share—diluted	.70	.71	.61	.77
Dividends paid per share	.26	.26	.26	.26
Common stock prices				
High	94.50	108.24	101.33	70.86
Low	80.64	67.18	64.13	54.34

The company's common stock is listed on the New York, London, Tokyo, and other stock exchanges.

<sup>1</sup>Extraordinary charges of \$12.8 million and \$16.6 million, net of a \$6.8 million and \$9.0 million income tax benefit, were recognized as a result of debt repurchased during the fourth quarter and third quarter of 2001, respectively.

## Selected Financial Data (unaudited)

Eli Lilly and Company and Subsidiaries  
(Dollars in millions, except per-share data)

	2001	2000	1999	1998	1997
<b>Operations</b>					
Net sales	\$11,542.5	\$10,862.2	\$10,002.9	\$9,236.8	\$7,987.7
Research and development	2,235.1	2,018.5	1,783.6	1,738.9	1,370.2
Other costs and expenses	5,755.3	4,985.0	4,973.9	4,832.9	4,348.2
Gain on sale of DowElanco	—	—	—	—	(631.8)
Income from continuing operations					
before taxes and extraordinary item	3,552.1	3,858.7	3,245.4	2,665.0	2,901.1
Income taxes	742.7	800.9	698.7	568.7	885.2
Income from:					
Continuing operations					
before extraordinary item	2,809.4	3,057.8	2,546.7	2,096.3	2,015.9
Discontinued operations	—	—	174.3	8.8	(2,401.0)
Net income (loss)	2,780.0 <sup>2</sup>	3,057.8	2,721.0	2,097.9 <sup>2</sup>	(385.1)
Income from continuing operations before extraordinary item as a percent of sales	24.3%	28.2%	25.5%	22.7%	25.2%
Per-share data—diluted:					
Income (loss) from:					
Continuing operations					
before extraordinary item	\$ 2.58	\$ 2.79	\$ 2.30	\$ 1.87	\$ 1.78
Discontinued operations	—	—	.16	.01	(2.12)
Net income (loss)	2.55 <sup>2</sup>	2.79	2.46	1.87 <sup>2</sup>	(.34)
Dividends declared per share	1.15	1.06	.95	.83	.76
Weighted-average number of shares outstanding—diluted (thousands)	1,090,793	1,097,725	1,106,055	1,121,486	1,130,579
<b>Financial Position</b>					
Current assets	\$ 6,938.9	\$ 7,943.0	\$ 7,055.5	\$5,406.8	\$5,320.7
Current liabilities	5,203.0	4,960.7	3,935.4	4,607.2	4,191.6
Property and equipment—net	4,532.4	4,176.6	3,981.5	4,096.3	4,101.7
Total assets	16,434.1	14,690.8	12,825.2	12,595.5	12,577.4
Long-term debt	3,132.1	2,633.7	2,811.9	2,185.5	2,326.1
Shareholders' equity	7,104.0	6,046.9	5,013.0	4,429.6	4,645.6
<b>Supplementary Data<sup>1</sup></b>					
Return on shareholders' equity	42.7%	55.3%	53.9%	46.2%	37.5%
Return on assets	18.0%	22.9%	21.3%	17.0%	15.4%
Capital expenditures	\$ 884.0	\$ 677.9	\$ 528.3	\$ 419.9	\$ 366.3
Depreciation and amortization	454.9	435.8	439.7	490.4	509.8
Effective tax rate	20.9%	20.8%	21.5%	21.3%	30.5% <sup>3</sup>
Number of employees	41,100	35,700	31,300	29,800	28,900
Number of shareholders of record	57,700	59,200	62,300	62,300	58,200

<sup>1</sup>All supplementary financial data have been computed using income from continuing operations except for capital expenditures and depreciation and amortization, which include amounts from discontinued operations. The number of employees reflects continuing operations, including controlled joint ventures.

<sup>2</sup>Reflects the impact of an extraordinary item in 2001 (see Note 7) and 1998.

<sup>3</sup>Excluding the impacts of the unusual transactions reflected in 1997, the effective tax rate would have been 24.1 percent.

# Notes to Consolidated Financial Statements

Eli Lilly and Company and Subsidiaries  
(Dollars in millions, except per-share data)

## Note 1: Summary of Significant Accounting Policies

**Basis of presentation:** The accounts of all wholly owned and majority-owned subsidiaries are included in the consolidated financial statements. All intercompany balances and transactions have been eliminated.

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses, and related disclosures at the date of the financial statements and during the reporting period. Actual results could differ from those estimates.

All per-share amounts, unless otherwise noted in the footnotes, are presented on a diluted basis, that is, based on the weighted-average number of outstanding common shares and the effect of all potentially dilutive common shares (primarily unexercised stock options).

**Reclassifications:** Certain reclassifications have been made to prior-year amounts to conform with current-year presentation.

**Cash equivalents:** The company considers all highly liquid investments, generally with a maturity of three months or less, to be cash equivalents. The cost of these investments approximates fair value. If items meeting this definition are part of a larger investment pool, they are classified consistent with the classification of the pool.

**Inventories:** The company states all its inventories at the lower of cost or market. The company uses the last-in, first-out (LIFO) method for substantially all its inventories located in the continental United States, or approximately 51 percent of its total inventories. Other inventories are valued by the first-in, first-out (FIFO) method. Inventories at December 31 consisted of the following:

	2001	2000
Finished products .....	\$ 315.1	\$284.3
Work in process .....	489.6	380.6
Raw materials and supplies .....	264.9	230.1
	1,069.6	895.0
Reduction to LIFO cost .....	(9.4)	(11.9)
	<u>\$1,060.2</u>	<u>\$883.1</u>

**Investments:** Substantially all debt and marketable equity securities are classified as available-for-sale. Available-for-sale securities are carried at fair value with the unrealized gains and losses, net of tax, reported in other comprehensive income. Unrealized losses considered to be other than temporary are recognized in earnings currently. Factors the company considers in making this evaluation include near-term prospects of the issuer, the length of time the value has been depressed, and the financial condition of the industry. Realized gains and losses on sales of available-for-sale securities are computed based upon initial cost adjusted for any other-than-temporary declines in fair value. The company owns no investments that are considered to be trading securities.

**Derivative financial instruments:** The company's derivative activities are initiated within the guidelines of documented corporate risk-management policies and do not create additional risk because gains and losses on derivative contracts offset losses and gains on the assets, liabilities, and transactions being hedged. As derivative contracts are initiated, the company designates the instruments individually as either a fair value hedge or a cash flow hedge. Management reviews the correlation and effectiveness of its derivatives on a periodic basis.

For derivative contracts that are designated and qualify as fair value hedges, the derivative instrument is marked to market with gains and losses recognized currently in income to offset the respective losses and gains recognized on the underlying exposure. For derivative contracts that are designated and qualify as cash flow hedges, the effective portion of gains and losses on these contracts is reported as a component of other comprehensive income and reclassified into earnings in the same period the hedged transaction affects earnings. Hedge ineffectiveness is immediately recognized in earnings. Derivative contracts that are not designated as hedging instruments are recorded at fair value with the gain or loss recognized in current earnings during the period of change.

The company enters into foreign currency forward and option contracts to reduce the effect of fluctuating currency exchange rates (principally the Japanese yen and the euro). Generally, foreign currency derivatives used for hedging are put in place using the same or like currencies and duration as the underlying exposures. Forward contracts are principally used to manage exposures arising from subsidiary trade and loan payables and receivables denominated in foreign currency. These contracts are recorded at fair value with the gain or loss recognized in current earnings. The purchased option contracts are used to hedge anticipated foreign currency transactions, primarily intercompany inventory activities expected to occur within the next year. These contracts are designated as cash flow hedges of those future transactions and the impact on earnings is included in cost of sales. The company may enter into foreign currency forward contracts and currency swaps as fair value hedges of firm commitments. Forward and option contracts generally have maturities not exceeding 12 months.

In the normal course of business, operations of the company are exposed to fluctuations in interest rates. These fluctuations can vary the costs of financing, investing, and operating. The company addresses a portion of these risks through a controlled program of risk management that includes the use of derivative financial instruments. The objective of controlling these risks is to limit the impact on earnings of fluctuations in interest rates. The company's primary interest rate risk exposure results from changes in short-term U.S. dollar interest rates. In an effort to manage interest rate exposures, the company strives to achieve an acceptable balance between fixed and floating rate debt and investment positions and may enter into interest rate swaps or collars to help maintain that balance. Interest rate swaps or collars that convert the company's fixed rate debt or investments to a floating rate are designated as fair value hedges of the underlying debt. Interest rate swaps or collars that convert floating rate debt or investments to a fixed rate are designated as cash flow hedges. Interest expense on the debt is adjusted to include the payments made or received under the swap agreements.

**Goodwill and other intangibles:** Goodwill and other intangibles arising from acquisitions and research alliances are amortized over their estimated useful lives, ranging from 5-25 years, using the straight-line method. Goodwill and other intangibles are reviewed to assess recoverability when impairment indicators are present. Assets are considered to be impaired and are written down to fair value if expected future operating cash flows of the related assets are less than their carrying amounts. Fair value is the present value of the expected future cash flows of the related assets using a discount rate commensurate with the risk involved. Assets are grouped at the lowest level for which there are identifiable cash flows for purposes of impairment testing. Goodwill and other intangibles and the related allowances for amortization were \$191.3 million and \$98.2 million, respectively, at December 31, 2001, and \$233.2 million and \$117.8 million, respectively, at December 31, 2000, and are included in sundry assets in the consolidated balance sheets. Upon adoption of Statement of Financial Accounting Standards (SFAS) 142, "Goodwill and Other Intangible Assets," effective in January 2002, amortization of goodwill and those intangible assets identified as having an indefinite life will cease. See Note 2 for additional information.

**Property and equipment:** Property and equipment is stated on the basis of cost. Provisions for depreciation of buildings and equipment are computed generally by the straight-line method at rates based on their estimated useful lives (generally 12 to 50 years for buildings and 5 to 18 years for equipment).

At December 31, property and equipment consisted of the following:

	2001	2000
Land .....	\$ 99.8	\$ 103.5
Buildings .....	2,593.1	2,395.1
Equipment .....	4,776.8	4,638.5
Construction in progress .....	945.7	647.6
	<u>8,415.4</u>	<u>7,784.7</u>
Less allowances for depreciation .....	3,883.0	3,608.1
	<u>\$4,532.4</u>	<u>\$4,176.6</u>

Depreciation expense related to continuing operations for 2001, 2000, and 1999 was \$414.9 million, \$393.5 million, and \$406.7 million, respectively. Approximately \$61.5 million, \$43.1 million, and \$29.0 million of interest costs were capitalized as part of property and equipment in 2001, 2000, and 1999, respectively. Total rental expense for all leases related to continuing operations, including contingent rentals (not material), amounted to approximately \$207.1 million, \$172.3 million, and \$154.9 million for 2001, 2000, and 1999, respectively. Capital leases included in property and equipment in the consolidated balance sheets, capital lease obligations entered into, and future minimum rental commitments are not material.

**Revenue recognition:** Revenue from sales of products is recognized at the time title of goods passes to

the buyer and the buyer assumes the risks and rewards of ownership. This is generally at the time products are shipped to the customer. Provisions for discounts and rebates to customers are established in the same period the related sales are recorded and are included in other current liabilities. Revenue from copromotion services is recognized at the time the copromotion partner records sales. Income received from milestone payments is recorded in other income and is recognized upon the occurrence of the event requiring the milestone payment.

**Acquired in-process research and development:** The cost of directly acquiring assets to be used in the research and development process that have not yet received regulatory approval for marketing and for which no alternative future use has been identified is expensed as incurred. Licensing milestone expense is generally recognized when the event requiring payment of the milestone occurs.

**Income taxes:** Deferred taxes are recognized for the future tax effects of temporary differences between financial and income tax reporting based on enacted tax laws and rates. Federal income taxes are provided on the portion of the income of foreign subsidiaries that is expected to be remitted to the United States and be taxable.

**Earnings per share:** Basic earnings per share are calculated based on the weighted-average number of outstanding common shares and incremental shares. Diluted earnings per share are calculated based on the weighted-average number of outstanding common shares plus the effect of dilutive stock options and other incremental shares.

## **Note 2: Implementation of New Financial Accounting Pronouncements**

The company adopted SFAS 133, "Accounting for Derivative Instruments and Hedging Activities," as amended on January 1, 2001. The statement requires the company to recognize all derivatives on the balance sheet at fair value. Derivatives that are not hedges must be adjusted to fair value through income. If the derivative is a hedge, depending on the nature of the hedge, changes in the fair value of derivatives will either be offset against the change in fair value of the hedged assets, liabilities, or firm commitments through earnings or recognized in other comprehensive income until the hedged item is recognized in earnings. Hedge ineffectiveness, the amount by which the change in the value of a hedge does not exactly offset the change in the value of the hedged item, will be immediately recognized in earnings. The adoption of SFAS 133 on January 1, 2001, did not have a material effect on the consolidated results of operations or financial position of the company, as it increased other income by less than \$1 million and decreased other comprehensive income by approximately \$15 million.

In 2001, the Financial Accounting Standards Board (FASB) issued SFAS 141, "Business Combinations," and SFAS 142, "Goodwill and Other Intangible Assets." SFAS 141 applies to all business combinations with a closing date after June 30, 2001, and effectively eliminates the pooling-of-interests method of accounting and further clarifies the recognition of intangible assets separately from goodwill.

SFAS 142 applies to all acquired intangible assets. Upon adoption, goodwill and other identifiable intangible assets with an indefinite useful life will not be amortized but are required to be tested for impairment at least annually. Identifiable intangible assets will be amortized when their useful life is determined to no longer be indefinite. The company will adopt this statement effective as of January 1, 2002, and does not expect that this statement will have a material impact on its consolidated financial position or results of operations.

In 2001, the FASB issued SFAS 143, "Accounting for Asset Retirement Obligations." SFAS 143 requires companies to record the fair value of a liability for an asset retirement obligation in the period in which it is incurred, which is adjusted to its present value each period. In addition, the companies must capitalize a corresponding amount by increasing the carrying amount of the related long-lived asset, which is depreciated over the useful life of the related asset. The company will adopt SFAS 143 on January 1, 2003, and does not expect that this statement will have a material impact on its consolidated financial position or results of operations.

In 2001, the FASB issued SFAS 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." SFAS 144 significantly changes the criteria that would have to be met to classify an asset as held-for-sale. This statement also requires expected future operating losses from discontinued operations to be recorded in the period in which the losses are incurred (rather than as of the date management commits to a formal plan to dispose of a segment as presently required). In addition, more dispositions will qualify for discontinued operations treatment in the income statement. The company will adopt SFAS 144 effective as of January 1, 2002, and does not expect that this statement will have a material impact on its consolidated financial position or results of operations.

## **Note 3: Collaborations and Dispositions**

In 2001, the company entered into significant collaboration arrangements with three companies. In August,

the company licensed Isis Pharmaceuticals, Inc.'s non-small-cell lung cancer drug candidate and entered into an agreement regarding an ongoing research collaboration. In September, the company entered into a collaboration with Bioprojet, Société Civile de Recherche to jointly develop and commercialize a vasopeptidase inhibitor (fasidotril) for hypertension and chronic heart failure. In October, the company entered into a collaboration with Minnesota Mining and Manufacturing Company to jointly develop and commercialize an immune response modifier (resiquimod) for various forms of herpes. These compounds are in the development phase (late Phase II / early Phase III clinical trials) and no alternative future uses were identified. As with many late Phase II / early Phase III compounds, launch of the products, if successful, is not expected in the near term. The company's charge for acquired in-process research and development expense related to these arrangements totaled \$190.5 million.

During the first quarter of 2000, the company sold its interest in Kinetra LLC, a joint venture between the company and EDS, to WebMD Corporation (WebMD) in exchange for shares of WebMD common stock. A gain of \$214.4 million was recognized on the combined effect of the transaction and the subsequent sale of the majority of those shares of WebMD stock. The gain is included in other income in the consolidated statements of income.

During 1999, the company recognized a pretax gain of \$67.8 million on the sale of the U.S. and Puerto Rican marketing rights of the antibiotic Lorabid to King Pharmaceuticals, Inc. The gain has been included in other income in the consolidated statements of income. The company has an opportunity to receive additional payments if certain sales performance milestones are achieved.

#### **Note 4: Asset Impairment and Other Site Charges**

The company periodically assesses its worldwide manufacturing capacity to maximize the efficiency of its worldwide manufacturing operations. As a result of this strategic review, the company recognized asset impairments and other site charges totaling \$121.4 million in the third quarter of 2001. The charges principally consist of impairments of facilities and equipment that are expected to be disposed of or destroyed in 2002, termination of third-party manufacturing arrangements, and a plant closure in Taiwan. The impairment charges were necessary to adjust the carrying value of certain manufacturing assets to fair value. The fair value of the assets was estimated based upon anticipated future cash flows, discounted at a rate commensurate with the risk involved. Approximately \$18 million of this charge was for severance-related costs, which are expected to be fully expended by the end of the second quarter of 2002.

The company recognized asset impairments and other site charges totaling \$87.4 million in 1999. The impairment charges were necessary to adjust the carrying value of certain manufacturing assets to fair value. Approximately \$75.0 million of these charges were related to the decommissioning of manufacturing buildings and the related equipment, which resulted from the consolidation of certain manufacturing processes. The company plans to continue ownership of the vacated buildings although no planned future uses have been identified. The fair values of the facilities were estimated based upon anticipated future cash flows, discounted at a rate commensurate with the risk involved.

#### **Note 5: Discontinued Operations**

In January 1999, the company sold PCS, its health-care-management subsidiary, to Rite Aid Corporation for \$1.6 billion in cash. The transaction generated a gain of \$174.3 million (\$.16 per share), net of \$8.7 million tax benefit, in the first quarter of 1999.

#### **Note 6: Financial Instruments**

Financial instruments that potentially subject the company to credit risk consist principally of trade receivables and interest-bearing investments. Wholesale distributors of life-sciences products and managed care organizations account for a substantial portion of trade receivables; collateral is generally not required. The risk associated with this concentration is mitigated by the company's ongoing credit review procedures. The company places substantially all its interest-bearing investments with major financial institutions, in U.S. government securities, or with top-rated corporate issuers. In accordance with documented corporate policies, the company limits the amount of credit exposure to any one financial institution. The company is exposed to credit-related losses in the event of nonperformance by counterparties to financial instruments, but it does not expect any counterparties to fail to meet their obligations given their high credit ratings.

## Fair Value of Financial Instruments

A summary of the company's outstanding financial instruments at December 31 follows:

	2001		2000	
	Carrying Amount	Fair Value	Carrying Amount	Fair Value
Short-term investments				
Debt securities	\$1,028.7	\$1,028.7	\$ 503.3	\$ 504.3
Noncurrent investments				
Marketable equity	179.6	179.6	79.8	90.1
Debt securities	1,983.7	1,984.1	266.2	271.2
Nonmarketable equity	12.7	12.7	7.5	7.5
Long-term debt, including current portion	3,144.3	3,258.1	2,796.6	2,861.7

The company determines fair values based on quoted market values where available or discounted cash flow analyses (principally long-term debt). The fair values of nonmarketable equity securities, which represent either equity investments in start-up technology companies or partnerships that invest in start-up technology companies, are estimated based on the fair value information provided by these ventures. The fair value and carrying amount of risk-management instruments were not material at December 31, 2001 and 2000. In addition to the financial instruments above, the company has an equity method investment in an investment company with a carrying amount of \$500.6 million at December 31, 2001. Approximately \$2.1 billion of the company's debt securities mature within five years.

At December 31, 2001 and 2000, the gross unrealized holding gains on available-for-sale securities were \$65.6 million and \$24.3 million, respectively, and the gross unrealized holding losses were \$8.5 million and \$14.9 million, respectively. The proceeds from sales of available-for-sale securities totaled \$262.1 million, \$773.8 million, and \$56.2 million in 2001, 2000, and 1999, respectively. Purchases of available-for-sale securities were \$3.23 billion, \$443.0 million, and negligible in 2001, 2000, and 1999, respectively. Realized gains on sales of available-for-sale securities were \$14.1 million, \$71.6 million, and \$25.0 million in 2001, 2000, and 1999, respectively. Realized losses on sales of available-for-sale securities were \$0.1 million, \$16.5 million, and negligible in 2001, 2000, and 1999, respectively. The net adjustment to unrealized gains and losses on available-for-sale securities increased (decreased) other comprehensive income by \$34.3 million, (\$12.3) million, and \$18.6 million in 2001, 2000, and 1999, respectively.

During the year ended December 31, 2001, net losses related to ineffectiveness and net losses related to the portion of fair value and cash flow hedging instruments excluded from the assessment of effectiveness were not material.

The company expects to reclassify approximately \$21.6 million of pretax net gains on cash flow hedges from accumulated other comprehensive loss to earnings during 2002.

## Note 7: Borrowings

Long-term debt at December 31 consisted of the following:

	2001	2000
6.57 to 7.13 percent notes (due 2016-2036)	\$ 787.4	\$1,000.0
5.50 to 8.38 percent notes (due 2001-2006)	711.4	650.0
Floating rate capital securities (due 2029)	525.0	525.0
Floating rate bonds (due 2008-2031)	505.0	—
8.38 percent eurodollar bonds (due 2005)	150.0	150.0
Resetable coupon capital securities (due 2029)	300.0	300.0
6.55 percent ESOP debentures (due 2017)	96.6	97.6
Other, including capitalized leases	68.9	74.0
	3,144.3	2,796.6
Less current portion	12.2	162.9
	<u>\$3,132.1</u>	<u>\$2,633.7</u>

In May 2001, the company issued \$250 million of 30-year floating rate bonds. The variable interest rate is at LIBOR (1.97 percent at December 31, 2001) for the first three years and will adjust every six months after the first three years to reflect the company's six-month credit spread. The interest accumulates over the life of the bonds and is payable upon maturity. The company has an option to begin periodic interest payments

any time after the first three years. At the time of option exercise, the company would owe all previously accrued interest on the bonds. In addition, in 2001, the company issued \$400.0 million of 5.50 percent notes due July 2006 and \$249.5 million of floating rate bonds due October 2008.

In 1999, the company issued \$525.0 million floating rate capital securities and \$300.0 million adjustable rate capital securities. These capital securities are subordinated to the notes, bonds, and debentures listed above. The floating rate capital securities pay cumulative interest at an annual rate equal to LIBOR plus a predetermined spread, reset quarterly. The rates at December 31, 2001 and 2000, were 3.41 percent and 7.95 percent, respectively. The securities may be redeemed any time on or after August 5, 2004, for a defined redemption price. The resettable coupon capital securities pay cumulative interest at an annual rate of 7.72 percent until August 1, 2004. At this date and every fifth anniversary thereafter, the interest rate will be reset equal to the weekly average interest rate of U.S. treasury securities having an index maturity of five years for the week immediately preceding the reset date plus a predetermined spread. The securities may be redeemed on August 1, 2004, and anytime thereafter for a defined redemption price.

The 6.55 percent Employee Stock Ownership Plan (ESOP) debentures are obligations of the ESOP but are shown on the consolidated balance sheet because they are guaranteed by the company. The principal and interest on the debt are funded by contributions from the company and by dividends received on certain shares held by the ESOP. Because of the amortizing feature of the ESOP debt, bondholders will receive both interest and principal payments each quarter.

In 2001, the company repurchased \$188.6 million of 8.38 percent notes due in 2006, \$14.0 million of 6.77 percent notes due in 2036, and \$198.6 million of 7.13 percent notes due in 2025. As a result of this debt repurchase, the company recognized an extraordinary charge of \$29.4 million, net of a \$15.8 million income tax benefit.

The aggregate amounts of maturities on long-term debt for the next five years are as follows: 2002, \$12.2 million; 2003, \$211.2 million; 2004, \$8.4 million; 2005, \$156.4 million; and 2006, \$514.1 million.

At December 31, 2001 and 2000, short-term borrowings included \$274.1 million and \$21.4 million, respectively, of notes payable to banks. Included in short-term borrowings are \$250 million of 4.25 percent one-year resettable notes issued in March 2001. The notes have a final maturity of 10 years. Annually, the notes will be remarketed or redeemed by the company at the option of the underwriter. At December 31, 2001, unused committed lines of credit totaled approximately \$2.02 billion. Compensating balances and commitment fees are not material, and there are no conditions that are probable of occurring under which the lines may be withdrawn.

The company has converted substantially all fixed rate debt to floating rates through the use of interest rate swaps.

Cash payments of interest on borrowings totaled \$133.7 million, \$195.9 million, and \$170.6 million in 2001, 2000, and 1999, respectively.

### **Note 8: Stock Plans**

Stock options are granted to employees at exercise prices equal to the fair market value of the company's stock at the dates of grant. Generally, options vest 100 percent 3 years from the grant date and have a term of 10 years. Performance awards are granted to officers and key employees and are payable in shares of the company's common stock. The number of performance award shares actually issued varies depending upon the achievement of certain earnings targets. In general, performance awards vest 100 percent at the end of the second fiscal year following the grant date.

The company issued a grant under the GlobalShares program in both 2001 and 1999. Essentially all employees were given an option to buy 125 shares in the 2001 grant and 100 shares in the 1999 grant of the company's stock at a price equal to the fair market value of the company's stock on the date of the grant. Options to purchase approximately 4.3 million and 2.8 million shares were granted as part of the program in 2001 and 1999, respectively. Individual grants generally become exercisable on or after the third anniversary of the grant date and have a term of 10 years.

In the fourth quarter of 2000, the company changed the timing of the annual option grant to management from the fourth quarter to the first quarter of the following year. This resulted in a reduction in options granted in 2000. The company also issued a special stock option grant in 2001 to global management and all employees in the U.S. and Puerto Rico. This option grant was designed to retain and motivate employees affected by the compensation changes due to the Prozac patent expiration. Options to purchase approximately 10.0 million shares were granted as part of this program at a price equal to the fair market value on the date of the grant. Approximately 7.3 million of these options vest in 2002 with the remainder vesting in 2003.

The company has elected to follow Accounting Principles Board (APB) Opinion 25, "Accounting for Stock Issued to Employees," and related interpretations in accounting for its stock options and performance awards. Under APB 25, because the exercise price of the company's employee stock options equals the market price of the underlying stock on the date of grant, no compensation expense is recognized. Total compensation expense for stock-based performance awards reflected in income on a pretax basis was \$13.9 million, \$88.3 million, and \$117.1 million in 2001, 2000, and 1999, respectively. However, SFAS 123, "Accounting for Stock-Based Compensation," requires presentation of pro forma information as if the company had accounted for its employee stock options and performance awards under the fair value method of that statement. For purposes of pro forma disclosure, the estimated fair value of the options and performance awards at the date of the grant is amortized to expense over the vesting period. Under the fair value method, the company's net income and earnings per share would have been as follows:

	2001	2000	1999
Net income .....	\$2,569.6	\$2,969.3	\$2,639.6
Earnings per share—diluted .....	2.36	2.70	2.39

The weighted-average per-share fair value of the individual options and performance awards granted during 2001, 2000, and 1999 were as follows on the date of grant:

	2001	2000	1999
Employee stock options .....	\$26.59	\$29.25	\$20.27
Performance awards .....	78.86	93.06	66.50

The fair values of the options were determined using a Black-Scholes option-pricing model with the following assumptions:

	2001	2000	1999
Dividend yield .....	1.80%	2.26%	2.73%
Volatility .....	33.10%	32.70%	25.20%
Risk-free interest rate .....	4.58%	5.02%	6.15%
Forfeiture rate .....	0	0	0
Expected life .....	7 years	7 years	7 years

Stock option activity during 1999-2001 is summarized below:

	Shares of Common Stock Attributable to Options (in thousands)	Weighted-Average Exercise Price of Options
Unexercised at January 1, 1999 .....	52,953	\$32.35
Granted .....	12,494	68.22
Exercised .....	(10,849)	19.04
Forfeited .....	(875)	50.46
Unexercised at December 31, 1999 .....	53,723	43.08
Granted .....	1,315	86.75
Exercised .....	(9,242)	22.33
Forfeited .....	(671)	64.97
Unexercised at December 31, 2000 .....	45,125	48.28
Granted .....	26,883	76.10
Exercised .....	(4,298)	26.72
Forfeited .....	(612)	71.20
Unexercised at December 31, 2001 .....	67,098	60.60

The following table summarizes information concerning outstanding and exercisable options at December 31, 2001 (shares in millions, contractual life in years):

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number Outstanding	Weighted-Average Remaining Contractual Life	Weighted-Average Exercise Price	Number Exercisable	Weighted-Average Exercise Price
\$10 - \$25	13.11	2.86	18.62	13.11	18.62
\$25 - \$65	8.20	5.40	52.24	8.17	52.20
\$65 - \$70	9.13	7.79	66.38	.58	66.38
\$70 - \$75	24.52	8.38	74.09	13.31	74.19
\$75 - \$95	12.14	9.66	80.01	.01	82.13

Shares exercisable at December 31, 2001, 2000, and 1999 were 35.2 million, 26.1 million, and 29.9 million, respectively.

As noted above, the number of shares ultimately issued pursuant to the performance award program is dependent upon the earnings achieved during the vesting period. Pursuant to this plan, approximately 0.8 million shares, 1.2 million shares, and 2.2 million shares were issued in 2001, 2000, and 1999, respectively. At December 31, 2001, plan participants had the right to receive up to 2.1 million additional shares (reduced to the extent necessary to satisfy payroll tax withholdings), contingent upon earnings achieved.

At December 31, 2001, additional options, performance awards, or restricted stock grants may be granted under the 1998 Lilly Stock Plan and the Lilly GlobalShares Stock Plan for not more than 16.5 million shares and 2.0 million shares, respectively.

### Note 9: Shareholders' Equity

Changes in certain components of shareholders' equity were as follows:

	Additional Paid-in Capital	Retained Earnings	Deferred Costs— ESOP	Common Stock in Treasury Shares (in thousands)	Amount
Balance at January 1, 1999	\$ —	\$4,228.8	\$(146.9)	995	\$ 109.0
Net income		2,721.0			
Cash dividends declared per share: \$.95		(1,030.5)			
Retirement of treasury shares	(1,488.4)			(19,689)	(1,500.8)
Purchase for treasury				19,147	1,455.1
Issuance of stock under employee stock plans	530.6			542	45.7
ESOP transactions	20.8		7.0		
Other	3.3			(6)	(0.7)
Reclassification	933.7	(933.7)			
Balance at December 31, 1999	—	4,985.6	(139.9)	989	108.3
Net income		3,057.8			
Cash dividends declared per share: \$1.06		(1,158.4)			
Retirement of treasury shares	(1,117.6)			(15,256)	(1,126.9)
Purchase for treasury	34.3			14,794	1,089.8
Issuance of stock under employee stock plans	405.6			494	39.8
Issuance of stock for employee benefit trust	2,610.0				
ESOP transactions	16.7		4.9		
Other	(0.6)	(0.2)		(14)	(1.5)
Reclassification	661.6	(661.6)			
Balance at December 31, 2000	2,610.0	6,223.2	(135.0)	1,007	109.5
Net income		2,780.0			
Cash dividends declared per share: \$1.15		(1,232.8)			
Retirement of treasury shares	(581.8)			(7,368)	(586.7)
Purchase for treasury	(24.8)			7,176	571.0
Issuance of stock under employee stock plans	229.0			170	13.6
ESOP transactions	18.4		5.9		
Other	0.1	(0.1)			
Reclassification	359.1	(359.1)			
Balance at December 31, 2001	\$2,610.0	\$7,411.2	\$(129.1)	985	\$ 107.4

As of December 31, 2001, the company has purchased \$1.41 billion of its announced \$3.0 billion share repurchase program. A \$1.5 billion share repurchase program was completed in 1999. The company acquired approximately 7.2 million, 14.8 million, and 19.1 million shares in 2001, 2000, and 1999, respectively, pursuant to these programs.

In connection with the share repurchase program, the company has entered into agreements to purchase shares of the company's stock. As of December 31, 2001, the company has agreements to purchase up to approximately 6.0 million shares of company stock from an independent third party at various times through the expiration of the agreements in December 2003 at prices ranging from \$80 to \$100 per share. The number of shares to be purchased will be reduced ratably each quarter through the expiration of the agreements. In addition, as of December 31, 2001, equity forward and other derivative contracts, which provide for purchase of a total of approximately 2.1 million shares, remain outstanding at prices ranging from \$83 to \$98 per share with expiration dates ranging from May 2002 to November 2002. If the options are exercised, the contracts allow the company, at its option, to repurchase the shares for cash or deliver to the holder cash or shares for the difference between the contractual exercise price and the market price of the company's stock. The company's objective with the above agreements is to reduce the average price of repurchased shares.

The company has five million authorized shares of preferred stock. As of December 31, 2001 and 2000, no preferred stock has been issued.

In 2000, the company funded an employee benefit trust with 40 million shares of Lilly common stock to provide a source of funds to assist the company in meeting its obligations under various employee benefit plans. The funding had no net impact on shareholders' equity as the employee benefit trust is consolidated with the company. The cost basis of the shares held in the trust was \$2.64 billion and is shown as a reduction in shareholders' equity, which offsets the resulting increases of \$2.61 billion in additional paid-in capital and \$25 million in common stock. Any dividend transactions between the company and the trust are eliminated. Stock held by the trust is not considered outstanding in the computation of earnings per share.

The company has an ESOP as a funding vehicle for the existing employee savings plan. The ESOP used the proceeds of a loan from the company to purchase shares of common stock from the treasury. The ESOP issued \$200 million of third-party debt, repayment of which was guaranteed by the company (see Note 7). The proceeds were used to purchase shares of the company's common stock on the open market. Shares of common stock held by the ESOP will be allocated to participating employees annually through 2017 as part of the company's savings plan contribution. The fair value of shares allocated each period is recognized as compensation expense.

Under a Shareholder Rights Plan adopted in 1998, all shareholders receive, along with each common share owned, a preferred stock purchase right entitling them to purchase from the company one one-thousandth of a share of Series B Junior Participating Preferred Stock (the "Preferred Stock") at a price of \$325. The rights are exercisable only after the "Distribution Date," which is generally the 10th business day after the date of a public announcement that a person (the "Acquiring Person") has acquired ownership of 15 percent or more of the company's common stock. The company may redeem the rights for \$.005 per right up to and including the Distribution Date. The rights will expire on July 28, 2008, unless redeemed earlier by the company.

The plan provides that, if an Acquiring Person acquires 15 percent or more of the outstanding common stock of the company and the company's redemption right has expired, generally each holder of a right (other than the Acquiring Person) will have the right to purchase at the exercise price the number of shares of common stock of the company as have a value of two times the exercise price.

Alternatively, if, in a transaction not approved by the board of directors, the company is acquired in a business combination transaction or sells 50 percent or more of its assets or earning power after a Distribution Date, generally each holder of a right (other than the Acquiring Person) will have the right to purchase at the exercise price the number of shares of common stock of the acquiring company as have a value of two times the exercise price.

At any time after an Acquiring Person has acquired 15 percent or more but less than 50 percent of the company's outstanding common stock, the board of directors may exchange the rights (other than those owned by the Acquiring Person) for company common stock or Preferred Stock at an exchange ratio of one common share (or one one-thousandth of a share of Preferred Stock) per right.

### Note 10: Earnings per Share

The following is a reconciliation of the denominators used in computing earnings per share from continuing operations before extraordinary item:

(Shares in thousands)	2001	2000	1999
Income from continuing operations before extraordinary item available to common shareholders . . . . .	<u>\$2,809.4</u>	<u>\$3,057.8</u>	<u>\$2,546.6</u>
Basic earnings per share			
Weighted-average number of common shares outstanding, including incremental shares . . . . .	<u>1,077,497</u>	<u>1,081,559</u>	<u>1,087,652</u>
Basic earnings per share from continuing operations before extraordinary item . . . . .	<u>\$2.61</u>	<u>\$2.83</u>	<u>\$2.34</u>
Diluted earnings per share			
Weighted-average number of common shares outstanding . . .	<u>1,077,390</u>	<u>1,081,409</u>	<u>1,087,368</u>
Stock options and other incremental shares . . . . .	<u>13,403</u>	<u>16,316</u>	<u>18,687</u>
Weighted-average number of common shares outstanding—diluted . . . . .	<u>1,090,793</u>	<u>1,097,725</u>	<u>1,106,055</u>
Diluted earnings per share from continuing operations before extraordinary item . . . . .	<u>\$2.58</u>	<u>\$2.79</u>	<u>\$2.30</u>

## Note 11: Income Taxes

Following is the composition of income taxes attributable to continuing operations before extraordinary item:

	2001	2000	1999
Current			
Federal .....	\$ 313.4	\$ 928.4	\$439.2
Foreign .....	247.9	322.4	260.4
State .....	16.6	(7.2)	(4.9)
	<u>577.9</u>	<u>1,243.6</u>	<u>694.7</u>
Deferred			
Federal .....	240.5	(81.2)	104.0
Foreign .....	34.6	(58.6)	22.4
State .....	0.2	0.9	2.7
	<u>275.3</u>	<u>(138.9)</u>	<u>129.1</u>
Utilization of capital loss carryforwards .....	(110.5)	(303.8)	(125.1)
Income taxes .....	<u>\$ 742.7</u>	<u>\$ 800.9</u>	<u>\$698.7</u>

Significant components of the company's deferred tax assets and liabilities as of December 31 are as follows:

	2001	2000
Deferred tax assets		
Sale of intangibles .....	\$ 416.4	\$ 230.6
Other carryforwards .....	341.8	450.4
Tax credit carryforwards and carrybacks .....	321.3	734.5
Compensation and benefits .....	230.2	109.0
Inventory .....	148.8	70.2
Capital loss carryforward .....	13.1	158.8
Other .....	399.6	378.6
	<u>1,871.2</u>	<u>2,132.1</u>
Valuation allowances .....	(332.2)	(408.0)
Total deferred tax assets .....	<u>1,539.0</u>	<u>1,724.1</u>
Deferred tax liabilities		
Property and equipment .....	(528.0)	(527.7)
Prepaid employee benefits .....	(474.0)	(429.2)
Unremitted earnings .....	(123.2)	(182.0)
Other .....	(19.4)	(29.2)
Total deferred tax liabilities .....	<u>(1,144.6)</u>	<u>(1,168.1)</u>
Deferred tax assets—net .....	<u>\$ 394.4</u>	<u>\$ 556.0</u>

At December 31, 2001, the company had other carryforwards for international and U.S. income tax purposes of \$201.2 million: \$161.2 million will expire within five years and \$32.3 million thereafter; \$7.7 million of the carryforwards will never expire. The primary component of the remaining portion of the deferred tax asset for other carryforwards is related to net operating losses for state income tax purposes that are fully reserved. The company also has tax credit carryforwards of \$321.3 million available to reduce future income taxes: \$2.5 million will expire within five years and \$261.6 million thereafter; \$57.2 million of the tax credit carryforwards will never expire.

Domestic and Puerto Rican companies contributed approximately 55 percent, 56 percent, and 56 percent in 2001, 2000, and 1999, respectively, to consolidated income from continuing operations before income taxes and extraordinary item. At December 31, 2001, the company had an aggregate of \$6.4 billion of unremitted earnings of foreign subsidiaries that have been, or are intended to be, permanently reinvested for continued use in foreign operations and that, if distributed, would result in taxes at approximately the U.S. statutory rate. The company has a subsidiary operating in Puerto Rico under a tax incentive grant that begins to expire at the end of 2007. Cash payments of income taxes totaled \$320.0 million, \$294.0 million, and \$252.0 million in 2001, 2000, and 1999, respectively.

Following is a reconciliation of the effective income tax rate applicable to income from continuing operations before extraordinary item:

	2001	2000	1999
United States federal statutory tax rate .....	35.0%	35.0%	35.0%
Add (deduct)			
International operations, including Puerto Rico .....	(13.9)	(12.9)	(7.5)
General business credits .....	(1.1)	(1.2)	(1.6)
Sundry .....	0.9	(0.1)	(4.4)
Effective income tax rate .....	20.9%	20.8%	21.5%

## Note 12: Retirement Benefits

The change in benefit obligation, change in plan assets, funded status, and amounts recognized in the consolidated balance sheets at December 31 for the company's defined benefit pension and retiree health benefit plans were as follows:

	Defined Benefit Pension Plans		Retiree Health Benefits	
	2001	2000	2001	2000
<b>Change in benefit obligation</b>				
Benefit obligation at beginning of year .....	\$3,380.1	\$3,004.4	\$751.3	\$687.6
Service cost .....	156.0	130.1	28.7	23.2
Interest cost .....	242.4	219.6	53.8	49.6
Actuarial loss .....	88.5	144.3	135.6	51.4
Benefits paid .....	(218.0)	(179.8)	(64.7)	(61.5)
Foreign currency exchange rate changes and other adjustments .....	(50.3)	61.5	23.5	1.0
Benefit obligation at end of year .....	3,598.7	3,380.1	928.2	751.3
<b>Change in plan assets</b>				
Fair value of plan assets at beginning of year .....	3,732.1	3,532.0	349.2	332.1
Actual return on plan assets .....	(382.3)	138.7	(37.6)	(16.4)
Employer contribution .....	63.1	270.0	126.5	95.0
Benefits paid .....	(218.0)	(179.8)	(64.7)	(61.5)
Foreign currency exchange rate changes and other adjustments .....	(12.8)	(28.8)	—	—
Fair value of plan assets at end of year .....	3,182.1	3,732.1	373.4	349.2
Funded status .....	(416.6)	352.0	(554.8)	(402.1)
Unrecognized net actuarial loss .....	1,142.7	298.8	531.1	317.1
Unrecognized prior service cost (benefit) .....	208.5	227.2	0.1	(0.1)
Unrecognized net obligation at January 1, 1986 .....	1.1	1.7	1.6	1.8
Net amount recognized .....	\$ 935.7	\$ 879.7	\$ (22.0)	\$ (83.3)

Amounts recognized in the consolidated balance sheet consisted of

	2001	2000	2001	2000
Prepaid pension .....	\$1,102.8	\$1,032.5	\$ 42.9	\$ —
Accrued benefit liability .....	(371.7)	(302.9)	(64.9)	(83.3)
Intangible asset .....	—	41.1	—	—
Accumulated other comprehensive income before income taxes .....	204.6	109.0	—	—
Net amount recognized .....	\$ 935.7	\$ 879.7	\$ (22.0)	\$ (83.3)

[Percents]	Defined Benefit Pension Plans		Retiree Health Benefits	
	2001	2000	2001	2000
<b>Weighted-average assumptions as of December 31</b>				
Discount rate .....	7.2	7.4	7.2	7.5
Expected return on plan assets .....	10.5	10.5	10.5	10.5
Rate of compensation increase .....	3.5-8.0	3.5-8.0	—	—

Health-care-cost trend rates were assumed to increase at an annual rate of 6.0 percent in 2002 and thereafter for all participants.

The projected benefit obligation, accumulated benefit obligation, and fair value of the plan assets for the defined benefit pension plans with projected benefit obligations in excess of plan assets were \$778.3 million, \$673.0 million, and \$325.1 million, respectively, as of December 31, 2001, and \$736.8 million, \$616.8 million, and \$381.6 million, respectively, as of December 31, 2000.

Net pension and retiree health benefit expense included the following components related to continuing operations:

	Defined Benefit Pension Plans			Retiree Health Benefits		
	2001	2000	1999	2001	2000	1999
Components of net periodic benefit cost						
Service cost	\$156.0	\$130.1	\$127.7	\$28.7	\$23.2	\$16.8
Interest cost	242.4	219.6	193.7	53.8	49.6	41.5
Expected return on plan assets	(382.3)	(341.0)	(295.1)	(40.1)	(30.1)	(24.2)
Amortization of prior service cost	19.3	16.9	11.5	0.1	0.1	—
Recognized actuarial loss	9.8	5.9	3.7	23.6	21.9	17.6
Net periodic benefit cost	\$45.2	\$31.5	\$41.5	\$66.1	\$64.7	\$51.7

The assumed health-care trend rates, discount rates, and expected return on plan assets have a significant effect on the amounts reported. If the health-care trend rates were to be increased by one percentage point each future year, the December 31, 2001, accumulated postretirement benefit obligation would increase by 14 percent and the aggregate of the service cost and interest cost components of 2001 annual expense would increase by 16 percent. A one-percentage-point decrease in these rates would decrease the December 31, 2001, accumulated postretirement benefit obligation by 12 percent and the aggregate of the 2001 service cost and interest cost by 13 percent. If the discount rate were to be changed by a quarter percentage point, the net periodic benefit cost of the defined benefit pension plans would change by approximately \$3 million. If the expected return on plan assets were to be changed by a quarter percentage point, the net periodic benefit cost of the defined benefit pension plans would change by approximately \$8 million.

The company has defined contribution savings plans that cover its eligible employees worldwide. The purpose of these defined contribution plans is generally to provide additional financial security during retirement by providing employees with an incentive to save. Company contributions to the plan are based on employee contributions and the level of company match. Expenses under the plans related to continuing operations totaled \$39.3 million, \$65.2 million, and \$56.4 million for the years 2001, 2000, and 1999, respectively.

The company provides certain other postemployment benefits primarily related to disability benefits and accrues for the related cost over the service lives of employees. Expenses associated with these benefit plans in 2001, 2000, and 1999 were not significant.

### Note 13: Contingencies

In February 2001, the company was notified that Zenith Goldline Pharmaceuticals, Inc. ("Zenith"), had submitted an Abbreviated New Drug Application (ANDA) under the Hatch-Waxman Act of 1984 seeking permission to market a generic version of Zyprexa in various dosage forms prior to the expiration of the company's U.S. patents for the product, alleging that the patents are invalid or not infringed. On April 2, 2001, the company filed suit against Zenith in federal district court in Indianapolis seeking a ruling that Zenith's challenge to the U.S. compound patent (expiring in 2011) is without merit. In May 2001, the company was notified that Dr. Reddy's Laboratories Ltd. ("Reddy") had also filed an ANDA covering two dosage forms, alleging that the patents are invalid or not infringed. On June 26, 2001, the company filed suit against Reddy in federal district court in Indianapolis seeking a ruling that Reddy's patent challenge is without merit. In January 2002, the company was notified that Reddy had supplemented its ANDA to include the remaining dosage forms. The company believes that the generic manufacturers' patent claims are without merit and expects to prevail in this litigation. However, it is not possible to predict or determine the outcome of this litigation and, accordingly, there can be no assurance that the company will prevail. An unfavorable outcome could have a material adverse impact on the company's consolidated results of operations, liquidity, and financial position.

Several generic manufacturers filed ANDAs for generic forms of Prozac in various dosage forms, challenging the company's patents under the Hatch-Waxman Act. On May 30, 2001, the Court of Appeals for the Federal Circuit held that the company's 2003 method of use patent was invalid. Generic fluoxetine entered the U.S. market in early August 2001. On January 14, 2002, the U.S. Supreme Court denied a petition filed by the company seeking review of the decision, bringing the litigation to a close. Prozac sales in the U.S. have historically represented a significant portion of the company's overall sales, accounting for approximately 20 percent in 2000.

The company has been named as a defendant in numerous product liability lawsuits involving primarily two products, diethylstilbestrol (DES) and Prozac. The company has accrued for its estimated exposure with respect to all current product liability claims. In addition, the company has accrued for certain claims incurred, but not filed, to the extent the company can formulate a reasonable estimate of their costs. The company's estimates of these expenses are based primarily on historical claims experience and data regarding product usage. The company expects the cash amounts related to the accruals to be paid out over the next several years. A portion of the costs associated with defending and disposing of these suits is covered by insurance. The company's estimate of insurance recoverables is based on existing deductibles, coverage limits, and the existing and projected future level of insolvencies among its insurance carriers.

Under the Comprehensive Environmental Response, Compensation, and Liability Act, commonly known as Superfund, the company has been designated as one of several potentially responsible parties with respect to fewer than 10 sites. Under Superfund, each responsible party may be jointly and severally liable for the entire amount of the cleanup. The company also continues remediation of certain of its own sites. The company has accrued for estimated Superfund cleanup costs, remediation, and certain other environmental matters, taking into account, as applicable, available information regarding site conditions, potential cleanup methods, estimated costs, and the extent to which other parties can be expected to contribute to payment of those costs. The company has reached a settlement with its primary liability insurance carrier and certain excess carriers providing coverage for certain environmental liabilities. Litigation seeking coverage from certain other excess carriers is ongoing.

The environmental liabilities and litigation accruals have been reflected in the company's consolidated balance sheet at the gross amount of approximately \$132.4 million at December 31, 2001. Estimated insurance recoverables of approximately \$65.2 million at December 31, 2001 have been reflected as assets in the consolidated balance sheet.

The company is nearing completion of an examination by the Internal Revenue Service (IRS) for tax years 1996 and 1997. Discussions between the company and the IRS are currently under way related to one remaining issue.

In 1999, the company recognized a pretax gain of \$110.0 million as a result of a cash payment received in settlement of litigation with Biochimica Opos S.p.A. relating to the manufacture, sale, or distribution of cefaclor and certain other products made by Biochimica Opos S.p.A. The gain, which was recorded in other income, increased earnings per share by approximately \$.06 in 1999.

While it is not possible to predict or determine the outcome of the patent, product liability, or other legal actions brought against the company or the ultimate cost of environmental matters or the resolution of the examination by the IRS, the company believes that, except as noted above with respect to the patent litigation, the costs associated with all such matters will not have a material adverse effect on its consolidated financial position or liquidity but could possibly be material to the consolidated results of operations in any one accounting period.

#### **Note 14: Other Comprehensive Income (Loss)**

The accumulated balances related to each component of other comprehensive income (loss) were as follows:

	Foreign Currency Translation	Unrealized Gains on Securities	Minimum Pension Liability Adjustment	Effective Portion of Cash Flow Hedges	Accumulated Other Comprehensive Loss
Beginning balance at January 1, 2001 . . . . .	\$(546.3)	\$ 7.8	\$ (72.7)	\$ —	\$(611.2)
Adoption of SFAS 133 . . . . .	—	—	—	(15.0)	(15.0)
Other comprehensive income (loss) . . . . .	(83.8)	34.3	(62.1)	(10.6)	(122.2)
Balance at December 31, 2001 . . . . .	\$(630.1)	\$42.1	\$(134.8)	\$(25.6)	\$(748.4)

The amounts above are net of income taxes. The income taxes related to other comprehensive income were not significant as income taxes were generally not provided for foreign currency translation.

The unrealized gains (losses) on securities is net of reclassification adjustments of \$12.3 million, \$43.9 million, and \$8.5 million, net of tax, in 2001, 2000, and 1999, respectively, for net realized gains on sales of securities included in net income. The effective portion of cash flow hedges is net of a reclassification adjustment of \$16.5 million, net of tax, in 2001 for realized gains on foreign currency options.

Generally, the assets and liabilities of foreign operations are translated into U.S. dollars using the current exchange rate. For those operations, changes in exchange rates generally do not affect cash flows; therefore, resulting translation adjustments are made in shareholders' equity rather than in income.

# Responsibility for Financial Statements

## **Eli Lilly and Company and Subsidiaries**

The consolidated financial statements and related notes have been prepared by management, who are responsible for their integrity and objectivity. The statements have been prepared in accordance with generally accepted accounting principles in the United States and include amounts based on judgments and estimates by management. The other financial information in this annual report is consistent with that in the financial statements.

The company maintains internal accounting control systems that are designed to provide reasonable assurance that assets are safeguarded, that transactions are executed in accordance with management's authorization and are properly recorded, and that accounting records are adequate for preparation of financial statements and other financial information. The design, monitoring, and revision of internal accounting control systems involve, among other things, management's judgments with respect to the relative cost and expected benefits of specific control measures. A staff of internal auditors regularly monitors, on a worldwide basis, the adequacy and effectiveness of internal accounting controls.

In addition to the system of internal accounting controls, the company maintains guidelines of company policy emphasizing proper overall business conduct, possible conflicts of interest, compliance with laws, and confidentiality of proprietary information. The guidelines are reviewed on a periodic basis with employees worldwide.

The financial statements have been audited by Ernst & Young LLP, independent auditors. Their responsibility is to examine the company's consolidated financial statements in accordance with generally accepted auditing standards in the United States and to express their opinion with respect to the fairness of presentation of the statements.

The members of the audit committee of the board of directors, none of whom are employees of the company, recommend independent auditors for appointment by the board of directors, review the services performed by the independent auditors, and receive and review the reports submitted by them. The audit committee meets several times during the year with management, the internal auditors, and the independent auditors to discuss audit activities, internal controls, and financial reporting matters. The internal auditors and the independent auditors have full and free access to the committee.

Sidney Taurel, Chairman of the Board, President, and Chief Executive Officer

Charles E. Golden, Executive Vice President and Chief Financial Officer

January 28, 2002

## Report of Independent Auditors

### **Board of Directors and Shareholders**

#### **Eli Lilly and Company**

We have audited the accompanying consolidated balance sheets of Eli Lilly and Company and subsidiaries as of December 31, 2001 and 2000, and the related consolidated statements of income, cash flows, and comprehensive income for each of the three years in the period ended December 31, 2001. These financial statements are the responsibility of the company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Eli Lilly and Company and subsidiaries at December 31, 2001 and 2000, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2001, in conformity with accounting principles generally accepted in the United States.

*Ernst & Young LLP*

Indianapolis, Indiana

January 28, 2002

## Board of Directors

Sidney Taurel

*Chairman of the Board, President, and Chief Executive Officer*

Steven C. Beering, M.D. <sup>2,5,6</sup>

*President Emeritus, Purdue University*

Sir Winfried F. W. Bischoff <sup>1,3,4</sup>

*Chairman, Citigroup Europe*

Martin S. Feldstein, Ph.D. <sup>1,3</sup>

*President and Chief Executive Officer, National Bureau of Economic Research, and George F. Baker Professor of Economics, Harvard University*

George M. C. Fisher <sup>2,5,6</sup>

*Retired Chairman of the Board and Chief Executive Officer, Eastman Kodak Company*

Alfred G. Gilman, M.D., Ph.D. <sup>3,6</sup>

*Regental Professor and Chairman, Department of Pharmacology, The University of Texas Southwestern Medical Center*

Charles E. Golden <sup>4</sup>

*Executive Vice President and Chief Financial Officer*

Karen N. Horn, Ph.D. <sup>2,4,5</sup>

*President, Global Private Client Services, and Managing Director, Marsh, Inc.*

Franklyn G. Prendergast, M.D., Ph.D. <sup>1,3,6</sup>

*Edmond and Marion Guggenheim Professor of Biochemistry and Molecular Biology, Professor of Molecular Pharmacology and Experimental Therapeutics, and Director, Mayo Clinic Cancer Center*

Kathi P. Seifert <sup>1,3,4</sup>

*Executive Vice President, Kimberly-Clark Corporation*

August M. Watanabe, M.D. <sup>6</sup>

*Executive Vice President, Science and Technology*

Alva O. Way <sup>1,2,5</sup>

*Chairman of the Board, IBJ Whitehall Bank & Trust Company*

### Board Committees

1 Audit Committee

2 Compensation Committee

3 Public Policy Committee

4 Finance Committee

5 Directors and Corporate Governance Committee

6 Science and Technology Committee

## Senior Management

Sidney Taurel <sup>A, B</sup>

*Chairman of the Board, President, and Chief Executive Officer*

Charles E. Golden <sup>A, B</sup>

*Executive Vice President and Chief Financial Officer*

Pedro P. Granadillo <sup>A, B</sup>

*Senior Vice President*

Rebecca O. Kendall <sup>A, B</sup>

*Senior Vice President and General Counsel*

John C. Lechleiter, Ph.D. <sup>A, B</sup>

*Executive Vice President, Pharmaceutical Products and Corporate Development*

Gerhard N. Mayr <sup>A, B</sup>

*Executive Vice President, Pharmaceutical Operations*

August M. Watanabe, M.D. <sup>A, B</sup>

*Executive Vice President, Science and Technology*

Scott A. Canute <sup>B</sup>

*Vice President, Manufacturing*

Bryce D. Carmine <sup>B</sup>

*President, Primary Care Products*

Newton F. Crenshaw <sup>B</sup>

*Vice President, e.Lilly*

Frank M. Deane, Ph.D. <sup>B</sup>

*Vice President, Quality*

Richard D. DiMarchi, Ph.D. <sup>B</sup>

*Group Vice President, Lilly Research Laboratories*

W. Roy Dunbar <sup>B</sup>

*Vice President and Chief Information Officer*

James A. Harper <sup>B</sup>

*Group Vice President, Global Marketing and Sales*

Patrick C. James <sup>B</sup>

*President, Elanco Animal Health*

Elizabeth H. Klimes <sup>B</sup>

*President, Diabetes and Growth Disorders Products*

Steven M. Paul, M.D. <sup>B</sup>

*Group Vice President, Lilly Research Laboratories*

Richard D. Pilnik <sup>B</sup>

*President, European Operations*

Gino Santini <sup>B</sup>

*President, U.S. Operations*

Deborah L. Steelman <sup>B</sup>

*Vice President, Corporate Affairs*

Lorenzo Tallarigo, M.D. <sup>B</sup>

*President, Intercontinental Operations*

Albertus J. van den Bergh <sup>B</sup>

*President, Neuroscience Products*

Alfonso G. Zulueta <sup>B</sup>

*President, Oncology and Critical Care Products*

### Senior Management Committees

A Policy Committee

*Establishes corporate strategy and policy and ensures compliance*

B Senior Management Forum

*Implements corporate strategies and ensures corporate performance, identifies issues and opportunities, and facilitates communication and learning*

# Corporate Information

## Annual meeting

The annual meeting of shareholders will be held at the Hilbert Circle Theatre, 45 Monument Circle, Indianapolis, Indiana, on Monday, April 15, 2002. Formal notice of the meeting, together with the proxy statement and form of proxy, is sent to each holder of common stock.

## 10-K and 10-Q reports

The company's Annual Report to the Securities and Exchange Commission on Form 10-K will be available in April. Quarterly reports on Form 10-Q are also available upon request. Anyone wishing to receive copies of the company's 10-K or 10-Q reports may send a written request to:

Eli Lilly and Company

P.O. Box 88665

Indianapolis, Indiana 46208-0665

or access these reports electronically on the Internet. Lilly's address on the Internet is <http://www.lilly.com>

## Stock listings

Eli Lilly and Company common stock is listed on the U.S. New York and Pacific stock exchanges and the London, Tokyo, and Swiss stock exchanges. NYSE ticker symbol: LLY

## Transfer agent and registrar

Wells Fargo Shareowner Services

Mailing address:

Shareowner Relations Department

P.O. Box 64854

St. Paul, Minnesota 55164-0854

Overnight address:

161 North Concord Exchange

South St. Paul, Minnesota 55075

Telephone: 1-800-833-8699

E-mail: [stocktransfer@wellsfargo.com](mailto:stocktransfer@wellsfargo.com)

Internet: [http://www.wellsfargo.com/com/shareowner\\_services](http://www.wellsfargo.com/com/shareowner_services)

## Dividend reinvestment and stock purchase plan

Wells Fargo Shareowner Services administers the Shareowner Service Plus Plan, which allows registered shareholders to purchase additional shares of Lilly common stock through the automatic investment of dividends. The plan also allows registered shareholders and new investors to purchase shares with cash payments, either by check or by automatic deductions from checking or savings accounts. The minimum initial investment for new investors is \$1,000. Subsequent investments must be at least

\$50. The maximum cash investment during any calendar year is \$150,000. Please direct inquiries concerning the Shareowner Service Plus Plan to:

Wells Fargo Shareowner Services

Shareowner Relations Department

P.O. Box 64854

St. Paul, Minnesota 55164-0854

Telephone: 1-800-833-8699

## Online delivery of proxy materials

Registered shareholders may now elect to receive annual reports and proxy materials online. This reduces paper mailed to the shareholder's home and saves the company printing and mailing costs. To enroll, go to <http://proxyonline.lilly.com> and follow the directions provided.

## Trademarks

Actos® (pioglitazone hydrochloride, Takeda), Takeda

Alimta® (pemetrexed, Lilly)

Axid® (nizatidine, Lilly), Reliant Pharmaceuticals LLC

Ceclor® (cefaclor, Lilly)

Cialis™ (tadalafil, ICOS), Lilly-ICOS LLC

Coban® (monensin sodium, Elanco)

Darvon® (propoxyphene hydrochloride, Lilly)

Dobutrex® (dobutamine hydrochloride, Lilly)

Evista® (raloxifene hydrochloride, Lilly)

Forteo™ (teriparatide, Lilly)

Gemzar® (gemcitabine hydrochloride, Lilly)

Humalog® (insulin lispro, Lilly)

Humalog® Mix75/25® (75% insulin lispro protamine suspension  
25% insulin lispro injection of recombinant DNA origin, Lilly)

Humatrope® (somatropin of recombinant DNA origin, Lilly)

Humulin® (human insulin of recombinant DNA origin, Lilly)

Keflex™ (cephalexin, Dista)

Lorabid® (loracarbef, Lilly), King Pharmaceuticals

Micotil® (tilmicosin, Elanco)

Nebcin® (tobramycin sulfate, Lilly)

Permax® (pergolide mesylate, Lilly)

Prozac® (fluoxetine hydrochloride, Lilly)

ReoPro® (abciximab, Centocor), Lilly

Rumensin® (monensin sodium, Elanco)

Sarafem™ (fluoxetine hydrochloride, Lilly)

Surmax® (avilamycin, Elanco)

Tylan® (tylosin, Elanco)

Vancocin® (vancomycin hydrochloride, Lilly)

Xigris™ (drotrecogin alfa (activated), Lilly)

Zyprexa® (olanzapine, Lilly)

Actos® is a trademark of Takeda Chemical Industries, Ltd.

Axid® is a trademark of Reliant Pharmaceuticals LLC.

Cialis™ is a trademark of Lilly-ICOS LLC.

EVA® is a trademark of Stern Stewart & Co.

Lorabid® is a trademark of King Pharmaceuticals, Inc.

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Answers That Matter.