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GILEAD SCIENCES INC

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HIS CHANGES EVERYTHING.



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2001 ANNUAL REPORT

increasing the number of individuals who are able to

of HIV-infected individuals in an increasingly complex

treatment landscape. This is critical to

the power of biopharmaceutical science to develop

medicines to treat life-threatening diseases worldwide.

Table of Contents

TABLE OF CONTENTS

Letter to Stockholders	
Milestones/Financial Highlights	6
The Viread Launch	8
Product Portfolio	12
Late-Stage Candidates	16
Refocusing on Anti-Infectives	20
Corporate Directory and Information	24

TO OUR STOCKHOLDERS, EMPLOYEES AND FRIENDS:

2001 was a defining year for Gilead in many ways. We reaffirmed our commitment to the fight against life-threatening diseases worldwide. Our research and product development teams made critical breakthroughs resulting in the approval of Viread™ (tenofovir disoproxil fumarate), a novel therapeutic that addresses significant unmet medical needs. We outperformed at the commercial level, demonstrating to customers and investors our ability to launch a global brand efficiently and adeptly. And we earned even greater recognition for the company's innovative medicines and thriving worldwide enterprise.

For Gilead, 2001

We introduced an urgently needed new treatment for HIV,

was the kind of

recorded remarkable progress in our drug development programs,

year that changes

sharpened our focus on the anti-infective arena and guided the

everything.

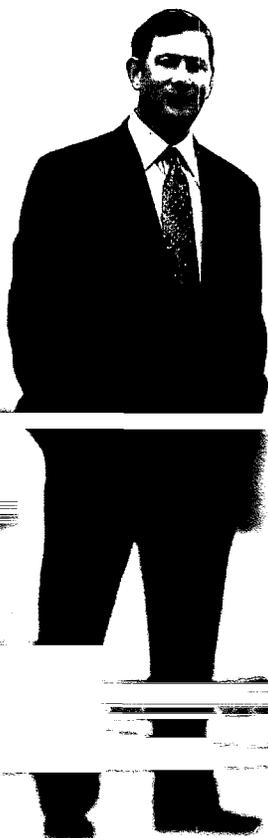
company toward profitability in 2002.

In fact, 2001 was a year of rapid transformation. While our foundation of therapeutic expertise and scientific excellence has remained the same, the year's accomplishments have improved both near-term and long-range prospects for Gilead. This report outlines our major achievements for 2001 and the opportunities we will leverage in the months and years ahead.

THE LAUNCH OF VIREAD FOR THE TREATMENT OF HIV.

With the October 2001 launch of Viread, the first nucleotide analogue to be approved for the treatment of HIV, Gilead did more than bring a much-needed drug to market. We set new standards in HIV drug development by introducing an innovative class of antiretroviral drugs – and in doing so, solidified our position as a leader in the antiviral market.

In many ways, the launch of Viread represents our unique drug development capabilities and our pursuit of therapeutics designed to significantly advance patient care. Leveraging our unparalleled expertise in nucleotides, scientists at Gilead engineered Viread's molecular structure with chemical properties that we believe confer definitive therapeutic advantages.



John C. Martin, PhD
President and Chief Executive Officer
Gilead Sciences

Our strategically designed clinical trials yielded compelling data that demonstrate both the significant and durable potency of Viread and a safety profile comparable to placebo. In the United States, where Viread is broadly indicated for the treatment of all patients with HIV when taken in combination with other antiretrovirals, the Food and Drug Administration (FDA) and national treatment advocates commended Gilead for studying the drug in the most difficult-to-treat patients. Our goal was to serve those HIV patients with the most urgent and demanding unmet medical needs. The FDA also publicly acknowledged the strength of our virology data, which define the favorable resistance profile of Viread and contribute to a package insert that contains more virology data than any other currently marketed antiretroviral.

We are particularly proud of our scientists, who have demonstrated that to meet the complex needs of today's patients, new anti-HIV therapies must satisfy all major treatment criteria: potent and sustained antiviral activity (even in the face of resistance), dosing convenience and long-term safety. We believe that Viread, with its ability to simplify treatment regimens and make combination therapy more effective and longer lasting, successfully addresses the multiple limitations of many current therapies and has the potential to become a cornerstone of antiretroviral regimens for people living with HIV.

The development of Viread also has proven the expertise of Gilead's international regulatory team. By preparing near-simultaneous regulatory filings, we were able to shorten the historical delay of availability of new antiretrovirals to European markets. During the first quarter of 2002, regulators approved Viread for marketing in the European Union, only nine months after beginning their review of the data – an important industry first that better serves patients.

On behalf of Gilead, I extend our gratitude to the patients and physicians who participated in the Viread clinical studies for helping us to bring this important new medicine to market.

LATE-STAGE INVESTIGATIONAL DRUGS MAKE CLINICAL ADVANCEMENTS.

Simultaneous with U.S. and European regulatory reviews and the subsequent U.S. launch of Viread, Gilead achieved remarkable clinical progress with our late-stage investigational drugs during 2001. As a result, in March 2002 we completed both U.S. and European regulatory filings for marketing approval of adefovir dipivoxil 10 mg for the treatment of chronic hepatitis B virus (HBV) infection, a life-threatening disease affecting more than 350 million people worldwide. We are preparing for the commercial introduction of this drug – potentially our second product launch in only a year's time. We believe that adefovir dipivoxil may provide this patient population with an important new therapeutic option that could overcome the limitations of existing therapies.

Gilead holds worldwide rights to adefovir dipivoxil and plans to market the drug independently in the United States and Europe. We are developing our commercialization strategy for Asia and the rest of the world. While proud of the progress of our early HBV clinical program in the People's Republic of China, we recognize the significant challenges for a company of our size to successfully address Asian markets. Accordingly, we plan to pursue a partnership to complete the development of and commercialize adefovir dipivoxil in Asia.

Early in 2001, Gilead added Cidecin® (daptomycin for injection) to our growing portfolio of anti-infectives. Cidecin is an antibiotic in late-stage development by Cubist Pharmaceuticals for the treatment of serious gram-positive bacterial infections and for which we hold exclusive European marketing rights. Two pivotal trials evaluating Cidecin's safety and efficacy in treating complicated skin and soft tissue infections yielded positive results. Although the primary endpoint was not achieved in a study of the drug for the treatment of community-acquired pneumonia, we still believe that Cidecin has the potential to become an important new treatment option for gram-positive bacterial infections. Gilead currently is in discussions with regulatory authorities in Europe to determine the best path forward in the development of this novel antibiotic.

OUR ANTI-INFECTIVE FRANCHISE IS STRONGER THAN EVER.

In 2001, we sharpened the focus of our business to capitalize on Gilead's leadership in the anti-infective arena, which includes antiviral, antifungal and antibacterial drug discovery, development and commercialization. Chief among our efforts was the fourth-quarter sale of Gilead's oncology assets to OSI Pharmaceuticals in a transaction worth up to \$200 million. Additionally, in the second half of 2001, we licensed our remaining rights under the SELEX® (Systemic Evolution of Ligands through EXponential Enrichment) drug discovery and target validation technologies patent estate to Archemix Corporation for \$17.5 million and sold our interest in Prologo LLC, an oligonucleotide manufacturing joint venture, to Degussa Corporation for \$14.3 million.

The proceeds and cost reductions associated with these divestitures will help strengthen the growth of our anti-infective franchise – through marketing infrastructure enhancements, commitment to anti-infective R&D programs and the in-licensing and acquisition of product candidates.

WE CLOSE IN ON PROFITABILITY.

Net sales in 2001 from the products marketed by Gilead totaled \$191 million, a 28 percent increase over sales in 2000. This growth was driven primarily by sales of AmBisome® (amphotericin B) liposome for injection, which have continued to grow each year since its European launch in 1990. Total revenues for the year were nearly \$234 million, up 20 percent from the previous year. Our revenue growth and the reduction of expenses associated with our oncology programs bolster our stability and change our outlook, giving us the strength to achieve profitability in 2002.

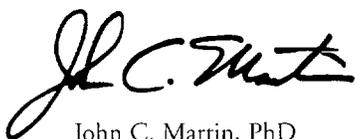
Toward that goal, in early 2001 we successfully renegotiated our rights to Viread and adefovir dipivoxil, reducing future royalty payments and increasing our profit margins. We broadened our stockholder base by completing a two-for-one common stock split in February 2001, and we completed a second two-for-one common stock split in March 2002. Also, on the basis of our stock performance, we were added to the Nasdaq-100 Index in October. These accomplishments represent important milestones as we become a more visible industry force – and as we fulfill our promise to our investors.

GILEAD'S CULTURE INSPIRES THE VERY BEST.

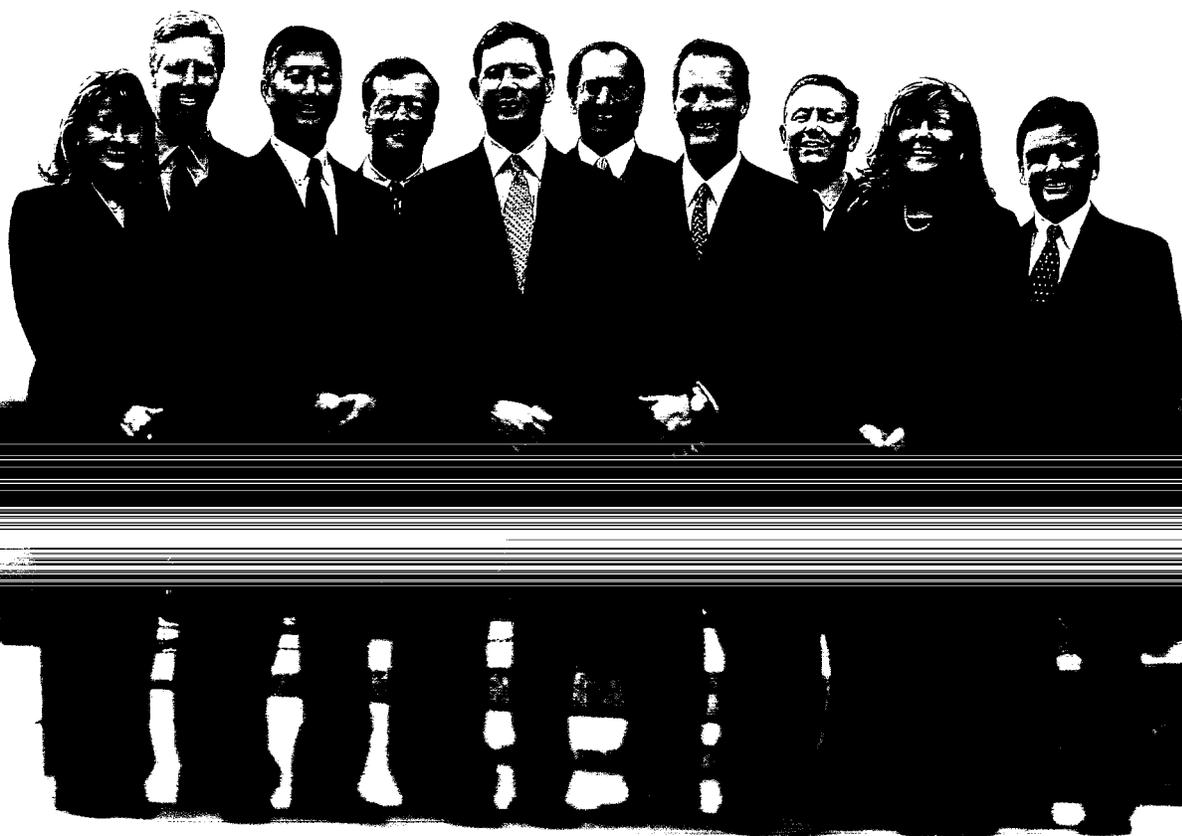
We can be very proud of our achievements in 2001 – around the world, across disciplines, in our laboratories and for physicians and the patients they treat. I would like to thank the people of Gilead – now more than 1,000 strong – for their relentless dedication to integrity, teamwork, accountability and excellence. This past year, as always, you have been Gilead's greatest asset. Thanks to your uncompromising efforts, we will continue our work to advance therapeutics that improve the lives of people suffering from life-threatening diseases.

I also would like to take this opportunity to recognize Mr. James M. Denny, our new Chairman of the Board of Directors, for his continued support, as well as welcome two distinguished additions to our board: Mr. Cordell W. Hull and Mrs. Gayle E. Wilson. I thank you and the entire board for your invaluable service and expert guidance.

2001 indeed was a year of significant growth for Gilead. It was a year in which many of our goals were realized and in which we set the course for our future. I am very pleased to invite you to share with us the successes that lie ahead.



John C. Martin, PhD
President and Chief Executive Officer



Gilead Executive Committee. *Front row (left to right):* Marsha Roberts; Michael K. Inouye; John C. Martin, PhD; Mark L. Perry, JD; Sharon A. Surrey-Barbari.
Back row (left to right): John F. Milligan, PhD; Norbert W. Bischofberger, PhD; Anthony D. Caracciolo; Crispin G. S. Eley, DPhil; William A. Lee, PhD.

<ul style="list-style-type: none"> Initiated early access programs for Viread in the United States and Europe for the treatment of HIV. 	<ul style="list-style-type: none"> Initiated Phase I trials in the People's Republic of China of adefovir dipivoxil for chronic HBV infection.
<ul style="list-style-type: none"> Received reimbursement approval for Tamiflu in Japan (Hoffmann-La Roche). 	<ul style="list-style-type: none"> Announced positive 48-week data from Study 437, a pivotal Phase III trial evaluating adefovir dipivoxil in patients with chronic HBV infection.
<ul style="list-style-type: none"> Signed exclusive European commercialization agreement with Cubist Pharmaceuticals for Cidecin. 	
<ul style="list-style-type: none"> Appointed James M. Denny Chairman of the Board of Directors, replacing Donald H. Rumsfeld. 	<ul style="list-style-type: none"> Sold 49 percent interest in Proligo LLC to Degussa Corporation for \$14.3 million in cash.
<ul style="list-style-type: none"> Announced 74-week efficacy and safety data from Study 907, a pivotal Phase III trial evaluating Viread in treatment-experienced patients with HIV. 	<ul style="list-style-type: none"> Announced positive 48-week data from Study 438, a pivotal Phase III trial of adefovir dipivoxil in patients with precore mutant chronic HBV infection.
<ul style="list-style-type: none"> Resubmitted application in Europe for approval of Viread for the treatment and prevention of influenza A and B in adults and for treatment of children (Hoffmann-La Roche). 	<ul style="list-style-type: none"> Received U.S. Food and Drug Administration approval of Viread for the treatment of HIV when taken in combination with other antiretroviral agents.
<ul style="list-style-type: none"> Implemented two-for-one common stock split. 	<ul style="list-style-type: none"> Launched Viread throughout the United States.
<ul style="list-style-type: none"> Initiated Phase II study of NX 211 in patients with colorectal cancer. 	<ul style="list-style-type: none"> Received recommendation from the Committee for Proprietary Medicinal Products for licensure of Viread for HIV in the 15 member states of the European Union.
<ul style="list-style-type: none"> Presented data from several key studies of adefovir dipivoxil for the treatment of chronic HBV infection. 	<ul style="list-style-type: none"> Appointed Cayle E. Wilson to the Board of Directors.
<ul style="list-style-type: none"> Appointed Cordell W. Hull to the Board of Directors. 	<ul style="list-style-type: none"> Licensed intellectual property rights under the SELEX process patent estate to Archemix Corporation.
<ul style="list-style-type: none"> Submitted New Drug Application for Viread to the U.S. Food and Drug Administration. 	<ul style="list-style-type: none"> Added to the Nasdaq-100 Index.
<ul style="list-style-type: none"> Submitted Marketing Authorisation Application for Viread to the European Medicines Evaluation Agency. 	<ul style="list-style-type: none"> Announced positive 16-week data from Study 461, a Phase III trial evaluating adefovir dipivoxil as monotherapy and in combination with lamivudine (3TC) in patients with lamivudine-resistant chronic HBV infection.
<ul style="list-style-type: none"> Presented data characterizing favorable resistance profile of Viread. 	<ul style="list-style-type: none"> Sold oncology assets to OSI Pharmaceuticals for net proceeds of \$200 million in cash and stock.

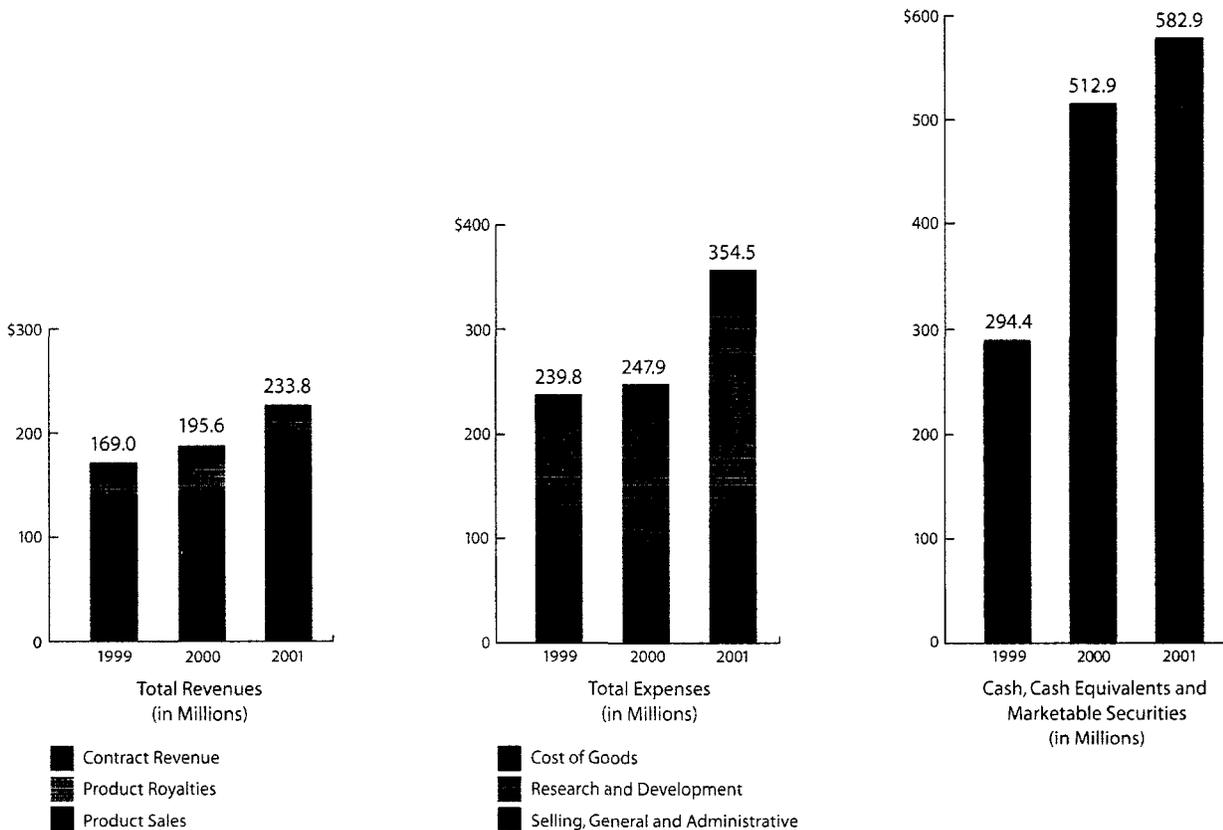
PRICE RANGE OF COMMON STOCK*

2001	High	Low
1st Quarter	\$20.88	\$12.44
2nd Quarter	\$30.98	\$14.41
3rd Quarter	\$31.75	\$22.85
4th Quarter	\$36.84	\$27.28

2000	High	Low
1st Quarter	\$21.25	\$11.19
2nd Quarter	\$19.13	\$10.82
3rd Quarter	\$29.53	\$16.50
4th Quarter	\$27.69	\$15.24

*The table above sets forth for the periods indicated the high and low intra-day sale price per share of our common stock on The Nasdaq Stock Market. On March 8, 2002, the company implemented a two-for-one common stock split. All share and per share amounts for all periods presented have been restated to reflect the March 2002 split and a previous two-for-one common stock split implemented in February 2001. For more information on the company's common stock, please refer to Item 5 in the enclosed Form 10-K.

2001 Financial Highlights



**NOVEL TARGETS, INNOVATIVE DESIGNS AND
NEW STANDARDS OF CARE.**

At Gilead, we make a difference by drawing upon our leadership in virology and our expertise in medicinal chemistry and molecular and cellular biology. We research new compounds, novel mechanisms of action and innovative drug formulations – all to bring advanced therapeutics to people facing life-threatening diseases worldwide.

In 2001, our commitment resulted in the U.S. approval of Viread™ (tenofovir disoproxil fumarate) for the treatment of people infected with the human immunodeficiency virus (HIV), the virus that causes AIDS.

The introduction

Viread is the first and only nucleotide reverse transcriptase inhibitor

of Viread

approved for the treatment of HIV in combination with other antiretrovirals.

dramatically

This next-generation drug combines a potent antiviral effect – even in the

changes the

face of drug resistance – with a favorable safety profile and more convenient

treatment of HIV.

dosing, marking a pivotal advance for people living with this disease.

Belonging to a novel class of antiviral drugs called nucleotide analogues, Viread works by selectively targeting and blocking reverse transcriptase, an enzyme essential for viral replication. Viread is designed to provide greater potency, longer duration of action and better tolerability than currently available anti-HIV treatments.

RESPONDING TO THE URGENT NEED FOR ADVANCED HIV THERAPIES.

It is estimated that more than 40 million people throughout the world are living with HIV, with approximately 90,000 new infections occurring each year in the United States and Europe combined (*Centers for Disease Control and Prevention, June 2001*). Because HIV mutates rapidly, over time the virus becomes increasingly resistant to all existing classes of

regimens designed to suppress it. In fact, according to recent studies, 50 percent of U.S. patients receiving traditional antiretroviral therapy show evidence of viral resistance, a key contributor to treatment failure (D.D. Richman et al. Presented at 41st ICAAC, 2001; Abstr. LB-17).

POSITIVE PIVOTAL DATA CONFIRM THE POTENTIAL OF VIREAD.

In Study 207, a Phase III clinical trial of 550 highly treatment-experienced patients, the addition of Viread 300 mg to existing regimens resulted in a 15 percent reduction in the level of circulating HIV after 24 weeks of treatment. Despite the presence of HIV resistance mutations in more than 70 percent of patients in this study, a reduction in viral load to undetectable levels was demonstrated in 68 percent of study participants over the 24 weeks of the study.



In other clinical studies, Viread has shown an average 1 million viral replication even to resistant strains, and has been associated with a low incidence of resistance development, providing a viable treatment option in combating HIV.

Viread's pharmacokinetic attributes also keep the drug in the body's cells for longer periods of time compared with most other medications. This extended duration of action allows for a manageable schedule of one tablet, once daily, dosing when taken in combination with other antiretrovirals — simplifying typical regimens consisting of numerous pills administered multiple times per day.

Effectively treat HIV, patients must strictly adhere to their antiretroviral regimen. Research shows that regimen adherence below 95 percent may result in viral rebound leading to the production of mutant strains, therefore increasing the likelihood of drug resistance (D. Paterson et al. *Ann Intern Med.* 2000; 133:27-30).



FDA APPROVAL AND OTHER REGULATORY FILINGS.

May 2001, Gilead submitted a New Drug Application (NDA) for Viread to the U.S. FDA and a Marketing Authorisation Application (MAA) to the European Medicines Administration Agency (EMA). The fact that these submissions were made just three days apart marks an unprecedented accomplishment and demonstrates the power of our integrated organization—an organization designed to effect real change through interdisciplinary scientific and regulatory expertise and efficiency.

Viread was granted priority review in the United States and received FDA marketing clearance in late October with the broad indication for the treatment of HIV when taken in combination with other antiretroviral agents. We shipped Viread to pharmacies within days of its approval, rapidly delivering this much-needed new medicine to people living with HIV.

In Europe, Viread received one of the fastest reviews on record for an HIV drug from the Committee for Proprietary Medicinal Products, the scientific advisory panel to the EMA, resulting in a positive recommendation in October 2001. Just four months later, we received the European Commission's approval to market Viread in all 15 member states of the European Union.

Applications for marketing approval also have been submitted in Australia, Canada and Switzerland. We will work closely with regulatory authorities during the coming year to complete filings in countries elsewhere in the world.



Andrew Cheng, MD, PhD
Director, Clinical Research
Gilead Sciences

Emily Beason
Therapeutic Specialist, Northwest Region
Gilead Sciences

OUR COMMITMENT TO THE HIV COMMUNITY.

In partnership with HIV patient advocacy groups and representatives of HIV/AIDS service organizations, Gilead initiated early access programs, ultimately making Viread available to more than 8,000 patients with advanced HIV in the United States, Europe, Australia and Canada.

Gilead is committed to the global fight against HIV/AIDS. We are actively working with government and international health organizations to establish clinical protocols to study Viread in a variety of settings and patient populations in the developing world. Recently, a phase III study was initiated to evaluate a topical microbicide formulation of tenofovir, the active agent in Viread, in preventing the sexual transmission of HIV in patients at a high risk of contracting the virus. This trial, co-sponsored by Gilead and the Division of AIDS, a branch of the U.S. National Institutes of Health, was begun on the basis of animal data demonstrating the ability of tenofovir topical gel to block vaginal transmission of HIV.

Other efforts will include studies of Viread for the prevention of mother-to-child transmission, one of the major causes of HIV in the developing world, and initiation of the first phase III trial evaluating the use of an oral antiretroviral agent in the prevention of HIV transmission in high-risk, uninfected populations. Additionally, we expect to evaluate Viread therapy as part of a combination regimen in clinical trials that will be initiated in Africa. Given Viread's once-daily dosing, strong safety profile and activity against resistant virus, we believe this drug has the potential to play an important role in addressing this global challenge.



Viread, for the treatment of HIV, is designed to provide significant suppression of viral replication – even of resistant viral strains – and to simplify multidrug regimens by providing one-tablet, once-daily dosing when taken in combination with other antiretrovirals.

VIREAD'S IMMEDIATE SUCCESS.

Because Gilead has retained worldwide rights for Viread, this drug represents a vehicle that can transform the company. In the three months following Viread's approval in the United States, more than 24,000 new prescriptions were dispensed – an impressive accomplishment, especially in light of the fact that Viread was launched during the winter holiday season, typically a slow period for introducing prescription medications (*NDCHealth*, 2002).

This immediate success underscores not only the demand for a unique product such as Viread but also the strength and commitment of our commercial organization.

ONGOING CLINICAL STUDIES TO SUPPORT LABEL EXPANSIONS.

Gilead intends to broaden the market for Viread in 2002 by obtaining additional clinical data through the study of the drug in specific combinations with other antiretrovirals. Study 903 is under way to further evaluate Viread in a potential once-daily regimen in treatment-naïve patients with HIV. This blinded trial is designed to compare the treatment regimen of Viread, lamivudine (3TC) and efavirenz with the regimen of stavudine (d4T), lamivudine and efavirenz in 601 treatment-naïve patients in the United States, Europe and South America. Enrollment in the study was completed in January 2001. Gilead also has initiated a program to evaluate Viread in treatment-experienced pediatric patients.



Therapeutic	Indication/Research Area	Status	Marketing Rights
Virad™ <small>(didanosine fumarate)</small>	HIV/AIDS	Approved	Gilead
Ambisome® <small>(amphotericin B liposome for injection)</small>	Systemic Fungal Infections	Approved	Gilead and Fujisawa (U.S.) Fujisawa (Canada) Fujisawa (Japan) and EMEA Other Territories
Amiflu® <small>(amantadine phosphate)</small>	Influenza A and B	Approved	E. Hoffmann-La Roche
Visdite® <small>(ganciclovir injection)</small>	CMV Retinitis/AIDS	Approved	Gilead (U.S.) Bristol-Myers (Outside U.S.)
DaunoXome® <small>(daunorubicin liposome injection)</small>	Kaposi's Sarcoma/AIDS	Approved	Gilead
Adefovir Dipivoxil 10 mg	Chronic Hepatitis B Virus Infection	NDA/MAA	Gilead
Idedcin® <small>(dicloxacillin for injection)</small>	Gram-Positive Bacterial Infections	Phase III	Gilead (Europe) Cubis (Outside Europe)
GS 7340	HIV/AIDS	Phase I	Gilead
Tenofovir Topical Gel	HIV/AIDS	Phase I	Gilead
Small-Molecule Therapeutics	Viral Infections	Research	Gilead

Our newest approved therapeutic – Viread for the treatment of HIV – joins an established portfolio of anti-infectives, which includes a number of category firsts and market leaders.

AMBISOME FOR THE TREATMENT OF SYSTEMIC FUNGAL INFECTIONS.

Approved in 44 countries worldwide, AmBisome® (amphotericin B) liposome for injection is a liposomal formulation of the antifungal drug amphotericin B and is indicated for the treatment of confirmed infections caused by various fungal species. These infections can be life threatening, particularly in patients who have depressed immune systems as a result of aggressive chemotherapy regimens, organ transplantation or infection with HIV. Additionally, AmBisome is used to treat patients who have failed, are refractory to or are intolerant of conventional amphotericin B therapy.

AmBisome was first approved in 1990 in Europe, where it is marketed exclusively by Gilead. Since the introduction of AmBisome, Gilead has consistently grown ex-U.S. revenues for the product year over year. In 2001, we recorded revenues from ex-U.S. sales of the drug of \$146 million, making AmBisome the second largest-selling injectable antifungal and currently our leading marketed product.

In 1997, AmBisome was granted marketing authorization in the United States, where Gilead co-promotes the drug with Fujisawa Healthcare. AmBisome is the first and only amphotericin B product approved in the United States for empiric therapy of presumed fungal infections in patients with low white blood cell counts and who exhibit fever of unknown origin. The drug has been cleared for this expanded indication in 14 countries throughout the world. In 2001, AmBisome royalty revenues paid to Gilead by Fujisawa totaled \$17.1 million.

In head-to-head clinical studies, AmBisome has demonstrated a superior safety profile compared with both conventional amphotericin B and AmBisome's chief liposomal competitor, ABELCET® (amphotericin B lipid complex), for the empiric treatment of febrile neutropenia and cryptococcal meningitis. These critical data help support the continued growth of AmBisome in key markets.

On the horizon, Gilead anticipates a challenge from the introduction of two new competitive products in the United States and Europe. We plan to protect our brand advantage by strengthening AmBisome's data package through additional clinical studies and marketing initiatives designed to increase physician awareness of the proven benefits of AmBisome therapy.



AmBisome, the leading liposomal formulation of amphotericin B for systemic fungal infections, has been used in more than 200,000 patients worldwide since its introduction in 1990.

TAMIFLU FOR THE TREATMENT AND PREVENTION OF INFLUENZA A AND B.

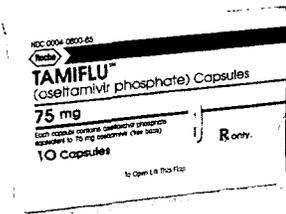
Tamiflu® (oseltamivir phosphate) is a neuraminidase inhibitor for the treatment and prevention of all common strains of influenza (types A and B). Discovered by Gilead and brought to market by F. Hoffmann-La Roche, our worldwide development and marketing partner, Tamiflu is the first and only approved neuraminidase inhibitor available in both convenient pill and liquid suspension form. It has been the number one prescribed neuraminidase inhibitor for influenza A and B in the United States since its launch in 1999 and now is approved in 44 countries worldwide.

Neuraminidase inhibitors belong to a novel class of drugs that work by attacking the influenza virus itself – targeting and blocking the action of an enzyme necessary for viral replication – not merely by masking symptoms.

Each year in the United States alone, up to 40 million people develop influenza, or the flu. About 100,000 of these become hospitalized, and up to 20,000 people die from this infection and its complications (*World Health Organization, 2001*). The use of previous influenza treatments has been limited because of their lack of activity against all strains of the virus, their adverse side effects and the rapid development of viral resistance.

Tamiflu was first approved in 1999 in the United States for treatment of adults. Then, in late 2000, the indication was broadened to include prevention in adults and treatment in children one year and older. In the first quarter of 2001, Tamiflu gained approval in Japan for use as treatment in adults. Applications for adult prevention and pediatric treatment are currently under review in that country. In March 2002, F. Hoffmann-La Roche announced that the Committee for Proprietary Medicinal Products, the scientific advisory panel to the European Medicines Evaluation Agency, recommended the marketing approval of Tamiflu in the 15 member states of the European Union for treatment and prevention of influenza in adults and treatment in children one year and older. A final decision from the European Commission is expected later this year.

After just three seasons of the drug's availability, Tamiflu leads the neuraminidase inhibitor market with an approximately 95 percent share. As of March 2002, Tamiflu also claimed more than 54 percent of the overall influenza antiviral market during the 2001-2002 flu season (*F. Hoffmann-La Roche*).



Tamiflu, for the treatment and prevention of influenza A and B, is the first and only neuraminidase inhibitor available in both pill and liquid form.

VISTIDE FOR THE TREATMENT OF AIDS-RELATED CMV RETINITIS.

Vistide® (cidofovir injection) is an antiviral approved for the treatment of cytomegalovirus (CMV) retinitis in AIDS patients. If left untreated, this debilitating opportunistic infection often leads to blindness. With a dosing schedule of one infusion every two weeks, Vistide offers an effective and convenient option to treatments requiring daily administration. Vistide is marketed in the United States by Gilead and internationally by Pharmacia Corporation.

Cidofovir, the active agent in Vistide, gained additional visibility during the year following terrorist activities that raised concerns about the potential use of smallpox as a biological weapon. As the U.S. government initiated studies in humans to determine whether diluted doses of the existing stockpile of smallpox vaccine could provide adequate protection for the country's populace, many experts turned their attention to the wide-spectrum antiviral activity of cidofovir.

In laboratory tests conducted in collaboration with the National Institute of Allergy and Infectious Diseases (NIAID), cidofovir has demonstrated potent antiviral activity against all 30 strains of smallpox, a life-threatening infectious disease that essentially was eradicated 25 years ago. In the current NIAID studies, cidofovir can be used as a treatment for trial volunteers who develop vaccinia, a potential adverse reaction following vaccination with the smallpox vaccine. Additionally, the U.S. National Institutes of Health holds an Investigational New Drug Application that allows for the emergency use of cidofovir in the event of a smallpox outbreak.



Vistide, for the treatment of AIDS-related CMV retinitis, is an antiviral that suppresses CMV replication by selective inhibition of viral DNA synthesis.

DAUNOXOME FOR THE TREATMENT OF AIDS-RELATED KAPOSI'S SARCOMA.

DaunoXome® (daunorubicin citrate liposome injection) is a liposomal formulation of the anticancer agent daunorubicin for the treatment of advanced AIDS-related Kaposi's sarcoma, an illness that results in groups of blood vessel tumors that cause lesions to skin tissue. The drug is approved in more than 20 countries and remains the only product to be approved in the United States as a first-line cytotoxic therapy for this potentially life-threatening illness. DaunoXome is marketed worldwide by Gilead and a network of specialty distributors.



DaunoXome is the only cytotoxic to have received FDA clearance as a first-line chemotherapy agent for the treatment of advanced AIDS-related Kaposi's sarcoma.

ADEFOVIR DIPIVOXIL FOR THE TREATMENT OF CHRONIC HBV INFECTION.

Approximately 350 million people around the world are chronically infected with HBV. Hepatitis B attacks the liver and can cause cirrhosis (scarring of the liver), liver failure and primary liver cancer (hepatocellular carcinoma). An estimated one million people die annually from complications of chronic HBV infection, making this disease the tenth leading cause of death worldwide (*World Health Organization, 2000*).

Remarkable clinical

Following the release of positive data from two pivotal Phase III trials, Gilead

progress enhances

now prepares for the commercialization of adefovir dipivoxil, our promising

the immediate

antiviral for chronic HBV infection. This innovative medicine could set

potential of our

new therapeutic standards through its unique combination of attributes –

late-stage pipeline.

potency, durability of action, dosing convenience and tolerability.

Clinical experience has demonstrated that the currently approved therapeutic options in the fight against chronic HBV infection have significant limitations. Synthetically produced interferons, for example, benefit less than half of the patients with chronic HBV infection and can lead to debilitating side effects. Further, the virus has shown the ability to develop resistance to the antiviral product lamivudine (3TC) in nearly a quarter of patients within one year of treatment and in up to 67 percent of patients after four years of treatment (*T Chang et al. Antivir Ther. 2000; 5:4*).

APPLYING OUR LEADERSHIP IN NUCLEOTIDE ANALOGUE TECHNOLOGY.

Adefovir dipivoxil is a nucleotide analogue designed to work by blocking HBV DNA polymerase, an enzyme essential for the replication of HBV. The drug belongs to a novel class of therapeutics designed for selective and potent antiviral activity, sustained efficacy and

improved dosing convenience. In clinical studies to date, the histologic response, safety profile and tolerability of adefovir dipivoxil, combined with the ease of its one-tablet, once-daily administration, suggest that the drug could represent a powerful new treatment option.

POSITIVE RESULTS IN PIVOTAL PHASE III TRIALS.

In June 2001, Gilead announced positive results from Study 437, the first of two pivotal Phase III trials evaluating once-daily adefovir dipivoxil versus placebo in patients with chronic HBV infection. From this study of 515 predominantly treatment-naïve patients, data analyses revealed a significant improvement in liver histology in patients receiving adefovir dipivoxil, meeting the study's primary endpoint. Additionally, treatment with adefovir dipivoxil for 48 weeks resulted in a 99.97 percent reduction in the amount of circulating virus.

In September 2001, we announced data from the second pivotal trial, Study 438, which had similarly positive results. At 48 weeks, treatment with adefovir dipivoxil, when used as monotherapy in patients chronically infected with precore mutant HBV (an emerging strain of the virus that has mutated to stop producing the hepatitis B "e" antigen), resulted in a significant improvement in liver histology, the study's primary endpoint, and a 99.99 percent reduction of circulating virus. These are the most encouraging results reported to date in the treatment of precore mutant chronic HBV infection.

HIGHLY EFFECTIVE, EVEN AGAINST RESISTANT HBV STRAINS.

Positive data also were reported in November 2001 from Study 435, which evaluated treatment with adefovir dipivoxil in 131 patients with lamivudine-resistant chronic HBV infection who are at risk of mortality and have received or are awaiting a liver transplant. In the study, adefovir dipivoxil demonstrated sustained viral load reductions for up to 48 weeks. Additionally, an analysis of resistance data from the study showed that HBV remained sensitive to adefovir dipivoxil *in vitro* regardless of the patterns of genetic mutations associated with lamivudine resistance. These are very important data showing that treatment with adefovir dipivoxil may provide favorable clinical outcomes for liver transplant patients with chronic HBV infection that is resistant to the only viable, commercially available antiviral (lamivudine) and who are at risk of disease progression.

Also in the third quarter of 2001, positive results were published in a prestigious medical journal from an independent open-label pilot study (*Y Benhamou et al. Lancet. 2001; 358:718-723*). These data demonstrated that over 48 weeks, adefovir dipivoxil is

Shelly Xiong, PhD
Senior Research Scientist, Clinical Virology
Gilead Sciences



effective in reducing the amount of circulating HBV in patients co-infected with HIV and lamivudine-resistant HBV. Approximately 15 percent of those diagnosed with HIV are co-infected with HBV (*Isis Research, HIV in the USA, 2001a data*).

Preliminary results from an ongoing 48-week Phase III clinical trial, Study 461, also were released during the fourth quarter of 2001. Study 461 is designed to evaluate the safety and efficacy of adefovir dipivoxil alone and in combination with lamivudine. Patients in this study have lamivudine-resistant chronic HBV infection and compensated liver disease. Results have demonstrated that after 16 weeks of treatment, patients receiving either adefovir dipivoxil alone or adefovir dipivoxil and lamivudine in combination showed similar reductions in the level of HBV DNA. These results are significant for two reasons: First, adefovir dipivoxil demonstrated significant antiviral activity in patients with lamivudine resistance. Second, the addition of lamivudine to adefovir dipivoxil resulted in no added therapeutic benefit for patients over the first 16 weeks of the study.

In most cases, the treatment of chronic HBV infection requires continual administration of antiviral medication. Therefore, it is important to devise new treatments that are slow to or do not give rise to the development of resistance. In all clinical trials of this drug conducted to date, no specific HBV mutations associated with resistance to adefovir dipivoxil have been identified, even in patients who have undergone more than two and a half years of treatment.

For HIV-infected patients, the need for new therapeutics to treat chronic HBV infection is real and immediate. The limitations of currently available treatments, including issues of modest efficacy and drug resistance, are particularly concerning for patients vulnerable to this life-threatening disease. Gilead is a global industry leader in the pursuit of developing a powerful and novel therapy that will address these concerns."

- Robert G. Gish, MD
Medical Director, Liver Transplant Program
Pacific Hepatology and Gastroenterology
California Pacific Medical Center

REGULATORY FILINGS COMPLETED IN THE UNITED STATES AND EUROPE.

On the basis of the quality of our pivotal data, we filed for regulatory approval in both the United States and Europe in March 2002. Also in the first quarter of 2002, we initiated an early access program in the United States and established plans for programs in Canada, Australia and countries in Europe to provide adefovir dipivoxil to patients with lamivudine-resistant chronic HBV infection. In France, Gilead has been providing the drug through a limited early access program since July 2001.

in the Peoples Republic of China, where an estimated 110 to 170 million people are living with chronic HIV infection (*Asian Liver Center at Stanford University*). Gilead was granted Class 1 designation in December 2000. Phase I trials were initiated there in June 2001. We anticipate commencing Phase II/III studies during 2002, most likely in collaboration with a marketing partner. Although we are seeking a partner for Asia, we intend to maintain our exclusive marketing rights for tenofovir disoproxil in the United States and Europe.

PROGRESS WITH OTHER LATE-STAGE CANDIDATES.

To expand the market strength of our anti-infective franchise, we have pursued the addition of innovative late-stage product candidates to our portfolio. In January 2001, Gilead and Cubist Pharmaceuticals signed a licensing agreement granting Gilead exclusive European commercialization rights to Cubist's Phase III investigational antibacterial drug Cidecin® (daptomycin for injection) and an oral formulation of daptomycin. The strength of our international commercialization infrastructure – especially our proven record of sales and marketing performance and our experience with European regulatory authorities – has made us an attractive alliance partner for Cubist.

CIDECIN FOR SERIOUS GRAM-POSITIVE BACTERIAL INFECTIONS.

Cidecin, the first in a new class of investigational antibacterial drugs called lipopeptides, is being developed by Cubist to treat serious and potentially life-threatening infections caused by gram-positive pathogens.

The dramatic increase in the number of bacterial strains resistant to even the most potent antibiotics available, such as vancomycin, has created the need to reestablish a strong last line of therapeutic defense. Cidecin brings new hope by exhibiting the unique ability *in vitro* to rapidly kill gram-positive bacteria, including those resistant to current therapies.

PIVOTAL TRIAL RESULTS AND REGULATORY FILING STRATEGIES.

In late October, Cubist completed Study 9801, their second pivotal Phase III clinical trial, and announced that the company met all endpoints in the program, which examined the safety and efficacy of Cidecin in the treatment of complicated skin and soft tissue infections (cSST) caused by gram-positive bacteria. The company had presented positive data from their first Phase III trial, Study 9901, in the first quarter of 2001.

In January 2002, Cubist announced preliminary results from the first of their two pivotal Phase III trials investigating Cidecin for the treatment of community-acquired pneumonia. These results did not meet the study's primary endpoint of demonstrating non-inferiority to an active comparator agent. In March 2002, Cubist reaffirmed their commitment to file for approval in the United States by year-end for the indication of cSST. In parallel, Gilead is evaluating the need for additional studies in other patient populations to support European regulatory requirements for marketing approval. We do not expect to file a marketing application in Europe during 2002.

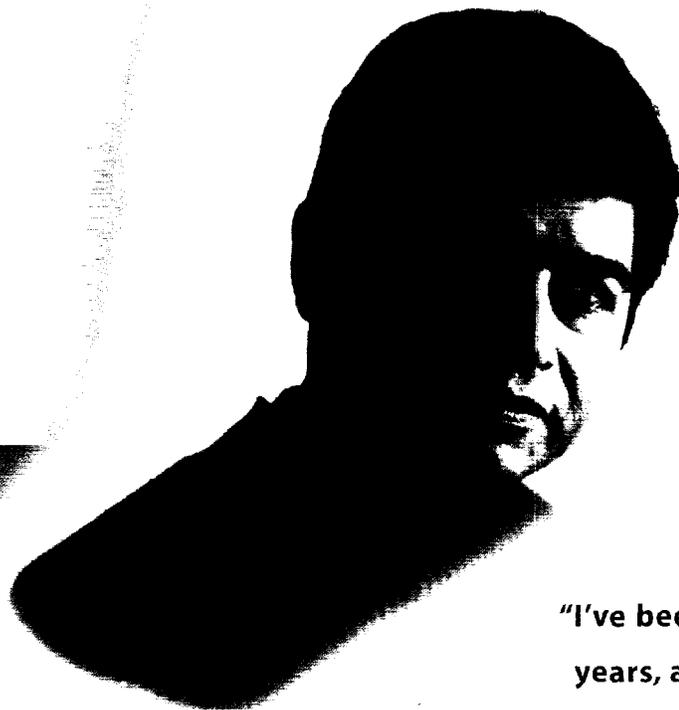
FOLLOWING A STRATEGIC PLAN.

From our inception, Gilead has followed a strategic course designed to take innovative compounds from discovery in the laboratory to leadership in global markets. We have been steadfast in our commitment to world-class research, providing therapeutic advances and rewards for investors. Our disciplined business approach has guided us in our scientific pursuits, corporate development, operations management and marketing efforts. And the same approach is the dynamic force that will help us achieve our full potential.

In 2001, we completed several critical initiatives that have put us ahead of schedule in our drive toward profitability in 2002. We streamlined our enterprise to secure the competitiveness of our anti-infective franchise. We reinforced our independent sales and marketing infrastructure to maximize the commercial success of our products. And we continued to invest in our early-stage pipeline to manage our enduring growth.

THE SALE OF OUR ONCOLOGY ASSETS ADVANCES OUR MISSION.

In December 2001, we sold our oncology assets to OSI Pharmaceuticals of Melville, New York in a transaction worth up to \$200 million in cash and stock. The sale of assets included our entire Boulder, Colorado facility and exclusive worldwide rights to our oncology pipeline—consisting of NX 211, the most advanced candidate now in Phase II trials, and Phase I compounds GS 7836 and GS 7904L.



"I've been with Gilead for over nine years, and still, I go home proud every day knowing I'm part of a company that makes a real difference in the lives of patients who benefit from our drugs."

**- Miguel Ramirez
Operations
Gilead Sciences**

In this transaction, Gilead received \$130 million in cash and 924,984 shares of OSI common stock. Additionally, we are entitled to receive up to \$30 million in either cash or a combination of cash and OSI common stock on the basis of the achievement of certain NX 211-related milestones. Under the terms of a manufacturing agreement with OSI, Gilead will continue to produce liposomal formulations of NX 211 and GS 7904L at our manufacturing facility in San Dimas, California.

ADDITIONAL ACTIVITIES AUGMENT OUR FINANCIAL RESOURCES.

In October, we elected to out-license our remaining rights under the SELEX® (Systemic Evolution of Ligands through EXponential Enrichment) process patent estate, licensing all remaining intellectual property rights to Archemix Corporation of Cambridge, Massachusetts. SELEX selection technologies offer a broad range of applications in therapeutic drug discovery and target validation. In this transaction, Archemix agreed to pay Gilead a total of \$17.5 million in cash – \$9.0 million of which was received in 2001 and \$8.5 million to be paid in 2002 – as well as warrants to purchase stock in Archemix. Gilead has retained its nonexclusive right to utilize these technologies for internal research purposes.

Additionally, in August we sold our 49 percent interest in Proligo LLC to Degussa Corporation of Parsippany, New Jersey. Proligo was a joint venture of Gilead and SKW Americas and focused on the development of nucleotides for genomic and proteomic applications.

SUBSTANTIAL COMMITMENT TO OUR CORE BUSINESS

In little more than a decade, Gilead has brought to market five important first-in-class therapies for life-threatening diseases worldwide. Today, we continue to invest in efficient research and development organizations, leveraging our unique expertise in small molecule medicinal chemistry to explore innovative antiviral, antifungal and immunology therapies.

The strategic diversities we implemented in 2001 support our high-priority therapeutic platforms. They have preserved our cash position and a focused R&D portfolio, free of the distractions associated with oncology assets. They have increased leverage to build and commercialize our pipeline of next-generation therapies.

OUR TEAM HAS STRENGTHENED OUR SALES AND COMMERCIALIZATION CAPABILITIES

Over the past several years, we have built the foundation of our specialized sales and marketing infrastructure, including our commercial infrastructure. Our commercialization infrastructure is a significant competitive advantage for our size. Perhaps most notably, it allows us to commercialize our pipeline of first-in-class therapies while retaining commercialization rights to our pipeline. This strategic advantage will be a key driver of our future growth.

We have also strengthened our sales and marketing capabilities in the United States and Europe. We reorganized our sales and marketing organizations for greater efficiency and reduced costs. European medical representatives are now in place. This facility provides specialized medical, marketing and advisory services to support the company's operations outside the United States.

In the United States, we have implemented a number of promotional activities to build the brand and increase awareness of our therapies in the United States and Europe. We also will implement high-impact strategies in anticipation of the launch of our new therapies. Additional programs will be established to support the launch of our therapies and to protect its international market position.

Corporate Directory and Information

BOARD OF DIRECTORS

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George P. Shultz, PhD
Distinguished Fellow, Hoover Institution,
Stanford University

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Ralph M. Parsons Foundation

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Vice President,
Sales and Marketing, Americas

Michael Wulfsohn, MD, PhD
Vice President, Biometrics

Taiyin Yang, PhD
Vice President,
Pharmaceutical Development
and Manufacturing

EQUAL OPPORTUNITY EMPLOYER

Gilead Sciences is an equal opportunity employer. Working together, we benefit from the unique ideas and skills that each individual contributes. We value different perspectives, styles and approaches to our work, viewing our differences as a catalyst for innovation that enables us to reach higher levels of excellence. For these reasons, we strive to enrich the diversity of our workforce in the way we recruit, retain and develop our people.

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2001

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File No. 0-19731

GILEAD SCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

333 Lakeside Drive, Foster City, California
(Address of principal executive offices)

94-3047598

(I.R.S. Employer Identification No.)

94404

(Zip Code)

Registrant's telephone number, including area code: **650-574-3000**

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT: NONE

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT:

COMMON STOCK \$.001 PAR VALUE

(Title of Class)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (Section 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

The aggregate market value of the voting stock held by non-affiliates of the Registrant based upon the closing price of the Common Stock on the Nasdaq Stock Market on February 28, 2002 was \$4,668,800,000*.

The number of shares outstanding of the Registrant's Common Stock on February 28, 2002 was 193,999,216. **

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of Registrant's Definitive Proxy Statement filed with the Commission pursuant to Regulation 14A in connection with the 2002 Annual Meeting are incorporated by reference into Part III of this Report.

* Based on a closing price of \$35.23 per share. Excludes 61,476,550 shares of the Registrant's Common Stock held by executive officers, directors and stockholders whose ownership exceeds 5% of the Common Stock outstanding at February 28, 2002. Exclusion of such shares should not be construed to indicate that any such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the Registrant or that such person is controlled by or under common control with the Registrant.

** On February 22, 2001 and on March 8, 2002, the Registrant implemented two-for-one stock splits in the form of stock dividends. All share and per share amounts for all periods presented have been restated to reflect both of these splits.

PART I

ITEM 1. BUSINESS

Forward-Looking Statements and Risk Factors

This report includes forward-looking statements. In particular, statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are contained or incorporated by reference in this report. We have based these forward-looking statements on our current expectations about future events. While we believe these expectations are reasonable, such forward-looking statements are inherently subject to risks and uncertainties, many of which are beyond our control. Our actual results may differ materially from those suggested by these forward-looking statements for various reasons, including those discussed in this report under the heading "Risk Factors" at page 31. Given these risks and uncertainties, you are cautioned not to place undue reliance on such forward-looking statements. The forward-looking statements included in this report are made only as of the date hereof. We do not undertake and specifically decline any obligation to update any such statements or to publicly announce the results of any revisions to any of such statements to reflect future events or developments.

Overview

We, Gilead Sciences, Inc., are an independent biopharmaceutical company that discovers, develops and commercializes therapeutics to advance the care of patients suffering from life-threatening diseases worldwide. We have five marketed products and focus our research and clinical programs on anti-infectives, including antivirals, antifungals and antibacterials. We are headquartered in Foster City, California and have marketing operations in ten countries, including the United States, Australia and eight European countries. We endeavor to grow our existing portfolio of products through proprietary clinical development programs, internal discovery programs and an active product acquisition and in-licensing strategy. Our internal discovery activities include identification of new molecular targets, target screening and medicinal chemistry. We also have expertise in liposomal drug delivery technology that we use to develop drugs that are safer, easier for patients to tolerate and more effective.

We were incorporated in Delaware on June 22, 1987.

We have five products that are currently marketed in the U.S. and in other countries worldwide.

- Viread™ is approved for sale in the U.S. for use in combination with other antiretroviral agents for the treatment of HIV infection and in the European Union for use in combination with other antiretroviral agents for the treatment of HIV infection in patients who are experiencing early virological failure.
- AmBisome® is approved for sale in 43 countries for the treatment of life-threatening fungal infections and in some of these countries for prevention of such infections. We market AmBisome in the major countries of Europe and co-promote AmBisome in the U.S. with Fujisawa Healthcare, Inc.
- Tamiflu® is sold by our corporate partner Hoffmann-La Roche in more than 40 countries for the treatment of influenza and is approved in the U.S. for the prevention of influenza.
- Vistide® is approved for sale in 25 countries for the treatment of CMV retinitis in AIDS patients.
- DaunoXome® is approved for sale in more than 20 countries for the treatment of AIDS-related Kaposi's sarcoma.

We have a U.S. sales force that promotes Viread, AmBisome, Vistide and DaunoXome, and an international sales force in Europe and Australia that promotes Viread, AmBisome and DaunoXome.

We also have corporate partners and distributors promoting AmBisome, Vistide and DaunoXome in more than 35 countries.

We are studying adefovir dipivoxil in two ongoing Phase III trials for the treatment of infection with hepatitis B virus, or HBV and have filed for regulatory approval in the U.S. and Europe based on results to date. We believe that adefovir dipivoxil has the potential to address many of the limitations of current HBV therapies, most notably drug resistance associated with long-term therapy.

In November 2001, we announced that we had entered into an agreement with OSI Pharmaceuticals, Inc. (OSI), valued at up to \$200.0 million in cash and stock, under which we agreed to sell our oncology assets to OSI. The transaction was completed in December 2001 and we recorded a gain of \$157.8 million. This transaction will allow us to focus on and continue to strengthen our core expertise in infectious diseases. In the transaction, we sold to OSI our pipeline of clinical candidates in oncology (NX 211, GS 7904L, and GS 7836) and all related intellectual property, as well as our Boulder, Colorado operations, including clinical research and drug development operations, infrastructure and facilities. Upon the completion of the transaction, OSI paid us \$130.0 million in cash and 924,984 shares of OSI common stock. OSI will also pay us up to an additional \$30.0 million in either cash or a combination of cash and OSI common stock upon the achievement of certain milestones by OSI related to the development of NX 211, the most advanced of the oncology product candidates sold in the transaction. Under a manufacturing agreement, using active ingredients supplied to us through OSI, we will produce NX 211 and GS 7904L, the two liposomal products included in the sale, at our manufacturing facility in San Dimas, California.

Our Marketed Products

The products that we have developed that are commercially available include:

- *Viread*: a drug for treating HIV infection;
- *AmBisome*: a drug for treating and preventing life-threatening fungal infections;
- *Tamiflu*: a drug for treating and preventing influenza;
- *Vistide*: a drug for treating cytomegalovirus (or CMV) retinitis in AIDS patients; and
- *DaunoXome*: a drug for treating AIDS-related Kaposi's sarcoma.

How these products are sold, and the indications that they are approved for, vary with each product and in each country or region where they are sold.

In 2001, we earned revenues of approximately \$213.9 million from sales of and royalties on these products. Of this amount, sales of AmBisome generated aggregate product sales and royalty revenues of approximately \$181.6 million, or 78% of our total revenues. We earned revenues from sales of, and royalties on, these products in the U.S. of \$53.3 million in 2001, \$30.5 million in 2000 and \$25.1 million in 1999. Outside of the U.S., we earned revenues from sales of, and royalties on, these products of \$160.7 million in 2001, \$143.6 million in 2000 and \$125.0 million in 1999. We did not begin recognizing revenues from commercial sales of Viread until November 2001. We expect that revenues we earn from sales of Viread in 2002 to comprise an increased percentage of our total revenues, which will decrease the percentage of our total revenues from sales of AmBisome, although we cannot predict with any certainty our future revenues from either AmBisome or Viread.

Viread

Viread is a formulation of a nucleotide analogue reverse transcriptase inhibitor, tenofovir DF, dosed as one 300 mg pill, once a day as part of combination therapy to treat HIV infection in adults. Viread is approved for sale in the U.S. for use in combination with other antiretroviral agents for the

treatment of HIV infection and for sale in the European Union for use in combination with other antiretroviral agents for the treatment of HIV infection in patients who are experiencing early virological failure. We sell Viread in the U.S. through our U.S. sales force and in the major European countries through our European sales forces. See "Marketing and Sales."

In September 2001 and February 2002, respectively, we announced 24 week and 48 week effectiveness and safety results from study 907, a 48-week pivotal Phase III clinical trial evaluating Viread as a component of combination therapy in 552 treatment-experienced patients at 70 sites in the U.S., Europe and Australia. We designed study 907 to provide us with conclusive data on the safety and effectiveness of Viread. In this study, patients were randomly divided into two groups: one group of patients who had Viread added to their existing therapy during the first 24 weeks (two-thirds of enrolled patients), and one group of patients who were given placebo in addition to their existing therapy during the first 24 weeks (one-third of enrolled patients). All patients were given Viread in addition to their existing therapy during the second 24 weeks. These results demonstrate that, following 24 weeks and 48 weeks of treatment:

- Viread reduced patients' serum HIV DNA, a measure of the amount of HIV, at 24 weeks by an average of approximately 75% ($-0.61 \log_{10}$ copies/mL), which meets the primary endpoint of this trial, compared to a reduction of approximately 7% ($-0.03 \log_{10}$ copies/mL) in patients who received placebo, and at 48 weeks by approximately 73% ($-0.57 \log_{10}$ copies/mL).
- Viread suppressed HIV viral loads to below 400 copies/mL at 24 weeks in approximately 45% of patients, compared to 13% of patients who received placebo, and at 48 weeks in 41% of patients.
- Viread increased patients' CD4 cell counts at both 24 weeks and 48 weeks while patients who received placebo had their CD4 cell counts decrease at 24 weeks. An increase in CD4 cell count is an important indication that an HIV drug is improving a patient's immune system.
- The rates of discontinuation of use at 24 weeks were equivalent for patients using Viread and patients using placebo (6%).
- Viread did not cause a significant increase of serious side effects relative to placebo at 24 weeks, and the safety profile of Viread at 48 weeks was similar to that at 24 weeks.
- Only three percent (3%) of patients receiving Viread developed resistance to Viread at both 24 and 48 weeks. Additionally, Viread treatment at 24 weeks significantly reduced the development of mutations associated with the class of antiretroviral agents known as protease inhibitors (2%), compared with the placebo group (8%).

In September 2000, we presented the results from a 48-week Phase II dose ranging clinical trial of tenofovir DF in 189 treatment-experienced patients. In this study, patients received one of three doses of tenofovir DF (300 mg, 150 mg or 75 mg) or placebo, in addition to their existing combination therapy. At week 24, patients receiving placebo were switched to the 300 mg dose. This trial showed that, in this patient population, following 24 weeks of treatment, higher doses of tenofovir DF were associated with lower levels of serum HIV DNA compared to placebo and that at week 48, higher doses of tenofovir DF were associated with lower levels of serum HIV DNA compared to baseline. At each measurement point, the greatest reduction was observed in the 300 mg group. The study also showed that 48 weeks of dosing with tenofovir DF did not result in an increase of serious adverse events compared to the lower doses of tenofovir DF.

The Phase III results from study 907, combined with our completed Phase II results, support our belief that Viread can be an important treatment option for these difficult to treat treatment-experienced patients. The data from study 902 and the 24 week data from study 907, together with data from other clinical trials, formed the basis of U.S. marketing application that the U.S. Food and Drug

Administration (FDA) approved in October 2001, and the European Union application approved in February 2002.

We are continuing to evaluate Viread for treating patients who have not had prior HIV therapy. In January 2001, we completed enrollment of 601 patients in study 903, a Phase III clinical trial that will compare the safety and effectiveness of treatment of patients who have not had prior HIV therapy with Viread in combination with lamivudine (3TC) and efavirenz to the safety and effectiveness of treatment with stavudine (d4T), lamivudine and efavirenz. This study will provide additional information about Viread for treating this patient population and, if successful, will form the basis of a supplemental marketing application in the European Union for this use.

One of the major challenges in treating HIV-infected patients is drug resistance. Because many of the existing therapies for treating HIV infection and AIDS rely on similar drug processes, patients who have developed resistance to one drug often develop resistance to other drugs within its class. We believe that Viread, when approved by regulatory authorities, could be a very important drug for treatment-experienced patients because available data have shown that patients do not develop rapid resistance to Viread and that Viread is effective in treating patients who have developed resistance to other therapies. We cannot be certain, however, that the resistance data we may obtain upon completion of our Phase III clinical trials will show similar resistance characteristics to the 24 week and 48 week data from study 907 or the data we obtained from the more limited Phase II clinical trials.

Another major concern in HIV treatment is convenience of dosing. The combination therapies that are having a very positive impact on the health of HIV-infected patients require these patients to take numerous different drugs. Some of these drugs require multiple doses every day and many have timing restrictions. This not only results in inconvenience for patients but also contributes to patients missing doses or not adhering to their therapy. Viread is approved to be administered as a once-daily oral pill, which is a schedule that may be appealing to HIV-infected patients and their physicians. The low discontinuation rate observed for Viread supports this belief.

In December 1999, we discontinued developing adefovir dipivoxil for treating HIV-infected patients. This decision followed a recommendation by an FDA Advisory Panel not to approve a 60 mg dose of adefovir dipivoxil for treating HIV infection due primarily to concerns of kidney toxicity that developed late in the trials, as well as a desire for additional evidence of treatment benefits. Tenofovir DF has a structure and activity similar to adefovir dipivoxil. While Viread has not been associated with kidney toxicity and has shown superior treatment benefits in our clinical trials, we cannot be certain that the kidney toxicity issues that occurred in the later stages of the Phase III clinical trials for adefovir dipivoxil for HIV will not arise for Viread.

Viread faces substantial competition. A number of drugs to treat HIV infection and AIDS are currently sold or are in advanced stages of clinical development, including 17 products currently sold in the U.S. Among the major pharmaceutical companies that are significant competitors in the HIV/AIDS market are GlaxoSmithKline, Bristol-Myers Squibb, Hoffmann-La Roche, Pfizer, Merck, Boehringer-Ingelheim and Abbott Laboratories. See "Competition."

We have an exclusive, worldwide license to patent rights and related technology for Viread from the Institute of Organic Chemistry and Biochemistry (part of the Academy of Sciences of the Czech Republic) and Rega Stichting v.z.w. (together, IOCB/REGA) and are obligated to pay 3% of any net revenues from sales of Viread to IOCB/REGA in the U.S., the European Union, and any other countries where the product is approved and has patent protection. See "Collaborative Relationships—IOCB/REGA."

AmBisome

AmBisome is a liposomal formulation of amphotericin B. Amphotericin B is a powerful antifungal agent that is known for its ability to attack and kill a broad variety of life-threatening fungal infections, but it also has serious side effects, including kidney toxicity. The patients most likely to suffer from these fungal infections are patients with weakened immune systems, including transplant patients, patients infected with HIV, and cancer patients undergoing chemotherapy. Studies show that by delivering amphotericin B in our proprietary liposomal formulation, AmBisome reduces the rate and severity of kidney toxicity and injection-related reactions and allows these patients to receive higher and more effective doses of amphotericin B.

AmBisome is approved for sale in 44 countries, including the U.S., all of the European Union, most of the rest of Europe, Australia, Canada, and several countries in the Middle East, Latin America and Asia. AmBisome is primarily used for treating patients who are known to have life-threatening fungal infections. In 19 of the countries where AmBisome is approved, including the U.S., we are authorized to promote AmBisome as a first line treatment for these patients. In the remaining 25 countries, AmBisome is approved for use in this indication after conventional amphotericin B therapy fails or when conventional amphotericin B cannot be used—thus, as a second line therapy. In addition, AmBisome is approved in the U.S. and 23 other countries as first line therapy for patients who, because of certain symptoms, are presumed to have fungal infections. In the U.S. and four other countries, AmBisome also has been approved as a first line treatment of acute cryptococcal meningitis in AIDS patients. In addition, AmBisome is approved as a treatment for preventing fungal infections in liver transplant patients in four countries and in additional types of transplant patients in Russia. AmBisome is approved for treating a parasitic infection called visceral leishmaniasis in more than 20 countries.

In the U.S., we co-promote AmBisome with Fujisawa Healthcare through our domestic sales force. Our agreement with Fujisawa entitles us to a percentage of revenues generated from these sales and provides that Fujisawa purchases AmBisome from us at our manufacturing cost. See “Collaborative Relationships—Fujisawa.” In the major European countries and in Australia, we sell AmBisome through our international sales force, in certain other countries we sell AmBisome through independent distributors. See “Marketing and Sales.” Our corporate partner, Sumitomo, is studying AmBisome in clinical trials in Japan, where the drug is not yet approved for marketing. Sumitomo has the exclusive right to sell AmBisome in Japan, and we will receive a percentage of any revenues that they receive from those sales. See “Collaborative Relationships—Sumitomo.” Most of our revenues from AmBisome are in Europe, and we expect this to be the case for the foreseeable future. In most major European countries, we sell AmBisome in the currency of that country, and our revenues in U.S. dollars could therefore decrease if the value of those currencies were to decrease relative to the value of the U.S. dollar.

AmBisome has several current and expected competitors:

- conventional amphotericin B in markets where AmBisome has been approved as a first line therapy. Conventional amphotericin B is made by Bristol-Myers Squibb Company and numerous generic manufacturers. In many countries, AmBisome cannot be prescribed until conventional amphotericin B therapy has failed or cannot be used.
- caspofungin, a product developed by Merck that received U.S. marketing approval in January 2001 and European Union marketing approval in October 2001.
- voriconazole, which is being developed by Pfizer, Inc. has received marketing approval from the European Union in March 2002. In the U.S., the FDA has deemed Pfizer's New Drug Application (NDA) for voriconazole approvable.

- other lipid-based amphotericin B products approved in the U.S. and throughout Europe, including Abelcet, sold by Elan Corporation, and Amphotec, sold by InterMune Pharmaceuticals, Inc. These products compete against AmBisome as both primary and secondary therapy and are generally offered at prices that are less than AmBisome's price.

See "Competition."

Tamiflu

Tamiflu is an oral pill for the treatment and prevention of influenza A and B. Tamiflu is in a class of prescription drugs called neuraminidase inhibitors that act by disabling all common strains of the flu virus and preventing the virus from spreading in a patient. Tamiflu originally was approved by the FDA in October 1999 for the treatment of uncomplicated influenza in adult patients, and in November 2000 was approved by the FDA for the prevention of influenza in adults and adolescents 13 years and older. In December 2000, Tamiflu was approved in Japan for the treatment of influenza in adults and in the U.S. for the treatment of children as young as one year old. In March 2002, the application in the European Union to market Tamiflu for treatment and prevention of influenza was recommended for approval by a scientific advisory committee of the responsible agency.

When used as approved for the treatment of influenza, Tamiflu has been shown to reduce the duration of the flu in adults by an average of 1.3 days, and to reduce the severity of flu symptoms and the incidence of secondary infections. When taken as approved for the prevention of influenza, studies have shown that Tamiflu is up to 92% effective in preventing the development of the flu. The most common side effects associated with Tamiflu are mild nausea and vomiting.

Hoffmann-La Roche, our corporate partner who developed Tamiflu with us and who has the exclusive right to sell Tamiflu, began selling Tamiflu in the U.S. in November 1999. In May 1999, Hoffmann-La Roche submitted a Marketing Authorisation Application to the European Union seeking to have Tamiflu approved under the centralized procedure there. This European Union application was withdrawn by Hoffmann-La Roche to enable Hoffmann-La Roche to submit additional data. This application was re-filed by Hoffmann-La Roche in February 2001. In January 2002, Hoffmann-La Roche announced that due to production problems the liquid suspension form of Tamiflu approved for treatment of children as young as one year old was not available but was expected to be available in the 2002-2003 flu season. These production issues do not affect availability of the tablet form of Tamiflu for adults and adolescents 13 years and older. We do not expect the current production issues to have a material effect on our earnings. We receive a percentage of the net revenues that Hoffmann-La Roche generates from sales of Tamiflu. See "Collaborative Relationships—Hoffmann-La Roche."

There are several products that have been available to treat the flu for some time, but they have not been shown to be as effective or as safe as neuraminidase inhibitors. Relenza, an anti-flu drug sold by GlaxoSmithKline, is the only other neuraminidase inhibitor that has been approved by the FDA. This drug, which is delivered as an inhaled powder, is direct competition for Tamiflu. Tamiflu currently is the only FDA-approved neuraminidase inhibitor that is available in a pill and we believe that this method of delivery gives Tamiflu a competitive advantage over Relenza. We are aware, however, that BioCryst Pharmaceuticals is developing a neuraminidase inhibitor, peramivir, that has the potential to be delivered as a once-daily pill (Tamiflu is taken twice daily for treatment of flu). When and if BioCryst Pharmaceuticals receives approval for this product, it will also be direct competition for Tamiflu. See "Competition."

Tamiflu is not being marketed as an alternative to influenza vaccinations. We believe that influenza vaccinations will remain the most effective method of preventing the flu.

Vistide

Vistide is an antiviral medication for the treatment of CMV retinitis in patients with AIDS. CMV retinitis is a condition caused by a viral infection that is characterized by lesions that form on a patient's retina. This condition affects persons with weakened immune systems and is most common in patients with AIDS. If left untreated, CMV retinitis can lead to blindness. Vistide was approved by the FDA in June 1996 and by the European regulatory authorities in May 1997 based on clinical trials demonstrating that the drug delays the progression of CMV retinitis lesions in newly diagnosed patients and in previously treated patients who had failed other therapies.

We sell Vistide in the U.S. through our U.S. sales force. See "Marketing and Sales." Outside the U.S., Pharmacia Corporation has the exclusive right to sell Vistide. Vistide is approved for sale in all 15 countries of the European Union as well as in several other countries throughout the world. Pharmacia Corporation pays us a percentage of revenues it generates from sales of Vistide. See "Collaborative Relationships—Pharmacia Corporation."

Vistide competes with a number of drugs that also treat CMV retinitis. These drugs include:

- ganciclovir, a drug that is sold in intravenous and oral formulations by Hoffman La-Roche and as an ocular implant by Bausch & Lomb Incorporated;
- valganciclovir, an oral pro-drug formulation of ganciclovir, also marketed by Hoffman La-Roche;
- foscarnet, an intravenous drug sold by AstraZeneca; and
- formivirsen, a drug that is injected directly into the eye that is sold by CibaVision.

See "Competition."

The most significant side effect associated with the use of Vistide is kidney toxicity. Due to this side effect, certain precautions must be taken when Vistide is used, and in certain circumstances Vistide may not be used. Each time Vistide is given to a patient, the patient must first be tested for warning signs of kidney toxicity. If the patient does not have warning signs of kidney toxicity, Vistide may be given to that patient but only in combination with certain solutions that reduce the possibility of kidney toxicity. In addition, Vistide may not be given to patients who are receiving other drugs that can cause kidney toxicity. Patients who are receiving other drugs that are known to cause kidney toxicity must discontinue taking those drugs and then wait seven days before using Vistide. In certain animal studies, cidofovir, the active ingredient in Vistide, has caused cancer. These side effects and dosing limitations are a competitive disadvantage of Vistide.

Cidofovir, the active agent in Vistide, is being considered as part of the U.S. government strategy for dealing with potential bioterror attacks involving smallpox, a life-threatening infectious disease. In laboratory tests, cidofovir has demonstrated activity against all 30 strains of the virus that causes smallpox. In current clinical trials of diluted smallpox vaccine conducted by the National Institute of Allergy and Infectious Diseases, cidofovir is a potential treatment for vaccinia infection, a potential adverse reaction sometimes caused by the smallpox vaccine. Additionally, the U.S. National Institutes of Health holds an IND that allows for the emergency use of cidofovir for smallpox outbreaks. We cannot predict whether the U.S. or other countries may stockpile Vistide for the treatment of smallpox.

We have an exclusive, worldwide license to patent rights and related technology for cidofovir from IOCB/REGA and are obligated to pay 5% of net revenues from sales of Vistide or any other products containing cidofovir to IOCB/REGA. See "Collaborative Relationships—IOCB/REGA."

DaunoXome

DaunoXome is a liposomal formulation of the anticancer agent daunorubicin. We have received approval to sell DaunoXome in the U.S. and more than 20 other countries as a first line therapy for

treating patients who suffer from certain types of HIV-associated Kaposi's sarcoma. Kaposi's sarcoma is a disease characterized by widely disseminated lesions in the skin, mucous membranes, lymph nodes and viscera that can be life threatening for patients suffering from AIDS.

DaunoXome uses our proprietary liposomal technology to deliver safer and more effective doses of daunorubicin to the disease site. Studies have shown that DaunoXome may actually locate and accumulate in the patient's tumor and allow a patient to receive higher concentrations of daunorubicin at the disease site than could be obtained with an equivalent dose of non-liposomal daunorubicin.

We market DaunoXome in the U.S. and abroad through our sales forces and, in certain foreign countries, by distributors. See "Marketing and Sales."

Our Products In Late Stage Clinical Trials

We are developing adefovir dipivoxil in large, late-stage human clinical trials for treating patients infected with HBV. Based on results to date, we applied for approval of adefovir dipivoxil for treatment of HBV infection in the U.S. and the European Union in March 2002.

We have exclusive commercial rights to market Cidecin™ in 16 European countries. Cidecin is an antibacterial that is being developed by Cubist Pharmaceuticals, Inc. in Phase II and Phase III clinical trials. Cubist has completed two successful pivotal Phase III clinical trials for treatment of complicated skin and soft tissue infections caused by gram-positive bacteria, and one pivotal Phase III clinical trial for treatment of community-acquired pneumonia caused by gram-positive bacteria, in which Cidecin was not successful in meeting the primary endpoint. We are evaluating our strategies for applying for regulatory approval of Cidecin in Europe and do not currently expect to file such an application in 2002.

We cannot determine with any certainty if any ongoing or future clinical trials for adefovir dipivoxil or Cidecin will be successful and, if they are successful, whether or not the FDA or other regulatory agencies will approve any of these drugs for marketing.

Adefovir Dipivoxil for Hepatitis B

Hepatitis B is caused by the highly contagious HBV, and HBV infection can cause acute liver failure. Some patients develop a chronic HBV infection which over many years can lead to complications (such as cirrhosis, liver cancer and liver failure) that can result in death. According to current estimates from the World Health Organization and the Centers for Disease Control, there are approximately 350 million people worldwide and about 1.25 million people in the U.S. who have chronic HBV infection. There are about one million deaths attributable to HBV infection worldwide each year, and hepatitis B is one of the ten leading causes of death worldwide. Adefovir dipivoxil is a nucleotide analogue reverse transcriptase inhibitor. Adefovir dipivoxil disables HBV by interfering with the activity of an enzyme known as HBV polymerase, which is necessary for HBV to replicate.

We have two separate Phase III clinical trials to evaluate the safety and effectiveness of adefovir dipivoxil pills for treating patients with chronic HBV infection. Both of our Phase III trials were designed as randomized, double-blind, placebo-controlled studies and are being conducted at clinical sites in the U.S., Canada, Europe, Australia and Southeast Asia. Study 437 is evaluating adefovir dipivoxil for treating patients who test positive for the HBV "e" antigen, the most common type of chronic hepatitis B. The other trial, study 438, is evaluating adefovir dipivoxil once daily at 10 mg for treating patients with a type of HBV known as "precore mutant hepatitis B." Precore mutant HBV is most common in Southeast Asian and the Mediterranean countries.

In June and November 2001, respectively, we announced interim and complete analyses of 48-week effectiveness and safety results from study 437, a 96-week pivotal Phase III clinical trial evaluating the safety and effectiveness of adefovir dipivoxil at a 10 mg dose once daily as monotherapy compared to

placebo in 515 patients with chronic HBV infection who were HBV “e” antigen positive at 78 sites in the United States, Canada, Europe, Australia and Southeast Asia. We designed Study 437 to provide us with data on the safety and effectiveness of the 10 mg dose of adefovir dipivoxil and, as a secondary objective, of a 30 mg dose of adefovir dipivoxil. In this study, 515 patients were randomly divided into three groups of approximately equal size: one group who received a 10 mg dose of adefovir dipivoxil, one group who received a 30 mg dose of adefovir dipivoxil, and one group who received placebo. The results for adefovir dipivoxil in the 10 mg once daily dose demonstrate that, following 48 weeks of treatment:

- Adefovir dipivoxil improved liver histology in 53% of patients as compared to 25% of patients who received placebo, which meets the primary endpoint of this trial. Change in liver histology is an important marker of disease progression in patients with chronic HBV infection.
- Adefovir dipivoxil caused seroconversion, the disappearance of the hepatitis B “e” antigen, a marker of HBV replication, and the appearance of antibodies specific for this antigen, in 12% of patients treated with adefovir dipivoxil for 48 weeks, compared to 6% of patients on placebo.
- Adefovir dipivoxil reduced patients’ serum HBV DNA, a measure of the amount of HBV, by an average of approximately 99.97% ($-3.52 \log_{10}$ copies/mL), which meets an endpoint of this trial, compared to a reduction of approximately 72% ($-0.55 \log_{10}$ copies/mL) in patients who received placebo.
- Adefovir dipivoxil reduced amino alanine transferase (ALT) levels by 51 IU/L, compared to a reduction of 17 IU/L for patients who received placebo. Forty-eight percent of patients treated with adefovir dipivoxil at 10 mg achieved normalization of ALT levels, compared to 16% of patients receiving placebo. ALT levels are indicators of disease severity.
- Adefovir dipivoxil did not cause a significant increase of serious side effects relative to placebo.
- There was no evidence of kidney abnormalities in either the adefovir dipivoxil or placebo groups.
- There were similar discontinuation rates for patients using adefovir dipivoxil (7%) and patients using placebo (8%).
- No patients receiving adefovir dipivoxil were observed to have developed resistance mutations to adefovir.

In September 2001, we announced 48-week preliminary effectiveness and safety results from study 438, a 96-week pivotal Phase III clinical trial evaluating the safety and effectiveness of adefovir dipivoxil at a dose of 10 mg once daily as monotherapy compared to placebo in 185 patients with precore mutant HBV, or HBV “e” antigen-negative virus and compensated liver function (where the liver is functioning at or near normal levels) at 32 sites in Australia, Canada, France, Greece, Israel, Italy and Southeast Asia. We designed study 438 to provide us with conclusive data on the safety and effectiveness of the 10 mg once daily dosage of adefovir dipivoxil for precore mutant HBV. In this study, patients were randomly divided into two groups: one group of patients who were treated with adefovir dipivoxil 10 mg once daily (two-thirds of enrolled patients), and one group of patients who were given placebo (one-third of enrolled patients). These results demonstrate that, following 48 weeks of treatment with adefovir dipivoxil in the 10 mg once daily dose:

- Adefovir dipivoxil improved liver histology in 64% of patients as compared to improvements in 33% of patients who received placebo, which meets the primary endpoint of this trial. Change in liver histology is an important marker of disease progression in patients with chronic HBV infection.

- Adefovir dipivoxil reduced patients' serum HBV DNA by an average of approximately 99.99% (-3.91 log₁₀ copies/mL), which meets an endpoint of this trial, compared to a reduction of approximately 95.53% (-1.35 log₁₀ copies/mL) in patients who received placebo.
- Adefovir dipivoxil reduced ALT levels by 55 IU/L, compared to a reduction of 38 IU/L for patients who received placebo. Seventy-two percent of patients treated with adefovir dipivoxil achieved normalization of ALT levels, compared to 29% of patients receiving placebo. ALT levels are indicators of disease severity.
- Adefovir dipivoxil did not cause a significant increase of serious side effects relative to placebo.
- There was no evidence of kidney abnormalities in either the adefovir dipivoxil or placebo groups.
- There were equivalent discontinuation rates (2%) for patients using adefovir dipivoxil and patients using placebo.
- No patients receiving adefovir dipivoxil were observed to have developed resistance mutations to adefovir.

A vaccine is available that can prevent the transmission of HBV, but it does not cure patients who become chronically infected with the virus. We expect that as this vaccine becomes more widely available, the incidence of new HBV infection will decrease. Existing therapies for treating patients who are infected with HBV include the drugs Epivir-HBV (a form of lamivudine that is sold by GlaxoSmithKline) and Intron-A (a form of interferon alpha 2b that is sold by Schering Plough). Epivir-HBV is an orally administered antiviral drug that prevents HBV from replicating in patients. Intron-A is an injectable drug that can provide a reduction in the amount of virus in the blood of some patients but is often associated with side effects. We believe that if the FDA approves adefovir dipivoxil, Epivir-HBV would be its most significant competition. We cannot be certain that adefovir dipivoxil will be approved for the treatment of HBV infection, and we cannot determine if adefovir dipivoxil would be competitive with Epivir-HBV. See "Competition."

As is the case with HIV infection, drug resistance is a serious problem with drugs that treat HBV infection. For example, after one year of therapy with Epivir-HBV, from 15% to 32% of patients develop resistance to lamivudine, increasing to 67% after four years of therapy. Based on published data, lamivudine resistance occurs in 50 percent of HIV/HBV co-infected patients after two years of lamivudine therapy and in 90 percent of patients treated up to four years. We have conducted or provided support for clinical trials designed to provide information as to whether adefovir dipivoxil could provide a treatment option for patients with lamivudine-resistant HBV infection. Data from four clinical studies of patients with lamivudine-resistant HBV infection who were treated with adefovir dipivoxil 10 mg once daily demonstrate that:

- Treating patients who have lamivudine-resistant HBV infection with adefovir dipivoxil can reduce serum HBV DNA levels.
- Study 461: In patients with lamivudine-resistant chronic HBV infection and compensated liver function (where the liver is functioning at normal or near normal levels), reductions at 16 weeks in serum HBV DNA in patients treated with only adefovir dipivoxil, 99.86% (-2.86 log₁₀ copies/mL), were similar to those in patients treated with adefovir dipivoxil in combination with lamivudine 100 mg daily, 99.87% (-2.87 log₁₀ copies/mL), and greater than those in patients treated only with lamivudine 100 mg daily, 14.89% (-0.07 log₁₀ copies/mL).
- Study 435: In liver transplant patients with lamivudine-resistant chronic HBV infection who were treated with adefovir dipivoxil for 48 weeks, serum HBV DNA levels were reduced 99.98% (-3.7 log₁₀ copies/mL) at 24 weeks and about 99.997% (-4.6 log₁₀ copies/mL) at 48 weeks, and

administration of adefovir dipivoxil sustained these reductions for up to 72 weeks, with a median reduction in HBV DNA of about 99.998% (-4.7 log₁₀ copies/mL).

- Study 465: In patients with lamivudine-resistant chronic HBV infection and decompensated liver disease (where the liver is no longer functioning normally, leading to signs and symptoms of liver disease) who were treated with adefovir dipivoxil added to ongoing lamivudine treatment, median reduction in serum HBV DNA was approximately 99.987% (-3.9 log₁₀ copies/mL) at 24 weeks of treatment.
- Study 460i: After 72 weeks of treatment with adefovir dipivoxil added to existing lamivudine therapy, patients co-infected with lamivudine-resistant chronic HBV and HIV infections had statistically significant mean reductions in serum HBV DNA of 99.998% (-4.74 log₁₀ copies/mL).
- In all four studies, patients who had markers indicating abnormal liver function prior to treatment showed improvements in clinical markers of liver function after treatment with adefovir dipivoxil.

Available data to date has not demonstrated a resistance-mutation associated with adefovir dipivoxil in HBV suggesting that the development of resistance to adefovir dipivoxil in HBV patients may be slow and infrequent. We believe that the resistance profile of adefovir dipivoxil could make it an important drug for treating chronic HBV infection. We cannot be certain, however, that the resistance data we may obtain from the continuing Phase III clinical trials on adefovir dipivoxil will continue to show these resistance characteristics.

As described above under Viread, we discontinued development of adefovir dipivoxil 60 mg for treatment of HIV infection due to safety and benefit concerns arising from our studies. Studies have shown that adefovir dipivoxil is significantly more effective against HBV than against HIV, allowing us to use lower doses than for treatment of HIV infection. The 10 mg doses of adefovir dipivoxil have not shown significant kidney toxicity in our clinical trials to date. Clinical data from our Phase III clinical trials on the 10 mg dose of adefovir dipivoxil have demonstrated that the 10 mg dose met the primary endpoints for those studies. We cannot be certain that the results from these Phase III clinical studies of adefovir dipivoxil at the 10 mg dose will demonstrate, to the satisfaction of the FDA and other regulatory agencies, that adefovir dipivoxil can be a safe and effective treatment for chronic HBV infection.

Hepatitis B infection is most common in China and Southeast Asian countries. In December 2000, we received a clinical trials permit to initiate Phase I clinical trials in China. We commenced these clinical trials in June 2001. We have limited regulatory expertise in China and no manufacturing or marketing capacity in China and Southeast Asia. Therefore, we will continue to rely on the assistance of third parties for these activities. It is also difficult to protect patents in these countries and we could be adversely affected if we were unable to obtain adequate patent protection for adefovir dipivoxil in China and Southeast Asia. As part of our approval to commence Phase I clinical trials in China, adefovir dipivoxil was granted Class I designation which, if adefovir dipivoxil is ultimately approved for sale in China, would give us 12 years of market exclusivity for adefovir dipivoxil with respect to competitors who may otherwise be able to begin clinical development of adefovir dipivoxil following such approval.

We have an exclusive, worldwide license to patent rights and related technology for adefovir dipivoxil from IOCB/REGA, and would be obligated to pay 3% of any net revenues from sales of adefovir dipivoxil to IOCB/REGA in countries where the product has patent protection, including the U.S. and the member states of the European Union. See "Collaborative Relationships—IOCB/REGA."

Cidecin

Cidecin (daptomycin for injection) is an investigational antibacterial compound being developed by Cubist Pharmaceuticals, Inc. In January 2001, we entered into an agreement with Cubist granting us exclusive commercial rights to Cidecin in 16 European countries. Under this arrangement, Cubist is responsible for the ongoing clinical trials for the product and we are responsible for European regulatory filings for countries in which we have exclusive commercial rights. We believe that this arrangement represents a strategic opportunity for us because Cidecin falls within our therapeutic focus of anti-infectives and is a product that, if approved, could be sold through an expanded version of our existing European sales and marketing infrastructure.

Laboratory tests have suggested that Cidecin may be effective in rapidly killing most gram-positive bacteria, including those that have become resistant to current therapies. Gram-positive bacterial infections include complicated skin and soft tissue infections, bacteremia, endocarditis or infection of the valves of the heart, complicated urinary tract infections, pneumonia and osteomyelitis or infection of bone or bone marrow. As is the case with HIV and HBV, resistance to existing anti-bacterial therapy has become a significant problem in treating these infections. If these laboratory tests are confirmed in clinical trials, Cidecin could be a very useful drug for treating these serious infections. There can be no assurance, however, that any of these results, other than those for complicated skin and soft tissues infections, will be confirmed in clinical trials.

Cubist has evaluated or is currently evaluating Cidecin in multiple Phase II and Phase III trials for the treatment of complicated skin and soft tissue infection, community-acquired pneumonia, resistant enterococcal infections, and complicated urinary tract infection. In two completed pivotal Phase III trials for the treatment of complicated skin and soft tissue infections caused by gram-positive bacteria, Cidecin achieved the primary endpoint of statistical equivalence to the comparator agents, which are currently considered optimal antibiotic standards of care for complicated skin and soft tissue infections. Data from these two trials also demonstrated that patients who were successfully treated with Cidecin required fewer days of intravenous therapy than patients who were successfully treated with the comparator agents and that Cidecin's safety profile was similar to that of the comparator agents. In January 2002, Cubist announced that the primary endpoint of demonstrating non-inferiority to an active comparator agent was not achieved in the first of Cubist's two Phase III trials investigating the safety and effectiveness of Cidecin in the treatment of community-acquired pneumonia requiring hospitalization. In February 2002, Cubist announced results from a Phase II clinical trial of Cidecin demonstrating that the primary endpoint of demonstrating no differences between the microbiologic and clinical cure rates for Cidecin versus the comparator agent had been achieved for the treatment of complicated urinary tract infection caused by gram-positive bacteria. In March 2002, Cubist announced that it will soon begin a Phase III clinical trial of Cidecin for the treatment of endocarditis (infection of the heart valves) and bacteremia (infection of the bloodstream).

Cubist has stated that it intends to file an NDA in the U.S. in 2002 for Cidecin for the indication of complicated skin and soft tissues infections involving both susceptible and resistant gram-positive organisms. Our agreement with Cubist does not require Cubist to continue, conduct or complete any additional clinical trials, but if Cubist successfully completes Phase III clinical trials for uses other than complicated skin and soft tissue infection, we could seek regulatory approval for these uses in our territory and would have exclusive commercial rights to these indications in our territory. We cannot predict the outcome of any clinical trials for Cidecin or if Cubist will evaluate Cidecin for additional uses.

We are currently evaluating our options for filing for marketing authorization of Cidecin in the European Union. We have received indications from regulatory authorities in the European Union that an application seeking marketing approval for Cidecin only for the single indication treatment of complicated skin and soft tissue infection may not be approved. We currently do not expect to file such

an application in 2002. We cannot accurately predict whether Cidecin will meet its primary endpoints in any clinical trials for indications other than complicated skin and soft tissue infection, whether conducted by Cubist or by us, or whether we will be able to obtain regulatory approval of Cidecin in Europe. If we file a marketing authorization application for Cidecin in Europe and if it is approved, we would sell Cidecin through our European sales and marketing infrastructure.

Cubist is also developing an oral formulation of daptomycin, which is not yet in human clinical trials. Our agreement with Cubist would give us exclusive commercial rights in our territory to any oral formulation of daptomycin that is developed by Cubist.

We are required to pay milestone payments to Cubist based upon certain development goals relating to the clinical development and regulatory approval of Cidecin and any oral formulation of daptomycin. We are also required to pay royalties to Cubist based upon any sales that we make of Cidecin and any oral formulation of daptomycin. See "Collaborative Relationships—Cubist."

Our Product in Preclinical Development

We intend to begin Phase I clinical trials of GS 7340, a novel nucleotide analogue reverse transcriptase inhibitor, during 2002. Both GS 7340 and Viread are processed in the body to yield the same active chemical, tenofovir, within cells. However, the chemical composition of GS 7340 may allow it to cross cell membranes more easily than Viread, so that with GS 7340, tenofovir may be present at much higher levels within cells. As a result, GS 7340 may have greater potency than Viread and may inhibit low-level HIV replication in cells that are otherwise difficult to reach with reverse transcriptase inhibitors. We cannot be certain that this Phase I clinical trial or any subsequent Phase II or Phase III clinical trials that we may conduct for GS 7340 will be completed successfully or within any specified time period. We may choose, or the FDA may require us to delay or suspend our clinical trials for GS 7340 at any time if it appears that the patients are being exposed to an unacceptable health risk or if GS 7340 does not appear to have sufficient treatment benefit.

Our Science

We have research scientists in Foster City and San Dimas, California engaged in the discovery and development of new molecules and technologies that we hope will lead to new medicines and novel formulations of existing drugs. Our therapeutic focus is in the areas of infectious diseases. In total, our research and development expenses for 2001 were \$185.6 million, compared with \$132.3 million for 2000 and \$110.9 million for 1999.

Nucleotide Analogues

Our scientists are working with our proprietary nucleotide analogues to develop treatments for viral infections. These compounds treat viral infections by interfering with the activity of certain enzymes that are necessary for the virus to grow. For example, Vistide, a nucleotide analogue of cytosine, inhibits the activity of an enzyme in CMV that is essential for that virus to spread. Viread and adefovir dipivoxil are nucleotide analogues that work by inhibiting the activity of reverse transcriptase, an enzyme necessary for replication of HIV (Viread) and HBV (adefovir dipivoxil).

We believe that small molecule nucleotide analogues can offer advantages as therapeutics. These advantages include:

- These molecules have demonstrated ability to work in both infected and uninfected cells. This could enable us to develop drugs that not only treat a patient who is infected with a virus but that can also prevent a healthy person from becoming infected in the first place; and

- Drugs developed with these molecules have been shown to have treatment activity in a patient for longer periods of time than other available drugs. This could enable us to develop drugs that require less frequent dosing and are thus more convenient for patients.

Given the complexity of drug development, we cannot be certain that any drug candidates we develop with this science will have any or all of these advantages. Even if we do develop drug candidates with some or each of these advantages, the FDA and other regulatory agencies could reject marketing approval of these drug candidates for other reasons, including safety and benefit concerns.

Liposomes

We also have scientists who are focused on applying our proprietary liposomal drug delivery technology to develop safer, more effective and more convenient drugs. Liposomes are sub-microscopic structures made of phospholipids, the basic components of human cell walls. They are hollow spheres into which drugs can be packed. We believe that we can influence the way compounds are released and distributed in the body by placing them in liposomes. This can, in turn, improve the safety and treatment benefits of such compounds. For example, we developed AmBisome by incorporating amphotericin B in a liposome. Pre-clinical studies have shown that AmBisome delivers amphotericin B in a manner that results in fewer side effects and improved treatment benefits over conventional amphotericin B, including concentrating the drug at the site of the infection, extending the time the drug remains in the blood stream to prolong the therapeutic effect and reducing kidney toxicity and injection related reactions. Clinical studies demonstrate that AmBisome does persist longer in the blood stream and has lower kidney toxicity and injection related reactions as compared to conventional amphotericin B.

Our current strategy is to use our liposomal technology with compounds we develop internally and to identify appropriate compounds developed by third parties for use with this technology. Compounds developed by third parties that are appropriate for our technology include those that, like amphotericin B, have proven therapeutic benefits but suffer from significant side effects, or that suffer from dosing and administration problems. We believe that we can use our liposomal technology to improve the safety of these drugs while maintaining or even improving their therapeutic benefits.

We have identified certain generic compounds (compounds that are not protected by patents) and proprietary compounds owned by third parties that may benefit substantially from our liposomal technology, and we have begun formulation studies for these compounds. In addition, we have discussed, and will continue to discuss, collaborative relationships with other companies to develop liposomal formulations of their compounds.

HIV Protease Inhibitors

We are evaluating a number of small molecule compounds known as "protease inhibitors" for the potential treatment of HIV infection. Protease inhibitors act by interfering with the activity of protease, an enzyme that, like reverse transcriptase, is necessary for replication of HIV. We have conducted a number of preclinical experiments on these compounds and have demonstrated that they have potent antiviral activity. Our scientists are trying to increase the safety and convenience of, and reduce resistance concerns with, these compounds.

Other Antiviral Research

We are undertaking additional research in the area of treatment of viral diseases. Many of these efforts focus on potential targets in HIV for therapeutic drugs.

Marketing and Sales

We established a U.S. sales force of therapeutic specialists when we began selling Vistide in 1996. We also have marketing subsidiaries in the United Kingdom, Germany, Italy, Spain, France, Portugal, Greece, the Netherlands and Australia. Our sales professionals promote and sell Viread, AmBisome and DaunoXome in the U.S. and Europe, AmBisome and DaunoXome in Australia, and Vistide in the U.S. AmBisome is also sold by Fujisawa in the U.S. (where we co-promote the product) and in Canada. Pharmacia Corporation promotes and sells Vistide in countries outside of the U.S. and Hoffmann-La Roche promotes and sells Tamiflu everywhere it is sold.

Our U.S. sales force promotes Viread and Vistide through direct contact with physicians, hospitals, clinics, and other healthcare providers who are involved in the treatment of patients with HIV, AmBisome to infectious disease specialists, hospitals, home health care providers and cancer specialists, and DaunoXome to cancer specialists and hospitals. The U.S. sales force is supported both by a field support force and by a marketing and sales support staff based at our headquarters in Foster City, California.

We have international sales forces in Europe and Australia. Each of our international marketing subsidiaries is headed by a general manager who oversees the operations in the market(s) served by that subsidiary. We have personnel located mainly in Europe, including medical, financial, regulatory, manufacturing and human resources personnel, who support our international sales and marketing operations. These subsidiaries also assist in obtaining regulatory approvals in the countries where they are located.

We sell Viread, Vistide and DaunoXome in the U.S. and Viread, AmBisome and DaunoXome in Europe to wholesalers and specialty distributors who, in turn, sell the products to physicians, hospitals, clinics, pharmacies and other healthcare providers. In some countries outside of the U.S., we have agreements with third-party distributors, including distributors in certain of the countries where we have marketing operations, to promote, sell and distribute AmBisome and DaunoXome. These international distribution agreements generally provide that the distributor has the exclusive right to sell AmBisome and DaunoXome in a particular country or several countries for a specified period of time. We intend to enter into similar arrangements with third-party distributors outside the U.S. for promotion, sale and distribution of Viread.

We have increased our sales force in the U.S. and are devoting additional marketing resources in the U.S. due to the approval of Viread to expand our coverage of healthcare professionals treating HIV-infected patients. We have also significantly increased the size of our commercial operations in Europe to manage the commercialization of Viread in the European Union. It is our current intention to retain the commercial rights to adefovir dipivoxil for HBV infection in the U.S. and Europe and sell it through marketing partners or distributors in Asia and the rest of the world. If we do retain significant commercial rights to adefovir dipivoxil for HBV infection and the product is approved, we would need to use additional marketing resources to sell this product. If Cidecin is approved for marketing in Europe, we believe that given the profile of the product and its target market, additional sales and marketing positions will need to be added.

In the U.S., Viread and Vistide are returnable in their original, unopened containers up to one year beyond the expiration date or, if damaged when received by the customer. Our customers may return AmBisome or DaunoXome if the shelf life has expired or if the product is damaged or defective when the customer receives it. AmBisome has an approved shelf life of 36 months in the U.S. and 30 months in most European countries. DaunoXome has a shelf life of 52 weeks in the U.S. and most European countries. Viread has a shelf life of 24 months in the U.S. and has been approved for the same shelf life in the European Union. Additionally, certain governmental agency customers and state AIDS drug assistance programs are entitled to or receive discounts, and we are required to provide rebates under state Medicaid programs. To date, returns, rebates and discounts have not been material.

Fujisawa establishes the return policy for AmBisome in North America, and Hoffmann-La Roche establishes the return policy for Tamiflu.

Collaborative Relationships

As part of our business strategy, we establish collaborations with other companies to assist in the clinical development and/or commercialization of certain of our products and product candidates and to provide support for our research programs. We also evaluate opportunities for acquiring from other companies products or rights to products and technologies that are complementary to our business. The accounting for each of these relationships can be found in Note 7 to the consolidated financial statements. Our existing collaborative relationships are as follows:

Hoffmann-La Roche

In September 1996, we entered into a collaboration agreement with Hoffmann-La Roche to develop and commercialize therapies to treat and prevent the flu. Under this agreement, we granted Hoffmann-La Roche exclusive worldwide rights to all of our proprietary influenza neuraminidase inhibitors, including Tamiflu. In October 1999, the FDA approved Tamiflu for marketing and in November 1999, Hoffmann-La Roche began selling Tamiflu.

As of December 31, 2001, we have received license fees and milestone payments from Hoffmann-La Roche totaling \$40.7 million relating to the execution of this agreement and to regulatory filings and approvals for Tamiflu. Hoffmann-La Roche also funded all of the research and development costs for Tamiflu, including reimbursement to us of \$28.1 million for the period from January 1, 1997 through December 31, 2001. In addition, under this agreement:

- Hoffmann-La Roche is responsible for pricing, promoting and selling Tamiflu on a worldwide basis;
- Hoffmann-La Roche pays us a percentage of its net revenues from sales of Tamiflu. In certain circumstances, the amount that Hoffmann-La Roche pays to us may be reduced, for example, if the cost of materials they use to manufacture Tamiflu increases. We receive payments and recognize revenue from Hoffmann-La Roche in the quarter following the quarter when the sales were made; and
- Hoffmann-La Roche will make milestone payments to us if and when Tamiflu is approved for sale in the European Union.

The agreement with Hoffman-La Roche terminates on a country-by-country basis after the later of:

- expiration of patent coverage for Tamiflu; or
- ten years from first commercial sale.

Hoffmann-La Roche has the right to terminate the agreement in its entirety or on a country-by-country basis prior to expiration at any time upon 12 months notice.

Fujisawa

In 1991, we entered into an agreement with Fujisawa providing that:

- We have the exclusive right to promote and sell AmBisome in all countries, except the U.S. and Canada;
- Fujisawa has the exclusive right to promote and sell AmBisome in Canada;
- We have the right to co-promote AmBisome with Fujisawa in the U.S., where Fujisawa has primary responsibility for promoting and selling AmBisome;

- We receive approximately 17% of the net revenues from sales of AmBisome in the U.S. for our co-promotion efforts;
- We receive payments and recognize revenue from Fujisawa in the month following the month when Fujisawa's sales are made;
- We would be required to pay Fujisawa 4% of our revenues in connection with sales of AmBisome in significant Asian markets, including Japan, Korea, Taiwan, China and India; and
- We manufacture AmBisome for all sales and Fujisawa purchases AmBisome from us for sale in the U.S. at a price equal to our cost to manufacture the product and for sale in Canada at that cost plus a specified percentage.

Our agreement with Fujisawa terminates when the last patent covering AmBisome in the U.S. or Japan expires.

IOCB/REGA

In 1991 and 1992, we entered into agreements with IOCB/REGA relating to nucleotide compounds discovered at these institutions. In December 2000, we paid IOCB/REGA \$11.0 million to reduce the royalties payable upon any sales of Viread and adefovir dipivoxil by 2% to a royalty rate of 3% in the U.S., the European Union, and any other countries where these products are approved and have patent protection. Under these agreements and amendments to these agreements:

- We received from IOCB/REGA the exclusive right to manufacture, use and sell the nucleotide compounds covered by these agreements;
- In countries where there is patent protection, we are required to pay to IOCB/REGA 3% of the net revenues generated from any sales of Viread and adefovir dipivoxil, and 5% of any net revenues generated from sales of Vistide and any other products containing these compounds, subject to minimum royalty payments; and
- In countries where there is no patent protection, we are not required to pay royalties to IOCB/REGA for sales of Viread and adefovir dipivoxil and are required to pay 2.5% of any net revenues generated from sales of Vistide and any other products containing these compounds.

We are currently making quarterly payments to IOCB/REGA based upon a percentage of sales of Vistide and Viread and will pay additional amounts upon any commercial sales of adefovir dipivoxil. We will amortize the \$11.0 million payment made in December 2000 over the estimated commercial lives of Viread and adefovir dipivoxil, which will reduce any reported earnings on these products.

The agreements with IOCB/REGA terminate on a country-by-country basis after the later of:

- expiration of patent coverage for any product licensed under the agreements; or
- ten years from first commercial sale.

IOCB/REGA may terminate the licenses under these agreements for a particular product in key markets if we do not make any sales of that product within 12 months after regulatory approval in those countries.

Cubist

In January 2001, we entered into an agreement with Cubist giving us exclusive commercial rights in 16 European countries to all oral and injectable formulations of Cubist's investigational antibacterial

compound daptomycin. These formulations include Cidecin, an intravenous formulation of daptomycin currently in Phase III clinical trials for treatment of bacterial infections. Under this agreement:

- Cubist is required to complete certain key clinical trials for Cidecin;
- We are responsible for all regulatory filings for products in our territory;
- If Cidecin is approved for marketing in our territory, we are responsible for marketing Cidecin in our territory;
- We paid an upfront fee to Cubist of \$13.0 million at the time we signed this agreement and paid milestone payments to Cubist totaling \$5.5 million in 2001 for achievement of milestones relating to the safety and effectiveness of Cidecin in the treatment of complicated skin and soft tissue infection caused by gram-positive bacteria. We may be required to make additional payments to Cubist of up to \$25.2 million if certain other goals related to the clinical development and regulatory approval of Cidecin and an oral formulation of daptomycin are achieved;
- We are required to pay to Cubist a percentage of our revenues from sales of daptomycin products in our territory;
- If Cubist desires to grant commercial rights to an oral or injectable daptomycin-related product in certain other countries including any country that joins the EU, Cubist must offer us such commercial rights on a priority basis; and
- Cubist is obligated to continue the preclinical development of an oral formulation of daptomycin and would have an obligation to pursue clinical development of that formulation if appropriate.

This agreement expires on a country by country basis with respect to each product developed upon the later of:

- ten years after first commercial sale of such product in such country; or
- the date that there is no patent coverage for such product.

Pharmacia Corporation

In August 1996, we entered into an agreement with Pharmacia Corporation relating to Vistide. Under this agreement we received \$10.0 million on signing and \$10.0 million upon approval of Vistide for marketing in Europe. In addition, under this agreement:

- Pharmacia Corporation has the exclusive right to market and sell Vistide in all countries outside of the U.S. and a right of first negotiation for any competitive products we own;
- We are responsible for maintaining the patents for cidofovir;
- We are required to sell bulk cidofovir to Pharmacia Corporation;
- Pharmacia Corporation will pay to us a percentage of its net sales of Vistide and any other products developed under the collaboration agreement. We receive payments and recognize revenue from Pharmacia Corporation in the quarter following the quarter when the sales were made; and
- Pharmacia Corporation holds 4,535,144 shares of our common stock that it purchased in connection with this agreement. Pharmacia Corporation may not sell their shares or acquire additional shares of our stock without our approval until June 2002.

Our agreement with Pharmacia Corporation expires on a country-by-country basis as patent coverage for Vistide expires or ten years from first commercial sale of Vistide in countries where the product is not covered by a patent.

In addition, Pharmacia Corporation may terminate the agreement:

- upon six months notice; or
- upon notice on a country-by-country basis, three months before applying for marketing approval of a competitive product.

Sumitomo Pharmaceuticals Co., Ltd.

In 1996, we entered into an agreement with Sumitomo Pharmaceuticals Co., Ltd. that gave Sumitomo the exclusive right to develop and market AmBisome in Japan. Sumitomo paid us \$7.0 million at the time we entered into this agreement and \$3.0 million in March 1998 when Sumitomo made a regulatory filing in Japan. Under the terms of this agreement:

- Sumitomo is required to make a payment of \$4.0 million to us if AmBisome is approved for sale in Japan;
- Sumitomo is required to pay to us a percentage of any revenue they generate from sales of AmBisome; and
- If AmBisome is approved for sale in Japan, we would manufacture AmBisome for sale by Sumitomo in Japan. The price that we would charge Sumitomo for the supply of AmBisome and the percentage of revenues that they would be required to pay to us would be determined by the price of AmBisome in Japan.

This agreement terminates on the later of:

- ten years after Sumitomo begins selling AmBisome in Japan; or
- the date the last patent for AmBisome in Japan expires.

EyeTech Pharmaceuticals

In March 2000, we entered into an agreement with EyeTech Pharmaceuticals, Inc. relating to NX 1838, now known as EYE001, which is an oligonucleotide that EyeTech is currently developing for treatment of age-related macular degeneration. We received a \$7.0 million up-front license fee from EyeTech upon execution of the agreement. Under the terms of the agreement:

- EyeTech received the exclusive right to develop and commercialize EYE001;
- We are entitled to additional cash payments from EyeTech of up to \$25.0 million if and when EyeTech reaches certain EYE001 development milestones; and
- If the product is successfully commercialized, EyeTech will pay us royalties on worldwide sales of the product.

As part of this transaction, we received a five-year warrant to purchase 833,333 shares of EyeTech series B convertible preferred stock, exercisable at a price of \$6.00 per share, the price at which the stock was issued to other investors. As required by our license agreement with the University Technology Corporation, we transferred 5% of this warrant to the University Technology Corporation (the right to acquire 41,666 shares) and therefore currently hold a warrant to purchase 791,667 shares.

This agreement expires upon the later of:

- ten years after first commercial sale of any product developed; or
- the date the last patent expires under the agreement.

GlaxoSmithKline—SELEX

In May 1998, we entered into agreement giving GlaxoSmithKline the non-exclusive right to use our SELEX technology for five years to identify aptamers. Under this agreement:

- GlaxoSmithKline would be required to pay to us a fee at the time we enter into an additional agreement;
- GlaxoSmithKline would be required to make payments to us based on achieving certain goals relating to the regulatory approval of any product they develop based on the aptamer; and
- GlaxoSmithKline would be required to pay to us a percentage of any revenues they may generate from sales of any product they develop based on the aptamer.

This agreement terminates on May 27, 2003 except:

- GlaxoSmithKline can extend this agreement for additional one year periods in which case GlaxoSmithKline would be required to pay to us an appropriate fee; and
- GlaxoSmithKline can terminate this agreement earlier at any time on 90 days notice to us.

Somalogic, Inc.

In November 1999, we entered into an agreement with Somalogic, Inc., a company formed by Larry Gold, the founder of NeXstar Pharmaceuticals, Inc. (NeXstar), relating to our SELEX technology. Under this agreement:

- We gave Somalogic the exclusive right to use our SELEX technology to make and sell in vitro diagnostic products (diagnostic products that are not used in a person or animal);
- We assigned and sold to Somalogic certain patents and materials relating to in vitro diagnostics, including robotic SELEX machines;
- We have the right to use the other drug discovery technology that is the subject of this agreement internally to study diseases and in our drug development and clinical trial programs; and
- Somalogic paid to us the first installment of a fee at the time we entered into the agreement and a second and final installment in November 2000.

This agreement terminates on the later of:

- on a country by country basis as patent coverage for this drug discovery technology expires; or
- November 2024.

Archemix Corporation

In October 2001, we entered into an agreement with Archemix Corporation relating to our SELEX technology. Under this agreement:

- We gave Archemix the exclusive rights to the SELEX process, including therapeutic and other commercial applications, to the extent not already licensed under pre-existing agreements;
- We have the right to use the SELEX technology for internal research purposes;
- Archemix paid us \$9.0 million in 2001 and is required to pay us \$8.5 million in 2002. As required by our license agreement with the University Technology Corporation, we paid 5% of the \$9.0 million payment to, and will pay 5% of the \$8.5 million payment to, the University Technology Corporation; and

- We received warrants to purchase Archemix stock. As required by our license agreement with the University Technology Corporation, we transferred 5% of this warrant to the University Technology Corporation.

OSI Pharmaceuticals, Inc.

In November 2001, we entered into an agreement with OSI Pharmaceuticals, Inc. for the sale to OSI of our oncology assets. This transaction was completed in December 2001 and we recorded a gain of \$157.8 million. Under this agreement:

- We sold to OSI our pipeline of clinical candidates in oncology and all related intellectual property, as well as our Boulder, Colorado operations, including clinical research and drug development operations, infrastructure and facilities. The three clinical development candidates sold to OSI are: NX 211 (liposomal lurtotecan), GS 7836 (a nucleoside analogue) and GS 7904L (a liposomal thymidylate synthase inhibitor).
- OSI paid to us \$130.0 million in cash and approximately \$38.8 million in shares of OSI common stock.
- We are entitled to additional payments from OSI of up to \$30.0 million in either cash or a combination of cash and OSI common stock if and when OSI reaches certain development milestones for NX 211, the most advanced of the oncology product candidates sold to OSI.
- Under a manufacturing agreement, we will produce for OSI liposomal formulations of NX 211 and GS 7904L, the two liposomal products sold to OSI, at our manufacturing facility in San Dimas, California.
- OSI assumed our rights and obligations under the amended 1998 agreement with Glaxo Wellcome, now GlaxoSmithKline (Glaxo) relating to NX 211, the 2000 license agreement with Glaxo relating to GS 7904L, and the 2000 license agreement relating to GS 7836 with Southern Research Institute.

International Distribution Agreements

We have various agreements with distributors in Europe, Asia, Latin America, the Middle East and Africa that grant these distributors the exclusive right to sell AmBisome, and in some cases DaunoXome, in a particular country or countries for a specified period of time. Most of these agreements also provide for collaborative efforts between us and the distributor for obtaining regulatory approval for the product in the particular country and for marketing the product in the country. Most of these agreements establish a price that the distributor must pay for our product and require us to deliver quantities of the product ordered by the distributor. We intend to enter into similar distribution agreements for Viread in countries where we will not promote and sell it directly.

Academic and Consulting Relationships

To supplement our research and development efforts, as part of our regular business we enter into arrangements with universities and medical research institutions. These arrangements often provide us with rights to patents, patent applications and technology owned by these institutions in return for payments and fees relating to our use of these rights.

University Technology Corporation

We have an ongoing collaborative arrangement relating to our SELEX technology with the University Technology Corporation, a technology holding company for the University of Colorado at Boulder. Under this arrangement:

- The University of Colorado at Boulder has given us all of its present and future rights to:
 - inventions covered by patents and patent applications for SELEX technology;
 - improvements to SELEX technology it makes or discovers;
 - oligonucleotides or other molecules it makes using SELEX technology;
 - results of certain research; and
 - computer software related to SELEX technology.
- We are required to pay to the University of Colorado at Boulder:
 - 2% of the revenues we generate from our sales of SELEX-derived products;
 - 15% of any amounts we receive from a third party that are based upon sales by those third parties of SELEX-derived products; and
 - 5% of other payments we receive from third parties as a result of certain arrangements we have with those third parties to develop and sell SELEX-derived products.

Manufacturing

AmBisome and DaunoXome

We manufacture AmBisome and DaunoXome in commercial quantities in two separate but adjacent facilities in San Dimas, California. AmBisome is produced in one of the buildings while DaunoXome is produced in a separate building. The Medicines Control Agency of the United Kingdom and the U.S. Food and Drug Administration have approved the commercial production of each of AmBisome and DaunoXome in the facility in which it is produced. To import AmBisome and DaunoXome into the European Union, we own a manufacturing facility in Dublin, Ireland where we perform quality control testing, final labeling and packaging for the European Union and elsewhere.

We use commercially available materials and equipment to manufacture these products. Currently, we obtain the amphotericin B that we use to manufacture AmBisome, the daunorubicin HCl and distearoylphosphatidylcholine that we use to manufacture DaunoXome, and the cholesterol that we use to manufacture both AmBisome and DaunoXome from single approved suppliers.

AmBisome is currently freeze dried at our San Dimas manufacturing facility and is sold as a freeze-dried product. Given our demands and projections for growth in AmBisome use, we are currently using a third party to fill and freeze dry some of the product and are evaluating the feasibility of installing additional freeze drying capacity in San Dimas. If we are unable to locate appropriate third parties or install and validate additional freeze drying capacity in San Dimas, our ability to increase AmBisome sales would be diminished. Manufacturing liposomal products is a particularly complex process and any new liposomal product we develop will require unique and complex variations in our manufacturing process.

Antiviral Products

We hire third parties to manufacture our antiviral drugs for clinical and commercial purposes, including Vistide, adefovir dipivoxil and Viread. Hoffmann-La Roche manufactures Tamiflu. We have no commercial-scale manufacturing facilities for our antiviral products that are qualified under the

FDA's current Good Manufacturing Practices, and we have no current plans to establish these facilities. In using third parties, we cannot be certain that they will perform their obligations effectively and on a timely basis. If these third parties do not perform effectively and timely, our clinical trials or regulatory filings could be delayed or we could be unable to deliver our products to customers on a timely basis, and this would adversely affect our operating results. In January 2002, Hoffmann-La Roche announced that due to production problems the liquid suspension form of Tamiflu approved for treatment of children as young as one year old was not available but was expected to be available in the 2002-2003 flu season.

We have two suppliers that have been approved by the FDA to manufacture the cidofovir used in Vistide. One of these suppliers has been approved by the European Union to manufacture cidofovir for use in Vistide, and we are having a second cidofovir supplier qualified to assure our supplies. We have a single FDA and EMEA approved supplier for the final drug product. We manufacture the active ingredient in Viread through three contract manufacturers who have been approved by the FDA and the European Union. We manufacture the Viread tablets through one contract manufacturer that has been approved by both agencies, and we are having a second contract manufacturer qualified for the manufacture of Viread tablets to assure our supplies. We are seeking qualification in the U.S. and the European Union for two contract manufacturers for the active ingredient in adefovir dipivoxil and one contract manufacturer for the final adefovir dipivoxil drug product for commercial supply. If manufacturing at any of these sites we use were interrupted for any reason, our ability to ship our products would be impaired, and this would adversely affect us.

The Viread and adefovir dipivoxil tablets used in our clinical trials are manufactured at two contract manufacturing sites. If manufacturing at either of these sites were interrupted for any reason, our ability to maintain clinical supplies would be impaired, and this would adversely affect us.

For our future antiviral products, we will need to develop additional manufacturing capabilities and establish additional third party suppliers in order to manufacture sufficient quantities of our product candidates to undertake clinical trials and to manufacture sufficient quantities of any candidates that are approved for commercial sale. If we are unable to develop manufacturing capabilities internally or contract for large scale manufacturing with third parties on acceptable terms for our future antiviral products, our ability to conduct large-scale clinical trials and meet customer demand for commercial products would be adversely affected.

We believe that the technology we use to manufacture our products and compounds is proprietary. For our antiviral products, we have disclosed all necessary aspects of this technology to contract manufacturers to enable them to manufacture the products and compounds for us. We have agreements with these manufacturers that are intended to restrict them from using or revealing this technology, but we cannot be certain that these manufacturers will comply with these restrictions. In addition, these manufacturers could develop their own technology related to the work they perform for us that we may need to manufacture our products or compounds. We could be required to enter into an agreement with that manufacturer if we wanted to use that technology ourselves or allow another manufacturer to use that technology. The manufacturer could refuse to allow us to use their technology or could demand terms to use their technology that are not acceptable.

We believe that we are in compliance with all material environmental regulations related to the manufacture of our products.

Patents and Proprietary Rights

Patents and other proprietary rights are very important to our business. If we have a properly designed and enforceable patent it can be more difficult for our competitors to use our technology to create competitive products and more difficult for our competitors to obtain a patent that prevents us from using technology we create. As part of our business strategy, we actively seek patent protection

both in the U.S. and internationally and file additional patent applications, when appropriate, to cover improvements in our compounds, products and technology. We also rely on trade secrets, internal know-how, technological innovations and agreements with third parties to develop, maintain and protect our competitive position. Our ability to be competitive will depend on the success of this strategy.

We have a number of patents, patent applications and rights to patents related to our compounds, products and technology, but we cannot be certain that issued patents will be enforceable or provide adequate protection or that pending patent applications will result in issued patents. The following table shows the actual or estimated expiration dates in the U.S. and Europe for the primary patents and for patents that may issue under pending applications that cover the compounds in our marketed products and our product candidates:

	<u>U.S. Patent Expiration</u>	<u>European Patent Expiration</u>
Products		
Viread	2017	2017*
AmBisome	2016	2008
Tamiflu	2016	2016
Vistide	2010	2012
DaunoXome	2009	2008
Product Candidates		
adefovir dipivoxil	2014	2011
Cidecin	N/A**	2019***

- * Applications for these patents are pending. If patents from these applications do not issue, we would not have patent protection through the dates indicated and would instead rely on other patents that expire earlier. For example, if this European patent on Viread does not issue, we have patents that expire in 2006 and 2013 that provide protection.
- ** We do not have commercial rights to Cidecin in the United States.
- *** These are method of use patents. In general, method of use patents do not provide the same level of protection as composition of matter patents.

Patents covering Vistide, Viread, adefovir dipivoxil, and Cidecin are held by third parties. We acquired exclusive rights to these patents in the agreements we have with these parties. See "Collaborative Relationships." Patents do not cover the active ingredients in AmBisome and DaunoXome. Instead, we hold patents to the liposomal formulations of these compounds and also protect these formulations through trade secrets. We do not have patent filings covering all forms of adefovir dipivoxil in China or in certain other Asian countries, although we do have applications pending in various Asian countries, including China, that relate to specific forms and formulations of adefovir dipivoxil. Asia is a major market for HBV therapies.

We may obtain patents for our compounds many years before we obtain marketing approval for them. This limits the time that we can prevent other companies from developing these compounds and therefore reduces the value of the product. However, we can apply for patent term extensions. For example, extensions for the patents on Vistide have been granted in the U.S. and a number of European countries, compensating in part for delays in obtaining marketing approval. Similar patent term extensions may be available for other products that we are developing, but we cannot be certain we will obtain them.

It is also very important that we do not infringe patents or proprietary rights of others and that we do not violate the agreements that grant proprietary rights to us. If we do infringe patents or violate

these agreements, we could be prevented from developing or selling products or from using the processes covered by those patents or agreements, or we could be required to obtain a license from the third party allowing us to use their technology. We cannot be certain that, if required, we could obtain a license to any third-party technology or that we could obtain one at a reasonable cost. If we were not able to obtain a required license, we could be adversely affected. Because patent applications are confidential for at least some period of time, including sometimes in the U.S. until a patent issues, there may be pending patent applications from which patents will eventually issue and prevent us from developing or selling certain products unless we can obtain a license to use the patented technology.

Patents relating to pharmaceutical, biopharmaceutical and biotechnology products, compounds and processes such as those that cover our existing compounds, products and processes and those that we will likely file in the future, do not always provide complete or adequate protection. Future litigation or reexamination proceedings regarding the enforcement or validity of our existing patents or any future patents could invalidate our patents or substantially reduce their protection. In addition, our pending patent applications and patent applications filed by our collaborative partners may not result in the issuance of any patents or may result in patents that do not provide adequate protection. As a result, we may not be able to prevent third parties from developing the same compounds and products that we are developing.

We also rely on unpatented trade secrets and improvements, unpatented internal know-how and technological innovation. In particular, a great deal of our liposomal manufacturing expertise, which is a key component of our liposomal technology, is not covered by patents but is instead protected as a trade secret. We protect these rights mainly through confidentiality agreements with our corporate partners, employees, consultants and vendors. These agreements provide that all confidential information developed or made known to an individual during the course of their relationship with us will be kept confidential and will not be used or disclosed to third parties except in specified circumstances. In the case of employees, the agreements provide that all inventions made by the individual while employed by us will be our exclusive property. We cannot be certain that these parties will comply with these confidentiality agreements, that we would have adequate remedies for any breach, or that our trade secrets will not otherwise become known or be independently discovered by our competitors. Under some of our research and development agreements, inventions discovered in certain cases become jointly owned by us and our corporate partner and in other cases become the exclusive property of one of us. It can be difficult to determine who owns a particular invention, and disputes could arise regarding those inventions.

Competition

Our products and development programs target a number of diseases and conditions, including viral, fungal and bacterial infections. There are many commercially available products for these diseases, and a large number of companies and institutions are spending considerable amounts of money and resources to develop additional products to treat these diseases. Our current products compete with other available products based primarily on:

- product performance;
- safety;
- tolerability;
- acceptance by doctors;
- patient compliance;
- patent protection;
- ease of use;

- price;
- insurance and other reimbursement coverage;
- distribution;
- marketing; and
- adaptability to various modes of dosing.

Any other products we market in the future will also compete with products offered by our competitors. If our competitors introduce data that shows improved characteristics of their products, improve or increase their marketing efforts or simply lower the price of their products, sales of our products could decrease. We also cannot be certain that any products we develop in the future will compare favorably to products offered by our competitors or that our existing or future products will compare favorably to any new products that are developed by our competitors. Our ability to be competitive also depends upon our ability to attract and retain qualified personnel, to obtain patent protection or otherwise develop proprietary products or processes and to secure sufficient capital resources for the substantial period that it takes to develop a product.

AmBisome has several current and expected competitors:

- conventional amphotericin B in markets where AmBisome has been approved as a first line therapy. Conventional amphotericin B is made by Bristol-Myers Squibb Company and numerous generic manufacturers. In many countries, AmBisome cannot be prescribed until conventional amphotericin B therapy has failed or cannot be used.
- caspofungin, a product developed by Merck that received marketing approval in January 2001 in the U.S., where it is sold as Cancidas, and that received marketing approval in the European Union in October 2001. We expect to face significant competition from caspofungin.
- voriconazole, which is being developed by Pfizer, Inc. has received marketing approval in the European Union in March 2002. Pfizer has filed an application for marketing approval for voriconazole in the U.S. and the FDA has deemed the NDA approvable. We expect to face significant competition from voriconazole.
- other lipid-based amphotericin B products approved in the U.S. and throughout Europe, including Abelcet, sold by Elan Corporation, and Amphotec, sold by InterMune Pharmaceuticals, Inc. These products compete against AmBisome as both primary and secondary therapy and are generally offered at prices that are less than AmBisome's price.

Viread faces substantial competition. A number of drugs to treat HIV infection and AIDS are currently sold or are in advanced stages of clinical development, including 17 products currently sold in the U.S. Among the major pharmaceutical companies that are significant competitors in the HIV/AIDS market are GlaxoSmithKline, Bristol-Myers Squibb, Hoffmann-La Roche, Pfizer, Merck, Boehringer-Ingelheim and Abbott Laboratories.

Tamiflu competes with Relenza, an anti-flu drug that is sold by GlaxoSmithKline. Relenza is a neuraminidase inhibitor that is delivered as an orally-inhaled dry powder. In addition, BioCryst Pharmaceuticals is developing a neuraminidase inhibitor anti-flu drug, peramivir, that will represent significant competition when and if the FDA approves it. This drug may be administered as a once-daily pill, as opposed to Tamiflu, which must be taken twice daily for treatment. We cannot be certain that Tamiflu will compare favorably to this drug based on performance, price, length of dosing, side effects or any other criteria. BioCryst Pharmaceuticals has commenced a Phase III clinical trial with peramivir, but it is unclear if or when this product may be on the market.

Vistide competes with a number of drugs that also treat CMV retinitis. These drugs include:

- ganciclovir, the most widely prescribed drug treatment for CMV retinitis, is sold by Hoffman La-Roche in an intravenous formulation for treatment of CMV retinitis and in an oral formulation for prevention and treatment of CMV retinitis, and by Bausch & Lomb Incorporated in a device implanted in a patient's infected eye that releases ganciclovir directly to the infected area;
- valganciclovir, an oral pro-drug formulation of ganciclovir marketed by Hoffman La-Roche, received marketing approval in the U.S. in April 2001 and in the Netherlands in September 2001 for treatment of CMV retinitis, and Hoffman La-Roche has stated it expects pan-European approval by mid-2002;
- foscarnet, an injectable drug for treatment of CMV retinitis, is sold by AstraZeneca; and
- formivirsen, a drug that is injected directly into the eye, is sold by CibaVision.

If adefovir dipivoxil is approved to treat HBV infection, lamivudine will be significant competition. Lamivudine is a drug that was developed by GlaxoSmithKline in collaboration with Biochem Pharma. Lamivudine is sold in the U.S., Europe, China and several other countries and has been shown to be effective in treating patients infected with HBV.

There are drugs that have been approved, or are awaiting approval, for the treatment of Kaposi's sarcoma in the U.S. and Europe, including one that is sold in a liposomal formulation. These drugs compete or are expected to compete with DaunoXome.

A number of companies are pursuing the development of technologies competitive with our research programs. These competing companies include specialized pharmaceutical firms and large pharmaceutical companies acting either independently or together with biopharmaceutical companies. Furthermore, academic institutions, government agencies and other public and private organizations conducting research may seek patent protection and may establish collaborative arrangements for competitive products and programs.

We anticipate that we will face increased competition in the future as our competitors introduce new products to the market and new technologies become available. We cannot determine if existing products or new products that our competitors develop will be more effective or more effectively marketed and sold than any that we develop. Competitive products could render our technology and products obsolete or noncompetitive before we recover the money and resources we used to develop these products.

Government Regulation

Our operations and activities are subject to extensive regulation by numerous government authorities in the U.S. and other countries. In the U.S., drugs are subject to rigorous FDA regulation. The Federal Food, Drug and Cosmetic Act and other federal and state statutes and regulations govern the testing, manufacture, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion of our products. As a result of these regulations, product development and the product approval process is very expensive and time consuming.

The FDA must approve a drug before it can be sold in the U.S. The general process for this approval is as follows:

Preclinical Testing

Before we can test a drug candidate in humans, we must study the drug in laboratory experiments and in animals to generate data to support the drug's potential safety and benefits. We submit this data

to the FDA in an investigational new drug application (IND) seeking their approval to test the compound in humans.

Clinical Trials

If the FDA accepts the investigational new drug application, we study the drug in human clinical trials to determine if the drug is safe and effective. These clinical trials involve three separate phases that often overlap, can take many years and are very expensive. These three phases, which are themselves subject to considerable regulation, are as follows:

- Phase I. The drug is given to a small number of healthy human subjects or patients to test for safety, dose tolerance, pharmacokinetics, metabolism, distribution, and excretion.
- Phase II. The drug is given to a limited patient population to determine the effect of the drug in treating the disease, the best dose of the drug, and the possible side effects and safety risks of the drug.
- Phase III. If a compound appears to be effective and safe in Phase II clinical trials, Phase III clinical trials are commenced to confirm those results. Phase III clinical trials are long-term, involve a significantly larger population, are conducted at numerous sites in different geographic regions and are carefully designed to provide reliable and conclusive data regarding the safety and benefits of a drug. It is not uncommon for a drug that appears promising in Phase II clinical trials to fail in the more rigorous and reliable Phase III clinical trials.

FDA Approval Process

If we believe that the data from the Phase III clinical trials show an adequate level of safety and effectiveness, we will file an NDA with the FDA seeking approval to sell the drug for a particular use. The FDA will review the new drug application and often will hold a public hearing where an independent advisory committee of expert advisors asks additional questions regarding the drug. This committee makes a recommendation to the FDA that is not binding on the FDA but is generally followed by the FDA. If the FDA agrees that the compound has a required level of safety and effectiveness for a particular use, it will allow us to sell the drug in the U.S. for that use. It is not unusual, however, for the FDA to reject an application because it believes that the drug is not safe enough or effective enough or because it does not believe that the data submitted is reliable or conclusive.

At any point in this process, the development of a drug could be stopped for a number of reasons including safety concerns and lack of treatment benefit. We cannot be certain that any clinical trials that we are conducting, including those for Viread for HIV infection and adefovir dipivoxil for chronic HBV infection, or any that we conduct in the future, will be completed successfully or within any specified time period. We may choose, or the FDA may require us to delay or suspend our clinical trials at any time if it appears that the patients are being exposed to an unacceptable health risk or if the drug candidate does not appear to have sufficient treatment benefit.

The FDA may also require us to complete additional testing, provide additional data or information, improve our manufacturing processes, procedures or facilities or require extensive post-marketing testing and surveillance to monitor the safety or benefits of our product candidates if they determine that our new drug application does not contain adequate evidence of the safety and benefits of the drug. In addition, even if the FDA approves a drug, it could limit the uses of the drug. Approvals can also be withdrawn if the FDA does not believe that we are complying with regulatory standards or if problems are uncovered or occur after approval.

In addition to obtaining FDA approval for each drug, the manufacturing facilities for any drug we sell, including those of companies who manufacture our drugs for us as well as our own, must be

approved by the FDA and are subject to periodic inspections by the FDA. Foreign establishments that manufacture products to be sold in the U.S. must also be approved by the FDA and are subject to periodic regulatory inspection. Manufacturing facilities located in California, including our San Dimas facility and Foster City facility, also must be licensed by the State of California in compliance with local regulatory requirements.

Drugs that treat serious or life-threatening diseases and conditions that are not adequately addressed by existing drugs may be designated as fast track products by the FDA and may be eligible for priority six month review and accelerated approval, as was the case for Viread. Drugs receiving accelerated approval must be monitored in post-marketing clinical trials in order to confirm the safety and benefits of the drug. We will seek priority six month review and accelerated approval for adefovir dipivoxil, but we cannot determine whether this will be granted or what the impact of this would be on the timing or likelihood of approval of adefovir dipivoxil.

We are also subject to other federal, state and local regulations regarding workplace safety and protection of the environment. We use hazardous materials, chemicals, viruses and various radioactive compounds in our research and development activities and cannot eliminate the risk of accidental contamination or injury from these materials. Any misuse or accidents involving these materials could lead to significant litigation, fines and penalties.

Drugs are also subject to extensive regulation outside of the U.S. In the European Union, there is a centralized approval procedure that authorizes marketing of a product in all countries in the European Union (which includes most major countries in Europe). If this procedure is not used, under a decentralized system an approval in one country of the European Union can be used to obtain approval in another country of the European Union under a simplified application process. After approval under the centralized procedure, pricing and reimbursement approvals are also required in most countries. Vistide and Viread were approved by the European Union under the centralized procedure. We are using the centralized approval procedure for adefovir dipivoxil. Tamiflu is being reviewed under the centralized procedure, but it has not been approved in Europe.

Pricing and Reimbursement

Insurance companies, health maintenance organizations (HMOs), other third-party payors and some governments seek to limit the amount we can charge for our drugs. For example, in certain foreign markets, pricing negotiations are often required to obtain approval of a product, and in the U.S. there have been, and we expect that there will continue to be, a number of federal and state proposals to implement drug price control. In addition, managed care organizations are becoming more common in the U.S. and will continue to seek lower drug prices. The announcement of these proposals or efforts can cause our stock price to lower, and if these proposals are adopted, our revenues would decrease.

Our ability to sell our drugs also depends on the availability of reimbursement from governments and private insurance companies. These governments and insurance companies often demand rebates or predetermined discounts from list prices. We expect that products we are developing, particularly for AIDS indications, will be subject to reimbursement issues. We cannot be certain that any of our other products that obtain regulatory approval will be reimbursed by these government and insurance companies.

Regulatory approval of prices is generally required in most foreign countries. In particular, certain countries will condition their approval of a product on the agreement of the seller not to sell that product for more than a certain price in that country and in the past have required price reductions after or in connection with product approval. We cannot be certain that regulatory authorities in the future will not establish lower prices or that any regulatory action reducing the price of our products in any one country will not have the practical effect of requiring us to reduce our prices in other

countries. In certain developing countries that are significantly affected by HIV and AIDS, parallel importing and generic competition may occur and adversely affect revenues from sales of or market share of Viread.

Employees

As of February 28, 2002, we had more than 1,000 full-time employees. We believe that we have good relations with our employees.

RISK FACTORS

In evaluating our business, you should carefully consider the following risks in addition to the other information in this report. Any of the following risks could materially and adversely affect our business, operating results and financial condition.

Viread is a new drug, and it may not gain significant market acceptance.

Viread is a new drug and faces an extremely competitive marketplace. There are currently 17 drugs sold in the U.S. for treatment of HIV infection and AIDS, and other potential drugs are in late stages of clinical development. Most of our competitors and potential competitors have substantially greater resources than we do. Those resources include greater experience in promoting and marketing HIV drugs, superior product development capabilities and financial, scientific, manufacturing, marketing, managerial and human resources. In order for Viread to be successful, we will have to establish it in the marketplace against these competitors' drugs. It is too early to determine if Viread will achieve significant market acceptance.

We have never marketed or sold a drug for treatment of HIV infection before and might not be successful in doing so. We have never before operated and managed a marketing and sales operation of this size or attempted to penetrate a potential market of this size and might not do so effectively. We cannot predict whether our Phase III clinical study 903 will demonstrate that Viread is safe and effective in combination therapy for patients who have not had prior HIV therapy, as compared to a competitor's drug. Long term use of Viread may reveal safety issues or the development of resistance to Viread in patients. If our marketing efforts are unsuccessful, if clinical trial results do not demonstrate that Viread is safe and effective in patients who have not had prior HIV therapy, or if Viread turns out to have safety or resistance issues, we may be unsuccessful in convincing physicians to prescribe Viread to their patients, and some government reimbursers and private insurance companies may not pay for Viread if prescribed patients who have not had prior HIV therapy. If Viread does not gain significant market acceptance, results of our operations will suffer.

Any significant reduction in AmBisome or Viread sales would significantly reduce our operating income and could require us to scale back our manufacturing operations and reduce our sales force.

AmBisome sales for the years ended December 31, 1999, 2000 and 2001 were approximately \$129.2 million, or 76%, \$141.1 million, or 72%, and \$164.5 million, or 70%, of our total revenues. We expect that revenues from sales of AmBisome will continue to constitute a substantial part of our total product revenues at least through 2002.

Viread sales for the year ended December 31, 2001 were approximately \$15.6 million, or 7% of our total revenues. This represents sales for access programs in the U.S. and Europe and initial product sales in the U.S. following the U.S. regulatory approval of Viread in October 2001. We expect that product sales of Viread will constitute a substantial part of our total revenues for the foreseeable future.

Accordingly, for the foreseeable future, we expect that we will continue to rely heavily on sales of AmBisome and Viread to support our existing manufacturing and sales infrastructure and to provide operating income to offset a significant portion of our administrative, research and development expenditures. Any significant reduction in sales of AmBisome or Viread, whether as a result of the introduction of competitive products or otherwise, would hurt our business, and we would have to scale back our manufacturing operations and reduce our sales force. There are several products on the market that compete with AmBisome and are generally priced lower than AmBisome. We expect to face significant competition from new antifungal products, including caspofungin, a product developed by Merck and voriconazole, a product developed by Pfizer, Inc. Merck received U.S. marketing approval in January 2001 and European Union marketing approval in October 2001 for caspofungin.

Pfizer received European Union marketing approval in March 2002 and has filed a U.S. marketing approval application that has been deemed approvable by the FDA. Viread faces competition from a number of drugs to treat HIV infection and AIDS, including 17 products currently sold in the U.S.

We have a history of losses, expect to operate at a loss for the foreseeable future and may never be profitable.

We have never been profitable on a full-year operating basis. We may never become profitable on an operating basis. At December 31, 2001, our accumulated deficit was approximately \$453.7 million. Our losses have resulted principally from expenses associated with our research and development programs and, to a lesser extent, from sales, general and administrative expenses. Our product sales and royalty revenues are derived from sales of AmBisome, Viread, Vistide and DaunoXome and royalty arrangements related to Tamiflu, AmBisome and Vistide.

We develop drugs to treat HIV infection and AIDS and related conditions, and therefore changes in the regulatory and commercial environment for HIV infection and AIDS therapies could harm our business.

Several of our products and products in development address HIV infection and AIDS or related conditions. These products include Viread for HIV infection and AIDS, Vistide for CMV retinitis and DaunoXome for HIV-associated Kaposi's sarcoma. We develop those products based upon current policy and the current marketplace for HIV infection and AIDS therapies, as well as our prediction of future policy and the future marketplace for these therapies. Our business is subject to substantial risk because these policies and markets change quickly and unpredictably and in ways that could impair our ability to obtain regulatory approval and commercial acceptance of these products.

Our operations depend on compliance with complex FDA and comparable international regulations.

Failure to obtain broad approvals on a timely basis or to achieve continued compliance could delay commercialization of our products.

The products that we will develop and sell must be approved and will be subject to extensive regulation by the FDA and comparable agencies in other countries. We are continuing clinical trials for AmBisome and Viread for currently approved and additional uses. We are also conducting clinical trials for adefovir dipivoxil. We anticipate that we will conduct a variety of clinical trials and file for marketing approval of additional products over the next several years. Our corporate partner Cubist Pharmaceuticals is conducting clinical trials for Cidecin, and we may conduct clinical trials for Cidecin in the future. These products may fail to receive marketing approval on a timely basis, or at all. In part due to the failure of Cidecin to meet the primary endpoint in Cubist Pharmaceuticals' first pivotal Phase III clinical trial of Cidecin for treatment of community-acquired pneumonia caused by gram-positive bacteria, we are reevaluating our regulatory strategy for Cidecin and do not expect to file a marketing approval application for Cidecin in 2002. We cannot be certain that adefovir dipivoxil or Cidecin will be approved by the FDA, the European Union, or regulatory authorities in other countries, or whether adefovir dipivoxil or Cidecin may receive marketing approvals that place limitations on their uses. These failures, delays or limitations, as well as other regulatory changes, actions and recalls, could delay commercialization of any products and adversely affect our results of operations.

In addition, even after our products are marketed, the products and their manufacturers are subject to continual review. Later discovery of previously unknown problems with our products, our own manufacturing or the production by third-party manufacturers may result in restrictions on our products or the manufacture of our products, including withdrawal of the products from the market. If we fail to comply with applicable regulatory requirements, we could be subject to penalties including fines, suspensions of regulatory approvals, product recalls, seizure of products and criminal prosecution.

Results of clinical trials and approval of products are uncertain, and we may be delayed in or prohibited from selling our products.

We have a number of potential products that have reached the development stage. These potential products include adefovir dipivoxil and Cidecin. We will be required to demonstrate the safety and effectiveness of these and any other products we develop in each intended use through extensive preclinical studies and clinical trials in order to obtain regulatory approval of these products. The results from preclinical and early clinical studies do not always accurately predict results in later, large-scale clinical trials for several reasons, including:

- Preliminary results may not be indicative of effectiveness;
- Further clinical trials may not achieve the desired result; and
- Further clinical trials may reveal unduly harmful side effects or may show the drugs to be less effective than other drugs or delivery systems for the desired indications.

Even successfully completed large-scale clinical trials may not result in marketable products for several reasons, including:

- The potential products are not shown to be safe and effective;
- Regulatory authorities disagree with the results or design of our studies and trials; or
- The potential products are too difficult to develop into commercially viable products.

In January 2001, Cubist Pharmaceuticals announced that in the first pivotal Phase III clinical trial of Cidecin for treatment of community-acquired pneumonia caused by gram-positive bacteria, Cidecin was not successful in meeting the primary endpoint. In November 1999, an FDA Advisory Committee recommended against approval of our application to approve a 60 mg dose of adefovir dipivoxil to treat HIV infection. Kidney toxicity associated with this 60 mg dose, as well as a desire for additional data, were the major concerns of this committee. Following this recommendation, we were informed by the FDA that it would not approve our application unless we obtained additional data that satisfied the concerns raised by this committee. Based on these discussions, we terminated our development of adefovir dipivoxil for the treatment of AIDS. We have used and are using 10 mg doses of adefovir dipivoxil in our Phase III clinical trials of adefovir dipivoxil for HBV infection and are seeking regulatory approval for the 10 mg dose. Clinical results to date indicate that these lower doses do not result in the kidney toxicity experienced with 60 mg and that adefovir dipivoxil can be effective in treating HBV infection at these lower doses. We cannot be certain, however, that these lower doses will be both safe enough and have sufficient treatment benefits to receive FDA approval. Viread is in the same class of drugs as adefovir dipivoxil. While we have not yet observed kidney toxicity in our clinical trials of Viread, the kidney toxicity in our clinical trials of adefovir dipivoxil for HIV infection did not arise until the later stages of our clinical trials. We cannot be certain that similar toxicity issues will not arise later in our ongoing clinical trials of Viread. A number of companies in our industry have suffered similar setbacks in advanced clinical trials despite promising results in earlier trials. In the end, we may be unable to develop additional marketable products.

Delays in enrolling patients or developing suitable protocols for clinical trials could increase costs and delay regulatory approvals.

The rate of completion of our clinical trials will depend on the rate of patient enrollment. There will be substantial competition to enroll patients in clinical trials for our drugs in development. This competition has delayed our clinical trials in the past. In addition, recent improvements in existing drug therapy, particularly for HIV and HBV infections, may make it more difficult for us to enroll patients in our clinical trials as the patient population may choose to enroll in clinical trials sponsored by other companies or choose alternative therapies. Delays in planned patient enrollment can result in increased development costs and delays in regulatory approvals.

Our clinical trials must be carried out under protocols that are acceptable to regulatory authorities and to the committees responsible for clinical studies at the sites at which the studies are conducted. There may be delays in preparing protocols or receiving approval for them that may delay either or both of the start and finish of our clinical trials. In addition, feedback from regulatory authorities or results from earlier stage clinical studies might require modifications or delays in later stage clinical trials. These types of delays can result in increased development costs and delayed regulatory approvals.

Our product development efforts may not yield marketable products due to results of studies or trials, failure to achieve regulatory approvals or market acceptance, proprietary rights of others or manufacturing issues.

Our success depends on our ability to successfully develop and obtain regulatory approval to market new pharmaceutical products. A significant portion of the research that we will conduct will involve new and unproven technologies. Development of a product requires substantial technical, financial and human resources even if the product is not successfully completed.

Our potential products may appear to be promising at various stages of development yet fail to reach the market for a number of reasons, including:

- lack of sufficient treatment benefit or unacceptable toxicity during preclinical studies or clinical trials;
- failure to receive necessary regulatory approvals;
- existence of proprietary rights of third parties; and
- inability to develop manufacturing methods that are efficient, cost-effective and capable of meeting stringent regulatory standards.

Most of our product sales occur outside the U.S., and currency fluctuations may impair our financial results.

A significant majority of our sales is denominated in foreign currencies. Increases in the value of the U.S. dollar against these foreign currencies in the past have reduced, and in the future may reduce, our U.S. dollar return on these sales and negatively impact our financial condition. We hedge with respect to foreign accounts receivable, but we did not in the past hedge our exposure to the impact of fluctuating foreign exchange rates on forecasted sales. Effective January 2002, we have begun to use forward contracts to hedge a percentage of our forecasted international sales, primarily those sales denominated in the euro currency. We expect the use of these forward contracts will reduce the impact of foreign currency fluctuations on our future results.

Product development expenses can cause our operating expenses to fluctuate from quarter to quarter.

The clinical trials required for regulatory approval of our products are extremely expensive. It is difficult to accurately predict or control the amount or timing of these expenses from quarter to

quarter. Uneven and unexpected spending on these programs causes our operating results to fluctuate from quarter to quarter.

We depend on relationships with other companies for research funding, clinical development, sales and marketing performance and revenues. Failure to maintain these relationships would negatively impact our business.

We rely on a number of significant collaborative relationships with major pharmaceutical companies for our research funding, clinical development and/or sales and marketing performance. These include collaborations with Fujisawa Healthcare, GlaxoSmithKline, Hoffmann-La Roche, Pharmacia Corporation, EyeTech Pharmaceuticals, Inc., and Sumitomo Pharmaceuticals Co. Inc. In certain countries, we only rely on international distributors for sales of AmBisome and in such countries intend to only rely on international distributors for sales of Viread. In addition, under our collaboration agreement with Cubist Pharmaceuticals, Inc. to commercialize Cubist's antibacterial drug Cidecin in several European countries following regulatory approval, Cubist is responsible for the ongoing clinical development of Cidecin. Accordingly, we will have no control over but will rely on Cubist's clinical trials for our regulatory filings for Cidecin. Cidecin did not meet the primary end point in Cubist's first Phase III clinical trial for community-acquired pneumonia caused by gram-positive bacteria. We do not expect to file a marketing approval application in the European Union in 2002 for only the complicated skin and soft tissue infection indication, for which Cidecin has achieved success in Phase III clinical trials. If ongoing clinical trials do not support regulatory approval, Cubist is not required to conduct additional clinical trials and we may choose to conduct these trials ourselves at our expense. Reliance on collaborative relationships poses a number of risks, including:

- We will not be able to control whether our corporate partners will devote sufficient resources to our programs or products;
- Disputes may arise in the future with respect to the ownership of rights to technology developed with corporate partners;
- Disagreements with corporate partners could lead to delays in or termination of the research, development or commercialization of product candidates, or result in litigation or arbitration;
- Contracts with our corporate partners may fail to provide significant protection or may fail to be effectively enforced if one of these partners fails to perform;
- Corporate partners have considerable discretion in electing whether to pursue the development of any additional products and may pursue alternative technologies or products either on their own or in collaboration with our competitors;
- Corporate partners with marketing rights may choose to devote fewer resources to the marketing of our products than they do to products of their own development; and
- Our distributors and corporate partners may be unable to pay us.

Given these risks, there is a great deal of uncertainty regarding the success of our current and future collaborative efforts. If these efforts fail, our product development or commercialization of new products could be delayed or revenue from existing products, including Tamiflu and AmBisome, could decline. In January 2002, Hoffmann-La Roche announced that due to production problems the liquid suspension form of Tamiflu approved for treatment of children as young as one year old was not available but was expected to be available in the 2002-2003 flu season. These production issues do not affect availability of the tablet form of Tamiflu for adults and adolescents 13 years and older. We do not expect the current production issues to have a material effect on our earnings.

**Our rights to market AmBisome in the U.S. and Canada are limited by an agreement with Fujisawa.
Failure of Fujisawa to effectively market AmBisome may reduce our revenues.**

Our rights to market AmBisome in the U.S. and Canada are subject to an agreement with Fujisawa. Under the terms of this agreement, we have sole marketing rights to AmBisome in all countries except the U.S. and Canada but must pay royalties in connection with sales in most significant Asian markets, including Japan. We co-promote AmBisome with Fujisawa in the U.S. We manufacture AmBisome for sale in the U.S. and Canada and sell AmBisome to Fujisawa at cost in the U.S. and at cost plus a specified percentage in Canada. Fujisawa collects all revenues from AmBisome sales in the U.S. and pays us approximately 17% of net sales. The success of AmBisome in the U.S. will be dependent primarily on the efforts of Fujisawa, and in Canada the success of AmBisome will depend entirely on Fujisawa. If Fujisawa fails in its efforts, potential revenues from the sales of AmBisome may be substantially reduced.

Failure of Hoffmann-La Roche to effectively market Tamiflu would reduce our potential revenues.

Hoffmann-La Roche has sole responsibility for promoting and selling Tamiflu on a worldwide basis and we have no control over their activities. Therefore, we are relying on the efforts of Hoffmann-La Roche for any revenues we receive from the sale of Tamiflu. If Hoffmann-La Roche does not dedicate sufficient resources to the promotion of Tamiflu, or if Hoffmann-La Roche fails in its marketing efforts, the royalties we receive from the sale of Tamiflu would decrease and we would be adversely affected.

Inability to establish future successful collaborative relationships may impair our financial results.

We may seek future collaborative relationships with corporate partners to fund some of our research and development expenses and to develop and commercialize some of our, or their, potential products. Further, we anticipate that our revenues from collaborative agreements will continue to be affected by existing agreements, as well as by the timing of drug development programs of our corporate partners. We may not be able to negotiate acceptable collaborative arrangements in the future, and any arrangements we do negotiate may not be successful. If we fail to establish additional collaborative relationships, we will be required to undertake research, development, marketing and manufacturing of our proposed products at our own expense or discontinue or reduce these activities.

Our existing products and products under development may not be accepted by physicians, insurers and patients.

Adefovir dipivoxil and Cidecin, if approved for marketing, would have no established market. The ability of these products to achieve and sustain market acceptance will depend on the receipt and scope of regulatory approvals and whether or not government authorities and managed care organizations will adequately reimburse patients who use these products.

In addition, we need to convince the medical and patient advocacy community of:

- the effectiveness of these products in treating disease;
- the safety of these products when administered to patients; and
- the advantages of these products over competitive products.

Physicians, patients, patient advocates, payors and the medical community in general may not accept or use any products that we may develop. If our products are not accepted, our results of operations will suffer.

Many other companies are targeting the same diseases and conditions as we are. Competitive products from other companies could significantly reduce the market acceptance of our products.

Our products and development programs target a number of diseases and conditions, including viral infections, fungal infections, and bacterial infections. There are many commercially available products for these diseases. Certain of these products are well-established therapies and have generated substantial sales. In addition, a large number of companies and institutions are conducting well-funded research and development activities directed at developing treatments for these diseases. Products currently on the market and those under development by our competitors could make our technology and products obsolete or noncompetitive. We expect that competition for the treatment of these diseases will increase in the future as new products enter the market and advanced technologies become available. We will also be competing to license or acquire technology from other companies.

Most of our competitors and potential competitors have substantially greater resources than we do. Those resources include superior product development capabilities and financial, scientific, manufacturing, marketing, managerial and human resources. These competitors may achieve superior patent protection, obtain key technology, receive regulatory approval or achieve product commercialization earlier than us.

The significantly greater resources of the marketing organizations of large pharmaceutical companies could hinder our ability to compete successfully.

Our products compete, and the products we may develop are likely to compete, with products of other companies that currently have extensive and well-funded marketing and sales operations. Because these companies are capable of devoting significantly greater resources to their marketing efforts, our marketing or sales efforts may not compete successfully against the efforts of these other companies.

Our existing products are subject to reimbursement from government agencies and other third parties. Pharmaceutical pricing and reimbursement pressures may reduce profitability.

Successful commercialization of our products depends, in part, on the availability of governmental and third party payor reimbursement for the cost of such products and related treatments. Government health administration authorities, private health insurers and other organizations generally provide reimbursement. Government authorities and third-party payors increasingly are challenging the price of medical products and services, particularly for innovative new products and therapies. This has resulted in lower average sales prices. For example, a majority of our sales of AmBisome, Vistide and DaunoXome are subject to reimbursement by government agencies, resulting in significant discounts from list price and rebate obligations. Our business may be adversely affected by an increase in U.S. or international pricing pressures. These pressures can arise from rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and health care reform, pharmaceutical reimbursement and pricing in general. In the U.S. in recent years, new legislation has been proposed at the federal and state levels that would effect major changes in the health care system, either nationally or at the state level. These proposals have included prescription drug benefit proposals for Medicare beneficiaries introduced in Congress. Although there has been no U.S. federal reform legislation, some states have enacted health care reform legislation. Further federal and state developments are possible. Although we cannot predict the exact nature of legislative health care reforms, if any, our results of operations could be adversely affected by such reforms. In Europe, the success of Tamiflu (if approved for sale) and Viread will also depend largely on obtaining government reimbursement in Europe because in many European countries, including the United Kingdom and France, patients are reluctant to pay for prescription drugs out of their own pocket. We also expect that the success of our products in development, particularly in Europe, will depend on the ability to obtain reimbursement. Even if reimbursement is available, reimbursement policies may adversely affect our ability to sell our products on a profitable basis.

In addition, in many international markets, governments control the prices of prescription pharmaceuticals. In these markets, once marketing approval is received, pricing negotiation can take another six to twelve months or longer. Product sales, attempts to gain market share or introductory pricing programs of our competitors could require us to lower our prices in these countries, which could adversely affect our results of operations.

We may not be able to obtain effective patents to protect our technologies from use by competitors, and patents of other companies could require us to stop using or pay for the use of required technology.

Our success will depend to a significant degree on our ability to:

- obtain patents and licenses to patent rights;
- preserve trade secrets; and
- operate without infringing on the proprietary rights of others.

We have rights to U.S. and foreign issued patents and have filed and will continue to file patent applications in the U.S. and abroad relating to our technologies. There is a risk, however, that patents may not issue from any of these applications or that the patents will not be sufficient to protect our technology. Patent applications are confidential for at least some period of time, sometimes in the U.S. until a patent issues. As a result, we may not know if our competitors filed patent applications for technology covered by our pending applications. We also cannot be certain that we were the first to invent the technology that is the subject of our patent applications. Cidecin is protected by method of use patents that generally do not provide the same level of protection as composition of matter patents. Competitors may have filed patent applications or received patents and may obtain additional patents and proprietary rights that block or compete with our patents.

We do not have patent filings covering all forms of adefovir dipivoxil in China or in certain other Asian countries, although we do have applications pending in various Asian countries, including China, that relate to various forms and formulations of adefovir dipivoxil. Asia is a major market for HBV therapies, one of the potential indications for adefovir dipivoxil. We may obtain patents for certain products many years before marketing approval is obtained for those products. Because patents have a limited life, which may begin to run prior to commercial sale, the commercial value of the product may be limited. In addition, patents may not provide adequate protection in certain countries in Africa and Asia, including China.

Our competitors may file patent applications covering our technology. If so, we may have to participate in interference proceedings or litigation to determine the right to a patent. Litigation and interference proceedings are expensive even if successful.

Our success depends in large part on our ability to operate without infringing upon the patents or other proprietary rights of third parties. If we infringe the patents of others, we may be prevented from commercializing products or may be required to obtain licenses from these third parties. We cannot be certain that we would be able to obtain alternative technologies or any required license. Even if we were to obtain such technologies or licenses, we cannot be certain that the terms would be reasonable. If we fail to obtain such licenses or alternative technologies, we may be unable to develop some or all of our products.

For example, we may decide to use an assay method in our drug screening programs. ICT Pharmaceuticals has patents that may cover parts of this program. ICT Pharmaceuticals has offered us a non-exclusive license under these patents as part of an industry-wide licensing program. If it is determined that we need these patents for this program, we would need to obtain this license or develop or acquire alternative technologies for this program. We cannot be certain that we would be

able to obtain this license on reasonable terms or that alternative technologies could serve our needs for future drug development.

In addition, we use significant proprietary technology and rely on unpatented trade secrets and proprietary know-how to protect certain aspects of our production and other technologies. Our trade secrets may become known or independently discovered by our competitors.

In a number of developing countries, government officials and other groups have suggested that pharmaceutical companies should make drugs for HIV infection available at a low cost. In some cases, governmental authorities have indicated that where pharmaceutical companies do not do so, their patents might not be enforceable to prevent generic competition. Some major pharmaceutical companies have greatly reduced prices for HIV drugs in certain developing countries. If certain countries do not permit enforcement of our patents, sales of Viread in those countries could be reduced by generic competition. Alternatively, governments in those countries could require that we grant compulsory licenses to allow competitors to manufacture and sell their own versions of Viread in those countries, thereby reducing our Viread sales, or we could respond to governmental concerns by reducing prices for Viread. In either case, our results of operations would be adversely affected.

Manufacturing problems could delay product shipments and regulatory approvals.

For Vistide, adefovir dipivoxil and Viread, we rely on third parties for the manufacture of bulk drug substance and final drug product for clinical and commercial purposes. Hoffmann-La Roche is responsible for manufacturing Tamiflu, and if they encounter problems in this process, our revenues from the sales of Tamiflu could decrease. We depend on these third parties to perform their obligations effectively and on a timely basis. If these third parties fail to perform as required, our clinical trials or submission of products for regulatory approval may be delayed. These delays could impair our ability to deliver commercial products on a timely basis and could impair our competitive position. Hoffmann-La Roche has announced that due to production problems the liquid suspension form of Tamiflu approved for treatment of children as young as one year old was not currently available but was expected to be available in the 2002-2003 flu season. We do not expect the current production issues to have a material effect on our earnings.

We manufacture AmBisome and DaunoXome at our facilities in San Dimas, California. Our only formulation and manufacturing facilities are in San Dimas, California; although we own a manufacturing facility in Ireland that performs certain quality control testing, labeling and packaging, and we use third parties as alternate contract suppliers to fill and freeze dry certain batches of product. In the event of a natural disaster, including an earthquake, equipment failure, strike or other difficulty, we may be unable to replace this manufacturing capacity in a timely manner and would be unable to manufacture AmBisome and DaunoXome to meet market needs.

We may not be able to obtain materials necessary to manufacture our products.

Many of the materials that we utilize in our operations are made at only one facility. For example, we depend on single suppliers for high quality amphotericin B, daunorubicin HCl, distearoylphosphatidylcholine and high quality cholesterol, each of which is used in the manufacture of one or more of our liposomal products. Because the suppliers of key components and materials must be named in the new drug application filed with the FDA for a product, significant delays can occur if the qualification of a new supplier is required. If supplies from our suppliers were interrupted for any reason, we could be unable to ship AmBisome, Viread, Vistide or DaunoXome, or supply any of our products in development for clinical trials.

We have limited experience in manufacturing products and may not be able to develop adequate manufacturing capacity.

For some of our potential products, we will need to develop further our production technologies for use on a larger scale in order to conduct clinical trials and produce such products for commercial sale at an acceptable cost. We cannot be certain that we will be able to implement any of these developments successfully.

The manufacturing process for pharmaceutical products is highly regulated, and regulators may shut down manufacturing facilities that they believe do not comply with regulations. The FDA's current Good Manufacturing Practices are extensive regulations governing manufacturing processes, stability testing, record-keeping and quality standards. In addition, our manufacturing operations are subject to routine inspections by regulatory agencies and similar regulations are in effect in other countries.

Our business may give rise to product liability claims not covered by insurance or indemnity agreements.

The testing, manufacturing, marketing and use of AmBisome, Viread, Vistide and DaunoXome, as well as products in development, involve substantial risk of product liability claims. These claims may be made directly by consumers, healthcare providers, pharmaceutical companies or others. A successful product liability claim against us could require us to pay substantial amounts, which could impair our financial condition and our ability to clinically test and to market our products.

Additionally, we are required by governmental regulations to test our products even after they have been sold and used by patients. As a result of such tests, we may be required to, or may determine that, we should recall products already in the market. Subsequent testing and product recalls may increase our potential exposure to product liability claims.

Our internal research programs and our efforts to obtain rights to new products from third parties may not yield potential products for clinical development.

Our long term success depends on our ability either to identify either internal research programs potential product candidates that may be developed into new pharmaceutical products or to obtain new products or product candidates through licenses from third parties.

A significant portion of the research that we will conduct will involve new and unproven technologies. Research programs to identify product candidates require substantial technical, financial and human resources whether or not such candidates are identified. Our research programs may appear to be a promising route to identifying potential product candidates yet fail to yield product candidates for clinical development for a number of reasons, including:

- the research methodology used may not be successful in identifying potential product candidates;
- potential product candidates may on further study be shown to have unduly harmful side effects or characteristics that indicate they are unlikely to be effective drugs;
- we may be unable to develop larger scale manufacturing methods that are efficient, cost-effective and capable of meeting stringent regulatory standards;
- others may hold intellectual property rights that prevent us from developing, making or selling certain products.

We may be unable to obtain suitable product candidates or products from third parties for a number of reasons, including:

- we may be unable to purchase or license such compounds on terms that would allow us to make an appropriate return from the product;
- competitors may be unwilling to assign or license product rights to us;

- we may be unable to identify suitable products or product candidates within our areas of expertise; or
- product candidates that we acquire may not be approved by regulatory authorities due to problems with their safety or effectiveness.

If we are unable to develop suitable potential product candidates through internal research programs or obtain rights to new products from third parties, our future revenue growth will suffer.

Our use of hazardous materials, chemicals, viruses and radioactive compounds exposes us to potential liabilities.

Our research and development involves the controlled use of hazardous materials, chemicals, viruses and various radioactive compounds. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by state and federal regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials. In the event of such an accident, we could be held liable for significant damages or fines.

ITEM 2. PROPERTIES

Our corporate headquarters, including our principal executive offices and certain of our research facilities, are located in Foster City, California. At this location, we lease approximately 260,000 square feet of space in eight proximately located buildings. One of the subleases covering approximately 59,000 square feet of space in this group of buildings expires in December 2003 and there are no renewal options. The remaining leases expire in March and September 2006 and we have an option to renew all of these leases for two additional five-year periods.

We also occupy facilities in San Dimas, California. At this location, we lease approximately 102,500 square feet of space, which houses research and development activities, manufacturing and certain administrative functions under leases that expire in May and November 2003, with two five-year renewal options. In addition, we lease an adjacent warehouse facility with about 53,000 square feet of space that we use for product distribution and administrative functions under a lease that expires in April 2006, with two additional five-year extensions.

In addition, we lease approximately 85,000 square feet of space for our sales and marketing, regulatory, finance, information technology and human resource operations in Europe and Australia, including a prepaid, 999-year lease for our 13,000 square foot manufacturing and distribution facility in Ireland. The other leases have various expiration dates.

We believe that our facilities are adequate and suitable for at least our current and near-term future needs.

ITEM 3. LEGAL PROCEEDINGS

On August 11, 1997, we entered into a settlement with Elan Corporation (the successor to The Liposome Company, Inc.) in which we each agreed to dismiss all legal proceedings involving patents related to our liposomal formulation of amphotericin B. In the settlement agreement, Elan agreed not to sue us in connection with the worldwide production and sales of AmBisome and gave us rights to use some of their patents. Under the terms of the settlement Agreement, we are required to make payments based on AmBisome sales over the next several years.

We are also a party to various other legal actions that arose in the ordinary course of our business. We do not believe that any of these other legal actions will have any significant impact on our business.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITIES HOLDERS

None

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON STOCK AND RELATED STOCKHOLDER MATTERS

Our common stock is traded on The Nasdaq Stock Market under the symbol "GILD." The following table sets forth for the periods indicated the high and low intra-day sale prices per share of our common stock on The Nasdaq Stock Market. These prices represent quotations among dealers without adjustments for retail mark-ups, mark-downs or commissions, and may not represent prices of actual transactions.

	<u>High</u>	<u>Low</u>
2001		
First Quarter	\$20.88	\$12.44
Second Quarter	\$30.98	\$14.41
Third Quarter	\$31.75	\$22.85
Fourth Quarter	\$36.84	\$27.28
2000		
First Quarter	\$21.25	\$11.19
Second Quarter	\$19.13	\$10.82
Third Quarter	\$29.53	\$16.50
Fourth Quarter	\$27.69	\$15.24

On February 22, 2001 and on March 8, 2002, the Company implemented two-for-one stock splits in the form of stock dividends. All share and per share amounts for all periods presented have been restated to reflect both of these splits.

As of February 28, 2002, we had 193,999,216 shares of common stock outstanding held by approximately 510 stockholders of record. We have not paid cash dividends on our common stock since our inception and we do not anticipate paying any in the foreseeable future.

ITEM 6. SELECTED FINANCIAL DATA

GILEAD SCIENCES, INC.
SELECTED CONSOLIDATED FINANCIAL DATA (1)(2)
(in thousands, except per share data)

	Years Ended December 31,				
	2001	2000	1999	1998	1997
CONSOLIDATED STATEMENT OF OPERATIONS DATA:					
Total revenues	\$233,769	\$195,555	\$168,979	\$151,119	\$132,258
Total costs and expenses	354,458	247,873	239,838	230,631	220,480
Loss from operations	(120,689)	(52,318)	(70,859)	(79,512)	(88,222)
Income/(loss) before cumulative effect of change in accounting principle	51,182	(43,106)	(66,486)	(44,758)	(72,893)
Cumulative effect of change in accounting principle(3)	1,089	(13,670)	—	—	—
Net income/(loss)	52,271	(56,776)	(66,486)	(44,758)	(72,893)
Amounts per common share—basic:(4)					
Income/(loss) before cumulative effect of change in accounting principle	\$ 0.27	\$ (0.24)	\$ (0.39)	\$ (0.27)	\$ (0.46)
Cumulative effect of change in accounting principle	0.01	(0.07)	—	—	—
Net income/(loss) per share—basic	\$ 0.28	\$ (0.31)	\$ (0.39)	\$ (0.27)	\$ (0.46)
Shares used in per share calculation—basic (4)	190,245	182,099	171,305	164,060	157,728
Amounts per common share—diluted:(4)					
Income/(loss) before cumulative effect of change in accounting principle	\$ 0.25	\$ (0.24)	\$ (0.39)	\$ (0.27)	\$ (0.46)
Cumulative effect of change in accounting principle	0.01	(0.07)	—	—	—
Net income/(loss) per share—diluted	\$ 0.26	\$ (0.31)	\$ (0.39)	\$ (0.27)	\$ (0.46)
Shares used in per share calculation—diluted (4)	202,321	182,099	171,305	164,060	157,728

	December 31,				
	2001	2000	1999	1998	1997
CONSOLIDATED BALANCE SHEET DATA:					
Cash, cash equivalents and marketable securities	\$ 582,851	\$ 512,878	\$ 294,394	\$ 348,743	\$ 387,361
Working capital	627,642	535,560	324,104	359,555	396,810
Total assets	794,786	678,099	436,808	487,764	516,989
Long-term obligations	389	2,238	5,253	8,883	9,658
Convertible subordinated debt	250,000	250,000	79,533	80,000	80,000
Accumulated deficit	(453,737)	(506,008)	(449,232)	(382,746)	(337,988)
Total stockholders' equity(5)	452,437	351,124	297,292	333,699	357,726

(1) During 2001, we completed the sale of our oncology assets and related technology to OSI and recorded a non-operating gain of \$157.8 million. We also recorded a non-operating gain in 2001 of \$8.8 million from the sale of our 49 percent interest in Prologo.

- (2) Periods prior to the year ended December 31, 1999 have been restated to reflect the merger with NeXstar Pharmaceuticals, Inc. on July 29, 1999, which was accounted for as a pooling of interests.
- (3) Gilead adopted Statement of Financial Accounting Standards Nos. 133 and 138, collectively referred to as SFAS 133, *Accounting for Derivative Instruments and Hedging Activities*, in the first quarter of 2001. The change was accounted for as a change in accounting principle. Effective in the first quarter of 2000, Gilead adopted the SEC's Staff Accounting Bulletin No. 101 (SAB 101), *Revenue Recognition in Financial Statements*, and the change was also accounted for as a change in accounting principle.
- (4) On February 22, 2001 and on March 8, 2002, the Company implemented two-for-one stock splits in the form of stock dividends. All share and per share amounts for all periods presented have been restated to reflect both of these splits.
- (5) No cash dividends have been declared or paid on the Company's common stock.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Overview

Gilead was incorporated in Delaware on June 22, 1987. We are an independent biopharmaceutical company focused on the discovery, development and commercialization of antivirals, antibacterials and antifungals to treat life-threatening infectious diseases. We are a multinational company, with revenues from five approved products and marketing operations in ten countries. Currently, we market Viread™ (tenofovir disoproxil fumarate) for the treatment of HIV infection, AmBisome® ((amphotericin B) liposome for injection), an antifungal agent, DaunoXome® (daunorubicin citrate liposome injection), a drug approved for the treatment of Kaposi's Sarcoma, and Vistide® (cidofovir injection) for the treatment of cytomegalovirus (CMV) retinitis. Hoffmann-La Roche Inc. markets Tamiflu™ (oseltamivir phosphate) for the treatment of influenza, under a collaborative agreement with Gilead. We are seeking to add to our existing portfolio of products through our clinical development programs, internal discovery programs and an active product acquisition and in-licensing strategy. Our internal discovery activities include identification of new molecular targets, target screening and medicinal chemistry. In addition, we are currently developing products to treat hepatitis B virus and bacterial infections. We also have expertise in liposomal drug delivery technology that we use to develop drugs that are safer, easier for patients to tolerate and more effective.

In December 2001, we completed the sale of our oncology assets to OSI Pharmaceuticals, Inc. in a transaction valued at up to \$200.0 million in cash and OSI stock. This transaction will allow us to focus on and continue to strengthen our core expertise in infectious diseases. See Note 4 to the consolidated financial statements for further information.

On February 22, 2001 and on March 8, 2002, Gilead completed two-for-one stock splits, effected in the form of a stock dividend, to stockholders of record as of February 2, 2001 and February 14, 2002, respectively. Accordingly, all share and per share amounts for all periods presented have been restated to reflect both of these splits.

In the year ended December 31, 2001, Gilead adopted Statement of Financial Accounting Standards Nos. 133 and 138, collectively referred to as SFAS 133, *Accounting for Derivative Instruments and Hedging Activities*, which resulted in a cumulative effect of change in accounting principle. In the year ended December 31, 2000, Gilead adopted the Securities and Exchange Commission's Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements*, also resulting in a cumulative effect of change in accounting principle.

On July 29, 1999, Gilead entered into a business combination with NeXstar Pharmaceuticals, Inc. (NeXstar). The business combination has been accounted for as a pooling of interests and the historical consolidated financial statements of Gilead for all periods prior to the business combination have been restated to include the financial position, results of operations and cash flows of NeXstar.

Certain prior period amounts have been reclassified to conform to the current presentation.

Forward-Looking Statements and Risk Factors

The following discussion contains forward-looking statements that involve risks and uncertainties. Gilead's actual results could differ materially from those discussed in any forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in this section, as well as under the caption "Business," including "Risk Factors" in Part I. All forward-looking statements included in this document are based on information currently available to Gilead, and we assume no obligation to update any such forward-looking statements. The following discussion should be read in conjunction with the consolidated financial statements and notes included elsewhere in this report.

AmBisome Sales. We rely on sales of AmBisome for a significant portion of our operating income. There are lower priced products that compete with AmBisome; a product that was recently approved that competes with AmBisome, a product that the FDA has deemed approvable; and products being developed that could compete with AmBisome in the future. If these other products achieve further market acceptance, or if the products in development become commercially available, revenues from sales of AmBisome would likely decrease, resulting in a reduction of operating income.

Viread Sales. In the future, we also expect to rely on sales of Viread for a portion of our operating income. A number of drugs to treat HIV infection and AIDS are currently sold or are in advanced stages of clinical development, including 17 products currently sold in the U.S. Among the companies that are significant competitors in the HIV/AIDS market are GlaxoSmithKline, Bristol-Myers Squibb, Hoffmann-La Roche, Pfizer, Merck, Boehringer-Ingelheim and Abbott Laboratories. Given the broad range of competitors and depth of their resources, it is too early to determine if Viread will achieve significant market penetration, particularly for use in treatment naïve patients given that the data supporting Viread's U.S. approval is in a treatment experienced patient population.

Market Acceptance of Products. The ability of our products to achieve and sustain market acceptance will depend on a number of factors, including: the receipt and scope of regulatory approvals; the availability of public and private insurance and reimbursement for our products; the safety, efficacy, tolerability and cost of our products; and how our products compare to competitive products. If our products do not achieve and sustain market acceptance, our results of operations will suffer. Tamiflu is in a new class of drugs that represent a new approach to treating and preventing the flu. In order for Tamiflu to achieve market acceptance, our marketing partner, Roche, must change attitudes toward the treatment and prevention of influenza.

Regulatory Process. The U.S. Food and Drug Administration and foreign agencies could reject or limit the commercialization of our products for a number of reasons including: if they disagree with the results or designs of our clinical trials; if they believe our products have unacceptable efficacy, toxicity or tolerability; or if they believe our products cannot be safely and efficiently manufactured on a commercial basis. If these agencies reject or limit the commercialization of our products, our financial results would be adversely affected. The clinical trials required for regulatory approval of our products are extremely expensive, and it is difficult for us to accurately predict or control the amount or timing of these expenses from quarter to quarter. In addition, regulatory agencies could require us to conduct additional unanticipated clinical trials on our products, the cost of which could be substantial.

Medicaid and other Governmental Reimbursement and Discount Programs. Our business may be adversely affected by an increase in pricing pressures, both in the U.S. and abroad. These pressures can arise from rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and health care reform, pharmaceutical reimbursement and pricing in general. The U.S. has enacted legislation that requires us to pay a set rebate or offer a discount for our products that are reimbursed by Medicaid, purchased as outpatient medicines by certain Public Health Service entities and certain hospitals, or sold to certain other federal purchasers including the Veterans' Administration. In recent years, new legislation has been proposed in the U.S. at the federal and state levels that would effect major changes in the health care system, either nationally or at the state level. These proposals have included prescription drug benefit proposals for Medicare beneficiaries introduced in Congress. Although there has been no U.S. federal reform legislation, some states have enacted health care reform legislation. Further federal and state developments are possible. Although we cannot predict the exact nature of legislative health care reforms, the results of our operations would be adversely affected if national or state governments require us to sell our marketed products at lower prices.

Compulsory Licensing and Generic Competition. In a number of developing countries, government officials and other groups have suggested that pharmaceutical companies should make drugs for HIV infection available at a low cost. In some cases, governmental authorities have indicated that where pharmaceutical companies do not do so, their patents might not be enforceable to prevent generic competition. Some major pharmaceutical companies have greatly reduced prices for HIV drugs in certain developing countries. If certain countries do not permit enforcement of our patents, sales of Viread in those countries could be reduced by generic competition. Alternatively, governments in those countries could require that we grant compulsory licenses to allow competitors to manufacture and sell their own versions of Viread in those countries, thereby reducing our Viread sales, or we could respond to governmental concerns by reducing prices for Viread. In either case, our results of operations would be adversely affected.

Collaborations. We depend on collaborations for the development and commercialization of certain products and for revenue, including the collaboration with Fujisawa for sales of AmBisome in the United States and Canada, the collaboration with Roche for sales of Tamiflu worldwide, and the collaboration with Cubist for the clinical development of Cidecin. These collaborations could fail for a number of reasons, including if our partners do not devote sufficient resources to the development, commercialization or marketing of our products, or if disputes arise with our partners. We will also seek additional collaborations. If our collaborations fail or if we are unable to establish additional collaborations, our financial results would be adversely affected.

Foreign Currency Fluctuations. A significant majority of our product sales is denominated in foreign currencies. Increases in the value of the U.S. Dollar against these foreign currencies in the past have reduced, and in the future may reduce, our U.S. Dollar return on these sales and negatively impact our financial condition. We did not in the past hedge our exposure to the impact of fluctuating foreign exchange rates on forecasted sales. Effective January 2002, we have begun to use forward contracts to hedge a percentage of our forecasted international sales, primarily those denominated in the euro currency. We do hedge accounts receivable balances denominated in foreign currencies, which minimizes but does not eliminate our exposure to currency fluctuations between the date a sale is recorded and the date that cash is collected. Additionally, to mitigate the impact of currency rate fluctuations on our cash outflows for certain foreign currency-denominated raw materials purchases, we enter into foreign exchange forward contracts to hedge our foreign currency-denominated accounts payable.

Uncertain Financial Results. We expect that our financial results will continue to fluctuate from quarter to quarter and that such fluctuations may be substantial. The fluctuations can be caused by

many factors that are beyond our control, including the risk factors listed above. We have never been profitable on a full-year operating basis and we may never achieve or sustain operating profitability. As of December 31, 2001, our accumulated deficit was \$453.7 million.

Critical Accounting Policies and Estimates

Gilead's discussion and analysis of its financial condition and results of operations are based upon its consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of assets and liabilities. On an on-going basis, we evaluate our estimates, including those related to revenue recognition, bad debts, inventories, accrued clinical and preclinical expenses, and contingencies. We base our estimates on historical experience and on various other market specific assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Gilead believes the following critical accounting policies affect its more significant judgments and estimates used in the preparation of its consolidated financial statements:

- We record estimated reductions to revenue for expected returns of expired products, Medicaid reimbursements and customer incentives such as cash discounts for prompt payment. Expected returns for our marketed drugs are generally low because the shelf life for these products ranges from 24 months for Viread up to 36 months for AmBisome in the U.S. If conditions become more competitive for any of the markets served by our drugs or if other circumstances change, we may take actions to increase our product return estimates or we may offer customer incentives. Each action could result in an incremental reduction of future revenue at the time the return estimate is changed or incentives are offered.
- We also maintain an allowance for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances may be required.
- We write down our inventory based on quality control reviews of our individual raw material batches. We generally do not maintain inventory reserves based on estimated obsolescence or risk of competition primarily because the shelf life of the products is long. However, if our current assumptions about future demand and competition were to change and if actual market conditions are less favorable than those projected by management, additional inventory write-downs may be required.
- We record accruals for estimated clinical and preclinical study costs. These costs are a significant component of research and development expenses. Management accrues costs for clinical studies performed by contract research organizations based on estimates that 25% to 30% of the work is for upfront costs with the remaining activity generally on a straight-line basis over the life of the individual contract or study. This estimate may or may not match the actual services performed by the organizations as determined by patient enrollment levels and related activities. We monitor patient enrollment levels and related activity to the extent possible, however, if management has underestimated activity levels associated with various studies at a given point in time, we could record significant research and development expenses in future periods.

Results of Operations

Revenues

We had total revenue of \$233.8 million for the year 2001, \$195.6 million for the year 2000 and \$169.0 million for the year 1999. Included in total revenue are net product sales, royalty income and contract revenue, including revenue from research and development (R&D) collaborations.

Net product sales revenue was \$191.0 million for 2001, compared with \$149.7 million for 2000 and \$139.9 million for 1999. Our revenues have been primarily derived from sales of AmBisome, which represented 86% of total product sales in 2001, 94% of total product sales in 2000 and 92% of total product sales in 1999. Reported sales of AmBisome were \$164.5 million in 2001, an increase of 17% over AmBisome sales of \$141.1 million in 2000. Excluding the impact of the decline in foreign currencies relative to the U.S. dollar in 2001, sales of AmBisome in 2001 would have increased 20%. A significant majority of Gilead's product sales is denominated in foreign currencies. We did not in the past hedge our exposure to the impact of fluctuating foreign exchange rates on forecasted sales. Effective January 2002, we have begun to use forward contracts to hedge a percentage of our forecasted international sales, primarily those denominated in the euro currency. We do hedge accounts receivable balances denominated in foreign currencies, which reduces our exposure to currency fluctuations between the date a sale is recorded and the date that cash is collected. Sales of AmBisome were \$129.2 million in 1999. Excluding the impact of the decline in foreign currencies relative to the U.S. dollar in 2000, sales of AmBisome in 2000 would have increased 21% versus 1999 reported sales. With the expected increase in competition, we would expect AmBisome sales for 2002 to remain relatively flat versus 2001 reported levels. This assumes foreign currency exchange rates remain at consistent levels throughout 2002 when compared to 2001.

In 2001, we also recognized \$15.6 million in Viread sales, representing 8% of total product sales. Sales of DaunoXome and Vistide were \$4.1 million and \$6.6 million, respectively, in 2001. In 2000, Gilead recognized product sales revenue of \$4.4 million from sales of DaunoXome and \$4.2 million from sales of Vistide. In 1999, DaunoXome sales were \$4.8 million and Vistide sales were \$5.9 million. We expect Viread sales to increase in 2002 and become a greater percentage of total revenues although we cannot predict with any certainty what our actual Viread sales will be in 2002.

We recorded royalty revenue of \$23.0 million in 2001, compared with \$24.6 million in 2000 and \$10.4 million in 1999. During this three-year period, the most significant source of royalty revenue was from sales of AmBisome in the United States by Fujisawa under a co-promotion arrangement with Gilead. During the fourth quarter of 1999, we began recognizing royalty revenues from Fujisawa's sales of AmBisome in the month following that in which the related product sales occur. Prior to the fourth quarter of 1999, we recognized this royalty revenue in the month the sales occurred. Royalty revenue from Fujisawa was \$17.1 million in 2001, compared with \$13.5 million in 2000 and \$8.3 million in 1999. The 1999 amount represents royalties from 11 months of Fujisawa sales of AmBisome.

We also recorded royalty revenue of \$4.5 million in 2001 and \$9.6 million in 2000 related to sales of Tamiflu. Tamiflu is an orally administered compound developed to treat and prevent viral influenza in humans. Gilead co-developed Tamiflu with F. Hoffmann-La Roche Ltd. and Hoffmann-La Roche Inc. (collectively, Roche). Roche owns the worldwide commercial rights to Tamiflu, and is required to pay Gilead a royalty on net sales of the product. In October 1999, the FDA approved Tamiflu for the treatment of influenza in adults, and Roche began selling the product commercially. We record royalty revenue from Roche in the quarter following the quarter in which the related Tamiflu sales occur. Accordingly, Gilead began recognizing royalties from Tamiflu in the first quarter of 2000. The significant declines in royalty revenue can be attributed to the significantly lower incidence of flu for the 2000/2001 season and the resulting product returns to Roche. We expect Tamiflu royalties to increase somewhat in 2002 as a result of broader market penetration. During the second half of 2000, Tamiflu was approved in the U.S. for the prevention in adults and as a treatment for influenza in

children, and approved in Japan as a treatment for influenza in adults. As of February 2001, Roche has filed for European regulatory approval of Tamiflu for the treatment of influenza in adults and children and prevention in adolescents and adults. It is unclear when and if this approval will be granted.

Substantially all of the remaining net royalty revenue recognized in 2001, 2000 and 1999 represents royalties from sales of Vistide by Pharmacia S.A. (Pharmacia) outside the United States. In future periods, royalties from sales of Vistide are expected to be relatively flat or decline slightly.

In December 1999, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 101 (SAB 101), *Revenue Recognition in Financial Statements*. Among other things, SAB 101 describes the SEC Staff's position on the recognition of certain nonrefundable up-front fees received in connection with collaboration agreements. We previously recognized nonrefundable technology access fees received in connection with collaboration agreements as revenue when received or when collectibility was probable, and when the technology had been transferred. Effective January 1, 2000, we changed our method of accounting for these fees to recognize them as the related manufacturing obligation is fulfilled or on a straight-line basis over the term of the related research and development collaboration, manufacturing or supply arrangement, as appropriate, as this method best matches the effort provided. We believe the change in accounting principle is preferable based on guidance provided in SAB 101. The cumulative effect of the change in accounting principle was recorded in the fourth quarter of 2000, retroactively effective as of January 1, 2000, as deferred revenue that will be recognized as contract revenue over the remaining term of the research and development, manufacturing or supply arrangements, as appropriate. For the year ended December 31, 2000, the impact of the cumulative change in accounting principle was to increase the net loss by \$13.7 million. We recognized additional contract revenue of \$3.5 million in 2001 and \$2.9 million in 2000, in accordance with SAB 101, related to up front fees which had been received in prior years. The \$3.5 million recognized in 2001 was related to two collaborative relationships: \$2.9 million related to an initial licensing fee from Sumitomo and \$0.6 million related to an initial license fee from Pharmacia. The \$2.9 million recognized in 2000 was related to three collaborative arrangements: \$1.6 million from Sumitomo; \$0.6 million from Pharmacia; and \$0.7 million related to an initial licensing fee from Roche. The remaining \$7.3 million of SAB 101 related deferred revenue at December 31, 2001 results from the Sumitomo and Pharmacia collaborations, and is expected to be recognized as contract revenue over the next eleven years. There is no remaining deferred revenue related to the Roche initial license fee as of December 31, 2001.

Total contract revenue was \$19.8 million in 2001, compared with \$21.3 million in 2000 and \$18.7 million in 1999. The primary source of contract revenue in 2001 was from our licensing of the SELEX process patent estate to Archemix. This provided \$8.5 million of contract revenue in 2001. Other sources of contract revenue in 2001 include a \$2.0 million milestone payment from Roche relating to the development of Tamiflu under an R&D collaboration agreement between Gilead and Roche and \$3.3 million recognized for work associated with marketing agreements. The single most significant source of contract revenue in 2000 and 1999 was milestone payments from Roche under the R&D collaboration agreement. We recorded contract revenue from Roche of \$11.2 million in 2000 and \$14.9 million in 1999. The \$11.2 million of contract revenue from Roche in 2000 included \$9.6 million in milestone payments related to Roche completing regulatory filings and approvals for Tamiflu in the U.S. and Japan, \$0.9 million of R&D expense reimbursements, and \$0.7 million resulting from the adoption of SAB 101 as discussed above. The 1999 amount included \$12.8 million of milestone payments and \$2.1 million of R&D reimbursements. R&D reimbursements from Roche in 2001 decreased compared to 2000, and reimbursements in 2000 similarly decreased relative to 1999, as Tamiflu development efforts ramped down while Roche's commercialization activities increased. As of December 31, 2001, Gilead is entitled to additional milestone payments of up to \$9.6 million upon Roche achieving certain developmental and regulatory milestones. While we may earn milestone payments under the Roche agreement in 2002, we expect expense reimbursements under the Roche

agreement to be minimal in 2002. Such reimbursements, if any, will approximate our actual related costs incurred.

In October 2001, we entered into an agreement with Archemix Corporation relating to our SELEX technology. Under this agreement, we gave Archemix the exclusive rights to the SELEX process, including therapeutic and other commercial applications to the extent not already licensed under pre-existing agreements. Archemix paid to us \$9.0 million in 2001 and is required to pay us \$8.5 million in 2002. As required by our license agreement with the University Technology Corporation, we paid 5% of the \$9.0 million payment to, and will pay 5% of the \$8.5 million payment to, the University Technology Corporation. We also received a warrant to purchase 350,000 shares of Archemix common stock, the value of which is not material. As required by our license agreement with the University Technology Corporation, we transferred 5% of this warrant to the University Technology Corporation.

In March 2000, we entered into an agreement with EyeTech Pharmaceuticals, Inc. relating to Gilead's proprietary aptamer EYE001, formerly known as NX 1838. Currently in early clinical trials, EYE001 is an inhibitor of vascular endothelial growth factor, or VEGF, which is known to play a role in the development of certain ophthalmic diseases. Under the terms of the agreement, EyeTech received worldwide rights to all therapeutic uses of EYE001, and, if the product is successfully commercialized, EyeTech will pay us royalties on worldwide sales of the product. EyeTech also will be responsible for all research and development costs. We provided clinical supplies of the product to EyeTech through March 2001. We received a \$7.0 million up-front licensing fee from EyeTech in April 2000, which has been recognized as revenue ratably over the one-year supply agreement period. Accordingly, \$5.2 million of the license fee was recorded as contract revenue in 2000, and the remainder recognized as revenue in the first quarter of 2001. We are also entitled to additional cash payments from EyeTech of up to \$25.0 million if and when EyeTech reaches certain EYE001 development milestones. Additionally, we received a warrant to purchase 791,667 shares of EyeTech series B convertible preferred stock, exercisable at a price of \$6.00 per share, the price at which the stock was issued to other investors.

In November 1999, Gilead and Somalogic, Inc. entered into an agreement under which Gilead assigned to Somalogic a sole and exclusive license to certain intellectual property, including patents and patent applications. Under the terms of the agreement, Somalogic was required to pay Gilead a total of \$2.5 million in two nonrefundable installments. The second installment totaled \$1.0 million and was received in November 2000 and recorded as contract revenue upon receipt. The first installment of \$1.5 million was received and recognized as contract revenue in November 1999.

Cost and Expenses

Cost of goods sold was \$43.8 million in 2001, compared with \$33.5 million in 2000 and \$29.5 million in 1999. As a percentage of net product sales, cost of goods sold was 23% in 2001, 22% in 2000 and 21% in 1999.

In connection with most of our European product sales, we price our products in the currency of the country into which the products are sold (Payment Currencies). A significant majority of our manufacturing cost is in U.S. Dollars. A decline in the value of the Payment Currencies relative to the U.S. Dollar will negatively impact gross margins since our manufacturing costs will remain approximately the same while our revenues, which are reported in U.S. Dollars, will decline. In 2001 and 2000, the gross margin was negatively impacted by these factors, as discussed in the product sales section under the caption "Revenues" above. Excluding the impact of foreign exchange rates on reported sales revenue, cost of sales as a percentage of net product sales would have been approximately 22% in 2001, consistent with 2000 levels. Our cost of sales percentage on an annual basis has been in the 20% to 23% range in recent years. Except for the potential impact of unpredictable

and uncontrollable changes in Payment Currencies relative to the U.S. Dollar, we expect the cost of goods sold as a percentage of net product sales in 2002 to remain materially consistent with the 2001 rate. In future years, changes in the nature or mix of our product sales, such as the recent commercial launch of Viread for HIV infection, could impact this relationship.

In 2001 and 2000, research and development (R&D) expenses exceeded 50% of our total costs and expenses. In 1999, R&D expenses represented approximately 46% of our total costs and expenses. The major components of R&D expenses consist of personnel costs, including salaries and benefits, clinical studies performed by contract research organizations, materials and supplies, and overhead allocations consisting of various support and facilities related costs. Our research and development activities are also separated into three main categories: research, clinical development and pharmaceutical development. Research costs typically consist of preclinical and toxicology work. Clinical development costs include Phase I, II, and III clinical trials as well as expanded access programs. Pharmaceutical development costs consist of product formulation and chemical analysis. During 2001, we spent approximately \$37.2 million on research, \$117.6 million on clinical development and \$30.8 million on pharmaceutical development activities. This compares to spending in 2000 of approximately \$27.0 million on research, \$78.9 million on clinical development and \$26.4 million on pharmaceutical development activities. Spending in 1999 consisted of \$27.3 million on research, \$59.8 million on clinical development and \$23.8 million on pharmaceutical development activities.

In total, R&D expenses for 2001 were \$185.6 million, compared with \$132.3 million for 2000 and \$110.9 million for 1999. The \$53.3 million increase in spending in 2001 versus 2000 was attributable in part to the recognition of \$10.6 million of a \$13.0 million up-front payment and \$5.5 million of clinical milestone payments to Cubist under the European licensing agreement for Cidecin. In addition, our expenses associated with the Phase III clinical trials and expanded access programs for Viread for HIV infection and the Phase III clinical programs for adefovir dipivoxil for HBV infection increased approximately \$18.2 million and \$13.3 million, respectively, during the year. Based on current budgeted programs, we expect R&D expenses in 2002 to be approximately \$140 million to \$150 million, or 15% to 25% lower than 2001, reflecting the sale of our oncology assets to OSI in December 2001 and the decreasing levels of activity associated with the U.S. and European expanded access programs for Viread. As a result of this expected decrease, R&D spending as a percentage of our total costs and expenses is expected to be below 50%.

R&D spending levels for 2000 also increased over 1999 levels. Major development projects in 2000 included Viread and adefovir dipivoxil for HBV infection. We incurred increased costs for both of these programs which were in Phase III clinical trials. Additionally, we made up-front payments in the fourth quarter of 2000 to in-license two oncology products from Glaxo Smith Kline and Southern Research Institute, the rights to both of which have been subsequently assigned to OSI as part of the sale of our oncology assets in December 2001. These increases more than offset significantly lower expenses in 2000 for the development of adefovir dipivoxil for HIV infection, a program we discontinued in the fourth quarter of 1999. Additionally, in 1999, we reduced the R&D workforce in Boulder by 30 employees upon completing the merger with NeXstar.

Recent industry reports indicate that a biopharmaceutical product generally takes 10 to 15 years (an average of 12 years) to research, develop and bring to market a new prescription medicine in the U.S. These averages are generally consistent with the projects that we develop internally, although our recent product development timelines have been on a more accelerated basis. Drug development in the U.S. is a process that includes several steps defined by the FDA. The process begins with the filing of an Initial Drug Application (or IND) which, if successful, allows opportunity for clinical study of the potential new medicine. Clinical development typically involves three phases of study: Phase I, II, and III, and generally accounts for an average of seven years of a drug's total development time. The most significant costs associated with clinical development are the Phase III trials as they tend to be the longest and largest studies conducted during the drug development process. We currently have products

in development that are in Phase III studies. The successful development of our products is highly uncertain. An estimation of completion dates and R&D expenses can vary significantly for each product and are difficult to predict. For a more complete discussion of the risks and uncertainties associated with completing development products, see the "Risk Factors" section of Item I above.

Selling, general and administrative (SG&A) expenses were \$125.1 million in 2001, compared with \$82.0 million in 2000 and \$99.4 million in 1999. The increase in expenses in 2001 versus 2000 is primarily due to Gilead's increased global marketing efforts and the expansion of our sales force to support the commercial launch of Viread for HIV infection. In 2002, we expect SG&A expenses to be approximately \$180 million to \$190 million, or 45% to 55% higher than 2001 levels, primarily due to the increase in marketing activities associated with the launch of Viread in the U.S. and European Union, but also our preparation for the commercial launch of adefovir dipivoxil for HBV infection.

The major factor contributing to the decrease in 2000 SG&A expenses from 1999 levels was the inclusion of \$18.3 million of merger-related expenses in 1999. These merger-related expenses primarily consisted of transaction costs, including professional fees, filing fees and printing costs; employee severance costs; and the write-down of certain NeXstar property and equipment that was not expected to be used in future operations. Total employee severance costs of \$5.3 million relate to the termination of 70 employees, the majority of which were from our Boulder, Colorado facility. Excluding merger expenses, SG&A expenses in 2000 were essentially flat compared with 1999. Higher general and administrative (G&A) expenses in 2000 were offset by savings in sales and marketing expenses. The increased G&A spending in 2000 included costs to implement new and upgraded information technology systems and legal costs incurred in connection with new collaboration agreements and various corporate projects. Sales and marketing expenses in 2000 reflect cost savings in the U.S. from the elimination in the second half of 1999 of duplicate positions and functions within the combined Gilead and NeXstar organization. Sales and marketing expenses in 1999 included costs to expand our sales and marketing capacity in anticipation of the then-planned commercial launch of adefovir dipivoxil for HIV infection, which was discontinued in the fourth quarter of 1999.

Litigation Settlement and Related Expenses

We incurred litigation settlement and related expenses of \$1.3 million in 2001, \$1.4 million in 2000 and \$1.5 million in 1999. In 1997 we reached a settlement with Elan Corporation, plc (Elan, the successor company to The Liposome Company) in which both companies agreed to dismiss all legal proceedings involving AmBisome, Gilead's liposomal formulation of amphotericin B. Under the terms of the settlement agreement, we made an initial payment to Elan of \$1.8 million and are required to make additional payments through 2006, based on AmBisome sales. The payments are subject to certain minimum and maximum amounts. A \$10.0 million accounting charge was recorded in 1997 representing the net present value of all future minimum payments we are required to make. We record an expense each quarter based on the difference between all future minimum payments and the amount previously accrued. These amounts have not been significant. We do not expect the difference between the future minimum and maximum payments to Elan to be material.

Gain on Sale of Oncology Assets

In December 2001, we completed the sale of our oncology assets, pipeline of clinical stage oncology products and related intellectual property, as well as our Boulder, Colorado operations, including clinical research and drug development personnel, infrastructure and facilities, to OSI. The pipeline of clinical candidates includes NX 211 (liposomal lurtotecan), GS 7836 (a nucleoside analogue) and GS 7904L (a liposomal thymidylate synthase inhibitor). On the closing date, we received \$130.0 million in cash and OSI common stock valued at approximately \$38.8 million. The Company recorded a non-operating gain of \$157.8 million in the fourth quarter of 2001 as a result of this transaction. In addition, we recorded income taxes of \$3.3 million in connection with this transaction.

Gain on Sale of Unconsolidated Affiliate

In August 2001, we also sold our 49 percent interest in Proligo L.L.C. (Proligo) to Degussa Corporation for \$14.3 million in cash. Proligo was a joint venture between Gilead and SKW Americas, Inc. focused on the manufacturing of oligonucleotides. SKW Americas, a subsidiary of Degussa Corporation, held the remaining 51 percent of Proligo. The proceeds, net of Gilead's investment in Proligo, are reflected as an \$8.8 million gain on the sale of unconsolidated affiliate.

Interest Income and Interest Expense

We recorded interest income of \$25.6 million in 2001, compared with \$17.6 million in 2000 and \$16.4 million in 1999. The increase in 2001 over 2000 was due to higher average balances of invested funds. In December 2000, we received approximately \$241.8 million from the issuance of convertible subordinated notes, net of debt issuance costs. The increase in 2000 over 1999 was due to higher interest rates on our investment portfolio. We expect interest income in 2002 to be materially consistent with 2001 levels due to the receipt of \$130 million in cash from the sale of our oncology assets in December 2001, offset by lower interest rates on our portfolio of fixed income securities.

We incurred interest expense of \$14.0 million in 2001, compared with \$4.4 million in 2000 and \$6.5 million in 1999. The significant increase in 2001 over 2000 is due to the full year of interest on our \$250.0 million 5% convertible subordinated notes. Interest expense for 2000 consisted primarily of interest on the \$79.5 million 6.25% convertible notes, which were converted to common stock in August 2000. The decrease in 2000 from 1999 levels occurred primarily because of the August 2000 debt conversion. Interest expense for 1999 included a full year of interest on the \$79.5 million 6.25% convertible notes. We expect interest expense in 2002 to remain consistent with 2001 expense levels as we again incur a full year of expense on the \$250.0 million 5% convertible subordinated notes.

Income Taxes

Our provision for income taxes was \$4.1 million, \$1.2 million and \$0.9 million in 2001, 2000 and 1999, respectively. In all periods, we recorded income tax expense associated with income from our foreign subsidiaries. The significant increase in income tax expense in 2001 resulted principally from the gain on the sale of our oncology assets to OSI, for which we recorded approximately \$3.3 million of federal and state alternative minimum taxes.

Equity in Loss of Unconsolidated Affiliate

In 2001, we recorded \$2.1 million as our equity in the loss of our unconsolidated affiliate, Proligo, prior to the date of the sale of our 49 percent interest. In 2000, we recorded \$2.9 million as our equity in the loss of Proligo. This represented our 49 percent share of Proligo's loss for the thirteen-month period ended December 31, 2000. During the fourth quarter of 2000, Proligo changed its fiscal year-end to December 31 from November 30. For 1999, we recorded \$4.7 million equity in the loss of Proligo for its fiscal year ended November 30, 1999.

Cumulative Effect of Change in Accounting Principle

In the year ended December 31, 2001, Gilead adopted SFAS 133, *Accounting for Derivative Instruments and Hedging Activities*, which resulted in a cumulative effect of change in accounting principle of \$1.1 million. In the year ended December 31, 2000, Gilead adopted the Securities and Exchange Commission's Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements*, resulting in a cumulative effect of change in accounting principle of (\$13.7) million. See Notes 2 and 3 to the consolidated financial statements for further discussion.

Liquidity and Capital Resources

Cash, cash equivalents and marketable securities totaled \$582.9 million at December 31, 2001, up from \$512.9 million at December 31, 2000. The increase of \$70.0 million was primarily due to the \$130.0 million cash and \$38.8 million in OSI common stock received as part of the sale of our oncology assets to OSI in December 2001. Other major sources and uses of cash included proceeds from issuances of stock under employee stock plans of \$36.3 million and proceeds of \$14.3 million from the sale of our interest in Proligo, offset by capital expenditures of \$26.3 million and cash used to fund our operating activities.

Our accounts receivable balance at December 31, 2001 was \$74.2 million compared to \$48.8 million at December 31, 2000. The growth was primarily due to the year-over-year increase in net product sales for AmBisome and also the initial sales of Viread in the U.S. In certain countries where payments are typically slow, primarily Greece, Spain, Portugal and Italy, our accounts receivable balances are significant. In most cases, these slow payment practices reflect the pace at which governmental entities reimburse our customers. This, in turn, may increase the financial risk related to certain of our customers. Sales to customers in countries that tend to be relatively slow paying have in the past increased, and in the future may further increase, the average length of time that accounts receivable are outstanding. At December 31, 2001, our past due accounts receivable for Greece, Spain, Portugal and Italy totaled approximately \$28.7 million, of which approximately \$9.9 million was more than 120 days past due. At December 31, 2000, past due receivables for these countries were \$19.3 million, of which approximately \$10.9 million was more than 120 days past due. To date, we have experienced only modest losses with respect to the collection of our accounts receivable and believe that all past due accounts receivable, including those due from customers in these four countries, are collectible. We continually seek to improve our collection processes to ensure that we fully collect amounts due to us based on our product sales and that collections are timely.

Significant changes in working capital during 2001 included an \$18.7 million increase in inventory. In addition, accounts payable increased \$8.5 million as a result of an increase in our raw material purchases and the increased use of contract manufacturers. Substantially all of this growth in inventory and accounts payable is in support of the recent U.S. and European launch of Viread. Other changes in working capital include an increase in accrued liabilities of \$11.5 million. Accrued clinical and preclinical expenses increased by \$6.0 million, primarily due to the advanced and accelerated Phase III clinical trials for adefovir dipivoxil for HBV infection. Accrued compensation has also increased from \$10.0 million at December 31, 2000 to \$14.7 million at December 31, 2001, principally due to the expansion of our sales force in support of the Viread launch. Other accrued liabilities increased \$5.5 million in 2001, consisting principally of transaction costs and income taxes payable arising from the sale of our oncology assets to OSI.

Other noncurrent assets decreased \$4.9 million to \$24.2 million at December 31, 2001 from \$29.1 million at December 31, 2000. The decrease was due to the sale of our 49 percent interest in Proligo. Our investment in Proligo at December 31, 2000 was approximately \$6.9 million and approximately \$4.8 million as of the date of the sale. The decrease was partially offset by increases resulting from the \$2.4 million unrecognized portion of the \$13.0 million license fee payment to Cubist and the \$1.1 million valuation of a warrant to purchase stock in EyeTech recognized in accordance with SFAS 133. The \$2.4 million balance resulting from the Cubist payment is included in other noncurrent assets at December 31, 2001 because if, prior to January 2002, Gilead terminated its rights under the agreement with respect to a preclinical oral formulation of daptomycin being developed by Cubist, or if Cubist discontinued development of that oral formulation, Gilead would have been entitled to receive a refund of this amount from Cubist.

We made capital expenditures of \$26.3 million in 2001, \$15.6 million in 2000 and \$12.5 million in 1999. These expenditures were primarily for facilities improvements to accommodate our growth, as

well as for laboratory and manufacturing equipment. Of the \$26.3 million spent in 2001, approximately 50% to 60% was research and development related. We expect our capital spending for 2002 to decrease somewhat compared with 2001 levels, however the percentage allocated for research and development should remain consistent with the previous year.

In August 2000, we redeemed our 6.25% convertible subordinated debentures at a cash price of \$1,030 per \$1,000 principal amount of debentures outstanding, plus accrued interest, which was the redemption price provided for in the original debenture indenture. Upon redemption, the entire \$79.5 million in principal amount of the debentures outstanding at that time was converted into 7,135,156 newly issued shares of Gilead common stock by August 15, 2000. Deferred debt issuance costs of \$1.6 million related to the debentures were charged to additional paid in capital in connection with the conversion of the debentures into common stock.

On December 13, 2000, we issued \$250.0 million of 5% convertible subordinated notes due December 15, 2007 in a private offering. The notes are currently convertible into a total of up to 10,178,116 shares of Gilead common stock at \$24.5625 per share. The \$24.5625 conversion price was higher than our common stock price at the notes' issuance date. The notes are redeemable in whole or in part, at our option, at any time on or after December 20, 2003, at specified redemption prices plus accrued interest. Debt issuance costs of \$8.2 million incurred in connection with the issuance of the notes were recorded as other noncurrent assets, and are being amortized to interest expense on a straight-line basis over the contractual term of the notes.

Through April 2001, we maintained a \$10.0 million unsecured line of credit that bears interest at a floating rate with a major financial institution. Under the terms of the line of credit, we were required to maintain certain financial ratios and there were limitations on our ability to incur additional debt or to engage in certain significant transactions. The line of credit, which included a foreign exchange facility, expired in April 2001. We renewed the foreign exchange facility through April 2002, but did not renew the line of credit. There are no required financial ratios or limitations on debt or other transactions under the foreign exchange facility.

We do not have any "special purpose" entities that are unconsolidated in our financial statements. We are also not involved in any non-exchange traded commodity contracts accounted for at fair value. We have no commercial commitments with related parties, except for employee loans. We have contractual obligations in the form of a litigation settlement, capital and operating leases, notes payable and clinical research organization contracts.

We believe that our existing capital resources, which includes all fixed income and equity securities, supplemented by net product sales and contract and royalty revenues, will be adequate to satisfy our capital needs for the foreseeable future. Our future capital requirements will depend on many factors, including:

- the commercial performance of AmBisome, Viread and any of our products in development that receive marketing approval,
- the progress of our research and development efforts,
- the scope and results of preclinical studies and clinical trials,
- the cost, timing and outcome of regulatory reviews,
- the rate of technological advances,
- determinations as to the commercial potential of our products under development,
- administrative expenses,
- the status of competitive products,

- the establishment of manufacturing capacity or third-party manufacturing arrangements,
- the expansion of sales and marketing capabilities,
- our possible geographic expansion, and
- the establishment of additional collaborative relationships with other companies.

We may in the future require additional funding, which could be in the form of proceeds from equity or debt financings or additional collaborative agreements with corporate partners. If such funding is required, we cannot assure you that it will be available on favorable terms, if at all.

Recent Accounting Pronouncements

In July 2001, the Financial Accounting Standards Board (FASB) issued Statements of Financial Accounting Standards No. 141, *Business Combinations* (SFAS 141), and No. 142, *Goodwill and Other Intangible Assets* (SFAS 142). SFAS 141 eliminates the pooling-of-interests method of accounting for business combinations except for qualifying business combinations that were initiated prior to July 1, 2001. SFAS 141 further clarifies the criteria to recognize intangible assets separately from goodwill. The requirements of SFAS 141 are effective for any business combination accounted for by the purchase method that is completed after June 30, 2001. Under SFAS 142, goodwill and indefinite lived intangible assets are no longer amortized but are reviewed annually (or more frequently if impairment indicators arise) for impairment. Separable intangible assets that are not deemed to have an indefinite life will continue to be amortized over their useful lives (but with no maximum life). The amortization provisions of SFAS 142 apply to goodwill and intangible assets acquired after June 30, 2001. As we have not accounted for any business combinations under the purchase method of accounting, the adoption of SFAS 141 on July 1, 2001 did not have a material impact on the Company's financial position or results of operations and the adoption of SFAS 142 on January 1, 2002 will not have a material impact on the Company's financial position or results of operations.

In August 2001, the FASB issued SFAS 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. SFAS 144 establishes a single accounting model for assets to be disposed of by sale whether previously held and used or newly acquired. SFAS 144 retains the presentation of discontinued operations in the income statement, but broadens the presentation to include a component of an entity. SFAS 144 is effective for fiscal years beginning after December 15, 2001 and the interim periods within. The adoption of SFAS 144 on January 1, 2002 will not have a material impact on the Company's financial position or results of operations.

Market Risk Disclosures

Foreign Currency Exchange Risk

Our operations include manufacturing and sales activities in the United States as well as sales activities in Europe and Australia. As a result, our financial results could be significantly affected by factors such as changes in foreign currency exchange rates or weak economic conditions in the foreign markets in which we distribute our products. Our operating results are exposed to changes in exchange rates between the U.S. Dollar and various foreign currencies, the most significant of which are the Euro, the British Pound and the Australian Dollar. When the U.S. Dollar strengthens against these currencies, the relative value of sales made in the respective foreign currency decreases. Conversely, when the U.S. Dollar weakens, the relative amounts of such sales increase. Overall, we are a net receiver of foreign currencies and, therefore, benefit from a weaker U.S. Dollar and are adversely affected by a stronger U.S. Dollar relative to those foreign currencies in which we transact significant amounts of business.

To mitigate the impact of changes in currency exchange rates on cash flows from our foreign currency sales transactions, we enter into foreign exchange forward contracts to hedge our foreign currency-denominated accounts receivable. Additionally, to mitigate the impact of currency rate fluctuations on our cash outflows for certain foreign currency-denominated raw materials purchases, we enter into foreign exchange forward contracts to hedge our foreign currency-denominated accounts payable.

The following table summarizes the notional amounts, average currency exchange rates and fair values of our open foreign exchange forward contracts at December 31, 2001. The contracts have maturities of one year or less with one exception. One hedge contract intended to hedge raw materials purchases in the first quarter of 2003, with a notional amount of \$3.7 million and an insignificant fair value at December 31, 2001, has a maturity of 13 months. Average rates are stated in terms of the amount of foreign currency per U.S. Dollar. Fair values represent estimated settlement amounts at December 31, 2001 (notional amounts and fair values in \$U.S. thousands):

<u>Currency</u>	<u>Notional Amount</u>	<u>Average Rate</u>	<u>Fair Value December 31, 2001</u>
Australian Dollar	\$ 1,260	1.9724	\$ (6)
British Pound	7,548	0.6918	(38)
Danish Krone	46	8.4844	(1)
Euro	63,187	1.1335	(875)
Norwegian Krone	150	9.1105	(3)
Swiss Franc	122	1.6910	(2)

A significant majority of our product sales is denominated in foreign currencies. Increases in the value of the U.S. Dollar against these foreign currencies in the past have reduced, and in the future may reduce, our U.S. Dollar return on these sales and negatively impact our financial condition. We did not in the past hedge our exposure to the impact of fluctuating foreign exchange rates on forecasted sales. Effective January 2002, we have begun to use forward contracts to hedge a percentage of our forecasted international sales, primarily those denominated in the euro currency.

Interest Rate Risk

Our portfolio of available-for-sale investment securities and our fixed-rate liabilities create an exposure to interest rate risk. With respect to the investment portfolio, we adhere to an investment policy that requires us to limit amounts invested in securities based on maturity, industry group, investment type and issuer, except for securities issued by the U.S. government. The goals of our investment policy, in order of priority, are as follows:

1. Safety and preservation of principal and diversification of risk;
2. Liquidity of investments sufficient to meet cash flow requirements; and
3. Competitive after-tax rate of return.

The following table summarizes the expected maturities and average interest rates of our interest-bearing assets and fixed-rate liabilities at December 31, 2001 (dollars in thousands).

	Years ending December 31,					Thereafter	Total	Fair Value December 31, 2001
	2002	2003	2004	2005	2006			
Assets								
Available-for-sale securities	\$282,947	\$142,679	\$73,751	—	—	—	\$499,377	\$499,377
Average interest rate	4.90%	5.80%	4.93%					
Liabilities								
Minimum litigation settlement, including current portion	\$ 1,281	\$ 1,394	\$ 1,516	\$1,649	\$ 435	—	\$ 6,275	\$ 6,275
Discount rate	8.50%	8.50%	8.50%	8.50%	8.50%			
Long-term obligations, including current portion(1)	\$ 11,963	\$ 10,351	\$ 7,092	\$7,276	\$4,143	\$ 1,288	\$ 42,113	\$ 42,113
Average interest rate	8.70%	15.20%	21.00%	21.00%	21.00%	21.00%		
Convertible subordinated debentures	—	—	—	—	—	\$250,000	\$250,000	\$382,812
Interest rate						5.00%		

(1) Long-term obligations consist of capital leases, operating leases (net of noncancelable subleases) and debt secured by property, plant and equipment. The interest portion of payments due is included.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Quantitative and qualitative disclosure about market risk is included under the caption "Market Risk Disclosures" in Item 7.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements required by this item are set forth beginning at page 64 of this report.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

The information required by this Item concerning our directors and executive officers is incorporated by reference to the sections of our Definitive Proxy Statement filed with the SEC pursuant to Regulation 14A in connection with the 2002 Annual Meeting (the Proxy Statement) under the headings "Nominees", "Executive Officers" and "Compliance with Section 16(a) of the Securities Exchange Act of 1934."

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item is incorporated by reference to the sections of our Proxy Statement under the headings "Executive Compensation" and "Compensation Committee Report."

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The information required by this Item is incorporated by reference to the section of our Proxy Statement under the heading "Security Ownership of Certain Beneficial Owners and Management."

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information required by this Item is incorporated by reference to the sections of our Proxy Statement under the headings "Compensation Committee Interlocks and Insider Participation," "Certain Transactions" and "Executive Compensation."

PART IV

ITEM 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K

(a) The following documents are filed as part of this Form 10-K:

- (1) Schedule II is included on page 104 of this report. All other schedules are omitted because they are not required or the required information is included in the financial statements or notes thereto.
- (2) Exhibits

The following exhibits are filed herewith or incorporated by reference:

<u>Exhibit Footnote</u>	<u>Exhibit Number</u>	<u>Description of Document</u>
(22)	2.1	Asset Purchase Agreement between Registrant and OSI Pharmaceuticals, Inc. dated as of November 26, 2001.
(21)	3.1	Amended and Restated Certificate of Incorporation of the Registrant, as amended.
(1)	3.2	Bylaws of the Registrant, as amended and restated March 30, 1999.
	4.1	Reference is made to Exhibit 3.1 and Exhibit 3.2.
(4)	4.2	Amended and Restated Rights Agreement dated as of October 21, 1999 between the Registrant and ChaseMellon Shareholder Services, LLC.
(10)	4.3	Agreement and Plan of Merger dated February 28, 1999 by and among Registrant, Gazelle Acquisition Sub, Inc. and NeXstar Pharmaceuticals, Inc.
(20)	4.4	Indenture dated as of December 18, 2000 between the Registrant and Chase Manhattan Bank and Trust Company, National Association, including therein the forms of the notes.
(20)	4.5	Registration Rights Agreement dated as of December 18, 2000 between the Registrant and J.P. Morgan Securities Inc., Chase Securities Inc., Lehman Brothers Inc. and Morgan Stanley & Co. Incorporated.
(5)	10.1	Form of Indemnity Agreement entered into between the Registrant and its directors and executive officers.
(5)	10.2	Form of Employee Proprietary Information and Invention Agreement entered into between Registrant and certain of its officers and key employees.
(5)	10.3	Registrant's 1987 Incentive Stock Option Plan and related agreements.
(5)	10.4	Registrant's 1987 Supplemental Stock Option Plan and related agreements.
(19)	10.5	Registrant's Employee Stock Purchase Plan, as amended March 30, 1999.
(21)	10.6	Registrant's 1991 Stock Option Plan, as amended and restated April 5, 2000.
(5)	10.7	Form of Non-Qualified Stock Option issued to certain executive officers and directors in 1991.
(6)	10.8	Vintage Park Research and Development Net Lease by and between Registrant and Vintage Park Associates dated March 27, 1992 for premises located at 344B, 346 and 353 Lakeside Drive, Foster City, California with related addendum, exhibits and amendments.
(5)	10.9	Letter Agreement, dated as of September 23, 1991 between Registrant and IOCB/REGA, with exhibits with certain confidential information omitted.
(6)	10.10	Vintage Park Research and Development Net Lease by and between Registrant and Vintage Park Associates dated September 16, 1993 for premises located at 335 Lakeside Drive, Foster City, California with related exhibits.

Exhibit Footnote	Exhibit Number	Description of Document
(7)	10.11	Amendment Agreement, dated October 25, 1993 between Registrant and IOCB/REGA, and related license agreements and exhibits with certain confidential information omitted.
(21)	10.12	Amendment Agreement, dated December 27, 2000 between Registrant and IOCB/REGA.
(2)	10.13	Loan Agreement, dated as of October 1, 1994 among Registrant and Mark L. Perry and Melanie P. Peña.
(18)	10.14	Registrant's 1995 Non-Employee Directors' Stock Option Plan, as amended January 26, 1999, and related form of stock option grant.
(8)	10.15	Vintage Park Research and Development Lease by and between Registrant and WCB Sixteen Limited Partnership dated June 24, 1996 for premises located at 333 Lakeside Drive, Foster City, California.
(8)	10.16	Amendment No. 1 to Vintage Park Research and Development Lease by and between Registrant and WCB Seventeen Limited Partnership dated June 24, 1996 for premises located at 335 Lakeside Drive, Foster City, California.
(8)	10.17	Amendment No. 2 to Vintage Park Research and Development Lease by and between Registrant and WCB Seventeen Limited Partnership dated June 24, 1996 for premises located at 344B, 346 and 353 Lakeside Drive, Foster City, California.
(9)	10.18	License and Supply Agreement between Registrant and Pharmacia & Upjohn S.A. dated August 7, 1996 with certain confidential information omitted.
(9)	10.19	Development and License Agreement between Registrant and F. Hoffmann-La Roche Ltd. and Hoffmann-La Roche Inc. dated September 27, 1996 with certain confidential information omitted.
(19)	10.20	Amendment No. 3 to Vintage Park Research and Development Lease by and between Registrant and Spieker Properties, L.P. dated August 14, 1998 for premises located at 355 Lakeside Drive, Foster City, California.
(3)	10.21	NeXstar Pharmaceuticals, Inc.'s 1993 Incentive Stock Plan, adopted February 8, 1993, as amended.
(13)	10.22	NeXstar Pharmaceuticals, Inc.'s 1995 Director Option Plan, adopted July 25, 1995.
(14)	10.23	Vestar, Inc. 1988 Stock Option Plan.
(14)	10.24	Lease, dated March 26, 1987, between Vestar, Inc. and Majestic Realty Co. and Patrician Associates, Inc. and Amendment No. 1 thereto and Amendment No. 2 thereto, dated as of June 8, 1992.
(12)	10.25	Third Amendment, dated January 11, 1996, between Majestic Realty Co. and Patrician Associates, Inc. and the Registrant, to Lease, dated March 26, 1987, between Vestar, Inc. and Majestic Realty Co. and Patrician Associates, Inc.
(15)	10.26	Assignment and Royalty Agreement, dated December 21, 1990, effective as of June 2, 1989, between Vestar, Inc. and City of Hope National MedicalCenter.
(12)	10.27	License Agreement, effective as of August 12, 1986, between Vestar, Inc. and The Regents of the University of California.
(14)	10.28	Agreement by and between Fujisawa USA, Inc. and Vestar, Inc., dated August 9, 1991, and Amendment No. 1 thereto, dated as of May 17, 1994.
(13)	10.29	Amendment No. 2 to agreement between Fujisawa USA, Inc. and Vestar, Inc., dated as of April 3, 1995, between Fujisawa USA, Inc. and Vestar, Inc. with certain confidential information omitted.

Exhibit Footnote	Exhibit Number	Description of Document
(12)	10.30	Amendment No. 3 to Agreement between Fujisawa USA, Inc. and the Registrant, dated March 4, 1996, to the Agreement by and between Fujisawa USA, Inc. and Vestar, Inc., dated August 9, 1991.
(14)	10.31	Lease, dated April 13, 1992, between Vestar, Inc. and Majestic Realty Co. and Patrician Associates, Inc.
(12)	10.32	First Amendment to Lease, dated April 10, 1993, between Majestic Realty Co. and Patrician Associates, Inc. and Vestar, Inc. amending Lease, dated April 13, 1992, between Majestic Realty Co. and Patrician Associates, Inc. and Vestar, Inc.
(11)	10.33	License and Distribution Agreement, dated September 26, 1997, by and between Sumitomo Pharmaceuticals Co., Ltd. and NeXstar Pharmaceuticals, Inc. with certain confidential information omitted.
(16)	10.34	Settlement Agreement, dated August 11, 1997, by and among NeXstar Pharmaceuticals, Inc., Fujisawa U.S.A., Inc. and The Liposome Company, Inc. with certain confidential information omitted.
(17)	10.35	Amendment, dated April 30, 1998, between Sumitomo Pharmaceuticals Co., Ltd. and NeXstar Pharmaceuticals, Inc. to the License and Distribution Agreement, dated September 26, 1996, between Sumitomo and NeXstar Pharmaceuticals, Inc.
	10.36	The Corporate Plan for Retirement Select Plan—Basic Plan Document.
	10.37	The Corporate Plan for Retirement Select Plan—Adoption Agreement.
	10.38	Addendum to the Gilead Sciences, Inc. Deferred Compensation Plan.
	21.1	Subsidiaries of the Registrant.
	23.1	Consent of Ernst & Young LLP, Independent Auditors.
	23.2	Consent of PricewaterhouseCoopers LLP, Independent Auditors.
	24.1	Power of Attorney. Reference is made to Signature Page.

- (1) Filed as an exhibit to Registrant's Annual Report on Form 10-K/A for the fiscal year ended December 31, 1998, and incorporated herein by reference.
- (2) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended December 31, 1994, and incorporated herein by reference.
- (3) Filed as an exhibit to NeXstar Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q for the quarter ended June 30, 1997, and incorporated herein by reference.
- (4) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on October 22, 1999, and incorporated herein by reference.
- (5) Filed as an exhibit to Registrant's Registration Statement on Form S-1 (No. 33-55680), as amended, and incorporated herein by reference.
- (6) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 1993, and incorporated herein by reference.
- (7) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended March 31, 1994, and incorporated herein by reference.
- (8) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1996, and incorporated herein by reference.
- (9) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 1996, and incorporated herein by reference.

- (10) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on March 9, 1999, and incorporated herein by reference.
- (11) Filed as an exhibit to NeXstar Pharmaceuticals, Inc.'s Form 10-K for the fiscal year ended December 31, 1996, and incorporated herein by reference.
- (12) Filed as an exhibit to NeXstar Pharmaceuticals, Inc.'s Form 10-K for the fiscal year ended December 31, 1995, and incorporated herein by reference.
- (13) Filed as an exhibit to NeXstar Pharmaceuticals, Inc.'s Form 10-Q for the quarterly period ended September 30, 1995, and incorporated herein by reference.
- (14) Filed as an exhibit to NeXstar Pharmaceuticals, Inc.'s Form 10-K for the fiscal year ended December 31, 1994, and incorporated herein by reference.
- (15) Filed on March 22, 1991 as an exhibit to NeXstar Pharmaceuticals, Inc.'s Registration Statement on Form S-2 (File No. 33-39549), and incorporated herein by reference.
- (16) Filed as an exhibit to NeXstar Pharmaceuticals, Inc.'s Form 10-Q for the quarterly period ended September 30, 1997, and incorporated herein by reference.
- (17) Filed as an exhibit to NeXstar Pharmaceuticals, Inc.'s Form 10-Q for the quarter ended June 30, 1998, and incorporated herein by reference.
- (18) Filed as an exhibit to Registrant's Form 10-K/A for the year ended December 31, 1998, and incorporated herein by reference.
- (19) Filed as an exhibit to Registrant's Form 10-K for the year ended December 31, 1998, and incorporated herein by reference.
- (20) Filed as an exhibit to Registrant's Registration Statement on Form S-3 (No. 333-54350), as amended, and incorporated herein by reference.
- (21) Filed as an exhibit to Registrant's Form 10-K for the year ended December 31, 2000, and incorporated herein by reference.
- (22) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on January 4, 2002, and incorporated herein by reference.

(b) Reports on Form 8-K

The Registrant did not file any reports on Form 8-K during the fourth quarter of 2001. On January 4, 2002, the Registrant filed a Current Report on Form 8-K relating to the completion of the sale of its oncology assets, pipeline of clinical stage oncology products and related intellectual property, as well as its Boulder, Colorado operations, including clinical research and drug development personnel, infrastructure and facilities, to OSI Pharmaceuticals, Inc. The Form 8-K includes an unaudited pro forma condensed consolidated balance sheet as of September 30, 2001 presented as if the transaction had occurred as of that date and unaudited pro forma condensed consolidated statements of operations for the year ended December 31, 2000 and the nine months ended September 30, 2001, presented as if the transaction had occurred January 1, 2000 and January 1, 2001, respectively.

GILEAD SCIENCES, INC.
CONSOLIDATED FINANCIAL STATEMENTS
Years ended December 31, 2001, 2000 and 1999

CONTENTS

Report of Independent Auditors	65
Report of Independent Accountants	66
Audited Consolidated Financial Statements:	
Consolidated Balance Sheets	67
Consolidated Statements of Operations	68
Consolidated Statement of Stockholders' Equity	69
Consolidated Statements of Cash Flows	70
Notes to Consolidated Financial Statements	72

REPORT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

The Board of Directors and Stockholders
Gilead Sciences, Inc.

We have audited the accompanying consolidated balance sheets of Gilead Sciences, Inc. and subsidiaries as of December 31, 2001 and 2000, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2001. Our audits also included the financial statement schedule listed in Item 14(a) of this Annual Report on Form 10-K. These financial statements and schedule are the responsibility of the management of Gilead Sciences, Inc. Our responsibility is to express an opinion on these financial statements and schedule based on our audits. We did not audit the financial statements of Proligo L.L.C., a limited liability company, the investment in which is reflected in the accompanying consolidated financial statements using the equity method of accounting. The investment in Proligo L.L.C. represents 1.0% of consolidated total assets at December 31, 2000, and the Company's equity in the net loss of Proligo L.L.C. is \$2,858,000 and \$4,656,000 in 2000 and 1999, respectively. The 2000 and 1999 financial statements of Proligo L.L.C. have been audited by other auditors whose report has been furnished to us; insofar as our opinion on the 2000 and 1999 consolidated financial statements relates to data included for Proligo L.L.C., it is based solely on their report.

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 and the report of other auditors provide a reasonable basis for our opinion.

In our opinion, based on our audits and the report of other auditors, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Gilead Sciences, Inc. 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. Also in our opinion, the financial statement schedule referred to above, when considered in relation to the basic financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

As discussed in Notes 2 and 3 to the consolidated financial statements, effective January 1, 2001, the Company changed its method of accounting for derivative instruments and hedging activities, and, effective January 1, 2000, changed its method of accounting for non-refundable up-front fees received in connection with collaboration agreements.

ERNST & YOUNG LLP

Palo Alto, California
January 25, 2002, except as to the
paragraph titled "Stock Split" of Note 1,
as to which the date is March 8, 2002

REPORT OF INDEPENDENT ACCOUNTANTS

To the Board of Directors and
Members of Proligo LLC:

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, of members' equity and of cash flows present fairly, in all material respects, the financial position of Proligo LLC and its subsidiaries at December 31, 2000 and November 30, 1999 and 1998, and the results of their operations and their cash flows for the thirteen-months ended December 31, 2000, the year ended November 30, 1999, and the period August 15, 1998 to November 30, 1998, respectively, in conformity with accounting principles generally accepted in the United States of America. 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 of these statements in accordance with auditing standards generally accepted in the United States of America, which 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, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

PricewaterhouseCoopers LLP

Broomfield, Colorado
January 12, 2001

GILEAD SCIENCES, INC.

Consolidated Balance Sheets

(in thousands, except per share amounts)

	December 31,	
	2001	2000
Assets		
Current assets:		
Cash and cash equivalents	\$162,339	\$197,292
Marketable securities	420,512	315,586
Accounts receivable, net of allowance for doubtful accounts of \$2,579 in 2001 and \$2,300 in 2000	74,228	48,814
Inventories	39,280	20,562
Prepaid expenses and other	11,400	11,544
Total current assets	707,759	593,798
Property, plant and equipment, net	62,828	55,174
Other noncurrent assets	24,199	29,127
	\$794,786	\$678,099
 Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 19,174	\$ 11,605
Accrued clinical and preclinical expenses	15,938	9,925
Accrued compensation and employee benefits	14,688	9,995
Other accrued liabilities	24,829	19,324
Deferred revenue	3,996	4,355
Long-term obligations due within one year	1,492	3,034
Total current liabilities	80,117	58,238
Long-term deferred revenue	7,252	10,730
Accrued litigation settlement expenses due after one year	4,591	5,769
Long-term obligations due after one year	389	2,238
Convertible subordinated debt	250,000	250,000
Commitments and contingencies (see accompanying notes)		
Stockholders' equity:		
Preferred stock, par value \$.001 per share, issuable in series; 5,000 shares authorized; none outstanding	—	—
Common stock, par value \$.001 per share; 500,000 shares authorized; 193,041 shares issued and outstanding at December 31, 2001 and 188,575 shares issued and outstanding at December 31, 2000	193	189
Additional paid-in capital	898,533	857,847
Accumulated other comprehensive income (loss)	7,448	(901)
Deferred compensation	—	(3)
Accumulated deficit	(453,737)	(506,008)
Total stockholders' equity	452,437	351,124
	\$794,786	\$678,099

See accompanying notes

GILEAD SCIENCES, INC.
Consolidated Statements of Operations
(in thousands, except per share amounts)

	Year Ended December 31,		
	2001	2000	1999
Revenues:			
Product sales, net	\$ 190,970	\$ 149,709	\$ 139,890
Royalty revenue, net	22,969	24,591	10,431
Contract revenue	16,352	18,315	18,658
Contract revenue—SAB 101	3,478	2,940	—
Total revenues	233,769	195,555	168,979
Costs and expenses:			
Cost of goods sold	43,764	33,512	29,546
Research and development	185,553	132,339	110,873
Selling, general and administrative	125,141	82,022	99,419
Total costs and expenses	354,458	247,873	239,838
Loss from operations	(120,689)	(52,318)	(70,859)
Gain on sale of oncology assets	157,771	—	—
Gain on sale of unconsolidated affiliate	8,754	—	—
Interest income	25,591	17,634	16,435
Interest expense	(13,980)	(4,365)	(6,518)
Income (loss) before provision for income taxes, equity in loss of unconsolidated affiliate and cumulative effect of change in accounting principle	57,447	(39,049)	(60,942)
Provision for income taxes	4,135	1,199	888
Equity in loss of unconsolidated affiliate	2,130	2,858	4,656
Income (loss) before cumulative effect of change in accounting principle	51,182	(43,106)	(66,486)
Cumulative effect of change in accounting principle	1,089	(13,670)	—
Net income (loss)	\$ 52,271	\$ (56,776)	\$ (66,486)
Amounts per common share—basic:			
Income (loss) before cumulative effect of change in accounting principle	\$ 0.27	\$ (0.24)	\$ (0.39)
Cumulative effect of change in accounting principle	0.01	(0.07)	—
Net income (loss) per share—basic	\$ 0.28	\$ (0.31)	\$ (0.39)
Shares used in per share calculation—basic	190,245	182,099	171,305
Amounts per common share—diluted:			
Income (loss) before cumulative effect of change in accounting principle	\$ 0.25	\$ (0.24)	\$ (0.39)
Cumulative effect of change in accounting principle	0.01	(0.07)	—
Net income (loss) per share—diluted	\$ 0.26	\$ (0.31)	\$ (0.39)
Shares used in per share calculation—diluted	202,321	182,099	171,305

See accompanying notes

GILEAD SCIENCES, INC.
Consolidated Statement of Stockholders' Equity
(in thousands)

	Preferred Stock	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Deferred Compensation	Accumulated Deficit	Total Stockholders' Equity
Balance at January 1, 1999	\$ 1	166,251	\$ 166	\$716,840	\$ (337)	\$(225)	\$(382,746)	\$333,699
Net loss	—	—	—	—	—	—	(66,486)	(66,486)
Unrealized loss on available-for-sale securities, net	—	—	—	—	(1,602)	—	—	(1,602)
Foreign currency translation adjustment	—	—	—	—	(588)	—	—	(588)
Comprehensive loss	—	—	—	—	—	—	—	(68,676)
Employee stock purchase plan	—	401	—	3,075	—	—	—	3,075
Option exercises, net	—	5,013	5	26,135	—	—	—	26,140
Warrant exercises, net	—	129	—	80	—	—	—	80
Conversion of 1,133,786 shares of preferred stock	(1)	4,535	5	(4)	—	—	—	—
Conversion of convertible subordinated debentures	—	42	—	467	—	—	—	467
Amortization of deferred compensation	—	—	—	—	—	151	—	151
Compensatory stock transactions	—	—	—	2,356	—	—	—	2,356
Balance at December 31, 1999	—	176,371	176	748,949	(2,527)	(74)	(449,232)	297,292
Net loss	—	—	—	—	—	—	(56,776)	(56,776)
Unrealized gain on available-for-sale securities, net	—	—	—	—	2,071	—	—	2,071
Foreign currency translation adjustment	—	—	—	—	(445)	—	—	(445)
Comprehensive loss	—	—	—	—	—	—	—	(55,150)
Employee stock purchase plan	—	408	—	3,942	—	—	—	3,942
Option exercises, net	—	4,634	5	26,504	—	—	—	26,509
Warrant exercises, net	—	25	—	—	—	—	—	—
Conversion of convertible subordinated debentures	—	7,137	8	77,939	—	—	—	77,947
Amortization of deferred compensation	—	—	—	—	—	71	—	71
Compensatory stock transactions	—	—	—	513	—	—	—	513
Balance at December 31, 2000	—	188,575	189	857,847	(901)	(3)	(506,008)	351,124
Net income	—	—	—	—	—	—	52,271	52,271
Unrealized gain on available-for-sale securities, net	—	—	—	—	7,735	—	—	7,735
Foreign currency translation adjustment	—	—	—	—	577	—	—	577
Unrealized gain on cash flow hedges, net	—	—	—	—	37	—	—	37
Comprehensive income	—	—	—	—	—	—	—	60,620
Employee stock purchase plan	—	368	—	5,357	—	—	—	5,357
Option exercises, net	—	4,098	4	30,950	—	—	—	30,954
Tax benefits of employee stock plans	—	—	—	1,500	—	—	—	1,500
Amortization of deferred compensation	—	—	—	—	—	3	—	3
Compensatory stock transactions	—	—	—	2,879	—	—	—	2,879
Balance at December 31, 2001	\$ —	193,041	\$ 193	\$898,533	\$7,448	\$ —	\$(453,737)	\$452,437

See accompanying notes

GILEAD SCIENCES, INC.
Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,		
	2001	2000	1999
Operating activities:			
Net income (loss)	\$ 52,271	\$(56,776)	\$(66,486)
Adjustments to reconcile net income (loss) to net cash used in operating activities:			
Depreciation and amortization	14,691	12,008	12,623
Net effect of change in accounting principle	(1,089)	10,730	—
Compensation expense from stock option transactions	165	513	2,356
Gain on sale of oncology assets, net of securities received	(118,924)	—	—
Gain on sale of unconsolidated affiliate	(8,754)	—	—
Equity in loss of unconsolidated affiliate	2,130	2,858	4,656
Litigation settlement charges	572	667	754
Net provision for doubtful accounts	(170)	30	888
Tax benefits from employee stock plans	1,500	—	—
Net unrealized (gain) loss on foreign currency transactions	298	(1,615)	2,846
Changes in operating assets and liabilities:			
Accounts receivable	(25,482)	(3,942)	(7,041)
Inventories	(18,718)	397	(4,409)
Prepaid expenses and other assets	(2,734)	766	(349)
Long-term prepaid royalties	—	(11,367)	—
Accounts payable	8,454	2,232	1,443
Accrued liabilities	11,495	5,775	(11,389)
Deferred revenue (excluding net effect of change in accounting principle)	(3,837)	(478)	1,558
Net cash used in operating activities	(88,132)	(38,202)	(62,550)
Investing activities:			
Purchases of marketable securities	(377,725)	(229,862)	(186,997)
Sales of marketable securities	143,684	29,490	101,943
Maturities of marketable securities	136,850	134,240	83,677
Capital expenditures	(26,329)	(15,621)	(12,475)
Proceeds from sale of oncology assets	130,000	—	—
Proceeds from sale of unconsolidated affiliate	14,300	—	—
Investment in unconsolidated affiliate	—	(2,450)	(2,450)
Net cash provided by (used in) investing activities	20,780	(84,203)	(16,302)
Financing activities:			
Proceeds from issuances of common stock	36,311	30,451	29,295
Repayments of long-term debt	(2,761)	(3,156)	(5,320)
Proceeds from issuance of convertible subordinated notes, net of issuance costs	—	241,750	—
Net cash provided by financing activities	33,550	269,045	23,975
Effect of exchange rate changes on cash	(1,151)	3,641	752
Net increase (decrease) in cash and cash equivalents	(34,953)	150,281	(54,125)
Cash and cash equivalents at beginning of year	197,292	47,011	101,136
Cash and cash equivalents at end of year	<u>\$162,339</u>	<u>\$197,292</u>	<u>\$ 47,011</u>

GILEAD SCIENCES, INC.
Consolidated Statements of Cash Flows (Continued)
(in thousands)

	Year Ended December 31,		
	2001	2000	1999
Supplemental disclosure of cash flow information:			
Interest paid	\$ 12,710	\$ 5,417	\$ 6,234
Income taxes paid	1,778	493	527
Non-cash investing and financing activities			
OSI common stock received upon sale of oncology assets	\$ 38,849	\$ —	\$ —
Common stock issued upon conversion of debentures	—	79,533	467
Reclassification of deferred debt issuance costs to additional paid-in capital upon conversion of subordinated debentures	—	1,586	—

See accompanying notes

GILEAD SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2001

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Overview

Gilead was incorporated in Delaware on June 22, 1987. We are an independent biopharmaceutical company focused on the discovery, development and commercialization of antivirals, antibacterials and antifungals to treat life-threatening infectious diseases. We are a multinational company, with revenues from five approved products and operations in ten countries. Currently, we market Viread for the treatment of HIV infection, AmBisome, an antifungal agent, DaunoXome, a drug approved for the treatment of Kaposi's Sarcoma, and Vistide for the treatment of cytomegalovirus (CMV) retinitis. Hoffmann-La Roche Inc. markets Tamiflu for the treatment of influenza, under a collaborative agreement with Gilead. We are seeking to add to our existing portfolio of products through our clinical development programs, internal discovery programs and an active product acquisition and in-licensing strategy. Our internal discovery activities include identification of new molecular targets, target screening and medicinal chemistry. In addition, we are currently developing products to treat hepatitis B virus and bacterial infections. We also have expertise in liposomal drug delivery technology that we use to develop drugs that are safer, easier for patients to tolerate and more effective.

As more fully described in Note 5, on July 29, 1999, Gilead entered into a business combination (the Merger) with NeXstar Pharmaceuticals, Inc. (NeXstar). The business combination was accounted for as a pooling of interests and the historical consolidated financial statements of Gilead for all years prior to the business combination have been restated to include the financial position, results of operations and cash flows of NeXstar. No material adjustments were necessary to conform the accounting policies of the two companies. Costs of the Merger were charged to operations in 1999.

The accompanying consolidated financial statements include the accounts of the Company and its wholly and majority-owned subsidiaries. Significant intercompany transactions have been eliminated. Certain prior period amounts have been reclassified to be consistent with the current presentation.

Stock Split

On February 22, 2001 and on March 8, 2002, Gilead completed two-for-one stock splits, effected in the form of a stock dividend, to stockholders of record as of February 2, 2001 and February 14, 2002, respectively. Accordingly, all share and per share amounts for all periods presented have been restated to reflect both of these splits.

Changes in Accounting Principles

Gilead adopted Statement of Financial Accounting Standards (SFAS) Nos. 133 and 138, collectively referred to as SFAS 133, *Accounting for Derivative Instruments and Hedging Activities*, in the first quarter of 2001. The change was accounted for as a change in accounting principle. See Note 3, "Derivative Financial Instruments." Effective in the first quarter of 2000, Gilead adopted the SEC's Staff Accounting Bulletin No. 101 (SAB 101), *Revenue Recognition in Financial Statements*, and the change was also accounted for as a change in accounting principle. See Note 2.

Critical Accounting Policies and Estimates

The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of assets

GILEAD SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
DECEMBER 31, 2001

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

and liabilities. On an on-going basis, we evaluate our estimates, including those related to revenue recognition, bad debts, inventories, accrued clinical and preclinical expenses, and contingencies. We base our estimates on historical experience and on various other market specific assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ significantly from these estimates under different assumptions or conditions.

Revenue Recognition

Product sales revenue is recognized upon passage of legal title of the inventory and satisfaction of all of the Company's performance obligations. The Company does not provide its customers with a general right of product return. However, the Company will accept returns of product that has expired or is deemed to be damaged or defective when delivered. Provisions are made for doubtful accounts, estimated product returns, cash discounts and government discounts and rebates.

Contract revenue for research and development is recorded as earned based on the performance requirements of the contract. Nonrefundable contract fees for which no further performance obligations exist, and there is no continuing involvement by Gilead, are recognized on the earlier of when the payments are received or when collection is assured.

Revenue from non-refundable up-front license fees where we continue involvement through development collaboration or an obligation to supply product, is recognized as the manufacturing obligation is fulfilled or ratably over the development period or the period of the manufacturing obligation, as appropriate.

Revenue associated with substantive performance milestones is recognized based upon the achievement of the milestones, as defined in the respective agreements. Revenue under research and development cost reimbursement contracts is recognized as the related costs are incurred.

Advance payments received in excess of amounts earned are classified as deferred revenue.

Royalty revenue from sales of AmBisome is recognized in the month following that in which the corresponding sales occur. Royalty revenue from sales of Vistide and Tamiflu is recognized when received, which is the quarter following the quarter in which the corresponding sales occur.

Research and Development Costs

Major components of R&D expenses consist of personnel costs, including salaries and benefits, clinical studies performed by contract research organizations, materials and supplies, and overhead allocations consisting of various administrative and facilities related costs. Our research and development activities are also separated into three main categories: research, clinical development and pharmaceutical development. Research costs typically consist of preclinical and toxicology work. Clinical development costs include Phase I, II, and III clinical trials as well as expanded access programs. Pharmaceutical development costs consist of product formulation and chemical analysis. We record accruals for estimated clinical and preclinical study costs. These costs are a significant component of research and development expenses. Management accrues costs for clinical studies performed by

GILEAD SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
DECEMBER 31, 2001

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

contract research organizations based on estimates that 25% to 30% of the work is for upfront costs with the remaining activity generally on a straight-line basis over the life of the individual contract or study. This estimate may or may not match the actual services performed by the organizations as determined by patient enrollment levels and related activities. We monitor patient enrollment levels and related activity to the extent possible, however, if management has underestimated activity levels associated with various studies at a given point in time, we could record significant research and development expenses in future periods.

Advertising Expenses

The Company expenses the costs of advertising, including promotional expenses, as incurred. Advertising expenses were \$16.5 million in 2001, \$8.4 million in 2000, and \$7.9 million in 1999.

Stock-Based Compensation

In accordance with the provisions of SFAS No. 123, *Accounting For Stock-Based Compensation*, the Company has elected to follow Accounting Principles Board Opinion (APB) No. 25, *Accounting For Stock Issued To Employees*, and Interpretation No. 44 (FIN 44), *Accounting for Certain Transactions Involving Stock Compensation—an Interpretation of APB Opinion No. 25* in accounting for its employee stock option plans. Under APB 25, if the exercise price of the Company's employee and director stock options equals or exceeds the fair value of the underlying stock on the date of grant, no compensation expense is recognized. See Note 14 for pro forma disclosures of stock-based compensation pursuant to SFAS 123.

Per Share Computations

For 2001, basic net income per common share is computed based on the weighted average number of common shares outstanding during the period. Diluted net income per common share for 2001 includes the effects of approximately 12.1 million stock options and warrants, but does not include the effect of the \$250.0 million 5% convertible notes which would convert to approximately 10.2 million shares, as their effect is antidilutive. For all periods presented prior to 2001, both basic and diluted loss per common share are computed based on the weighted average number of common shares outstanding during the period. The convertible notes, stock options and warrants, as well as the convertible debentures that were previously outstanding, were excluded from the computation of diluted loss per share as their effect is antidilutive for the periods presented prior to 2001. All share and per share amounts for all periods presented have been restated to reflect the stock splits of February 22, 2001 and March 8, 2002.

Cash and Cash Equivalents

The Company considers highly liquid investments with insignificant interest rate risk and a remaining maturity of three months or less at the purchase date to be cash equivalents. Gilead may enter into overnight repurchase agreements under which it purchases securities with an obligation to resell them the following day. Securities purchased under agreements to resell are recorded at face value and reported as cash and cash equivalents. Under the Company's investment policy, it may enter into repurchase agreements (repos) with major banks and authorized dealers provided that such repos

GILEAD SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
DECEMBER 31, 2001

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

are collateralized by U.S. government securities with a fair value of at least 102% of the fair value of securities sold to Gilead.

Marketable Securities

Management determines the appropriate classification of our marketable securities at the time of purchase and reevaluates such designation at each balance sheet date. All of the Company's marketable securities are classified as available-for-sale and carried at estimated fair values and reported in either cash equivalents or marketable securities. At December 31, 2001, cash and cash equivalents include \$121.2 million of securities designated as available-for-sale (\$137.6 million at December 31, 2000). Unrealized gains and losses on available-for-sale securities are excluded from earnings and reported as a separate component of stockholders' equity. Interest income includes interest, dividends, amortization of purchase premiums and discounts, and realized gains and losses on sales of securities. The cost of securities sold is based on the specific identification method. We regularly review all of our investments for other-than-temporary declines in fair value. When we determine that the decline in fair value of an investment below our accounting basis is other-than-temporary, we reduce the carrying value of the securities we hold and record a loss in the amount of any such decline. No such reductions have been required during the past three years.

Concentrations of Credit Risk

Gilead is subject to credit risk from its portfolio of cash equivalents and marketable securities. By policy, the Company limits amounts invested in such securities by maturity, industry group, investment type and issuer, except for securities issued by the U.S. government. Gilead is not exposed to any significant concentrations of credit risk from these financial instruments, however we do hold 924,984 shares of OSI common stock as a result of the sale of our oncology assets to OSI (see Note 4). These shares, with a fair value of \$42.3 million at December 31, 2001, represent our entire portfolio of marketable equity securities. The goals of the Company's investment policy, in order of priority, are as follows: safety and preservation of principal and diversification of risk; liquidity of investments sufficient to meet cash flow requirements; and competitive after-tax rate of return.

Gilead is also subject to credit risk from its accounts receivable related to product sales. A majority of the Company's trade accounts receivable arises from sales of AmBisome, primarily through sales to our European subsidiaries and export sales to our distributors in Europe. In certain countries where payments are typically slow, primarily Greece, Spain, Portugal and Italy, our accounts receivable balances are significant. In most cases, these slow payment practices reflect the pace at which governmental entities reimburse our customers. This, in turn, may increase the financial risk related to certain of our customers. Sales to customers in countries that tend to be relatively slow paying have in the past increased, and in the future may further increase, the average length of time that accounts receivable are outstanding. To date, we have experienced only modest losses with respect to the collection of our accounts receivable and believe that all past due accounts receivable, including those due from customers in these four countries, are collectible. We continually seek to improve our collection processes to ensure that we fully collect amounts due to us based on our product sales and that collections are timely. We perform credit evaluations of our customers' financial condition and

GILEAD SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
DECEMBER 31, 2001

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

generally have not required collateral. To date, we have experienced only modest credit losses with respect to our accounts receivable.

Inventories

Inventories are recorded at the lower of cost or market, with cost determined on a first-in, first-out basis. Management periodically reviews the composition of inventory in order to identify obsolete, slow-moving or otherwise unsaleable items. If such items are observed and there are no alternate uses for the inventory, the Company will record a write-down to net realizable value in the period that the units are identified as impaired. Historically, inventory write-downs have been insignificant and consistent with management's expectations.

Property, Plant and Equipment

Property, plant and equipment is stated at cost less accumulated depreciation and amortization. Depreciation and amortization are recognized using the straight-line method. Estimated useful lives are as follows:

<u>Description</u>	<u>Estimated Useful Life (in years)</u>
Building and leasehold improvements	20
Laboratory and manufacturing equipment	4-10
Office and computer equipment	2-6

Office and computer equipment includes capitalized computer software. All of the Company's capitalized software is purchased. The Company has no internally developed computer software. Leasehold improvements and capitalized leased equipment are amortized over the shorter of the lease term or the item's useful life.

Other Noncurrent Assets

Other noncurrent assets at December 31, 2001 includes \$11.0 million of prepaid royalties paid to the Institute of Organic Chemistry and Biochemistry of the Academy of Sciences of the Czech Republic and Rega Stichting (IOCB/REGA), as discussed under the "IOCB/REGA" caption of Note 7. Also included in other noncurrent assets at December 31, 2001 are deferred debt issuance costs of \$6.9 million, net of accumulated amortization of \$1.3 million, related to the \$250.0 million 5% subordinated convertible notes Gilead issued in December 2000.

GILEAD SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
DECEMBER 31, 2001

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Long-Lived Assets

The carrying value of long-lived assets is reviewed on a regular basis for the existence of facts or circumstances both internally and externally that may suggest impairment. Specific potential indicators of impairment include:

- a significant decrease in the fair value of an asset;
- a significant change in the extent or manner in which an asset is used or a significant physical change in an asset;
- a significant adverse change in legal factors or in the business climate that affects the value of an asset;
- an adverse action or assessment by the U.S. Food and Drug Administration or another regulator;
- an accumulation of costs significantly in excess of the amount originally expected to acquire or construct an asset; and
- operating or cash flow losses combined with a history of operating or cash flow losses or a projection or forecast that demonstrates continuing losses associated with an income-producing asset.

Should there be indication of impairment, the Company will confirm this by comparing the estimated future cash flows expected to result from the use of the asset and its eventual disposition to the carrying amount of the asset. In estimating these future cash flows, assets are grouped at the lowest level for which there are identifiable cash flows that are largely independent of the cash flows generated by other asset groups. If the sum of the expected future cash flows (undiscounted and without interest changes) is less than the carrying amount of the asset, an impairment loss, measured as the excess of the carrying value of the asset over its fair value, will be recognized. The cash flow estimates used in such calculations are based on management's best estimates, using appropriate and customary assumptions and projections at the time.

Other Current Accrued Liabilities

At December 31, 2001 and December 31, 2000, other accrued liabilities included \$2.4 million of accrued litigation settlement costs. See the Legal Proceedings discussion in Note 13.

Foreign Currency Translation, Transactions and Contracts

Adjustments resulting from translating the financial statements of the Company's foreign subsidiaries into U.S. dollars are excluded from the determination of net income and are accumulated in a separate component of stockholders' equity. Net foreign exchange transaction losses are reported as a selling, general and administrative expense in the consolidated statements of operations. Such losses were \$1.4 million in 2001, \$0.5 million in 2000 and \$0.5 million in 1999.

The Company hedges certain of its foreign currency exposures related to outstanding trade accounts receivable and firmly committed purchase transactions with foreign exchange forward contracts. In general, these contracts do not expose the Company to market risk because gains and losses on the contracts offset gains and losses on the transactions being hedged. The Company's

GILEAD SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
DECEMBER 31, 2001

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

exposure to credit risk from these contracts is a function of changes in interest and currency exchange rates and, therefore, varies over time. Gilead limits the risk that counterparties to these contracts may be unable to perform by transacting only with major U.S. banks. The Company also limits its risk of loss by entering into contracts that provide for net settlement at maturity. Therefore, the Company's overall risk of loss in the event of a counterparty default is limited to the amount of any unrecognized and unrealized gains on outstanding contracts (i.e., those contracts that have a positive fair value) at the date of default. The Company does not enter into speculative foreign currency transactions and does not write options.

In accounting for hedges of accounts receivable, the Company's aggregate net foreign currency transaction gain or loss is reported as a selling, general and administrative expense. Prior to the adoption of SFAS 133 on January 1, 2001, the Company recognized the net unrealized gain or loss on outstanding forward contracts based on the difference between the contract exchange rate and the market exchange rate at each balance sheet date. With respect to hedges of firmly committed purchase transactions, unrealized gains and losses on the underlying forward contracts were deferred and reported as a component of the related transaction in the period in which it occurred. At December 31, 2001, the Company has net unrealized losses on its open foreign exchange forward contracts of \$0.9 million.

The Company had forward exchange contracts outstanding of \$72.3 million at December 31, 2001 and \$53.8 million at December 31, 2000. The contracts have maturities of one year or less with one exception. One hedge contract intended to hedge raw materials purchases in the first quarter of 2003, with a notional amount of \$3.7 million and no fair value at December 31, 2001, has a maturity of 13 months.

The Company presently does not hedge its net investment in any of its foreign subsidiaries. Effective January 2002, we have begun to use forward contracts to hedge a percentage of our forecasted international sales, primarily those denominated in the euro currency.

See Note 3 for a further discussion of derivative financial instruments and our adoption of SFAS 133.

Fair Value of Financial Instruments

The Company's financial instruments consist principally of cash and cash equivalents, marketable securities, accounts receivable, certain other non-current assets, forward foreign exchange contracts, accounts payable, long-term obligations and convertible subordinated notes. Cash and cash equivalents, marketable securities and forward foreign exchange contracts that hedge accounts receivable are reported at their respective fair values on the balance sheet. Forward foreign exchange contracts that hedge firmly committed purchases are recorded at fair value, net of the related deferred gain or loss, resulting in a reported net balance of zero. Management believes the remaining financial instruments, with the exception of the convertible subordinated notes, are reported on the balance sheet at amounts that approximate current fair values. The fair value of the convertible subordinated notes at December 31, 2001 was \$382.8 million and the fair value at December 31, 2000 was \$211.6 million. The carrying value at the end of each period was \$250 million. The fair value at December 31, 2001 was determined by obtaining a quote from a market maker for the notes. The fair value at December 31,

GILEAD SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
DECEMBER 31, 2001

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

2000 was obtained by multiplying the number of shares into which the notes can be converted, by the per share market price of Gilead's common stock at December 31, 2000, plus accrued interest.

Recent Accounting Pronouncements

In July 2001, the Financial Accounting Standards Board (FASB) issued SFAS No. 141, *Business Combinations* (SFAS 141), and No. 142, *Goodwill and Other Intangible Assets* (SFAS 142). SFAS 141 eliminates the pooling-of-interests method of accounting for business combinations except for qualifying business combinations that were initiated prior to July 1, 2001. SFAS 141 further clarifies the criteria to recognize intangible assets separately from goodwill. The requirements of SFAS 141 are effective for any business combination accounted for by the purchase method that is completed after June 30, 2001. Under SFAS 142, goodwill and indefinite lived intangible assets are no longer amortized but are reviewed annually (or more frequently if impairment indicators arise) for impairment. Separable intangible assets that are not deemed to have an indefinite life will continue to be amortized over their useful lives (but with no maximum life). The amortization provisions of SFAS 142 apply to goodwill and intangible assets acquired after June 30, 2001. As Gilead has not accounted for any business combinations under the purchase method of accounting, the adoption of SFAS 141 on July 1, 2001 did not have a material impact on the Company's financial position or results of operations and the adoption of SFAS 142 on January 1, 2002 will not have a material impact on the Company's financial position or results of operations.

In August 2001, the FASB issued SFAS 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. SFAS 144 establishes a single accounting model for assets to be disposed of by sale, whether previously held and used or newly acquired. SFAS 144 retains the presentation of discontinued operations in the income statement, but broadens the presentation to include a component of an entity. SFAS 144 is effective for fiscal years beginning after December 15, 2001 and the interim periods within. The adoption of SFAS 144 on January 1, 2002 will not have a material impact on the Company's financial position or results of operations.

2. CUMULATIVE CHANGE IN ACCOUNTING PRINCIPLE

In December 1999, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 101 (SAB 101), *Revenue Recognition in Financial Statements*. Among other things, SAB 101 describes the SEC Staff's position on the recognition of certain nonrefundable up-front fees received in connection with collaboration agreements. The Company previously recognized nonrefundable technology access fees received in connection with collaboration agreements as revenue when received or when collectibility was probable, and when the technology had been transferred. Effective January 1, 2000, Gilead changed its method of accounting for these fees to recognize them as the related manufacturing obligation is fulfilled or on a straight-line basis over the term of the related research and development collaboration, manufacturing or supply arrangement, as appropriate, as this method best matches the effort provided. Management believes the change in accounting principle is preferable based on guidance provided in SAB 101.

The cumulative effect of the change in accounting principle was recorded in the fourth quarter of 2000, retroactively effective as of January 1, 2000, as deferred revenue that will be recognized as contract revenue over the remaining term of the research and development, manufacturing or supply arrangements, as appropriate. For the year ended December 31, 2000, the net impact of the change in

GILEAD SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
DECEMBER 31, 2001

2. CUMULATIVE CHANGE IN ACCOUNTING PRINCIPLE (Continued)

accounting principle was to increase the net loss by \$10.7 million, or \$0.06 per share. The loss consists of a \$13.7 million cumulative effect of the change as of January 1, 2000, net of \$2.9 million of related deferred revenue that was recognized as contract revenue during the year 2000. An additional \$3.5 million of contract revenue was recognized in 2001 and the remainder of the \$7.3 million related deferred revenue balance as of December 31, 2001, is expected to be recognized as revenue in fiscal years 2002 through 2012.

3. DERIVATIVE FINANCIAL INSTRUMENTS

On January 1, 2001, Gilead adopted SFAS 133. The standard requires that Gilead recognize all derivatives as either assets or liabilities measured at fair value. If the derivative is designated as, and meets the definition of, a fair value hedge, the changes in the fair value of the derivative and of the hedged item attributable to the hedged risk are recognized in earnings. If the derivative is designated as, and meets the definition of, a cash flow hedge, the effective portions of changes in the fair value of the derivative are recorded in other comprehensive income and are recognized in the income statement when the hedged item affects earnings. Ineffective portions of changes in the fair value of cash flow hedges are recognized in earnings immediately. SFAS 133 also classifies warrants to purchase capital stock of a non-public company, which include a net exercise feature as derivatives, and as such upon adoption are to be recorded in the balance sheet at fair value with an offsetting amount recorded in the results of operations. Subsequent changes in the fair value of the warrants are required to be remeasured at each balance sheet date, with changes in the fair value of the warrants recorded in results of operations.

Gilead sells product and purchases raw materials internationally in both US dollars and local currency. Forecasted and actual foreign currency risks are hedged with forward currency contracts, generally with maturities of 12 months or less. These derivative instruments are employed to eliminate or minimize certain foreign currency exposures that can be confidently identified and quantified. Forward contracts hedging non-functional currency assets and liabilities are not SFAS 133 designated hedges and changes in fair value are recognized immediately in earnings. In accordance with SFAS 133, hedges related to anticipated foreign currency purchases of raw materials designated and documented at the inception of the respective hedge are designated as cash flow hedges and evaluated for effectiveness quarterly. As the terms of the forward contract and the underlying transaction are matched at inception, forward contract effectiveness is calculated by comparing the fair value of the contract to the change in the forward value of the underlying hedged item, with the effective portion of the gain or loss on the derivative instrument reported as a component of other comprehensive income in stockholders' equity and reclassified into earnings in the same period or periods during which the hedged transaction affects earnings. Upon adoption of SFAS 133, we recorded a fair value of \$0.6 million related to forward contracts previously not reflected in the balance sheet and recognized a cumulative transition adjustment to other comprehensive income of \$0.6 million for the effective component of the hedge. Substantially all values reported in other comprehensive income at December 31, 2001 will be reclassified to earnings within 12 months. Any residual changes in fair value of the instruments or other ineffectiveness are recognized immediately in selling, general and administrative expense. Ineffectiveness during 2001 was not significant.

Gilead holds warrants to purchase stock in two non-public companies. These warrants have net exercise features and under SFAS 133 are classified as a derivative instruments. Upon adoption, Gilead

GILEAD SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
DECEMBER 31, 2001

3. DERIVATIVE FINANCIAL INSTRUMENTS (Continued)

recorded the fair value of one of these warrants at \$1.1M with an offsetting adjustment to cumulative change in accounting principle.

During the year ended 2001, a \$1.4 million loss on hedging contracts has been recognized in the income statement and a \$0.6 million reduction in the fair value of derivatives has been recognized in other comprehensive income. At December 31, 2001, the fair value of derivatives recognized in other comprehensive income is not material.

4. SALE OF ONCOLOGY ASSETS

On December 21, 2001, Gilead completed the sale of its oncology assets, pipeline of clinical candidates in oncology and all related intellectual property, as well as our Boulder, Colorado operations, including clinical research and drug development operations, infrastructure and facilities, to OSI Pharmaceuticals, Inc (OSI). The three clinical development candidates sold to OSI are: NX 211 (liposomal lurtotecan), GS 7836 (a nucleoside analogue) and GS 7904L (a liposomal thymidylate synthase inhibitor). As consideration, Gilead received \$130.0 million in cash and 924,984 shares of OSI common stock valued at approximately \$38.8 million as of December 21, 2001. The number of shares issued to Gilead was determined by dividing \$40.0 million by the average closing sale price of OSI common stock for the 5 days preceding December 21, 2001. We are also entitled to additional payments from OSI of up to \$30.0 million in either cash or a combination of cash and OSI common stock if and when OSI reaches certain development milestones for NX 211, the most advanced of the oncology product candidates sold to OSI. Based upon the December 21, 2001 net book value of the oncology assets sold of \$5.0 million, transaction costs of \$3.2 million, and \$2.8 million related to the acceleration of approximately 78,000 options to purchase Gilead common stock, the Company realized a pretax gain of \$157.8 million in the fourth quarter of 2001. The carrying value of the transferred assets relates primarily to certain property and equipment. OSI assumed all of Gilead's oncology-related clinical and preclinical obligations, as well as various lease obligations. Under a related manufacturing agreement, we will produce for OSI liposomal formulations of NX 211 and GS 7904L, the two liposomal products sold to OSI, at our manufacturing facility in San Dimas, CA.

5. ACQUISITION OF NEXSTAR

On July 29, 1999, the Company acquired all of the outstanding common stock of NeXstar Pharmaceuticals under an agreement dated as of February 28, 1999. As a result, NeXstar became a wholly owned subsidiary of Gilead. In connection with the Merger, Gilead issued a total of 44.8 million shares of Gilead common stock to NeXstar's stockholders as consideration for all shares of common stock of NeXstar. In addition, holders of options and warrants outstanding at the time of the merger to purchase an aggregate of approximately 2.2 million shares of NeXstar common stock would receive, upon exercise of such options and warrants, the same fraction of a share of Gilead common stock. Holders of \$80.0 million principal amount of 6.25% convertible subordinated debentures of NeXstar received the right to convert the debentures into approximately 7.2 million shares of Gilead common stock. The Merger qualified as a tax-free reorganization and was accounted for as a pooling of interests.

GILEAD SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2001

5. ACQUISITION OF NEXSTAR (Continued)

The table below presents the separate 1999 results of operations for Gilead and NeXstar for the periods prior to the merger and combined results after the merger (in thousands):

	<u>Gilead</u>	<u>NeXstar</u>	<u>Merger-related adjustments</u>	<u>Total</u>
Year ended December 31, 1999				
Revenues	\$24,659	\$144,320	\$ —	\$168,979
Net income (loss)	(73,534)	25,351	(18,303)(a)	(66,486)

(a) Merger-related costs

(b) Adjustment required to conform accounting policy. NeXstar's policy was to capitalize certain patent and trademark costs, while it was Gilead's policy to charge such items to selling, general and administrative expense in the period incurred. The accompanying financial statements have been restated for all periods such that all patent and trademark costs are expensed as incurred.

As a result of its merger with NeXstar, the Company incurred merger-related costs consisting of transaction costs (primarily professional fees, filing fees, printing costs and other related charges), employee severance costs and the write-down of certain NeXstar assets that would not be used in continuing operations. The following table shows the details of the merger-related costs and accruals at December 31, 1999 (in thousands):

	<u>Charged to Expense Through December 31, 1999</u>	<u>Utilized</u>	<u>December 31, 1999 Accrual Balance</u>
Merger transaction costs	\$12,214	\$12,196	\$ 18
Employee severance	5,309	2,821	2,488
Write-down of NeXstar assets	536	N/A	N/A
Other	244	244	—
Total	<u>\$18,303</u>	<u>\$15,261</u>	<u>\$2,506</u>

All employees for which severance costs were accrued had been terminated as of December 31, 1999. Substantially all remaining accrued severance costs were paid to former employees by December 31, 2000. All merger transaction costs were utilized by December 31, 2000.

GILEAD SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
DECEMBER 31, 2001

6. AVAILABLE-FOR-SALE SECURITIES

The following is a summary of available-for-sale securities. Estimated fair values of available-for-sale securities are based on prices obtained from commercial pricing services (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
December 31, 2001				
U.S. treasury securities and obligations of U.S.				
government agencies	\$ 64,898	\$ 854	\$ (41)	\$ 65,711
Certificates of deposit	6,093	7	—	6,100
Corporate debt securities	265,532	3,533	(717)	268,348
Corporate equity securities	38,849	3,459	—	42,308
Asset-backed securities	58,309	1,154	(2)	59,461
Other debt securities	99,757	—	—	99,757
Total	<u>\$533,438</u>	<u>\$9,007</u>	<u>\$(760)</u>	<u>\$541,685</u>
December 31, 2000				
U.S. treasury securities and obligations of U.S.				
government agencies	\$ 57,938	\$ 93	\$(125)	\$ 57,906
Certificates of deposit	132	1	—	133
Corporate debt securities	190,604	504	(252)	190,856
Asset-backed securities	43,752	349	(58)	44,043
Other debt securities	160,204	—	—	160,204
Total	<u>\$452,630</u>	<u>\$ 947</u>	<u>\$(435)</u>	<u>\$453,142</u>

Other debt securities consist primarily of money market funds.

The following table presents certain information related to sales of available-for-sales securities (in thousands):

	Year Ended December 31,		
	2001	2000	1999
Proceeds from sales	\$143,684	\$29,490	\$101,943
Gross realized gains on sales	\$ 1,284	\$ 62	\$ 92
Gross realized losses on sales	\$ (59)	\$ (146)	\$ (475)

At December 31, 2001, \$223.5 million of the Company's portfolio of marketable securities (excluding \$59.5 million of asset-backed securities and \$42.3 million of equity securities) has a contractual maturity of less than one year and \$216.4 million of the portfolio has a contractual maturity greater than one year but less than three years. None of the estimated maturities of the Company's asset-backed securities exceed three years. Marketable equity securities, consisting of OSI common stock, are expected to be available for sale during the first half of 2002.

GILEAD SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
DECEMBER 31, 2001

7. COLLABORATIVE ARRANGEMENTS AND CONTRACTS

Cubist Pharmaceuticals

In January 2001, Gilead entered into an agreement with Cubist Pharmaceuticals, Inc. (Cubist) relating to Cubist's antibacterial compound daptomycin, including Cidecin™, an intravenous formulation of the compound that is currently in Phase III clinical trials for treatment of bacterial infections. Under the terms of the agreement, Gilead paid Cubist an upfront license fee of \$13.0 million and received exclusive commercial rights to the compound in sixteen European countries (Gilead's territory) as well as the right to develop the compound for commercialization in this territory. Research and development expense has been charged for \$10.6 million of the \$13.0 million payment. The \$2.4 million balance is included in other noncurrent assets at December 31, 2001 because if, prior to January 2002, Gilead terminated its rights under the agreement with respect to a preclinical oral formulation of daptomycin being developed by Cubist, or if Cubist discontinued development of that oral formulation, Gilead would have been entitled to receive a refund of this amount from Cubist. Subsequent to January 2002, this refundable amount is reduced ratably on a monthly basis over a four-year period and is being amortized to research and development expense. Cubist will continue to be responsible for worldwide clinical development of Cidecin and the preclinical oral formulation. Gilead will be responsible for both regulatory filings and marketing and selling of the product within Gilead's territory. Gilead also agreed to make additional payments to Cubist of up to \$30.7 million if certain clinical and regulatory milestones related to Cidecin and the oral formulation are reached. Through 2001, three of these milestones had been met and Gilead paid \$5.5 million related to those milestones. These payments have been recorded as research and development expense. Additionally, if Cidecin is successfully commercialized in Gilead's territory, Gilead will pay Cubist a royalty on net sales of the product.

Archemix

In October 2001, we entered into an agreement with Archemix Corporation relating to our SELEX technology. Under this agreement, we gave Archemix the exclusive rights to the SELEX process, including therapeutic and other commercial applications to the extent not already licensed under pre-existing agreements. Archemix paid to us \$9.0 million in 2001 and is required to pay us \$8.5 million in 2002. As required by our license agreement with the University Technology Corporation, we paid 5% of the \$9.0 million payment to, and will pay 5% of the \$8.5 million payment to, the University Technology Corporation. We also received a warrant to purchase 350,000 shares of Archemix common stock, the value of which is not material. As required by our license agreement with the University Technology Corporation, we transferred 5% of this warrant to the University Technology Corporation.

EyeTech

In March 2000, Gilead entered into an agreement with EyeTech Pharmaceuticals, Inc. relating to Gilead's proprietary aptamer EYE001. Currently in early clinical trials, EYE001 is an inhibitor of vascular endothelial growth factor, or VEGF, which is known to play a role in the development of certain ophthalmic diseases. Under the terms of the agreement, EyeTech received worldwide rights to all therapeutic uses of EYE001, and, if the product is successfully commercialized, EyeTech will pay Gilead royalties on worldwide sales of the product. EyeTech also will be responsible for all research

GILEAD SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
DECEMBER 31, 2001

7. COLLABORATIVE ARRANGEMENTS AND CONTRACTS (Continued)

and development costs. Gilead will provide clinical supplies of the product to EyeTech through March 2001. Gilead received a \$7.0 million up-front licensing fee from EyeTech in April 2000, which was recognized as revenue ratably over the one-year supply agreement period. Accordingly, \$5.2 million of the license fee was recorded as contract revenue under the agreement in 2000, and the remainder of the license fee was recognized as revenue in 2001. Gilead is also entitled to additional cash payments from EyeTech of up to \$25.0 million if and when EyeTech reaches certain EYE001 development milestones. Additionally, Gilead received a warrant to purchase 791,667 shares of EyeTech series B convertible preferred stock, exercisable at a price of \$6.00 per share, the price at which the stock was issued to other investors. See Note 3 for a description of the accounting treatment of the warrant.

Fujisawa

The Company's rights to market AmBisome are subject to an agreement between the Company and Fujisawa Healthcare, Inc., as successor to Fujisawa USA, Inc. (Fujisawa). Under the terms of the Fujisawa agreement, as amended, Fujisawa and the Company co-promote AmBisome in the United States; Fujisawa has sole marketing rights to AmBisome in Canada and the Company has exclusive marketing rights to AmBisome in the rest of the world, provided the Company pays royalties to Fujisawa in connection with sales in most significant Asian markets, including Japan. In connection with U.S. sales, Fujisawa purchases AmBisome from the Company at cost. For sales in Canada, Fujisawa purchases AmBisome at cost plus a specified percentage. Fujisawa collects all payments from the sale of AmBisome in the United States and Canada. The Company receives 20% of Fujisawa's gross profits from the sale of AmBisome in the United States. Gross profits include a deduction for cost of goods sold, giving the Company a current effective royalty rate of approximately 17% of Fujisawa's net sales of AmBisome in the United States. In connection with the agreement between the Company and Fujisawa, Gilead recorded royalty revenue of \$17.1 million in 2001, \$13.5 million in 2000 and \$8.3 million in 1999.

Sumitomo

In September 1996, the Company and Sumitomo Pharmaceuticals Co., Ltd. (Sumitomo) entered into an agreement (Sumitomo License) pursuant to which Sumitomo agreed to develop and market AmBisome in Japan. Under the terms of the Sumitomo License, Sumitomo paid the Company an initial \$7.0 million licensing fee (less withholding taxes of \$0.7 million) in October 1996 and a \$3.0 million milestone payment (less withholding taxes of \$0.3 million) in March 1998. Sumitomo also is required to make additional payments to the Company if certain clinical and commercial milestones are met and to pay the Company royalties on all Japanese AmBisome sales. Under the Sumitomo License, Gilead is obligated to provide a certain quantity of AmBisome to Sumitomo at no charge. AmBisome is not yet approved for marketing in Japan.

Subsequent to the cumulative effect of the change in accounting principle that was recorded effective in the first quarter of 2000 resulting from the adoption of SAB 101, Gilead is recognizing the initial license fee over the remaining free supply arrangement period, which is currently expected to be over the next five years. The net impact of the change in accounting principle for the Sumitomo License was to increase the net loss in 2000 by \$3.4 million. The cumulative effect of the change in accounting principle was a charge of \$5.0 million. Contract revenue of \$1.6 million related to the initial

GILEAD SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
DECEMBER 31, 2001

7. COLLABORATIVE ARRANGEMENTS AND CONTRACTS (Continued)

licensing fee from Sumitomo was recognized as contract revenue in 2000 and \$2.8 million was recognized as contract revenue in 2001. The remaining \$0.6 million of related deferred revenue at December 31, 2001 will be recognized as contract revenue over the remaining free supply obligation period.

Hoffmann-La Roche

In September 1996, Gilead entered into a collaboration agreement with F. Hoffmann-La Roche Ltd. and Hoffmann-La Roche Inc. (collectively, Roche) to develop and commercialize therapies to treat and prevent viral influenza (the Roche Agreement). Under the Roche Agreement, Roche received exclusive worldwide rights to Gilead's proprietary influenza neuraminidase inhibitors. Prior to 1999, Roche made license fee and developmental milestone payments totaling \$16.3 million. During 1999, Gilead recognized a total of \$12.8 million of additional milestone payments due to the commencement of certain clinical trials in Japan, the filing of an application to market Tamiflu in the European Union, and the filing and subsequent approval to market Tamiflu in the United States. During 2000, Gilead recognized \$9.6 million of contract revenue from milestone payments from Roche related to Tamiflu milestones achieved during the year. The milestones included filing for regulatory approval in Japan for treatment of influenza, the Japanese approval of the application, the filing for U.S. regulatory approval for the prevention of influenza, and the receipt of such approval in the U.S. In 2001, we recognized a \$2.0 million milestone payment for the filing of an application to market Tamiflu as a prophylaxis in the European Union.

Subsequent to the cumulative effect of the change in accounting principle that was recorded effective in the first quarter of 2000 resulting from the adoption of SAB 101, Gilead recognized the initial license fee over the remaining research and development period, which ended in the first quarter of 2000. The net impact of the change in accounting for the initial license fee was zero. The cumulative effect of the change in accounting principle related to the Roche license fee was a \$0.7 million charge to results of operations, which was offset by additional contract revenue of \$0.7 million also recognized in the first quarter of 2000. There is no remaining deferred revenue related to the Roche initial license fee as of December 31, 2001.

As of December 31, 2001, Gilead is entitled to additional cash payments from Roche of up to \$9.6 million upon Roche achieving additional developmental and regulatory milestones. In addition, Roche is required to pay Gilead royalties on net product sales. Gilead began receiving royalties from Roche's sales of Tamiflu in the first quarter of 2000. We recorded a total of \$4.5 million of Tamiflu royalties in the year 2001 and \$9.6 million of royalties in 2000. No Tamiflu royalties were recorded in 1999. The Company recognizes royalty revenue from Roche in the quarter following the quarter in which the related Tamiflu sales occur.

Under the Roche Agreement, Roche also reimburses the Company for its related R&D costs under the program by funding such costs quarterly and generally in advance, based on an annual budget. Reimbursements are included in contract revenue as the Company incurs the related R&D costs. Amounts incurred by the Company in excess of amounts funded may also be reimbursed, subject to Roche's approval. In this event, revenue is not recognized until such approval has been obtained. Conversely, if amounts funded by Roche exceed the Company's related R&D costs, the Company may be required to repay such excess funding to Roche. The Company recorded contract revenue for R&D

GILEAD SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
DECEMBER 31, 2001

7. COLLABORATIVE ARRANGEMENTS AND CONTRACTS (Continued)

reimbursements related to the Roche Agreement of approximately \$0.1 million in 2001, \$0.9 million in 2000 and \$2.1 million in 1999. R&D costs related to the Roche Agreement approximate the reimbursement revenue in each year presented and are included in R&D expenses.

Pharmacia

In August 1996, the Company and Pharmacia Corporation (Pharmacia) entered into a License and Supply Agreement (Pharmacia Agreement) to market Vistide in all countries outside the United States. Under the terms of the Pharmacia Agreement, Pharmacia paid Gilead an initial license fee of \$10.0 million.

Subsequent to the cumulative effect of the change in accounting principle recorded effective in the first quarter of 2000, Gilead is recognizing the initial license fee on a straight-line basis over the supply arrangement period, which is sixteen years from the agreement date. The net impact of the change in accounting principle for the Pharmacia Agreement was to increase the net loss in 2000 by \$7.3 million. The cumulative effect of the change in accounting principle related to the initial license fee from Pharmacia was a \$7.9 million charge to results of operations, and additional contract revenue of \$0.6 million was recognized in 2000 subsequent to the accounting change. The remaining \$7.3 million of related deferred revenue is expected to be recognized on a straight-line basis as contract revenue over the remaining supply period, or twelve years beginning January 2001.

During the second quarter of 1997, Vistide was approved for marketing in the European Union by the European Commission, which triggered an additional cash milestone payment of \$10.0 million by Pharmacia to the Company. Also as a result of achieving this milestone, in the second quarter of 1997, Pharmacia purchased 1,133,786 shares of Series B Convertible Preferred Stock for approximately \$40.0 million, or \$35.28 per share. The preferred stock automatically converted into 4,535,144 shares of common stock in 1999. For additional information about the preferred stock, see Note 14. Under the terms of the Pharmacia Agreement and related agreements covering expanded access programs for Vistide outside of the United States, Gilead is responsible for maintaining the cidofovir patent portfolio and for supplying to Pharmacia bulk cidofovir used to manufacture the finished Vistide product. Gilead is entitled to receive a royalty based upon Pharmacia's sales of Vistide. Gilead receives a portion of the royalty upon shipping either bulk drug substance or Vistide to Pharmacia, and the remainder upon Pharmacia's sale of Vistide to third parties. Any royalties that Gilead receives before the product is sold to third parties are recorded as deferred revenue until such third-party sales occur. At December 31, 2001, the Company has recorded on its balance sheet approximately \$3.1 million of such deferred revenue (\$2.2 million at December 31, 2000). The Company recognized royalty revenue from sales of Vistide outside of the United States by Pharmacia of \$1.4 million in 2001, \$1.5 million in 2000 and \$2.0 million in 1999.

GILEAD SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
DECEMBER 31, 2001

7. COLLABORATIVE ARRANGEMENTS AND CONTRACTS (Continued)

Somalogic

In November 1999, Gilead and Somalogic, Inc. (Somalogic) entered into an agreement whereby Gilead assigned to Somalogic under a sole and exclusive license, certain intellectual property related to the SELEX process for diagnostic purposes, including patents and patent applications. Under the terms of the agreement, Somalogic was required to pay Gilead a total of \$2.5 million in two nonrefundable installments. The first \$1.5 million was paid in November 1999 and was included in contract revenue for the year ended December 31, 1999. The remaining \$1.0 million, which was reported as deferred revenue at December 31, 1999, was received and recorded as contract revenue in 2000. Gilead has no ongoing research or funding obligations under the agreement.

Schering A.G.

In 1993, the Company entered into a collaborative research agreement (Schering Research Agreement) and license agreement (Schering License Agreement) with Schering A.G. Under the Schering Research Agreement, Schering A.G. has funded research at Gilead for the discovery and development of aptamers as *in vivo* diagnostic agents. The level of funding under this agreement varied annually, from a high of \$2.4 million to \$0.3 million received and recorded as contract revenue in 1999. The Schering Research Agreement expired in 1999 and the Company does not expect to receive any additional payments thereunder.

Under the Schering License Agreement, Schering A.G. has the right to develop and commercialize aptamers as *in vivo* diagnostic agents or radiotherapeutics discovered and developed under the Schering Research Agreement. Schering A.G. is required to make milestone and royalty payments to the Company upon commercialization and sale of any products developed under the collaboration with the Company. The milestone payments for any one product total \$6.0 million and are triggered by the filing of an Investigational New Drug application, the initiation of Phase III clinical trials, the filing of an NDA and approval of a product for commercial sale. The Schering License Agreement, which was still in effect as of December 31, 2001, permits the Company to develop and commercialize aptamers discovered under the Schering Research Agreement outside the field of *in vivo* diagnostic agents or radiotherapeutics, subject to royalty payments to Schering A.G.

GlaxoSmithKline

In December 2000, Gilead entered into an agreement with Glaxo Wellcome, now GlaxoSmithKline (Glaxo) giving Gilead the rights to GS 7904L, a novel anti-tumor compound. Gilead was developing GS 7904L in a liposome and was evaluating it in preclinical studies. Under the agreement, Gilead had exclusive worldwide rights to develop and commercialize GS 7904L for all indications other than malaria. Gilead paid Glaxo an upfront fee that was included in R&D expense in 2000. In December 2001, this compound was assigned to OSI as part of the sale of oncology assets.

In May 1998, Gilead entered into a three-part collaboration with Glaxo in which (a) Glaxo received a non-exclusive right to use Gilead's proprietary SELEX process for target validation; (b) Gilead received exclusive rights (subject to Glaxo's right to elect to participate in such activities) to develop and commercialize NX 211, a liposomal formulation of Glaxo's proprietary topoisomerase I inhibitor (lurtotecan); and (c) Glaxo acquired 1,457,028 shares of Gilead common stock for

GILEAD SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
DECEMBER 31, 2001

7. COLLABORATIVE ARRANGEMENTS AND CONTRACTS (Continued)

\$10.0 million in a private offering. In December 2000, the collaboration and license agreement was modified. Under the revised terms of agreement, Glaxo waived its right to participate in the development and commercialization of NX 211 and its right to receive royalties, giving Gilead exclusive rights to the compound. In December 2001, this compound was also assigned to OSI as part of the sale of oncology assets.

IOCB/REGA

In 1991 and 1992, Gilead entered into agreements with the Institute of Organic Chemistry and Biochemistry of the Academy of Sciences of the Czech Republic and Rega Stichting (IOCB/REGA) relating to certain nucleotide compounds discovered at these two institutions. Under the agreements, Gilead received the exclusive right to manufacture, use and sell these nucleotide compounds, and Gilead is obligated to pay IOCB/REGA a percentage of net revenues received from sales of products containing the compounds, subject to minimum royalty payments. The products covered by the agreement include Vistide, adefovir dipivoxil and Viread, but exclude Tamiflu. Gilead currently makes quarterly payments to IOCB/REGA based on a percentage of Vistide and Viread sales. If marketing approval is received from the FDA for adefovir dipivoxil, Gilead would be obligated to pay additional amounts to IOCB/REGA upon future sales of this product.

In December 2000, the agreements with IOCB/REGA were amended to provide for a reduced royalty rate on future sales of adefovir dipivoxil or Viread, in return for an upfront payment from Gilead of \$11.0 million upon signing the agreement. This payment was recorded as a long-term prepaid royalty and is classified in other noncurrent assets on the balance sheet at December 31, 2001. It is being recognized as royalty expense over the expected commercial life of Viread and will be recognized as royalty expense over the expected commercial life of adefovir dipivoxil when and if FDA approval is obtained and sales of the product commence. Amortization of the \$11.0 million payment was not significant through December 31, 2001.

Southern Research Institute

In December 2000, Gilead entered into an agreement with Southern Research Institute giving Gilead worldwide rights to develop and commercialize GS 7836, an anti-tumor compound that Gilead was evaluating in preclinical studies. Under the terms of the agreement, Gilead paid Southern Research Institute an upfront fee, which was included in research and development expense in 2000. In December 2001, this compound was assigned to OSI as part of the sale of oncology assets.

8. INVENTORIES

Inventories are summarized as follows (in thousands):

	December 31,	
	2001	2000
Raw materials	\$18,086	\$ 9,647
Work in process	10,004	7,781
Finished goods	11,190	3,134
	\$39,280	\$20,562

GILEAD SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
DECEMBER 31, 2001

9. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment consist of the following (in thousands):

	December 31,	
	2001	2000
Building and improvements (including leasehold improvements)	\$ 55,658	\$ 55,877
Laboratory and manufacturing equipment	32,867	34,167
Office and computer equipment	22,574	21,511
Capitalized leased equipment	13,791	13,530
Construction in progress	6,238	2,961
	<u>131,128</u>	<u>128,046</u>
Less accumulated depreciation and amortization	(68,300)	(72,872)
	<u>\$ 62,828</u>	<u>\$ 55,174</u>

10. INVESTMENT IN AND SALE OF UNCONSOLIDATED AFFILIATE

In July 1998, the Company established Proligo L.L.C., a Delaware limited liability company (Proligo), as a wholly owned subsidiary and transferred all of the assets of the NeXstar Technology Products division to Proligo. Proligo supplies nucleic acid and peptide synthesis products to the pharmaceutical and biopharmaceutical industry for sale and use as laboratory research reagents and in therapeutic and diagnostic products.

On August 15, 1998, the Company sold a 51% interest (Interest) in Proligo to SKW Americas, Inc. (SKW). As payment for the Interest, the Company received \$15.0 million in cash and a 49% interest in PerSeptive Biosystems GmbH, a company in Hamburg, Germany (Hamburg Company), which specializes in the manufacture of nucleoside phosphoramidite monomers. The 49% interest in the Hamburg Company had a fair market value of approximately \$5.5 million. In addition, SKW agreed to pay the Company \$3.0 million in guaranteed payments (discounted at 8.5% for gain recognition purposes) and up to \$20.5 million in performance-based milestones over the next four years. Gilead received the full \$3.0 million of guaranteed payments from SKW over the past three years. In 1999, Gilead also received a performance-based milestone payment of \$1.0 million that was included in contract revenue. As part of the original transaction, the Company contributed \$4.9 million and its 49% interest in the Hamburg Company to Proligo. The Company recorded a \$22.1 million gain in connection with this sale in 1998. SKW contributed \$5.1 million and the remaining 51% interest in the Hamburg Company to Proligo. Also in connection with this transaction, the Company and Proligo agreed that Proligo would manufacture oligonucleotides required by the Company at cost plus a fixed percentage. The Company purchased oligonucleotides from Proligo for a total of \$0.5 million up through 2000. No purchases were made in 2001. The purchases up through 2000 were charged to R&D expense.

In January 2000 and October 1999, Gilead made two additional cash investments in Proligo for a total of \$5.0 million to maintain its 49% ownership interest in Proligo. Gilead had no commitments to provide additional funding to Proligo beyond January 2000.

The Company accounted for its investment in Proligo using the equity method of accounting. The net book value of its investment was \$6.9 million at December 31, 2000 and is reported in other

GILEAD SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
DECEMBER 31, 2001

10. INVESTMENT IN AND SALE OF UNCONSOLIDATED AFFILIATE (Continued)

noncurrent assets on the Company's consolidated balance sheet. In 2001, Gilead recorded \$2.1 million as equity in the loss of Proligo prior to the date of the sale. In 2000, we recognized \$2.9 million equity in Proligo's net loss, representing our 49% share of Proligo's loss for the thirteen-month period ended December 31, 2000. During the fourth quarter of 2000, Proligo changed its fiscal year end to December 31 from November 30. In 1999, Gilead recorded \$4.7 million equity in the loss of Proligo for Proligo's fiscal year ended November 31, 1999.

During 2001, Gilead sold its 49% interest in Proligo to Degussa Corporation for \$14.3 million in cash. The proceeds, net of Gilead's investment in Proligo, are reflected as an \$8.8 million gain on the sale of unconsolidated affiliate.

11. LONG-TERM OBLIGATIONS

Long-term obligations consist of the following (in thousands):

	December 31,	
	2001	2000
Capital lease obligations: monthly installments; interest rates ranging from 7.98% to 21.02%	\$1,466	\$3,512
Fixed rate debt: monthly installments through 2003; secured by equipment; interest rates ranging from 11.49% to 11.90%	415	1,760
Total long-term obligations	1,881	5,272
Less current portion	(1,492)	(3,034)
Long-term obligations due after one year	\$ 389	\$2,238

Maturities of long-term obligations, including capital lease obligations, are as follows (in thousands):

Year	
2002	\$1,616
2003	236
2004	106
2005	74
2006	74
Thereafter	12
	2,118
Less amount representing interest	(237)
Total	\$1,881

The terms of the various debt agreements require the Company to comply with certain financial and operating covenants. At December 31, 2001, the Company was in compliance with all such covenants.

GILEAD SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
DECEMBER 31, 2001

12. CONVERTIBLE SUBORDINATED NOTES AND DEBENTURES

On December 13, 2000, Gilead issued \$250 million of 5% convertible subordinated notes due December 15, 2007 in a private offering to J.P. Morgan & Co., Lehman Brothers and Morgan Stanley Dean Whitter, which resold the notes to private institutional investors. The notes are convertible into a total of up to 10,178,116 shares of Gilead common stock at \$24.5625 per share. The \$24.5625 conversion price is higher than Gilead's common stock price on the note's issue date. The notes are redeemable in whole or in part, at the option of the Company, at any time on or after December 20, 2003, at specified redemption prices plus accrued interest. Debt issuance costs of \$8.2 million incurred in connection with the issuance of the notes were recorded as other noncurrent assets, and are being amortized to interest expense on a straight-line basis over the contractual term of the notes.

During the third quarter of 1997, Gilead issued \$80.0 million of 6.25% convertible subordinated debentures due 2004 in a private offering to SBC Warburg Inc. and Oppenheimer & Co., Inc., which resold the debentures to a group of private investors. The debentures were issued pursuant to an indenture and were convertible into a total of up to 7,179,376 shares of Gilead common stock at \$11.14 per share. The debentures were redeemable in whole or in part, at the option of the Company, at any time on or after August 10, 2000, at specified redemption prices plus accrued interest. Gilead called the debentures for redemption on August 15, 2000 at a cash price of \$1,030 per \$1,000 principal amount of debentures outstanding, plus accrued interest, which was the redemption price provided for in the original debenture indenture. The entire \$79.5 million in principal amount of the debentures outstanding at that time was converted into 7,135,156 newly issued shares of Gilead common stock prior to August 15, 2000. Deferred debt issuance costs of \$1.6 million that related to the debentures were charged to additional paid in capital in connection with the conversion of the debentures into common stock.

13. COMMITMENTS AND CONTINGENCIES

Leases Arrangements

The Company has entered into various long-term noncancelable operating leases for facilities in Foster City and San Dimas, California. The leases expire on various dates in 2003 and 2006. Each of the leases has two five-year renewal options, with the exception of one lease in Foster City that expires in 2003 and contains no renewal options. The Company has operating leases for sales, marketing and administrative facilities in Europe and Australia with various terms, and miscellaneous equipment leases.

Rent expense net of sublease income under the Company's operating leases totaled approximately \$12.0 million in 2001, \$8.6 million in 2000 and \$7.9 million in 1999.

The Company has entered into capital leases to finance equipment purchases and facilities improvements. Title to assets acquired under lease lines of credit resides with the lessor. The Company has the option to purchase the assets at the end of the lease terms at fair market value. The leases have remaining terms of up to three years. At December 31, 2001, no additional amounts were available under these agreements.

GILEAD SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
DECEMBER 31, 2001

13. COMMITMENTS AND CONTINGENCIES (Continued)

Aggregate noncancelable future minimum rental payments under operating and capital leases, net of aggregate future minimum rentals to be received by the Company under noncancelable subleases, are as follows (in thousands):

<u>Years ending December 31,</u>	<u>Operating Leases, Net of Noncancelable Subleases</u>	<u>Capital Leases</u>
2002	\$10,347	\$ 1,291
2003	10,115	111
2004	6,986	106
2005	7,202	74
2006	4,069	74
Thereafter	1,276	12
	<u>\$39,995</u>	<u>1,668</u>
Less amount representing interest		<u>(202)</u>
Total capital lease obligations		1,466
Less current portion		<u>(1,197)</u>
Capital lease obligations due after one year		<u>\$ 269</u>

At December 31, 2001, the Company has placed \$0.5 million in a bank escrow deposit to secure aggregate future payments due under one of its facilities leases.

Contingent Liability

Gilead has subleased certain of its facilities, primarily in California, through 2003. If any of the sublessees default on their obligations under these subleases, the Company would be primarily liable to the original lessor. The total amount due under these leases as of December 31, 2001 is \$1.4 million.

Line of Credit

Through April 2001, we maintained a \$10.0 million unsecured line of credit that bears interest at a floating rate with a major financial institution. Under the terms of the line of credit, we were required to maintain certain financial ratios and there were limitations on our ability to incur additional debt or to engage in certain significant transactions. The line of credit, which included a foreign exchange facility, expired in April 2001. We renewed the foreign exchange facility, but did not renew the line of credit. There are no required financial ratios or limitations on debt or other transactions under the foreign exchange facility.

Legal Proceedings

On August 11, 1997, the Company and Elan Corporation, plc (Elan, the successor company to The Liposome Company, Inc.) reached a settlement (Settlement Agreement) in which both companies agreed to dismiss all legal proceedings involving AmBisome, Gilead's liposomal formulation of amphotericin B. In the Settlement Agreement, Elan granted the Company immunity from suit in connection with the worldwide production and sales of AmBisome and a worldwide right to use two of

GILEAD SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
DECEMBER 31, 2001

13. COMMITMENTS AND CONTINGENCIES (Continued)

their patents. Under the terms of the Settlement Agreement, Gilead made an initial payment to Elan of \$1.8 million and was required to make payments beginning in 1998 based on AmBisome sales over the next several years. Because the payments are subject to certain minimum and maximum amounts, the Company recorded accounting charges in 1997 of \$11.8 million, of which \$10.0 million represented the net present value of all future minimum payments and \$1.8 million represented the initial cash payment. Beginning in 1998, Gilead records an expense each quarter based on the difference between all future minimum payments and the expense recorded in 1997. In addition, beginning in 1998, the Company is recognizing as cost of goods sold the difference between the minimum and maximum payments, if any. Gilead does not expect the difference between its future minimum and maximum payments to Elan to be material.

The Company is involved from time to time in legal proceedings arising in the ordinary course of its business. In the opinion of management, none of these matters is expected to have a material adverse effect on the financial position or operations of the Company based on factors currently known to management.

14. STOCKHOLDERS' EQUITY

Stock Split

On February 22, 2001 and on March 8, 2002, Gilead completed two-for-one stock splits, effected in the form of a stock dividend, to stockholders of record as of February 2, 2001 and February 14, 2002, respectively. Accordingly, all share and per share amounts for all periods presented have been restated to reflect both of these splits.

Preferred Stock

The Company has 5,000,000 shares of authorized preferred stock issuable in series. The Company's Board of Directors (Board) is authorized to determine the designation, powers, preferences and rights of any such series. The Company has reserved 400,000 shares of preferred stock for potential issuance under the Preferred Share Purchase Rights Plan.

In June 1997, the Company issued 1,133,786 shares of Series B Convertible Preferred Stock (Preferred Stock) to Pharmacia for approximately \$40.0 million, or \$35.28 per share. On July 15, 1999, the average of the closing price of Gilead's common stock for the thirty days then ended was \$12.45. This event triggered the automatic conversion of the Preferred Stock owned by Pharmacia into the Company's common stock. Accordingly, the Preferred Stock converted into 4,535,144 shares of common stock at a price of \$8.82 per share on July 16, 1999. There was no preferred stock outstanding as of December 31, 2001.

Employee Stock Purchase Plan

Under Gilead's Employee Stock Purchase Plan (ESPP), employees can purchase shares of Gilead common stock based on a percentage of their compensation. The purchase price per share must equal at least the lower of 85 percent of the market value on the date offered or the date purchased. A total of 6,320,000 shares of common stock have been reserved for issuance under the ESPP. As of

GILEAD SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
DECEMBER 31, 2001

14. STOCKHOLDERS' EQUITY (Continued)

December 31, 2001, 4,300,708 shares of the total shares reserved had been issued under the ESPP (3,932,732 shares as of December 31, 2000).

Stock Option Plans

In December 1987, Gilead adopted the 1987 Incentive Stock Option Plan and the Supplemental Stock Option Plan for issuance of common stock to employees, consultants and scientific advisors. In April 1991, the Board approved the granting of certain additional nonqualified stock options with terms and conditions substantially similar to those granted under the 1987 Supplemental Stock Option Plan. None of the options described above had exercise prices that were less than the fair value of the underlying stock on the date of grant. The options vest over five years pursuant to a formula determined by the Board and expire after ten years. No shares are available for grant of future options under any of these plans.

In November 1991, Gilead adopted the 1991 Stock Option Plan (1991 Plan) for issuance of common stock to employees and consultants. Options issued under the 1991 Plan shall, at the discretion of the Board, be either incentive stock options or nonqualified stock options. In May 1998, the 1991 Plan was amended such that the exercise price of all stock options must be at least equal to the fair value of Gilead's common stock on the date of grant. The options vest over five years pursuant to a formula determined by the Board and expire after ten years. In May 2001 the stockholders approved an Amendment to the 1991 Plan that increased the total number of authorized shares under the plan from 43,000,000 to 47,000,000. At December 31, 2001, there were 11,911,158 shares available for grant of future options under the 1991 Plan.

In November 1995, Gilead adopted the 1995 Non-Employee Directors' Stock Option Plan (Directors' Plan) for issuance of common stock to non-employee Directors pursuant to a predetermined formula. The exercise price of options granted under the Directors' Plan must be at least equal to the fair value of Gilead's common stock on the date of grant. The options vest over five years from the date of grant in quarterly five percent installments and expire after ten years. At December 31, 2001, there were 463,200 shares available for grant of future options under the Directors' Plan.

Stock plans assumed by Gilead in the merger with NeXstar include the 1988 Stock Option Plan (1988 Plan), the 1993 Incentive Stock Plan, and the 1995 Director Option Plan (collectively, NeXstar Plans). Options pursuant to the 1988 Stock Option Plan and the 1993 Incentive Stock Plan that were issued and outstanding as of July 29, 1999 have been converted into options to purchase Gilead common stock as a result of the Merger and remain subject to their original terms and conditions. No shares are available for grant of future options under any of the NeXstar Plans.

NeXstar's 1988 Plan allows certain option holders to execute cashless exercises of options. In a cashless exercise transaction, the option holder specifies how many shares will be exercised and the Company issues the specified number of shares, less the number that would be required to cover the exercise price based on the fair value of the stock on the exercise date. During 2001, 2000 and 1999, several option holders performed cashless exercises. As a result, such option awards are considered to be variable and, therefore, the Company recognized compensation expense of \$0.6 million in 2001, \$0.5 million in 2000 and \$2.3 million in 1999. Of the 2001 amount, \$0.5 million relates to exercised

GILEAD SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
DECEMBER 31, 2001

14. STOCKHOLDERS' EQUITY (Continued)

options and the remaining \$0.1 million relates to options that remain outstanding under the 1988 Plan at December 31, 2001.

The following table summarizes activity under all Gilead and NeXstar stock option plans for each of the three years in the period ended December 31, 2001. All option grants presented in the table had exercise prices not less than the fair value of the underlying stock on the grant date (shares in thousands):

	Year ended December 31,					
	2001		2000		1999	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted average Exercise Price
Outstanding, beginning of year	21,672	\$11.09	22,524	\$ 8.34	22,624	\$6.10
Granted	6,708	21.11	6,064	17.19	6,676	13.71
Forfeited	(2,596)	16.10	(2,208)	10.99	(1,484)	8.40
Exercised	(4,098)	7.58	(4,708)	5.79	(5,292)	5.38
Outstanding, end of year	<u>21,686</u>	<u>\$14.26</u>	<u>21,672</u>	<u>\$11.09</u>	<u>22,524</u>	<u>\$8.34</u>
Exercisable, end of year	9,022	\$ 9.62	8,452	\$ 7.31	9,104	\$5.64
Weighted average fair value of options granted		\$14.29		\$11.25		\$8.38

The following is a summary of Gilead options outstanding and options exercisable at December 31, 2001 (options in thousands):

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Options Outstanding	Weighted Average Remaining Contractual Life in Years	Weighted Average Exercise Price	Options Exercisable	Weighted Average Exercise price
\$1.94-\$6.81	4,804	5.01	\$ 5.46	3,606	\$ 5.25
\$6.94-\$14.16	4,952	5.99	\$10.53	3,118	\$ 9.59
\$14.60-\$14.81	5,778	8.33	\$14.72	1,310	\$14.65
\$15.02-\$34.33	6,152	8.96	\$23.69	988	\$19.00
Total	<u>21,686</u>	7.24	\$14.26	<u>9,022</u>	\$ 9.62

GILEAD SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

DECEMBER 31, 2001

14. STOCKHOLDERS' EQUITY (Continued)

Pro Forma Disclosures

The table below presents the combined net income (loss) and basic and diluted net income (loss) per common share if compensation cost for the Gilead and NeXstar stock option plans and the ESPP had been determined based on the estimated fair value of awards under those plans on the grant or purchase date.

	Year Ended December 31,		
	2001	2000	1999
Pro forma net income (loss) (in thousands)	\$2,190	\$(91,775)	\$(93,816)
Pro forma net income (loss) per common share—basic	\$ 0.01	\$ (0.50)	\$ (0.55)
Pro forma net income (loss) per common share—diluted	\$ 0.01	\$ (0.50)	\$ (0.55)

Fair values of awards granted under the stock option plans and ESPP were estimated at grant or purchase dates using a Black-Scholes option pricing model. The Company used the multiple option approach and the following assumptions:

	Year Ended December 31,		
	2001	2000	1999
Expected life in years (from vesting date):			
Stock options	1.95	1.88	1.86
ESPP	1.29	1.45	1.21
Discount rate:			
Stock options	4.6%	6.3%	5.6%
ESPP	4.7%	5.5%	5.0%
Volatility	83%	84%	67%
Expected dividend yield	0%	0%	0%

The weighted average estimated fair value of ESPP shares purchased was \$11.57 for 2001, \$6.06 for 2000 and \$4.06 for 1999.

Preferred Share Purchase Rights Plan

In November 1994, the Company adopted a Preferred Share Purchase Rights Plan. The plan provides for the distribution of a preferred stock purchase right as a dividend for each share of Gilead common stock. The purchase rights are not currently exercisable. Under certain conditions involving an acquisition or proposed acquisition by any person or group of 15% or more of the Company's common stock, the purchase rights permit the holders (other than the 15% holder) to purchase Gilead common stock at a 50% discount from the market price at that time, upon payment of a specified exercise price per purchase right. In addition, in the event of certain business combinations, the purchase rights permit the purchase of the common stock of an acquirer at a 50% discount from the market price at that time. Under certain conditions, the purchase rights may be redeemed by the Board in whole, but not in part, at a price of \$.0025 per purchase right. The purchase rights have no voting privileges and are attached to and automatically trade with Gilead common stock.

GILEAD SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

DECEMBER 31, 2001

14. STOCKHOLDERS' EQUITY (Continued)

In October 1999, the Board of Directors approved an amendment to the purchase rights plan. The amendment provided, among other things, for an increase in the exercise price of a right under the plan from \$15 to \$100 and an extension of the term of the plan from November 21, 2004 to October 20, 2009.

Acceleration of Stock Options

In December 2001, we completed the sale of our oncology assets to OSI. As part of this transaction, we accelerated approximately 78,000 options to purchase Gilead common stock with a value of \$2.8 million. See Note 4 for further discussion.

15. COMPREHENSIVE INCOME (LOSS)

The following reclassification adjustments are required to avoid double-counting net realized gains (losses) on sales of securities that were previously included in comprehensive income prior to the sales of the securities (in thousands):

	Year ended December 31,		
	2001	2000	1999
Net gain (loss) on sales of securities included in interest income	\$1,225	\$ (84)	\$ (383)
Other comprehensive income:			
Net unrealized gain (loss) arising during the year	\$8,960	\$1,987	\$(1,985)
Reclassification adjustment	(1,225)	84	383
Net unrealized gain (loss) reported in other comprehensive income	\$7,735	\$2,071	\$(1,602)

The balance of accumulated other comprehensive income (loss) as reported on the balance sheet consists of the following components (in thousands):

	December 31,	
	2001	2000
Net unrealized gain on available-for-sale securities	\$8,247	\$ 512
Net unrealized gain on cash flow hedges	37	—
Net foreign currency translation loss	(836)	(1,413)
Accumulated other comprehensive income (loss)	\$7,448	\$ (901)

16. DISCLOSURES ABOUT SEGMENTS OF AN ENTERPRISE AND RELATED INFORMATION

The Company has determined that it has only one reportable segment because management has organized the business along its functional lines.

GILEAD SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

DECEMBER 31, 2001

16. DISCLOSURES ABOUT SEGMENTS OF AN ENTERPRISE AND RELATED INFORMATION (Continued)

Product sales consist of the following (in thousands):

	Year ended December 31,		
	2001	2000	1999
AmBisome	\$164,533	\$141,118	\$129,177
Viread	15,586	—	—
Other	10,851	8,591	10,713
	<u>\$190,970</u>	<u>\$149,709</u>	<u>\$139,890</u>

The following table summarizes revenues from external customers and collaborative partners by geographic region. Revenues are attributed to countries based on the location of the customer or collaborative partner (in thousands):

	Year Ended December 31,		
	2001	2000	1999
United States	\$ 63,888	\$ 37,476	\$ 28,389
United Kingdom	28,533	23,827	19,259
Germany	19,256	21,340	21,647
Italy	18,783	16,978	16,293
Spain	18,283	15,074	14,625
France	16,775	9,528	8,347
Switzerland	7,721	21,531	15,763
Other European countries	40,499	32,053	31,500
Other countries	20,031	17,748	13,156
Consolidated total revenues	<u>\$233,769</u>	<u>\$195,555</u>	<u>\$168,979</u>

At December 31, 2001, the net book value of the Company's property, plant and equipment was \$62.8 million. Approximately 94% of such assets were located in the United States. At December 31, 2000, the net book value of property, plant and equipment was \$55.2 million, and approximately 95% of such assets were located in the United States.

Product sales to any one distributor in 2001 did not exceed 10% of total revenues. Product sales to one distributor accounted for approximately 12% of total revenues in 2000 and 11% in 1999. Total revenues from Fujisawa Healthcare, Inc., which included product sales and royalties, were approximately 15% of total revenues in 2001, 13% in 2000, and 11% in 1999. Revenues from Roche, including royalties, milestone payments and reimbursement of research and development expenses, did not exceed 10% of total revenues in 2001 or in 1999, but did account for approximately 11% of total revenues in 2000.

GILEAD SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

DECEMBER 31, 2001

17. INCOME TAXES

The Company has no deferred provision for income taxes. The current provision for income taxes consisted of the following (in thousands):

	<u>Year ended December 31,</u>		
	<u>2001</u>	<u>2000</u>	<u>1999</u>
Current provision:			
Federal	\$2,800	\$ —	\$ 65
State	506	21	30
Foreign	829	1,178	793
	<u>\$4,135</u>	<u>\$1,199</u>	<u>\$888</u>

Foreign pre-tax income (loss) was \$(67.8) million in 2001, \$(40.3) million in 2000 and \$2.0 million in 1999.

The difference between the provision for taxes on income and the amount computed by applying the federal statutory income tax rate to income before provision for income taxes, equity in loss of unconsolidated affiliate and the cumulative effect of a change in accounting principle is explained below (in thousands):

	<u>Year ended December 31,</u>		
	<u>2001</u>	<u>2000</u>	<u>1999</u>
Income (loss) before provision for income taxes, equity in loss of unconsolidated affiliate and the cumulative effect of a change in accounting principle	<u>\$ 57,447</u>	<u>\$(39,049)</u>	<u>\$(60,942)</u>
Tax at federal statutory rate	\$ 19,532	\$(13,277)	\$(20,720)
(Benefitted) unbenefitted losses	(19,339)	13,617	21,074
Federal alternative minimum taxes	2,800	—	—
Other	<u>1,142</u>	<u>859</u>	<u>534</u>
	<u>\$ 4,135</u>	<u>\$ 1,199</u>	<u>\$ 888</u>

At December 31, 2001, the Company had U.S. federal net operating loss carryforwards of \$415.8 million and state net operating loss carryforwards of \$25.0 million. The federal net operating loss carryforwards will expire at various dates beginning in 2010 through 2020, if not utilized. The state net operating loss carryforwards will expire at various dates from 2002 through 2011, if not utilized. In addition, the Company had federal and state tax credit carryforwards of approximately \$27.2 million and \$15.3 million respectively, which expire in the years 2003 through 2021.

Utilization of net operating losses and credits may be subject to an annual limitation due to ownership change limitations provided in the Internal Revenue Code and similar state provisions. This annual limitation may result in the expiration of the net operating losses and credits before utilization.

GILEAD SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
DECEMBER 31, 2001

17. INCOME TAXES (Continued)

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets and liabilities as of December 31, 2001 and 2000 are as follows (in thousands):

	December 31,	
	2001	2000
Net operating loss carryforwards	\$142,400	\$166,500
Research and other credits	37,300	35,400
Capitalized R&D for California	14,400	17,100
Other, net	18,600	9,600
	212,700	228,600
Total deferred tax assets	212,700	228,600
Valuation allowance	(212,700)	(228,600)
Net deferred tax assets recognized	\$ —	\$ —

The valuation allowance decreased by \$15.9 million for the year ended December 31, 2001, and increased by \$34.4 million for the year ended December 31, 2000. Approximately \$33.8 million of the valuation allowance at December 31, 2001 relates to the tax benefits of stock option deductions, which will be credited to additional paid-in capital when realized.

18. RETIREMENT SAVINGS PLAN

As of December 31, 2001, the Company maintains one retirement savings plan under which eligible employees may defer compensation for income tax purposes under Section 401(k) of the Internal Revenue Code. Prior to January 1, 2001, Gilead maintained two separate retirement savings plans. One plan primarily covered former NeXstar employees (NeXstar Plan), and the other plan primarily covered Gilead's remaining eligible employees (Gilead Plan). Under the NeXstar Plan, employee contributions could not exceed 15% of eligible annual compensation. In addition, the NeXstar Plan included a Company match of 50% of employee contributions up to a maximum of 6% of contributions up to an annual maximum Company match of \$2,500. At December 31, 2000, approximately \$0.6 million, representing 13,857 shares of Gilead common stock, was held by the NeXstar Plan in trust for plan participants. Effective January 2001, the NeXstar Plan was terminated and combined with the Gilead Plan. The shares of Gilead common stock held by the NeXstar Plan were subsequently liquidated and the proceeds were deposited into the various other investment options available under the Gilead plan. Under the Gilead Plan, employees may contribute up to 15% of their eligible annual compensation. Effective January 1, 2000, Gilead began making matching contributions under the Gilead Plan. The Company contributes up to 50% of an employee's first 6% of contributions up to an annual maximum Company match of \$2,500. The Company's total matching contribution for the Gilead Plan was \$1.2 million in 2001, a combined \$0.9 million in 2000 for both plans and \$0.5 million in 1999 for the NeXstar Plan.

GILEAD SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
DECEMBER 31, 2001

19. RELATED PARTY TRANSACTIONS

Through December 31, 2000, the Chairman of Gilead's Board of Directors was a senior advisor to an investment fund that owns a controlling interest in PharmaResearch Corporation, a contract research organization that performs services in connection with clinical studies. Gilead's payments to PharmaResearch Corporation were \$10.2 million in 2000 and \$6.7 million in 1999.

20. QUARTERLY RESULTS (UNAUDITED)

The following table is in thousands, except per share amounts:

	<u>1st Quarter</u>	<u>2nd Quarter</u>	<u>3rd Quarter</u>	<u>4th Quarter</u>
2001(1)(3)(4)(5)				
Total revenues	\$57,836	\$50,687	\$50,915	\$74,331
Total costs and expenses	83,638	84,582	86,983	99,255
Income (loss) before cumulative effect of change in accounting principle	(22,812)	(32,387)	(25,196)	131,577
Cumulative effect of change in accounting principle	1,089	—	—	—
Net loss	(21,723)	(32,387)	(25,196)	131,577
Amounts per common share—basic:				
Income (loss) before cumulative effect of change in accounting principle	\$ (0.12)	\$ (0.17)	\$ (0.13)	\$ 0.69
Cumulative effect of change in accounting principle	0.01	—	—	—
Net income (loss) per share—basic	<u>\$ (0.11)</u>	<u>\$ (0.17)</u>	<u>\$ (0.13)</u>	<u>\$ 0.69</u>
Amounts per common share—diluted:				
Income (loss) before cumulative effect of change in accounting principle	\$ (0.12)	\$ (0.17)	\$ (0.13)	\$ 0.62
Cumulative effect of change in accounting principle	0.01	—	—	—
Net income (loss) per share—diluted	<u>\$ (0.11)</u>	<u>\$ (0.17)</u>	<u>\$ (0.13)</u>	<u>\$ 0.62</u>
	<u>1st Quarter</u>	<u>2nd Quarter</u>	<u>3rd Quarter</u>	<u>4th Quarter</u>
2000(2)(3)				
Total revenues	\$ 47,712	\$50,129	\$ 45,239	\$ 52,475
Total costs and expenses	52,163	55,764	66,030	73,916
Loss before cumulative effect of change in accounting principle	(3,271)	(4,036)	(17,414)	(18,385)
Cumulative effect of change in accounting principle	(13,670)	—	—	—
Net loss	(16,941)	(4,036)	(17,414)	(18,385)
Basic and diluted amounts per share:				
Loss before cumulative effect of change in accounting principle	\$ (0.03)	\$ (0.02)	\$ (0.09)	\$ (0.10)
Cumulative effect of change in accounting principle	(0.07)	—	—	—
Net loss	<u>\$ (0.10)</u>	<u>\$ (0.02)</u>	<u>\$ (0.09)</u>	<u>\$ (0.10)</u>

(1) In the year ended December 31, 2001, Gilead adopted SFAS133 and reported a cumulative effect of a change in accounting principle in the first quarter of 2001.

GILEAD SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
DECEMBER 31, 2001

20. QUARTERLY RESULTS (UNAUDITED) (Continued)

- (2) In the year ended December 31, 2000, we adopted SAB 101 and reported a cumulative effect of a change in accounting principle. The accounting change was adopted in the fourth quarter of 2000, effective as of the first quarter of 2000, and the first three quarters of 2000 were restated to retroactively reflect the change.
- (3) On February 22, 2001 and on March 8, 2002, Gilead completed two-for-one stock splits, effected in the form of a stock dividend, to stockholders of record as of February 2, 2001 and February 14, 2002, respectively. Accordingly, all share and per share amounts for all periods presented have been restated to reflect both of these splits.
- (4) Diluted net income per common share in the fourth quarter of 2001 includes the effects of both stock options and the \$250.0 million 5% convertible subordinated notes.
- (5) In December 2001, we completed the sale of our oncology assets to OSI. The Company recorded a non-operating gain of \$157.8 million in the fourth quarter of 2001 as a result of this transaction.

GILEAD SCIENCES, INC.
Schedule II: Valuation and Qualifying Accounts

	Balance at Beginning of Period	Additions		Deductions	Balance at End of Period
		Charged to Expense	Charged to Other		
Year ended December 31, 2001:					
Allowance for doubtful accounts	\$ 2,300	\$ 467	\$ —	\$ 188	\$ 2,579
Valuation allowance for deferred tax assets	<u>228,600</u>	<u>—</u>	<u>—</u>	<u>15,900 (1)</u>	<u>212,700</u>
	<u>\$230,900</u>	<u>\$ 467</u>	<u>\$ —</u>	<u>\$16,088</u>	<u>\$215,279</u>
Year ended December 31, 2000:					
Allowance for doubtful accounts	\$ 2,333	\$ 30	\$ —	\$ 63	\$ 2,300
Valuation allowance for deferred tax assets	<u>194,200</u>	<u>—</u>	<u>34,400 (2)</u>	<u>—</u>	<u>228,600</u>
	<u>\$196,533</u>	<u>\$ 30</u>	<u>\$34,400</u>	<u>\$ 63</u>	<u>\$230,900</u>
Year ended December 31, 1999:					
Allowance for doubtful accounts	\$ 1,480	\$1,059	\$ —	\$ 206	\$ 2,333
Valuation allowance for deferred tax assets	<u>170,611</u>	<u>—</u>	<u>23,589 (2)</u>	<u>—</u>	<u>194,200</u>
	<u>\$172,091</u>	<u>\$1,059</u>	<u>\$23,589</u>	<u>\$ 206</u>	<u>\$196,533</u>

(1) Charged against current tax expense.

(2) Charged to deferred tax benefit.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

GILEAD SCIENCES, INC.

By:

/s/ JOHN C. MARTIN

John C. Martin

President and Chief Executive Officer

POWER OF ATTORNEY KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints John C. Martin and Mark L. Perry, and each of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in his or her name, place, and stead, in any and all capacities, to sign any and all amendments to this Report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming that all said attorneys-in-fact and agents, or any of them or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof. Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the Registrant and on the dates indicated.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ JOHN C. MARTIN	President and Chief Executive Officer, Director (Principal Executive Officer)	March 25, 2002
/s/ SHARON SURREY-BARBARI	Vice President, Chief Financial Officer (Principal Financial and Accounting Officer)	March 25, 2002
/s/ JAMES M. DENNY	Chairman of the Board of Directors	March 25, 2002
/s/ PAUL BERG	Director	March 25, 2002
/s/ ETIENNE F. DAVIGNON	Director	March 25, 2002
/s/ CORDELL W. HULL	Director	March 25, 2002
/s/ GORDON E. MOORE	Director	March 25, 2002
/s/ GEORGE P. SHULTZ	Director	March 25, 2002
/s/ GAYLE E. WILSON	Director	March 25, 2002

INTERNATIONAL OPERATIONS MANAGEMENT

Mercedes Garcia – Spain and Portugal
Christiane Harloff – Germany
Gerard Lamperti – France
Antonio Messa – European Distributor Region
Alaa Nouri – Asia, Australia, Greece and Middle East Region
Julie O'Neill – Ireland
Antonio Spagna – Italy
Steve Tague – United Kingdom and Ireland

CORPORATE SECRETARY

Mark L. Perry, JD
Executive Vice President, Operations

CORPORATE COUNSEL

Cooley Godward LLP
Palo Alto, California

INDEPENDENT AUDITORS

Ernst & Young LLP
Palo Alto, California

CORPORATE HEADQUARTERS

Gilead Sciences, Inc.
333 Lakeside Drive
Foster City, CA 94404 USA
(800) 445-3235 or (650) 574-3000
www.gilead.com

TRANSFER AGENT AND REGISTRAR

Communications concerning stock transfer requirements,
lost certificates and changes of address should be directed to the
Transfer Agent:

Mellon Investor Services LLC
PO Box 3315
South Hackensack, NJ 07606 USA
(800) 647-4273
www.melloninvestor.com

STOCKHOLDER INQUIRIES

Inquiries from our stockholders and potential investors regarding
our company are always welcomed and will receive a prompt
response. Please direct your requests for information to:

Investor Relations
Gilead Sciences, Inc.
333 Lakeside Drive
Foster City, CA 94404 USA
(800) 445-3235 or (650) 574-3000

Information regarding Gilead is also available via the World Wide
Web at www.gilead.com.

STOCK LISTING

Gilead common stock is traded on The Nasdaq Stock Market
under the symbol GILD.

ANNUAL MEETING

The annual meeting of stockholders will be held at 10 a.m. on
Wednesday, May 22, 2002 at Hotel Sofitel, 223 Twin Dolphin
Drive, Redwood City, California.



Gilead Sciences, Inc. is a biopharmaceutical company that discovers, develops and commercializes therapeutics to advance the care of patients suffering from life-threatening diseases worldwide. The company has five marketed products and focuses its research and clinical programs on anti-infectives, including antivirals, antifungals and antibacterials. Headquartered in Foster City, California, Gilead has operations in the United States, Europe and Australia.

GILEAD

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