

# GILEAD SCIENCES INC

## FORM 10-K (Annual Report)

Filed 3/20/2001 For Period Ending 12/31/2000

Address	333 LAKESIDE DR FOSTER CITY, California 94404
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CIK	0000882095
Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

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# SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

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## FORM 10-K

(MARK ONE)

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

**FOR THE FISCAL YEAR ENDED DECEMBER 31, 2000**  
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**

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## GILEAD SCIENCES, INC.

(Exact name of registrant as specified in its charter)

DELAWARE  
(State or other jurisdiction of  
incorporation or organization)

94-3047598  
(I.R.S. Employer Identification No.)

333 LAKESIDE DRIVE, FOSTER CITY,  
CALIFORNIA  
(Address of principal executive  
offices)

94404  
(Zip Code)

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

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

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

**COMMON STOCK \$.001 PAR VALUE**  
(Title of Class)

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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 /X/ 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. Yes / / No /X/

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, 2001 was \$2,843,500,000\*.

The number of shares outstanding of the Registrant's Common Stock on February 28, 2001 was 94,353,314. \*\*

#### **DOCUMENTS INCORPORATED BY REFERENCE**

Specified portions of Registrant's Definitive Proxy Statement filed with the Commission pursuant to Regulation 14A in connection with the 2001 Annual Meeting are incorporated by reference into Part III of this Report.

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\* Based on a closing price of \$37.375 per share. Excludes 18,273,770 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, 2001. 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, the Registrant implemented a two-for-one stock split in the form of a stock dividend. All share and per share amounts for all periods presented have been restated to reflect the split.

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## 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 28. 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

Gilead is an independent bio-pharmaceutical company dedicated to discovering, developing, manufacturing and commercializing proprietary therapeutics for antiviral, anti-infective and oncology applications. We currently derive revenue from four approved products and have five products in development. We are adding to our existing portfolio of compounds through internal discovery 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 have expanded our business and intend to continue to expand through acquisition activities.

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

- AmBisome-Registered Trademark- is approved for sale in 42 countries for the treatment and prevention of life-threatening fungal infections. We co-promote AmBisome in the U.S. with Fujisawa Healthcare, Inc.

- Tamiflu-TM- is sold by our corporate partner Hoffmann-La Roche in 31 countries for the treatment of influenza and recently received U.S. FDA approval for the prevention of influenza.

- VISTIDE-Registered Trademark- is approved for sale in 21 countries for the treatment of CMV retinitis in AIDS patients.

- DaunoXome-Registered Trademark- is approved for sale in 25 countries for the treatment of AIDS-related Kaposi's sarcoma.

We have a sales force of 30 in the U.S. who promote AmBisome, VISTIDE and DaunoXome, and a sales force of 85 in Europe and Australia who promote AmBisome and DaunoXome. We also have corporate partners and distributors promoting these products in over 30 countries.

We believe that our most advanced clinical candidate, tenofovir DF, a once-daily pill taken as part of combination therapy to treat HIV infection, could address a significant unmet medical need. We recently announced preliminary data from an ongoing Phase III clinical trial suggesting that 24 weeks of treatment with tenofovir DF reduced HIV levels in treatment-experienced patients by an average of approximately 75%, reduced viral levels to undetectable levels in approximately 45% of these patients,

and improved patients' immune systems. We are gathering data from ongoing trials and anticipate filing for approval of tenofovir DF in the U.S. and Europe in mid-2001. We have retained all commercial rights to tenofovir DF and, if we receive marketing approval, will promote it through our U.S. and European sales forces.

We are studying adefovir dipivoxil in two Phase III trials for the treatment of hepatitis B virus infection, or HBV. 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. We are conducting a Phase II program for NX 211 in relapsed ovarian cancer and small cell lung cancer and are evaluating two oncology compounds in preclinical studies.

## **OUR MARKETED PRODUCTS**

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

- AMBISOME: a drug for treating and preventing life-threatening fungal infections;
- TAMIFLU: a drug for treating and preventing influenza;
- VISTIDE: a drug for treating 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 2000, we earned revenues of approximately \$174 million from sales of these products. Of this amount, sales of AmBisome generated aggregate product sales and royalty revenues of approximately \$155 million, or 79% of our total revenues. We earned revenues from sales of, and royalties on, these products in the U.S. of \$30 million in 2000, \$25 million in 1999 and \$25 million in 1998. Outside of the U.S., we earned revenues from sales of, and royalties on, these products of \$144 million in 2000, \$125 million in 1999 and \$120 million in 1998. We did not begin recognizing revenues from sales of Tamiflu until 2000.

## **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 the HIV virus, 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 42 countries, including the U.S., all of the European Union, most of the rest of Europe, Australia, Canada and several countries in Latin America and Asia. AmBisome is primarily used for treating patients who are known to have life-threatening fungal infections. AmBisome is also approved in the U.S. and 20 other countries to treat patients who, because of certain symptoms, are presumed to have fungal infections, either as a first choice therapy (first line) or after traditional amphotericin B has failed or cannot be used. In the U.S., AmBisome also has been approved as a first line treatment of acute cryptococcal meningitis in AIDS patients. In addition, AmBisome is approved in five countries as a precautionary treatment for preventing fungal infections in liver transplant patients and is approved for treating a rare parasitic infection called visceral leishmaniasis in several countries. In 16 of the countries where AmBisome is approved, including the U.S., we are authorized to promote AmBisome as a first line treatment for patients who

are known to have a fungal infection. In the other 26 countries, AmBisome is approved for use after traditional amphotericin B therapy fails or when traditional amphotericin B cannot be used--a second line therapy.

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. We also sell AmBisome through independent distributors in a number of countries in Europe, Latin America and Asia. Our corporate partner, Sumitomo, is studying AmBisome in clinical trials in Japan. 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.

Traditional amphotericin B is the most significant competition for AmBisome. In many countries, AmBisome cannot be prescribed until traditional amphotericin B therapy has failed or cannot be used. In addition, there are other lipid-based formulations of amphotericin B that compete with AmBisome. The most significant lipid-based amphotericin B product that currently competes with AmBisome is Abelcet, a drug sold by Elan Corporation plc, a company with significantly greater resources than we have. Traditional amphotericin B is significantly less expensive than AmBisome, and Abelcet is also less expensive than AmBisome. We expect to face significant competition from new antifungal products, including caspofungin a product developed by Merck that received marketing approval in January 2001 and voriconazole, which is being developed by Pfizer, Inc. Pfizer has filed an application for marketing approval of voriconazole. See "Competition."

## **TAMIFLU**

Tamiflu is an oral pill for the treatment and prevention of influenza A and B. Tamiflu is in a new 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.

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 Commission seeking to have Tamiflu approved under the centralized procedure in the European Union. This European 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. We cannot be certain that this application will be approved. 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 and significant 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 Johnson & Johnson is developing a neuraminidase inhibitor that has the potential to be delivered as a once-daily pill (Tamiflu is taken twice daily for treatment of flu). When and if Johnson & Johnson receives approval for this product, it will also be direct and significant competition for Tamiflu. See "Competition."

Tamiflu is not being marketed as an alternative to influenza vaccinations. 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 sales force of 30 therapeutic specialists and five regional directors. These specialists promote VISTIDE through direct contact with physicians, hospitals, clinics, and other healthcare providers who are involved in the treatment of patients with CMV retinitis. We sell VISTIDE to wholesalers and specialty distributors who sell the product in the U.S. to healthcare providers. 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."

There are several other products that compete with VISTIDE. Ganciclovir, which is sold by Roche Laboratories, is the most widely prescribed drug treatment for CMV retinitis. Ganciclovir is available in injectable and oral formulations, and the oral formulation is approved for both preventing and treating CMV retinitis. There is a device that is marketed by Bausch & Lomb Incorporated that is implanted in a patient's infected eye and releases ganciclovir directly to the infected area. In addition, AstraZeneca sells an injectable drug for the treatment of CMV retinitis called foscarnet, and CibaVision sells a CMV retinitis drug called fomivirsen, that is injected directly into the eye. We believe that sales of VISTIDE will be lower in future periods because the CMV retinitis market continues to decline due to the success of combination antiretroviral drug therapies in treating HIV-infected patients.

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.

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 24 other countries as a first line therapy for treating patients who suffer from 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.

DaunoXome is marketed in the U.S. and abroad by our therapeutic specialists and, in certain foreign countries, by distributors. We believe that sales of DaunoXome will be lower in future periods because the number of HIV-infected patients who develop Kaposi's sarcoma has declined significantly in recent years due to the success of combination therapies in treating HIV patients.

## **OUR PRODUCTS IN LATE STAGE CLINICAL TRIALS**

We have two product candidates that we are developing in large, late-stage human clinical trials: tenofovir DF for treating patients with HIV and adefovir dipivoxil for treating patients with HBV. If these Phase III clinical trials are successful, we will apply to the FDA and other foreign regulatory agencies for approval to sell these drugs. Based on results to date, we expect to apply to the FDA and the European Union for approval of tenofovir DF in mid-2001. In addition, in January 2001 we acquired exclusive rights to market Cidecin-TM- in 16 European countries. Cidecin is an antibacterial that is being developed by Cubist Pharmaceuticals, Inc. in Phase II and Phase III clinical trials. If Cubist's Phase III clinical trials are successful, we will apply for regulatory approval of Cidecin in Europe. We cannot, however, determine with any certainty if any of these clinical trials 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.

## **TENOFOVIR DISOPROXIL FUMARATE**

Tenofovir DF is a nucleotide analogue reverse transcriptase inhibitor given once daily as part of combination therapy to treat HIV infection.

In February 2001, we announced preliminary 24-week data from study 907, a 48-week Phase III clinical trial evaluating a 300 mg dose of tenofovir DF 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 efficacy of this dosage of tenofovir DF. In this study, patients were randomly divided into two groups: one group of patients who had tenofovir DF added to their existing combination therapy (two-thirds of enrolled patients), and one group of patients who were given placebo in addition to their existing therapy (one-third of enrolled patients). These results suggest that, following 24 weeks of treatment:

- Tenofovir DF reduced patients' HIV viral loads by an average of approximately 75% ( $-.61 \log(10)$ ), a primary endpoint of this trial.
- Tenofovir DF suppressed HIV viral loads to undetectable levels in approximately 45% of patients, compared to 13% of patients who received placebo.



- Tenofovir DF increased patients' CD4 cell counts while patients who received placebo had their CD4 cell counts decrease. An increase in CD4 cell count is an important indication that an HIV drug is improving a patient's immune system.
- The rate that patients discontinued the use of tenofovir DF (6%) was equivalent to the discontinuation rate for placebo.
- Tenofovir DF did not cause a significant increase of serious side effects relative to placebo.

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 HIV compared to placebo and that at week 48, higher doses of tenofovir DF were associated with lower levels of HIV 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.

These preliminary Phase III results, combined with our completed Phase II results, support our belief that tenofovir DF can be an important treatment option for these difficult to treat patients. We expect that data from these trials, together with data from other clinical trials, will form the basis of marketing applications for treating this patient population that we expect to file in the U.S. and Europe in mid-2001.

In January 2001, we completed enrollment of 601 patients in study 903, a Phase III clinical trial to evaluate tenofovir DF for treating patients who have not had prior HIV therapy. This study will compare the safety and efficacy of treatment with tenofovir DF in combination with lamivudine (3TC) and efavirenz to the safety and efficacy of treatment with stavudine (d4T), lamivudine and efavirenz. This study will help us determine the potential role of tenofovir DF for treating this patient population and, if successful, form the basis of a supplemental marketing application for this use.

We cannot be certain that the data obtained from our clinical trials will support regulatory approval of tenofovir DF as the FDA and other regulatory authorities could reject our marketing application for a number of reasons including if they require a higher level of safety or efficacy or more data than we anticipated, or if they disagree with our design or interpretation of these trials.

One of the major challenges in treating HIV-infected patients is drug resistance. Because many of the existing therapies for treating HIV 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 tenofovir DF, if eventually approved by the FDA, could be a very important drug for treatment-experienced patients because available data have shown that patients do not develop rapid resistance to tenofovir DF and that tenofovir DF 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 preliminary 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 results not only in inconvenience for patients but also contributes to patients missing doses or not adhering to their therapy. We believe that tenofovir DF can be administered as a once-daily oral pill on a schedule that may be appealing to HIV patients and their physicians. The low discontinuation rate observed for tenofovir DF in study 907 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 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 tenofovir DF 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 will not arise in the clinical trials for tenofovir DF or that we will achieve adequate treatment benefits.

We have an exclusive, worldwide license to patent rights and related technology for tenofovir DF from IOCB/REGA and would be obligated to pay 3% of any net revenues from sales of tenofovir DF to IOCB/REGA in countries where the product has patent protection. See "Collaborative Relationships--IOCB/REGA."

## **ADEFOVIR DIPIVOXIL FOR HEPATITIS B**

Hepatitis B is a highly contagious viral infection that can cause acute liver failure. Some patients develop a chronic infection which over many years can lead to complications (such as cirrhosis and cancer) that can lead to death. The World Health Organization estimates that there are approximately 350 million people worldwide who are infected with chronic HBV, including 1.25 million people in the United States. Adefovir dipivoxil is a nucleotide analogue reverse transcriptase inhibitor. Adefovir dipivoxil disables the HBV virus by interfering with the activity of an enzyme known as HBV polymerase which is necessary for the HBV virus to replicate. In randomized, double-blind, placebo-controlled Phase II clinical trials, a 30 mg dose of adefovir dipivoxil reduced the median HBV viral load by over 99% (approximately 4 log(10)) after twelve weeks of treatment.

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. One of these trials, which is fully enrolled with 515 patients, is evaluating adefovir dipivoxil once daily at 10 mg or 30 mg for treating patients who test positive for the HBV "e" antigen, the most common type of hepatitis. The other trial, which is fully enrolled with 185 patients, 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 countries of Southeast Asia and the Mediterranean.

A vaccine is available that can prevent the transmission of HBV, but it does not cure patients who become chronically infected with the virus. It is expected that as this vaccine becomes more widely available, the incidence of HBV 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 drug that prevents the virus 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. Of course we cannot be certain that adefovir dipivoxil will be approved for the treatment of HBV and we cannot determine if adefovir dipivoxil would be competitive with Epivir-HBV. See "Competition."

As is the case with HIV, drug resistance is a serious problem with drugs that treat HBV. 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 adefovir dipivoxil an

important drug for treating chronic HBV infection. We cannot be certain, however, that the resistance data we may obtain from the much broader and longer term Phase III clinical trials on adefovir dipivoxil will also show these resistance characteristics.

As described above under tenofovir DF, we discontinued development of 60 mg doses of adefovir dipivoxil for treatment of HIV due to safety and benefit concerns from the FDA. Studies have shown that adefovir dipivoxil is significantly more effective against the HBV virus than against the HIV virus, allowing us to use lower doses that have not shown significant kidney toxicity in our clinical trials to date. We have limited clinical data on the 10 mg dose of adefovir dipivoxil that we obtained from open label safety studies of adefovir dipivoxil in patients with lamivudine resistant HBV who are either pre and post liver transplant patients or who are co-infected HIV/HBV. These studies have demonstrated a decrease in HBV viral load that was similar to what has been seen with the 30 mg dose in phase II studies. We cannot be certain that the broad, long term studies of adefovir dipivoxil at 10 mg and 30 mg doses 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.

Hepatitis B is most common in China and Southeast Asian countries. In December 2000, we received approval and were granted a clinical trials permit to initiate Phase I clinical trials in China. We expect to commence these clinical trials in 2001. We have limited regulatory expertise and no manufacturing or marketing capacity in China and Southeast Asia. Therefore, we will 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 would give us 12 years of market exclusivity for adefovir dipivoxil following any regulatory approval in China.

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. 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. 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 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 these results will be confirmed in clinical trials.

Cubist is currently evaluating Cidecin in multiple Phase III trials for the treatment of complicated skin and soft tissue infection and community-acquired pneumonia. If Cubist obtains data from these Phase III clinical trials that show appropriate safety and efficacy of Cidecin for these uses, we would

file for marketing authorization in the European Union and, if the application is approved, would sell Cidecin through our European sales and marketing infrastructure.

On March 14, 2001, Cubist announced preliminary data from study 9901. Study 9901 is a pivotal phase III clinical trial evaluating Cidecin for complicated skin and soft tissue infection. According to this announcement, a primary endpoint of this trial, demonstrating equivalency to comparable agents, was achieved.

We cannot accurately predict the outcome of these clinical trials. If the trials being conducted by Cubist are not successful, we may be prevented from obtaining regulatory approval of Cidecin in Europe or may elect to conduct additional trials ourselves or together with Cubist and pay for all or a portion of the costs associated with those trials. Cubist does not have an obligation to conduct or pay for additional clinical trials.

Cubist is also evaluating Cidecin in a Phase III clinical trial for the treatment of complicated urinary tract infection and an open-label Phase II clinical trial for the treatment of bacteremia, and may evaluate Cidecin for the treatment of endocarditis and other infections. Our agreement with Cubist does not require Cubist to continue or complete these trials but, if Cubist successfully completes Phase III clinical trials for these uses, we would 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 these clinical trials or if Cubist will evaluate Cidecin for additional uses.

Cubist is also developing an oral formulation of daptomycin. 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 our sales of Cidecin and any oral formulation of daptomycin. See "Collaborative Relationships--Cubist."

## **OUR ONCOLOGY PORTFOLIO**

We are developing three investigational compounds in our oncology program. One of these product candidates, NX 211, is in Phase II clinical trials, and the other two product candidates, GS 7904L and GS 7836, are in preclinical development.

### **NX 211**

NX 211 is a liposomal formulation of lurtotecan, an anti-cancer compound developed by GlaxoSmithKline. GlaxoSmithKline granted to us the exclusive right to develop and commercialize NX 211. See "Collaborative Relationships--GlaxoSmithKline--NX 211."

Prior to granting us these development and commercialization rights, GlaxoSmithKline conducted Phase II clinical trials on non-liposomal lurtotecan as a treatment for various forms of cancer. These Phase II clinical trials showed that lurtotecan has anti-cancer activity but we believe that GlaxoSmithKline did not continue pursuing development of non-liposomal lurtotecan because they were not convinced that these Phase II clinical trials showed sufficient treatment benefits at safe doses when compared to other available anti-cancer agents. We entered into the development and commercialization relationship with GlaxoSmithKline because we believe that by delivering lurtotecan in a liposome, we may be able to increase the treatment benefits of lurtotecan and give patients doses that are safe, effective and convenient.

Lurtotecan is in a class of compounds called camptothecins. These compounds work by disrupting a cell's ability to use topoisomerase I, an enzyme that is required for cells to replicate. Studies show

that the ability of these compounds to kill and stop the spread of cancer cells is directly related to the length of time that cancer cells are exposed to the compound. We believe that by formulating lurtotecan in a liposome, we may be able to increase its time of exposure and its treatment benefits.

In 2000, we completed three Phase I single agent clinical trials that evaluated different doses and treatment schedules of NX 211. These studies, which involved 108 patients, established a maximum tolerated dose for NX 211 with hematological toxicity as the dose limiting factor. We also observed anti-tumor or biological activity in seven of these difficult to treat patients. We cannot be certain that the anti-tumor activity was related to NX 211 since these trials were not designed to evaluate efficacy. One additional Phase I single agent trial is ongoing. NX211 is also being evaluated in Phase I trials in combination with another cancer therapy.

Based on these Phase I results, we commenced a Phase II clinical program evaluating NX 211 for treating patients with ovarian cancer. In November 2000, two ovarian trials were initiated: one in patients who had failed first-line chemotherapy and one in patients resistant to topotecan. In addition, we initiated a separate Phase II clinical trial in December 2000 that will evaluate NX 211 for the treatment of patients with small-cell lung cancer after failure of initial therapy. We also expect to evaluate NX 211 in other cancer types. We cannot accurately predict the outcome of these clinical trials.

We are required to pay milestone payments to GlaxoSmithKline if we achieve certain development goals related to the clinical development and regulatory approval of NX 211. We are not required to pay any royalties or other payments to GlaxoSmithKline based upon any sales of NX 211. See "Collaborative Relationships--GlaxoSmithKline--NX 211."

#### **GS 7904L**

GS 7904L is also a liposomal formulation of a compound that was developed by GlaxoSmithKline for the treatment of cancer. We acquired exclusive worldwide rights to develop and commercialize this compound from GlaxoSmithKline in December 2000.

Prior to our acquiring these rights, GlaxoSmithKline had discontinued development of this compound during Phase I clinical trials. As is the case with NX 211, we hope that by delivering the compound using our proprietary liposomal technology, we will be able to improve the safety and efficacy profile of this compound.

This investigational compound is part of a class of compounds known as thymidilate synthase inhibitors, or TS inhibitors. TS inhibitors act by preventing the production of the thymidilate synthase enzyme, an enzyme that is necessary for cell growth. This enzyme is expressed at significantly higher levels in tumor cells than in healthy cells making it an appropriate target for cancer therapy. Other TS inhibitors that have been approved by regulatory agencies are used for treating colorectal and breast cancer. Our preclinical studies to date indicate that the liposomal formulation of the compound is associated with significant tumor growth inhibition and may improve the safety profile of the compound.

If our preclinical studies are successful, we plan to begin Phase I human clinical trials of GS 7904L in 2001. We cannot be certain that our preclinical studies will be successful. Even if these preclinical studies are successful, we cannot be certain that we will be able to submit an application to begin clinical testing in 2001, or that if commenced, these clinical trials would be successful.

We are required to pay milestone payments to GlaxoSmithKline if we achieve certain development goals relating to the clinical development and regulatory approval of GS 7904L. We are also required to pay royalties to GlaxoSmithKline based upon any sales of GS 7904L. See "Collaborative Relationships--GlaxoSmithKline--GS 7904L."

## **GS 7836**

Also in December 2000, we acquired exclusive, worldwide rights to GS 7836 (4'-thio-araC) from the Southern Research Institute, or SRI. We are evaluating GS 7836 in preclinical studies for the potential treatment of cancer.

GS 7836 is in a class of compounds called nucleoside analogs. It is believed that nucleoside analogues inhibit tumor cell growth by preventing the replication of DNA. FDA-approved drugs in this class have been used to treat acute and chronic leukemias, pancreatic and non-small cell lung cancer. GS 7836 has demonstrated anti-cancer activity against solid tumors in preclinical studies conducted by SRI and Gilead. We cannot be certain that our preclinical studies will be successful.

We are required to pay milestone payments to SRI if we achieve certain development goals relating to the clinical development and regulatory approval of GS 7836. We are also required to pay royalties to SRI based upon our sales of GS 7836. See "Collaborative Relationships--Southern Research Institute."

## **OUR SCIENCE**

We have research scientists in Foster City and San Dimas, California, and Boulder, Colorado 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 and cancer.

## **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 the cytomegalovirus that is essential for that virus to spread. Tenofovir DF and adefovir dipivoxil are nucleotide analogues that work by inhibiting the activity of reverse transcriptase, an enzyme necessary for replication of the HIV virus (tenofovir DF) and the HBV virus (adefovir dipivoxil). Other viruses we are seeking to treat using nucleotide analogues include the herpes and pox viruses. We are also evaluating several nucleotide analogues in animals for activity against cancer.

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.

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 treatment of HIV. Protease inhibitors act by interfering with the activity of protease, an enzyme that, like reverse transcriptase, is necessary for replication of the HIV virus. 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 treatment benefits of and to reduce resistance concerns with these compounds before conducting further preclinical development.

## **ADENOSINE RECEPTOR REGULATORS**

We are working with the National Institute of Diabetes, Digestive and Kidney Diseases at the National Institutes of Health (NIH) to study compounds known as adenosine receptor agonists and antagonists for the treatment and prevention of neurodegenerative disorders (disorders of the brain and upper spine) associated with stroke. We also intend to evaluate the use of these compounds in inflammatory and allergic conditions. NIH researchers have developed a number of these compounds, some of which have shown therapeutic benefits in stroke.

## **DRUG DISCOVERY TECHNOLOGIES**

We have a technology that we call the "SELEX process" that is used to identify potential drug candidates. This process works by identifying drug compounds, known as "aptamers", that tend to bind to the molecule that is causing the disease. Because these aptamers tend to bind to the disease molecules, we believe that they can be effective for treating disease at relatively low doses. NX 1838 is an example of an aptamer identified with the SELEX process. See "Collaborative Relationships--EyeTech."

## MARKETING AND SALES

We established a U.S. sales force of therapeutic specialists when we began selling VISTIDE in 1996. As a result of our merger with NeXstar in July 1999, we also have marketing subsidiaries in the United Kingdom, Germany, Italy, Spain, France, Portugal and Australia and a marketing operation in Greece. Our sales professionals in the U.S., Europe and Australia promote and sell AmBisome and DaunoXome. 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. In March 2000, we entered into a promotion agreement with The Virco Group. We amended this agreement in February, 2001. Under this arrangement, our U.S. therapeutic specialists will promote Virco's HIV resistance monitoring services to HIV-treating physicians through June 2001.

Our U.S. sales force currently consists of approximately 30 sales representatives and five regional directors who promote VISTIDE to physicians, hospitals, clinics, and other healthcare providers who treat AIDS patients, 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 by a managed care/national accounts team and by a marketing and sales support staff of approximately 20 people based at our headquarters in Foster City, California.

Our international marketing subsidiaries are each headed by a general manager who oversees the operations in the market(s) served by that subsidiary. We currently have approximately 140 people located mainly in Europe, including medical, financial 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.

In the U.S., we sell VISTIDE and DaunoXome to wholesalers and specialty distributors who, in turn, sell the products to physicians, hospitals, clinics, pharmacies and other healthcare providers. 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.

If tenofovir DF is approved for treatment of HIV, a larger sales force and additional marketing resources would be required in the U.S. and Europe to expand our coverage of healthcare professionals treating HIV patients. It is our current intention to retain the commercial rights to adefovir dipivoxil for HBV 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 and the product is approved, we would need to increase our sales force in the U.S. and Europe and 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, our existing sales force in Europe will be sufficient to market Cidecin.

VISTIDE is returnable in its original, unopened container 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 it is received by the customer. 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. Additionally, certain governmental agency customers are entitled to 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. 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, 2000, we have received license fees and milestone payments from Hoffmann-La Roche totaling \$39 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 million for the period from January 1, 1997 through December 31, 2000. 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 in Europe.

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

- the 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 million to reduce the royalties payable upon any sales of tenofovir DF and adefovir dipivoxil by 2% to a royalty rate of 3%. 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 tenofovir DF 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 tenofovir DF 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 are obligated to pay additional amounts upon any commercial sales of adefovir dipivoxil or tenofovir DF. We will amortize the \$11 million payment made in December 2000 over the estimated commercial lives of tenofovir DF 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 ongoing 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 million at the time we signed this agreement and may be required to make additional payments to Cubist of up to \$31 million if certain 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 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.

## **GLAXOSMITHKLINE--NX 211**

In May 1998, we entered into agreements with GlaxoSmithKline giving us rights to GlaxoSmithKline's proprietary compound lurtotecan and granting GlaxoSmithKline rights to use our SELEX process to identify aptamers for therapeutic uses. In December 2000, GlaxoSmithKline waived its right to participate in the commercialization of NX 211 and its rights to royalties based on any sales of NX 211 in exchange for our agreement to increase milestone payments upon marketing approvals of NX 211.

Under the agreement relating to lurtotecan, we are developing NX 211, a liposomal formulation of lurtotecan. This agreement provides that:

- We have the exclusive right to develop and commercialize NX 211; and
- We may be required to make one time milestone payments to GlaxoSmithKline if we achieve certain goals related to the clinical development and regulatory approval of NX 211.

## **PHARMACIA CORPORATION**

In August 1996, we entered into an agreement with Pharmacia Corporation relating to VISTIDE. Under this agreement we received \$10 million on signing and \$10 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 2,267,572 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.

#### **GLAXOSMITHKLINE--GS 7904L**

In December 2000, we entered into an agreement with GlaxoSmithKline giving us rights to GS 7904L, a novel anti-tumor compound. Under this agreement:

- We have the exclusive worldwide right to develop and commercialize GS 7904L for all indications, other than malaria;
- We are developing GS 7904L in a liposome and are evaluating it in preclinical studies for oncology;
- We paid an upfront fee to GlaxoSmithKline at the time we signed this agreement and may be required to make payments to GlaxoSmithKline if we achieve certain goals related to the clinical development and regulatory approval of GS 7904L; and
- If we successfully commercialize the product, we would be required to pay to GlaxoSmithKline a percentage of our net sales.

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.

#### **SOUTHERN RESEARCH INSTITUTE**

In December 2000, we entered into an agreement with SRI giving us rights to GS 7836, a novel anti-tumor compound. Under this agreement:

- We have the exclusive worldwide right to develop and commercialize GS 7836 for all indications;
- We are evaluating this compound in preclinical studies for oncology;
- We paid an upfront fee to SRI at the time we signed this agreement and may be required to make payments to SRI if we achieve certain goals related to the clinical development and regulatory approval of GS 7836; and
- If we successfully commercialize the product, we would be required to pay to SRI a percentage of our net sales.

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.

## **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 to us \$7 million at the time we entered into this agreement and \$3 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 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 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. We received a \$7 million up-front licensing fee from EyeTech upon execution of the agreement. Under the terms of the agreement:

- EyeTech received the exclusive right to develop and commercialize NX 1838;
- We are entitled to additional cash payments from EyeTech of up to \$25 million if and when EyeTech reaches certain NX 1838 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. In addition, we agreed to provide clinical supplies of the product to EyeTech for an initial one-year period.

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.

## **VIRCO GROUP**

In March 2000, we entered into an agreement with the Virco Group relating to Virco's HIV resistance monitoring services. Under this agreement:

- We help to promote Virco's HIV resistance monitoring services; and
- Virco pays to us a fixed fee for this promotion.

This agreement will terminate in June 2001.

## **PROLIGO L.L.C.**

We own a 49% interest in Proligo L.L.C., a company that manufactures oligonucleotides. We also have agreements with Proligo and SKW Americas, Inc. (the owner of the remaining 51% of Proligo) relating to the ownership, operations and funding of Proligo. Under these agreements:

- We contributed a total of \$4.9 million to Proligo to fund its operations in late 1999 and early 2000 and we have no further funding obligations to Proligo;
- SKW Americas will have the right to purchase our ownership interest in Proligo for a 90-day period beginning on July 29, 2001 for the amount they would have been required to pay for that interest had they purchased it in 1999;
- Over the next three years, SKW Americas is obligated to pay to us approximately \$300,000; and
- Proligo agreed to manufacture oligonucleotides for us and we would pay them an amount equal to their manufacturing cost plus a pre-determined percentage.

Proligo will dissolve and any remaining assets will be distributed to its owners in August 2028, unless the owners of Proligo at that time decide to extend the term. The agreement relating to the manufacture and supply of oligonucleotides expires in August 2008.

## **GLAXOSMITHKLINE--SELEX**

At the time we entered into the agreement with GlaxoSmithKline relating to NX 211, we also entered into an agreement giving GlaxoSmithKline the non-exclusive right to use our SELEX technology for five years to identify aptamers.

- 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, 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.

## **INTERNATIONAL DISTRIBUTION AGREEMENTS**

We have various agreements with distributors in Europe, Asia, South 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.

## **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. The Medicines Control Agency of the United Kingdom has

approved both of these facilities to manufacture AmBisome and DaunoXome for commercial use. The FDA has approved both these facilities to manufacture AmBisome but only one of these facilities to manufacture DaunoXome for distribution in the U.S. 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, daunorubicin HCl and cholesterol that we use to manufacture 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 two different third parties to 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 tablets and tenofovir DF tablets. 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.

We have one supplier that has been approved by the FDA and EMEA to manufacture the cidofovir used in VISTIDE and a single FDA approved supplier for the final drug product, and we have submitted information on a second cidofovir supplier to assure our supplies. We manufacture the active ingredient in tenofovir DF in small quantities at our own facilities and in larger quantities through two contract manufacturers. The final tenofovir DF and adefovir tablets used in our clinical trials are manufactured at two contract manufacturing sites. If manufacturing at any of these sites we use were interrupted for any reason, our ability to complete our clinical trials or ship our products would be impaired, and this would adversely affect us.

For our antiviral products in particular, 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 complete 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 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.S. PATENT EXPIRATION	EUROPEAN PATENT EXPIRATION
PRODUCTS		
AmBisome.....	2016	2008
Tamiflu.....	2016	2016
VISTIDE.....	2010	2012
DaunoXome.....	2009	2008
PRODUCT CANDIDATES		
tenofovir DF.....	2017	2017*
adefovir dipivoxil.....	2014	2011
NX 211.....	2013*	2012*
NX 1838.....	2012*	2016*
GS 7904L.....	2015	2011
GS 7836.....	2019**	2019**
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 patent on tenofovir DF does not issue, we have patents that expire in 2006 and 2013 that provide protection.

\*\* 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.

\*\*\* We do not have commercial rights to Cidecin in the United States.

Patents covering VISTIDE, tenofovir DF and adefovir dipivoxil, lurtotecan (the active ingredient in NX 211), Cidecin, GS 7904L and GS 7836 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 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 applied for or 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.

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. Also, in the U.S., patent applications are generally maintained in secrecy until patents are issued so we cannot be certain that we are the inventor of technologies covered by our pending patent applications or that we were the first to file patent applications for those inventions.

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 fungal infections, viral infections and cancer. 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.

In markets where AmBisome has been approved as a first line therapy, it competes against traditional amphotericin B, which is made by Bristol-Myers Squibb Company and numerous generic manufacturers. We expect to face significant competition from new antifungal products, including caspofungin, a product developed by Merck that received marketing approval in January 2001 and voriconazole, which is being developed by Pfizer, Inc. Pfizer has filed an application for marketing approval for voriconazole. There is also a number of other lipid-based amphotericin B products that have been approved in the U.S. and throughout Europe, including Abelcet, which is sold by Elan Corporation, and Amphotec, which is sold by InterMune Pharmaceuticals, Inc. These products compete against AmBisome as both primary and secondary therapy and have been offered at prices that are less than AmBisome's price.

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, Johnson & Johnson and Biocryst are developing a neuraminidase inhibitor anti-flu drug 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. 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. Johnson & Johnson is in advanced clinical trials with this compound, 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, a drug that is sold in intravenous and oral formulations by Hoffman La-Roche and as an ocular implant by Bausch & Lomb Incorporated;
- Foscarnet, an intravenous drug sold by AstraZeneca; and
- Formivirsen, a drug that is injected directly into the eye that is sold by CibaVision.

If approved, tenofovir DF will face substantial competition. A number of drugs to treat HIV infection and AIDS are currently sold or are in advanced stages of clinical development, including 16 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 and DuPont Pharma.

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

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, or 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 which 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 a new drug application, or 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 Phase I, Phase II or Phase III clinical trials that we are conducting, including those for tenofovir DF for HIV and adefovir dipivoxil for chronic HBV, 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. Drugs receiving accelerated approval must be monitored in post-marketing clinical trials in order to confirm the safety and benefits of the drug. Tenofovir DF for HIV has qualified as a fast track product and may be eligible for accelerated approval. We have not determined if we would seek "fast track" status of any other products if they qualified or the impact of this status on the timing or likelihood of approval of any of these potential products or those of our competitors.

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 was approved by the European Union under the centralized procedure. Tamiflu and tenofovir DF will be reviewed under the centralized procedure, but neither drug has 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.

## **EMPLOYEES**

As of February 28, 2001, we had more than 850 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.

### **ANY SIGNIFICANT REDUCTION IN AMBISOME 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 and 2000 were approximately \$129 million, or 76%, and \$141 million, or 72%, of our total revenues. We expect that revenues from sales of AmBisome will continue to constitute a substantial majority of our total product revenues at least through 2001.

Accordingly, for the foreseeable future, we expect that we will continue to rely on sales of AmBisome 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, 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 that received marketing approval in January 2001, and voriconazole, which is being developed by Pfizer, Inc. Pfizer has filed an application for marketing approval of voriconazole.

### **TAMIFLU IS A NEW DRUG, AND IT MAY NOT GAIN SIGNIFICANT MARKET ACCEPTANCE.**

Most people who become infected with the flu use over-the-counter drugs to treat the flu symptoms and rely on their immune system to fight the infection. Tamiflu is in a new class of prescription drugs designed to prevent and treat the flu. Patients may be reluctant to visit a physician or seek a prescription drug for the flu, physicians may be reluctant to prescribe a flu drug, and government reimbursers and private insurance companies may refuse to pay for an anti-flu drug. In order for Tamiflu to be successful, our marketing partner Hoffmann-La Roche will need to increase awareness and acceptance of this new approach to preventing and treating the flu. The 1999-2000 flu season was the first flu season that Tamiflu was commercially available. To date the incidence of flu for the 2000-2001 flu season has been very low. It is too early to determine if Tamiflu will achieve significant market acceptance.

### **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 basis. We may never become profitable. At December 31, 2000, our accumulated deficit was approximately \$506 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, VISTIDE and DaunoXome and royalty arrangements related to Tamiflu, AmBisome and VISTIDE.

### **WE DEVELOP DRUGS TO TREAT HIV AND AIDS AND RELATED CONDITIONS, AND THEREFORE CHANGES IN THE REGULATORY AND COMMERCIAL ENVIRONMENT FOR HIV AND AIDS THERAPIES COULD HARM OUR BUSINESS.**

Several of our products and products in development address HIV and AIDS or related conditions. These products include VISTIDE for CMV retinitis, tenofovir DF for HIV and AIDS, and DaunoXome for HIV-associated Kaposi's sarcoma. We develop those products based upon current

policy and the current marketplace for HIV 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 for currently approved and additional uses. We are also conducting clinical trials for three other products: tenofovir DF, adefovir dipivoxil and NX 211. We anticipate that we will conduct a variety of clinical trials and file for marketing approval of additional products over the next several years. These products may fail to receive marketing approval on a timely basis, or at all. We also cannot be certain that we will file an NDA for tenofovir DF in mid-year 2001, or at all, as unexpected results of ongoing clinical trials or unexpected requests from the FDA for additional data could delay or prevent that filing. In addition, tenofovir DF may not be granted priority review by the FDA, which means that any NDA would not be reviewed within 6 months of submission. In addition, these products 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 tenofovir DF, adefovir dipivoxil, NX 211, GS 7904L and GS 7836. 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 November 1999, an FDA Advisory Committee recommended against approval of our application to approve a 60 mg dose of adefovir dipivoxil to treat HIV. 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 they 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 are using 10 and 30 mg doses of adefovir dipivoxil in our Phase III clinical trials of adefovir dipivoxil for HBV. We believe that these lower doses will not result in the kidney toxicity experienced with 60 mg and that adefovir dipivoxil can be effective in treating HBV 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. Tenofovir DF is in the same class of drugs as adefovir dipivoxil. While we have not yet observed kidney toxicity in our clinical trials of tenofovir DF, the kidney toxicity in our clinical trials of adefovir dipivoxil for HIV 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 clinical trials of tenofovir DF. 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 PATIENT ENROLLMENT 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, HBV and certain cancers, 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 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 do not hedge our exposure to the impact of fluctuating foreign exchange rates on forecasted sales. Foreign currency fluctuations will continue to affect 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. We also only rely on international distributors for sales of AmBisome in certain countries. In addition, we recently entered into a collaboration agreement with Cubist Pharmaceuticals, Inc. to commercialize Cubist's antibacterial drug Cidecin in several European countries following regulatory approval. Under this agreement, 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. If these 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
- there are risks related to the ability of our distributors and corporate partners 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.

**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.**

Many of our products in development, 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, bacterial infections and cancer. 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. If Tamiflu is approved for sale in Europe, its success 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 in the U.S. are generally confidential until a patent is granted. 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. GS 7836 and Cidecin are 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 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 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, Ohio State University holds a patent that we may need to develop and commercialize NX 211. Ohio State University has offered us a non-exclusive license under this patent, and we have entered into an option with Ohio State University to enter into this license. Should we elect to enter into an agreement with Ohio State University under this option, we will be required to pay fees and a product royalty on NX 211.

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.

#### **MANUFACTURING PROBLEMS COULD DELAY PRODUCT SHIPMENTS AND REGULATORY APPROVALS.**

For VISTIDE, adefovir dipivoxil and tenofovir DF, 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.

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 and high quality cholesterol, each of which is used in the manufacture of one or more of our liposome 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, 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, 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 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 260,300 square feet of space in eight proximately located buildings. One of the subleases covering 59,039 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.

In Boulder, Colorado, we lease a facility of approximately 11,000 square feet of office space, which we use as administrative offices. This lease expires in February 2005 and has an option to renew for two additional five-year periods. We also lease approximately 60,000 square feet of space, which we use both as research laboratories and as administrative offices. This lease expires in October 2001, but we have an option to renew the lease for two successive five-year periods.

We also occupy facilities in San Dimas, California under leases that expire in May and November 2003, with two five-year renewal options. These facilities cover 102,500 square feet of space and house research and development activities, manufacturing and certain administrative functions. In 2000, we also leased a warehouse facility adjacent to these facilities that we use for product distribution and administrative functions. This facility has 53,000 square feet of space and the lease expires in April 2006, with two additional five-year extensions.

In addition, we lease approximately 48,000 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.

## **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**

A Special Meeting of Stockholders was held on February 2, 2001 in Redwood City, California. Of the 94,171,488 shares of Gilead Common Stock entitled to vote at the meeting, 75,644,638 shares were represented at the meeting in person or by proxy, constituting a quorum. The stockholders approved an amendment to Gilead's Certificate of Incorporation to increase the authorized number of shares of Common Stock from 100,000,000 shares to 500,000,000 shares. There were 59,152,774 votes cast for the proposal, 16,451,600 votes cast against, 60,264 abstentions, and no broker non-votes.



## 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.

	HIGH	LOW
	-----	-----
2000		
First Quarter.....	\$42.50	\$22.38
Second Quarter.....	\$38.25	\$21.63
Third Quarter.....	\$59.06	\$33.00
Fourth Quarter.....	\$55.38	\$30.47
1999		
First Quarter.....	\$28.75	\$17.63
Second Quarter.....	\$27.06	\$17.94
Third Quarter.....	\$46.69	\$25.31
Fourth Quarter.....	\$37.88	\$18.50

On February 22, 2001, the Company implemented a two-for-one stock split in the form of a stock dividend. All share and per share amounts for all periods presented in this Form 10-K have been restated to reflect the split.

As of February 28, 2001, we had 94,353,314 shares of common stock outstanding held by approximately 519 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.

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.

## ITEM 6. SELECTED FINANCIAL DATA

### GILEAD SCIENCES, INC. SELECTED CONSOLIDATED FINANCIAL DATA(1) (IN THOUSANDS, EXCEPT PER SHARE DATA)

	YEARS ENDED DECEMBER 31,				
	2000	1999	1998	1997	1996
CONSOLIDATED STATEMENT OF OPERATIONS DATA:					
Total revenues.....	\$195,555	\$168,979	\$151,119	\$132,258	\$122,121
Total costs and expenses.....	247,873	239,838	230,631	220,480	181,403
Loss from operations.....	(52,318)	(70,859)	(79,512)	(88,222)	(59,282)
Loss before cumulative effect of change in accounting principle.....	(43,106)	(66,486)	(44,758)	(72,893)	(45,614)
Cumulative effect of change in accounting principle(2).....	(13,670)	--	--	--	--
Net loss.....	(56,776)	(66,486)	(44,758)	(72,893)	(45,614)
Basic and diluted loss per common share:(3)					
Loss before cumulative effect of change in accounting principle.....	\$ (0.47)	\$ (0.78)	\$ (0.55)	\$ (0.92)	\$ (0.61)
Cumulative effect of change in accounting principle.....	(0.15)	--	--	--	--
Net loss.....	\$ (0.62)	\$ (0.78)	\$ (0.55)	\$ (0.92)	\$ (0.61)
Common shares used to calculate basic and diluted net loss per common share(3)....	91,050	85,652	82,030	78,864	75,282
DECEMBER 31,					
	2000	1999	1998	1997	1996
CONSOLIDATED BALANCE SHEET DATA:					
Cash, cash equivalents and marketable securities.....	\$ 512,878	\$ 294,394	\$ 348,743	\$ 387,361	\$ 338,354
Working capital.....	535,560	324,104	359,555	396,810	332,352
Total assets.....	678,099	436,808	487,764	516,989	450,540
Long-term obligations.....	2,238	5,253	8,883	9,658	18,120
Convertible subordinated debt.....	250,000	79,533	80,000	80,000	--
Accumulated deficit.....	(506,008)	(449,232)	(382,746)	(337,988)	(265,095)
Total stockholders' equity(4).....	351,124	297,292	333,699	357,726	374,649

(1) 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.

(2) Gilead adopted Staff Accounting Bulletin No. 101, "REVENUE RECOGNITION IN FINANCIAL STATEMENTS", in the fourth quarter of 2000. The effect of the change was recorded as the cumulative effect of a change in accounting principle effective as of the first quarter 2000.

(3) On February 22, 2001, the Company implemented a two-for-one stock split in the form of a stock dividend. All share and per share amounts for all periods presented have been restated to reflect the split.

(4) 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 Sciences, Inc. ("Gilead" or "we") was incorporated in Delaware on June 22, 1987, and is an independent biopharmaceutical company that seeks to provide accelerated solutions for patients and the people who care for them. We discover, develop, manufacture and commercialize proprietary therapeutics for challenging infectious diseases (viral, fungal and bacterial diseases) and cancer. Gilead also has expertise in liposomal drug delivery technology. Currently, we market AmBisome-Registered Trademark- ((amphotericin B) liposome for injection), an antifungal agent, DaunoXome-Registered Trademark- (daunorubicin citrate liposome injection), a drug approved for the treatment of Kaposi's Sarcoma, and VISTIDE-Registered Trademark- (cidofovir injection) for the treatment of cytomegalovirus ("CMV") retinitis. Hoffmann-La Roche Inc. markets Tamiflu-TM- (oseltamivir phosphate) for the treatment of influenza, under a collaborative agreement with Gilead. In addition, we are developing products to treat diseases caused by human immunodeficiency virus ("HIV"), hepatitis B virus ("HBV"), bacterial infections and cancer.

On February 22, 2001, Gilead completed a two-for-one stock split, effected in the form of a stock dividend, to stockholders of record as of February 2, 2001. Accordingly, all share and per share amounts for all periods presented have been restated to retroactively reflect the split.

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 a 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 will compete with AmBisome; 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.

**REGULATORY PROCESS.** The U.S. Food and Drug Administration ("FDA") 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 can not 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.

**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; 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 the flu. In order for Tamiflu to achieve market acceptance, our marketing partner, Hoffmann-La Roche, Inc., must change attitudes toward the treatment of influenza.

**COLLABORATIONS.** We depend on collaborations for the development and commercialization of certain products and for revenue, including the collaboration with Hoffmann-La Roche, Inc. for sales of Tamiflu worldwide and the collaboration with Fujisawa Healthcare, Inc. ("Fujisawa") for sales of AmBisome in the United States and Canada. 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 do not hedge our exposure to the impact of fluctuating foreign exchange rates on forecasted sales. We do hedge accounts receivable balances denominated in foreign currencies, which minimizes our exposure to currency fluctuations between the date a sale is recorded and the date that cash is collected.

**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 basis and we may never achieve or sustain profitability. As of December 31, 2000, our accumulated deficit was \$506.0 million.

## **RESULTS OF OPERATIONS**

### **REVENUES**

We had total revenue of \$195.6 million for the year 2000, \$169.0 million for the year 1999 and \$151.1 million for the year 1998. Included in total revenue are net product sales, royalty income and contract revenue, including research and development ("R&D") collaborations.

Net product sales revenue was \$149.7 million for 2000, compared with \$139.9 million for 1999 and \$114.2 million for 1998. Our revenues are primarily derived from sales of AmBisome, which represented 94% of total product sales in 2000, 92% of total product sales in 1999 and 91% of total product sales in 1998. Reported sales of AmBisome were \$141.1 million in 2000, an increase of 9% over AmBisome sales of \$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%. A significant majority of Gilead's product sales is denominated in foreign currencies. We do not hedge our exposure to the impact of fluctuating foreign exchange rates on forecasted sales. We do hedge

accounts receivable balances denominated in foreign currencies, which minimizes our exposure to currency fluctuations between the date a sale is recorded and the date that cash is collected. Sales of AmBisome were \$103.4 million in 1998. The increase in AmBisome sales in 1999 compared with 1998 was not materially affected by changes in foreign currency rates.

In 2000, Gilead also 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. In 1998, we reported DaunoXome sales of \$4.7 million and VISTIDE sales of \$6.1 million. We expect combined sales of DaunoXome and VISTIDE in the future to decrease slightly compared to 2000 levels.

We reported royalty revenue of \$24.6 million in 2000, compared with \$10.4 million in 1999 and \$7.3 million in 1998. 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 \$13.5 million in 2000, compared with \$8.3 million in 1999 and \$4.8 million in 1998. The 1999 amount represents royalties from 11 months of Fujisawa sales of AmBisome.

We also reported royalty revenue of \$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. We expect Tamiflu royalties to increase in 2001 as a result of broader market penetration and additional regulatory approvals received during the second half of 2000. During that time period Tamiflu was approved in the U.S. as a prophylaxis (preventive) in adults and as a treatment for influenza in children, and approved in Japan as a treatment for influenza in adults.

Substantially all of the remaining net royalty revenue recognized in 2000, 1999 and 1998 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 \$2.9 million in 2000, in accordance with SAB 101, related

to up front fees which had been received in prior years. The \$2.9 million was related to three collaborative arrangements: \$1.6 million related to an initial licensing fee from Sumitomo; \$0.7 million related to an initial licensing fee from Roche; and \$0.6 million related to an initial license fee from Pharmacia. The remaining \$10.7 million of related deferred revenue at December 31, 2000 results from the Sumitomo and Pharmacia collaborations, and is expected to be recognized as contract revenue over the next twelve years. There is no remaining deferred revenue related to the Roche initial license fee as of December 31, 2000. The pro forma results included in the Consolidated Statements of Operations in Part IV reflect amounts that would have been reported if the change in accounting principle had been applied retroactively.

Total contract revenue was \$21.3 million in 2000, compared with \$18.7 million in 1999 and \$29.6 million in 1998. The single most significant source of contract revenue in each of these three years was payments from Roche relating to the development of Tamiflu under an R&D collaboration agreement between Gilead and Roche. We recorded contract revenue from Roche of \$11.2 million in 2000, \$14.9 million in 1999 and \$16.4 million in 1998. 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. The \$16.4 million recorded during 1998 represented reimbursements of R&D expenses, and included \$5.2 million attributable to R&D expenses incurred in the fourth quarter of 1997, which were subject to Roche's approval as of December 31, 1997. Such expenses were approved for reimbursement and recognized as revenue in 1998. R&D reimbursements from Roche in 2000 decreased compared to 1999, and reimbursements in 1999 similarly decreased relative to 1998, as Tamiflu development efforts ramp down while Roche's commercialization activities increased. As of December 31, 2000, Gilead is entitled to additional milestone payments of up to \$11.6 million upon Roche achieving certain developmental and regulatory milestones. While we may earn milestones payments under the Roche agreement in 2001, we expect expense reimbursements under the Roche agreement to continue to decline in 2001. Such reimbursements will approximate our actual related costs incurred.

In March 2000, we entered into an agreement with EyeTech Pharmaceuticals, Inc. relating to Gilead's proprietary aptamer NX 1838. Currently in early clinical trials, NX 1838 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 NX 1838, 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 will provide 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 is being 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 will be 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 NX 1838 development milestones. Additionally, Gilead received a 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. We are obligated to transfer 5% of the total shares subject to the warrant to the University of Colorado at Boulder under a collaborative agreement with the university, and we expect to retain the remaining 791,667 shares. We did not recognize revenue related to the warrant as there was no readily determinable fair value at the time of the transaction.

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. Contract revenue recognized in 1999 also included a \$1.0 million performance-based milestone payment received from SKW Americas, Inc. ("SKW"). SKW is the 51% owner of Proligo L.L.C. ("Proligo"), an entity in which we hold the remaining 49% ownership interest.

In 1998, we recorded as contract revenue a \$3.0 million milestone payment from Sumitomo Pharmaceuticals Co., Ltd. related to a license of AmBisome rights in Japan. Also in 1998, we entered into an agreement with Isis Pharmaceuticals, Inc. ("Isis") under which we sold to Isis the holdings of our antisense patent estate, including patents and patent applications. Under the terms of the agreement, Isis is required to pay Gilead a total of \$6.0 million in four installments. The total sale price of \$6.0 million was included in contract revenue in 1998.

Contract revenue for 1998 also includes reimbursement of research expenses under our collaborative agreements with GlaxoSmithKline, formerly Glaxo Wellcome Inc. ("Glaxo") and Schering A.G. ("Schering"). Under the agreement with Schering related to the discovery and development of aptamers as IN VIVO diagnostic agents ("Schering Research Agreement"), we recognized \$2.4 million of contract revenue in 1998. The Schering Research Agreement expired in 1999, but a related license agreement remains in effect. Our collaborative agreement with Glaxo was related to its code blocker program. Contract revenue recognized in connection with the Glaxo agreement was \$1.8 million in 1998.

## **COST OF GOODS SOLD**

Cost of goods sold was \$33.5 million in 2000, compared with \$29.5 million in 1999 and \$23.4 million in 1998. As a percentage of product sales revenue, cost of goods sold was 22% in 2000, 21% in 1999 and 20% in 1998.

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 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 sales would have been approximately 20%, down slightly from 1999 primarily due to larger production quantities in 2000 absorbing our fixed costs. Our cost of sales percentage on an annual basis has been in the 20% to 22% 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 sales as a percentage of sales revenue in 2001 to remain materially consistent with the 2000 rate. In future years, changes in the nature or mix of our product sales could impact this relationship.

## **OPERATING EXPENSES**

Research and development ("R&D") expenses for 2000 were \$131.6 million, compared with \$110.2 million for 1999 and \$124.8 million for 1998. Major development projects in 2000 include tenofovir DF for HIV and adefovir dipivoxil for hepatitis B virus ("HBV"). We incurred increased costs for both of these programs which are 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 and Southern Research Institute. These increases more than offset significantly lower expenses in 2000 for the development of adefovir dipivoxil for HIV, a program we discontinued in the fourth quarter of 1999. We expect R&D expenses in 2001 to be approximately 20% to 30% higher than 2000 due to increased spending on the continued late-stage development of tenofovir DF for HIV and adefovir dipivoxil for HBV.

The decrease in R&D expenses in 1999 compared to 1998 was primarily attributable to reduced research activities at our Boulder, Colorado facility. In August 1998, we transferred our Boulder-based NeXstar Technology Products division to Prologo, our equity investee. In addition, in October 1998, we reduced our R&D workforce in Boulder by 47 employees and recorded an expense of \$1.6 million related to severance packages for the discharged employees. In 1999, we reduced the R&D workforce in Boulder by 30 employees upon completing the merger with NeXstar. Finally, Gilead had a reduced level of involvement in the development of Tamiflu in 1999 compared to 1998. These decreases were offset in part by greater levels of expense in 1999 for the development programs for adefovir dipivoxil for HBV and tenofovir DF for HIV, as well as an adjustment of \$2.9 million to fully reserve our supply of adefovir dipivoxil for HIV. This adjustment was made as a result of our decision to discontinue the development of this product candidate in the United States after a negative recommendation from an FDA advisory panel.

Selling, general and administrative ("SG&A") expenses were \$82.8 million in 2000, compared with \$100.1 million in 1999 and \$82.4 million in 1998. The major factor contributing to the decrease in 2000 from 1999 levels was the inclusion in SG&A of \$18.3 million of merger-related expenses in 1999. 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 included costs to implement new and upgraded information technology systems; legal costs incurred in connection with new collaboration agreements and various corporate projects; and expenses to meet general corporate reporting requirements. 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, which was discontinued in the fourth quarter of 1999. Additionally, 2000 sales and marketing expenses 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. In 2001, we expect SG&A expenses to be 25% to 40% higher than 2000 levels, primarily due to the activities necessary to prepare for the anticipated U.S. and European commercial launch of tenofovir DF.

The increase in SG&A expenses in 1999 compared with 1998 was due to merger expenses of \$18.3 million. Excluding the merger expenses, SG&A spending was flat from 1998 to 1999. During 1999, we recorded \$2.3 million of compensation expense related to a NeXstar stock option plan that requires the use of variable plan accounting. This charge was substantially offset by cost savings related to the elimination of duplicate selling, general and administrative positions and functions within the combined Gilead and NeXstar organization in the second half of 1999.

Merger expenses of \$18.3 million are included in total SG&A expenses for 1999. These 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. As of December 31, 1999, all employees for whom severance costs were accrued had been terminated. The balance of the accrued liability was \$2.5 million at December 31, 1999 and substantially all remaining accrued severance costs were paid to former employees by December 31, 2000. We do not expect to realize any further cost savings resulting from staff reductions that occurred after the merger.

## **LITIGATION SETTLEMENT AND RELATED EXPENSES**

We incurred litigation settlement and related expenses of \$1.4 million in 2000, \$1.5 million in 1999 and \$1.3 million 1998. 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 SUBSIDIARY**

In 1998, we recognized a \$22.1 million gain on the sale of our 51% interest in our newly established subsidiary, Proligo, a Delaware limited liability company, to SKW. Proligo was formed in July 1998 and initially consisted of the assets of our NeXstar Technology Products division, a manufacturer of oligonucleotides and specialty chemicals for the pharmaceuticals industry. As payment for the sale of our interest in Proligo, we received \$15.0 million and a 49% interest in PerSeptive Biosystems GmbH, a company in Hamburg, Germany, which specializes in the manufacture of nucleoside phosphoramidite monomers. In addition, SKW agreed to pay us \$3.0 million in guaranteed payments and up to \$20.5 million in performance-based milestones through 2003. As part of the transaction, we contributed \$4.9 million and our 49% interest in PerSeptive Biosystems GmbH to Proligo. The 49% interest in PerSeptive Biosystems GmbH had a fair value of approximately \$5.5 million. SKW contributed \$5.1 million and the remaining 51% of PerSeptive Biosystems to Proligo.

## **INTEREST INCOME AND INTEREST EXPENSE**

We reported interest income of \$17.6 million in 2000, compared with \$16.4 million in 1999 and \$21.8 million in 1998. The increase in 2000 over 1999 was due to higher interest rates on our investment portfolio, as well as slightly higher average balances of invested funds. The decrease in interest income in 1999 compared to 1998 was due to both a declining balance of invested cash as well as slightly lower investment returns in 1999. We expect interest income in 2001 to increase from 2000 levels due to higher cash balances as a result of our \$250.0 million 5% convertible subordinated notes financing completed in December 2000.

We incurred interest expense of \$4.4 million in 2000 compared with \$6.5 million in 1999 and \$7.2 million in 1998. The decrease in 2000 from 1999 occurred primarily because we incurred interest expense on our 6.25% convertible debentures only through August 1, 2000, when they were converted to common stock. Interest expense on other debt, including capital leases, decreased also, due to continually declining outstanding balances as we repay the debt. This decrease, however, was offset by interest on our new \$250.0 million 5% convertible subordinated notes issued in December 2000. Interest expense decreased in 1999 compared to 1998 primarily due to the repayment of debt obligations including capital leases. We expect interest expense in 2001 to increase to approximately three times the 2000 expense level as we incur a full year of expense on the \$250 million 5% convertible subordinated notes.

## **EQUITY IN LOSS OF UNCONSOLIDATED AFFILIATE**

In 2000, Gilead recorded \$2.9 million as our equity in the loss of our unconsolidated affiliate, Proligo. This represented 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. For 1999, we recorded \$4.7 million equity in the loss of Proligo for Proligo's fiscal year ended November 30, 1999. In 1998, we recorded \$1.1 million as our equity in the loss of Proligo for the period from August 15, 1998 (Proligo's inception date) through November 30, 1998. We expect to continue to recognize losses on our equity investment in Proligo during 2001.

Our investment in Proligo is reported in other noncurrent assets on our consolidated balance sheet. The carrying amount of this investment was \$6.9 million at December 31, 2000 and \$7.6 million at December 31, 1999. In the three-year period ended December 31, 2000, we funded Proligo with a total of \$9.8 million to maintain our percentage ownership interest in Proligo. We have no further commitments to provide additional funding to Proligo, and we do not expect to provide any.

## **LIQUIDITY AND CAPITAL RESOURCES**

Cash, cash equivalents and marketable securities totaled \$512.9 million at December 31, 2000, up from \$294.4 million at December 31, 1999. The increase of \$218.5 million was due to the net proceeds of \$241.8 million from our \$250.0 million 5% convertible subordinated notes financing in December 2000. Other major sources and uses of cash included proceeds from issuances of stock under employee stock plans, offset by cash used to fund operating activities and capital expenditures.

Significant changes in working capital during 2000 included an increase in accrued clinical and preclinical expenses of \$4.5 million, primarily due to the advanced and accelerated Phase III clinical trials for tenofovir DF for HIV and adefovir dipivoxil for HBV. Other accrued liabilities increased \$4.3 million in 2000, the largest component of which was an unrealized loss on foreign exchange contracts of \$1.7 million at December 31, 2000. This unrealized loss was partially offset by unrealized foreign exchange gains on accounts receivable balances at that date, however the gain on receivables is included in the accounts receivable balance on the balance sheet. Other components of the increase in other accrued liabilities during 2000 included higher marketing accruals and various other accruals due to the timing of invoice receipts, and higher foreign tax liabilities primarily in Italy. Another significant change in working capital in 2000 was an increase in accounts payable of approximately \$2.1 million, primarily due to the timing of payments to vendors.

Our accounts receivable balance at December 31, 2000 was \$48.8 million compared to \$45.6 million at December 31, 1999. The growth was primarily due to increased receivable balances in countries in which payments tend to be relatively slow. In certain cases, these slow payment practices reflect the pace at which governmental entities reimburse 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. This, in turn, may increase the financial risk related to certain of our customers. In certain countries in which payments have been slow, particularly Greece, Spain and Italy, our accounts receivable are significant. At December 31, 2000, our past due accounts receivable for Greece, Spain and Italy totaled approximately \$19.3 million, of which approximately \$10.9 million was more than 120 days past due. At December 31, 1999, past due receivables for these countries was \$15.8 million, of which approximately \$5.0 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 the past due accounts receivable for Greece, Spain and Italy are collectible. We continually seek to improve our collection process to ensure that we fully collect amounts due to us based on our product sales and that collections are timely.

Other noncurrent assets increased to \$29.1 million at December 31, 2000 from \$13.4 million at December 31, 1999. The increase was primarily due to \$11.4 million of long-term prepaid royalties recorded in the fourth quarter of 2000 related to payments made to IOCB/REGA. These prepayments will be amortized to royalty expense over the expected commercial life of tenofovir DF and adefovir dipivoxil when and if FDA approval is obtained and sales of the products commence. Also included in other noncurrent assets at December 31, 2000 is \$8.2 million of deferred debt issuance costs related to the \$250 million 5% convertible subordinated notes financing completed in December 2000. These costs are being amortized to interest expense over the contractual term of the notes. These increases in other noncurrent assets were offset by a \$2.0 million decrease due to a receivable from Isis related to a payment due to us in December 2001. This balance was reclassified to current assets as of December 31, 2000. Additionally, other noncurrent assets as of December 31, 1999 included deferred

debt issuance costs of \$1.4 million related to our 6.25% subordinated debentures which were converted to common stock in August 2000; these costs were reclassified to additional paid-in capital upon the conversion.

Long-term deferred revenue at December 31, 2000 is \$10.7 million. This balance represents up-front payments received under two collaboration agreements that are being recognized as contract revenue over the life of the related research and development collaboration, manufacturing or supply arrangement. Upon our adoption of SAB 101 effective January 1, 2000, a total of \$13.7 million of previously recognized contract revenue was recorded as deferred revenue, of which \$2.9 million was recognized as contract revenue in 2000.

We made capital expenditures of \$15.6 million in 2000, \$12.5 million in 1999 and \$11.0 million in 1998. These expenditures were primarily for facilities improvements to accommodate our growth, as well as for laboratory and manufacturing equipment. We expect our capital spending to continue at the 2000 level or higher in the future, particularly to accommodate our expanded research and development activities.

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 debentures indenture. Upon redemption, the entire \$79.5 million in principal amount of the debentures outstanding at that time was converted into 3,567,578 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 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 5,089,058 shares of Gilead common stock at \$49.125 per share. The \$49.125 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.

We maintain 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 are required to maintain certain financial ratios and there are limitations on our ability to incur additional debt or to engage in certain significant transactions. The line of credit, which includes a foreign exchange facility, expires on April 16, 2001. We currently do not intend to renew this line when it expires, but we will maintain the foreign exchange facility. As of December 31, 2000, we had no outstanding borrowings under the line.

We believe that our existing capital resources, supplemented by net product revenues and contract and royalty revenues, will be adequate to satisfy our capital needs for the foreseeable future. As of December 31, 2000, we were entitled to additional cash payments of up to \$11.6 million from Roche if and when Roche achieves specific additional Tamiflu developmental and regulatory milestones. We are also entitled to additional cash payments from EyeTech of up to \$25.0 million if and when EyeTech reaches certain NX 1838 development milestones. We cannot assure you that any of these milestones will be met. Our future capital requirements will depend on many factors, including:

- 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,
- the commercial performance of AmBisome and any of our products in development that receive marketing approval,
- 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 can not assure you that it will be available on favorable terms, if at all.

## **PROSPECTIVE ACCOUNTING PRONOUNCEMENT**

Statement of Financial Accounting Standards No. 133 ("SFAS 133"), ACCOUNTING FOR DERIVATIVE INSTRUMENTS AND HEDGING ACTIVITIES, as amended by SFAS 137, ACCOUNTING FOR DERIVATIVE INSTRUMENTS AND HEDGING ACTIVITIES--DEFERRAL OF THE EFFECTIVE DATE OF FASB STATEMENT NO. 133, and SFAS 138, ACCOUNTING FOR CERTAIN DERIVATIVE INSTRUMENTS AND CERTAIN HEDGING ACTIVITIES, is effective for Gilead as of January 1, 2001. The standards require that we 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 requires warrants to purchase capital stock of a non-public company which include a net settlement feature to be recorded in the balance sheet at fair value, with an offsetting amount recorded in the results of operations. 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. We have cash flow hedges and warrants in private companies with a net settlement feature covered by SFAS 133. Upon adoption of SFAS 133 on January 1, 2001, we will recognize an aggregate credit to results of operations, recorded as a cumulative change in accounting principle, of approximately \$1.1 million; an increase in net assets of approximately \$1.7 million; and an increase in other comprehensive income of approximately \$0.6 million.

## **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, 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 2002, with a notional amount of \$4.1 million and fair value of \$0.2 million, 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, 2000 (notional amounts and fair values in \$U.S. thousands):

CURRENCY	NOTIONAL AMOUNT	AVERAGE RATE	FAIR VALUE DECEMBER 31, 2000
-----	-----	-----	-----
Australian Dollar.....	\$ 1,499	1.8021	\$ (11)
British Pound.....	5,314	0.6893	(155)
Danish Krone.....	6	8.1678	(6)
Euro.....	37,152	1.1026	(1,451)
Norwegian Krone.....	187	9.2359	(10)
Swedish Krona.....	235	9.5820	(4)
Swiss Franc.....	305	1.7233	(21)
French Franc.....	9,062	7.3891	558

## 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, 2000 (dollars in thousands).

	YEARS ENDING DECEMBER 31,							FAIR VALUE
	2001	2002	2003	2004	2005	THEREAFTER	TOTAL	DECEMBER 31, 2000
ASSETS								
Available-for-sale securities...	\$311,023	\$116,693	\$25,426	--	--	--	\$453,142	\$453,142
Average interest rate.....	6.43%	6.54%	6.18%					
LIABILITIES								
Minimum litigation settlement, including current portion....	\$ 1,178	\$ 1,281	\$ 1,394	\$1,516	\$1,649	\$ 435	\$ 7,453	\$ 7,453
Discount rate.....	8.50%	8.50%	8.50%	8.50%	8.50%	8.50%		
Long-term obligations, including current portion(1).....	\$ 3,420	\$ 2,022	\$ 334	--	--	--	\$ 5,776	\$ 5,776
Average interest rate.....	9.58%	9.95%	11.50%					
Convertible subordinated debentures.....	--	--	--	--	--	\$250,000	\$250,000	\$211,597
Interest rate.....						5.00%		

(1) Long-term obligations consist of capital leases 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 58 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 2001 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 Other 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 96 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:

EXHIBIT FOOTNOTE	EXHIBIT NUMBER	DESCRIPTION OF DOCUMENT
-----	-----	-----
	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.
(24)	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.
(24)	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.
(22)	10.5	Registrant's Employee Stock Purchase Plan, as amended March 30, 1999.
	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.
(5)	10.8	Relocation Loan Agreement, dated as of November 1, 1990 among Registrant, John C. Martin and Rosemary Martin.
(6)	10.9	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.



EXHIBIT FOOTNOTE	EXHIBIT NUMBER	DESCRIPTION OF DOCUMENT
(5)	10.10	Letter Agreement, dated as of September 23, 1991 between Registrant and IOCB/ REGA, with exhibits with certain confidential information omitted.
(6)	10.11	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.
(7)	10.12	Amendment Agreement, dated October 25, 1993 between Registrant and IOCB/ REGA, and related license agreements and exhibits with certain confidential information omitted.
	10.13	Amendment Agreement, dated December 27, 2000 between Registrant and IOCB/ REGA.
(22)	10.14	Patent Rights Purchase Agreement between Registrant and Isis Pharmaceuticals, Inc. dated December 18, 1998 with certain confidential information omitted.
(2)	10.15	Loan Agreement, dated as of October 1, 1994 among Registrant and Mark L. Perry and Melanie P. Pena.
(21)	10.16	Registrant's 1995 Non-Employee Directors' Stock Option Plan, as amended January 26, 1999, and related form of stock option grant.
(8)	10.17	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)	10.18	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)	10.19	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)	10.20	License and Supply Agreement between Registrant and Pharmacia & Upjohn S.A. dated August 7, 1996 with certain confidential information omitted.
(9)	10.21	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.
(22)	10.22	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)	10.23	NeXstar Pharmaceuticals, Inc.'s 1993 Incentive Stock Plan, adopted February 8, 1993, as amended.
(13)	10.24	NeXstar Pharmaceuticals, Inc.'s 1995 Director Option Plan, adopted July 25, 1995.
(14)	10.25	Vestar, Inc. 1988 Stock Option Plan.
(14)	10.26	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.

EXHIBIT FOOTNOTE	EXHIBIT NUMBER	DESCRIPTION OF DOCUMENT
(12)	10.27	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)	10.28	Assignment and Royalty Agreement, dated December 21, 1990, effective as of June 2, 1989, between Vestar, Inc. and City of Hope National Medical Center.
(12)	10.29	License Agreement, effective as of August 12, 1986, between Vestar, Inc. and The Regents of the University of California.
(14)	10.30	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)	10.31	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.
(12)	10.32	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)	10.33	Lease, dated April 13, 1992, between Vestar, Inc. and Majestic Realty Co. and Patrician Associates, Inc.
(12)	10.34	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.
(16)	10.35	Industrial Real Estate Lease, dated July 1, 1996, by and between Wilderness Place, Ltd. and NeXstar Pharmaceuticals, Inc.
(17)	10.36	Sublease Agreement, dated July 31, 1996, between Sybase, Inc. and NeXstar Pharmaceuticals, Inc.
(11)	10.37	License and Distribution Agreement, dated September 26, 1997, by and between Sumitomo Pharmaceuticals Co., Ltd. and NeXstar Pharmaceuticals, Inc. with certain confidential information omitted.
(18)	10.38	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.
(19)	10.39	Amended and Restated Limited Liability Company Agreement of Proligo L.L.C., dated August 15, 1998, by and among NeXstar Pharmaceuticals International, Inc., SKW Americas, Inc. and NeXstar Pharmaceuticals, Inc.
(20)	10.40	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.
(23)	10.41	Office/Light Manufacturing Lease between THW Partners Limited Partnership and Registrant dated January 25, 2000.
	21.1	Subsidiaries of the Registrant.
	23.1	Consent of Ernst & Young LLP, Independent Auditors.
	23.2	Consent of PricewaterhouseCoopers LLP, Independent Auditors.

EXHIBIT FOOTNOTE	EXHIBIT NUMBER	DESCRIPTION OF DOCUMENT
-----	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 June 30, 1996, and incorporated herein by reference.
- (17) Filed as an exhibit to NeXstar Pharmaceuticals, Inc.'s Form 10-Q for the quarterly period ended September 30, 1996, and incorporated herein by reference.
- (18) 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.

(19) Filed as an exhibit to NeXstar Pharmaceuticals, Inc.'s Form 10-Q for the quarter ended September 30, 1998, and incorporated herein by reference.

(20) Filed as an exhibit to NeXstar Pharmaceuticals, Inc.'s Form 10-Q for the quarter ended June 30, 1998, and incorporated herein by reference.

(21) Filed as an exhibit to Registrant's Form 10-K/A for the year ended December 31, 1998, and incorporated herein by reference.

(22) Filed as an exhibit to Registrant's Form 10-K for the year ended December 31, 1998, and incorporated herein by reference.

(23) Filed as an exhibit to Registrant's Form 10-K for the year ended December 31, 1999, and incorporated herein by reference.

(24) Filed as an exhibit to Registrant's Registration Statement on Form S-3 (No. 333-54350), as amended, and incorporated herein by reference.

(b) Reports on Form 8-K

On December 12, 2000, the Registrant filed a Current Report on Form 8-K relating to its intention to sell convertible subordinated notes. On December 14, 2000, the Registrant filed a Current Report on Form 8-K relating to entering into an agreement to sell convertible subordinated notes. On January 12, the Registrant filed a Current Report on Form 8-K relating to entering into an agreement with Cubist Pharmaceuticals, Inc.

**GILEAD SCIENCES, INC.**

**CONSOLIDATED FINANCIAL STATEMENTS**

**YEARS ENDED DECEMBER 31, 2000, 1999 AND 1998**

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## **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, 2000 and 1999, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2000. 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% and 1.7% of consolidated total assets at December 31, 2000 and 1999, respectively, and the Company's equity in the net loss of Proligo L.L.C. is \$2,858,000, \$4,656,000, and \$1,101,000 in 2000, 1999 and 1998, respectively. The 2000, 1999 and 1998 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, 1999 and 1998 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, 2000 and 1999, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2000, 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 Note 2 to the consolidated financial statements, effective January 1, 2000, the Company changed its method of accounting for non-refundable up-front fees received in connection with collaboration agreements.

### **ERNST & YOUNG LLP**

Palo Alto, California  
January 23, 2001

## 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 SHARE AND PER SHARE AMOUNTS)

	DECEMBER 31,	
	2000	1999
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents.....	\$ 197,292	\$ 47,011
Marketable securities.....	315,586	247,383
Accounts receivable, net of allowance for doubtful accounts of \$2,300 in 2000 and \$2,333 in 1999.....	48,814	45,599
Inventories.....	20,562	20,959
Prepaid expenses and other.....	11,544	11,029
	-----	-----
Total current assets.....	593,798	371,981
Property, plant and equipment, net.....	55,174	51,398
Other noncurrent assets.....	29,127	13,429
	-----	-----
	\$ 678,099	\$ 436,808
	=====	=====
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable.....	\$ 11,605	\$ 9,481
Accrued clinical and preclinical expenses.....	9,925	5,467
Accrued compensation and employee benefits.....	9,995	9,901
Other accrued liabilities.....	19,324	15,004
Deferred revenue.....	4,355	4,833
Long-term obligations due within one year.....	3,034	3,191
	-----	-----
Total current liabilities.....	58,238	47,877
Long-term deferred revenue.....	10,730	--
Accrued litigation settlement expenses due after one year...	5,769	6,853
Long-term obligations due after one year.....	2,238	5,253
Convertible subordinated debt.....	250,000	79,533
Commitments and contingencies (see accompanying notes)		
Stockholders' equity:		
Preferred stock, par value \$.001 per share, issuable in series; 5,000,000 shares authorized; none outstanding...	--	--
Common stock, par value \$.001 per share; 100,000,000 shares authorized; 94,287,602 shares issued and outstanding at December 31, 2000 and 88,185,558 shares issued and outstanding at December 31, 1999.....	94	88
Additional paid-in capital.....	857,942	749,037
Accumulated other comprehensive loss.....	(901)	(2,527)
Deferred compensation.....	(3)	(74)
Accumulated deficit.....	(506,008)	(449,232)
	-----	-----
Total stockholders' equity.....	351,124	297,292
	-----	-----
	\$ 678,099	\$ 436,808
	=====	=====

See accompanying notes



**GILEAD SCIENCES, INC.**

**CONSOLIDATED STATEMENTS OF OPERATIONS**

(IN THOUSANDS, EXCEPT PER SHARE AMOUNTS)

	YEAR ENDED DECEMBER 31,		
	2000	1999	1998
Revenues:			
Product sales, net.....	\$149,709	\$139,890	\$114,176
Royalty revenue, net.....	24,591	10,431	7,305
Contract revenue.....	18,315	18,658	29,638
Contract revenue--SAB 101.....	2,940	--	--
Total revenues.....	195,555	168,979	151,119
Expenses:			
Cost of goods sold.....	33,512	29,546	23,357
Research and development.....	131,568	110,212	124,827
Selling, general and administrative.....	82,793	100,080	82,447
Total costs and expenses.....	247,873	239,838	230,631
Loss from operations.....	(52,318)	(70,859)	(79,512)
Gain on sale of a majority interest in a subsidiary.....	--	--	22,132
Interest income.....	17,634	16,435	21,765
Interest expense.....	(4,365)	(6,518)	(7,183)
Loss before provision for income taxes, equity in loss of unconsolidated affiliate and cumulative effect of change in accounting principle.....	(39,049)	(60,942)	(42,798)
Provision for income taxes.....	1,199	888	859
Equity in loss of unconsolidated affiliate.....	(2,858)	(4,656)	(1,101)
Loss before cumulative effect of change in accounting principle.....	(43,106)	(66,486)	(44,758)
Cumulative effect of change in accounting principle.....	(13,670)	--	--
Net loss.....	\$(56,776)	\$(66,486)	\$(44,758)
Basic and diluted net loss per common share:			
Loss before cumulative effect of change in accounting principle.....	\$ (0.47)	\$ (0.78)	\$ (0.55)
Cumulative effect of change in accounting principle.....	(0.15)	--	--
Net loss.....	\$ (0.62)	\$ (0.78)	\$ (0.55)
Pro forma amounts assuming the change in accounting principle had been applied retroactively:			
Net loss.....	\$(43,106)	\$(62,826)	\$(40,098)
Basic and diluted net loss per common share.....	\$ (0.47)	\$ (0.73)	\$ (0.49)
Common shares used to calculate basic and diluted net loss per common share.....	91,050	85,652	82,030

See accompanying notes

**GILEAD SCIENCES, INC.**  
**CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY**  
(IN THOUSANDS, EXCEPT SHARE AMOUNTS)

	PREFERRED STOCK	COMMON STOCK SHARES	AMOUNT	ADDITIONAL PAID-IN CAPITAL	ACCUMULATED OTHER COMPREHENSIVE INCOME (LOSS)	DEFERRED COMPENSATION	ACCUMULATED DEFICIT
Balance at December 31, 1997.....	\$ 1	80,850,434	\$81	\$696,119	\$ (50)	\$ (437)	\$ (337,988)
Net loss.....	--	--	--	--	--	--	(44,758)
Unrealized loss on available-for-sale investments, net.....	--	--	--	--	(301)	--	--
Foreign currency translation adjustment.....	--	--	--	--	14	--	--
Comprehensive loss.....	--	--	--	--	--	--	--
Private issuance of common stock.....	--	728,514	1	9,982	--	--	--
Employee stock purchase plan.....	--	266,808	--	2,879	--	--	--
Option exercises.....	--	1,279,918	1	7,509	--	--	--
Amortization of deferred compensation.....	--	--	--	--	--	212	--
Compensatory stock transactions...	--	--	--	434	--	--	--
Balance at December 31, 1998.....	1	83,125,674	83	716,923	(337)	(225)	(382,746)
Net loss.....	--	--	--	--	--	--	(66,486)
Unrealized loss on available-for-sale investments, net.....	--	--	--	--	(1,602)	--	--
Foreign currency translation adjustment.....	--	--	--	--	(588)	--	--
Comprehensive loss.....	--	--	--	--	--	--	--
Employee stock purchase plan.....	--	200,332	--	3,075	--	--	--
Option exercises, net.....	--	2,506,446	3	26,137	--	--	--
Warrant exercises, net.....	--	64,604	--	80	--	--	--
Conversion of 1,133,786 shares of preferred stock.....	(1)	2,267,572	2	(1)	--	--	--
Conversion of convertible subordinated debentures.....	--	20,930	--	467	--	--	--
Amortization of deferred compensation.....	--	--	--	--	--	151	--
Compensatory stock transactions...	--	--	--	2,356	--	--	--
Balance at December 31, 1999.....	--	88,185,558	88	749,037	(2,527)	(74)	(449,232)
Net loss.....	--	--	--	--	--	--	(56,776)
Unrealized gain on available-for-sale investments, net.....	--	--	--	--	2,071	--	--
Foreign currency translation adjustment.....	--	--	--	--	(445)	--	--
Comprehensive loss.....	--	--	--	--	--	--	--
Employee stock purchase plan.....	--	203,800	--	3,942	--	--	--
Option exercises, net.....	--	2,316,996	2	26,507	--	--	--
Warrant exercises, net.....	--	12,550	--	--	--	--	--
Conversion of convertible subordinated debentures.....	--	3,568,698	4	77,943	--	--	--
Amortization of deferred compensation.....	--	--	--	--	--	71	--
Compensatory stock transactions...	--	--	--	513	--	--	--
Balance at December 31, 2000.....	\$ --	94,287,602	\$94	\$857,942	\$ (901)	\$ (3)	\$ (506,008)

	TOTAL STOCKHOLDERS' EQUITY
Balance at December 31, 1997.....	\$357,726
Net loss.....	(44,758)
Unrealized loss on available-for-sale investments, net.....	(301)
Foreign currency translation adjustment.....	14
Comprehensive loss.....	(45,045)
Private issuance of common stock.....	9,983
Employee stock purchase plan.....	2,879
Option exercises.....	7,510
Amortization of deferred compensation.....	212
Compensatory stock transactions...	434
Balance at December 31, 1998.....	333,699
Net loss.....	(66,486)
Unrealized loss on available-for-sale investments,	

net.....	(1,602)
Foreign currency translation adjustment.....	(588)
	-----
Comprehensive loss.....	(68,676)
Employee stock purchase plan.....	3,075
Option exercises, net.....	26,140
Warrant exercises, net.....	80
Conversion of 1,133,786 shares of preferred stock.....	--
Conversion of convertible subordinated debentures.....	467
Amortization of deferred compensation.....	151
Compensatory stock transactions...	2,356
	-----
Balance at December 31, 1999.....	297,292
Net loss.....	(56,776)
Unrealized gain on available-for-sale investments, net.....	2,071
Foreign currency translation adjustment.....	(445)
	-----
Comprehensive loss.....	(55,150)
Employee stock purchase plan.....	3,942
Option exercises, net.....	26,509
Warrant exercises, net.....	--
Conversion of convertible subordinated debentures.....	77,947
Amortization of deferred compensation.....	71
Compensatory stock transactions...	513
	-----
Balance at December 31, 2000.....	\$351,124
	=====

See accompanying notes

**GILEAD SCIENCES, INC.**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

(IN THOUSANDS)

	YEAR ENDED DECEMBER 31,		
	2000	1999	1998
<b>OPERATING ACTIVITIES:</b>			
Net loss.....	\$ (56,776)	\$ (66,486)	\$ (44,758)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization.....	12,008	12,623	13,231
Net effect of change in accounting principle.....	10,730	--	--
Compensation expense from stock option transactions...	513	2,356	434
Gain on sale of a majority interest in a subsidiary...	--	--	(22,483)
Equity in loss of unconsolidated affiliate.....	2,858	4,656	1,101
Litigation settlement charges.....	667	754	827
Net provision for doubtful accounts.....	30	888	(407)
Reduction in allowance for note receivable.....	--	--	(550)
Net unrealized (gain) loss on foreign currency transactions.....	(1,615)	2,846	(1,628)
Changes in operating assets and liabilities:			
Accounts receivable.....	(3,942)	(7,041)	(6,523)
Inventories.....	397	(4,409)	860
Prepaid expenses and other assets.....	766	(349)	5,298
Long-term prepaid royalties.....	(11,367)	--	--
Accounts payable.....	2,232	1,443	(502)
Accrued liabilities.....	5,775	(11,389)	10,159
Deferred revenue (excluding net effect of change in accounting principle).....	(478)	1,558	(6,383)
Net cash used in operating activities.....	(38,202)	(62,550)	(51,324)
<b>INVESTING ACTIVITIES:</b>			
Purchases of marketable securities.....	(229,862)	(186,997)	(488,407)
Sales of marketable securities.....	29,490	101,943	390,426
Maturities of marketable securities.....	134,240	83,677	166,129
Capital expenditures.....	(15,621)	(12,475)	(11,010)
Proceeds from sale of a majority interest in a subsidiary, net of closing costs.....	--	--	14,652
Investment in unconsolidated affiliate.....	(2,450)	(2,450)	(4,900)
Payments received on note receivable.....	--	--	550
Net cash provided by (used in) investing activities.....	(84,203)	(16,302)	67,440
<b>FINANCING ACTIVITIES:</b>			
Proceeds from issuances of common stock.....	30,451	29,295	20,372
Payments on short-term borrowings, net.....	--	--	(5,102)
Proceeds from issuance of long-term debt.....	--	74	4,478
Repayments of long-term debt.....	(3,156)	(5,394)	(6,606)
Proceeds from issuance of convertible subordinated notes, net of issuance costs.....	241,750	--	--
Net cash provided by financing activities.....	269,045	23,975	13,142
Effect of exchange rate changes on cash.....	3,641	752	573
Net increase (decrease) in cash and cash equivalents.....	150,281	(54,125)	29,831
Cash and cash equivalents at beginning of year.....	47,011	101,136	71,305
Cash and cash equivalents at end of year.....	\$ 197,292	\$ 47,011	\$ 101,136
	=====	=====	=====

See accompanying notes

**GILEAD SCIENCES, INC.**

**CONSOLIDATED STATEMENTS OF CASH FLOWS (CONTINUED)**

(IN THOUSANDS)

	YEAR ENDED DECEMBER 31,		
	2000	1999	1998
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:			
Interest paid.....	\$ 5,417	\$ 6,234	\$ 6,793
Income taxes paid.....	493	527	790
DISCLOSURES OF GAIN ON SALE OF A MAJORITY INTEREST IN A SUBSIDIARY:			
Cash receipts, net of closing costs.....	\$ --	\$ --	\$ 14,652
Receipt of 49% interest in manufacturing facility.....	--	--	5,500
Net present value of guaranteed payments.....	--	--	2,668
Other.....	--	--	63
Net book value of 51% interest sold.....	--	--	(751)
	\$ --	\$ --	\$ 22,132
NON-CASH INVESTING AND FINANCING ACTIVITIES			
Purchase of equipment and leasehold improvements through accounts payable.....	\$ 48	\$ 124	\$ 757
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, 2000

### 1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

#### OVERVIEW

Gilead Sciences, Inc. (the "Company" or "Gilead") was incorporated in Delaware on June 22, 1987, and is an independent biopharmaceutical company that seeks to provide accelerated solutions for patients and the people who care for them. The Company discovers, develops, manufactures and commercializes proprietary therapeutics for challenging infectious diseases (viral, fungal and bacterial infections) and cancer. Gilead also has expertise in liposomal drug delivery technology. Currently, the Company markets AmBisome-Registered Trademark- (amphotericin B) liposome for injection), an antifungal agent, DaunoXome-Registered Trademark- (daunorubicin citrate liposome injection), a drug approved for the treatment of Kaposi's Sarcoma, and VISTIDE-Registered Trademark- (cidofovir injection) for the treatment of cytomegalovirus ("CMV") retinitis. Hoffmann-La Roche, Inc. markets Tamiflu-TM- (oseltamivir phosphate) for the treatment of influenza, under a collaborative agreement with Gilead. In addition, Gilead is developing products to treat diseases caused by human immunodeficiency virus ("HIV") and hepatitis B virus ("HBV"), bacterial infections and cancer.

As more fully described in Note 3, 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, Gilead completed a two-for-one stock split, effected in the form of a stock dividend, to stockholders of record as of February 2, 2001. Accordingly, all share and per share amounts for all periods presented have been restated to retroactively reflect the split.

#### 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 ("SAB 101"), "REVENUE RECOGNITION IN FINANCIAL STATEMENTS", resulting in a cumulative effect of a change in accounting principle. See Note 2.

#### USE OF ESTIMATES

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ from those estimates.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

DECEMBER 31, 2000

**1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED) 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. Provisions are made for doubtful accounts, estimated product returns, cash discounts and government discounts and rebates.

In connection with most of its European product sales, the Company prices its products in the currency of the country into which they are sold ("Payment Currencies"). A significant majority of the Company's manufacturing costs are in U.S. Dollars. Therefore, any decline in the value of the Payment Currencies relative to the U.S. Dollar is likely to negatively impact gross margins since the Company's manufacturing costs would remain approximately the same while its revenue in terms of U.S. Dollars would decline. Periodically, the Company's gross margin is adversely affected by such currency fluctuations.

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 based on a substantive risk assessment.

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**

All R&D costs, including those funded by third parties, are charged to expense as incurred.

**STOCK-BASED COMPENSATION**

In accordance with the provisions of Statement of Financial Accounting Standards ("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 related interpretations 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

# GILEAD SCIENCES, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

DECEMBER 31, 2000

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED) underlying stock on the date of grant, no compensation expense is recognized. See Note 12 for pro forma disclosures of stock-based compensation pursuant to SFAS 123.

In March 2000, the Financial Accounting Standards Board ("FASB") issued Interpretation No. 44 ("FIN 44"), "Accounting for Certain Transactions Involving Stock Compensation--an Interpretation of APB Opinion No. 25." FIN 44 clarifies the application of APB 25 with respect to stock-related compensation. Gilead's adoption of FIN 44 on July 1, 2000, did not have a material effect on the financial position or results of operations of Gilead.

### BASIC AND DILUTED LOSS PER COMMON SHARE

For all periods presented, both basic and diluted loss per common share are computed based on the weighted average number of common shares outstanding during the period. Convertible notes, stock options and warrants could potentially dilute basic earnings per share in the future, but these instruments, 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. All share and per share amounts for all periods presented have been restated to retroactively reflect the two-for-one stock split of February 22, 2001.

### 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 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 Gilead's marketable debt securities at the time of purchase and reevaluates such designation at each balance sheet date. All of the Company's marketable debt 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, 2000, cash and cash equivalents include \$137.6 million of securities designated as available-for-sale (\$14.3 million at December 31, 1999). 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.

### 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



# GILEAD SCIENCES, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

DECEMBER 31, 2000

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED) 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. 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 the Company's European subsidiaries and export sales to its distributors in Europe. The Company performs credit evaluations of its customers' financial condition and generally has not required collateral. To date, the Company has experienced only modest credit losses with respect to its 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:

DESCRIPTION -----	ESTIMATED USEFUL LIFE (IN YEARS) -----
Buildings.....	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, 2000 includes \$11.4 million (including withholding taxes of approximately \$0.4 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 5. Also included in other noncurrent assets at December 31, 2000 are deferred debt issuance costs of \$8.2 million related to the \$250.0 million 5% subordinated convertible notes Gilead issued in December 2000. Other noncurrent assets at

# **GILEAD SCIENCES, INC.**

## **NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

DECEMBER 31, 2000

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED) December 31, 1999 included \$1.4 million of deferred debt issuance costs related to the 6.25% subordinated convertible debentures. Gilead called the debentures for redemption in August 2000, at which time they were converted to Gilead common stock. Upon the conversion, the remaining balance of the deferred debt issuance costs of the debentures was charged to additional paid in capital.

### **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, 2000 and December 31, 1999, other accrued liabilities included \$2.4 million of accrued litigation settlement costs. See the Legal Proceedings discussion in Note 11.

### **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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

DECEMBER 31, 2000

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED) as a selling, general and administrative expense in the consolidated statements of operations. Such losses were \$0.5 million in 2000, \$0.5 million in 1999 and \$0.3 million in 1998.

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 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. The Company recognizes 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 are deferred and reported as a component of the related transaction in the period in which it occurs. At December 31, 2000, the Company has net unrealized losses on its open foreign exchange forward contracts of \$1.1 million.

The Company had forward exchange contracts outstanding of \$53.8 million at December 31, 2000 and \$42.9 million at December 31, 1999. These 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 2002, with a notional amount of \$4.1 million, and fair value of \$0.2 million, has a maturity of thirteen months.

The Company presently does not hedge its net investment in any of its foreign subsidiaries or its forecasted foreign currency denominated sales.

**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, 2000 was \$211.6 million, and the carrying value was \$250 million. The fair value of notes

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

DECEMBER 31, 2000

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED) was determined 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. The fair value of Gilead's prior convertible subordinated debentures, which were redeemed and converted to Gilead common stock in the third quarter of 2000, was \$101.8 million at December 31, 1999, and the carrying value was \$79.5 million at that date. The fair value of the debentures at December 31, 1999 was determined by obtaining a quote from a market maker for the debentures.

**PROSPECTIVE ACCOUNTING PRONOUNCEMENT**

Statement of Financial Accounting Standards No. 133 ("SFAS 133"), ACCOUNTING FOR DERIVATIVE INSTRUMENTS AND HEDGING ACTIVITIES, as amended by SFAS 137, ACCOUNTING FOR DERIVATIVE INSTRUMENTS AND HEDGING ACTIVITIES--DEFERRAL OF THE EFFECTIVE DATE OF FASB STATEMENT NO. 133, and SFAS 138, ACCOUNTING FOR CERTAIN DERIVATIVE INSTRUMENTS AND CERTAIN HEDGING ACTIVITIES, is effective for the Company as of January 1, 2001. The standards require that the Company 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 require warrants to purchase capital stock of a non-public company which include a net settlement feature to be recorded in the balance sheet at fair value, with an offsetting amount recorded in the results of operations. 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 has cash flow hedges and warrants in private companies with a net settlement feature covered by SFAS 133. Upon adoption of SFAS 133 on January 1, 2001, Gilead will recognize an aggregate credit to results of operations, recorded as a cumulative change in accounting principle, of approximately \$1.1 million; an increase in net assets of approximately \$1.7 million; and an increase in other comprehensive income of approximately \$0.6 million.

**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.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

DECEMBER 31, 2000

2. CUMULATIVE CHANGE IN ACCOUNTING PRINCIPLE (CONTINUED) 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 accounting principle was to increase the net loss by \$10.7 million, or \$0.12 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. The remainder of the \$10.7 million related deferred revenue balance as of December 31, 2000, is expected to be recognized as revenue in fiscal years 2001 through 2012. The pro forma results included in the Consolidated Statements of Operations reflect amounts that would have been reported if the change in accounting principle had been applied retroactively.

## 3. ACQUISITION OF NEXSTAR

On July 29, 1999, the Company acquired all of the outstanding common stock of NeXstar, a Delaware corporation, 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 22.4 million shares of Gilead common stock, or 0.1893 of a share of Gilead common stock for each share of NeXstar 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 3.6 million shares of Gilead common stock. The Merger qualified as a tax-free reorganization and was accounted for as a pooling of interests.

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

	GILEAD	NEXSTAR	MERGER-RELATED ADJUSTMENTS	TOTAL
	-----	-----	-----	-----
Year ended December 31, 1999				
Revenues.....	\$ 24,659	\$144,320	\$ --	\$168,979
Net income (loss).....	(73,534)	25,351	(18,303) (a)	(66,486)
Year ended December 31, 1998				
Revenues.....	\$ 32,570	\$118,549	\$ --	\$151,119
Net income (loss).....	(56,075)	10,920	397 (b)	(44,758)

(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.

**GILEAD SCIENCES, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

DECEMBER 31, 2000

3. ACQUISITION OF NEXSTAR (CONTINUED) 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):

	CHARGED TO EXPENSE THROUGH DECEMBER 31, 1999	UTILIZED	DECEMBER 31, 1999 ACCRUAL BALANCE
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.....	\$18,303	\$15,261	\$2,506
	=====	=====	=====

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.

4. 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, 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.....	\$452,630	\$947	\$ (435)	\$453,142
	=====	=====	=====	=====
DECEMBER 31, 1999	-----	-----	-----	-----
U.S. treasury securities and obligations of U.S. government agencies.....	\$133,444	\$512	\$ (1,243)	\$132,713
Certificates of deposit.....	5,309	1	--	5,310
Corporate debt securities.....	70,726	19	(583)	70,162
Asset-backed securities.....	39,554	2	(266)	39,290
Other debt securities.....	14,256	--	--	14,256
	-----	-----	-----	-----
Total.....	\$263,289	\$534	\$ (2,092)	\$261,731
	=====	=====	=====	=====

# GILEAD SCIENCES, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

DECEMBER 31, 2000

### 4. AVAILABLE-FOR-SALE SECURITIES (CONTINUED)

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,		
	2000	1999	1998
Proceeds from sales.....	\$29,490	\$101,943	\$390,426
Gross realized gains on sales.....	\$ 62	\$ 92	\$ 1,127
Gross realized losses on sales.....	\$ (146)	\$ (475)	\$ (654)

At December 31, 2000, \$267.0 million of the Company's portfolio of marketable securities (excluding \$44.0 million of asset-backed securities) has a contractual maturity of less than one year and \$142.1 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.

### 5. COLLABORATIVE ARRANGEMENTS AND CONTRACTS

#### EYETECH

In March 2000, Gilead entered into an agreement with EyeTech Pharmaceuticals, Inc. relating to Gilead's proprietary aptamer NX 1838. Currently in early clinical trials, NX 1838 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 NX 1838, 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 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 is being 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 will be recognized as revenue in the first quarter of 2001. Gilead is also entitled to additional cash payments from EyeTech of up to \$25.0 million if and when EyeTech reaches certain NX 1838 development milestones. Additionally, Gilead received a 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. Gilead is obligated to transfer 5% of the shares subject to the warrant to the University of Colorado at Boulder under a collaborative agreement with the university, and Gilead expects to retain the remaining 791,667 shares. Gilead did not recognize revenue related to the warrant as there was no readily determinable fair value at the time of the transaction. See the Prospective Accounting Pronouncement caption under Note 1 for a description of the future accounting treatment of the warrant.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

DECEMBER 31, 2000

**5. COLLABORATIVE ARRANGEMENTS AND CONTRACTS (CONTINUED) 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 \$13.5 million in 2000, \$8.3 million in 1999 and \$4.8 million in 1998.

**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 licensing fee from Sumitomo was recognized as contract revenue in 2000. The remaining \$3.4 million of related deferred revenue at December 31, 2000, 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. In 1996, Roche made an initial license fee payment to Gilead of \$10.3 million. Upon achieving certain



NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

DECEMBER 31, 2000

5. COLLABORATIVE ARRANGEMENTS AND CONTRACTS (CONTINUED) developmental milestones in 1997, Gilead earned cash payments of \$6.0 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.

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, and 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, 2000.

As of December 31, 2000, Gilead is entitled to additional cash payments from Roche of up to \$11.6 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, and recorded a total of \$9.6 million of Tamiflu royalties in the year 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 reimbursements related to the Roche Agreement of approximately \$0.9 million in 2000, \$2.1 million in 1999 and \$16.4 million in 1998. The \$16.4 million recorded as revenue during 1998 included \$5.2 million attributable to R&D expenses incurred in the fourth quarter of 1997, which were subject to Roche's approval as of December 31, 1997. Such expenses were approved for reimbursement and recognized in contract revenue in 1998. Except for this \$5.2 million, 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.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

DECEMBER 31, 2000

**5. COLLABORATIVE ARRANGEMENTS AND CONTRACTS (CONTINUED)** 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.

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 the Company issued and 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 2,267,572 shares of common stock in 1999. For additional information about the preferred stock, see Note 12.

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, 2000, the Company has recorded on its balance sheet approximately \$2.2 million of such deferred revenue (\$3.7 million at December 31, 1999). The Company recognized royalty revenue from sales of VISTIDE outside of the United States by Pharmacia of \$1.5 million in 2000, \$2.0 million in 1999 and \$1.7 million in 1998.

**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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

DECEMBER 31, 2000

5. COLLABORATIVE ARRANGEMENTS AND CONTRACTS (CONTINUED) 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, 2000, 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.

**ISIS PHARMACEUTICALS**

In December 1998, Gilead and Isis Pharmaceuticals, Inc. ("Isis") entered into an agreement under which Gilead sold to Isis certain intellectual property, including patents and patent applications covering antisense chemistry and antisense drug delivery systems. Under the terms of the agreement, Isis is required to pay to Gilead a total of \$6.0 million in four nonrefundable installments. The first installment of \$2.0 million was paid to Gilead in December 1998, the second installment of \$1.0 million was paid in December 1999, the third installment of \$1.0 million was paid in December 2000, and remaining \$2.0 million is payable in December 2001. The total sale price of \$6.0 million was included in contract revenue for the year ended December 31, 1998. Gilead has no ongoing research or funding obligations under the agreement.

**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 is developing GS 7904L in a liposome and is evaluating it in preclinical studies. Under this agreement, Gilead has exclusive worldwide rights to develop and commercialize GS 7904L for all indications other than malaria. Gilead paid Glaxo an upfront fee which was included in R&D expense in 2000, and may be required to make additional payments to Glaxo if certain developmental goals related to regulatory approval are achieved. Additionally, if the product is successfully commercialized, Gilead would be required to pay Glaxo a percentage of the product's net sales. The agreement expires ten years after the first commercial sale of the product or the date the last related patent expires.

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 the 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 728,514 shares of Gilead common stock for \$10.0 million in a private offering. In December 2000, the collaboration and license agreement was

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

DECEMBER 31, 2000

5. COLLABORATIVE ARRANGEMENTS AND CONTRACTS (CONTINUED) 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 exchange, Gilead agreed to increase milestone payments to Glaxo upon achieving certain regulatory approvals.

In July 1990, Gilead entered into a collaborative research agreement with Glaxo with respect to Gilead's antisense technology. Under the terms of the Glaxo agreement, as amended over time, the Company received \$1.8 million in 1998, which was reported as contract revenue, to fund research. The R&D costs reimbursed by Glaxo approximate the related revenue and are included in R&D expense. This agreement and the related funding were terminated in June 1998.

**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 compounds covered by the agreement include cidofovir, adefovir dipivoxil and tenofovir DF, but exclude Tamiflu or other compounds that Gilead has in clinical development. Gilead currently makes quarterly payments to IOCB/REGA based on a percentage of VISTIDE sales. If marketing approval is received from the FDA for adefovir dipivoxil or tenofovir DF, Gilead would be obligated to pay additional amounts to IOCB/REGA upon future sales of these products.

In December 2000, the agreements with IOCB/REGA were amended to provide for a reduced royalty rate on future sales of adefovir dipivoxil or tenofovir DF, in return for a upfront payment from Gilead of \$11.0 million (plus withholding taxes of approximately \$0.4 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, 2000. It will be recognized as royalty expense over the expected commercial life of the related products when and if FDA approval is obtained and sales of the products commence.

**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 is evaluating in preclinical studies. Under the terms of the agreement, Gilead paid Southern Research Institute an up-front fee, which is included in R&D expense in 2000, and may be required to make additional payments to Southern Research Institute if Gilead achieves certain development and regulatory goals. Gilead would also be required to pay Southern Research Institute royalties on net sales of GS 7836 if the product is successfully commercialized.

**GILEAD SCIENCES, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

DECEMBER 31, 2000

**6. INVENTORIES**

Inventories are summarized as follows (in thousands):

	DECEMBER 31,	
	2000	1999
Raw materials.....	\$ 9,647	\$10,703
Work in process.....	7,781	6,793
Finished goods.....	3,134	3,463
	\$20,562	\$20,959
	=====	=====

**7. PROPERTY, PLANT AND EQUIPMENT**

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

	DECEMBER 31,	
	2000	1999
Building and improvements (including leasehold improvements).....	\$ 55,877	\$ 46,597
Laboratory and manufacturing equipment.....	34,167	27,204
Office and computer equipment.....	21,511	20,127
Capitalized leased equipment.....	13,530	16,042
Construction in progress.....	2,961	5,540
	128,046	115,510
Less accumulated depreciation and amortization.....	(72,872)	(64,112)
	\$ 55,174	\$ 51,398
	=====	=====

**8. INVESTMENT IN UNCONSOLIDATED AFFILIATE**

In late 1997, the Company established its NeXstar Technology Products division which included the Company's proprietary technology called Product Anchored Sequential Synthesis ("PASS"), a method of synthesizing the oligonucleotides that are the basis for the products being developed using the SELEX process. 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 (the "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 (the "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

**GILEAD SCIENCES, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

DECEMBER 31, 2000

8. INVESTMENT IN UNCONSOLIDATED AFFILIATE (CONTINUED) four years. Gilead received \$0.1 million of the guaranteed payments from SKW in 2000, and \$2.6 million in 1999. In 1999, Gilead also received a performance-based milestone payment of \$1.0 million which 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 \$0.1 million in 2000 and \$0.4 million in 1999. The purchases were charged to R&D expense.

The Company accounts 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 \$7.6 million at December 31, 1999, and is reported in other noncurrent assets on the Company's consolidated balance sheets. In 2000, Gilead 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. In 1998, the Company recorded its equity in the loss of Proligo of \$1.1 million for the period from August 15, 1998 through November 30, 1998.

In January 2000, Gilead made an additional cash investment in Proligo of \$2.5 million to maintain its 49% ownership interest in Proligo. In October 1999, Gilead also made a \$2.5 million cash investment in Proligo to maintain its 49% ownership interest. Gilead has no commitments to provide additional funding to Proligo.

**9. LONG-TERM OBLIGATIONS**

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

	DECEMBER 31,	
	2000	1999
Capital lease obligations: Monthly installments; interest rates ranging from 6.89% to 11.50%.....	\$3,512	\$5,681
Fixed rate debt: Monthly installments through 2003; secured by equipment; interest rates ranging from 11.49% to 12.56%.....	1,760	2,763
Total long-term obligations.....	5,272	8,444
Less current portion.....	(3,034)	(3,191)
Long-term obligations due after one year.....	\$2,238	\$5,253
	=====	=====

# GILEAD SCIENCES, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

DECEMBER 31, 2000

### 9. LONG-TERM OBLIGATIONS (CONTINUED)

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

YEAR	
----	
2001.....	\$3,420
2002.....	2,022
2003.....	334
	-----
	\$5,776
Less amount representing interest.....	(504)
	-----
Total.....	\$5,272
	=====

The terms of the various debt agreements require the Company to comply with certain financial and operating covenants. At December 31, 2000, the Company was in compliance with all such covenants.

### 10. 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 5,089,058 shares of Gilead common stock at \$49.125 per share. The \$49.125 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 3,589,688 shares of Gilead common stock at \$22.285 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 3,567,578 newly issued shares of Gilead common stock prior to 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.

**GILEAD SCIENCES, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

DECEMBER 31, 2000

**11. 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 and Boulder, Colorado. Leases in Foster City and San Dimas expire on various dates in 2003 and 2006; and leases in Boulder expire in 2001 and 2005. 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 \$8.6 million in 2000, \$7.9 million in 1999 and \$6.8 million in 1998.

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, 2000, no additional amounts were available under these agreements.

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):

YEARS ENDING DECEMBER 31, -----	OPERATING LEASES, NET OF NONCANCELABLE SUBLEASES -----	CAPITAL LEASES -----
2001.....	\$ 7,675	\$ 2,450
2002.....	9,149	1,296
2003.....	9,060	23
2004.....	5,875	--
2005.....	5,808	--
Thereafter.....	1,817	--
	-----	-----
	\$39,384	3,769
	=====	
Less amount representing interest.....		(257)
		-----
Total capital lease obligations.....		3,512
Less current portion.....		(2,228)
		-----
Capital lease obligations due after one year.....		\$ 1,284
		=====

The Company has placed \$0.5 million in a bank escrow deposit to secure aggregate future payments due under one of its facilities leases. At December 31, 2000, a total of \$0.5 million was secured under this deposit.

**CONTINGENT LIABILITY**

In connection with the August 1998 sale of a majority interest in its Proligo subsidiary, as described in Note 8, the Company transferred certain property and equipment with a net book value of



NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

DECEMBER 31, 2000

11. COMMITMENTS AND CONTINGENCIES (CONTINUED) \$4.5 million to Proligo. The majority of such property and equipment is financed or leased by the Company in accordance with the capital leases described above. Concurrent with this transfer of property and equipment, the Company transferred the underlying debt to Proligo pursuant to various Sublease, Consent and Assignment Agreements (collectively, the "Sublease Agreements"). As a result, the Company is required to pay the debt financing and lease liabilities to the financial institutions and lessors directly for Proligo's share of the liabilities. Proligo is required to reimburse the Company for these amounts and is bound by the same terms and conditions as those in the Company's agreements with the financial institutions and lessors. If Proligo were to default on its obligations under the Sublease Agreements, the Company would continue to be liable for amounts outstanding as of the date of the default. However, in this event, SKW would be obligated to reimburse the Company for 51% of such amounts paid. At December 31, 2000, Proligo was current with respect to its reimbursements to the Company and the balance of Proligo's future lease and debt obligations under the Sublease Agreements was \$1.1 million.

Additionally, the Company and Proligo entered into Assignment, Assumption and Consent Agreements ("Agreements") with the landlords of two laboratory facilities Proligo occupies. Under the Agreements, Proligo has assumed the obligations to the landlords, but the Company remains contingently liable in the event of default. The total unpaid amount of such operating lease commitments as of December 31, 2000 was approximately \$0.2 million.

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 subleases as of December 31, 2000 is \$2.1 million.

**LINE OF CREDIT**

In September 1997, the Company entered into an unsecured bank line of credit for \$10.0 million. Under the terms of the line of credit, the Company is required to maintain certain financial ratios and was in compliance with all required ratios at December 31, 2000. There are also limitations on the Company's ability to incur additional debt or to engage in certain significant transactions. The Credit Agreement, which includes a foreign exchange facility, was renegotiated as of December 31, 1999 and was subsequently extended until April 2001. There were no amounts outstanding under this agreement as of either December 31, 2000 or 1999.

**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 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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

DECEMBER 31, 2000

11. COMMITMENTS AND CONTINGENCIES (CONTINUED) 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.

**12. STOCKHOLDERS' EQUITY**

**STOCK SPLIT**

On February 22, 2001, Gilead completed a two-for-one stock split, effected in the form of a stock dividend, to stockholders of record as of February 2, 2001. Accordingly, all share and per share amounts for all periods presented have been restated to retroactively reflect the split.

**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 \$24.90. 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 2,267,572 shares of common stock at a price of \$17.64 per share on July 16, 1999. There was no preferred stock outstanding as of December 31, 2000.

**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 3,160,000 shares of common stock have been reserved for issuance under the ESPP. As of December 31, 2000, 1,966,366 shares of the total shares reserved had been issued under the ESPP (1,762,566 shares as of December 31, 1999).

Emerging Issues Task Force ("EITF") Issue No. 97-12, ACCOUNTING FOR INCREASED SHARE AUTHORIZATIONS IN AN IRS SECTION 423 EMPLOYEE STOCK PURCHASE PLAN UNDER APB OPINION NO. 25, provides that new shares authorized under existing Section 423 employee stock purchase plans may give rise to

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

DECEMBER 31, 2000

12. STOCKHOLDERS' EQUITY (CONTINUED) compensation expense under circumstances specified in that accounting standard. During 1998, Gilead recognized compensation expense of \$0.4 million related to an ESPP share authorization approved in 1998 in accordance with the provisions of EITF Issue No. 97-12. In future years, the Company will not be required to recognize additional compensation expense related to the 1998 share authorization.

**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 2000 the shareholders approved an Amendment to the 1991 Plan that increased the total number of authorized shares under the plan from 20,000,000 to 21,500,000. At December 31, 2000, there were 5,918,370 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, 2000, there were 390,000 shares available for grant of future options under the Directors' Plan.

NeXstar's stock plans 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. Options outstanding under the 1995 Director Option Plan became fully vested at the close of the Merger and are exercisable for a period of 24 months thereafter. 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

**GILEAD SCIENCES, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

DECEMBER 31, 2000

12. STOCKHOLDERS' EQUITY (CONTINUED) exercise price based on the fair value of the stock on the exercise date. During 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 \$0.5 million in 2000 and \$2.3 million in 1999. Of the 2000 amount, \$0.4 million relates to exercised options and the remaining \$0.1 million relates to options that remain outstanding under the 1988 Plan at December 31, 2000.

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, 2000. 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,					
	2000		1999		1998	
	SHARES	WEIGHTED AVERAGE EXERCISE PRICE	SHARES	WEIGHTED AVERAGE EXERCISE PRICE	SHARES	WEIGHTED AVERAGE EXERCISE PRICE
Outstanding, beginning of year.....	11,262	\$16.68	11,312	\$12.19	10,492	\$11.18
Granted.....	3,032	34.37	3,338	27.42	2,856	13.75
Forfeited.....	(1,104)	21.98	(742)	16.81	(756)	15.60
Exercised.....	(2,354)	11.58	(2,646)	10.76	(1,280)	5.87
Outstanding, end of year.....	10,836	\$22.18	11,262	\$16.68	11,312	\$12.19
Exercisable, end of year.....	4,226	\$14.63	4,552	\$11.28	5,036	\$10.26
Weighted average fair value of options granted...		\$22.50		\$16.77		\$ 7.73

The following is a summary of Gilead options outstanding and options exercisable at December 31, 2000 (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
\$0.30-\$13.06.....	3,226	5.39	\$ 9.99	2,142	\$ 9.18
\$13.13-\$22.12.....	2,668	5.92	\$16.85	1,554	\$16.80
\$22.13-\$29.63.....	2,882	8.71	\$28.73	348	\$28.54
\$30.03-\$49.38.....	2,060	9.24	\$39.01	182	\$33.66
Total.....	10,836	7.14	\$22.18	4,226	\$14.63

**PRO FORMA DISCLOSURES**

The table below presents the combined net loss and basic and diluted net loss per common share if compensation cost for the Gilead and NeXstar stock option plans and the ESPP had been

**GILEAD SCIENCES, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

DECEMBER 31, 2000

12. STOCKHOLDERS' EQUITY (CONTINUED) determined based on the estimated fair value of awards under those plans on the grant or purchase date.

	YEAR ENDED DECEMBER 31,		
	2000	1999	1998
Pro forma net loss (in thousands).....	\$(91,775)	\$(93,816)	\$(61,444)
Pro forma basic and diluted net loss per share.....	\$ (1.01)	\$ (1.10)	\$ (0.75)

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,		
	2000	1999	1998
Expected life in years (from vesting date):			
Stock options.....	1.88	1.86	1.44 to 1.78
ESPP.....	1.45	1.21	1.51
Discount rate:			
Stock options.....	6.3%	5.6%	4.7% to 5.5%
ESPP.....	5.5%	5.0%	5.2%
Volatility(1).....	84%	67%	66%
Expected dividend yield.....	0%	0%	0%

(1) NeXstar's volatility rate for 1998 was 61%.

The weighted average estimated fair value of ESPP shares purchased was \$12.12 for 2000, \$8.11 for 1999 and \$5.99 for 1998.

**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 held of record at the close of business on December 14, 1994. 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 an exercise price 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 \$.005 per purchase right. The purchase rights have no voting privileges and are attached to and automatically trade with Gilead common stock.

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

**GILEAD SCIENCES, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

DECEMBER 31, 2000

12. STOCKHOLDERS' EQUITY (CONTINUED) plan from \$30 to \$200 and an extension of the term of the plan from November 21, 2004 to October 20, 2009.

13. COMPREHENSIVE INCOME

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,		
	2000	1999	1998
Net gain (loss) on sales of securities included in interest income.....	\$ (84)	\$ (383)	\$ 473
	=====	=====	=====
Other comprehensive income:			
Net unrealized gain (loss) arising during the year.....	\$1,987	\$ (1,985)	\$ 172
Reclassification adjustment.....	84	383	(473)
	-----	-----	-----
Net unrealized gain (loss) reported in other comprehensive income.....	\$2,071	\$ (1,602)	\$ (301)
	=====	=====	=====

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

	DECEMBER 31,	
	2000	1999
Net unrealized gain (loss) on available-for-sale securities.....	\$ 512	\$ (1,559)
Cumulative loss on foreign currency translation.....	(1,413)	(968)
	-----	-----
Accumulated other comprehensive loss.....	\$ (901)	\$ (2,527)
	=====	=====

**GILEAD SCIENCES, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

DECEMBER 31, 2000

**14. 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.

Product sales revenues consisted of the following (in thousands):

	YEAR ENDED DECEMBER 31,		
	2000	1999	1998
AmBisome.....	\$141,118	\$129,177	\$103,430
DaunoXome.....	4,354	4,775	4,672
VISTIDE.....	4,237	5,938	6,074
	\$149,709	\$139,890	\$114,176
	=====	=====	=====

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,		
	2000	1999	1998
United States.....	\$ 37,476	\$ 28,389	\$ 23,601
United Kingdom.....	23,827	19,259	17,241
Switzerland.....	21,531	15,763	16,400
Germany.....	21,340	21,647	22,254
Italy.....	16,978	16,293	13,420
Spain.....	15,074	14,625	11,934
France.....	9,528	8,347	4,993
Other European countries.....	32,053	31,500	27,036
Other countries.....	17,748	13,156	14,240
	\$195,555	\$168,979	\$151,119
	=====	=====	=====

At December 31, 2000, the net book value of the Company's property, plant and equipment was \$55.2 million. Approximately 95% of such assets were located in the United States. At December 31, 1999, the net book value of property, plant and equipment was \$51.4 million, and approximately 93% of such assets were located in the United States.

Product sales to one distributor accounted for approximately 12% of total revenues in 2000, 11% in 1999 and 10% in 1998. Total revenues from Fujisawa Healthcare, Inc., which included product sales and royalties, were approximately 13% of total revenues in 2000, 11% in 1999 and less than 10% in 1998. Revenues from Roche, including royalties, milestone payments and reimbursement of research and development expenses, accounted for approximately 11% of total revenues in 2000, 9% in 1999 and 11% in 1998.

**GILEAD SCIENCES, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

DECEMBER 31, 2000

**15. INCOME TAXES**

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

	YEAR ENDED DECEMBER 31,		
	2000	1999	1998
Current provision:			
Federal.....	\$ --	\$ 65	\$160
State.....	21	30	21
Foreign.....	1,178	793	678
	-----	-----	-----
	\$1,199	\$888	\$859
	=====	=====	=====

Foreign pre-tax (loss) income was \$(40.3) million in 2000, \$2.0 million in 1999 and \$0.1 million in 1998.

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):

	YEAR ENDED DECEMBER 31,		
	2000	1999	1998
Loss before provision for income taxes, equity in loss of unconsolidated affiliate and the cumulative effect of a change in accounting principle.....	\$(39,049)	\$(60,942)	\$(42,798)
	=====	=====	=====
Tax at federal statutory rate.....	\$(13,277)	\$(20,720)	\$(14,552)
Unbenefitted losses.....	13,617	21,074	14,698
Other.....	859	534	713
	-----	-----	-----
	\$ 1,199	\$ 888	\$ 859
	=====	=====	=====

At December 31, 2000, the Company had U.S. federal net operating loss carryforwards of \$484.3 million and state net operating loss carryforwards of \$33.0 million. The federal net operating loss carryforwards will expire at various dates beginning in 2002 through 2020, if not utilized. The state net operating loss carryforwards will expire at various dates from 2001 through 2013, if not utilized. Utilization of net operating losses 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.

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



**GILEAD SCIENCES, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

DECEMBER 31, 2000

15. INCOME TAXES (CONTINUED) purposes. Significant components of the Company's deferred tax assets and liabilities as of December 31, 2000 and 1999 are as follows (in thousands):

	DECEMBER 31,	
	2000	1999
Net operating loss carryforwards.....	\$ 166,500	\$ 144,600
Research and other credits.....	35,400	27,400
Capitalized R&D for California.....	17,100	14,800
Other, net.....	9,600	7,400
Total deferred tax assets.....	228,600	194,200
Valuation allowance.....	(228,600)	(194,200)
Net deferred tax assets recognized.....	\$ --	\$ --
	=====	=====

The valuation allowance increased by \$34.4 million for the year ended December 31, 2000, and by \$23.6 million for the year ended December 31, 1999. Approximately \$42.5 million of the valuation allowance at December 31, 2000 relates to the tax benefits of stock option deductions, which will be credited to additional paid-in capital when realized.

16. RETIREMENT SAVINGS PLAN

As of December 31, 2000, Gilead maintained two separate retirement savings plans under which eligible employees may defer compensation for income tax purposes under Section 401(k) of the Internal Revenue Code of 1986. One plan primarily covers NeXstar employees ("NeXstar Plan"), and the other plan primarily covers Gilead's remaining eligible employees ("Gilead Plan"). Under the NeXstar Plan, employee contributions may not exceed 15% of eligible annual compensation. In addition, the NeXstar Plan includes a Company match of 50% of employee contributions up to a maximum of 6% of eligible annual compensation 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 February 1995, contributions to the NeXstar Plan may not be invested in the Company's common stock. 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 NeXstar Plan and the Gilead Plan was \$0.9 million in 2000. The Company's matching contribution related to the NeXstar Plan was \$0.5 million in 1999 and \$0.5 million in 1998. In January 2001, the NeXstar Plan was terminated and combined with the Gilead Plan.

17. RELATED PARTY TRANSACTIONS

During 2000, Gilead paid an aggregate of \$10.2 million to PharmaResearch Corporation, a contract research organization, for services rendered in connection with clinical studies. The Chairman of Gilead's Board of Directors is a senior advisor to an investment fund that owns a controlling interest

**GILEAD SCIENCES, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

DECEMBER 31, 2000

17. RELATED PARTY TRANSACTIONS (CONTINUED) in PharmaResearch Corporation. Gilead's payments to PharmaResearch Corporation were \$6.7 million in 1999 and \$4.7 million in 1998.

18. SUBSEQUENT EVENTS

**CUBIST COLLABORATION**

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 which 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"). Cubist will continue to be responsible for worldwide clinical development of Cidecin, while Gilead will be responsible for both regulatory filings and marketing and sales of the product within Gilead's territory. Gilead may make additional payments to Cubist of up to \$31.0 million if certain clinical and regulatory milestones are reached. Additionally, if Cidecin is successfully commercialized in Gilead's territory, Gilead will pay Cubist a royalty on net sales of the product.

**INCREASE IN AUTHORIZED SHARES OF COMMON STOCK**

On February 2, 2001, at a special meeting of stockholders, the stockholders approved an amendment to Gilead's certificate of incorporation to increase the number of authorized shares of common stock from 100,000,000 to 500,000,000.

19. QUARTERLY RESULTS (UNAUDITED)

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

	1ST QUARTER	2ND QUARTER	3RD QUARTER	4TH QUARTER
	-----	-----	-----	-----
	(RESTATED)	(RESTATED)	(RESTATED)	
2000(1)(2)				
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.....	\$ (0.04)	\$ (0.04)	\$ (0.19)	\$ (0.20)
Cumulative effect of change in accounting principle.....	\$ (0.15)	--	--	--
Net loss.....	\$ (0.19)	\$ (0.04)	\$ (0.19)	\$ (0.20)
	=====	=====	=====	=====

**GILEAD SCIENCES, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

DECEMBER 31, 2000

**19. QUARTERLY RESULTS (UNAUDITED) (CONTINUED)**

AS PREVIOUSLY REPORTED				
	1ST QUARTER	2ND QUARTER	3RD QUARTER	
-----				
2000 as previously reported:				
Total revenues.....	\$ 45,222	\$ 49,979	\$ 45,089	
Total costs and expenses.....	52,163	55,764	66,030	
Net loss.....	(5,761)	(4,186)	(17,564)	
Basic and diluted net loss per share.....	\$ (0.06)	\$ (0.05)	\$ (0.19)	
-----				
	1ST QUARTER	2ND QUARTER	3RD QUARTER	4TH QUARTER
	-----	-----	-----	-----
1999(2)				
Total revenues.....	\$ 38,276	\$ 43,537	\$ 38,390	\$ 48,776
Total costs and expenses.....	54,828	55,900	69,608	59,502
Net loss.....	(15,476)	(11,691)	(30,365)	(8,954)
Basic and diluted net loss per share.....	\$ (0.19)	\$ (0.14)	\$ (0.35)	\$ (0.10)

(1) In the year ended December 31, 2000, Gilead adopted SAB 101 and reported the change as the 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. Quarterly information as originally reported is presented under the caption "2000 as previously reported."

(2) On February 22, 2001, Gilead completed a two-for-one stock split, effected in the form of a stock dividend, to stockholders of record as of February 2, 2001. Accordingly, all share and per share amounts for all periods presented have been restated to retroactively reflect the split.

**GILEAD SCIENCES, INC.**

**SCHEDULE II: VALUATION AND QUALIFYING ACCOUNTS**

(IN THOUSANDS)

	BALANCE AT BEGINNING OF PERIOD	ADDITIONS			BALANCE AT END OF PERIOD
		CHARGED TO EXPENSE	CHARGED TO OTHER	DEDUCTIONS	
Year ended December 31, 2000:					
Allowance for doubtful accounts.....	\$ 2,333	\$ 30	\$ --	\$ 63	\$ 2,300
Valuation allowance for deferred tax assets.....	194,200	--	34,400 (3)	--	228,600
	<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.....	170,611	--	23,589 (3)	--	194,200
	<u>\$172,091</u>	<u>\$1,059</u>	<u>\$23,589</u>	<u>\$ 206</u>	<u>\$196,533</u>
	=====	=====	=====	=====	=====
Year ended December 31, 1998:					
Allowance for doubtful accounts.....	\$ 1,883	\$ (294) (1)	\$ --	\$ 109	\$ 1,480
Allowance for other noncurrent assets.....	1,737	(550) (2)	--	1,187 (2)	--
Valuation allowance for deferred tax assets.....	136,411	--	34,200 (3)	--	170,611
	<u>\$140,031</u>	<u>\$ (844)</u>	<u>\$34,200</u>	<u>\$1,296</u>	<u>\$172,091</u>
	=====	=====	=====	=====	=====

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(1) In August 1996, a major customer of the Company filed for bankruptcy protection under Chapter 11 of the U.S. Bankruptcy Code. The total outstanding receivable of \$0.6 million from that customer as of December 31, 1996 was reserved. In 1997, the Company collected approximately \$0.1 million of this amount by assigning its claim to a third party. In 1998, the Company reversed that portion of the allowance for doubtful accounts no longer deemed necessary.

(2) The Company accepted \$550,000 in full settlement of an outstanding note receivable that was fully reserved on the balance sheet.

(3) 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 here 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 in the capacities 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 ----- John C. Martin	President and Chief Executive Officer, Director (Principal Executive Officer)	March 16, 2001
/s/ SHARON SURREY-BARBARI ----- Sharon Surrey-Barbari	Vice President, Chief Financial Officer (Principal Financial and Accounting Officer)	March 16, 2001
/s/ JAMES M. DENNY ----- James M. Denny	Chairman of the Board of Directors	March 16, 2001
/s/ PAUL BERG ----- Paul Berg	Director	March 16, 2001

## SIGNATURES (CONTINUED)

SIGNATURE -----	TITLE -----	DATE ----
/s/ ETIENNE F. DAVIGNON ----- Etienne F. Davignon	Director	March 16, 2001
/s/ GORDON E. MOORE ----- Gordon E. Moore	Director	March 16, 2001
/s/ GEORGE P. SHULTZ ----- George P. Shultz	Director	March 16, 2001

**Exhibit 3.1**

**RESTATED**

**CERTIFICATE OF INCORPORATION  
OF  
GILEAD SCIENCES, INC.**

GILEAD SCIENCES, INC., a corporation organized and existing under the General Corporation Law of the State of Delaware, does hereby certify as follows:

FIRST: The name of the Corporation is Gilead Sciences, Inc.

SECOND: The Corporation's original Certificate of Incorporation was filed with the Secretary of State on June 22, 1987.

THIRD: The amended and Restated Certificate of Incorporation of the Corporation, in the form attached hereto as Exhibit A, has been duly adopted in accordance with the provisions of Sections 228, 242 and 245 of the General Corporation Law of the State of Delaware by the Board of Directors and stockholders of the Corporation.

FOURTH: The amended and Restated Certificate of Incorporation so adopted reads in full as set forth in Exhibit A attached hereto and hereby incorporated by reference.

IN WITNESS WHEREOF, Gilead Sciences, Inc. has caused this Restated Certificate of Incorporation to be signed by its President and attested to by its Secretary this 24th day of January, 1992.

**GILEAD SCIENCES, INC.**

*By /s/ Michael L. Riordan*

-----  
*MICHAEL L. RIORDAN  
President*

*ATTEST:*

*/s/ James C. Gaither*

-----  
*JAMES C. GAITHER  
Secretary*

**EXHIBIT A**

**RESTATED  
CERTIFICATE OF INCORPORATION  
OF  
GILEAD SCIENCES, INC.**

**I.**

**The name of the Corporation is Gilead Sciences, Inc.**

**II.**

The address of the registered office of the Corporation in the State of Delaware is 1209 Orange Street, in the City of Wilmington, County of New Castle, Delaware 19801, and the name of the registered agent of the Corporation in the State of Delaware at such address is The Corporation Trust Company.

**III.**

The purpose of the Corporation is to engage in any lawful act or activity for which a Corporation may be organized under the General Corporation Law of Delaware.

**IV.**

(a) The liability of the directors of the Corporation for monetary damages shall be eliminated to the fullest extent permissible under Delaware law.

(b) The Corporation is authorized to provide indemnification of agents (as defined in Section 145 of the Delaware General Corporation Law) for breach of duty to the Corporation and its stockholders through bylaw provisions, through agreements with the agents, and/or through stockholder resolutions, or otherwise, in excess of the indemnification otherwise permitted by Section 145 of the Delaware General Corporation Law, subject to the limitations on such excess indemnification set forth in Section 102 of the Delaware General Corporation Law.

(c) Any repeal or modification of this Article IV shall be prospective and shall not affect the rights under this Article IV in effect at the time of the alleged occurrence of any act or omission to act giving rise to liability or indemnification.

**V.**

A. The Corporation is authorized to issue two classes of stock to be designated, respectively, "Common Stock" and "Preferred Stock." The total number of shares which the corporation is authorized to issue is forty million (40,000,000) shares. Thirty-five million (35,000,000) shares shall be Common Stock, each having a par value of one-tenth of one cent (\$.001). Five million (5,000,000) shares shall be Preferred Stock, each having a par value of one-tenth of one cent (\$.001).

B. The Preferred Stock may be issued from time to time in one or more series. The Board of Directors is hereby authorized, by filing a certificate pursuant to the Delaware General Corporation Law, to fix or alter from time to time the designation, powers, preferences and rights of the shares of each such series and the qualifications, limitations or restrictions thereof, including without limitation the dividend rights, dividend rate, conversion rights, voting rights, rights and terms of redemption (including sinking fund provisions), redemption price or prices, and the liquidation preferences of any wholly unissued series of Preferred Stock, and to establish from time to time the number of shares constituting any such series and the designation thereof, or any of them (a "Preferred Stock Designation"); and to increase or decrease the number of shares of any series subsequent to the



issuance of shares of that series, but not below the number of shares of such series then outstanding. In case the number of shares of any series shall be decreased in accordance with the foregoing sentence, the shares constituting such decrease shall resume the status that they had prior to the adoption of the resolution originally fixing the number of shares of such series.

## VI.

For the management of the business and for the conduct of the affairs of the Corporation, and in further definition, limitation and regulation of the powers of the Corporation, of its directors and of its stockholders or any class thereof, as the case may be, it is further provided that:

### SECTION 1. BOARD OF DIRECTORS.

(a) **MANAGEMENT OF CORPORATION.** The management of the business and the conduct of the affairs of the Corporation shall be vested in its Board of Directors. The number of directors which shall constitute the whole Board of Directors shall be fixed exclusively by one or more resolutions adopted from time to time by the Board of Directors.

Notwithstanding any other provisions of this Certificate of Incorporation, each director shall serve until his successor is duly elected and qualified or until his death, resignation or removal. No decrease in the number of directors constituting the Board of Directors shall shorten the term of any incumbent director.

#### (b) REMOVAL.

(i) Prior to the Qualifying Record Date and subject to any limitations imposed by law, the Board of Directors, or any individual director, may be removed from office at any time, with or without cause, by the affirmative vote of the holders of a majority of the outstanding Voting Stock (as hereinafter defined).

(ii) On and after the Qualifying Record Date and subject to any limitations imposed by law, Section 1(b)(i) of this Article VI shall no longer apply and the Board of Directors or any individual director may be removed from office at any time (A) with cause by the affirmative vote of the holders of a majority of the outstanding Voting Stock; or (B) without cause by the affirmative vote of the holders of at least 66-2/3% of the outstanding Voting Stock.

(c) **VACANCIES.** Any vacancies on the Board of Directors resulting from death, resignation, disqualification, removal or other causes shall be filled by either (i) the affirmative vote of the holders of a majority of the Voting Stock voting together as a single class; or (ii) by the affirmative vote of a majority of the remaining directors then in office, even though less than a quorum of the Board of Directors. Newly created directorships resulting from any increase in the number of directors shall, unless the Board of Directors determines by resolution that any such newly created directorship shall be filled by the stockholders, be filled only by the affirmative vote of the directors then in office, even though less than a quorum of the Board of Directors. Any director elected in accordance with the preceding sentence shall hold office for the remainder of the full term of the class of directors in which the new directorship was created or the vacancy occurred and until such director's successor shall have been elected and qualified.

### SECTION 2. CUMULATIVE VOTING.

(a) Prior to the date upon which the Corporation is no longer subject to Section 2115 of the California Corporations Code (the "Qualifying Record Date"), every stockholder entitled to vote in any election of directors of the Corporation may cumulate such stockholder's votes and give one candidate a number of votes equal to the number of directors to be elected multiplied by the number of votes to which the stockholder's shares are otherwise entitled, or distribute the stockholder's votes on the same principle among as many candidates as such stockholder thinks fit. No stockholder, however, may cumulate such stockholder's votes for one or more candidates unless (i) the names of such candidates have been properly placed in nomination, in accordance with the Bylaws of

the Corporation, prior to the voting, (ii) the stockholder has given advance notice to the Corporation of the intention to cumulate votes in accordance with the Bylaws, and (iii) the stockholder has given proper notice to the other stockholders at the meeting, prior to voting, of such stockholder's intention to cumulate such stockholder's votes. If any stockholder has given proper notice, all stockholders may cumulate their votes for any candidates who have been properly placed in nomination. The candidates receiving the highest number of votes of the shares entitled to be voted for them up to the number of directors to be elected by such shares shall be declared elected.

(b) On and after the Qualifying Record Date, cumulative voting shall no longer be available to the stockholders of the Corporation.

### SECTION 3. GENERAL.

(a) The Bylaws may be altered or amended or new Bylaws adopted by the affirmative vote of at least 66-2/3% of the voting power of all of the then-outstanding shares of the Voting Stock. In furtherance and not in limitation of the power conferred by statute, the Board of Directors is expressly authorized to adopt, amend, supplement or repeal the Bylaws. The Board of Directors may from time to time make, amend, supplement or repeal the Bylaws; provided, however, that the stockholders may change or repeal any Bylaw adopted by the Board of Directors by the requisite affirmative vote of stockholders as set forth in the Bylaws; and, provided further, that no amendment or supplement to the Bylaws adopted by the Board of Directors shall vary or conflict with any amendment or supplement thus adopted by the stockholders.

(b) The directors of the Corporation need not be elected by written ballot unless the Bylaws so provide.

(c) No action shall be taken by the stockholders of the Corporation except at an annual or special meeting of stockholders called in accordance with the Bylaws, and no action shall be taken by the stockholders by written consent.

(d) Advance notice of stockholder nominations for the election of directors and of business to be brought by stockholders before any meeting of the stockholders of the Corporation shall be given in the manner provided in the Bylaws of the Corporation.

### VII.

No holder of shares of stock of the Corporation shall have any preemptive or other right, except as such rights are expressly provided by contract, to purchase or subscribe for or receive any shares of any class, or series thereof, of stock of the Corporation, whether now or hereafter authorized, or any warrants, options, bonds, debentures or other securities convertible into, exchangeable for or carrying any right to purchase any share of any class, or series thereof, of stock; but such additional shares of stock and such warrants, options, bonds, debentures or other securities convertible into, exchangeable for or carrying any right to purchase any shares of any class, or series thereof, of stock may be issued or disposed of by the Board of Directors to such persons, and on such terms and for such lawful consideration, as in its discretion it shall deem advisable or as the Corporation shall have by contract agreed.

### VIII.

The Corporation is to have perpetual existence.

### IX.

(a) The Corporation reserves the right to amend, alter, change or repeal any provision contained in this Certificate of Incorporation, in the manner now or hereafter prescribed by statute, except as provided in paragraph

(b) of this Article IX, and all rights conferred upon the stockholders herein are granted subject to this reservation.

(b) Notwithstanding any other provisions of this Certificate of Incorporation or any provision of law which might otherwise permit a lesser vote or no vote, but in addition to any affirmative vote of the holders of any particular class or series of the Voting Stock required by law, this Certificate of Incorporation or any Preferred Stock Designation, the affirmative vote of the holders of at least 66-2/3% of the voting power of all of the then-outstanding shares of the Voting Stock, voting together as a single class, shall be required to alter, amend or repeal Article VI, Article VII or Article IX.

5.

**CERTIFICATE OF AMENDMENT OF  
RESTATED CERTIFICATE OF INCORPORATION OF  
GILEAD SCIENCES, INC.**

JOHN C. MARTIN and MARK L. PERRY hereby certify as follows:

ONE: The name of the corporation is Gilead Sciences, Inc.

TWO: The Restated Certificate of Incorporation of Gilead Sciences, Inc. was filed with the Secretary of State of the State of Delaware on January 29, 1992.

THREE: That they are the duly elected and acting President and Secretary, respectively, of Gilead Sciences, Inc., a Delaware corporation.

FOUR: The Board of Directors of Gilead Sciences, Inc., acting in accordance with the provisions of Sections 141 and 242 of the General Corporation Law of the State of Delaware, adopted resolutions to amend its Restated Certificate of Incorporation as follows:

Article V shall be amended and restated to read in its entirety as follows:

"V.

A. The Corporation is authorized to issue two classes of stock to be designated, respectively, "Common Stock" and "Preferred Stock." The total numbers of shares which the corporation is authorized to issue is one hundred five million (105,000,000) shares. One hundred million (100,000,000) shares shall be designated Common Stock, each having a par value of one-tenth of one cent (\$0.001). Five million (5,000,000) shares shall be designated Preferred Stock, each having a par value of one-tenth of one cent (\$0.001).

B. The Preferred Stock may be issued from time to time in one or more series. The Board of Directors is hereby authorized, by filing a certificate pursuant to the Delaware General Corporation Law, to fix or alter from time to time the designation, powers, preferences and rights or the shares of each such series and the qualifications, limitations or restrictions thereof, including without limitation the dividend rights, dividend rate, conversion rights, voting rights, rights and terms of redemption (including sinking fund provisions), redemption price or prices, and the liquidation preferences of any wholly unissued series of Preferred Stock, and to establish from time to time the number of shares constituting any such series and the designation thereof, or any of them (a "Preferred Stock Designation"); and to increase or decrease the number of shares of that series then outstanding. In case the number of shares of any series shall be decreased in accordance with the foregoing sentence, the shares constituting such decrease shall resume the status that they had prior to the adoption of the resolution originally fixing the number of shares of such series."

FIVE: Thereafter, pursuant to a resolution of the Board of Directors, this Certificate of Amendment was submitted to the stockholders of the Corporation for their approval, and was duly adopted in accordance with the provisions of Section 242 of the General Corporation Law of the State of Delaware.

SIX: All other provisions of the Restated Certificate of Incorporation shall remain in full force and effect.

IN WITNESS WHEREOF, Gilead Sciences, Inc. has caused this Certificate of Amendment to be signed by its President and attested to by its Secretary this 17th day of July, 1999.

*/s/ John C. Martin*  
-----  
*John C. Martin*  
*President*

*/s/ Mark L. Perry*  
-----  
*Mark L. Perry*  
*Secretary*

**CERTIFICATE OF AMENDMENT  
OF THE  
AMENDED AND RESTATED  
CERTIFICATE OF INCORPORATION  
OF  
GILEAD SCIENCES, INC.**

John C. Martin and Mark L. Perry do hereby certify as follows:

ONE: The name of the corporation is Gilead Sciences, Inc.

TWO: The date on which the Amended and Restated Certificate of Incorporation of the corporation was filed with the Secretary of State of the State of Delaware was January 29, 1992. A Certificate of Amendment to the Amended and Restated Certificate of Incorporation was filed with the Secretary of State of the State of Delaware on July 29, 1999.

THREE: They are duly elected and acting President and Secretary, respectively of Gilead Sciences, Inc., a Delaware corporation.

FOUR: The Board of Directors of the corporation, acting in accordance with the provisions of Section 242 of the General Corporation Law of the State of Delaware, adopted resolutions to amend the Amended and Restated Certificate of Incorporation of the corporation in the following form:

Article V shall be amended and restated to read in its entirety as follows:

"V

A. This corporation is authorized to issue two classes of stock to be designated, respectively, 'Common Stock' and 'Preferred Stock.' The total number of shares which the corporation is authorized to issue is five hundred five million (505,000,000) shares. Five hundred million (500,000,000) shares shall be Common Stock, each having a par value of one-tenth of one cent (\$.001). Five million (5,000,000) shares shall be Preferred Stock, each having a par value of one-tenth of one cent (\$.001).

B. The Preferred Stock may be issued from time to time in one or more series. The Board of Directors is hereby authorized, by filing a certificate pursuant to the Delaware General Corporation Law, to fix or alter from time to time the designation, powers, preferences and rights or the shares of each such series and the qualifications, limitations or restrictions thereof, including without limitation the dividend rights, dividend rate, conversion rights, voting rights, rights and terms of redemption (including sinking fund provisions), redemption price or prices, and the liquidation preferences of any wholly unissued series of Preferred Stock, and to establish from time to time the number of shares constituting any such series and the designation thereof, or any of them (a "Preferred Stock Designation"); and to increase or decrease the number of shares of that series then outstanding. In case the number of shares of any series shall be decreased in accordance with the foregoing sentence, the shares constituting such decrease shall resume the status that they had prior to the adoption of the resolution originally fixing the number of shares of such series."

FIVE: Thereafter, pursuant to a resolution of the Board of Directors, this Certificate of Amendment was submitted to the stockholders of the corporation for their approval and was duly adopted in accordance with the provision of Section 242 of the General Corporation Law of the State of Delaware.

SIX: All stock provisions of the Amended and Restated Certificates of Incorporation shall remain in full force and effect.

IN WITNESS WHEREOF, Gilead Sciences, Inc. has caused this Certificate of Amendment to be signed by its President and attested to by its Secretary this day of February 02, 2001.

**GILEAD SCIENCES, INC.**

*/s/ John C. Martin*  
-----  
*John C. Martin*  
*PRESIDENT*

*ATTEST:*

*/s/ Mark L. Perry*  
-----  
*Mark L. Perry*  
*SECRETARY*

**Exhibit 10.6**

**GILEAD SCIENCES, INC.  
1991 STOCK OPTION PLAN**

**ADOPTED NOVEMBER 15, 1991  
AMENDED APRIL 8, 1992  
AMENDED APRIL 21, 1993  
AMENDED OCTOBER 17, 1995  
AMENDED AND RESTATED JANUARY 22, 1998  
AMENDED MARCH 30, 1999  
AMENDED AND RESTATED APRIL 5, 2000**

**TERMINATION DATE: APRIL 30, 2010**

**1. PURPOSES.**

(a) The Plan initially was adopted on November 15, 1991 and amended through October 17, 1995 (the "Initial Plan"). The Initial Plan was amended and restated in its entirety effective as of January 22, 1998 and amended through March 30, 1999. Subject to the approval of stockholders of the Company, the Plan hereby is amended and restated in its entirety, effective as of April 5, 2000. The terms of the Plan (excluding the previously amended provision relating to the exercise price of Nonstatutory Stock Options) shall apply to all options granted pursuant to the Initial Plan.

(b) The purpose of the Plan is to provide a means by which selected Employees and Directors of, and Consultants to, the Company and its Affiliates may be given an opportunity to purchase stock of the Company.

(c) The Company, by means of the Plan, seeks to retain the services of persons who are now Employees of or Consultants to the Company, to secure and retain the services of new Employees and Consultants, and to provide incentives for such persons to exert maximum efforts for the success of the Company.

(d) The Company intends that the Options issued under the Plan shall, in the discretion of the Board or any Committee to which responsibility for administration of the Plan has been delegated pursuant to subsection 3(c), be either Incentive Stock Options or Nonstatutory Stock Options. All Options shall be separately designated Incentive Stock Options or Nonstatutory Stock Options at the time of grant, and in such form as issued pursuant to Section 6, and a separate certificate or certificates will be issued for shares purchased on exercise of each type of Option.

**2. DEFINITIONS.**

(a) "AFFILIATE" means any parent corporation or subsidiary corporation of the Company, whether now or hereafter existing, as those terms are defined in Sections 424(e) and (f) respectively, of the Code.

(b) "BOARD" means the Board of Directors of the Company.

(c) "CODE" means the Internal Revenue Code of 1986, as amended.

(d) "COMMITTEE" means a Committee appointed by the Board in accordance with subsection 3(c) of the Plan.

(e) "COMPANY" means Gilead Sciences, Inc., a Delaware corporation.

(f) "CONSULTANT" means any person, including an advisor, engaged by the Company or an Affiliate to render services and who is compensated for such services, provided that the term "Consultant" shall not include Directors who are paid only a director's fee by the Company or who are not otherwise compensated by the Company for their services as Directors. The term "Consultant" shall include a member of the Board of Directors of an Affiliate.

(g) "CONTINUOUS SERVICE" (formerly designated as "CONTINUOUS STATUS AS AN EMPLOYEE OR CONSULTANT") means that the Optionee's service with the Company or its Affiliates is not interrupted or terminated. The Optionee's Continuous Service shall not be deemed to have terminated merely because of a change in the capacity in which the Optionee renders service to the Company or its



Affiliates or a change in the entity for which the Optionee renders such service, provided that there is no interruption or termination of the Optionee's Continuous Service. For example, a change in status from an Employee of the Company to a Consultant or Director of the Company or a member of the Board of Directors of an Affiliate will not constitute an interruption of Continuous Service. The Board or the chief executive officer of the Company, in that party's sole discretion, may determine whether Continuous Service shall be considered interrupted in the case of any leave of absence approved by the Board or the chief executive officer of the Company, including sick leave, military leave, or any other personal leave.

(h) "COVERED EMPLOYEE" means the chief executive officer and the four

(4) other highest compensated officers of the Company for whom total compensation is required to be reported to shareholders under the Exchange Act, as determined for purposes of Section 162(m) of the Code.

(i) "DIRECTOR" means a member of the Board.

(j) "DISABILITY" means total and permanent disability as defined in Section 22(e)(3) of the Code.

(k) "EMPLOYEE" means any person, including Officers and Directors, employed by the Company or any Affiliate of the Company. Neither service as a Director nor payment of a director's fee by the Company shall be sufficient to constitute "employment" by the Company.

(l) "EXCHANGE ACT" means the Securities Exchange Act of 1934, as amended.

(m) "FAIR MARKET VALUE" means, as of any date, the value of the common stock of the Company determined as follows:

(i) If the common stock is listed on any established stock exchange or a national market system, including without limitation the National Market System of the National Association of Securities Dealers, Inc. Automated Quotation ("NASDAQ") System, the Fair Market Value of a share of common stock shall be the closing sales price for such stock (or the closing bid, if no sales were reported) as quoted on such system or exchange (or the exchange with the greatest volume of trading in common stock) on the last market trading day prior to the day of determination, as reported in the Wall Street Journal or such other source as the Board deems reliable;

(ii) If the common stock is quoted on the NASDAQ System (but not on the National Market System thereof) or is regularly quoted by a recognized securities dealer but selling prices are not reported, the Fair Market Value of a share of common stock shall be the mean between the high bid and high asked prices for the common stock on the last market trading day prior to the day of determination, as reported in the Wall Street Journal or such other source as the Board deems reliable;

(iii) In the absence of an established market for the common stock, the Fair Market Value shall be determined in good faith by the Board.

(n) "INCENTIVE STOCK OPTION" means an Option intended to qualify as an incentive stock option within the meaning of Section 422 of the Code and the regulations promulgated thereunder.

(o) "NON-EMPLOYEE DIRECTOR" means a Director who either (i) is not a current Employee or Officer of the Company or its parent or subsidiary, does not receive compensation (directly or indirectly) from the Company or its parent or subsidiary for services rendered as a consultant or in any capacity other than as a Director (except for an amount as to which disclosure would not be required under Item 404(a) of Regulation S-K promulgated pursuant to the Securities Act), does not possess an interest in any other transaction as to which disclosure would be required under Item 404(a) of Regulation S-K, and is not engaged in a business relationship as to which disclosure would be required under Item 404(b) of Regulation S-K; or (ii) is otherwise considered a "non-employee director" for purposes of Rule 16b-3.

(p) "NONSTATUTORY STOCK OPTION" means an Option not intended to qualify as an Incentive Stock Option.

(q) "OFFICER" means a person who is an officer of the Company within the meaning of Section 16 of the Exchange Act and the rules and regulations promulgated thereunder.

(r) "OPTION" means a stock option granted pursuant to the Plan.

(s) "OPTION AGREEMENT" means a written agreement between the Company and an Optionee evidencing the terms and conditions of an individual Option grant. The Option Agreement is subject to the terms and conditions of the Plan.

(t) "OPTIONED STOCK" means the common stock of the Company subject to an Option.

(u) "OPTIONEE" means a person who holds an outstanding Option.

(v) "OUTSIDE DIRECTOR" means a Director who either (i) is not a current employee of the Company or an "affiliated corporation" (within the meaning of the Treasury regulations promulgated under Section 162(m) of the Code), is not a former employee of the Company or an "affiliated corporation" receiving compensation for prior services (other than benefits under a tax qualified pension plan), was not an officer of the Company or an "affiliated corporation" at any time, and is not currently receiving direct or indirect remuneration from the Company or an "affiliated corporation" for services in any capacity other than as a Director, or (ii) is otherwise considered an "outside director" for purposes of Section 162(m) of the Code.

(w) "PLAN" means this 1991 Stock Option Plan.

(x) "RULE 16b-3" means Rule 16b-3 of the Exchange Act or any successor to Rule 16b-3, as in effect when discretion is being exercised with respect to the Plan.

### 3. ADMINISTRATION.

(a) The Board shall administer the Plan unless and until the Board delegates administration to a Committee, as provided in subsection 3(c).

(b) The Board shall have the power, subject to, and within the limitations of, the express provisions of the Plan:

(i) To determine from time to time which of the persons eligible under the Plan shall be granted Options; when and how the Option shall be granted; whether the Option will be an Incentive Stock Option or a Nonstatutory Stock Option; the provisions of each Option granted (which need not be identical), including the time or times such Option may be exercised in whole or in part; and the number of shares for which an Option shall be granted to each such person.

(ii) To construe and interpret the Plan and Options granted under it, and to establish, amend and revoke rules and regulations for its administration. The Board, in the exercise of this power, may correct any defect, omission or inconsistency in the Plan or in any Option Agreement, in a manner and to the extent it shall deem necessary or expedient to make the Plan fully effective.

(iii) To amend the Plan as provided in Section 11.

(iv) Generally, to exercise such powers and to perform such acts as the Board deems necessary or expedient to promote the best interests of the Company.

(c) The Board may delegate administration of the Plan to a Committee or Committees of one or more members of the Board. In the discretion of the Board, a Committee may consist solely of two or more Outside Directors, in accordance with Code Section 162(m), or solely of two or more Non-Employee Directors, in accordance with Rule 16b-3 of the Exchange Act. If administration is delegated to a Committee, the Committee shall have, in connection with the administration of the Plan, the powers theretofore possessed by the Board (and references in this Plan to the Board shall thereafter be to the Committee), subject, however, to such resolutions, not inconsistent with the provisions of the Plan, as may be adopted from time to time by the Board. The Board may abolish the Committee at any time and revert in the Board the administration of the Plan. Within the scope of this authority, the Board or the Committee may delegate to a committee of one or more members of the Board the authority to grant Options to eligible persons who (1) are not then subject to Section 16 of the Exchange Act and/or (2) are either (i) not then Covered Employees and are not expected to be Covered Employees at the time of recognition of income resulting from such Option, or (ii) not persons with respect to whom the Company wishes to comply with Section 162(m) of the Code.

### 4. SHARES SUBJECT TO THE PLAN.

(a) Subject to the provisions of Section 10 relating to adjustments upon changes in stock, the stock that may be sold pursuant to Options shall not exceed in the aggregate ten million seven hundred fifty thousand (10,750,000) shares of the Company's common stock. If any Option shall for any reason expire or otherwise terminate, in whole or in part, without having been exercised in full, the stock not purchased under such Option shall revert to again become available for issuance under the Plan.

(b) The stock subject to the Plan may be unissued shares or reacquired shares, bought on the market or otherwise.

### 5. ELIGIBILITY.

(a) Incentive Stock Options may be granted only to Employees. Nonstatutory Stock Options may be granted to Employees, Directors and Consultants.

(b) No person shall be eligible for the grant of an Incentive Stock Option if, at the time of grant, such person owns (or is deemed to own pursuant to Section 424(d) of the Code) stock possessing more than ten percent (10%) of the total combined voting power of all classes of stock of the Company or of any of its Affiliates unless the exercise price of such Option is at least one hundred ten percent (110%) of the Fair Market Value of such stock at the date of grant and the Option is not exercisable after the expiration of five (5) years from the date of grant.

(c) Subject to the provisions of Section 10 relating to adjustments upon changes in stock, no person shall be eligible to be granted Options covering more than Five Hundred Thousand (500,000) shares of the Company's common stock in any calendar year.

## 6. OPTION PROVISIONS.

Each Option shall be in such form and shall contain such terms and conditions as the Board shall deem appropriate. The provisions of separate Options need not be identical, but each Option shall include (through incorporation of provisions hereof by reference in the Option or otherwise) the substance of each of the following provisions:

(a) **TERM.** No Option shall be exercisable after the expiration of ten (10) years from the date it was granted.

(b) **PRICE.**

(i) **EXERCISE PRICE.** The exercise price of each Incentive Stock Option and each Nonstatutory Stock Option shall be not less than one hundred percent (100%) of the fair market value of the stock subject to the Option on the date the Option is granted.

(ii) **NO AUTHORITY TO REPRICE.** Without the consent of the stockholders of the Company, the Board shall have no authority to effect (a) the repricing of any outstanding Options under the Plan and/or

(b) the cancellation of any outstanding Options under the Plan and the grant in substitution therefor of new Options under the Plan covering the same or different numbers of shares of Common Stock.

(c) **CONSIDERATION.** The purchase price of stock acquired pursuant to an Option shall be paid, to the extent permitted by applicable statutes and regulations, either

(i) in cash at the time the Option is exercised, or

(ii) at the discretion of the Board or the Committee, at the time of the grant of the Option, (A) by delivery to the Company of other common stock of the Company, (B) according to a deferred payment arrangement, except that payment of the common stock's "par value" (as defined in the Delaware General Corporation Law) shall not be made by deferred payment or other arrangement (which may include, without limiting the generality of the foregoing, the use of other common stock of the Company) with the person to whom the Option is granted or to whom the Option is transferred pursuant to subsection 6(d), or (C) in any other form of legal consideration that may be acceptable to the Board.

In the case of any deferred payment arrangement, interest shall be compounded at least annually and shall be charged at the minimum rate of interest necessary to avoid the treatment as interest, under any applicable provisions of the Code, of any amounts other than amounts stated to be interest under the deferred payment arrangement.

(d) **TRANSFERABILITY.** An Incentive Stock Option shall not be transferable except by will or by the laws of descent and distribution, and shall be exercisable during the lifetime of the person to whom the Option is granted only by such person. A Nonstatutory Stock Option but not an Incentive Stock Option, may be transferred to the extent provided in the Option Agreement; provided that if the Option Agreement does not expressly permit the transfer of a Nonstatutory Stock Option, the Nonstatutory Stock Option shall not be transferable except by will, by the laws of descent and distribution and shall be exercisable during the lifetime of the person to whom the Option is granted only by such person. The person to whom the Option is granted may, by delivering written notice to the Company, in a form satisfactory to the Company, designate a third party who, in the event of the death of the Optionee, shall thereafter be entitled to exercise the Option.

(e) **VESTING.** The total number of shares of stock subject to an Option may, but need not, be allotted in periodic installments (which may, but need not, be equal). The Option Agreement may provide that from time to time during each of such installment periods, the Option may become exercisable ("vest") with respect to some or all of the shares allotted to that period, and may be exercised with respect to some or all of the shares allotted to such period and/or any prior period as to which the Option became vested but was not fully exercised. During the remainder of the term of the Option (if its term extends beyond the end of the installment periods), the option may be exercised from time to time with respect to any shares then remaining subject to the Option. The Option may be subject to such other terms and conditions on the time or times when it may be exercised (which may be based on performance or other criteria) as the Board may deem appropriate. The provisions of this subsection 6(e) are subject to any Option provisions governing the minimum number of shares as to which an Option may be exercised.

(f) **SECURITIES LAW COMPLIANCE.** The Company may require any Optionee, or any person to whom an Option is transferred under

subsection

6(d), as a condition of exercising any such Option, (1) to give written assurances satisfactory to the Company as to the Optionee's knowledge and experience in financial and business matters and/or to employ a purchaser representative reasonably satisfactory to the Company who is knowledgeable and

experienced in financial and business matters, and that he or she is capable of evaluating, alone or together with the purchaser representative, the merits and risks of exercising the Option; and (2) to give written assurances satisfactory to the Company stating that such person is acquiring the stock subject to the Option for such person's own account and not with any present intention of selling or otherwise distributing the stock. These requirements, and any assurances given pursuant to such requirements, shall be inoperative if (i) the issuance of the shares upon the exercise of the Option has been registered under a then currently effective registration statement under the Securities Act of 1933, as amended (the "Securities Act"), or (ii) as to any particular requirement, a determination is made by counsel for the Company that such requirement need not be met in the circumstances under the then applicable securities laws. The Company may require the Optionee to provide such other representations, written assurances, or information which the Company shall determine is necessary, desirable or appropriate to comply with applicable securities and other laws as a condition of granting an Option to such Optionee or permitting the Optionee to exercise such Option. The Company may, upon advice of counsel to the Company, place legends on stock certificates issued under the Plan as such counsel deems necessary or appropriate in order to comply with applicable securities laws, including, but not limited to, legends restricting the transfer of the stock.

(g) **TERMINATION OF EMPLOYMENT OR CONSULTING RELATIONSHIP.** In the event an Optionee's Continuous Service terminates (other than upon the Optionee's death or Disability), the Optionee may exercise his or her Option, but only within such period of time as is determined by the Board, and only to the extent that the Optionee was entitled to exercise it at the date of termination (but in no event later than the expiration of the term of such Option as set forth in the Option Agreement). In the case of an Incentive Stock Option, the Board shall determine such period of time (in no event to exceed ninety (90) days from the date of termination) when the Option is granted. If, at the date of termination, the Optionee is not entitled to exercise his or her entire Option, the shares covered by the unexercisable portion of the Option shall revert to the Plan. If, after termination, the Optionee does not exercise his or her Option within the time specified in the Option Agreement, the Option shall terminate, and the shares covered by such Option shall revert to the Plan.

(h) **DISABILITY OF OPTIONEE.** In the event an Optionee's Continuous Service terminates as a result of the Optionee's Disability, the Optionee may exercise his or her Option, but only within twelve (12) months from the date of such termination (or such shorter period specified in the Option Agreement), and only to the extent that the Optionee was entitled to exercise it at the date of such termination (but in no event later than the expiration of the term of such Option as set forth in the Option Agreement). If, at the date of termination, the Optionee is not entitled to exercise his or her entire Option, the shares covered by the unexercisable portion of the Option shall revert to the Plan. If, after termination, the Optionee does not exercise his or her Option within the time specified herein, the Option shall terminate, and the shares covered by such Option shall revert to the Plan.

(i) **DEATH OF OPTIONEE.** In the event of the death of an Optionee, the Option may be exercised, at any time within twelve (12) months following the date of death (or such shorter period specified in the Option Agreement) (but in no event later than the expiration of the term of such Option as set forth in the Option Agreement), by the Optionee's estate or by a person who acquired the right to exercise the Option by bequest or inheritance, but only to the extent the Optionee was entitled to exercise the Option at the date of death. If, at the time of death, the Optionee was not entitled to exercise his or her entire Option, the shares covered by the unexercisable portion of the Option shall revert to the Plan. If, after death, the Optionee's estate or a person who acquired the right to exercise the Option by bequest or inheritance does not exercise the Option within the time specified herein, the Option shall terminate, and the shares covered by such Option shall revert to the Plan.

(j) **EARLY EXERCISE.** The Option may, but need not, include a provision whereby the Optionee may elect at any time while an Employee or Consultant to exercise the Option as to any part or all of the shares subject to the Option prior to the full vesting of the Option. Any unvested shares so purchased may be subject to a repurchase right in favor of the Company or to any other restriction the Board determines to be appropriate.

(k) **WITHHOLDING.** To the extent provided by the terms of an Option Agreement, the Optionee may satisfy any federal, state or local tax withholding obligation relating to the exercise of such Option by any of the following means or by a combination of such means: (1) tendering a cash payment; (2) authorizing the Company to withhold shares from the shares of the common stock otherwise issuable to the Optionee as a result of the exercise of the Option; or (3) delivering to the Company owned and unencumbered shares of the common stock of the Company.

## 7. COVENANTS OF THE COMPANY.

(a) During the terms of the Options, the Company shall keep available at all times the number of shares of stock required to satisfy such Options.

(b) The Company shall seek to obtain from each regulatory commission or agency having jurisdiction over the Plan such authority as may be required to issue and sell shares of stock upon exercise of the Options; provided, however, that this undertaking shall not require the Company to register under the Securities Act either the Plan, any Option or any stock issued or issuable pursuant to any such Option. If, after reasonable efforts, the Company is unable to obtain from any such regulatory commission or agency the authority which counsel for the Company deems necessary for the lawful issuance and sale of stock under the Plan, the Company shall be relieved from any liability for failure to issue and sell stock upon exercise of such Options unless and until such authority is obtained.

## 8. USE OF PROCEEDS FROM STOCK.

Proceeds from the sale of stock pursuant to Options shall constitute general funds of the Company.

## 9. MISCELLANEOUS.

(a) The Board shall have the power to accelerate the time at which an Option may first be exercised or the time during which an Option or any part thereof will vest pursuant to subsection 6(e), notwithstanding the provisions in the Option stating the time at which it may first be exercised or the time during which it will vest.

(b) Neither an Optionee nor any person to whom an Option is transferred under subsection 6(d) shall be deemed to be the holder of, or to have any of the rights of a holder with respect to, any shares subject to such Option unless and until such person has satisfied all requirements for exercise of the Option pursuant to its terms.

(c) Nothing in the Plan or any instrument executed or Option granted pursuant thereto shall confer upon any Employee, Consultant or Optionee any right to continue in the employ of the Company or any Affiliate (or to continue acting as a Consultant) or shall affect the right of the Company or any Affiliate to terminate the employment or relationship as a Consultant of any Employee, Consultant or Optionee with or without cause.

(d) To the extent that the aggregate Fair Market Value (determined at the time of grant) of stock with respect to which Incentive Stock Options are exercisable for the first time by any Optionee during any calendar year under all plans of the Company and its Affiliates exceeds one hundred thousand dollars (\$100,000), the Options or portions thereof which exceed such limit (according to the order in which they were granted) shall be treated as Nonstatutory Stock Options.

## 10. ADJUSTMENTS UPON CHANGES IN STOCK.

(a) If any change is made in the stock subject to the Plan, or subject to any Option (through merger, consolidation, reorganization, recapitalization, stock dividend, dividend in property other than cash, stock split, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or otherwise), the Plan will be appropriately adjusted in the class(es) and maximum number of shares subject to the Plan pursuant to subsection 4(a) and the maximum number of shares subject to award to any person during any calendar year period pursuant to subsection 5(d), and the outstanding Options will be appropriately adjusted in the class(es) and number of shares and price per share of stock subject to such outstanding Options.

(b) In the event of: (1) a dissolution or liquidation of the Company; (2) a merger or consolidation in which the Company is not the surviving corporation; (3) a reverse merger in which the Company is the surviving corporation but the shares of the Company's common stock outstanding immediately preceding the merger are converted by virtue of the merger into other property, whether in the form of securities, cash or otherwise; or (4) any other capital reorganization in which more than fifty percent (50%) of the shares of the Company entitled to vote are exchanged, then, at the sole discretion of the Board and to the extent permitted by applicable law: (i) any surviving corporation shall assume any Options outstanding under the Plan or shall substitute similar Options for those outstanding under the Plan, (ii) the time during which such Options may be exercised shall be accelerated and the Options terminated if not exercised prior to such event, or (iii) such Options shall continue in full force and effect.

(c) Notwithstanding any other provisions of this Plan to the contrary, if an event occurs as specified in subsection 10(b) (a "Change in Control") and if within one (1) month before or thirteen (13) months after the date of such Change in Control the Continuous Service of an Optionee terminates due to an involuntary termination (not including death or Disability) without Cause (as such term is defined below) or a voluntary termination by the Optionee due to a Constructive Termination (as such term is defined below), then the vesting and exercisability of all Options held by such Optionee shall be accelerated, or any reacquisition or repurchase rights held by the Company with respect to an option shall lapse, as follows. With respect to those Options held by an Optionee at the time of such termination, one hundred percent (100%) of the unvested shares covered by such Options shall vest and become exercisable (or reacquisition or repurchase rights held by the Company shall lapse with respect to one hundred percent (100%) of the shares still subject to such rights, as appropriate) as of the date of such termination. Notwithstanding the foregoing, however, if such potential acceleration of the vesting and exercisability of Options (or lapse of reacquisition or repurchase rights held by the Company with respect to Options) would cause a contemplated Change in Control transaction that would otherwise be eligible to be accounted for as a "pooling-of-interests" transaction to become ineligible for such accounting treatment under generally accepted accounting principles as determined by the Company's independent public accountants (the "Accountants") prior to the Change of Control, such acceleration shall not occur.

For the purposes of this subsection 10(c) only, "Cause" means (i) conviction of, a guilty plea with respect to, or a plea of NOLO CONTENDERE to a charge that an Optionee has committed a felony under the laws of the United States or of any state or a crime involving moral turpitude, including, but not limited to, fraud, theft, embezzlement or any crime that results in or is intended to result in personal enrichment at the expense of the Company or an Affiliate; (ii) material breach of any agreement entered into between the Optionee and the

Company or an Affiliate that impairs the Company's or the Affiliate's interest therein; (iii) willful misconduct, significant failure of the Optionee to perform the Optionee's duties, or gross neglect by the Optionee of the Optionee's duties; or (iv) engagement in any activity that constitutes a material conflict of interest with the Company or any Affiliate.

For purposes of this subsection 10(c) only, "Constructive Termination" means the occurrence of any of the following events or conditions: (i) (A) a change in the Optionee's status, title, position or responsibilities (including reporting responsibilities) which represents an adverse change from the Optionee's status, title, position or responsibilities as in effect at any time within ninety (90) days preceding the date of a Change in Control or at any time thereafter; (B) the assignment to the Optionee of any duties or responsibilities which are inconsistent with the Optionee's status, title, position or responsibilities as in effect at any time within ninety (90) days preceding the date of a Change in Control or at any time thereafter; or (C) any removal of the Optionee from or failure to reappoint or reelect the Optionee to any of such offices or positions, except in connection with the termination of the Optionee's Continuous Service for Cause, as a result of the Optionee's Disability or death or by the Optionee other than as a result of Constructive Termination; (ii) a reduction in the Optionee's annual base compensation or any failure to pay the Optionee any compensation or benefits to which the Optionee is entitled within five (5) days of the date due; (iii) the Company's requiring the Optionee to relocate to any place outside a fifty (50) mile radius of the Optionee's current work site, except for reasonably required travel on the business of the Company or its Affiliates which is not materially greater than such travel requirements prior to the Change in Control; (iv) the failure by the Company to (A) continue in effect (without reduction in benefit level and/or reward opportunities) any material compensation or employee benefit plan in which the Optionee was participating at any time within ninety (90) days preceding the date of a Change in Control or at any time thereafter, unless such plan is replaced with a plan that provides substantially equivalent compensation or benefits to the Optionee, or (B) provide the Optionee with compensation and benefits, in the aggregate, at least equal (in terms of benefit levels and/or reward opportunities) to those provided for under each other employee benefit plan, program and practice in which the Optionee was participating at any time within ninety (90) days preceding the date of a Change in Control or at any time thereafter; (v) any material breach by the Company of any provision of an agreement between the Company and the Optionee, whether pursuant to this Plan or otherwise, other than a breach which is cured by the Company within fifteen (15) days following notice by the Optionee of such breach; or (vi) the failure of the Company to obtain an agreement, satisfactory to the Optionee, from any successors and assigns to assume and agree to perform the obligations created under this Plan.

(d) In the event that the acceleration of the vesting and exercisability of the Options or lapse of reacquisition or repurchase rights held by the Company with respect to Options provided for in subsection 10(c) and benefits otherwise payable to an Optionee (i) constitute "parachute payments" within the meaning of Section 280G (as it may be amended or replaced) of the Code, and (ii) but for this subsection 10(d) would be subject to the excise tax imposed by Section 4999 (as it may be amended or replaced) of the Code (the "Excise Tax"), then such Optionee's benefits hereunder shall be delivered to such lesser extent which would result in no portion of such benefits being subject to the Excise Tax; PROVIDED, HOWEVER, that the benefits hereunder shall be reduced only to the extent necessary after all cash amounts otherwise payable to such Optionee and which constitute "parachute payments" have been returned. Unless the Company and such Optionee otherwise agree in writing, any determination required under this subsection 10(d) shall be made in writing in good faith by the Accountants. For purposes of making the calculations required by this subsection 10(d), the Accountants may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of the Code. The Company and such Optionees shall furnish to the Accountants such information and documents as the Accountants may reasonably request in order to make a determination under this subsection 10(d). The Company shall bear all costs the Accountants may reasonably incur in connection with any calculations contemplated by this subsection 10(d).

## 11. AMENDMENT OF THE PLAN.

(a) The Board at any time, and from time to time, may amend the Plan. However, except as provided in Section 10 relating to adjustments upon changes in stock, no amendment shall be effective unless approved by the stockholders of the Company within twelve (12) months before or after the adoption of the amendment, where the amendment will:

(i) Increase the number of shares reserved for options under the Plan;

(ii) Effect (a) the repricing of any outstanding Options under the Plan and/or (b) the cancellation of any outstanding Options under the Plan and the grant in substitution therefor of new Options under the Plan covering the same or different numbers of shares of Common Stock;

(iii) Modify the requirements as to eligibility for participation in the Plan (to the extent such modification requires stockholder approval in order for the Plan to satisfy the requirements of Section 422 of the Code); or

(iv) Modify the Plan in any other way if such modification requires stockholder approval in order for the Plan to satisfy the requirements of Section 422 of the Code or to comply with the requirements of Rule 16b-3 or any Nasdaq or securities exchange listing requirements.

(b) The Board may in its sole discretion submit any other amendment to the Plan for stockholder approval, including, but

not limited to, amendments to the Plan intended to satisfy the requirements of Section 162(m) of the Code and the regulations promulgated thereunder regarding the exclusion of performance-based compensation from the limit on corporate deductibility of compensation paid to certain executive officers.

(c) It is expressly contemplated that the Board may amend the Plan in any respect the Board deems necessary or advisable to provide Optionees with the maximum benefits provided or to be provided under the provisions of the Code and the regulations promulgated thereunder relating to Incentive Stock Options and/or to bring the Plan and/or Incentive Stock Options granted under it into compliance therewith.

(d) Rights and obligations under any Option granted before amendment of the Plan shall not be altered or impaired by any amendment of the Plan unless

(i) the Company requests the consent of the person to whom the Option was granted and (ii) such person consents in writing.

## 12. TERMINATION OR SUSPENSION OF THE PLAN.

(a) The Board may suspend or terminate the Plan at any time. Unless sooner terminated, the Plan shall terminate on April 30, 2010, which is a date within ten (10) years following stockholder approval of the amended and restated Plan adopted by the Board on April 5, 2000. No Options may be granted under the Plan while the Plan is suspended or after it is terminated.

(b) Rights and obligations under any Option granted while the Plan is in effect shall not be altered or impaired by suspension or termination of the Plan, except with the consent of the person to whom the Option was granted.

## 13. EFFECTIVE DATE OF PLAN.

The Plan shall become effective as determined by the Board, but no Options granted under the Plan shall be exercised unless and until the stockholders of the Company have approved the Plan.

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## EXHIBIT 10.13

Institute of Organic Chemistry and  
Biochemistry of the Academy of Sciences  
of the Czech Republic  
Flemingovo nám. 2  
166 10 Praha 6  
Czech Republic  
Attention: Dr. Antonin Holy

Rega Institute for Medical Research  
Katholieke Universiteit Leuven  
Minderbroedersstraat 10  
B-3000 Leuven  
Belgium  
Attention: Professor Dr. De Clercq

December 27, 2000

RE: License Agreement between Gilead Sciences, Inc. ("Gilead"), the Institute of Organic Chemistry and Biochemistry, as an integral part of the Ceskoslovenska akademie ved ("IOCB"), and Rega Stichting v.z.w. ("REGA") dated November 15, 1991, as amended prior to the date of this letter agreement (such Agreement, the "1991 License Agreement"), and License Agreement between Gilead Sciences, Inc., IOCB and REGA dated December 1, 1992, as amended prior to the date of this letter agreement (such Agreement, the "1992 License Agreement"). The 1991 License Agreement and the 1992 License Agreement are referred to collectively as the "License Agreements".

Dear Drs. Holy and De Clercq:

We are writing to set forth the terms upon which we have agreed to amend the License Agreements, as described below.

"Amendment Date" as used herein shall mean the date the last signatory to this letter agreement signs this letter agreement.

We agree as of the Amendment Date as follows:

1. The following definition shall be added to Article I of the 1991 License Agreement:

"Adefovir" shall mean adefovir dipivoxil, or 9-[2-[[bis[(pivaloyloxy)methyl]phosphinyl]-methoxy]ethyl]adenine.

2. The following definition shall be added to Article I of the 1992 License Agreement:

"Tenofovir" shall mean (R) PMPA or tenofovir disoproxil fumarate or 9-[(R)-2-[[bis[[isopropoxycarbonyl]oxy]-methoxy]phosphinyl]methoxy] propyl]adenine fumarate.

3. All capitalized terms used in this Section 3 but not defined herein shall have the meanings given in the 1991 License Agreement. Section IV A. b) and

Section IV A. c) of the 1991 License Agreement shall be deleted and replaced in its entirety with the following:

"b) five percent (5%) of NET SALES of LICENSED PRODUCT other than LICENSED PRODUCT containing Adefovir as a LICENSED COMPOUND, and three percent (3%) of NET SALES of LICENSED PRODUCT containing Adefovir as a LICENSED COMPOUND, sold by GILEAD and its AFFILIATES and sublicensees, the manufacture, use or sale of which would, but for the LICENSE, infringe a VALID CLAIM of LICENSED PATENTS in the country of sale, except as set forth in the following sentence. With respect to NET SALES which would be royalty-bearing as set forth in the previous sentence, but as to which the same LICENSED COMPOUND or LICENSED PRODUCT is being sold in such country by any THIRD PARTY except under this Agreement, and as to which GILEAD or IOCB/REGA is not seeking diligently to enforce its LICENSED PATENTS, GILEAD shall pay to IOCB/REGA a total of two and one-half percent (2.5%) of NET SALES if such LICENSED COMPOUND or LICENSED PRODUCT is not or does not contain Adefovir as a LICENSED COMPOUND, and one and one-half percent (1.5%) if such LICENSED COMPOUND or LICENSED PRODUCT is, or does contain Adefovir as a LICENSED COMPOUND.

c) two and one-half percent (2.5%) of NET SALES of LICENSED PRODUCT not containing Adefovir as a Licensed Compound and sold by GILEAD and its AFFILIATES and sublicensees that is not covered by LICENSED PATENTS but exploits the TECHNICAL INFORMATION and the KNOW-HOW and no royalties on LICENSED PRODUCT containing Adefovir as a LICENSED COMPOUND and sold by GILEAD and its AFFILIATES and sublicensees that is not covered by LICENSED PATENTS but exploits the TECHNICAL INFORMATION and the KNOW-HOW."

4. All capitalized terms used in this Section 4 but not defined herein shall have the meanings given in the 1992 License Agreement. Section IV A. b) and

Section IV A. c) of the 1992 License Agreement shall be deleted and replaced in its entirety with the following:

"b) five percent (5%) of NET SALES of LICENSED PRODUCT other than LICENSED PRODUCT containing Tenofovir as a LICENSED COMPOUND, and three percent (3%) of NET SALES of LICENSED PRODUCT containing Tenofovir as a LICENSED COMPOUND, sold by GILEAD and its AFFILIATES and sublicensees, the manufacture, use or sale of which would, but for the LICENSE, infringe a VALID CLAIM of LICENSED PATENTS in the country of sale, except as set forth in the following sentence. With respect to NET SALES which would be royalty-bearing as set forth in the previous sentence, but as to which the same LICENSED COMPOUND or LICENSED PRODUCT is being sold in such country by any THIRD PARTY except under this Agreement, and as to which GILEAD or IOCB/REGA is not seeking diligently to enforce its LICENSED PATENTS, GILEAD shall pay to IOCB/REGA a total of two and one-half percent (2.5%) of NET SALES if such LICENSED COMPOUND or LICENSED PRODUCT is not or does not contain Tenofovir as a LICENSED COMPOUND, and one and one-half percent (1.5%) if such LICENSED COMPOUND or LICENSED PRODUCT is, or does contain Tenofovir as a LICENSED COMPOUND.

c) two and one-half percent (2.5%) of NET SALES of LICENSED PRODUCT not containing Tenofovir as a LICENSED COMPOUND and sold by GILEAD and its AFFILIATES and sublicensees that is not covered by LICENSED PATENTS but exploits the TECHNICAL INFORMATION and the KNOW-HOW and no royalties on LICENSED PRODUCT containing Tenofovir as a LICENSED COMPOUND and sold by GILEAD and its AFFILIATES and sublicensees that is not covered by LICENSED PATENTS but exploits the TECHNICAL INFORMATION and the KNOW-HOW."

5. In consideration of your agreement to amend the 1991 License Agreement, GILEAD will pay for LICENSED PRODUCT containing Adefovir as provided in Section 3 above, to IOCB and REGA together a single payment of One Million Seven Hundred Seventy Thousand United States dollars (\$1,770,000) as follows:

**// Gilead will pay \$885,000 to REGA; and**

**// Gilead will pay \$885,000 to IOCB.**

6. In consideration of your agreement to amend the 1992 License Agreement, GILEAD will pay for LICENSED PRODUCT containing Tenofovir as provided in Section 4 above, to IOCB and REGA together a single payment of Nine Million Two Hundred Thirty Thousand United States dollars (\$9,230,000) as follows:

**// Gilead will pay \$4,615,000 to REGA; and**

**// Gilead will pay \$4,615,000 to IOCB.**

7. REGA, IOCB and Gilead each agree that Section 1 of ANNEX 1 to the Agreement made by and between REGA, IOCB and Gilead, effective April 1, 1997 ("Section 1"), shall be amended such that IOCB and REGA shall each receive 50% of the amounts payable by Gilead instead of 52% and 48%, respectively.  
Section 1 shall otherwise remain unchanged.

8. The payments under Section 5 and 6 above shall be net, and no deduction shall be made by Gilead in respect of any withholding or other tax payable in respect thereof imposed in the United States of America, which shall be the responsibility of Gilead for its own account. Gilead hereby agrees to indemnify and hold harmless REGA and IOCB against and to reimburse REGA and IOCB for all withholding or other taxes paid or payable in the United States of America in respect of the payments under Section 5 and 6 above. Gilead shall make the payments required under Section 5 and 6 above by wire transfer of immediately available funds within five (5) business days of Gilead's receipt of a fully countersigned copy of this letter agreement to the following accounts:

To REGA: Generale Bank  
Account No. 230-0190070-67  
Stichting REGA v.z.w., Minderbroedersstraat 10, 3000 Leuven, Belgium

To IOCB: Ceska narodni banka Praha 1  
Account No. 11338031/0710  
Bank code 0710  
Account holder: Ustav organicke chemie a biochemie, Praha 6, Flemingovo nam.2.  
Czech Republic

9. IOCB and REGA each agree that no commission, royalty or other obligation shall be owed by Gilead to any third party as a result of any payments made under this letter agreement.

10. Except as expressly provided in this letter agreement, the License Agreements shall remain unchanged.

The offer contained in this letter agreement shall be valid until, and this letter agreement shall become binding upon each of us only if Gilead receives a executed counterpart of this letter agreement by facsimile from all of the signatories listed below on or before, 11:59 p.m., Pacific Standard Time on December 27, 2000. To indicate your agreement to amend the License Agreements and other provisions of this letter agreement as specified above, please sign below and return to me one copy of this letter by facsimile (650-522-5444). This letter agreement may be executed in multiple counterparts, each of which shall be an original and all of which shall together constitute the same document.

Yours sincerely,

**Gilead Sciences, Inc.**

By:        /s/ John C. Martin, Ph.D.  
             John C. Martin, Ph.D.  
             President and Chief Executive Officer

Accepted and Agreed,  
  
Institute of Organic Chemistry and  
Biochemistry of the Academy of Sciences  
of the Czech Republic

By:        /s/ Dr. Antonin Holy  
  
Name: Dr. Antonin Holy  
  
Date: December 27, 2000

Accepted and Agreed,  
  
Rega Stichting v.z.w.

By:        /s/ Professor Dr. De Clercq  
  
Name: Professor Dr. De Clercq  
  
Date: December 27, 2000

## EXHIBIT 21.1

### SUBSIDIARIES OF GILEAD SCIENCES, INC.

NAME OF SUBSIDIARY -----	COUNTRY OR STATE OF INCORPORATION -----
Gilead Sciences Limited	Ireland
Gilead Sciences GmbH	Germany
Gilead Sciences Sarl	France
Gilead Sciences S.r.l.	Italy
Gilead Sciences, S.A.	Spain
Gilead Sciences, Lda.	Portugal
Gilead Sciences Ltd.	United Kingdom
Gilead Sciences International Ltd.	United Kingdom
Gilead Sciences PTY Limited	Australia
Gilead Sciences B.V.	Netherlands
NeXstar Pharmaceuticals International, Inc.	Delaware
Gilead Irish Holdings, Ltd.	Ireland

## **EXHIBIT 23.1**

### **CONSENT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS**

We consent to the incorporation by reference in the Registration Statement (Form S-8 No. 333-47520) pertaining to the Gilead Sciences, Inc. 1991 Stock Option Plan, the Registration Statement (Form S-8 No. 33-46058) pertaining to the Gilead Sciences, Inc. 1987 Incentive Stock Option Plan, 1987 Supplemental Stock Option Plan, 1991 Stock Option Plan, Employee Stock Purchase Plan, and 1995 Non-Employee Directors' Stock Option Plan, the Registration Statement (Form S-8 No. 333-84719) pertaining to the Gilead Sciences, Inc. 1991 Stock Option Plan, 1995 Non-Employee Directors' Stock Option Plan and Employee Stock Purchase Plan, the Registration Statement (Form S-8 No. 333-84713) pertaining to the NeXstar Pharmaceuticals, Inc. 1993 Incentive Stock Plan, NeXstar Pharmaceuticals, Inc. 1995 Director Option Plan and Vestar, Inc. 1988 Stock Option Plan, the Registration Statement (Form S-3 No. 333-54350) of Gilead Sciences, Inc. and in the related Prospectus, and the Registration Statement (Form S-3 No. 333-87167) of Gilead Sciences, Inc. and in the related Prospectus of our report dated January 23, 2001, with respect to the consolidated financial statements and schedule of Gilead Sciences, Inc., included in this Annual Report (Form 10-K) for the year ended December 31, 2000.

### **ERNST & YOUNG LLP**

Palo Alto, California

March 19, 2001

## EXHIBIT 23.2

### CONSENT OF INDEPENDENT ACCOUNTANTS

We hereby consent to the inclusion in the Annual Report on Form 10-K (No. 0-19731) of Gilead Sciences, Inc. of our report dated January 12, 2001 relating to the financial statements of Prologo LLC for the thirteen-month period ended December 31, 2000, which is incorporated in this Annual Report on Form 10-K.

**PricewaterhouseCoopers LLP**

Broomfield, Colorado

March 16, 2001

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**End of Filing**

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