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# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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## FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2003

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 ☒ 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. ☒

Indicate by check mark whether registrant is an accelerated filer (as defined in Rule 12B-2 of the Act). Yes ☒ No ☐

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 June 30, 2003 was \$9,397,600,000.\*

The number of shares outstanding of the Registrant's Common Stock on February 27, 2004 was 213,780,787.

#### DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of Registrant's Definitive Proxy Statement filed with the Commission pursuant to Regulation 14A in connection with the 2004 Annual Meeting are incorporated by reference into Part III of this Report.

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\* Based on a closing price of \$55.55 per share. Excludes 31,780,729 shares of the registrant's common stock held by executive officers, directors and stockholders whose ownership exceeds 5% of the Common Stock outstanding at June 30, 2003. 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.

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**GILEAD SCIENCES, INC.**

**2003 Form 10-K Annual Report**

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We own or have rights to various trademarks, copyrights and trade names used in our business including the following: GILEAD®, GILEAD SCIENCES®, HEPSERA®, Leaf and Shield Design, Leaf and Shield Design (b/w), Liver Design, Tablet Design (b/w), Tablet Design (color), VIREAD®, VISTIDE®, DAUNOXOME®, AMBISOME®, EMTRIVA™. TAMIFLU® is a registered trademark belonging to Hoffmann-La Roche. This report also includes other trademarks, service marks and trade names of other companies.

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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 That Affect Gilead" at page 23. 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. When used in the report, unless otherwise indicated, "we," "our" and "us" refers to Gilead and its subsidiaries.

#### Overview

Gilead Sciences, Inc. is a biopharmaceutical company that discovers, develops and commercializes therapeutics to advance the care of patients suffering from life-threatening diseases worldwide. We have six products that are currently marketed in the U.S., all of which are also marketed in other countries worldwide. Our research and clinical programs are focused on anti-infectives, including antivirals and antifungals. We endeavor to grow our existing portfolio of products through proprietary clinical development programs, internal discovery programs and an active product acquisition and in-licensing strategy.

Our worldwide headquarters are in Foster City, California and our European headquarters are in Paris, France. We were incorporated in Delaware on June 22, 1987.

On January 23, 2003, we completed the acquisition of all of the net assets of Triangle Pharmaceuticals, Inc. (Triangle) to expand our antiviral pipeline. The aggregate purchase price was \$525.2 million, including the cash paid for the outstanding stock, the fair value of stock options assumed, estimated direct transaction costs and employee related costs. Approximately \$488.6 million of the purchase price was recorded to in-process research and development expense. Triangle developed drug candidates in the antiviral area, with a particular focus on potential therapies for HIV, including AIDS, and the hepatitis B virus. Triangle's portfolio consisted of several drug candidates in clinical trials, including Emtriva™ (emtricitabine) for the treatment of HIV infection, emtricitabine for the treatment of chronic hepatitis B, amdoxovir for the treatment of HIV infection and clevudine for the treatment of chronic hepatitis B. In July 2003, the U.S. Food and Drug Administration (FDA) approved for marketing Emtriva for the treatment of HIV and in October 2003, the European Commission granted Marketing Authorisation for Emtriva in all fifteen member states of the European Union. We subsequently returned the rights to amdoxovir and clevudine to the licensors and will have no further commercial interest in these compounds.

## Our Products

- ***Viread*** is approved for sale and is sold in the U.S. by our U.S. commercial team for use in combination with other antiretroviral agents for the treatment of HIV infection. Viread is also sold

internationally by our international commercial teams, including in the European Union and Australia.

- **Emtriva** is approved for sale and is sold in the U.S. by our U.S. commercial team for use in combination with other antiretroviral agents for the treatment of HIV infection in adults. Emtriva is also sold in the European Union by our international commercial teams. We are currently developing a fixed-dose combination of Viread and Emtriva.
- **AmBisome** is approved for sale and is sold in more than 45 countries for the treatment of life-threatening fungal infections and in some of these countries for prevention of such infections. We market AmBisome in the major countries of Europe and co-promote AmBisome in the U.S. with Fujisawa Healthcare, Inc. ("Fujisawa").
- **Hepsera** is approved for sale and is sold in the U.S. by our U.S. commercial team for the treatment of chronic hepatitis B. Hepsera received marketing approval in the European Union in March 2003 and has been launched in 13 countries in the European Union. Additional launches in the other countries in the European Union and other parts of the world are expected to occur in 2004.
- **Tamiflu** is approved for sale and is sold by our corporate partner Hoffmann-La Roche ("Roche") in more than 60 countries, including the U.S. and the European Union, for the prevention and treatment of influenza, and in Japan, where it is approved for the treatment of influenza.
- **Vistide** is approved for sale and is sold in the U.S. by our U.S. commercial team, and by Gilead's ex-U.S. partner, Pfizer Inc. ("Pfizer") (formerly Pharmacia Corporation), in 25 countries for the treatment of cytomegalovirus ("CMV") retinitis in patients with AIDS.
- **DaunoXome** is approved for sale and has been sold in more than 20 countries for the treatment of AIDS-related Kaposi's sarcoma. It was sold in the U.S. by our U.S. commercial team and by independent distributors abroad. In December 2003, we decided to discontinue selling this product.

In 2003, we earned revenues of \$861.6 million from sales of, and royalties on, these products. Of this amount, sales of Viread generated aggregate product sales and royalty revenues of \$566.5 million, or 65% of our total revenues, and sales of AmBisome generated aggregate product sales and royalty revenues of \$210.9 million, or 24% of our total revenues. We earned revenues from sales of, and royalties on, all our products in the U.S. of \$439.0 million in 2003, \$206.4 million in 2002 and \$53.3 million in 2001. Outside of the U.S., we earned revenues from sales of, and royalties on, all of our products of \$422.6 million in 2003, \$237.9 million in 2002 and \$160.7 million in 2001.

#### ***Viread (tenofovir disoproxil fumarate)***

Viread is an oral formulation of a nucleotide analogue reverse transcriptase inhibitor, tenofovir DF, dosed once a day as part of combination therapy to treat HIV infection in adults. The drug works by blocking reverse transcriptase, an enzyme involved in the replication of HIV. We sell Viread in the U.S. through our U.S. commercial team and in the major European countries through our European commercial team. See "Commercial Operations."

The FDA approved Viread for marketing in the U.S. in October 2001 and the European Agency for the Evaluation of Medicinal Products (EMA) granted similar approval in the European Union in February 2002. In May 2003, the EMA expanded the indication of Viread to include its use in antiretroviral-naïve HIV infected patients. In August 2003 the FDA similarly expanded the indication of Viread in the U.S. In the U.S., Viread is approved for use in combination with other antiretroviral agents for the treatment of HIV infection. The indication is based on analyses of plasma HIV RNA levels and CD4 cell counts in a controlled dose-ranging study of Viread of 24 weeks duration (Study 902) and in a placebo-controlled study of Viread of 48 weeks duration (Study 907). Both studies were conducted in

treatment-experienced adults with evidence of HIV viral replication despite ongoing antiretroviral therapy. The expanded indication was based on 96-week results from an on-going three-year, randomized, double-blind clinical trial (Study 903) designed to compare the efficacy and safety of a combination treatment regimen of Viread, lamivudine (3TC) and efavirenz to a combination treatment regimen of stavudine (d4T), lamivudine and efavirenz in 600 antiretroviral-naïve patients with HIV infection. In February 2004, we reported 144-week data from this study. Data from Study 903 demonstrates that treatment-naïve patients who received Viread experienced substantially less lipodystrophy and lower elevations in fasting cholesterol and triglyceride levels, as well as improved levels of limb fat and weight gain, while achieving similar reductions in HIV viral load and increases in CD4 cell counts, compared to those who received stavudine. The most common adverse events reported included viral infection, diarrhea and headache, and each occurred with similar frequency in the two study arms. The discontinuation rate was approximately 18 percent of patients in the Viread arm and 21 percent of patients in the stavudine arm. This 144-week data supplements the 96 and 48-week results from Study 903 that we submitted to the FDA in support of the use of Viread.

One of the major challenges in treating HIV-infected patients is drug resistance. Because many of the existing therapies for treating HIV infection and AIDS rely on similarly-designed drug processes, patients who have developed resistance to one drug often develop resistance to other drugs within the same class. We believe that Viread, when approved by regulatory authorities, offers advantages over other approved HIV treatments because available data have shown that few patients have developed resistance to Viread and that Viread is effective in treating patients who have developed resistance to other therapies. We cannot be certain, however, that the resistance data we may obtain upon completion of our Phase 3 clinical trials will show similar resistance characteristics to the 48-week data from Study 907 or the data we obtained from the more limited Phase 2 clinical trials.

Another major concern in HIV treatment is convenience of dosing. While combination therapies have a positive impact, they require HIV-infected patients to take numerous drugs. Some of these drugs require multiple doses every day and many have timing and dietary restrictions. This not only results in inconvenience for patients but also contributes to patients missing doses or not adhering to therapy. Viread is approved to be administered as a once-daily oral pill, which is a schedule that may be appealing to HIV-infected patients and their physicians.

The HIV competitive landscape is becoming more crowded and complicated as treatment trends continue to evolve. Twenty-two branded anti-HIV drugs are currently sold in the U.S. and many others are in advanced stages of clinical development. See “Competition.”

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

### ***Emtriva (emtricitabine)***

Emtriva is an oral formulation of a nucleoside analogue reverse transcriptase inhibitor, dosed once a day as part of a combination therapy to treat HIV infection in adults. We sell Emtriva in the U.S. through our U.S. commercial team and in the major European countries through our European commercial team. See “Commercial Operations.”

The FDA approved Emtriva for marketing in the U.S. for the treatment of HIV in July 2003 and the European Commission granted Marketing Authorisation for Emtriva in all fifteen member states of the European Union in October 2003.

Emtriva is an antiviral agent against HIV strains obtained from a geographically diverse set of HIV-infected patients. Laboratory studies have shown that Emtriva shares cross-resistance patterns with lamivudine. The most common resistance mutation to these two agents also reverses resistance of HIV to AZT in some cases. Four Phase 3 clinical studies for Emtriva have been completed, one in collaboration with the Agence Nationale de Recherches sur le Sida (ANRS) in France. One of these studies, Study FTC-301, compared Emtriva (200 mg once-a-day) to stavudine (40 mg twice-a-day) in combination with didanosine (400 mg once-a-day) and efavirenz (600 mg once-a-day) in patients without previous antiretroviral therapy. In July 2002, an independent data safety monitoring board (DSMB) established to provide oversight of the study recommended that Emtriva be offered to all patients enrolled in this study. The interim results evaluated by the study's DSMB showed that the Emtriva arm was statistically superior to the stavudine arm for primary and secondary endpoints for safety and efficacy. Eighty-seven percent (87%) of the patients in the once-a-day Emtriva arm had persistent virologic response through six months compared to 80% for the twice-daily stavudine arm. Patients in the Emtriva arm also had significant improvements in immunologic function. In view of a compelling difference in favor of the Emtriva arm, the DSMB recommended that the study be amended and all patients were given the option to switch to open-label Emtriva or continue on blinded therapy until the last randomized patient completed week 48 in October 2004. The final analysis of the study confirmed the superior efficacy and safety of Emtriva compared to stavudine in combination with didanosine and efavirenz.

We have an exclusive, worldwide license to patent rights and related technology for Emtriva from Emory University. See "Academic and Consulting Relationships—Emory University and University of Georgia Research Foundation."

#### ***AmBisome (amphotericin B liposome for injection)***

AmBisome is a proprietary liposomal formulation of amphotericin B. Amphotericin B is a powerful antifungal agent that is known for its ability to treat serious invasive fungal infections caused by various fungal species. These infections are generally life threatening, particularly in patients who have depressed immune systems due to aggressive chemotherapy regimens, stem cell or organ transplant or HIV infection. Amphotericin B treatment also has serious side effects, including kidney toxicity. Studies show, however, 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 doses of amphotericin B.

AmBisome is approved for sale in more than 45 countries, including the U.S., all of the European Union, most of the rest of Europe, Australia, Canada, and several countries in the Middle East, Latin America and Asia. In more than 20 of the countries where AmBisome is approved, including the U.S., we are authorized to promote AmBisome for empirical treatment of fungal infections, i.e. treatment of patients where a strong suspicion, without definite confirmation, exists for a potentially life-threatening invasive fungal infection. In the remaining countries where AmBisome is approved for sale, it is approved for use either as first-line treatment of serious invasive fungal infection or as second-line treatment after conventional amphotericin B therapy fails or when conventional amphotericin B cannot be tolerated. Finally, AmBisome is approved in a number of countries for various other indications, for example, cryptococcal meningitis in AIDS patients, prophylaxis in liver transplant patients and visceral leishmaniasis.

In the U.S., we co-promote AmBisome with Fujisawa through our U.S. commercial team. 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 commercial teams; in certain other countries we sell AmBisome through independent distributors. Most of our revenues from AmBisome are in Europe, and we expect this to be the case for the foreseeable future.

We have licensed commercial rights for AmBisome in Japan to Sumitomo Pharmaceuticals Co., Ltd. (Sumitomo) in exchange for royalties generated from those activities; however, AmBisome is not yet approved for sale in Japan.

AmBisome faces strong competition from several current competitors, and expected competitors whose treatments are in late stage clinical trials. See “Competition.” Competition from these current and expected competitors is likely to erode the revenues we receive from sales of AmBisome.

### ***Hepsera ( adefovir dipivoxil)***

Hepsera is an oral formulation of a nucleotide analogue HBV DNA polymerase inhibitor, adefovir dipivoxil, dosed once a day to treat chronic hepatitis B. Hepatitis B is caused by the highly contagious hepatitis B virus (HBV) and can cause acute liver failure. Some patients develop a chronic hepatitis B infection, which over many years can lead to complications, such as cirrhosis, liver cancer and liver failure, and in approximately 33% of patients can result in death. According to recent estimates from the World Health Organization and the Centers for Disease Control, there are over 400 million people worldwide and about 1.25 million people in the U.S. who have chronic hepatitis B. There are about one million deaths attributable to chronic hepatitis B worldwide each year, and it is one of the ten leading causes of death worldwide. Hepsera disables HBV by interfering with the activity of an enzyme known as HBV polymerase, which is necessary for the virus to replicate.

Our applications for U.S. and European Union marketing authorizations included data from two separate Phase 3 clinical trials designed to evaluate the safety and efficacy of Hepsera in a 10 mg dosage for treating patients with the hepatitis B virus. Both of our Phase 3 trials were designed as randomized, double-blind, placebo-controlled studies at clinical sites in the U.S., Canada, Europe, Australia and Southeast Asia. Study 437 evaluated Hepsera for treating patients who test positive for the HBV “e” antigen, the most common type of hepatitis B in the U.S. The other trial, Study 438, evaluated Hepsera for treating patients with a type of hepatitis B known as “precore mutant hepatitis B,” the most common in Southeast Asian and Mediterranean countries. Through 48 weeks, no adefovir-associated resistance mutations were identified in the hepatitis B patients treated in these clinical trials, which suggests that the development of resistance to Hepsera in hepatitis B patients may be delayed and infrequent. Consequently, we believe that Hepsera’s resistance profile could make it an important drug for treating chronic hepatitis B. We cannot be certain, however, that the resistance data we may obtain from the continuing Phase 3 clinical trials on Hepsera will continue to show these resistance characteristics.

Hepsera is approved for sale in the U.S. for the treatment of chronic hepatitis B in adults with evidence of active viral replication and either evidence of persistent elevations in serum aminotransferases (ALT or AST) or histologically active liver disease. Our U.S. commercial team sells Hepsera in the U.S. In March 2002, we applied for approval by the EMEA of Hepsera for treatment of chronic hepatitis B in the European Union. Approval by the EMEA was recommended by the Committee for Proprietary Medicinal Products (CPMP) in November 2002 and was received in March 2003. We plan to sell Hepsera in the major European Union countries through our European commercial team.

A vaccine is available that can prevent the transmission of HBV, but it is not effective in people who already have become chronically infected with HBV. We expect that as this vaccine becomes more widely available, the incidence of new hepatitis B infections will decrease. However, even with these advances in the prevention of hepatitis B, the individuals suffering from chronic hepatitis B represent a patient pool with a significant risk of morbidity and mortality due to their underlying chronic viral infection.

Chronic hepatitis B is most common in China and Southeast Asia. We commenced Phase 1 clinical trials in China in June 2001. We have licensed the rights to commercialize Hepsera solely for the treatment of hepatitis B in China, Korea, Japan, Taiwan, the rest of Asia, Latin America and certain other territories to GlaxoSmithKline (GSK). To date, GSK has begun selling Hepsera in Hong Kong, Singapore, the

Philippines, Indonesia and Pakistan. In China, Hepsera was granted Class I designation which, if Hepsera is ultimately approved for sale in China, would give GSK 12 years of market exclusivity for Hepsera with respect to competitors who may otherwise be able to begin clinical development of adefovir dipivoxil following such approval. After receiving the Chinese government's approval of the Phase 1 study, we were given approval to move forward with the Phase 2/3 program, and completed patient enrollment in March 2003.

Several existing therapies for treating patients who are infected with HBV compete with Hepsera. These treatments represent significant competition for Hepsera. See "Competition."

We have an exclusive, worldwide license to patent rights and related technology for adefovir dipivoxil from IOCB/REGA, and pay a percentage of net revenues from sales of Hepsera to IOCB/REGA in countries where the product has patent protection, including the U.S. and the European Union. In addition, we pay a small variable percentage of net revenues from U.S. sales of Hepsera to the M.D. Anderson Cancer Center. See "Academic and Consulting Relationships—M.D. Anderson Cancer Center."

#### ***Tamiflu (oseltamivir phosphate)***

Tamiflu is an oral pill for the treatment and prevention of influenza A and B. Tamiflu is in a class of prescription drugs called neuraminidase inhibitors that act by disabling all common strains of the flu virus and preventing the virus from spreading in a patient. 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 30%, 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.

Tamiflu is approved in more than 60 countries, including the U.S., Japan and the European Union for treatment of influenza in children and adults. Tamiflu is also approved in the U.S. and the European Union for the prevention of influenza in adolescents and adults. We developed Tamiflu with Roche, and Roche has the exclusive right to manufacture and sell Tamiflu, subject to its obligation to pay us a percentage of the net revenues that Roche generates from Tamiflu sales. To date, Roche's sales of Tamiflu have been significantly below expectations. Moreover, Roche has experienced problems in the manufacturing and distribution of Tamiflu, which have reduced the net sales and our royalty. This has not had a material effect on our revenues. See "Collaborative Relationships—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. See "Competition."

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

#### ***Vistide (cidofovir injection)***

Vistide is an antiviral medication for the treatment of CMV retinitis in patients with AIDS. CMV retinitis is a condition characterized by lesions that form on a patient's retina that affects persons with weakened immune systems and is most common in patients with AIDS. If left untreated, CMV retinitis can lead to blindness.

Vistide is approved for sale in the U.S., the European Union and several other countries. Demand for Vistide has been low and product revenues are immaterial. Our U.S. commercial team sells Vistide in the U.S. Outside the U.S., Pfizer has the exclusive right to sell Vistide. Pfizer pays us a percentage of revenues it generates from sales of Vistide. See "Collaborative Relationships—Pfizer."



The active agent in Vistide, cidofovir, is being considered as part of the U.S. government strategy for dealing with potential bioterrorism attacks involving smallpox, a life-threatening and highly communicable infectious disease. In laboratory tests, cidofovir has demonstrated activity against all 31 strains of the virus that causes smallpox. In current clinical trials of diluted smallpox vaccine conducted by the National Institute of Allergy and Infectious Diseases, cidofovir is being considered as a potential treatment for vaccinia infection, an adverse reaction sometimes caused by the smallpox vaccine. Additionally, the U.S. National Institutes of Health holds an investigational new drug application (IND) that allows for the emergency use of cidofovir for smallpox outbreaks without marketing approval from the FDA. We do not know what the efficacy of cidofovir might be in such emergency use, or what side effects, if any, may appear with the use of cidofovir for smallpox. We also cannot predict whether the U.S. or other countries' governments may stockpile Vistide for the treatment of smallpox.

#### ***DaunoXome (daunorubicin citrate liposome injection)***

DaunoXome is a liposomal formulation of the anticancer agent daunorubicin. It is a first-line therapy for treating patients who suffer from certain types of HIV-associated Kaposi's sarcoma, 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 is approved for sale in the U.S. and more than 20 other countries. We sold DaunoXome in the U.S. and sell it abroad through independent distributors. Demand for DaunoXome has been low and product revenues are immaterial. In December 2003, we made the decision to discontinue selling this product.

### **Our Products in Clinical Trials**

#### ***Fixed-Dose Combination of Viread and Emtriva***

We are currently developing a fixed-dose combination of Viread and Emtriva. We have completed a bioequivalence study, which evaluated the systemic exposure to patients of the combination tablet in comparison with the two individual products taken together, and are currently conducting two 48-week trials in which Emtriva and Viread are taken together as separate pills.

#### ***Emtricitabine for Hepatitis B***

Emtricitabine has been shown to be an inhibitor of hepatitis B virus replication in patients chronically infected with HBV. We are currently in Phase 3 clinical development of emtricitabine for the treatment of chronic hepatitis B. Some of the development activities undertaken with emtricitabine for the treatment of HIV will also be used in the assessment of emtricitabine for the treatment of chronic hepatitis B. In November 2003 we announced results from a 48-week clinical trial comparing the efficacy and safety of emtricitabine 200 mg once a day versus placebo in 248 patients with chronic hepatitis B (Study FTCB-301). We believe that a second Phase 3 clinical trial will be necessary before emtricitabine could be submitted for review to any regulatory agency. This second Phase 3 trial has not yet been designed and the strategy for emtricitabine for the treatment of hepatitis B is still evolving.

#### ***GS 7340***

GS 7340 is a novel nucleotide analogue reverse transcriptase inhibitor that, when processed in the body, yields tenofovir, the active chemical yielded by Viread, selectively within lymphatic cells. The chemical composition of GS 7340 may allow it to cross cell membranes more easily than Viread, leading to greater potency than Viread. Based on data from our Phase 1/2 clinical trials of GS 7340, we have begun developing a Phase 2 program for the treatment of HIV infection which will evaluate patients who are treatment naive and those who are highly resistant to thymidine analogues.

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### **Research & Development**

We are seeking to add to our existing portfolio of products through our internal discovery and clinical development programs and through an active product acquisition and in-licensing strategy, such as our acquisition of Triangle completed in January 2003. We have research scientists in Foster City and San Dimas, California and Durham, North Carolina 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 life threatening infectious diseases. In total, our research and development (R&D) expenses for 2003 were \$164.9 million, compared with \$134.8 million for 2002 and \$185.6 million for 2001.

#### ***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.

We believe that small molecule nucleotide analogues can offer advantages as therapeutics. First, 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. Second, drugs developed using 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.

#### ***HIV Protease Inhibitors***

We are evaluating a number of small molecule compounds known as protease inhibitors for the potential treatment of HIV infection.

Protease inhibitors act by interfering with the activity of protease, an enzyme that, like reverse transcriptase, is necessary for replication of HIV. We have conducted a number of preclinical experiments on these compounds and have demonstrated that they have potent antiviral activity. Our lead candidate is GS 9005 (formerly known as GS 4338), which is currently undergoing extensive preclinical evaluations. We submitted an investigational new drug application to the FDA for GS 9005 in January 2004.

#### ***Other Antiviral Research***

We are undertaking additional research in the area of treatment of viral diseases. Many of these efforts focus on potential targets in HIV for therapeutic drugs. We also have significant research efforts aimed at hepatitis C viral infection. See “Collaborative Relationships—Chiron Corporation.”

#### **Commercial Operations**

We have U.S. and international commercial sales operations. We have marketing subsidiaries in the United Kingdom, Germany, Italy, Spain, France, Portugal, Greece and Australia. Our commercial teams promote and sell Viread, Emtriva, Hepsera and AmBisome in the U.S., Europe and Australia. AmBisome is also sold by Fujisawa in the U.S. and by Sumitomo in Japan. GSK will promote and sell Hepsera in Asia and South America. We sell Vistide in the U.S and our commercial partner, Pfizer, sells Vistide outside of the U.S. Our commercial partner, Roche, promotes and sells Tamiflu everywhere it is sold. Japan Tobacco Inc. (Japan Tobacco) will promote and sell Viread and Emtriva in Japan when approved by Japanese regulatory authorities.

Our commercial teams promote Viread, Emtriva and Hepsera through direct field contact with physicians, hospitals, clinics and other healthcare providers who are involved in the treatment of patients with HIV (for Viread) or chronic hepatitis B (for Hepsera). They also promote AmBisome to infectious disease specialists, hematologists, intensive care units, hospitals, home health care providers and cancer specialists.

The European commercial team is supported by medical, sales operations, marketing, financial, regulatory, legal affairs, manufacturing and human resources and information technology personnel located primarily in our European headquarters in Paris, France. The U.S. and Australian commercial teams are supported by our worldwide headquarters in Foster City, California. In some countries outside of the U.S., we have agreements with third-party distributors, including distributors in certain of the countries where we have marketing operations, to promote, sell and distribute Viread, Emtriva, Hepsera and AmBisome. These international distribution agreements generally provide that the distributor has the exclusive right to sell Viread, Emtriva and AmBisome in a particular country or several countries for a specified period of time.

In January 2003, we announced a program pursuant to which we will be selling Viread at our cost to all countries in Africa and to the 15 other countries designated “Least Developed Countries” by the United Nations. We are taking steps to ensure that the Viread product sold under this program is used to serve patients in the developing world and not diverted to other markets. See “International Distribution.”

To support and expand the commercialization of Viread, Hepsera and Emtriva, we have significantly increased our sales force in the U.S. and are devoting additional marketing resources in the U.S. to improve our coverage of healthcare professionals treating HIV-infected and HBV-infected patients. We have also significantly increased the size of our commercial operations in Europe to manage the commercialization of Viread, Emtriva and Hepsera in the European Union.

In April 2002, we entered into a licensing agreement with GSK, under which GSK received exclusive rights to commercialize Hepsera in Asia, Latin America, Africa and certain other territories. Under the agreement, we retained rights to Hepsera in the U.S., Canada, Eastern and Western Europe, Australia, New Zealand and Turkey. GSK also received exclusive rights to develop Hepsera solely for the treatment of chronic hepatitis B in all other countries, the most significant of which include China, Korea, Japan and Taiwan. GSK will have full responsibility for development and commercialization of Hepsera in its territories.

In July 2003, we entered into a licensing agreement with Japan Tobacco under which Japan Tobacco will commercialize products in Gilead’s HIV portfolio in Japan. The agreement includes Viread, Emtriva and a future co-formulation of the two products. Japan Tobacco has submitted an application for Viread and expects to submit an application for Emtriva and co-formulation of the two products to Japanese regulatory authorities this year.

In the U.S., Viread, Hepsera, Emtriva, Vistide and DaunoXome are returnable in their original, unopened containers after expiration up to one year beyond the expiration date or, if damaged when received by the customer. Our customers may return AmBisome if the shelf life has expired or if the product is damaged or defective when the customer receives it. AmBisome has an approved shelf life of 36 months in the U.S. and 30 months in most European countries. DaunoXome has a shelf life of 52 weeks in the U.S. and most European countries. Viread has a shelf life of 24 months in the U.S. and the European Union. Hepsera has a shelf life of 24 months in the U.S. and the European Union. Emtriva has a shelf life of 24 months in the U.S. and the European Union. To date, returns, rebates and discounts have not been material to our financial results. Fujisawa establishes the return policy for AmBisome in North America, and Roche establishes the return policy for Tamiflu. At the end of each flu season, there have been significant returns of Tamiflu to Roche, which reduce the net sales on which our royalty from Roche is based.

Additionally, certain governmental agency customers and state AIDS drug assistance programs are entitled to or receive discounts, and we are required to provide rebates under state Medicaid programs. We believe that we provide adequate provisions for these discounts and rebates in accordance with our revenue recognition policy.

### **Collaborative Relationships**

As part of our business strategy, we establish collaborations with other companies to assist in the clinical development and/or commercialization of certain of our products and product candidates and to provide support for our research programs. We also evaluate opportunities for acquiring from other companies products or rights to products and technologies that are complementary to our business. The accounting for each of these relationships can be found in Note 10 to our consolidated financial statements included in this report. Our existing collaborative relationships are as follows:

#### ***Archemix Corporation***

In October 2001, we entered into an agreement with Archemix Corporation (Archemix). Under this agreement we granted Archemix an exclusive sublicense to the SELEX technology to identify aptamers, subject to the exclusion of all development areas as to which rights have not already been granted or forfeited. Our rights to the SELEX technology derive from a license to us from University License Equity Holdings, Inc., (“ULEHI”), the successor to University Technology Corporation and its predecessor University Research Corporation. The financial terms of the agreement with Archemix provide for lump sum payments to us totaling \$17.5 million. Archemix has now made these payments. We also received warrants to purchase Archemix stock under the agreement. As required by our agreements with ULEHI, we shared a portion of the cash payments with, and transferred the warrants to ULEHI. See “Academic and Consulting Relationships—University License Equity Holdings, Inc.”

#### ***Chiron Corporation***

In August 2003, we entered into a non-exclusive licensing agreement with Chiron Corporation (Chiron) for the research, development and commercialization of small molecule therapeutics against selected hepatitis C virus (HCV) drug targets. Under the agreement, we received non-exclusive rights to Chiron’s HCV technology for drug screening purposes. We expect this technology to assist us in our research and discovery effort to identify and develop potential HCV therapies. Under the terms of the agreement, we paid Chiron an up-front license fee and agreed to make milestone payments and royalty payments if a product is developed using the licensed technology.

#### ***EyeTech Pharmaceuticals***

In March 2000, we entered into an agreement with EyeTech Pharmaceuticals, Inc. (EyeTech) relating to a product named Macugen that it has developed for the treatment of age-related macular degeneration (AMD) and diabetic macular edema (DME). We invented the compound upon which Macugen is based, NX 1838, using SELEX technology licensed to us from ULEHI. See “Academic and Consulting Relationships—University License Equity Holdings, Inc.” We then licensed NX 1838 to EyeTech who further developed it into Macugen. Under its license from us, EyeTech is required to pay us fees and milestone payments, as well as a percentage of any revenue they generate from worldwide sales of Macugen. In addition, EyeTech granted us warrants to purchase EyeTech preferred stock. Our agreement with EyeTech 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. EyeTech granted Pfizer a sublicense relating to Macugen in December 2002. In December 2002, in connection with this sublicense, we entered into a license with Pfizer on the same terms as contained in our agreement with EyeTech. In December 2003, we also entered into an agreement with EyeTech to supply Macugen to EyeTech for three years.

### ***Fujisawa***

In 1991, we entered into an agreement granting Fujisawa the exclusive right to promote and sell AmBisome in Canada and the primary responsibility to promote and sell AmBisome in the U.S. with Gilead as a co-promoter. Fujisawa pays us approximately 17% of Fujisawa's net revenues from sales of AmBisome in the U.S. We reserved the right to promote and sell AmBisome in the rest of the world, and pay Fujisawa 4% of our net revenues for AmBisome sales in significant Asian markets, including Japan, Korea, Taiwan, China and India. We manufacture all AmBisome that is sold worldwide. We sell AmBisome to Fujisawa for sale in the U.S. at a price equal to our cost to manufacture the product, and for sale in Canada at a price equal to our cost to manufacture the product, plus a specified percentage. Our agreement with Fujisawa terminates when the last patent covering AmBisome in the U.S. or Japan expires.

### ***GlaxoSmithKline***

In April 2002, we entered into a licensing agreement with GSK giving it exclusive rights to commercialize Hepsera solely for the treatment of chronic hepatitis B in Asia, Latin America and certain other territories. In addition to fees, milestone payments and other contract revenues, GSK is required to pay us a percentage of any revenue they generate from sales of Hepsera in the licensed territories. Under our agreement with GSK, we have entered into a clinical and commercial supply agreement with GSK under which we are required to supply them with their clinical and commercial requirements at our fully burdened cost to do so, subject to reasonable forecasting and ordering procedures. Our agreement with GSK expires on an individual country basis the later of patent expiration or ten years from first commercial sale in the particular country. In addition, GSK has the right to electively terminate the agreement on 12 months notice to Gilead, subject to a fee for elective termination under some circumstances early during the term of the agreement.

### ***Japan Tobacco***

In July 2003, we entered into a licensing agreement with Japan Tobacco under which Japan Tobacco obtained the rights to commercialize products in Gilead's HIV portfolio in Japan. The agreement includes Viread, Emtriva and a future co-formulation of the two products. We received an up-front fee and are entitled to receive milestone payments. Japan Tobacco also is required to make payments to us based on product sales in Japan. Japan Tobacco has submitted an application for Viread and expects to submit an application for Emtriva and a co-formulation of the two products to Japanese regulatory authorities this year. As contemplated by the license agreement, in December 2003 we completed a supply agreement with Japan Tobacco under which we will supply Japan Tobacco with Viread and Emtriva and a future co-formulation of the two products.

### ***OSI Pharmaceuticals***

In December 2001, we sold to OSI Pharmaceuticals (OSI) our pipeline of clinical stage oncology products and related intellectual property, as well as our Boulder, Colorado operations. In consideration for the assets, we received from OSI \$130.0 million in cash and 924,984 shares of OSI common stock. Additionally, OSI is required to pay us up to an additional \$30.0 million in either cash or a combination of cash and OSI common stock upon the achievement by OSI of certain milestones related to the development of NX 211, the most advanced of the oncology product candidates. Separately, under a manufacturing agreement with OSI, we have agreed to produce for OSI liposomal formulations of two products, including NX 211, at our manufacturing facility in San Dimas, California.

## ***Pfizer***

In 1996, we entered into an agreement with Pfizer (formerly Pharmacia Corporation) relating to Vistide. Under this agreement, Pfizer has the exclusive right to market and sell Vistide in all countries outside of the U.S., subject to payment to us of a percentage of net revenues. We are required to sell Pfizer bulk Vistide and to maintain the Vistide patents. Our agreement with Pfizer expires on an individual country basis upon patent expiration or ten years from first commercial sale in countries where the product is not covered by a patent. In addition, Pfizer may terminate the agreement as a whole upon six months notice or upon notice on an individual country basis, three months before applying for marketing approval of a competitive product.

## ***Roche***

In 1996, we entered into a collaboration agreement with Roche granting Roche exclusive worldwide rights to Tamiflu, as well as other proprietary influenza neuraminidase inhibitors. As of December 31, 2003, we have received license fees and milestone payments from Roche totaling \$48.7 million relating to the execution of this agreement and to regulatory filings and approvals for Tamiflu. Roche also funded all of the research and development costs for Tamiflu, including reimbursement to us of \$28.1 million for the period from January 1, 1997 through December 31, 2001. Under the agreement, Roche is responsible for pricing, manufacturing, promoting and selling Tamiflu on a worldwide basis and pays us a percentage of its net revenues from sales of Tamiflu, subject to reduction for certain defined manufacturing costs. Our agreement with Roche terminates on an individual country basis on the later of patent expiration or ten years from first commercial sale in the particular country. In addition, Roche has the right to terminate the agreement in its entirety or an individual country basis prior to expiration at any time upon 12 months notice.

## ***Sumitomo***

In 1996, we entered into an agreement with Sumitomo that gave Sumitomo the exclusive right to develop and market AmBisome in Japan. In addition to milestone payments, Sumitomo is required to pay us a percentage of any revenue they generate from Japanese sales of AmBisome. If AmBisome is approved for sale in Japan, we would manufacture AmBisome for sale by Sumitomo in Japan. The price that we would charge Sumitomo for the supply of AmBisome and the percentage of revenues that they would be required to pay to us would be determined by the price of AmBisome in Japan. Our agreement with Sumitomo terminates on the later of patent expiration in Japan or ten years from first commercial sale in Japan.

## **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.

### ***Emory University and University of Georgia Research Foundation, Inc.***

*Emtricitabine.* In April 1996, Triangle obtained, and we acquired as part of our acquisition of Triangle, an exclusive worldwide license to all of Emory University's rights to purified forms of emtricitabine for use in the HIV and the hepatitis B fields. We are obligated to make certain milestone and royalty payments to Emory, including annual minimum royalties beginning the third year after the first FDA registration is granted for an anti-HIV product incorporating the emtricitabine technology in the U.S. and the third year after the first registration is granted for an anti-hepatitis B product incorporating the emtricitabine technology in certain major market countries, for the HIV and hepatitis B indications,

respectively. In 2002, Triangle began paying license maintenance fees because development milestones had not yet been achieved.

In May 1999, Emory and GSK settled their litigation pending in the United States District Court relating to emtricitabine, and we became the exclusive licensee of all U.S. and foreign patents and patent applications filed by Burroughs Wellcome Co. on the use of emtricitabine to treat hepatitis B. Under the license and settlement agreements, we and Emory were also given access to development and clinical data and drug substance held by GSK relating to emtricitabine.

In May 2002, Emory, GSK and Shire Pharmaceuticals Group, plc (Shire) settled worldwide patent disputes involving lamivudine and emtricitabine. Under the terms of the settlement, Emory received an exclusive license from Shire under Shire's patents relating to emtricitabine and methods for its use and manufacture and Shire and GSK received exclusive licenses under Emory's patents relating to lamivudine. Under the terms of our license agreement with Emory, we automatically acquired an exclusive sublicense to the Shire patents relating to emtricitabine granted under the terms of the settlement, thereby resolving all previously pending patent disputes regarding emtricitabine.

The license agreement with Emory terminates upon the later of patent expiration or the expiration of our obligation to pay royalties. In addition, we have the right to terminate the agreement in its entirety or with respect to one or both indications (HIV and HBV) in one or more countries prior to expiration at any time upon 90 days notice.

**Amdoxovir.** In March 1996, Triangle entered into, and we acquired as part of our acquisition of Triangle, a license agreement with Emory and the University of Georgia Research Foundation, Inc. (UGRF) pursuant to which we received an exclusive worldwide license to all of Emory's and UGRF's rights to a series of nucleoside analogues including amdoxovir and DXG (i.e., the active anti-HIV agent) for use in the HIV and hepatitis B fields. In March 1999, Triangle began paying license maintenance fees because development milestones had not yet been achieved. In January 2004, we announced our intent to terminate the license agreement for amdoxovir.

#### ***M.D. Anderson Cancer Center***

In 1994, we entered into an agreement with the M.D. Anderson Cancer Center relating to Hepsera. Under this agreement, we currently pay M.D. Anderson Cancer Center a percentage of net revenues based upon sales of Hepsera. The agreement with M.D. Anderson Cancer Center terminates the later of patent expiration or ten years from first commercial sale.

#### ***IOCB/REGA***

In 1991 and 1992, we entered into agreements with IOCB/REGA relating to Viread, Hepsera and Vistide. Under these agreements, we received from IOCB/REGA the exclusive right to manufacture, use and sell the nucleotide compounds covered by these agreements. We currently pay a percentage of net revenues based upon sales of Viread, Hepsera and Vistide to IOCB/REGA. The agreements with IOCB/REGA terminate on an individual country basis the later of patent expiration or ten years from first commercial sale. In addition, IOCB/REGA may terminate the licenses for a particular product in a key market in the absence of commercial sales of that product within 12 months after regulatory approval.

#### ***University License Equity Holdings, Inc.***

We have an ongoing collaborative arrangement with University License Equity Holdings, Inc., ("ULEHI"), the successor to University Technology Corporation and its predecessor University Research Corporation, a technology holding company for the University of Colorado at Boulder, relating to its SELEX technology to identify aptamers. Under this arrangement, ULEHI has granted 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 and computer software related to SELEX technology. We are required to pay ULEHI certain variable royalties based on revenues generated from sales of products derived using the SELEX technology.

## **Developing World Collaborations**

### ***The Bill & Melinda Gates Foundation & Family Health International***

In October 2002, we entered into an agreement with the Bill & Melinda Gates Foundation and Family Health International (FHI) to provide Viread for FHI's multinational clinical trial evaluating Viread's effectiveness as a method of reducing the risk of HIV infection among sexually active adults who are regularly exposed to HIV. The clinical trials, to be conducted by FHI, are funded by a \$6.5 million, three-year grant from the Gates Foundation.

### ***The DART Study***

In November 2002, we entered into a collaborative agreement with the Medical Research Council (MRC) of the United Kingdom, Boehringer Ingelheim GmbH, and GSK in connection with a five-year clinical study conducted by the MRC on antiretroviral HIV therapy in Africa. The trial is called the DART Trial ( Development of Anti Retroviral Therapy in Africa) and is aimed at studying clinical versus laboratory monitoring practices, and structured treatment interruptions versus continuous antiretroviral therapy in adults with HIV infection in sub-Saharan Africa. We will provide Viread at no cost for the DART study.

### ***The Institute for One World Health***

In January 2003, we entered into an agreement with the Institute for One World Health, pursuant to which we will provide AmBisome at our cost for a Phase 3 clinical trial evaluating AmBisome for the treatment of visceral leishmaniasis with paromomycin in India, which has the greatest global burden of visceral leishmaniasis. The clinical trial will be conducted by the Institute for One World Health in partnership with the World Health Organization.

## **International Distribution**

We have various agreements with distributors in Europe, Asia, Latin America, the Middle East and Africa that grant these distributors the exclusive right to sell Viread, Emtriva, Hepsera and AmBisome 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.

## **Manufacturing**

### ***AmBisome***

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

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

AmBisome is sold as a freeze-dried product. We currently freeze-dry AmBisome at our San Dimas manufacturing facility and also use a third party to freeze-dry additional product as needed. Given our current projections for AmBisome demand, we believe we have sufficient capacity to meet future demand. We also have the option of installing additional freeze-drying capacity in San Dimas should such additional supply become necessary. If we were unable to install additional freeze-drying capacity in San Dimas or locate appropriate third parties to meet this need, our ability to meet increased AmBisome demand would be diminished.

### ***Antiviral Products***

We contract with third parties to manufacture our antiviral drugs for clinical and commercial purposes, including Viread, Emtriva, Hepsera and Vistide.

We manufacture Viread tablets through a single contract manufacturer for the U.S. and the European Union and for sales and distribution in other territories. In addition, we have a second contract manufacturer in Europe for European Union distributed product. All have been approved by their respective agencies.

We have obtained qualification in the U.S. and European Union for two contract manufacturers for adefovir dipivoxil, the active ingredient in Hepsera. We have one contract manufacturer for the final Hepsera drug product for commercial supply and are seeking to qualify a second supplier.



We entered into an agreement with Abbott Laboratories (Abbott) to manufacture emtricitabine bulk drug substance and final drug product for us. We have qualified a second contract manufacturer for bulk drug substance in both the U.S. and the European Union.

We have two suppliers that have been approved by the FDA and the European Union to manufacture cidofovir bulk drug substance, which is used in Vistide. We have a single FDA and EMEA approved supplier for Vistide drug product.

In January 2002, Roche announced that, due to production problems, the liquid suspension form of Tamiflu approved for treatment of children as young as one year-old was not available; however, the liquid suspension form of Tamiflu was returned to market in time for the 2002-2003 flu season. These production issues did not affect availability of the tablet form of Tamiflu for adults and adolescents 13 years and older. In Japan, where the 2002-2003 flu season was particularly severe, Roche's sublicensee, Chugai Corporation, was unable to meet the heightened demand satisfactorily. In January 2003, Chugai issued a press release attributing this failure, in part, to manufacturing problems. In November 2003, Chugai announced a recall of Tamiflu. These problems in Japan have reduced the net sales and royalty from Roche. While royalties from Roche for Tamiflu have been below our expectations, to date, these production and commercialization issues have not had a material effect on our earnings, and we do not expect them to have a material effect on our earnings in the future.

We have no commercial-scale manufacturing facilities for our antiviral products. For our future antiviral products, we will need to develop additional manufacturing capabilities and establish additional third party suppliers in order to manufacture sufficient quantities of our product candidates to undertake clinical trials and to manufacture sufficient quantities of any products that are approved for commercial sale. If we are unable to develop manufacturing capabilities internally or contract for large scale manufacturing with third parties on acceptable terms for our future antiviral products, our ability to conduct large-scale clinical trials and meet customer demand for commercial products would be adversely affected.

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

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

### Patents and Proprietary Rights

Patents and other proprietary rights are very important to our business. If we have a properly designed and enforceable patent it can be more difficult for our competitors to use our technology to create competitive products and more difficult for our competitors to obtain a patent that prevents us from using technology we create. As part of our business strategy, we actively seek patent protection both in the U.S. and internationally and file additional patent applications, when appropriate, to cover improvements in our compounds, products and technology. We also rely on trade secrets, internal know-how, technological innovations and agreements with third parties to develop, maintain and protect our competitive position. Our ability to be competitive will depend on the success of this strategy.

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

	<u>U.S. Patent Expiration</u>	<u>European Patent Expiration</u>
<b>Products</b>		
Viread	2017	2018
Hepsera	2014	2011
AmBisome	2016	2008
Tamiflu	2016	2016
Vistide	2010	2012
Emtriva	2021	2011

Patents covering Viread, Hepsera, Vistide and Emtriva are held by third parties. We acquired exclusive rights to these patents in the agreements we have with these parties. See “Collaborative Relationships” and “Academic and Consulting Relationships.” Patents do not cover the active ingredients in AmBisome. Instead, we hold patents to the liposomal formulations of this compound and also protect formulations through trade secrets. We do not have patent filings covering all forms of Hepsera 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 Hepsera. Asia is a major market for HBV therapies.

We may obtain patents for our compounds many years before we obtain marketing approval for them. This limits the time that we can prevent other companies from developing these compounds and therefore

reduces the value of the product. However, we can apply for patent term extensions. For example, extensions for the patents on Vistide have been granted in the U.S. and a number of European countries, compensating in part for delays in obtaining marketing approval. Similar patent term extensions may be available for other products that we are developing, but we cannot be certain we will obtain them.

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

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

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

## **Competition**

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

- efficacy;
- 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 may 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.

**Viread and Emtriva.** The HIV competitive landscape is becoming more crowded and complicated as treatment trends continue to evolve. A growing number of anti-HIV drugs are currently sold or are in advance stages of clinical development. Of the 22 branded drugs available in the U.S., Zerit (stavudine, d4T) sold by Bristol-Myers Squibb (BMS) and the fixed combination products, Combivir (AZT and 3TC) and Trizivir (AZT, 3TC, ABC), both sold by GSK, represent the most direct competition for Viread. These companies are in the process of launching formulations of existing drugs now indicated by the FDA for once-daily oral dosing. These include GSK's 300 mg dose of Epivir (3TC) and BMS's new extended release formulation of Zerit. Other recently approved antiretroviral products include atazanavir (QD protease inhibitor from BMS) and Fuzeon (injectable integrase inhibitor from Roche/Trimeris). GSK has filed an application for approval of a once-daily dose of Ziagen (abacavir), as well as a new fixed dose combination of Ziagen and Epivir. Other companies competing in the HIV therapeutic category are Pfizer, Merck, Boehringer-Ingelheim and Abbott.

**AmBisome.** AmBisome faces strong competition from several current and expected competitors. Current competitors include:

- conventional amphotericin B, made by BMS and numerous generic manufacturers;
- caspofungin, a product developed by Merck, which is marketed as Cancidas in the U.S. and as Caspofungin elsewhere;
- voriconazole, developed by Pfizer, which is marketed as Vfend; and
- other lipid-based amphotericin B products approved in the U.S. and throughout Europe, including Abelcet, sold by Enzon Corp. in the U.S., Canada and Japan and by Medeus Pharma Ltd. in Europe, and Amphotec, sold by InterMune Pharmaceuticals, Inc.

Presently unapproved but expected competitors include a class of treatments called echinocandins, including Fujisawa's micafungin, which received marketing approval in Japan in October 2002 and is under review for regulatory approval in the U.S. and Canada, and anidulafungin, a Vircuron, Inc. (formerly Versicor, Inc.) product candidate, which is being evaluated in multiple late-stage clinical trials. Finally, Schering Plough is developing Noxafil (posaconazole), which is currently in Phase 3 trials. Competition from these current and expected competitors has eroded and is likely to continue to erode the revenues we receive from sales of AmBisome.

**Hepsera.** Hepsera faces significant competition from existing therapies for treating patients who are infected with HBV. Most significantly:

- Epivir-HBV (lamivudine) was developed by GSK in collaboration with Shire Pharmaceuticals, and is sold in all major countries throughout North and South America, Europe, and Asia. It is an orally administered nucleoside analogue that inhibits HBV DNA polymerase.
- Intron-A (interferon alfa-2b) is sold by Schering Plough in major countries throughout North and South America, Europe, and Asia. Intron-A is an injectable drug with immunomodulatory effects.

Hepsera may also face competition from clinical-stage candidates, including Bristol-Myers Squibb's entecavir and Idenix's LdT, two oral nucleoside analogues currently in Phase 3 trials. Other competition will include Roche's Pegasys (pegylated interferon alfa-2a), which is currently being studied for chronic hepatitis B.

**Tamiflu.** Tamiflu competes with Relenza, an anti-flu drug that is sold by GSK. Relenza is a neuraminidase inhibitor that is delivered as an orally-inhaled dry powder.

**Vistide.** Vistide competes with a number of drugs that also treat CMV retinitis, including ganciclovir, sold in intravenous and oral formulations by Roche and as an ocular implant by Bausch & Lomb Incorporated; valganciclovir, also marketed by Roche; foscarnet, an intravenous drug sold by AstraZeneca; and, fomivirsen, a drug injected directly into the eye sold by CibaVision.

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

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

## Government Regulation

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

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

## ***Preclinical Testing***

Before we can test a drug candidate in humans, we must study the drug in laboratory experiments and in animals to generate data to support the drug's potential safety and benefits. We submit this data to the FDA in an investigational new drug application (IND) seeking their approval to test the compound in humans.

## ***Clinical Trials***

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

- Phase 1. 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 2. 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 3. If a compound appears to be effective and safe in Phase 2 clinical trials, Phase 3 clinical trials are commenced to confirm those results. Phase 3 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 2 clinical trials to fail in the more rigorous and reliable Phase 3 clinical trials.

## ***FDA Approval Process***

If we believe that the data from the Phase 3 clinical trials show an adequate level of safety and effectiveness, we will file a new drug application (NDA) with the FDA seeking approval to sell the drug for a particular use. The FDA will review the NDA and often will hold a public hearing where an independent advisory committee of expert advisors asks additional questions regarding the drug. This committee makes a recommendation to the FDA that is not binding on the FDA but is generally followed by the FDA. If the FDA agrees that the compound has a required level of safety and effectiveness for a particular use, it will allow us to sell the drug in the U.S. for that use. It is not unusual, however, for the FDA to reject an application because it believes that the drug is not safe enough or effective enough or because it does not believe that the data submitted is reliable or conclusive.

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

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

In addition to obtaining FDA approval for each drug, the manufacturing facilities for any drug we sell, including those of companies who manufacture our drugs for us as well as our own, must be approved by the FDA and are subject to periodic inspections by the FDA. Foreign establishments that manufacture products to be sold in the U.S. must also be approved by the FDA and are subject to periodic regulatory inspection. Manufacturing facilities located in California, including our San Dimas facility and Foster City facility, also must be licensed by the State of California in compliance with local regulatory requirements.

Drugs that treat serious or life-threatening diseases and conditions that are not adequately addressed by existing drugs may be designated as fast track products by the FDA and may be eligible for priority six month review and accelerated approval, as was the case for Viread. Drugs receiving accelerated approval must be monitored in post-marketing clinical trials in order to confirm the safety and benefits of the drug.

We 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, Viread, Hepsera and Emtriva were approved by the European Union under the centralized procedure. Viread as an HIV drug was reviewed for accelerated approval in the European Union. Hepsera received a traditional review, as did Emtriva.

### ***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 decrease, and if these proposals are adopted, our revenues could 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. Some European governments, notably Germany and Italy, have implemented, or are considering, legislation that would require pharmaceutical companies to sell their products subject to reimbursement at a mandatory

discount. Such mandatory discounts would reduce the revenue we receive from our drug sales. In certain developing countries that are significantly affected by HIV and AIDS, parallel importing and generic competition may occur and adversely affect revenues from sales of or market share of Viread.

## **Employees**

As of February 27, 2004, we had approximately 1,425 full-time employees. We believe that we have good relations with our employees.

## **Website**

Our website address is [www.gilead.com](http://www.gilead.com). We make available free of charge through our website, our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, our director and officers' Section 16 reports, and all amendments to these reports as soon as reasonably practicable after filing, by providing a hyperlink to the EDGAR website directly to our reports.

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## **RISK FACTORS THAT AFFECT GILEAD**

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.

### **Substantially all of our revenues are derived from sales of two products. If we are unable to maintain or continue growing sales of Viread or to maintain sales of AmBisome our results of operations may be adversely affected.**

We are currently dependent on sales of our two lead products, Viread and AmBisome, to support our existing operations. Together these products accounted for approximately 90% of our total revenues for the year ended December 31, 2003. If we are unable to continue growing Viread revenues or to maintain AmBisome sales, our results of operations are likely to suffer and we may need to scale back our operations. Viread product sales for the year ended December 31, 2003 were \$566.5 million, or 65%, of our total revenues and AmBisome product sales and royalties for the year ended December 31, 2003 were \$210.9 million, or 24% of our total revenues. We may not be able to maintain the growth rate of Viread or the current sales level of AmBisome for the reasons stated in this risk factor section and, in particular, the following reasons:

- We face significant competition from businesses that have substantially greater resources than we do. For example, in 2003, we experienced declining sales volumes for AmBisome due in part to the introduction of new European competitors. On a volume basis, AmBisome sales decreased by 5% in Europe in 2003 compared to 2002.
- As Viread and AmBisome are used over a longer period of time and additional studies are conducted, new issues with respect to safety, resistance and interactions with other drugs may arise which could cause us to provide additional warnings on our labels, narrow our approved indications or halt sales of a product, each of which could reduce our revenues.
- As a product matures, private insurers and government reimbursers may reduce the amount they will reimburse patients for these products, which will increase pressure on us to reduce prices. For example, in 2003, authorities in Germany and Italy reduced the amount of reimbursement they will provide for patients using Viread and we expect similar reductions in France in 2004.

### **If we fail to commercialize new products or expand the indications for existing products, our prospects for future revenues and stock price may be adversely affected.**

If we do not introduce new products or increase revenues from our existing products, we may not be able to grow our revenues. In order to expand our products, we have begun marketing Hepsera for the treatment of chronic hepatitis B and Emtriva for the treatment of HIV in the United States and in the European Union. In addition, we are developing a co-formulation of tenofovir with emtricitabine. Failure to achieve any of these objectives when expected, or at all, may have a material adverse effect on our business and results of operations. We may not be able to achieve these objectives for the following reasons:

- Hepsera is a new drug and faces a competitive marketplace in which we have less experience than established competitors. For example, Hepsera primarily competes with lamivudine in the United States and with interferon-alfa 2b in the European hepatitis B market. Hepsera's primary advantage over lamivudine is that patients have so far been less likely to develop resistance to Hepsera than they have to lamivudine. However, lamivudine has been on the market longer than Hepsera and lamivudine's resistance problems did not surface until after the product was marketed. Hepsera may not continue to show superior resistance properties to lamivudine. Hepsera's primary advantages



over interferon-alfa 2b are greater safety, tolerability and oral dosing. Newer versions of interferon (pegylated-interferon) are under development and may prove to be safer, more tolerable and offer once-weekly injectable dosing. Marketing a treatment for hepatitis B is also difficult since many infected individuals are not diagnosed and there is not a consensus among physicians as to the appropriate methods of treatment.

- A physical combination of emtricitabine with tenofovir may not be technically feasible or cost-effective. In addition, we may not be able to develop a chemistry, manufacturing and bioequivalence package that shows the co-formulated tablet gives the same exposure to tenofovir and emtricitabine as the two drugs given individually that will support regulatory approval. We have not completed stability studies necessary to support approval of a co-formulation of tenofovir and emtricitabine.

If we fail to increase our sales of Hepsera or if we do not obtain regulatory approval and successfully market a co-formulation of emtricitabine and tenofovir, we may not be able to increase revenues and expand our research and development efforts.

**If significant safety issues arise for our marketed products, our sales may decline, which would adversely affect our results of operations.**

The data that support the marketing approvals for our products, including Viread, AmBisome, Hepsera and Emtriva and that form the basis for the safety warnings in our product labels, were obtained in controlled clinical trials of limited duration, and, in the case of Viread, from limited post-approval use. Following approval, these products are and will be used over longer periods of time in many patients taking numerous other medicines, who have underlying health problems and who will not be monitored for dosing compliance. If new safety issues are reported in post-marketing use and we cannot rule out the contributory role of our products, we may be required to provide additional warnings on our labels or narrow our approved indications, each of which could reduce the market acceptance of these products. For example, while we did not observe kidney toxicity in our clinical trials of Viread, kidney toxicity has been reported with post-approval use of Viread and the Viread label has been updated to include this warning. If serious safety issues with our marketed products were to arise, sales of these products could be halted by us or by regulatory authorities. In 1999, we discontinued development of adefovir dipivoxil 60 mg for treatment of HIV infection due to concerns about kidney toxicity arising from our studies. The 10 mg dose of adefovir dipivoxil used in Hepsera has not been associated with significant kidney toxicity in our clinical trials to date, other than in patients who have pre-existing kidney problems or who are taking drugs known to cause kidney toxicity. However, kidney toxicity may develop in the broader hepatitis B patient population.

**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 develop must be approved for marketing and sale by regulatory authorities and will be subject to extensive regulation by the FDA and comparable regulatory agencies in other countries. We are continuing clinical trials for AmBisome, Viread, Hepsera and Emtriva for currently approved and additional uses. We anticipate that we will file for marketing approval in additional countries and for additional products over the next several years. These products may fail to receive marketing approval on a timely basis, or at all. Also, our current filing strategy for a co-formulation of tenofovir and emtricitabine is based on data from completed studies: if the FDA requires additional pivotal studies for a combination product our regulatory filing will be delayed. Regulatory authorities outside of the U.S. and the European Union may not approve emtricitabine for treatment of HIV because it does not have sufficient efficacy advantages over a currently marketed lamivudine product. We also may not be able to obtain the regulatory approvals necessary to expand our commercial efforts into new markets. 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, our marketed products and how we sell these products are subject to extensive regulation and review. Later discovery of previously unknown problems with our products or problems with our promotional activities may result in restrictions on our products, including withdrawal of the products from the market. For example, on August 7, 2003, the FDA issued a written warning concerning our promotional activities of Viread. 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. In addition, we have been named in a multi-party lawsuit alleging that we inflated the reimbursement rates under the Medicaid Program of certain pharmaceuticals we manufacture.

**Results of clinical trials are uncertain and may not support continued development of a product pipeline, which would adversely affect our prospects for future revenue growth.**

We are required to demonstrate the safety and effectiveness of products we develop in each intended use through extensive preclinical studies and clinical trials. The results from preclinical and early clinical studies do not always accurately predict results in later, large-scale clinical trials. Even successfully completed large-scale clinical trials may not result in marketable products. A number of companies in our industry have suffered setbacks in advanced clinical trials despite promising results in earlier trials. For example, in 1999 the FDA denied approval of adefovir dipivoxil (60 mg), a drug developed by Gilead for the treatment of HIV, based on concerns regarding kidney toxicity. We may in the future seek clinical development of similar compounds that also have the potential for kidney toxicity or other adverse effects. If any of our products under development fail to achieve their primary endpoint in clinical trials or if safety issues arise, commercialization of that drug candidate could be delayed or halted.

**Manufacturing problems could delay product shipments and regulatory approvals, which may adversely affect our results of operations.**

We depend on third parties to perform manufacturing activities effectively and on a timely basis. If these third parties fail to perform as required, this could impair our ability to deliver our products on a timely basis or cause delays in our clinical trials and applications for regulatory approval, and these events could harm our competitive position. 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.

For Viread, Hepsera, Vistide and Emtriva, we rely on third parties for the manufacture of bulk drug substance and final drug product for clinical and commercial purposes. In addition, Roche is responsible for manufacturing Tamiflu. These third-party manufacturers may develop problems over which we have no control and these problems may adversely affect our business. For example, in January 2002, Roche announced that due to production problems the liquid suspension form of Tamiflu approved for treatment of children as young as one year old was not available. In Japan, where the 2002-2003 flu season was particularly severe, Roche's sublicensee, Chugai Corporation, was unable to meet heightened demand satisfactorily. In January 2003, Chugai issued a press release attributing this failure, in part, to manufacturing problems. These problems in Japan have reduced the net sales and our royalty from Roche.

We manufacture AmBisome at our facilities in San Dimas, California. These are our only formulation and manufacturing facilities in the U.S. We own a manufacturing facility in Ireland that performs certain

quality control testing, labeling and packaging. In addition, 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 to meet market needs.

**We may not be able to obtain materials necessary to manufacture our products, which could limit our ability to generate revenues.**

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, distearoylphosphatidylcholine and high quality cholesterol, each of which is used in the manufacture of one or more of our liposomal products. Because the suppliers of key components and materials must be named in the new drug application filed with the FDA for a product, significant delays can occur if the qualification of a new supplier is required. If supplies from our suppliers were interrupted for any reason, we may be unable to ship Viread, AmBisome, Hepsera, Emtriva or Vistide, or to supply any of our products in development for clinical trials.

**We may need to develop additional manufacturing capacity for our existing and future products, which will increase our expenses.**

We have evaluated in the past, and continue to evaluate, the feasibility of acquiring manufacturing capabilities to support the production of our products, principally Viread and Emtriva. These facilities may be required to increase production capacities in order to support clinical trials and to produce such products for commercial sale at an acceptable cost. We have not manufactured these products in the past. Developing these technological capabilities and building or purchasing a facility will increase our expenses with no guarantee that we will be able to recover our investment in our manufacturing capabilities.

**We depend on relationships with other companies for 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 sales and marketing performance. These include collaborations with Fujisawa and Sumitomo for AmBisome, GSK for Hepsera, Roche for Tamiflu, Pfizer for Vistide and Japan Tobacco for Viread and Emtriva. In certain countries, we rely on international distributors for sales of AmBisome, Viread and Emtriva and in some European countries, we intend to rely only on international distributors for sales of Hepsera. Some of these relationships also involve the clinical development of these products by our partners. Reliance on collaborative relationships poses a number of risks, including:

- we will not be able to control whether our corporate partners will devote sufficient resources to our programs or products;
- disputes may arise in the future with respect to the ownership of rights to technology developed with corporate partners;
- disagreements with corporate partners could lead to delays in or termination of the research, development or commercialization of product candidates, or result in litigation or arbitration;
- contracts with our corporate partners may fail to provide significant protection or may fail to be effectively enforced if one of these partners fails to perform;
- corporate partners have considerable discretion in electing whether to pursue the development of any additional products and may pursue alternative technologies or products either on their own or in collaboration with our competitors;

- corporate partners with marketing rights may choose to devote fewer resources to the marketing of our products than they do to products of their own development; and
- our distributors and corporate partners may be unable to pay us

Given these risks, there is a great deal of uncertainty regarding the success of our current and future collaborative efforts. If these efforts fail, our product development or commercialization of new products could be delayed or revenue from existing products, including Viread, Emtriva, Hepsera, AmBisome and Tamiflu, could decline.

Under our April 2002 licensing agreement with GSK, we gave GSK the right to control clinical and regulatory development and commercialization of Hepsera in territories in Asia, Africa and Latin America. These include major markets for Hepsera, such as China, Japan, Taiwan and Korea. The success of Hepsera in these territories will depend almost entirely on the efforts of GSK. In this regard, GSK promotes Epivir—HBV, a product that competes with Hepsera. Consequently, GSK's marketing strategy for Hepsera may be influenced by its promotion of Epivir—HBV. We receive royalties from GSK equal to a percentage of net sales made by GSK. If GSK fails to devote sufficient resources to, or does not succeed in developing or commercializing Hepsera in its territories, our potential revenues from sales of Hepsera may be substantially reduced.

**Expenses associated with clinical trials and sales fluctuations as a result of inventory levels held by wholesalers may cause our earnings to fluctuate, which could adversely affect our stock price.**

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 may cause our operating results to fluctuate from quarter to quarter. In addition, a substantial portion of our sales activity in the United States is conducted with three distributors, Amerisource Bergen Corp., McKesson Corp. and Cardinal Health, Inc. Inventory levels held by these and other wholesalers may fluctuate significantly which could cause our sales to them and as a result, our operating results, to fluctuate unexpectedly from quarter to quarter. For example, based on our review of NDC prescription trends, IMS inventory data and actual Viread sales, we believe, in the quarter ended June 30, 2003, wholesalers built up inventory levels by an estimated 1.2 months. We believe this inventory build-up was followed by an equivalent or possibly greater inventory reduction during the quarter ended September 30, 2003.

**Approximately half of our product sales occur outside the U.S., and currency fluctuations may cause our earnings to fluctuate, which could adversely affect our stock price.**

A significant percentage of our product sales are 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 equivalent sales and negatively impact our financial condition and results of operations. We use foreign currency forward contracts to hedge a percentage of our forecasted international sales, primarily those denominated in the Euro currency. We also hedge a portion of our accounts receivable balances denominated in foreign currencies, which reduces but does not eliminate our exposure to currency fluctuations between the date a sale is recorded and the date that cash is collected. Additionally, to mitigate the impact of currency rate fluctuations on our cash outflows for certain foreign currency-denominated raw materials purchases, we enter into foreign exchange forward contracts to hedge our foreign currency-denominated accounts payable. Although we use forward contracts to reduce the impact of foreign currency fluctuations on our future results, these efforts may not be successful and any such fluctuations could adversely affect our results of operations.

**We face credit risks from our European customers that may adversely affect our results of operations.**

We are particularly subject to credit risk from our European customers. Our European product sales to government owned or supported customers in Greece, Spain, Portugal, and Italy are subject to significant payment delays due to government funding and reimbursement practices. Our accounts receivable from government owned or supported customers in these countries totaled \$148.4 million as of December 31, 2003. If significant changes were to occur in the reimbursement practices of European governments or if government funding becomes unavailable, we may not be able to collect on amounts due to us from these customers and our results of operations would be adversely affected.

**Our plan to supply Viread at our cost to certain developing countries may expose us to liability that would have a material adverse affect on our results of operations and financial condition.**

We are launching a distribution program pursuant to which we will supply Viread at our cost to all countries in Africa and to the 15 other countries designated “Least Developed Countries” by the United Nations. The supply and distribution of drugs in a resource-poor environment is a complicated undertaking. As this program develops, we could face unforeseen challenges and risks, which could give rise to unforeseen liabilities. For example, patients in less developed countries using Viread may not be as closely supervised by a doctor as they would be in more developed nations. Accordingly, there may be an increased likelihood of Viread-related complications going undetected or untreated, which could result in significant liability to Gilead.

**Our product revenues could be reduced by imports from countries where our products are available at lower prices.**

Prices for our products are based on local market economics and competition and sometimes differ from country to country. Our sales in countries with relatively higher prices may be reduced if products can be imported into those countries from lower price markets. There have been cases in which pharmaceutical products were sold at steeply discounted prices in the developing world and then re-exported to European countries, where they could be re-sold at much higher prices. If this happens with our products, particularly Viread, which we have agreed to provide at our cost to all countries in Africa and to the 15 other countries designated “Least Developed Countries” by the United Nations, our revenues would be adversely affected.

In addition, in the European Union, we are required to permit cross border sales. This allows buyers in countries where government-approved prices for our products are relatively high to purchase our products legally from countries where they must be sold at lower prices. Additionally, some U.S. consumers have been able to purchase products, including HIV medicines, from Internet pharmacies in other countries at substantial discounts. Such cross-border sales could adversely affect our revenues.

**In some countries, we may be required to grant compulsory licenses for our HIV products or face generic competition for our HIV products.**

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

increase the risk of counterfeiting as we would no longer have control over manufacturing and distribution in those markets. In addition, countries such as Canada are considering amending their patent laws to permit the export of otherwise patented products to countries in the developing world. In all of these situations, our results of operations could be adversely affected.

**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 and Vistide, and a significant percentage of our sales of Viread and Hepsera, are subject to reimbursement by government agencies, resulting in significant discounts from list price and rebate obligations. Our business may be adversely affected by an increase in U.S. or international pricing pressures. These pressures can arise from rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and health care reform, pharmaceutical reimbursement and pricing in general. In the U.S. in recent years, new legislation has been proposed at the federal and state levels that would effect major changes in the health care system, either nationally or at the state level. These proposals have included prescription drug benefit proposals for Medicare beneficiaries recently passed by Congress. Additionally, some states have enacted health care reform legislation. Further federal and state developments are possible. Our results of operations could be adversely affected by future health care reforms. In Europe, the success of Hepsera, Tamiflu, Emtriva and Viread will also depend largely on obtaining and maintaining government reimbursement 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 regulatory marketing approval is received, pricing negotiations with governmental authorities can take twelve months or longer. Some foreign governments have passed, or are considering, legislation to require us to sell our products subject to reimbursement at a mandatory discount. Sales of competing products, attempts to gain market share or introductory pricing programs of our competitors could also require us to lower our prices in these countries, which could adversely affect our results of operations.

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

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

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

We have rights to U.S. and foreign issued patents and have filed and will continue to file patent applications in the U.S. and abroad relating to our technologies. There is a risk, however, that patents may not issue from any of these applications or that the patents will not be sufficient to protect our technology.

Patent applications are confidential for at least some period of time, sometimes in the U.S. until a patent issues. As a result, we may not know if our competitors filed patent applications for technology covered by our pending applications or if we were the first to invent the technology that is the subject of our patent applications. 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 in China or certain other Asian countries covering all forms of adefovir dipivoxil, the active ingredient in Hepsera, although we do have applications pending in various Asian countries that relate to various forms and formulations of adefovir dipivoxil. Asia is a major market for therapies for hepatitis B, the indication for which Hepsera has been developed. 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 we are ultimately successful.

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

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.

**We may face significant liability resulting from our products that may not be covered by insurance and successful claims could materially reduce our earnings.**

The testing, manufacturing, marketing and use of Viread, AmBisome, Hepsera, Emtriva, Tamiflu, and Vistide 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. Although we maintain product liability insurance, a successful product liability claim against us may not be covered by our insurance or could require us to pay amounts beyond that provided by our insurance, either of which could impair our financial condition and our ability to clinically test and to market our products.

## **ITEM 2. PROPERTIES**

Our corporate headquarters, including our principal executive offices and some of our research facilities, are located in Foster City, California. At this location, we own approximately 496,000 square feet of space in 16 proximately located buildings. We currently occupy 10 of the 16 buildings and also have a tenant occupying some of the remaining buildings.

We also occupy facilities in San Dimas, California. At this location, we lease approximately 102,500 square feet of space, which houses research and development activities, manufacturing and certain administrative functions. These leases expire in May 2008 and November 2013, with no renewal options at present. In addition, we lease an adjacent warehouse facility with about 53,000 square feet of space that we use for product distribution and administrative functions. This lease expires in May 2006, with two additional five-year extensions.

In Durham, North Carolina, we lease approximately 101,000 square feet of administrative office and laboratory space, of which we sublease approximately 21,000 square feet to third parties. This lease expires in October 2009, after which Gilead has the option to renew for two seven-year terms.

In addition, we lease approximately 141,000 square feet of space for our sales and marketing, regulatory, finance, information technology and human resource operations in Europe and Australia, including a prepaid, 999-year lease for our 13,000 square foot manufacturing and distribution facility in Ireland. The other leases have various expiration dates.

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

### **ITEM 3. LEGAL PROCEEDINGS**

On September 4, 2003, Gilead entered into a Settlement Agreement and Release with University License Equity Holdings, Inc. (ULEHI) and Archemix Corporation concerning rights to identify aptamers using the SELEX technology licensed by ULEHI to Gilead. The Settlement Agreement and Release resolves disputes among the parties arising out of Gilead's assignment of rights to identify certain aptamers to Archemix.

On September 2, 2003, the County of Westchester, New York ("Westchester") served Gilead with a complaint filed in the United States District Court for the Southern District of New York which alleges that Gilead and a large number of other pharmaceutical manufacturer defendants report prices for products that overstate the Average Wholesale Price ("AWP"), allegedly inflating reimbursement rates under the Medicaid Program and causing Westchester to pay artificially inflated prices for covered drugs including, in the case of Gilead, Viread. In addition, Westchester argues that the defendants, including Gilead, did not accurately report the "best price" under the Medicaid Program. The complaint asserts varying claims under the federal RICO statutes, their state law corollaries, as well as state law claims for deceptive trade practices and common law fraud. Gilead intends to vigorously defend itself against the allegations. The complaint seeks an undetermined amount of damages, as well as other relief, including declaratory and injunctive relief. Other defendants in this lawsuit have been named in numerous other lawsuits with comparable AWP allegations. To our knowledge, Gilead has not been named in these other lawsuits. Were Gilead to be named and served in other lawsuits with comparable AWP allegations, adverse results could result in material damages.

A purported class action complaint was filed on November 10, 2003 in the United States District Court for the Northern District of California against Gilead and our Company's Chief Executive Officer, Chief Financial Officer, Executive Vice Presidents of Operations and Research and Development, and Senior Vice Presidents of Manufacturing and Research. The complaint alleges that the defendants violated the federal securities laws, specifically Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 of the Securities and Exchange Commission, by making certain alleged false and misleading statements. The plaintiff seeks unspecified damages on behalf of a purported class of purchasers of the Gilead's securities during the period from July 14, 2003 through October 28, 2003. Other similar actions were subsequently filed and the court issued an order consolidating the lawsuits into a single action on December 22, 2003. We believe that we have meritorious defenses to the allegations contained in the complaint and intend to defend the case vigorously. No trial date has been scheduled. On February 9, 2004, the court issued an order appointing lead plaintiffs in the action, and these lead plaintiffs have until March 25, 2004 to file a consolidated complaint.

In December 2003, two purported shareholder derivative lawsuits were filed by individual shareholders on behalf of Gilead against its directors and certain executive officers in the Superior Court of the State of California, County of San Mateo alleging, among other things, that defendants violated the California Corporations Code and breached fiduciary duties owing to Gilead. Gilead is named as a



nominal defendant. The plaintiffs seek unspecified damages on behalf of Gilead in connection with alleged insider trading during the period between July 14, 2003 and October 28, 2003 and defendants' alleged breach of their fiduciary duties, abuse of control, waste and mismanagement. The two cases were consolidated into a single action on January 15, 2004 and plaintiffs filed a consolidated complaint on February 12, 2004. No trial date has been scheduled. We intend to take all appropriate action to defend our interests in connection with this litigation.

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 a material adverse impact on our business, results of operations or financial position.

#### **ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

No matters were submitted to a vote of securities holders during the quarter ended December 31, 2003.

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### **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, markdowns or commissions, and may not represent prices of actual transactions.

	<u>High</u>	<u>Low</u>
<b>2003</b>		
First Quarter	\$ 43.20	\$ 31.24
Second Quarter	\$ 57.37	\$ 40.58
Third Quarter	\$ 70.61	\$ 53.37
Fourth Quarter	\$ 61.65	\$ 50.27
<b>2002</b>		
First Quarter	\$ 39.00	\$ 28.95
Second Quarter	\$ 38.19	\$ 28.05
Third Quarter	\$ 37.25	\$ 26.08
Fourth Quarter	\$ 40.00	\$ 30.61

As of February 27, 2004, we had 213,780,787 shares of common stock outstanding held by approximately 511 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 18, 2002 we issued \$345.0 million of 2% convertible senior notes due December 15, 2007 in a private offering to Goldman, Sachs & Co., which resold the notes to qualified institutional investors. The notes are currently convertible into a total of 7,340,425 shares of common stock at \$47.00 per share. Net proceeds were approximately \$336.6 million.

**ITEM 6. SELECTED FINANCIAL DATA**

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

	Year Ended December 31,				
	2003	2002	2001	2000	1999
<b>CONSOLIDATED STATEMENT OF OPERATIONS DATA:</b>					
Total revenues	\$ 867,864	\$ 466,790	\$ 233,769	\$ 195,555	\$ 168,979
In-process research and development	488,599	—	—	—	—
Total costs and expenses	1,026,539	385,783	354,458	247,873	239,838
Income (loss) from operations	(158,675)	81,007	(120,689)	(52,318)	(70,859)
Gain on sale of oncology assets	—	—	157,771	—	—
Provision for (benefit from) income taxes	(95,530)	1,300	4,135	1,199	888
Income (loss) before cumulative effect of change in accounting principle	(72,003)	72,097	51,182	(43,106)	(66,486)
Cumulative effect of change in accounting principle(2)	—	—	1,089	(13,670)	—
Net income (loss)	<u>\$ (72,003)</u>	<u>\$ 72,097</u>	<u>\$ 52,271</u>	<u>\$ (56,776)</u>	<u>\$ (66,486)</u>
Amounts per common share—basic:					
Income (loss) before cumulative effect of change in accounting principle	\$ (0.36)	\$ 0.37	\$ 0.27	\$ (0.24)	\$ (0.39)
Cumulative effect of change in accounting principle	—	—	0.01	(0.07)	—
Net income (loss) per share—basic	<u>\$ (0.36)</u>	<u>\$ 0.37</u>	<u>\$ 0.28</u>	<u>\$ (0.31)</u>	<u>\$ (0.39)</u>
Shares used in per share calculation—basic	<u>201,105</u>	<u>195,543</u>	<u>190,245</u>	<u>182,099</u>	<u>171,305</u>
Amounts per common share—diluted:					
Income (loss) before cumulative effect of change in accounting principle	\$ (0.36)	\$ 0.35	\$ 0.25	\$ (0.24)	\$ (0.39)
Cumulative effect of change in accounting principle	—	—	0.01	(0.07)	—
Net income (loss) per share—diluted	<u>\$ (0.36)</u>	<u>\$ 0.35</u>	<u>\$ 0.26</u>	<u>\$ (0.31)</u>	<u>\$ (0.39)</u>
Shares used in per share calculation—diluted	<u>201,105</u>	<u>206,477</u>	<u>202,321</u>	<u>182,099</u>	<u>171,305</u>

**GILEAD SCIENCES, INC.**  
**SELECTED CONSOLIDATED FINANCIAL DATA (Continued)**  
(in thousands)

	December 31,				
	2003	2002	2001	2000	1999
<b>CONSOLIDATED BALANCE SHEET DATA:</b>					
Cash, cash equivalents and marketable securities	\$ 707,000	\$ 942,374	\$ 582,851	\$ 512,878	\$ 294,394
Working capital	1,080,003	1,078,868	627,642	535,560	324,104
Total assets	1,554,722	1,288,183	794,786	678,099	436,808
Long-term obligations	323	273	389	2,238	5,253
Convertible debt	345,000	595,000	250,000	250,000	79,533
Accumulated deficit	(453,643)	(381,640)	(453,737)	(506,008)	(449,232)
Total stockholders' equity(3)	1,002,974	571,341	452,437	351,124	297,292

- (1) During 2003, Gilead completed the acquisition of all of the net assets of Triangle for an aggregate purchase price of \$525.2 million. Approximately \$488.6 million of the purchase price was allocated to in-process research and development. Also during 2003, we recorded an income tax benefit of \$111.6 million related to the reduction of the valuation allowance on certain of our net deferred tax assets. During 2002, we sold all of our shares of OSI common stock and recognized a loss on the sale of marketable securities of \$16.0 million. These shares were partial consideration for the sale of our oncology assets in 2001. During 2001, we completed the sale of our oncology assets and related technology to OSI Pharmaceuticals, Inc. and recorded a non-operating gain of \$157.8 million. In 2001, we also recorded a non-operating gain of \$8.8 million from the sale of our 49 percent interest in Prologo.
- (2) Gilead adopted Statement of Financial Accounting Standards Nos. 133 and 138, collectively referred to as SFAS 133, *Accounting for Derivative Instruments and Hedging Activities*, in the first quarter of 2001. The change was accounted for as a change in accounting principle. Effective in the first quarter of 2000, Gilead adopted the SEC's Staff Accounting Bulletin No. 101 (SAB 101), *Revenue Recognition in Financial Statements*, and the change was also accounted for as a change in accounting principle.
- (3) No cash dividends have been declared or paid on our common stock.

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

**Executive Summary**

We are a biopharmaceutical company that discovers, develops and commercializes therapeutics to advance the care of patients suffering from life-threatening diseases. We are a multinational company, with revenues from six approved products and marketing operations in ten countries. We focus our research and clinical programs on anti-infectives. Currently, we market Viread (tenofovir disoproxil fumarate) and Emtriva (emtricitabine) for the treatment of HIV infection; Hepsera (adefovir dipivoxil) for the treatment of chronic hepatitis B infection; AmBisome (amphotericin B liposome for injection), an antifungal agent; and Vistide (cidofovir injection) for the treatment of CMV retinitis. Roche markets Tamiflu (oseltamivir phosphate) for the treatment of influenza, under a royalty paying collaborative agreement with us. In December 2003, we made the decision to discontinue selling DaunoXome (daunorubicin citrate liposome injection), a drug approved for the treatment of Kaposi's Sarcoma. We are seeking to add to our existing portfolio of products through our internal discovery and clinical development programs and through an

active product acquisition and in-licensing strategy, such as our acquisition of the assets of Triangle Pharmaceuticals, Inc. completed in January 2003. Our internal discovery activities include identification of new molecular targets, target screening and medicinal chemistry. In addition, we are currently developing clinical stage products to treat HIV infection and chronic hepatitis B.

Our operating results for 2003 in comparison to 2002 were characterized by solid growth in our key HIV drug, Viread and represent our second consecutive year of significant increases in total product revenues. Based on independent third party data, Viread has become one of the most widely prescribed antiretrovirals in its class of drugs, achieving more new and total prescriptions than competing drugs in the nucleotide/nucleoside reverse transcriptase inhibitor (NRTI) market. As a result of the growth of Viread sales, higher than expected AmBisome sales and controlled spending, we have generated positive cash flow from operations for each of the last two years, with an increase to \$234.6 million in 2003 from \$74.4 million in 2002, or 215% year over year growth. We expect our HIV drug sales to grow in the near term, although we expect it to be at a slower rate than we have experienced in the past two years. Enabling this growth is the increasing importance of once-daily regimens in prescribing HIV medications. The availability of both Viread and Emtriva (acquired from Triangle) now provide physicians the ability to construct once-daily regimens.

Operating results for 2003 were impacted by the acquisition of all of the assets of Triangle in January 2003. We completed this acquisition to expand our antiviral pipeline. Triangle was a development stage company with a particular focus on potential therapies for HIV, including AIDS, and the hepatitis B virus (HBV). The aggregate purchase price was \$525.2 million, including cash paid of \$463.1 million for the outstanding stock, the fair value of stock options assumed of \$41.3 million, estimated direct transaction costs of \$14.2 million and employee related costs of \$6.6 million. Approximately \$488.6 million of the purchase price was allocated to in-process research and development and represented the fair value of Triangle's incomplete research and development programs that had not yet reached technological feasibility and had no alternative future use as of the acquisition date. As a result of this transaction and the related in-process research and development charge, our operating loss for 2003 was \$158.7 million versus operating income of \$81.0 million in 2002. This acquisition was important to us not only for the compounds we acquired, but also for the opportunity it provided us to create a co-formulation of Viread and Emtriva into a single pill that can be dosed once a day. If successful, we expect this co-formulated product to further grow our HIV franchise. See Note 3 to the consolidated financial statements for further information on the Triangle acquisition.

In December 2001, we completed the sale of our oncology assets to OSI Pharmaceuticals, Inc. in a transaction valued at up to \$200.0 million in cash and OSI stock. This transaction has allowed us to focus on and continue to strengthen our core expertise in infectious diseases. See Note 6 to the consolidated financial statements for further information.

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. Please read "Risk Factors that Affect Gilead" in Part I for factors that could cause or contribute to material differences between these forward-looking statements and actual results. The "Risk Factors" discussion should be read in conjunction with the consolidated financial statements and notes included elsewhere in this report.

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## **Critical Accounting Policies, Estimates and Judgments**

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

We believe the following critical accounting policies reflect the more significant judgments and estimates used in the preparation of our consolidated financial statements:

- We record estimated reductions to revenue for expected returns of expired products, government rebate programs, such as Medicaid reimbursements, and customer incentives, such as cash discounts for prompt payment. Estimates for government rebate programs and cash discounts are based on contractual terms, historical utilization rates and expectations regarding future utilization rates for these programs. Estimates for product returns, including new products, are based on an on-going analysis of industry and historical return patterns. This includes monitoring the feedback that we receive from our sales force regarding customer use and satisfaction, the purchase of third-party data to assist us in monitoring channel inventory levels and subsequent prescriptions as well as, for new products, a review of our other long shelf life products we have sold through the same or similar channels. Further, we monitor the activities and clinical trials of our key competitors and assess the potential impact on our future sales and return expectations where necessary. Expected returns for our marketed drugs are generally low because the shelf life for these products ranges from 24 months for Viread up to 36 months for AmBisome in the U.S. If conditions become more competitive for any of the markets served by our drugs or if other circumstances change, we may take actions to increase our product return estimates or we may offer additional customer incentives. This would result in an incremental reduction of future revenue at the time the return estimate is changed or incentives are offered. For example, between 2002 and 2003, we increased our reserve for government discounts on Viread sales by more than 3% as a result of our review of historical utilization rates and the impact of a 2003 mid-year price increase for Viread. We

could see similar increases in the future based on our continued reviews of utilization rates and any potential U.S. price increases for Viread.

- We also maintain an allowance for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. This allowance is based on our analysis of several factors including, but not limited to, historical payment patterns of our customers and individual customer circumstances, an analysis of days sales outstanding by customer and geographic region, and a review of the local economic environment and its potential impact on the government funding and reimbursement practices. If the financial condition of our customers or the economic environment in which they operate were to deteriorate, resulting in an inability to make payments, additional allowances may be required. Our allowance for doubtful accounts balance as a percentage of total accounts receivable did not materially change from December 31, 2002 to December 31, 2003. We believe that the allowance for doubtful accounts is adequate to cover anticipated losses under current conditions; however, significant deterioration in any of the above factors, especially with respect to the government funding and reimbursement practices in the European market, could materially change these expectations and result in an increase to our allowance for doubtful accounts.

- We write down our inventory based on historical review of the quantity of raw material bad batches experienced in a given year and expectations of production and inventory levels. We also perform quality control reviews of our individual raw material batches. We generally do not maintain inventory reserves based on estimated obsolescence or risk of competition primarily because the shelf life of the products is long. However, if our current assumptions about future production or inventory levels, demand and competition were to change and if actual market conditions are less favorable than those projected by management, additional inventory reserves may be required which could negatively impact our product gross margins.
- We record accruals for estimated clinical and preclinical study costs. Most of our clinical and preclinical studies are performed by third party contract research organizations (CROs). These costs are a significant component of research and development expenses. During 2003, 2002, and 2001, we incurred \$15.0 million, \$23.9 million and \$33.6 million, respectively, of CRO costs. We accrue costs for clinical studies performed by CROs on a straight-line basis over the term of the service period and adjust our estimates, if required, based upon our on-going review of the level of effort actually incurred by the CRO. Initially we estimate that the work performed under the contracts occurs ratably over the periods to the expected milestone, event or total contract completion date. The expected completion dates are estimated based upon the terms of the contracts and past experience with similar contracts. These estimates may or may not match the actual services performed by the organizations as determined by patient enrollment levels and other measures of activities specified in the contract. As a result, we validate our accruals quarterly through written vendor confirmations and detailed reviews of the activities performed under each contract. Based upon the results of these validation processes, we assess the appropriateness of our accruals and make any adjustments we deem necessary so that our expenses reflect the actual effort incurred by the CROs. Generally, a significant portion of the total costs are associated with start up activities for the trial and patient enrollment. Gilead extensively outsources its clinical trial activities and usually performs only a small portion of the start-up activities in-house. As a result, CROs typically perform most of the total start-up activities for our trials, including document preparation, site identification, screening and preparation, pre-study visits, training, and program management. On a budgeted basis, these costs are typically 25% to 30% of the total contract value. On an actual basis, this percentage range is significantly wider as many of our contracts are either expanded or contracted in scope compared to the original budget while the start-up costs for the particular trial do not change significantly. Start-up costs usually occur within a few months after the contract has been established and are milestone or event driven in nature. The remaining activities and related costs, such as patient monitoring and administration, generally occur ratably throughout the life of the individual contract or study. Most contracts are negotiated as fixed price and can vary in length between six months for a single dose Phase 1 study and up to two years or more for a more complex Phase 3 study. The average length of contract for 2002 and 2003 has been at the upper end of this range in order to provide long term safety and efficacy data to support the commercial launches of Viread, Hepsera and Emtriva. Through December 31, 2003, we have not understated or overstated activity levels for any particular study such that a material adjustment was required. All of our material CRO contracts are terminable by us upon written notice and Gilead is generally only liable for actual effort expended by the CRO at any point in time during the contract, regardless of payment status. Amounts paid in advance of services being performed will be refunded if a contract is terminated. However, if management does not receive complete and accurate information from our vendors or has underestimated activity levels associated with a study at a given point in time, we would have to record additional and potentially significant research and development expenses in future periods.
- We develop our income tax provision including deferred tax assets and liabilities based on significant management judgment. We record a valuation allowance to reduce our deferred tax

assets to the amount that is likely to be realized. We consider future taxable income, ongoing tax planning strategies and our historical financial performance in assessing the need for a valuation allowance. If it were determined that we would be able to realize certain deferred tax assets related to the valuation allowance, an adjustment to the deferred tax asset would increase income in the period in which such determination was made. Such an adjustment was made in the fourth quarter of 2003 when we determined that it was more likely than not that certain of our deferred tax assets will be realized and therefore released the related valuation allowance. This resulted in an income tax benefit of approximately \$111.6 million. Likewise, if we determine that we would not be able to realize all or part of our deferred tax asset in the future, an adjustment to the deferred tax asset would be charged to income in the period in which such determination was made. We evaluate the realizability of our deferred tax assets on a quarterly basis. Our future effective tax rate may be affected by such factors as changes in tax laws or rates, changes in interpretation to these laws and overall changes in future levels of earnings and research and development and capital spending.

Management has discussed the development and selection of these critical accounting policies with the Audit Committee of Gilead's Board of Directors and the Audit Committee has reviewed the disclosure presented above relating to them.

## Results of Operations

### *Total revenues*

We had total revenue of \$867.9 million in 2003, \$466.8 million in 2002 and \$233.8 million in 2001. Included in total revenue are net product sales, royalty revenue and contract revenue, including revenue from research & development (R&D) and manufacturing collaborations. Product sales consisted of the following (in thousands):

### *Product sales*

	<u>2003</u>	<u>Change</u>	<u>2002</u>	<u>Change</u>	<u>2001</u>
Viread	\$ 566,478	151%	\$ 225,815	1349%	\$ 15,586
AmBisome	198,350	7%	185,669	13%	164,533
Other	71,513	477%	12,395	14%	10,851
Total product sales	<u>\$ 836,341</u>	<u>97%</u>	<u>\$ 423,879</u>	<u>122%</u>	<u>\$ 190,970</u>

Product sales increased 97% in 2003 compared to 2002 primarily due to significant increases in sales of Viread for HIV, which was approved for sale in the U.S. in October 2001 and the European Union in February 2002 and has since become an antiretroviral therapy widely prescribed by physicians. A significant percentage of our product sales continue to be denominated in foreign currencies. Prior to 2002, we did not hedge our exposure to the impact of fluctuating foreign exchange rates on forecasted sales. In January 2002, we began to use forward contracts to hedge a percentage of our forecasted international sales, primarily those denominated in the Euro currency. This reduces, but does not eliminate, fluctuations in sales due to changes in foreign currency exchange rates. Losses on these revenue hedges reduced product revenues by \$2.8 million in 2003 and \$1.0 million in 2002.

Sales of Viread were 68% of total product sales in 2003, compared to 53% of total product sales in 2002 and 8% of total product sales in 2001. Of the Viread sales in 2003, \$355.9 million were U.S. sales, an increase of 113% versus 2002, and \$210.6 million were international sales, an increase of 258% versus 2002. With the continued market expansion of Viread, we expect Viread sales in 2004 to grow approximately 25% to 30% and be in the range of \$700 million to \$750 million.

During 2003, we experienced significant fluctuations in U.S. distribution channel inventory levels due to speculative purchasing by the major wholesalers. As a result, we experienced increased quarter to quarter sales volatility from these purchasing patterns. While we have enacted certain policies to reduce this type of purchasing and are in discussions with our key wholesalers, we expect to continue to experience sales volatility for the foreseeable future.

Prior to 2002, our revenues were primarily derived from sales of AmBisome, which represented 44% of total product sales in 2002 and 86% of total product sales in 2001. AmBisome sales in 2003 were \$21.7 million higher due to the favorable currency environment compared to 2002. On a volume basis, AmBisome sales in Europe decreased by 5% compared to 2002 due to increasing competition. Excluding the impact of foreign currencies relative to the U.S. dollar, AmBisome sales grew 9% for 2002 over 2001. The increase in sales in 2002 compared to 2001 was primarily due to volume sales increases in Europe, which offset declining sales in the U.S. With the expected increase in competition, we expect AmBisome sales for 2004 to be lower than 2003 and in the range of \$160 million to \$180 million.

#### *Royalty Revenue*

We recorded royalty revenue of \$25.2 million in 2003, compared with \$20.4 million in 2002 and \$23.0 million in 2001. During this three-year period, the most significant source of royalty revenue was from sales of AmBisome in the U.S. by Fujisawa under a co-promotion arrangement with us. Royalty revenue from Fujisawa was \$12.5 million in 2003, compared with \$15.7 million in 2002 and \$17.1 million in 2001.

We also recorded royalty revenue of \$12.0 million in 2003, \$3.4 million in 2002 and \$4.5 million in 2001 related to sales of Tamiflu. We began recognizing royalties from Tamiflu in the first quarter of 2000. In June 2002, Roche received European regulatory approval of Tamiflu for the treatment of influenza in adults and children and prevention in adolescents and adults. As it is difficult to estimate third party product sales, we record royalty revenue one quarter in arrears. Due to this lag in reporting, the royalties related to the severe flu epidemic in the U.S. in the fourth quarter of 2003 will be recorded in the first quarter of 2004.

#### *Contract Revenue*

Total contract revenue was \$6.3 million in 2003, compared with \$22.5 million in 2002 and \$19.8 million in 2001. In 2002 and 2001 a primary source of contract revenue was our licensing of the SELEX process patent estate to Archemix, which, due to collectibility concerns, we recognized as the cash was received. This provided contract revenue of \$8.1 million in 2002 and \$8.6 million in 2001. In 2002, Roche made milestone payments of \$8.0 million for the European prophylaxis and treatment approvals of Tamiflu, and in 2001 made a \$2.0 million milestone payment relating to the development of Tamiflu under an R&D collaboration agreement. As of December 31, 2003, we are entitled to additional milestone payments of up to \$1.6 million upon Roche achieving certain developmental and regulatory milestones.

In April 2002, Gilead and GSK entered into a licensing agreement providing GSK the rights to commercialize Hepsera, our antiviral for the treatment of chronic hepatitis B, in Asia, Latin America and certain other territories. Under the agreement, Gilead retained rights to Hepsera in the U.S., Canada, Eastern and Western Europe, Australia and New Zealand. GSK received exclusive rights to develop Hepsera solely for the treatment of chronic hepatitis B in all of its territories, the most significant of which include China, Korea, Japan and Taiwan. GSK paid us an up-front licensing fee of \$10.0 million and, may pay up to an additional \$30.0 million upon achievement by GSK of certain regulatory, development and commercial milestones. Of this \$30.0 million, \$2.0 million was received for the U.S. approval of Hepsera in September 2002 and \$2.0 million was received for the Canadian approval of Hepsera in August 2003. GSK also will pay us a royalty on net sales, if any, of Hepsera in the GSK territories. GSK will have full



responsibility for development and commercialization of Hepsera in GSK's territories. The \$10.0 million up-front fee and \$4.0 million of approval milestone fees have been recorded as deferred revenue with a total of \$0.9 million and \$0.5 million being recognized as contract revenue in 2003 and 2002, respectively. The \$12.6 million balance of deferred revenue at December 31, 2003 will be amortized into contract revenue over the period of our remaining obligations under the agreement, approximately 12 years.

In December 2001, we completed the sale of our oncology assets to OSI. To date, we have received \$130.0 million in cash and \$38.8 million in OSI stock from this sale. Under this agreement, we are entitled to additional payments from OSI of up to \$30.0 million in either cash or a combination of cash and OSI stock if and when OSI reaches certain development milestones for NX 211, the most advanced of the oncology product candidates sold to OSI. Under a related manufacturing agreement, we will produce NX 211 and GS 7904L, the two liposomal products included in the sale at our manufacturing facility in San Dimas, California. In 2003 and 2002, we recognized \$1.1 million and \$3.3 million, respectively, of contract revenue under this manufacturing agreement.

In October 2001, we entered into an agreement with Archemix Corporation relating to our SELEX technology. Under this agreement, we gave Archemix exclusive rights to the SELEX process, including therapeutic and other commercial applications to the extent not already licensed under pre-existing agreements. Archemix paid to us \$8.5 million in 2002 and \$9.0 million in 2001 and recorded the net amounts of \$8.1 million and \$8.6 million as contract revenue in 2002 and 2001, respectively. As required by our license agreement with ULEHI, we paid 5% of the \$8.5 million and \$9.0 million payments to ULEHI. We also received a warrant to purchase 350,000 shares of Archemix common stock, the value of which is not material. As required by our license agreement with ULEHI, we transferred 5% of this warrant to ULEHI at that time. We have since transferred the remainder of the warrant to ULEHI.

In March 2000, we entered into an agreement with EyeTech Pharmaceuticals, Inc. relating to our proprietary aptamer EYE001, currently known as Macugen. Currently in Phase 3 clinical trials, Macugen 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 Macugen, and, if the product is successfully commercialized, EyeTech will pay us royalties on worldwide sales of the product. EyeTech also will be responsible for all research and development costs. We provided clinical supplies of the product to EyeTech through March 2001. We received a \$7.0 million up-front licensing fee from EyeTech in April 2000, which has been recognized as revenue ratably over the one-year supply agreement period. Accordingly, \$5.2 million of the license fee was recorded as contract revenue in 2000, and \$1.8 million was recognized as revenue in 2001. We are also entitled to additional cash payments from EyeTech of up to \$25.0 million if and when EyeTech reaches certain Macugen development milestones. Additionally, we received a warrant to purchase 791,667 shares of EyeTech series B convertible preferred stock, exercisable at a price of \$6.00 per share, the price at which the stock was issued to other investors. In January 2004, EyeTech completed its initial public offering. We intend to exercise our warrant for shares of common stock and sell the shares subject to a 180-day lock-up period. The fair value of the warrant has been adjusted in the first quarter of 2004 as a result of the EyeTech public offering.

#### *Cost of Goods Sold*

The following table indicates cost of goods sold (in thousands):

	<u>2003</u>	<u>Change</u>	<u>2002</u>	<u>Change</u>	<u>2001</u>
Cost of goods sold	\$ 112,691	62 %	\$ 69,724	59 %	\$ 43,764

Substantially all of the increase from each year to year period can be attributed to increases in the volume of Viread sold, as this product was launched in the U.S. late in the third quarter of 2001.

### *Gross Margins*

Product gross margins were 86.5% in 2003, compared with 83.6% in 2002 and 77.1% in 2001. The improvement from 2002 to 2003 and 2001 to 2002 is primarily driven by product mix as Viread, a higher margin product, contributed more significantly to net product sales in each succeeding year.

Movements in foreign currency exchange rates also impact gross margins as we price our products in the currency of the country into which the products are sold while a significant majority of our manufacturing costs are in U.S. Dollars. For example, an increase in the value of these foreign currencies relative to the U.S. Dollar will positively impact gross margins since our manufacturing costs will remain approximately the same while our revenues after being translated into U.S. Dollars, will increase. In 2003 and 2002, gross margins were positively impacted by the weakening U.S. dollar while in 2001, gross margins were negatively impacted by these factors. Since 2002, forward contracts have been used to hedge a percentage of our forecasted international sales, which can reduce the impact that changes in foreign currency exchange rates have on our gross margins. Except for the potential impact of unpredictable and uncontrollable changes in exchange rates relative to the U.S. Dollar and the mix of product sales between Viread, Hepsera and AmBisome, we expect gross margins in 2004 to remain relatively stable compared to 2003.

### *Research and Development Expenses*

In 2003, R&D expenses were 31% of total costs and expenses, excluding purchased in-process research and development expense. In total, R&D expenses were \$164.9 million in 2003, compared with \$134.8 million in 2002 and \$185.6 million in 2001. The major components of R&D expenses consist of personnel costs, including salaries and benefits, clinical studies performed by contract research organizations, materials and supplies, and overhead allocations consisting of various support and facilities related costs. Our R&D activities are also separated into three main categories: research, clinical development and pharmaceutical development. Research costs typically consist of preclinical and toxicology work. Clinical development costs include Phase 1, 2, and 3 clinical trials as well as expanded access programs. Pharmaceutical development costs consist of product formulation and chemical analysis.

The following table breaks down research and development expenses into these major components (in thousands):

	<u>2003</u>	<u>Change</u>	<u>2002</u>	<u>Change</u>	<u>2001</u>
Research	\$ 37,497	35 %	\$ 27,856	(9)%	\$ 30,535
Clinical development	90,547	10 %	82,261	(23)%	107,229
Pharmaceutical development	36,829	49 %	24,641	(3)%	25,392
Oncology (divested)	—	—	—	—	22,397
Total	<u>\$ 164,873</u>	<u>22 %</u>	<u>\$ 134,758</u>	<u>(27)%</u>	<u>\$ 185,553</u>

The \$30.1 million increase in R&D spending in 2003 versus 2002 was attributable to increased headcount and the clinical trials associated with the development of Emtriva and the co-formulation of Viread and Emtriva. In addition, during 2003, we settled a contractual dispute with a vendor that resulted in reimbursement to us of \$13.2 million that was recorded to research and development expense. We expect R&D expenses in 2004 to be approximately \$200 million to \$220 million, or approximately 20% to 30% higher than 2003 expenses, due primarily to costs associated with the development of the fixed-dose combination of Viread and Emtriva.

The \$50.8 million decrease in R&D spending in 2002 compared to 2001 was primarily due to the reduction in expenses associated with the clinical program for Viread, which was approved by the FDA for sale in the U.S. in October 2001, and the elimination of expenses associated with our oncology program as

a result of the sale of that program to OSI in December 2001 . Additionally, in 2001 we recognized as expense \$10.6 million of a \$13.0 million up-front license fee paid to Cubist Pharmaceuticals related to the European licensing agreement for daptomycin, also known as Cidecin, signed in January 2001. Upon termination of this agreement in September 2002, we recorded \$2.0 million of R&D expense, which represented the remaining unamortized asset related to the preclinical oral formulation of daptomycin .

Industry reports indicate that a biopharmaceutical company generally takes 10 to 15 years (an average of 12 years) to research, develop and bring to market a new prescription medicine in the U.S. These averages are generally consistent with the projects that we develop internally, although our recent product development timelines have been on a more accelerated basis. Drug development in the U.S. is a process that includes several steps defined by the FDA. The process begins with the filing of an IND, which, if successful, allows opportunity for clinical study of the potential new medicine. Clinical development typically involves three phases of study: Phase 1, 2, and 3, and generally accounts for an average of seven years of a drug's total development time. The most significant costs associated with clinical development are the Phase 3 trials as they tend to be the longest and largest studies conducted during the drug development process. We currently have products in development that are in Phase 3 studies. The successful development of our products is highly uncertain. Completion dates and R&D expenses can vary significantly for each product and are difficult to predict. Even after successful development and FDA approval of a product, we undertake additional studies to try and expand the product's label and market potential. For a more complete discussion of the risks and uncertainties associated with completing the development of products, see the "Risk Factors That Affect Gilead" section of Item I above.

### *Selling, General and Administrative Expenses*

The following table highlights selling, general and administrative expenses (in thousands):

	<u>2003</u>	<u>Change</u>	<u>2002</u>	<u>Change</u>	<u>2001</u>
Selling, general and administrative	\$ 250,157	38 %	\$ 181,301	45 %	\$ 125,141

The increase in expenses in 2003 compared to 2002 is primarily due to our global sales and marketing efforts, including the expansion of our U.S. and European sales forces and increased infrastructure investments required to support the growth of our business.

The increase in expenses in 2002 compared to 2001 is primarily due to our global sales and marketing efforts, including the expansion of our U.S. and European sales forces to support the commercial launches of Viread and Hepsera.

In 2004, we expect SG&A expenses to be approximately \$310 million to \$330 million, or 25% to 30% higher than 2003 levels, primarily due to the increase in marketing activities associated with the continued promotion of Viread, Emtriva, Hepsera and AmBisome.

### *In-process Research and Development*

In connection with the acquisition of the net assets of Triangle completed in January 2003, we recorded in-process research and development expenses of \$488.6 million in the first quarter of 2003. The charge was due to Triangle's incomplete research and development programs that had not yet reached technological feasibility and had no alternative future use as of the acquisition date.

The remaining efforts for completion of Triangle's research and development projects primarily consist of clinical trials, the cost, length and success of which are extremely difficult to predict. Numerous risks and uncertainties exist that could prevent completion of development, including the ability to enroll patients in clinical trials, the possibility of unfavorable results of our clinical trials, and the risk of failing to obtain FDA and other regulatory body approvals. Feedback from regulatory authorities or results from

clinical trials might require modifications or delays in later stage clinical trials or additional trials to be performed. We cannot be certain that emtricitabine for the treatment of chronic hepatitis B, purchased from Triangle, will be approved in the U.S. or the European Union or whether marketing approvals will have significant limitations on its use. We have terminated our rights with respect to the other potential products that we acquired with the acquisition of Triangle. We also do not yet have approval of the fixed-dose combination product containing tenofovir DF and emtricitabine. Future discussions with regulatory agencies will determine the amount of data needed and timelines for review, which may differ materially from current projections. The acquired products under development may never be successfully commercialized. Emtriva, for example, is a product with many similarities to other existing products. As a result, it may be difficult to successfully penetrate the market and to achieve significant revenues. In addition, emtricitabine for the treatment of chronic hepatitis B faces significant uncertainties associated with pricing, efficacy, and the cost to produce that may not be successfully resolved. As a result, we may make a strategic decision to discontinue development of this product, as we did with clevidine and amdoxovir, if we believe commercialization will be difficult relative to other opportunities in our pipeline. If these programs cannot be completed on a timely basis or at all, then our prospects for future revenue growth would be adversely impacted.

The value of the acquired in-process research and development was determined by estimating the related future net cash flows between 2003 and 2020 using a present value risk adjusted discount rate of 15.75%. This discount rate is a significant assumption and is based on our estimated weighted average cost of capital adjusted upward for the risks associated with the projects acquired. The projected cash flows from the acquired projects were based on estimates of revenues and operating profits related to the projects considering the stage of development of each potential product acquired, the time and resources needed to complete the development and approval of each product, the life of each potential commercialized product and associated risks including the inherent difficulties and uncertainties in developing a drug compound including obtaining FDA and other regulatory approvals, and risks related to the viability of and potential alternative treatments in any future target markets.

#### *Asset Impairment*

During 2003, we recorded an asset impairment charge of \$10.2 million on certain of our long-lived assets, primarily leasehold improvements, manufacturing and laboratory equipment. This non-cash charge was driven by the decision in December 2003 to terminate our liposomal research and development activities in San Dimas and discontinue the DaunoXome product line. The impairment was based on our analysis of the undiscounted cash flows to be generated from the affected assets as compared to their carrying value. As the carrying value exceeded the related estimated undiscounted cash flows, we wrote the carrying value of the long-lived assets down to their estimated fair value.

#### *Gain on Sale of Oncology Assets*

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

#### *Loss on Sale of Marketable Securities*

In July 2002, we sold all of our remaining shares of OSI common stock for approximately \$22.0 million. These shares were partial consideration for the sale of our oncology assets to OSI in

December 2001, at which time they were recorded at a fair market value of approximately \$38.0 million. In connection with the sale of these remaining shares, we recognized a non-operating loss of approximately \$16.0 million in the year ended December 31, 2002.

#### *Gain on Sale of Unconsolidated Affiliate*

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

#### *Interest and Other Income, net*

We recorded interest and other income of \$13.0 million in 2003, compared with \$22.3 million in 2002 and \$25.6 million in 2001. The decrease in 2003 compared to 2002 is attributable to the significant decline in interest rates and a lower average cash balance due to the acquisition of the net assets of Triangle and the purchase of our Foster City campus, partially offset by positive cash flow from operations. The decrease in 2002 compared to 2001 is attributable to the significant decline in interest rates, partially offset by a higher average cash balance due to positive cash flow from operations and to the proceeds from the sale of the oncology assets to OSI. Interest income in 2004 will depend principally upon prevailing interest rates, over which we have no control and the level of our cash, cash equivalent and marketable securities balances.

#### *Interest Expense*

We incurred interest expense of \$21.9 million in 2003, compared with \$13.9 million in 2002 and \$14.0 million in 2001. The significant increase in 2003 over 2002 is due to the full year of interest on our \$345.0 million 2% convertible senior notes, issued in December 2002. Interest expense for 2002 and 2001 consisted primarily of interest on the \$250.0 million 5.0% convertible subordinated notes, which were converted to common stock in December 2003. We expect interest expense in 2004 to decrease as compared with 2003 primarily due to the redemption of the \$250.0 million 5% convertible subordinated notes in December 2003.

#### *Provision for (Benefit from) Income Taxes*

Our provision for (benefit from) income taxes was (\$95.5) million, \$1.3 million and \$4.1 million in 2003, 2002 and 2001, respectively. The benefit in 2003 includes the reversal of our valuation allowance against certain of our deferred tax assets. In December of 2003, we concluded that it was more likely than not that we would realize a portion of the benefit related to our deferred tax assets. Accordingly, we reduced the valuation allowance against the assets and recorded a tax benefit of \$111.6 million. The recognition of these deferred tax assets has no impact on our current period cash flows. The recognition of these deferred tax assets increased reported earnings per share due to the resulting benefit recorded in the statement of operations from the reduction in our valuation allowance. Partially offsetting the tax benefit recorded is income tax expense associated with income earned by our foreign subsidiaries, foreign losses at lower rates and the non-tax deductibility of the purchased in-process research and development charge. We had significant net operating losses reducing our U.S. liability. Excluding the benefit relating to the reversal of our valuation allowance, and the write off of purchased in-process research and development, our effective tax rate for 2003 was 5%. For 2004, we expect our effective tax rate to be in the 32% to 35% range for the full year, reflecting a more normalized tax rate going forward.

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The income tax expense in 2002 and 2001 was primarily associated with income earned by our foreign subsidiaries as we had significant net operating losses, which reduced our U.S. tax liability. The significant increases in income tax expense in 2001 resulted principally from the gain on the sale of our oncology assets to OSI, for which we recorded approximately \$3.3 million of federal and state alternative minimum taxes. The provision for 2002 was reduced by a change in the U.S. income tax law. This law allowed net operating loss carryforward deductions to offset 100% of alternative minimum taxable income, resulting in a reduction of U.S. income tax recorded in the previous years of \$1.3 million.

#### *Equity in Loss of Unconsolidated Affiliate*

In 2001, we recorded \$2.1 million as our equity in the loss of our unconsolidated affiliate, Proligo. We sold our 49 percent interest in August 2001.

#### *Cumulative Effect of Change in Accounting Principle*

In 2001, we adopted SFAS 133, *Accounting for Derivative Instruments and Hedging Activities*, which resulted in a cumulative effect of change in accounting principle of \$1.1 million. See Note 2 to the consolidated financial statements for further discussion.

#### **Liquidity and Capital Resources**

Cash, cash equivalents and marketable securities totaled \$707.0 million at December 31, 2003, down from \$942.4 million at December 31, 2002. The decrease of \$235.4 million was primarily due to the acquisition of Triangle, for which the net cash impact was \$375.5 million, and the purchase of our Foster City campus for \$123.0 million. Other major sources and uses of cash included net cash provided by operations of \$234.6 million and proceeds from issuances of stock under employee stock plans of \$83.8 million, partially offset by additional capital expenditures of \$38.6 million.

Working capital at December 31, 2003 was \$1,080.0 million compared to \$1,078.9 million at December 31, 2002. Significant changes in working capital during 2003 included a \$97.1 million increase in accounts receivable, a \$46.5 million increase in inventory and a \$197.6 million increase in current deferred tax assets. The accounts receivable increase was primarily due to increased sales of Viread in the U.S. and Europe. The \$46.5 million increase in inventory was primarily due to an increase in the purchase of raw materials and the production of Viread inventory to meet increasing sales demand. The \$197.6 million increase in current deferred tax assets was due to the reversal of the valuation allowance against certain of our net deferred tax assets. The \$6.1 million increase in accounts payable is primarily due to increases in our raw material purchases in support of Viread sales growth.

Significant changes in current liabilities during 2003 included a \$44.5 million increase in accrued liabilities. The significant components of the \$44.5 million increase in accrued liabilities, exclusive of the assumed liabilities associated with the acquisition of the net assets of Triangle, consist of a \$44.2 million increase in other accrued liabilities and a \$6.2 million increase in accrued compensation and employee benefits, partially offset by a \$5.9 million decrease in accrued clinical and preclinical expenses. The \$44.2 million increase in other accrued liabilities is primarily due to Medicaid rebate obligations associated with higher sales of Viread, an increase in our income taxes payable and an increase in the recorded liability associated with the fair value of our forward currency contracts. The \$6.2 million increase in accrued compensation is primarily due to increased bonus accruals and the expansion of our sales force. The \$5.9 million decrease in accrued clinical and preclinical expenses is primarily due to decreasing activity associated with the clinical trial programs for Viread and Hepsera.

In addition to the purchase of our Foster City campus, we made capital expenditures of \$38.6 million in 2003, compared to \$17.6 million in 2002 and \$26.3 million in 2001. These expenditures were primarily for facilities improvements to accommodate our growth, as well as for laboratory and manufacturing

equipment. Capital expenditures related to research and development were between 50% and 60% of the \$38.6 million spent in 2003, 20% to 25% of the \$17.6 million spent in 2002 and 50% to 60% of the \$26.3 million spent in 2001. We expect our capital spending for 2004 to be \$55.0 million to \$65.0 million due to increased infrastructure needs and higher R&D spending associated with the pilot plant we are constructing at our Foster City facilities.

In December 2002, we issued \$345.0 million of 2% convertible senior notes due December 15, 2007 in a private offering. The notes are currently convertible into a total of up to 7,340,425 shares of Gilead common stock at \$47.00 per share. The \$47.00 conversion price was higher than Gilead's 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 June 19, 2004, at specified redemption prices plus accrued interest. Debt issuance costs of \$8.4 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.

In December 2000, we issued \$250.0 million of 5% convertible subordinated notes due December 15, 2007 in a private offering. The notes were convertible into a total of up to 10,178,116 shares of Gilead common stock at \$24.5625 per share. The \$24.5625 conversion price was higher than Gilead's common stock price at the notes' issuance date. Gilead called the \$250.0 million 5% convertible subordinated notes for redemption in November 2003 and converted them to Gilead common stock in December 2003. Upon the conversion, the \$4.6 million remaining balance of the related debt issuance costs was reclassified to additional paid in capital.

We believe that our existing capital resources, supplemented by cash generated from our operations, will be adequate to satisfy our capital needs for the foreseeable future. Our future capital requirements will depend on many factors, including:

- the commercial performance of our current and future products,
- the progress and scope of our research and development efforts, including preclinical studies, and clinical trials,
- the cost, timing and outcome of regulatory reviews,
- the expansion of our sales and marketing capabilities,
- administrative expenses,
- the costs associated with our no-profit Global Access program for least developed nations,
- the possibility of acquiring manufacturing capabilities or office facilities,
- the possibility of acquiring other companies or new products, 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, such as from our universal shelf registration filing in December 2003 for the potential issuance of up to \$500.0 million of our securities, or additional collaborative agreements with corporate partners. If such funding is required, we cannot assure that it will be available on favorable terms, if at all.

### **Subsidiaries and Other**

We have established a variety of subsidiaries in various countries for the purpose of conducting business in those locations. All of these subsidiaries are consolidated in our financial statements. We do not have any "special purpose" entities that are unconsolidated in our financial statements. We are also

not involved in any non-exchange traded commodity contracts accounted for at fair value. We have no commercial commitments with related parties, except for employee loans.

## Contractual Obligations

We have contractual obligations in the form of capital and operating leases, notes payable, raw material supply arrangements and clinical research organization contracts.

The following table summarizes these contractual obligations (in thousands):

Contractual Obligations	Payments due by period				
	Total	Less than one year	1-3 years	3-5 years	More than 5 years
Long-term debt obligations	\$ 345,000	\$ —	\$ —	\$ 345,000	\$ —
Capital lease obligations	563	196	367	—	—
Operating lease obligations	55,238	7,036	25,169	12,838	10,195
Capital commitments(1)	15,700	15,700	—	—	—
Inventory purchase obligations(2)	70,536	36,637	33,899	—	—
Clinical trials(3)	53,638	41,631	8,631	3,376	—
Total	<u>\$ 540,675</u>	<u>\$ 101,200</u>	<u>\$ 68,066</u>	<u>\$ 361,214</u>	<u>\$ 10,195</u>

- (1) At December 31, 2003, we had firm capital project commitments of approximately \$15.7 million, related to our chemical development pilot plant currently under construction at our Foster City facility. Our budgeted capital expenditures for 2004 are significantly higher and we anticipate increasing our capital spending in future years.
- (2) At December 31, 2003, we had firm commitments to purchase inventory-related materials. The amounts disclosed only represent minimum purchase requirements. Actual purchases may differ significantly from these amounts.
- (3) At December 31, 2003, we had several clinical studies in various clinical trial phases. Our most significant expenditures are to contract research organizations. Although most contracts are cancelable, we generally have not cancelled contracts. These amounts reflect commitments based on existing contracts and do not reflect any future modifications to existing contracts and anticipated or potential new contracts.

## Recent Accounting Pronouncements

In January 2003, the FASB issued FASB Interpretation No. 46 (FIN 46), *Consolidation of Variable Interest Entities*, an Interpretation of ARB No. 51. FIN 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN 46 is effective immediately for all new variable interest entities created or acquired after January 31, 2003. We did not create or acquire any new variable interest entities after January 31, 2003. For variable interest entities created or acquired prior to February 1, 2003, the provisions of FIN 46, as amended, must be applied at the end of the first interim or annual period ending after March 15, 2003. The adoption of FIN 46 did not have a material impact on our consolidated financial statements.



## ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

### *Foreign Currency Exchange Risk*

Our operations include manufacturing and sales activities in the U.S. 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.

A significant percentage 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. Prior to 2002, we did not hedge our exposure to the impact of fluctuating foreign exchange rates on forecasted sales. In January 2002, we began to use forward contracts to hedge a percentage of our forecasted international sales, primarily those denominated in the Euro currency.

The following table summarizes the notional amounts, average currency exchange rates and fair values of our open foreign exchange forward contracts at December 31, 2003. All contracts have maturities of one year or less. 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, 2003 (notional amounts and fair values in U.S. dollars in thousands):

<u>Currency</u>	<u>Notional Amount</u>	<u>Average Rate</u>	<u>Fair Value December 31, 2003</u>
British Pound	\$ 43,441	0.7111	\$ (61)
Euro	361,574	0.8335	(14,479)

The total notional amount of \$405.0 million and fair value of (\$14.5) million on our open foreign exchange forward contracts at December 31, 2003 compares with a total notional amount of \$53.5 million and fair value of (\$1.1) million on our open foreign exchange forward contracts at December 31, 2002. The significant increase in outstanding contracts from 2002 to 2003 can be attributed to our decision to expand the time horizon that we include from three months to twelve months when hedging our forecasted international sales. This decision was made due to the growth in our international business and the increasing fluctuations in exchange rates, primarily the Euro.

### *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 duration, 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:

- 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.

The following table summarizes the expected maturities and average interest rates of our interest-bearing assets and fixed-rate liabilities at December 31, 2003 (dollars in thousands).

	Years ending December 31,							Fair Value December 31 ,
	2004	2005	2006	2007	2008	Thereafter	Total	2003
<b>Assets</b>								
Available-for-sale securities	\$ 543,119	\$ 76,104	\$ 9,016	—	—	—	\$ 628,239	\$ 628,239
Average interest rate	1.5%	1.7%	1.3%					
<b>Liabilities</b>								
Long-term obligations, including current portion(1)	\$ 7,232	\$ 4,217	\$ 10,610	\$ 10,709	\$ 10,289	\$ 12,744	\$ 55,801	\$ 55,801
Average interest rate	13.5%	13.8%	14.3%	20.7%				
Convertible senior debentures	—	—	—	\$ 345,000	—	—	\$ 345,000	\$ 472,650
Interest rate				2.0%				

- (1) Long-term obligations consist of capital leases and operating leases (net of noncancelable subleases). The interest portion of payments due is included.

#### *International Credit Risk*

Our accounts receivable balance at December 31, 2003 was \$235.2 million compared to \$125.0 million at December 31, 2002. The growth was primarily due to higher product sales for Viread in the U.S. and Europe. In certain countries where payments are typically slow, primarily Greece, Spain, Portugal and Italy, our accounts receivable balances are significant. In most cases, these slow payment practices reflect the pace at which governmental entities reimburse our customers. This, in turn, may increase the financial risk related to certain of our customers. Sales to customers in countries that tend to be relatively slow paying have in the past increased, and in the future may further increase, the average length of time that accounts receivable are outstanding. At December 31, 2003, our past due accounts receivable for Greece, Spain, Portugal and Italy totaled approximately \$102.7 million, of which approximately \$59.0 million was more than 120 days past due. At December 31, 2002, past due receivables for these countries were \$49.7 million, of which approximately \$26.6 million was more than 120 days past due. To date, we have not experienced significant losses with respect to the collection of our accounts receivable and we believe that all accounts receivable balances as reflected on the consolidated balance sheet, including those due from customers in these four countries, are collectible. We perform credit evaluations of our customer's financial condition and generally have not required collateral.

## **ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

The financial statements required by this item are set forth beginning at page 60 of this report and are incorporated herein by reference.

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

None.

## **ITEM 9A. CONTROLS AND PROCEDURES**

### **(a) Evaluation of Disclosure Controls and Procedures**

An evaluation as of December 31, 2003 was carried out under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our “disclosure controls and procedures,” which are defined under SEC rules as controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files under the Securities Exchange Act of 1934 (the “Exchange Act”) is recorded, processed, summarized and reported within required time periods. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective.

### **(b) Changes in Internal Controls over Financial Reporting**

Our management, including our Chief Executive Officer and Chief Financial Officer, has evaluated any changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2003, and has concluded that there was no change during such quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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## **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 2004 Annual Meeting (the Proxy Statement) under the headings “Nominees”, “Executive Officers”, “Board of Directors”, “Audit Committee” and “Compliance with Section 16(a) of the Securities Exchange Act of 1934”.

## **ITEM 11. EXECUTIVE COMPENSATION**

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

## **ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT**

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

## **ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS**

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

## **ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

The information required by this item is incorporated by reference to the sections of our Definitive Proxy Statement filed with the SEC pursuant to Regulation 14A in connection with the 2004 Annual Meeting (the Proxy Statement) under the headings “Independent Accountants.”

## **PART IV**

## **ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K**

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

#### **(1) Index list to Financial Statements:**

Report of Ernst & Young LLP, Independent Auditors	61
Audited Consolidated Financial Statements:	
Consolidated Balance Sheets	62
Consolidated Statements of Operations	63
Consolidated Statement of Stockholders' Equity	64
Consolidated Statements of Cash Flows	65
Notes to Consolidated Financial Statements	66

(2) Schedule II is included on page 101 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.

(3) Exhibits

The following exhibits are filed herewith or incorporated by reference:

<u>Exhibit Footnote</u>	<u>Exhibit Number</u>	<u>Description of Document</u>
(21)	2.1	Asset Purchase Agreement between Registrant and OSI Pharmaceuticals, Inc. dated as of November 26, 2001.
(25)	2.2	Agreement and Plan of Merger, among Registrant, Simbolo Acquisition Sub, Inc., a wholly-owned subsidiary of Registrant, and Triangle Pharmaceuticals, Inc., dated as of December 3, 2002.
(20)	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.
(19)	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.
	4.5	Indenture dated as of December 18, 2002 between the Registrant and J.P. Morgan Trust Company, National Association, including therein the forms of the notes.
	4.6	Registration Rights Agreement dated as of December 18, 2002 between the Registrant and Goldman, Sachs & Co.
(35)	4.7	First Amendment to Amended and Restated Rights Agreement dated as of October 29, 2003 between the Registrant and Mellon Investor Services, LLC.
(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.
(1)	10.5	Registrant's Employee Stock Purchase Plan, as amended March 30, 1999.
(26)	10.6	Registrant's 1991 Stock Option Plan, as amended and restated April 5, 2000, as amended January 18, 2001 and as amended January 30, 2002.
(5)	10.7	Form of Non-Qualified Stock Option issued to certain executive officers and directors in 1991.
(6)	10.8	Vintage Park Research and Development Net Lease by and between Registrant and Vintage Park Associates dated March 27, 1992 for premises located at 344B, 346 and 353 Lakeside Drive, Foster City, California with related addendum, exhibits and amendments.

- (5) 10.9 Letter Agreement, dated as of September 23, 1991 between Registrant and IOCB/REGA, with exhibits with certain confidential information omitted.
- (7) 10.11 Amendment Agreement, dated October 25, 1993 between Registrant and IOCB/REGA, and related license agreements and exhibits with certain confidential information omitted.
- (20) 10.12 Amendment Agreement, dated December 27, 2000 between Registrant and IOCB/REGA.
- (2) 10.13 Loan Agreement, dated as of October 1, 1994 among Registrant and Mark L. Perry and Melanie P. Peña.
- (26) 10.14 Registrant's 1995 Non-Employee Directors' Stock Option Plan, as amended January 26, 1999, and as amended January 30, 2002.
- (8) 10.17 Amendment No. 2 to Vintage Park Research and Development Lease by and between Registrant and WCB Seventeen Limited Partnership dated June 24, 1996 for premises located at 344B, 346 and 353 Lakeside Drive, Foster City, California.
- (9) 10.18 License and Supply Agreement between Registrant and Pharmacia & Upjohn S.A. dated August 7, 1996 with certain confidential information omitted.
- (9) 10.19 Development and License Agreement between Registrant and F. Hoffmann-La Roche Ltd. and Hoffmann-La Roche Inc. dated September 27, 1996 with certain confidential information omitted.
- (3) 10.21 NeXstar Pharmaceuticals, Inc.'s 1993 Incentive Stock Plan, adopted February 8, 1993, as amended.
- (13) 10.22 NeXstar Pharmaceuticals, Inc.'s 1995 Director Option Plan, adopted July 25, 1995.
- (14) 10.23 Vestar, Inc. 1988 Stock Option Plan.
- (14) 10.24 Lease, dated March 26, 1987, between Vestar, Inc. and Majestic Realty Co. and Patrician Associates, Inc. and Amendment No. 1 thereto and Amendment No. 2 thereto, dated as of June 8, 1992.
- (12) 10.25 Third Amendment, dated January 11, 1996, between Majestic Realty Co. and Patrician Associates, Inc. and the Registrant, to Lease, dated March 26, 1987, between Vestar, Inc. and Majestic Realty Co. and Patrician Associates, Inc.
- (15) 10.26 Assignment and Royalty Agreement, dated December 21, 1990, effective as of June 2, 1989, between Vestar, Inc. and City of Hope National Medical Center.
- (12) 10.27 License Agreement, effective as of August 12, 1986, between Vestar, Inc. and The Regents of the University of California.
- (14) 10.28 Agreement by and between Fujisawa USA, Inc. and Vestar, Inc., dated August 9, 1991, and Amendment No. 1 thereto, dated as of May 17, 1994.
- (13) 10.29 Amendment No. 2 to agreement between Fujisawa USA, Inc. and Vestar, Inc., dated as of April 3, 1995, between Fujisawa USA, Inc. and Vestar, Inc. with certain confidential information omitted.

- (12) 10.30 Amendment No. 3 to Agreement between Fujisawa USA, Inc. and the Registrant, dated March 4, 1996, to the Agreement by and between Fujisawa USA, Inc. and Vestar, Inc., dated August 9, 1991.
- (14) 10.31 Lease, dated April 13, 1992, between Vestar, Inc. and Majestic Realty Co. and Patrician Associates, Inc.
- (12) 10.32 First Amendment to Lease, dated April 10, 1993, between Majestic Realty Co. and Patrician Associates, Inc. and Vestar, Inc. amending Lease, dated April 13, 1992, between Majestic Realty Co. and Patrician Associates, Inc. and Vestar, Inc.
- (11) 10.33 License and Distribution Agreement, dated September 26, 1997, by and between Sumitomo Pharmaceuticals Co., Ltd. and NeXstar Pharmaceuticals, Inc. with certain confidential information omitted.
- (16) 10.34 Settlement Agreement, dated August 11, 1997, by and among NeXstar Pharmaceuticals, Inc., Fujisawa U.S.A., Inc. and The Liposome Company, Inc. with certain confidential information omitted.
- (17) 10.35 Amendment, dated April 30, 1998, between Sumitomo Pharmaceuticals Co., Ltd. and NeXstar Pharmaceuticals, Inc. to the License and Distribution Agreement, dated September 26, 1996, between Sumitomo and NeXstar Pharmaceuticals, Inc.
- (24) 10.36 The Corporate Plan for Retirement Select Plan—Basic Plan Document.
- (24) 10.37 The Corporate Plan for Retirement Select Plan—Adoption Agreement.
- (24) 10.38 Addendum to the Gilead Sciences, Inc. Deferred Compensation Plan.
- (22) 10.39 Licensing Agreement, dated April 26, 2002, by and between Gilead World Markets, Limited and Glaxo Group Limited.
- (23) 10.40 Employment Agreement, dated July 1, 2002, by and between Gilead Sciences, Inc. and Sharon Surrey-Barbari.
- (27) 10.41 Triangle Pharmaceuticals, Inc. 1996 Stock Incentive Plan.
- (27) 10.42 Option Agreement between Triangle Pharmaceuticals, Inc. and Daniel G. Welch, dated August 5, 2002.
- (28) 10.43 License Agreement among Triangle Pharmaceuticals, Inc., Emory University and the University of Georgia Research Foundation, Inc. for compound amdoxovir (DAPD), dated March 31, 1996.
- (28) 10.44 License Agreement between Triangle Pharmaceuticals, Inc. and Emory University for Coviracil (FTC), dated April 17, 1996.
- (30) 10.46 Exclusive License Agreement among Triangle Pharmaceuticals, Inc., Glaxo Group Limited, The Wellcome Foundation Limited, Glaxo Wellcome Inc. and Emory University, dated May 6, 1999.
- (30) 10.47 Settlement Agreement among Triangle Pharmaceuticals, Inc., Emory University, Dr. David W. Barry, Glaxo Wellcome plc, Glaxo Wellcome Inc., Glaxo Group Limited and The Wellcome Foundation Limited, dated May 6, 1999.

- (30) 10.49 First Amendment to License Agreement between Triangle Pharmaceuticals, Inc. and Emory University, dated May 6, 1999.
- (31) 10.50 First Amendment to License Agreement among Triangle Pharmaceuticals, Inc., Emory University and the University of Georgia Research Foundation, Inc., dated July 10, 2000.
- (31) 10.51 Second Amendment to License Agreement between Triangle Pharmaceuticals, Inc. and Emory University, dated July 10, 2000.
- (32) 10.54 Supply and Manufacturing Agreement between Triangle Pharmaceuticals, Inc. and Abbott Laboratories, dated July 30, 2002.
- (32) 10.55 Settlement and Exclusive License Agreement among Triangle Pharmaceuticals, Inc., Shire Biochem Inc., Shire Pharmaceuticals Group plc, Emory University and the University of Georgia Research Foundation, dated August 30, 2002.
- (33) 10.56 Second Amendment to License Agreement among Triangle Pharmaceuticals, Inc., Emory University and the University of Georgia Research Foundation, Inc., dated August 30, 2002.
- (38) 10.62 Manufacturing Supply Agreement between Gilead World Markets, Ltd. and PPG-Sipsy S.A.S, entered into as of January 1, 2003.
- (36) 10.63 Gilead Sciences, Inc. Severance Plan, as adopted effective January 29, 2003
- (36) 10.64 Third Amendment to License Agreement between Triangle Pharmaceuticals, Inc. and Emory University, dated May 31, 2002.
- (37) 10.65 Lease Agreement, dated June 12<sup>th</sup>, 2003, between Registrant and GRA Associates Limited, L.L.C. for premises located at 4611 and 4615 University Drive, Durham, North Carolina
- + 10.66 Master Clinical and Commercial Supply Agreement dated January 1, 2003 among Gilead World Markets, Ltd., Gilead Sciences, Inc. and Patheon Inc.
- + 10.67 Toll Manufacturing Agreement dated August 1, 2003 by and among Gilead World Markets, Ltd., Gilead Sciences, Inc. and ALTANA Pharma Oranienburg GmbH
- + 10.68 Licensing Agreement, dated as of March 31, 2000 and amended on May 9, 2000, December 4, 2001 and April 12, 2002, by and between Gilead Sciences, Inc. and EyeTech Pharmaceuticals, Inc.
- 10.69 Amendment No. 1 to Licensing Agreement, dated as of May 9, 2000 by and between EyeTech Pharmaceuticals, Inc. and Gilead Sciences, Inc.
- 10.70 Amendment No. 2 to Licensing Agreement, dated as of December 4, 2001 by and between EyeTech Pharmaceuticals, Inc. and Gilead Sciences, Inc.
- + 10.71 Amendment No. 3 to Licensing Agreement, dated as of August 30, 2002 by and between EyeTech Pharmaceuticals, Inc. and Gilead Sciences, Inc.
- + 10.72 Amendment No. 1 dated May 19, 2003 to Licensing Agreement dated 26 April 2002 between Glaxo Group Limited and Gilead World Markets Limited



+ 10.73	Amendment No. 2 dated January 9, 2004 to Licensing Agreement dated 26 April 2002 between Glaxo Group Limited and Gilead World Markets Limited
21.1	Subsidiaries of the Registrant.
23.1	Consent of Ernst & Young LLP, Independent Auditors.
24.1	Power of Attorney. Reference is made to Signature Page.
31.1	Section 302 Certification.
31.2	Section 302 Certification
32	Section 906 Certification

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- (1) Filed as an exhibit to Registrant's Annual Report on Form 10-K/A for the fiscal year ended December 31, 1998, and incorporated herein by reference.
- (2) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended December 31, 1994, and incorporated herein by reference.
- (3) Filed as an exhibit to NeXstar Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q for the quarter ended June 30, 1997, and incorporated herein by reference.
- (4) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on October 22, 1999, and incorporated herein by reference.
- (5) Filed as an exhibit to Registrant's Registration Statement on Form S-1 (No. 33-55680), as amended, and incorporated herein by reference.
- (6) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 1993, and incorporated herein by reference.
- (7) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended March 31, 1994, and incorporated herein by reference.
- (8) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1996, and incorporated herein by reference.
- (9) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 1996, and incorporated herein by reference.
- (10) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on March 9, 1999, and incorporated herein by reference.
- (11) Filed as an exhibit to NeXstar Pharmaceuticals, Inc.'s Form 10-K for the fiscal year ended December 31, 1996, and incorporated herein by reference.
- (12) Filed as an exhibit to NeXstar Pharmaceuticals, Inc.'s Form 10-K for the fiscal year ended December 31, 1995, and incorporated herein by reference.
- (13) Filed as an exhibit to NeXstar Pharmaceuticals, Inc.'s Form 10-Q for the quarterly period ended September 30, 1995, and incorporated herein by reference.
- (14) Filed as an exhibit to NeXstar Pharmaceuticals, Inc.'s Form 10-K for the fiscal year ended December 31, 1994, and incorporated herein by reference.

- (15) Filed on March 22, 1991 as an exhibit to NeXstar Pharmaceuticals, Inc.'s Registration Statement on Form S-2 (File No. 33-39549), and incorporated herein by reference.
- (16) Filed as an exhibit to NeXstar Pharmaceuticals, Inc.'s Form 10-Q for the quarterly period ended September 30, 1997, and incorporated herein by reference.
- (17) Filed as an exhibit to NeXstar Pharmaceuticals, Inc.'s Form 10-Q for the quarter ended June 30, 1998, and incorporated herein by reference.
- (18) Filed as an exhibit to Registrant's Form 10-K for the fiscal year ended December 31, 1998, and incorporated herein by reference.
- (19) Filed as an exhibit to Registrant's Registration Statement on Form S-3 (No. 333-54350), as amended, and incorporated herein by reference.
- (20) Filed as an exhibit to Registrant's Form 10-K for the fiscal year ended December 31, 2000, and incorporated herein by reference.
- (21) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on January 4, 2002, and incorporated herein by reference.
- (22) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, and incorporated herein by reference.
- (23) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002, and incorporated herein by reference.
- (24) Filed as an exhibit to Registrant's Form 10-K for the fiscal year ended December 31, 2001, and incorporated herein by reference.
- (25) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on December 10, 2002, and incorporated herein by reference.
- (26) Filed as an exhibit to Registrant's Registration Statement on Form S-8 (No. 333-102912) filed on January 31, 2003, and incorporated herein by reference.
- (27) Filed as an exhibit to Registrant's Registration Statement on Form S-8 (No. 333-102911) filed on January 31, 2003, and incorporated herein by reference.
- (28) Filed as an exhibit to Triangle Pharmaceuticals, Inc.'s Registration Statement on Form S-1 (No. 333-11793), as amended, and incorporated herein by reference.
- (30) Filed as an exhibit to Triangle Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 1999, and incorporated herein by reference.
- (31) Filed as an exhibit to Triangle Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2000, and incorporated herein by reference.
- (32) Filed as an exhibit to Triangle Pharmaceuticals, Inc.'s Current Report on Form 8-K filed on September 19, 2002, and incorporated herein by reference.
- (33) Filed as an exhibit to Triangle Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2002, and incorporated herein by reference.
- (35) Filed as an exhibit to the Registrant's Current Report on Form 8-K filed on October 31, 2003, and incorporated herein by reference.
- (36) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2003, and incorporated herein by reference.

- (37) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2003, and incorporated herein by reference
- (38) Filed as an exhibit to Registrant's Form 10-K for the fiscal year ended December 31, 2002, and incorporated herein by reference.
- + Certain confidential portions of this Exhibit were omitted by means of marking such portions with an asterisk (the "Mark"). This Exhibit has been filed separately with the Secretary of the SEC without the Mark pursuant to the Registrant's Application Requesting Confidential Treatment under Rule 24b-2 under the Securities Exchange Act of 1934

(b) Reports on Form 8-K

On October 28, 2003, the Company filed a Form 8-K announcing the earnings of the Company for the third quarter and nine months ended September 30, 2003.

On October 31, 2003, the Company filed a Form 8-K announcing that the Board of Directors approved an amendment to the Company's Amended and Restated Rights Agreement, originally adopted as of November 21, 1994 and amended and restated as of October 21, 1999.

On November 19, 2003, the Company filed a Form 8-K announcing that a purported class action complaint had been filed on November 10, 2003 in the United States District Court for the Northern District of California against the Company and the Company's Chief Executive Officer, Chief Financial Officer, Executive Vice Presidents of Operations and Research and Development, and Senior Vice Presidents of Manufacturing and Research.

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**GILEAD SCIENCES, INC.**  
**CONSOLIDATED FINANCIAL STATEMENTS**  
**Years ended December 31, 2003, 2002 and 2001**

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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. as of December 31, 2003 and 2002, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2003. Our audits also included the financial statement schedule listed at Item 15(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 conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Gilead Sciences, Inc. at December 31, 2003 and 2002, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2003, in conformity with accounting principles generally accepted in the United States. Also, in our opinion, the related financial statement schedule, 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, 2001, the Company changed its method of accounting for derivative instruments and hedging activities.

/s/ ERNST & YOUNG LLP

Palo Alto, California  
January 23, 2004

**GILEAD SCIENCES, INC.**  
**Consolidated Balance Sheets**  
(in thousands, except per share amounts)

	<b>December 31,</b>	
	<b>2003</b>	<b>2002</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 194,719	\$ 616,931
Marketable securities	512,281	325,443
Accounts receivable, net of allowance for doubtful accounts of \$10,644 at December 31, 2003 and \$5,329 at December 31, 2002	235,217	125,036
Note receivable from Triangle Pharmaceuticals, Inc.	—	50,000
Inventories	98,102	51,628
Deferred tax assets	197,567	—
Prepaid expenses and other	28,012	14,722
Total current assets	1,265,898	1,183,760
Property, plant and equipment, net	198,200	67,727
Noncurrent deferred tax assets	52,494	—
Other noncurrent assets	38,130	36,696
	<u>\$ 1,554,722</u>	<u>\$ 1,288,183</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 35,649	\$ 24,406
Accrued clinical and preclinical expenses	11,859	7,063
Accrued compensation and employee benefits	35,772	21,511
Other accrued liabilities	97,002	44,026
Deferred revenue	5,474	7,692
Long-term obligations due within one year	139	194
Total current liabilities	185,895	104,892
Long-term deferred revenue	20,530	16,677
Long-term obligations due after one year	323	273
Convertible senior debt	345,000	345,000
Convertible subordinated debt	—	250,000
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, par value \$.001 per share, issuable in series; 5,000 shares authorized; none outstanding	—	—
Common stock, par value \$.001 per share; 500,000 shares authorized; 213,253 and 197,595 shares issued and outstanding at December 31, 2003 and December 31, 2002, respectively	213	198
Additional paid-in capital	1,453,203	950,308
Accumulated other comprehensive income	4,507	2,475
Deferred compensation	(1,306)	—
Accumulated deficit	<u>(453,643)</u>	<u>(381,640)</u>

Total stockholders' equity	1,002,974	571,341
	<u>\$ 1,554,722</u>	<u>\$ 1,288,183</u>

See accompanying notes

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

	Year Ended December 31,		
	2003	2002	2001
Revenues:			
Product sales	\$ 836,341	\$ 423,879	\$ 190,970
Royalty revenue	25,219	20,406	22,969
Contract revenue	6,304	22,505	19,830
Total revenues	<u>867,864</u>	<u>466,790</u>	<u>233,769</u>
Costs and expenses:			
Cost of goods sold	112,691	69,724	43,764
Research and development	164,873	134,758	185,553
Selling, general and administrative	250,157	181,301	125,141
In-process research and development	488,599	—	—
Asset impairment	10,219	—	—
Total costs and expenses	<u>1,026,539</u>	<u>385,783</u>	<u>354,458</u>
Income (loss) from operations	(158,675)	81,007	(120,689)
Gain on sale of oncology assets	—	—	157,771
Gain on sale of unconsolidated affiliate	—	—	8,754
Loss on sale of marketable securities	—	(16,048)	—
Interest and other income, net	13,039	22,291	25,591
Interest expense	(21,897)	(13,853)	(13,980)
Income (loss) before provision for (benefit from) income taxes, equity in loss of unconsolidated affiliate and cumulative effect of change in accounting principle	(167,533)	73,397	57,447
Provision for (benefit from) income taxes	(95,530)	1,300	4,135
Equity in loss of unconsolidated affiliate	—	—	2,130
Income (loss) before cumulative effect of change in accounting principle	(72,003)	72,097	51,182
Cumulative effect of change in accounting principle	—	—	1,089
Net income (loss)	<u>\$ (72,003)</u>	<u>\$ 72,097</u>	<u>\$ 52,271</u>
Amounts per common share—basic:			
Income (loss) before cumulative effect of change in accounting principle	\$ (0.36)	\$ 0.37	\$ 0.27
Cumulative effect of change in accounting principle	—	—	0.01
Net income (loss) per share—basic	<u>\$ (0.36)</u>	<u>\$ 0.37</u>	<u>\$ 0.28</u>
Shares used in per share calculation—basic	<u>201,105</u>	<u>195,543</u>	<u>190,245</u>
Amounts per common share—diluted:			
Income (loss) before cumulative effect of change in accounting principle	\$ (0.36)	\$ 0.35	\$ 0.25
Cumulative effect of change in accounting principle	—	—	0.01
Net income (loss) per share—diluted	<u>\$ (0.36)</u>	<u>\$ 0.35</u>	<u>\$ 0.26</u>
Shares used in per share calculation—diluted	<u>201,105</u>	<u>206,477</u>	<u>202,321</u>

See accompanying notes

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

	Common Stock		Additional	Accumulated Other Comprehensive			Total Stockholders'
	Shares	Amount	Paid-In Capital	Income (Loss)	Deferred Compensation	Accumulated Deficit	Equity
Balance at December 31, 2000	188,575	\$ 189	\$ 857,847	\$ (901)	\$ (3)	\$ (506,008)	\$ 351,124
Net income	—	—	—	—	—	52,271	52,271
Unrealized gain on available- for-sale securities, net	—	—	—	7,735	—	—	7,735
Foreign currency translation adjustment	—	—	—	577	—	—	577
Unrealized gain on cash flow hedges, net	—	—	—	37	—	—	37
Comprehensive income							60,620
Employee stock purchase plan	368	—	5,357	—	—	—	5,357
Option exercises, net	4,098	4	30,950	—	—	—	30,954
Tax benefits of employee stock plans	—	—	1,500	—	—	—	1,500
Amortization of deferred compensation	—	—	—	—	3	—	3
Compensatory stock transactions	—	—	2,879	—	—	—	2,879
Balance at December 31, 2001	193,041	193	898,533	7,448	—	(453,737)	452,437
Net income	—	—	—	—	—	72,097	72,097
Unrealized loss on available- for-sale securities, net	—	—	—	(4,577)	—	—	(4,577)
Foreign currency translation adjustment	—	—	—	(580)	—	—	(580)
Unrealized gain on cash flow hedges, net	—	—	—	184	—	—	184
Comprehensive income							67,124
Employee stock purchase plan	342	—	6,701	—	—	—	6,701
Option exercises, net	4,212	5	44,680	—	—	—	44,685
Tax benefits of employee stock plans	—	—	350	—	—	—	350
Compensatory stock transactions	—	—	44	—	—	—	44
Balance at December 31, 2002	197,595	198	950,308	2,475	—	(381,640)	571,341
Net loss	—	—	—	—	—	(72,003)	(72,003)
Unrealized loss on available- for-sale securities, net	—	—	—	(4,022)	—	—	(4,022)
Foreign currency translation adjustment	—	—	—	7,040	—	—	7,040
Unrealized loss on cash flow hedges, net	—	—	—	(986)	—	—	(986)
Comprehensive loss							(69,971)
Conversion of convertible subordinated debt	10,178	10	245,382	—	—	—	245,392
Acquisition of Triangle Pharmaceuticals, Inc.	—	—	41,339	—	(3,305)	—	38,034
Employee stock purchase plan	280	—	8,238	—	—	—	8,238
Option exercises, net	5,200	5	75,563	—	—	—	75,568
Tax benefits of employee stock plans	—	—	132,363	—	—	—	132,363
Amortization of deferred compensation	—	—	—	—	1,999	—	1,999
Compensatory stock transactions	—	—	10	—	—	—	10
Balance at December 31, 2003	<u>213,253</u>	<u>\$ 213</u>	<u>\$ 1,453,203</u>	<u>\$ 4,507</u>	<u>\$ (1,306)</u>	<u>\$ (453,643)</u>	<u>\$ 1,002,974</u>

See accompanying notes

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

	Year Ended December 31,		
	2003	2002	2001
<b>Operating activities:</b>			
Net income (loss)	\$ (72,003)	\$ 72,097	\$ 52,271
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation	16,533	13,189	13,509
Amortization	4,326	1,239	1,182
Purchased in-process research and development	488,599	—	—
Asset impairment	10,219	—	—
Net effect of change in accounting principle	—	—	(1,089)

Gain on sale of oncology assets	—	—	(157,771)
Gain on sale of unconsolidated affiliate	—	—	(8,754)
Loss on sale of marketable securities	—	16,048	—
Equity in loss of unconsolidated affiliate	—	—	2,130
Net movement in provision for doubtful accounts	4,879	3,262	(170)
Deferred tax assets	(250,061)	—	—
Tax benefits from employee stock plans	132,363	350	1,500
Other non-cash transactions	1,844	3,480	1,035
Changes in operating assets and liabilities:			
Accounts receivable	(97,086)	(43,890)	(25,482)
Inventories	(46,474)	(12,348)	(18,718)
Prepaid expenses and other assets	(10,806)	(8,915)	(2,734)
Accounts payable	6,144	5,232	8,454
Accrued liabilities	44,495	11,544	11,495
Deferred revenue	1,635	13,121	(3,837)
Net cash provided by (used in) operating activities	234,607	74,409	(126,979)
<b>Investing activities:</b>			
Purchases of marketable securities	(934,759)	(490,259)	(377,725)
Proceeds from sales and maturities of marketable securities	744,530	603,678	280,534
Acquisition of Triangle net assets, net of cash acquired	(375,507)	—	—
Acquisition of real estate	(123,000)	—	—
Other capital expenditures	(38,609)	(17,597)	(26,331)
Issuance of note to Triangle	—	(50,000)	—
Proceeds from sale of oncology assets	—	—	130,000
Proceeds from sale of unconsolidated affiliate	—	—	14,300
Net cash provided by (used in) investing activities	(727,345)	45,822	20,778
<b>Financing activities:</b>			
Proceeds from issuances of common stock	83,806	51,386	36,311
Repayments of long-term debt	(1,715)	(1,414)	(2,761)
Proceeds from issuance of convertible senior notes, net of issuance costs	—	336,637	—
Net cash provided by financing activities	82,091	386,609	33,550
Effect of exchange rate changes on cash	(11,565)	(13,399)	(1,151)
Net increase (decrease) in cash and cash equivalents	(422,212)	493,441	(73,802)
Cash and cash equivalents at beginning of year	616,931	123,490	197,292
Cash and cash equivalents at end of year	<u>\$ 194,719</u>	<u>\$ 616,931</u>	<u>\$ 123,490</u>
<b>Supplemental disclosure of cash flow information:</b>			
Interest paid	\$ 19,647	\$ 12,657	\$ 12,710
Income taxes paid	8,779	851	1,778
<b>Non-cash investing and financing activities</b>			
OSI common stock received upon sale of oncology assets	\$ —	\$ —	\$ 38,849
Common stock issued upon conversion of debt	250,000	—	—
Reclassification of deferred debt issuance costs to additional paid-in capital upon conversion of subordinated debt	4,608	—	—

See accompanying notes

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**GILEAD SCIENCES, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**DECEMBER 31, 2003**

## 1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

### Overview

Gilead was incorporated in Delaware on June 22, 1987. We are a biopharmaceutical company that discovers, develops and commercializes therapeutics to advance the care of patients suffering from life-threatening diseases. We are a multinational company, with revenues from six approved products and marketing operations in ten countries. We focus our research and clinical programs on anti-infectives. Currently, we market Viread (tenofovir disoproxil fumarate) and Emtriva (emtricitabine) for the treatment of HIV infection; Hepsera (adefovir dipivoxil) for the treatment of chronic hepatitis B infection; AmBisome (amphotericin B liposome for injection), an antifungal agent; and Vistide (cidofovir injection) for the treatment of CMV retinitis. Roche markets Tamiflu (oseltamivir phosphate) for the treatment of influenza, under a royalty paying collaborative agreement with us. We are seeking to add to our existing portfolio of products through our internal discovery and clinical development programs and through an active product acquisition and in-licensing strategy, such as our acquisition of the net assets of Triangle Pharmaceuticals, Inc. completed in January 2003. Our internal discovery activities include identification of new molecular targets, target screening and medicinal chemistry. In addition, we are currently developing clinical stage products to treat HIV infection and chronic hepatitis B.

The accompanying consolidated financial statements include the accounts of Gilead 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 year presentation.

### **Stock Split**

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

### **Change in Accounting Principle**

Gilead adopted Statement of Financial Accounting Standards (SFAS) Nos. 133 and 138, collectively referred to as SFAS 133, *Accounting for Derivative Instruments and Hedging Activities*, in the first quarter of 2001. The change was accounted for as a change in accounting principle. See Note 2.

### **Critical Accounting Policies, Estimates and Judgments**

The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of assets and liabilities. On an on-going basis, management evaluates its estimates, including those related to revenue recognition, bad debts, inventories, income taxes, accrued clinical and preclinical expenses, and contingencies. We base our estimates on historical experience and on various other market specific and other relevant assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ significantly from these estimates.



**GILEAD SCIENCES, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**DECEMBER 31, 2003**

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

**Revenue Recognition**

We recognize revenue from product sales when there is persuasive evidence an arrangement exists, delivery to the customer has occurred, the price is fixed or determinable and collectibility is reasonably assured. We do not provide our customers with a general right of product return. However, we will accept returns of products in the U.S. that have expired for one year after their expiration, or products that are deemed to be damaged or defective when received by the customer. Upon recognition of revenue from product sales, provisions are made for expected returns of expired products, government reimbursements and customer incentives, such as cash discounts for prompt payment. Estimates for government reimbursements and cash discounts are based on contractual terms and expectations regarding the utilization rates for these programs. Estimates for product returns, including new products, are based on an on-going analysis of industry and historical return patterns, as well as the purchase of third party data to assist the Company in monitoring channel inventory levels and subsequent prescriptions.

Contract revenue for research and development is recorded as performance occurs and the earnings process is completed 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 and milestone payments where we continue involvement through development collaboration or an obligation to supply product, is recognized as performance occurs and performance obligations are completed. In accordance with the specific terms of Gilead's obligations under the contract, revenue is recognized as the manufacturing obligation is fulfilled or ratably over the development period or the period of the manufacturing obligation, as appropriate.

Revenue associated with substantive performance milestones is recognized based upon the achievement of the milestones on completion of all performance requirements, 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.

**Shipping and Handling Costs**

Shipping and handling costs incurred for inventory purchases and product shipments are recorded in "Cost of goods sold" in the Consolidated Statements of Operations.

**Research and Development Expenses**

Major components of R&D expenses consist of personnel costs, including salaries and benefits, clinical studies performed by contract research organizations (CRO's), materials and supplies, and overhead allocations consisting of various administrative and facilities related costs. Our research and development activities are also separated into three main categories: research, clinical development and

**GILEAD SCIENCES, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**DECEMBER 31, 2003**

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

pharmaceutical development. Research costs typically consist of preclinical and toxicology work. Clinical development costs include Phase 1, 2, and 3 clinical trials as well as expanded access programs. Pharmaceutical development costs consist of product formulation and chemical analysis.

We charge clinical and preclinical study costs to expense when incurred, consistent with SFAS No. 2, *Accounting for Research and Development Costs*. These costs are a significant component of R&D expenses. Most of our clinical and preclinical studies are performed by third party CRO's. We accrue costs for clinical studies performed by CRO's on a straight-line basis over the service periods specified in the contracts and adjust our estimates, if required, based upon our on-going review of the level of effort actually incurred by the CRO. Initially we estimate that the work performed under the contracts occurs ratably over the service periods to the expected milestone, event or total contract completion date. The expected completion dates are estimated based upon the terms of the contracts and past experience with similar contracts. We monitor levels of performance under each contract including the extent of patient enrollment and other activities through communications with our CRO's, and we adjust our estimates, if required, on a quarterly basis so that our expenses reflect the actual effort incurred by each CRO.

All of our material CRO contracts are terminable by us upon written notice and Gilead is generally only liable for actual effort expended by the CRO at any point in time during the contract, regardless of payment status. Amounts paid in advance of services being performed will be refunded if a contract is terminated. Some contracts include additional termination payments that become due and payable only if Gilead terminates the contract. Such additional termination payments are only recorded to expense if the contract is terminated.

**Advertising Expenses**

We expense the costs of advertising, including promotional expenses, as incurred. Advertising expenses were \$43.4 million in 2003, \$39.3 million in 2002, and \$16.5 million in 2001.

**Stock-Based Compensation**

In accordance with the provisions of SFAS No. 123, *Accounting For Stock-Based Compensation*, as amended by SFAS No. 148 *Accounting for Stock-Based Compensation—Transition and Disclosure* (SFAS 123), we have elected to continue to follow Accounting Principles Board Opinion (APB) No. 25, *Accounting For Stock Issued To Employees*, and Interpretation No. 44 (FIN 44), *Accounting for Certain Transactions Involving Stock Compensation—an Interpretation of APB Opinion No. 25*, in accounting for our employee stock option plans. Under APB 25, if the exercise price of Gilead's employee and director stock options equals or exceeds the fair value of the underlying stock on the date of grant, no compensation expense is recognized. Although we have elected to follow the intrinsic value method prescribed by APB 25, we will continue to evaluate our approach to accounting for stock options in light of ongoing industry and regulatory developments.

**GILEAD SCIENCES, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**DECEMBER 31, 2003**

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

The table below presents the combined net income (loss) and basic and diluted net income (loss) per common share if compensation cost for the Gilead, NeXstar Pharmaceuticals, Inc. (NeXstar) and Triangle stock option plans and the employee stock purchase plan (ESPP) had been determined based on the estimated fair value of awards under those plans on the grant or purchase date in accordance with SFAS 123 (in thousands, except per share amounts):

	<b>Year Ended December 31,</b>		
	<b>2003</b>	<b>2002</b>	<b>2001</b>
Net income (loss)—as reported	\$ (72,003)	\$ 72,097	\$ 52,271
Add: Stock-based employee compensation expense included in reported net income (loss), net of related tax effects	1,219	44	2,882
Deduct: Total stock-based employee compensation expense determined under the fair value based method for all awards, net of related tax effects	(61,429)	(72,137)	(50,081)
Pro forma net income (loss)	<u>\$ (132,213)</u>	<u>\$ 4</u>	<u>\$ 5,072</u>
Net income (loss) per share:			
Basic-as reported	\$ (0.36)	\$ 0.37	\$ 0.28
Basic-pro forma	\$ (0.66)	\$ 0.00	\$ 0.03
Diluted-as reported	\$ (0.36)	\$ 0.35	\$ 0.26
Diluted-pro forma	\$ (0.66)	\$ 0.00	\$ 0.03

The effect on net income (loss) and basic and diluted net income (loss) per common share presented above is not likely to be representative of the effects on net income (loss) and net income (loss) per share pursuant to SFAS 123 in future years, due to subsequent years including additional grants and years of vesting.

**GILEAD SCIENCES, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**DECEMBER 31, 2003**

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

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 Black-Scholes option valuation model was developed for use in estimating the fair value of traded options, which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions including the expected stock price volatility. Because our employee stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock options. We used the multiple option approach and the following assumptions:

	<u>Year Ended December 31,</u>		
	<u>2003</u>	<u>2002</u>	<u>2001</u>
Expected life in years (from vesting date):			
Stock options	1.84	1.86	1.95
ESPP	1.32	1.31	1.29
Discount rate:			
Stock options	2.8%	3.9%	4.6%
ESPP	1.8%	3.0%	4.7%
Volatility	78%	82%	83%
Expected dividend yield	0%	0%	0%

Through the end of the third quarter of 2003, the fair value of stock awards granted in 2003 was determined utilizing a volatility rate of 80%. In the fourth quarter of 2003, we changed the volatility assumption we used to arrive at a fair value for our stock awards from 80% to 52%. The most recent two-year time period was used for purposes of calculating the expected volatility. After considering such factors as our stage of development, the length of time that we have been a public company and several drug approvals over the past few years which have enabled us to achieve positive cash flow from operations, we believe this volatility rate better reflects the expected volatility of our stock going forward. The 78% volatility used in the table above represents the weighted average volatility of 80% for the first three quarters and 52% for the fourth quarter.

The weighted average estimated fair value of ESPP shares purchased was \$19.63 for 2003, \$18.54 for 2002 and \$11.57 for 2001.

**Per Share Computations**

For 2003, both basic and diluted net loss per common share are computed based on the weighted average number of common shares outstanding during the period. The potential common shares from convertible notes of 17.2 million shares and outstanding stock options and warrants of 9.9 million shares were excluded from the computation of diluted net loss per share in 2003, as their effect would be antidilutive. For 2002 and 2001, basic net income per common share is computed based on the weighted average number of common shares outstanding during the period. Diluted net income per common share for 2002 includes the effects of approximately 10.9 million stock options but does not include the effect of the \$250.0 million 5% convertible notes, which would convert to approximately 10.2 million shares, or the

**GILEAD SCIENCES, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**DECEMBER 31, 2003**

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

\$345.0 million 2% convertible notes, which would convert to approximately 7.3 million shares, as the effect of their assumed conversion is antidilutive. Diluted net income per common share for 2001 includes the effects of approximately 12.1 million stock options and warrants, but does not include the effect of the \$250.0 million 5% convertible notes which would convert to approximately 10.2 million shares, as the effect of their assumed conversion is antidilutive.

**Cash and Cash Equivalents**

We consider 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. We may enter into overnight repurchase agreements under which we purchase 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 our investment policy, we 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. Other eligible investments under our investment policy include commercial paper, money market funds and other bank obligations.

**Marketable Securities**

We determine the appropriate classification of our marketable securities, which consists solely of debt securities, at the time of purchase and reevaluate such designation at each balance sheet date. All of our marketable securities are classified as available-for-sale and carried at estimated fair values and reported in either cash equivalents or marketable securities. At December 31, 2003, cash and cash equivalents include \$116.0 million of securities designated as available-for-sale (\$559.8 million at December 31, 2002). Unrealized gains and losses on available-for-sale securities are excluded from earnings and reported as a separate component of stockholders' equity. Interest income includes interest, dividends, amortization of purchase premiums and discounts, and realized gains and losses on sales of securities. The cost of securities sold is based on the specific identification method. We regularly review all of our investments for other-than-temporary declines in fair value. When we determine that the decline in fair value of an investment below our accounting basis is other-than-temporary, we reduce the carrying value of the securities we hold and record a loss in the amount of any such decline. No such reductions have been required during the past three years.

**Concentrations of Credit Risk**

We are subject to credit risk from our portfolio of cash equivalents and marketable securities. By policy, we limit amounts invested in such securities by duration, industry group, investment type and issuer, except for securities issued by the U.S. government. We are not exposed to any significant concentrations of credit risk from these financial instruments. The goals of our 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.

We are also subject to credit risk from our accounts receivable related to product sales. A significant amount of our trade accounts receivable arises from sales of AmBisome and Viread, primarily through

**GILEAD SCIENCES, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**DECEMBER 31, 2003**

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

sales by our European subsidiaries and export sales to our distributors in Europe. In certain countries where payments are typically slow, primarily Greece, Spain, Portugal and Italy, our accounts receivable balances are significant. In most cases, these slow payment practices reflect the pace at which governmental entities reimburse our customers. This, in turn, may increase the financial risk related to certain of our customers. Sales to customers in countries that tend to be relatively slow paying have in the past increased, and in the future may further increase, the average length of time that accounts receivable are outstanding. At December 31, 2003, our past due accounts receivable for Greece, Spain, Portugal and Italy totaled approximately \$102.7 million, of which approximately \$59.0 million was more than 120 days past due based on the contractual terms of the receivables. At December 31, 2002, past due receivables for these countries were \$49.7 million, of which approximately \$26.6 million was more than 120 days past due. To date, we have not experienced significant losses with respect to the collection of our accounts receivable and believe that all our past due accounts receivable as reflected in the consolidated balance sheet, including those due from customers in these four countries, are collectible. We perform credit evaluations of our customer's financial condition and generally have not required collateral.

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, distearoylphosphatidylcholine and high quality cholesterol, each of which is used in the manufacture of AmBisome. If supplies from our suppliers were interrupted for any reason, we may be unable to ship Viread, AmBisome, Hepsera, Emtriva or Vistide, or to supply any of our products in development for clinical trials.

**Inventories**

Inventories are recorded at the lower of cost or market, with cost determined on a first-in, first-out basis. We periodically review 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, we 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. Land is not depreciated. Estimated useful lives are as follows (in years):

<u>Description</u>	<u>Estimated Useful Life</u>
Buildings and improvements	20
Laboratory and manufacturing equipment	4-10
Office and computer equipment	2-6
Leasehold improvements	Life of related lease

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**GILEAD SCIENCES, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**DECEMBER 31, 2003**

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

Office and computer equipment includes capitalized computer software. All of our capitalized software is purchased. We have 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. Capitalized interest on construction in progress is included in property, plant and equipment.

**Intangible Assets**

Intangible assets with definite lives are amortized over their estimated useful lives and are reviewed for impairment when facts or circumstances suggest that the carrying value of these assets may not be recoverable. Our in-place lease intangible asset is being amortized over the remaining period of the related lease term as discussed in Note 4.

**Impairment of 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 an indication of impairment, we will test for recoverability by comparing the estimated undiscounted 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 and liabilities are grouped at the lowest level for which there are identifiable cash flows that are largely independent of the cash flows generated by other such groups. If the undiscounted future cash flows are 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.

**GILEAD SCIENCES, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**DECEMBER 31, 2003**

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

**Foreign Currency Translation, Transactions and Contracts**

Adjustments resulting from translating the financial statements of our 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 gains (losses) are reported as selling, general and administrative expenses in the consolidated statements of operations. Such realized gains (losses) were (\$2.2) million in 2003, \$0.6 million in 2002 and (\$1.4) million in 2001.

We hedge certain of our foreign currency exposures related to outstanding trade accounts receivable, firmly committed purchase transactions, and forecasted product sales with foreign exchange forward contracts. In general, these contracts do not expose us to market risk because gains and losses on the contracts offset gains and losses on the transactions being hedged. Our 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. We also limit risk of loss by entering into contracts that provide for net settlement at maturity. Therefore, our 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. We do not enter into speculative foreign currency transactions and do not write options. We presently do not hedge our net investment in any of our foreign subsidiaries. In accounting for hedges of accounts receivable, we record the changes in the fair value in selling, general and administrative expense, as these derivative instruments are not designated as hedges under SFAS 133.

We selectively hedge anticipated currency exposures by purchasing forward contracts to hedge firmly committed purchases transactions and anticipated product sales over the next year or less, which are designated as cash flow hedges under SFAS 133. The unrealized gains and losses on the underlying forward contracts are recorded in other comprehensive income and recognized in earnings when the forecasted transaction occurs. At December 31, 2003 and December 31, 2002, we have net unrealized losses on our open foreign exchange forward contracts of \$14.5 million and \$1.1 million, respectively. Losses on revenue hedges reduced product sales by \$2.8 million in 2003 and by \$1.0 million in 2002.

We had notional amounts on forward exchange contracts outstanding of \$405.0 million at December 31, 2003 and \$53.5 million at December 31, 2002. All contracts have maturities of one year or less.

See Note 2 for a further discussion of derivative financial instruments and our adoption of SFAS 133.

**Fair Value of Financial Instruments**

The Company's financial instruments consist principally of cash and cash equivalents, marketable securities, accounts receivable, certain other non-current assets, forward foreign exchange contracts, accounts payable, long-term obligations and convertible 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 and sales are recorded at fair value, net of the related deferred gain or loss, resulting in a reported net balance of zero. The fair value of the convertible senior notes at December 31, 2003 was



**GILEAD SCIENCES, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**DECEMBER 31, 2003**

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

\$472.6 million and the fair value at December 31, 2002 was \$357.4 million. The carrying value at the end of each period was \$345.0 million. The fair value of the convertible subordinated notes at December 31, 2002 was \$381.9 million and the carrying value was \$250.0 million. Gilead called the convertible subordinated notes for redemption in November 2003 and converted them to Gilead common stock in December 2003. The fair values at December 31, 2003 and December 31, 2002 for each of the convertible notes were determined by obtaining quotes from a market maker for the notes. We believe the remaining financial instruments are reported on the consolidated balance sheet at amounts that approximate current fair values.

**Recent Accounting Pronouncements**

In January 2003, the FASB issued FASB Interpretation No. 46 (FIN 46), *Consolidation of Variable Interest Entities*, an Interpretation of ARB No. 51. FIN 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN 46 is effective immediately for all new variable interest entities created or acquired after January 31, 2003. We did not create or acquire any new variable interest entities after January 31, 2003. For variable interest entities created or acquired prior to February 1, 2003, the provisions of FIN 46, as amended, must be applied at the end of the first interim or annual period ending after March 15, 2003. The adoption of FIN 46 did not have a material impact on our consolidated financial statements.

**2. DERIVATIVE FINANCIAL INSTRUMENTS**

On January 1, 2001, Gilead adopted SFAS 133. The standard requires that Gilead recognize all derivatives as either assets or liabilities measured at fair value. We enter into foreign currency forward contracts to hedge against changes in the fair value of monetary assets and liabilities denominated in a non-functional currency. 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.

The Company enters into foreign currency forward contracts, generally with maturities of 12 months or less, to hedge future cash flows related to purchase transactions and forecasted product sales in foreign denominated currencies. These derivative instruments are employed to eliminate or minimize certain foreign currency exposures that can be confidently identified and quantified. In accordance with SFAS 133, hedges related to anticipated foreign currency purchases of raw materials and forecasted product sales designated and documented at the inception of the respective hedge are designated as cash flow hedges and evaluated for effectiveness quarterly. As the terms of the forward contract and the underlying transaction are matched at inception, forward contract effectiveness is calculated by comparing the fair value of the contract to the change in the forward value of the underlying hedged item. The effective component of the hedge is recorded in accumulated other comprehensive income. Substantially all values reported in accumulated other comprehensive income at December 31, 2003 will be reclassified to earnings within 12 months. Any residual changes in fair value of the instruments or other ineffectiveness are

**GILEAD SCIENCES, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**DECEMBER 31, 2003**

**2. DERIVATIVE FINANCIAL INSTRUMENTS (Continued)**

recognized immediately in selling, general and administrative expense. Ineffectiveness during 2003 and 2002 was not significant.

As a result of entering into collaborations in prior years, Gilead holds warrants to purchase stock in two non-public companies, one of which completed its initial public offering in January 2004. See Note 10. These warrants have net exercise features and under SFAS 133 are classified as derivative instruments. Upon adoption, Gilead recorded the fair value of one of these warrants at \$1.1 million with an offsetting adjustment to cumulative change in accounting principle.

During 2003, a \$5.1 million loss on hedging contracts has been recognized in the consolidated income statement and a \$1.0 million decrease in the fair value of derivatives has been recognized in accumulated other comprehensive income. At December 31, 2003, the fair value of derivatives included in accumulated other comprehensive income is not material.

**3. ACQUISITION OF TRIANGLE PHARMACEUTICALS, INC.**

On January 23, 2003, we completed the acquisition of all of the net assets of Triangle to expand our antiviral pipeline. Triangle was a development stage company with a particular focus on potential therapies for HIV, including AIDS, and the hepatitis B virus (HBV). Triangle's portfolio consisted of several drug candidates in clinical trials, including Emtriva (emtricitabine) for the treatment of HIV infection, emtricitabine for the treatment of chronic hepatitis B, amdoxovir for the treatment of HIV infection and clevudine for the treatment of chronic hepatitis B. In July 2003, the U.S. Food and Drug Administration (FDA) approved for marketing Emtriva for the treatment of HIV and in October 2003, the European Commission granted Marketing Authorisation for Emtriva in all fifteen member states of the European Union.

The Triangle acquisition has been accounted for as an acquisition of assets rather than as a business combination in accordance with the criteria outlined in Emerging Issues Task Force 98-3. Triangle was a development stage company that had not commenced its planned principal operations. It lacked the necessary elements of a business because it did not have completed products and, therefore, no ability to access customers. The results of operations of Triangle since January 23, 2003 have been included in our consolidated financial statements and primarily consist of research and development expenses and to a lesser extent, selling, general and administrative expenses.

In December 2002, as part of the arrangements contemplated by the proposed acquisition of Triangle by Gilead, a \$50.0 million loan was extended to Triangle for working capital and other corporate purposes. Triangle issued to Gilead a 7.50% unsecured convertible promissory note. Upon completion of the acquisition in January 2003, this loan was eliminated in our consolidated financial statements.

The aggregate purchase price was \$525.2 million, including cash paid of \$463.1 million for all of the outstanding stock, the fair value of stock options assumed of \$41.3 million, estimated direct transaction costs of \$14.2 million and employee related costs of \$6.6 million.

As part of the purchase, we established a workforce reduction plan and also assumed obligations under various change of control agreements. As of the acquisition date, approximately \$6.2 million of employee termination costs and change of control obligations had been recorded as a liability to be paid

**GILEAD SCIENCES, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**DECEMBER 31, 2003**

**3. ACQUISITION OF TRIANGLE PHARMACEUTICALS, INC. (Continued)**

out over a period of approximately two years. At December 31, 2003, approximately \$3.6 million remained as a liability.

The following table summarizes the purchase price allocation at January 23, 2003 (in thousands):

Net tangible assets	\$ 28,700
Assembled workforce	4,590
Deferred compensation	3,305
In-process research and development	488,599
	<u>\$ 525,194</u>

The \$28.7 million of net tangible assets includes assumed liabilities of \$20.8 million. The \$4.6 million value assigned to the assembled workforce was being amortized over three years, the estimated useful life of the asset. The deferred compensation represents the intrinsic value of the unvested stock options assumed in the transaction and will be amortized over the remaining vesting period of the options, which extends through January 2007.

Upon the reversal of the deferred tax asset valuation allowance in the fourth quarter of 2003, the remaining \$3.2 million assembled workforce asset was eliminated. See Note 18.

**GILEAD SCIENCES, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**DECEMBER 31, 2003**

**3. ACQUISITION OF TRIANGLE PHARMACEUTICALS, INC. (Continued)**

Approximately \$488.6 million of the purchase price was allocated to in-process research and development and represented the fair value of Triangle's incomplete research and development programs that had not yet reached technological feasibility and had no alternative future use as of the acquisition date. A summary of these programs at the acquisition date and updated for subsequent developments follows:

<u>Program</u>	<u>Description</u>	<u>Status of Development</u>	<u>Value (in millions )</u>
Emtricitabine for HIV—Single Agent	A nucleoside analogue that has been shown to be an inhibitor of HIV replication in patients.	Four phase 3 studies completed. U.S. marketing approval received from the FDA in July 2003 and European Union approval received from the European Commission in October 2003.	\$178.8
Emtricitabine/Tenofovir DF Fixed Dose Combination for HIV Therapy	A potential co-formulation of tenofovir and emtricitabine.	As of the acquisition date, work had not yet commenced on the potential co-formulation except to the extent that work on emtricitabine as a single agent was progressing. We have since successfully completed co-formulating tenofovir and emtricitabine into a single pill, completed three stability studies and a bioequivalence study required for approval.	\$106.4
Amdoxovir for HIV	A purine dioxolane nucleoside that may offer advantages over other marketed nucleosides because of its activity against drug resistant viruses as exhibited in patients with HIV infection.	Phase 2 trials at acquisition date. Effective January 28, 2004, we announced our intent to terminate the licensing agreement with Emory University and the University of Georgia Research Foundation, Inc. and development will be discontinued.	\$114.8
Clevudine for HBV	A pyrimidine nucleoside analogue that has been shown to be an inhibitor of HBV replication in patients chronically infected with HBV.	Phase 1/2 trials at acquisition date. Effective August 6, 2003, the licensing agreement with Bukwang Pharm. Ind. Co., Ltd was terminated and development was discontinued.	\$58.8
Emtricitabine for HBV	An inhibitor of HBV replication in patients chronically infected with HBV.	Phase 3 trial ongoing.	\$29.8

**GILEAD SCIENCES, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**DECEMBER 31, 2003**

**3. ACQUISITION OF TRIANGLE PHARMACEUTICALS, INC. (Continued)**

The remaining efforts for completion of Triangle's research and development projects primarily consist of clinical trials, the cost, length and success of which are extremely difficult to predict. Numerous risks and uncertainties exist that could prevent completion of development, including the ability to enroll patients in clinical trials, the possibility of unfavorable results of our clinical trials, and the risk of failing to obtain FDA and other regulatory body approvals. Feedback from regulatory authorities or results from clinical trials might require modifications or delays in later stage clinical trials or additional trials to be performed. We cannot be certain that emtricitabine for the treatment of chronic hepatitis B, purchased from Triangle, will be approved in the U.S. or the European Union or whether marketing approvals will have significant limitations on its use. We have terminated our rights with respect to the other potential products that we acquired with the acquisition of Triangle. We also do not yet have approval of the fixed-dose combination product containing tenofovir DF and emtricitabine. Future discussions with regulatory agencies will determine the amount of data needed and timelines for review, which may differ materially from current projections. The acquired products under development may never be successfully commercialized. Emtriva, for example, is a product with many similarities to other existing products. As a result, it may be difficult to successfully penetrate the market and to achieve significant revenues. In addition, emtricitabine for the treatment of chronic hepatitis B faces significant uncertainties associated with pricing, efficacy, and the cost to produce that may not be successfully resolved. As a result, we may make a strategic decision to discontinue development of this product, as we did with clevidine and amdoxovir, if we believe commercialization will be difficult relative to other opportunities in our pipeline. If these programs cannot be completed on a timely basis or at all, then our prospects for future revenue growth would be adversely impacted.

The value of the acquired in-process research and development was determined by estimating the related future net cash flows between 2003 and 2020 using a present value risk adjusted discount rate of 15.75%. This discount rate is a significant assumption and is based on our estimated weighted average cost of capital adjusted upward for the risks associated with the projects acquired. The projected cash flows from the acquired projects were based on estimates of revenues and operating profits related to the projects considering the stage of development of each potential product acquired, the time and resources needed to complete the development and approval of each product, the life of each potential commercialized product and associated risks including the inherent difficulties and uncertainties in developing a drug compound including obtaining FDA and other regulatory approvals, and risks related to the viability of and potential alternative treatments in any future target markets.

**4. ACQUISITION OF REAL ESTATE**

In September 2003, we completed the purchase of our Foster City campus for approximately \$123.0 million in cash. This purchase included 16 buildings, totaling 496,000 square feet of office and laboratory space on Lakeside Drive in Foster City, California.

In accordance with SFAS No. 141, *Business Combinations* and SFAS No. 142, *Goodwill and Other Intangible Assets*, the purchase price should be allocated between land, buildings and existing in-place leases based on the estimated relative fair values. Land and buildings were recorded at \$45.1 million and

**GILEAD SCIENCES, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**DECEMBER 31, 2003**

**4. ACQUISITION OF REAL ESTATE (Continued)**

\$71.4 million, respectively. The fair value of the buildings will be depreciated over their remaining economic life estimated to be 20 years. We used the market approach to value the existing leases we acquired and recorded an intangible asset of approximately \$6.5 million that will be amortized on a straight-line basis to net rental income over approximately two years, the remaining term of the leases. The net rental income we generate from these leases, after amortization of the intangible asset, is included in interest and other income, net and was approximately \$0.4 million for the year ended December 31, 2003. Accumulated amortization on the intangible asset was \$0.8 million as of December 31, 2003.

**5. ASSET IMPAIRMENT**

During 2003, we recorded an asset impairment charge of \$10.2 million on certain of our long-lived assets, primarily leasehold improvements, manufacturing and laboratory equipment, which we have classified as held for use. This non-cash charge was driven by the decision to terminate our liposomal research and development activities in San Dimas and discontinue the DaunoXome product line. The impairment was based on our analysis of the undiscounted cash flows to be generated from the affected assets as compared to their carrying value. As the carrying value exceeded the related undiscounted cash flows, we wrote the carrying value of the long-lived assets down to fair value in accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. Fair value was derived using an expected cash flow approach.

**6. SALE OF ONCOLOGY ASSETS**

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

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**GILEAD SCIENCES, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**DECEMBER 31, 2003**

**7. SALE OF MARKETABLE SECURITIES**

In July 2002, Gilead sold all of its remaining shares of OSI common stock for approximately \$22.0 million. These shares were partial consideration for the sale of our oncology assets to OSI in December 2001, at which time they were recorded at a fair market value of approximately \$38.0 million. In connection with the sale of these remaining shares, we recognized a non-operating loss of approximately \$16.0 million that is reflected in our consolidated results of operations for the year ended December 31, 2002.

**8. 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):

	Gross Unrealized	Gross Unrealized	Estimated Fair Value
Cost	Gains	Losses	
December 31, 2003			

U.S. treasury securities and obligations of U.S. government agencies	\$ 167,825	\$ 304	\$ (5)	\$ 168,124
Corporate debt securities	104,549	256	(15)	104,790
Asset-backed securities	208,557	165	(299)	208,423
Other debt securities	146,901	—	—	146,901
Total	<u>\$ 627,832</u>	<u>\$ 725</u>	<u>\$ (319)</u>	<u>\$ 628,238</u>

**December 31, 2002**

U.S. treasury securities and obligations of U.S. government agencies	\$ 419,784	\$ 1,781	\$ (9)	\$ 421,556
Corporate debt securities	102,891	1,195	(17)	104,069
Asset-backed securities	68,708	852	(6)	69,554
Other debt securities	290,018	—	—	290,018
Total	<u>\$ 881,401</u>	<u>\$ 3,828</u>	<u>\$ (32)</u>	<u>\$ 885,197</u>

Other debt securities consist primarily of money market funds. We also maintain other marketable securities of nominal value recorded in other noncurrent assets. At December 31, 2003 and December 31, 2002, these securities have a net unrealized loss of approximately \$0.8 million and \$0.1 million, respectively.

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

	<u>Year Ended December 31,</u>		
	<u>2003</u>	<u>2002</u>	<u>2001</u>
Proceeds from sales	\$ 579,362	\$ 422,168	\$ 143,684
Gross realized gains on sales	\$ 1,897	\$ 3,492	\$ 1,284
Gross realized losses on sales	\$ (1,120)	\$ (16,705)	\$ (59)

**GILEAD SCIENCES, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**DECEMBER 31, 2003**

**8. AVAILABLE-FOR-SALE SECURITIES (Continued)**

At December 31, 2003, \$361.9 million of our portfolio of marketable securities (which excludes \$208.4 million of asset-backed securities) has a contractual maturity of less than one year and \$57.9 million of the portfolio has a contractual maturity greater than one year but less than three years. None of the estimated maturities of our asset-backed securities exceed three years.

**9. BALANCE SHEET DETAIL (in thousands)**

	<b>December 31,</b>	
	<b>2003</b>	<b>2002</b>
<b>Inventories:</b>		
Raw materials	\$ 54,178	\$ 24,840
Work in process	11,775	16,548
Finished goods	32,149	10,240
Total	<u>\$ 98,102</u>	<u>\$ 51,628</u>
<b>Property, plant and equipment, net:</b>		
Buildings and improvements (including leasehold improvements)	\$ 146,445	\$ 61,010
Laboratory and manufacturing equipment	35,819	37,108
Office and computer equipment	34,193	27,005
Capitalized leased equipment	16,333	14,915
Construction in progress	10,292	8,467
	<u>243,082</u>	<u>148,505</u>
Less accumulated depreciation and amortization	(89,938)	(80,778)
Subtotal	153,144	67,727
Land	45,056	—
Total	<u>\$ 198,200</u>	<u>\$ 67,727</u>
<b>Accrued compensation and employee benefits:</b>		
Accrued bonuses	\$ 13,313	\$ 9,928
Other accrued compensation and employee benefits	22,459	11,583
Total	<u>\$ 35,772</u>	<u>\$ 21,511</u>
<b>Other accrued liabilities:</b>		
Accrued Medicaid rebates	\$ 22,097	\$ 10,805
Fair value of forward currency contracts	15,096	1,796
Income taxes payable	13,305	2,997
Accrued sales and marketing expenses	5,883	8,205
Other liabilities	40,621	20,223
Total	<u>\$ 97,002</u>	<u>\$ 44,026</u>



**GILEAD SCIENCES, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**DECEMBER 31, 2003**

**10. COLLABORATIVE ARRANGEMENTS AND CONTRACTS**

**Chiron Corporation**

In August 2003, we entered into a non-exclusive licensing agreement with Chiron Corporation (Chiron) for the research, development and commercialization of small molecule therapeutics against selected hepatitis C virus (HCV) drug targets. Under the agreement, Gilead received non-exclusive rights to use Chiron's HCV technology to develop and commercialize products for the treatment of HCV. Under the terms of the agreement, we paid Chiron an up-front license fee that was recorded as research and development expense as there is no future alternative use for this technology. We also agreed to make additional payments to Chiron if certain clinical and regulatory milestones are met and royalty payments in the event a product is developed using the licensed technology.

**Japan Tobacco Inc.**

In July 2003, Gilead entered into a licensing agreement with Japan Tobacco Inc. (Japan Tobacco) under which Japan Tobacco will commercialize products in our HIV portfolio in Japan. The agreement includes Viread, Emtriva and a future co-formulation of the two products. Under the terms of the agreement, we received an up-front fee and are entitled to receive additional cash payments upon achievement of certain milestones. Japan Tobacco also will pay us a royalty on net sales, if any, of these products in Japan. The up-front fee has been recorded as deferred revenue and will be amortized into contract revenue over the period of our remaining obligations under the agreement, approximately 14 years.

**Emory University**

In April 1996, Triangle obtained, and in January 2003 we acquired as part of our acquisition of Triangle, an exclusive worldwide license to all of Emory University's rights to purified forms of emtricitabine for use in the HIV and the hepatitis B fields. We are obligated to make certain milestone and royalty payments to Emory, including annual minimum royalties beginning the third year after the first FDA registration is granted for an anti-HIV product incorporating the emtricitabine technology in the U.S. and the third year after the first registration is granted for an anti-hepatitis B product incorporating the emtricitabine technology in certain major market countries, for the HIV and hepatitis B indications, respectively. In 2002, Triangle began paying license maintenance fees because development milestones had not yet been achieved.

The license agreement with Emory terminates upon the later of patent expiration or the expiration of our obligation to pay royalties. In addition, we have the right to terminate the agreement in its entirety or with respect to one or both indications (HIV and HBV) in one or more countries prior to expiration at any time upon 90 days notice.

**GlaxoSmithKline**

In April 2002, Gilead and GSK entered into a licensing agreement providing GSK the rights to commercialize Hepsera, our antiviral for the treatment of chronic hepatitis B, in Asia, Latin America and certain other territories. Under the agreement, we retained rights to Hepsera in the U. S., Canada, Eastern and Western Europe, Australia and New Zealand. GSK received exclusive rights to develop Hepsera solely

**GILEAD SCIENCES, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**DECEMBER 31, 2003**

**10. COLLABORATIVE ARRANGEMENTS AND CONTRACTS (Continued)**

for the treatment of chronic hepatitis B in all of its territories, the most significant of which include China, Korea, Japan and Taiwan. In addition, GSK paid us an up-front licensing fee of \$10.0 million as the first payment against these additional obligations and, may pay up to \$30.0 million upon achievement by GSK of certain regulatory, development and commercial milestones. Of this \$30.0 million, \$2.0 million was received for the U.S. approval of Hepsera in September 2002 and \$2.0 million was received for the Canadian approval of Hepsera in August 2003. GSK also will pay us a royalty on net sales, if any, of Hepsera in the GSK territories. GSK will have full responsibility for development and commercialization of Hepsera in GSK's territories. The \$10.0 million up-front fee and \$4.0 million of approval fees have been recorded as deferred revenue with a total of \$0.9 million and \$0.5 million being recognized as contract revenue in 2003 and 2002, respectively. The \$12.6 million balance of deferred revenue at December 31, 2003 will be amortized into contract revenue over the period of our remaining obligations under the agreement, approximately 12 years.

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

In May 1998, Gilead entered into a three-part collaboration with GSK in which: (a) GSK received a non-exclusive right to use Gilead's proprietary SELEX process for target validation; (b) Gilead received exclusive rights (subject to GSK's right to elect to participate in such activities) to develop and commercialize NX 211, a liposomal formulation of GSK's proprietary topoisomerase I inhibitor (lurtotecan); and (c) GSK acquired 1,457,028 shares of Gilead common stock for \$10.0 million in a private offering. In December 2000, the collaboration and license agreement was modified. Under the revised terms of agreement, GSK waived its right to participate in the development and commercialization of NX 211 and its right to receive royalties, giving Gilead exclusive rights to the compound. In December 2001, this compound was also assigned to OSI as part of the sale of oncology assets.

**Cubist Pharmaceuticals**

In September 2002, Gilead and Cubist Pharmaceuticals jointly announced the termination of their licensing agreement for the commercialization of Cidecin<sup>®</sup> (daptomycin for injection) and an oral formulation of daptomycin. The agreement, executed in January 2001, granted Gilead exclusive commercialization rights to the products in 16 European countries following regulatory approval. Under the terms of the termination agreement, Gilead does not owe any future payments to Cubist, and Cubist reacquired all European rights to both products. Upon termination, \$2.0 million was recorded to research and development expense, which represented the remaining unamortized asset related to the preclinical oral formulation of daptomycin.

**GILEAD SCIENCES, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**DECEMBER 31, 2003**

**10. COLLABORATIVE ARRANGEMENTS AND CONTRACTS (Continued)**

**Archemix**

In October 2001, we entered into an agreement with Archemix Corporation relating to our SELEX technology. Under this agreement, Archemix obtained the exclusive rights to the SELEX process, including therapeutic and other commercial applications to the extent not already licensed under pre-existing agreements. Archemix paid to us \$9.0 million in 2001 and \$8.5 million in 2002. As required by our license agreement with License Equity Holdings, Inc. (ULEHI), we paid 5% of these receipts to ULEHI, therefore we recognized \$8.1 million and \$8.6 million as revenue in 2002 and 2001, respectively. We also received a warrant to purchase 350,000 shares of Archemix common stock, the value of which is not material. As required by our license agreement with ULEHI, we transferred 5% of this warrant at that time. We have since transferred the remainder of the warrant to ULEHI. No additional payments are due by Archemix under this agreement.

**EyeTech**

In March 2000, we entered into an agreement with EyeTech Pharmaceuticals, Inc. relating to our proprietary aptamer EYE001, now known as Macugen. Currently in Phase 3 clinical trials, Macugen 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 Macugen, and, if the product is successfully commercialized, EyeTech will pay us royalties on worldwide sales of the product. EyeTech also will be responsible for all research and development costs. We provided clinical supplies of the product to EyeTech through March 2001. We also received a \$7.0 million up-front licensing fee from EyeTech in April 2000, which was recognized as revenue ratably over the one-year supply agreement period. Accordingly, \$5.2 million of the license fee was recorded as contract revenue under the agreement in 2000, and the remainder of the license fee was recognized as revenue in 2001. We are also entitled to additional cash payments from EyeTech of up to \$25.0 million if and when EyeTech reaches certain Macugen development milestones. Additionally, we received a warrant to purchase 791,667 shares of EyeTech series B convertible preferred stock, exercisable at a price of \$6.00 per share, the price at which the stock was issued to other investors. See Note 2 for a description of the accounting treatment of the warrant.

**Fujisawa**

Our rights to market AmBisome are subject to a 1991 agreement between Gilead and Fujisawa Healthcare, Inc., as successor to Fujisawa USA, Inc. (Fujisawa). Under the terms of the Fujisawa agreement, as amended, Fujisawa and Gilead co-promote AmBisome in the U.S. Fujisawa has sole marketing rights to AmBisome in Canada and we have exclusive marketing rights to AmBisome in the rest of the world, provided we pay royalties to Fujisawa in connection with sales in most significant Asian markets, including Japan. In connection with U.S. sales, Fujisawa purchases AmBisome from Gilead 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 U.S. and Canada. We receive 20% of Fujisawa's gross profits from the sale of AmBisome in the U.S. Gross profits include a deduction for cost of goods sold, giving us a current effective royalty rate of approximately 17% of Fujisawa's net sales of AmBisome in

**GILEAD SCIENCES, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
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**10. COLLABORATIVE ARRANGEMENTS AND CONTRACTS (Continued)**

the U.S. In connection with the agreement between us and Fujisawa, we recorded royalty revenue of \$12.5 million in 2003, \$15.7 million in 2002 and \$17.1 million in 2001.

**Sumitomo**

In September 1996, Gilead and Sumitomo entered into an agreement pursuant to which Sumitomo agreed to develop and market AmBisome in Japan. Under the terms of the agreement, Sumitomo paid us 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 us if certain clinical and commercial milestones are met and to pay us royalties on all Japanese AmBisome sales. Under the agreement, Gilead is obligated to provide a certain quantity of AmBisome to Sumitomo at no charge. AmBisome is not yet approved for marketing in Japan.

**Roche**

In September 1996, Gilead entered into a collaboration agreement with Roche to develop and commercialize therapies to treat and prevent viral influenza (the Roche Agreement). Under the Roche Agreement, Roche received exclusive worldwide rights to Gilead's proprietary influenza neuraminidase inhibitors. Prior to 2000, Roche made license fee and developmental milestone payments totaling \$29.1 million. During 2000, Gilead recognized \$9.6 million of contract revenue from milestone payments from Roche related to Tamiflu milestones achieved during the year. The milestones included filing for regulatory approval in Japan for treatment of influenza, the Japanese approval of the application, the filing for U.S. regulatory approval for the prevention of influenza, and the receipt of such approval in the U.S. In 2001, we recognized a \$2.0 million milestone payment for the filing of an application to market Tamiflu as a prophylaxis in the European Union. In 2002, we recognized \$8.0 million in milestone payments for the European approval of Tamiflu for treatment and prophylaxis.

As of December 31, 2003, Gilead is entitled to additional cash payments from Roche of up to \$1.6 million upon Roche achieving additional developmental and regulatory milestones. In addition, Roche is required to pay Gilead royalties on net product sales. Gilead began receiving royalties from Roche's sales of Tamiflu in the first quarter of 2000. We recorded a total of \$12.0 million of Tamiflu royalties in 2003, \$3.4 million of royalties in 2002 and \$4.5 million of royalties in 2001. We recognize royalty revenue from Roche in the quarter following the quarter in which the related Tamiflu sales occur.

**Pfizer**

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

Subsequent to the cumulative effect of the change in accounting principle recorded effective in the first quarter of 2000, Gilead is recognizing the initial license fee on a straight-line basis over the supply arrangement period, which is sixteen years from the agreement date. The net impact of the change in accounting principle for the Pfizer Agreement was to increase the net loss in 2000 by \$7.3 million. The

**GILEAD SCIENCES, INC.**  
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**10. COLLABORATIVE ARRANGEMENTS AND CONTRACTS (Continued)**

cumulative effect of the change in accounting principle related to the initial license fee from Pfizer 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, through 2013.

Under the terms of the Pfizer Agreement and related agreements covering expanded access programs for Vistide outside of the U.S., Gilead is responsible for maintaining the cidofovir patent portfolio and for supplying to Pfizer bulk cidofovir used to manufacture the finished Vistide product. Gilead is entitled to receive a royalty based upon Pfizer's sales of Vistide. Gilead receives a portion of the royalty upon shipping either bulk drug substance or Vistide to Pfizer, and the remainder upon Pfizer'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, 2003, we have recorded on our balance sheet approximately \$2.6 million of such deferred revenue (\$1.9 million at December 31, 2002). We recognized royalty revenue from sales of Vistide outside of the United States by Pharmacia of \$1.3 million in 2003, \$1.3 million in 2002 and \$1.4 million in 2001.

**IOCB/REGA**

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

In December 2000, the agreements with IOCB/REGA were amended to provide for a reduced royalty rate on future sales of Hepsera or Viread, in return for an up-front payment from Gilead of \$11.0 million upon signing the agreement. This payment was recorded as a long-term prepaid royalty and is classified in other noncurrent assets on the balance sheet at December 31, 2003 and 2002. It is being recognized as royalty expense over the expected commercial life of Viread and Hepsera. Amortization of the \$11.0 million payment began as of the product launch dates of Viread and Hepsera and totaled \$1.7 million through December 31, 2003.

**Southern Research Institute**

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

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**GILEAD SCIENCES, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**DECEMBER 31, 2003**

**11. INVESTMENT IN AND SALE OF UNCONSOLIDATED AFFILIATE**

In July 1998, we 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. In August 1998, we sold a 51% interest (Interest) in Proligo to a third party. As payment for the Interest, we received \$15.0 million in cash and a 49% interest in PerSeptive Biosystems GmbH, a company in Hamburg, Germany, which specializes in the manufacture of nucleoside phosphoramidite monomers. Prior to February 2000, we made two additional cash investments in Proligo for a total of \$5.0 million to maintain our 49% ownership interest in Proligo.

We accounted for our investment in Proligo using the equity method of accounting. During 2001, Gilead sold its 49% interest in Proligo to Degussa Corporation for \$14.3 million in cash. The proceeds, net of Gilead's investment in Proligo, are reflected as an \$8.8 million gain on the sale of unconsolidated affiliate. In 2001, prior to the date of the sale, Gilead recorded \$2.1 million as equity in the loss of Proligo.

**12. LONG-TERM OBLIGATIONS**

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

	<u>December 31,</u>	
	<u>2003</u>	<u>2002</u>
Capital lease obligations: monthly installments through 2007; interest rates ranging from 6% to 21%	\$ 462	\$ 361
Fixed rate debt: monthly installments through 2003; secured by equipment; interest rates ranging from 2% to 11%	—	106
Total long-term obligations	462	467
Less current portion	(139)	(194)
Long-term obligations due after one year	<u>\$ 323</u>	<u>\$ 273</u>

Future minimum lease payments under capital lease obligations are as follows (in thousands):

<u>Year ending December 31,</u>	
2004	\$ 196
2005	184
2006	171
2007	12
2008	—
	563
Less amount representing interest	(101)
Total	<u>\$ 462</u>

The terms of the various agreements require us to comply with certain financial and operating covenants. At December 31, 2003, we were in compliance with all such covenants.

**GILEAD SCIENCES, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**DECEMBER 31, 2003**

**13. CONVERTIBLE NOTES**

On December 18, 2002, Gilead issued \$345.0 million of 2% convertible senior notes due December 15, 2007 in a private offering to Goldman, Sachs & Co. who resold the notes to qualified institutional investors. The notes are convertible into a total of up to 7,340,425 shares of Gilead common stock at \$47.00 per share. The \$47.00 conversion price is higher than Gilead's common stock price on the note's issuance date. The notes are redeemable in whole or in part, at the option of Gilead, at any time on or after June 20, 2004, at specified redemption prices plus accrued interest. Debt issuance costs of \$8.4 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.

On December 13, 2000, Gilead issued \$250.0 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 Witter, which resold the notes to private institutional investors. The notes were convertible into a total of up to 10,178,116 shares of Gilead common stock at \$24.5625 per share. The \$24.5625 conversion price was higher than Gilead's common stock price on the note's issuance date. The notes were redeemable in whole or in part, at the option of Gilead, 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 were being amortized to interest expense on a straight-line basis over the contractual term of the notes. In November 2003, Gilead called the convertible subordinated notes for redemption and converted them to shares of common stock in December 2003. Upon conversion, the \$4.6 million remaining balance of the related debt issuance costs was reclassified to additional paid in capital.

**14. COMMITMENTS AND CONTINGENCIES**

**Lease Arrangements**

We have entered into various long-term noncancelable operating leases for equipment and facilities.

Facility leases in San Dimas, California and Durham, North Carolina expire on various dates between 2006 and 2013. One of the San Dimas leases contains two five-year renewal options. The Durham lease has two seven-year renewal options. We also have operating leases for sales, marketing and administrative facilities in Europe and Australia with various terms. Our equipment leases include a corporate airplane, which has an initial term of two years and an annual renewal option of up to ten years.

Lease expense net of sublease income under our operating leases totaled approximately \$15.5 million in 2003, \$13.4 million in 2002 and \$12.0 million in 2001.

**GILEAD SCIENCES, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**DECEMBER 31, 2003**

**14. COMMITMENTS AND CONTINGENCIES (Continued)**

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

<u>Years ending December 31,</u>	<u>Operating Leases, Net of Noncancelable Subleases</u>
2004	\$ 7,036
2005	4,033
2006	10,439
2007	10,697
2008	10,289
Thereafter	12,744
	<u>\$ 55,238</u>

Future minimum rental receipts due to us under noncancelable subleases are \$6.1 million in 2004, \$6.3 million in 2005 and \$0.5 million in 2006.

**Legal Proceedings**

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 initial settlement agreement in 1997, we made an initial payment to Elan of \$1.8 million and agreed to make additional royalty payments through 2006, based on AmBisome sales. In 1997, we recorded a \$10.0 million accounting charge for the accrued litigation settlement expenses, representing the estimated net present value of all future minimum payments we were required to make. In June 2002, Elan and Gilead entered into an agreement terminating our remaining AmBisome payment obligations under the initial settlement agreement in exchange for a payment to Elan of \$7.3 million. The excess of the \$7.3 million settlement amount over the remaining accrued litigation settlement expenses balance of \$6.0 million is being amortized over the remaining life of the patents, approximately four years.

On September 4, 2003, Gilead entered into a Settlement Agreement and Release with University License Equity Holdings, Inc. (ULEHI) and Archemix Corporation concerning rights to identify aptamers using the SELEX technology licensed by ULEHI to Gilead. The Settlement Agreement and Release resolves disputes among the parties arising out of Gilead's assignment of rights to identify certain aptamers to Archemix.

On September 2, 2003, the County of Westchester, New York ("Westchester") served Gilead with a complaint which alleges that Gilead and a large number of other pharmaceutical manufacturer defendants report prices for products that overstate the Average Wholesale Price ("AWP"), allegedly inflating reimbursement rates under the Medicaid Program and causing Westchester to pay artificially inflated prices for covered drugs including, in the case of Gilead, Viread. In addition, Westchester argues that the defendants, including Gilead, did not accurately report the "best price" under the Medicaid Program. The complaint asserts varying claims under the federal RICO statutes, their state law corollaries, as well as state law claims for deceptive trade practices and common law fraud. Gilead intends to vigorously defend



**GILEAD SCIENCES, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**DECEMBER 31, 2003**

**14. COMMITMENTS AND CONTINGENCIES (Continued)**

itself against the allegations. The complaint seeks an undetermined amount of damages, as well as other relief, including declaratory and injunctive relief.

Other defendants in this lawsuit have been named in numerous other lawsuits with comparable AWP allegations. To our knowledge, Gilead has not been named in these other lawsuits. Were Gilead to be named and served in other lawsuits with comparable AWP allegations, adverse results could result in material damages.

A purported class action complaint was filed on November 10, 2003 in the United States District Court for the Northern District of California against Gilead and our Company's Chief Executive Officer, Chief Financial Officer, Executive Vice Presidents of Operations and Research and Development, and Senior Vice Presidents of Manufacturing and Research. The complaint alleges that the defendants violated the federal securities laws, specifically Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 of the Securities and Exchange Commission, by making certain alleged false and misleading statements. The plaintiff seeks unspecified damages on behalf of a purported class of purchasers of the Gilead's securities during the period from July 14, 2003 through October 28, 2003. Other similar actions were subsequently filed and the court issued an order consolidating the lawsuits into a single action on December 22, 2003. We believe that we have meritorious defenses to the allegations contained in the complaint and intend to defend the case vigorously. No trial date has been scheduled. On February 9, 2004, the court issued an order appointing lead plaintiffs in the action, and these lead plaintiffs have until March 25, 2004 to file a consolidated complaint.

In December 2003, two purported shareholder derivative lawsuits were filed by individual shareholders on behalf of Gilead against its directors and certain executive officers in the Superior Court of the State of California, County of San Mateo alleging, among other things, that defendants violated the California Corporations Code and breached fiduciary duties owing to Gilead. Gilead is named as a nominal defendant. The plaintiffs seek unspecified damages on behalf of Gilead in connection with alleged insider trading during the period between July 14, 2003 and October 28, 2003 and defendants' alleged breach of their fiduciary duties, abuse of control, waste and mismanagement. The two cases were consolidated into a single action on January 15, 2004 and plaintiffs filed a consolidated complaint on February 12, 2004. No trial date has been scheduled. We intend to take all appropriate action to defend our interests in connection with this litigation.

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 a material adverse impact on our business, results of operations or financial position.

**15. STOCKHOLDERS' EQUITY**

**Preferred Stock**

Gilead has 5,000,000 shares of authorized preferred stock issuable in series. Our Board of Directors (Board) is authorized to determine the designation, powers, preferences and rights of any such series. We have reserved 400,000 shares of preferred stock for potential issuance under the Preferred Share Purchase Rights Plan. There was no preferred stock outstanding as of December 31, 2003 and December 31, 2002.

**GILEAD SCIENCES, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**DECEMBER 31, 2003**

**15. STOCKHOLDERS' EQUITY (Continued)**

**Employee Stock Purchase Plan**

Under Gilead's Employee Stock Purchase Plan (ESPP), employees can purchase shares of Gilead common stock based on a percentage of their compensation. The purchase price per share must equal at least the lower of 85 percent of the market value on the date offered or the date purchased. A total of 6.3 million shares of common stock have been reserved for issuance under the ESPP. As of December 31, 2003, 4.9 million shares of the total shares reserved had been issued under the ESPP (4.6 million shares as of December 31, 2002).

**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 issued under the plans 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. The 1991 Plan was amended and restated in April 2000 to extend the term of the plan through 2010. In May 2002 the stockholders approved an amendment to the 1991 Plan that increased the total number of authorized shares under the plan from 47,000,000 to 53,000,000. At December 31, 2003, there were 9,570,258 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. For options granted before January 2003, vesting is over five years from the date of grant in quarterly five percent installments. Initial options granted after January 2003 to new Directors vest over three years from the date of grant in equal annual installments. Annual grants thereafter to existing Directors vest after 12 months. All options expire after ten years. In May 2002, the stockholders approved an amendment to the Directors' Plan that increased the total number of authorized shares under the Plan from 2,200,000 to 2,800,000. At December 31, 2003, there were 781,200 shares available for grant of future options under the Directors' Plan.

Stock plans assumed by Gilead in the merger with NeXstar include the 1988 Stock Option Plan (1988 Plan), the 1993 Incentive Stock Plan, and the 1995 Director Option Plan (collectively, NeXstar Plans). Options pursuant to the NeXstar Plans that were issued and outstanding as of July 29, 1999 have been

**GILEAD SCIENCES, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**DECEMBER 31, 2003**

**15. STOCKHOLDERS' EQUITY (Continued)**

converted into options to purchase Gilead common stock as a result of the merger and remain subject to their original terms and conditions. No shares are available for grant of future options under any of the NeXstar Plans.

NeXstar's 1988 Plan allows certain option holders to execute cashless exercises of options. In a cashless exercise transaction, the option holder specifies how many shares will be exercised and Gilead issues the specified number of shares, less the number that would be required to cover the exercise price based on the fair value of the stock on the exercise date. During 2002 and 2001, several option holders performed cashless exercises. As a result, such option awards are considered to be variable and, therefore, we recognized a nominal amount of compensation expense in 2002 and \$0.6 million in 2001. As of July 2002, there were no more options outstanding in this category.

Stock plans assumed by Gilead in the acquisition of the net assets of Triangle include the 1996 Stock Option Plan and a separate plan for the chief executive officer of Triangle (collectively, Triangle Plans). Options pursuant to each plan that were issued and outstanding as of January 23, 2003 have been converted into options to purchase approximately 2.0 million shares of Gilead common stock as a result of the acquisition and remain subject to their original terms and conditions. No shares are available for grant of future options under either of the Triangle Plans.

The following table summarizes activity under all Gilead, NeXstar and Triangle stock option plans for each of the three years in the period ended December 31, 2003. 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,					
	2003		2002		2001	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted average Exercise Price
Outstanding, beginning of year	21,060	\$ 18.67	21,686	\$ 14.26	21,672	\$ 11.09
Granted and assumed	7,871	\$ 41.74	4,371	\$ 33.37	6,708	\$ 21.11
Forfeited	(971)	\$ 32.57	(785)	\$ 21.90	(2,596)	\$ 16.10
Exercised	(5,200)	\$ 14.53	(4,212)	\$ 10.61	(4,098)	\$ 7.58
Outstanding, end of year	<u>22,760</u>	\$ 27.00	<u>21,060</u>	\$ 18.67	<u>21,686</u>	\$ 14.26
Exercisable, end of year	<u>9,998</u>	\$ 18.09	<u>9,275</u>	\$ 11.82	<u>9,022</u>	\$ 9.62
Weighted average fair value of options granted		\$ 27.36		\$ 22.01		\$ 14.29

**GILEAD SCIENCES, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
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**15. STOCKHOLDERS' EQUITY (Continued)**

The following is a summary of Gilead options outstanding and options exercisable at December 31, 2003 (options in thousands):

<u>Range of Exercise Prices</u>	<u>Options Outstanding</u>			<u>Options Exercisable</u>	
	<u>Options Outstanding</u>	<u>Weighted Average Remaining Contractual Life in Years</u>	<u>Weighted Average Exercise Price</u>	<u>Options Exercisable</u>	<u>Weighted Average Exercise price</u>
\$ 0.45-\$14.59	5,772	4.38	\$ 10.08	5,047	\$ 9.51
\$14.80-\$27.20	5,853	6.93	\$ 18.71	2,976	\$ 18.35
\$27.32-\$34.32	6,288	8.37	\$ 33.37	1,533	\$ 33.02
\$34.36-\$140.93	4,847	9.02	\$ 48.92	442	\$ 62.50
Total	<u>22,760</u>	7.13	\$ 27.00	<u>9,998</u>	\$ 18.09

The Company has reserved an aggregate of 11.7 million shares of common stock for future issuance under equity compensation plans as of December 31, 2003, including 1.4 million issuable under the ESPP and 10.3 million issuable under the 1991 and 1995 Stock Option Plans. Approximately 7.3 million shares have been reserved for issuance for the 2% senior convertible notes.

**Preferred Share Purchase Rights Plan**

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

In October 1999 and again in October 2003, the Board of Directors approved amendments to the Rights Plan. The first amendment provided, among other things, for an increase in the exercise price of a right under the plan from \$15 to \$100 and an extension of the term of the plan from November 21, 2004 to October 20, 2009. The second amendment provides, among other things, for an increase in the exercise price of a right under the plan from \$100 (after adjusting for two 2-for-1 stock splits) to \$400 and an extension of the term of the Rights Plan to October 27, 2013.

**Acceleration of Stock Options**

In December 2001, we completed the sale of our oncology assets to OSI. As part of this transaction, we accelerated approximately 78,000 options to purchase Gilead common stock with a value of \$2.8 million. See Note 6 for further discussion.

**GILEAD SCIENCES, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**DECEMBER 31, 2003**

**16. COMPREHENSIVE INCOME (LOSS)**

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

	<u>Year ended December 31,</u>		
	<u>2003</u>	<u>2002</u>	<u>2001</u>
Net gain (loss) on sales of securities	<u>\$ 777</u>	<u>\$ (13,213)</u>	<u>\$ 1,225</u>
Other comprehensive income:			
Net unrealized gain (loss) arising during the year	\$ (3,245)	\$ (17,790)	\$ 8,960
Reclassification adjustment	<u>(777)</u>	<u>13,213</u>	<u>(1,225)</u>

Net unrealized gain (loss) reported in other comprehensive income (loss)	<u>\$ (4,022)</u>	<u>\$ (4,577)</u>	<u>\$ 7,735</u>
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The balance of accumulated other comprehensive income as reported on the balance sheet consists of the following components (in thousands):

	<u>December 31,</u>	
	<u>2003</u>	<u>2002</u>
Net unrealized gain (loss) on available-for-sale securities	\$ (352)	\$ 3,670
Net unrealized gain (loss) on cash flow hedges	(765)	221
Net foreign currency translation gain (loss)	<u>5,624</u>	<u>(1,416)</u>
Accumulated other comprehensive income	<u>\$ 4,507</u>	<u>\$ 2,475</u>

## 17. DISCLOSURES ABOUT SEGMENTS OF AN ENTERPRISE AND RELATED INFORMATION

SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information* (SFAS 131), establishes standards for the way public business enterprises report information about operating segments in annual financial statements and requires that those enterprises report selected information about operating segments in interim financial reports. SFAS 131 also establishes standards for related disclosures about products and services, geographic areas, and major customers.

The Company operates in one business segment, which primarily focuses on the development and commercialization of human therapeutics for infectious diseases. All products have been aggregated into one segment, because a majority of our products, Viread and AmBisome, which accounted for 90% of sales in 2003, have similar economic characteristics and other similarities, including the nature of our products and production processes, type of customers, distribution methods, and regulatory environment.

The Company derives its revenues primarily from product sales of Viread and AmBisome as well as royalty and contract revenue. The royalty revenue relates primarily to sales of AmBisome by Fujisawa as well as sales of Tamiflu by Roche. Contract revenue relates to the licensing of the SELEX process patent estate to Archemix, milestone payments from Roche related to the development of Tamiflu, license and milestone payments from GSK related to the development of Hepsera and license fees from EyeTech for the rights to the aptamer EYE001, currently known as Macugen.

**GILEAD SCIENCES, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**DECEMBER 31, 2003**

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

Product sales consist of the following (in thousands):

	<b>Year ended December 31,</b>		
	<b>2003</b>	<b>2002</b>	<b>2001</b>
Viread	\$ 566,478	\$ 225,815	\$ 15,586
AmBisome	198,350	185,669	164,533
Other	71,513	12,395	10,851
	<u>\$ 836,341</u>	<u>\$ 423,879</u>	<u>\$ 190,970</u>

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

	<b>Year Ended December 31,</b>		
	<b>2003</b>	<b>2002</b>	<b>2001</b>
United States	\$ 443,506	\$ 218,958	\$ 63,888
United Kingdom	63,066	43,427	28,533
France	89,176	42,417	16,775
Spain	78,391	33,591	18,283
Germany	42,996	29,461	19,256
Italy	42,722	20,818	18,783
Switzerland	16,492	12,445	7,721
Other European countries	64,273	47,527	40,499
Other countries	27,242	18,146	20,031
Consolidated total revenues	<u>\$ 867,864</u>	<u>\$ 466,790</u>	<u>\$ 233,769</u>

At December 31, 2003, the net book value of our property, plant and equipment was \$198.2 million. Approximately 95% of such assets were located in the U.S. At December 31, 2002, the net book value of property, plant and equipment was \$67.7 million, and approximately 89% of such assets were located in the U.S.

Product sales to three distributors accounted for approximately 17%, 14% and 12% of total revenues in 2003. Product sales to these same three distributors accounted for approximately 10%, 12% and 11% of total revenues in 2002. Product sales to any one distributor in 2001 did not exceed 10% of total revenues. Total revenues from Fujisawa, which included product sales and royalties, were approximately 3% of total revenues in 2003, 7% in 2002, and 15% in 2001.

**GILEAD SCIENCES, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**DECEMBER 31, 2003**

**18. INCOME TAXES**

The provision for income taxes consisted of the following (in thousands):

		<b>Year ended December 31,</b>		
		<b>2003</b>	<b>2002</b>	<b>2001</b>
Federal	Current	\$ 5,175	\$ (1,300)	\$ 2,800
	Deferred	(89,363)	—	—
		<u>(84,188)</u>	<u>(1,300)</u>	<u>2,800</u>
State	Current	1,016	4	506
	Deferred	(20,824)	—	—
		<u>(19,808)</u>	<u>4</u>	<u>506</u>
Foreign	Current	9,849	2,596	829
	Deferred	(1,383)	—	—
		<u>8,466</u>	<u>2,596</u>	<u>829</u>
		<u><u>\$ (95,530)</u></u>	<u><u>\$ 1,300</u></u>	<u><u>\$ 4,135</u></u>

Foreign pre-tax loss was \$(79.7) million in 2002, \$(24.1) million in 2002 and \$(67.8) million in 2001. The Company's foreign subsidiaries generated operating losses in 2003, 2002, and 2001 reflecting the costs of building a commercial infrastructure in Europe and the foreign subsidiaries' investment in the Company's research and development efforts.

The difference between the provision for taxes on income and the amount computed by applying the federal statutory income tax rate to income (loss) 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):

		<b>Year ended December 31,</b>		
		<b>2002</b>	<b>2001</b>	<b>2001</b>
Income (loss) before provision for income taxes, equity in loss of unconsolidated affiliate and the cumulative effect of a change in accounting principle		<u>\$ (167,533)</u>	<u>\$ 73,397</u>	<u>\$ 57,447</u>
Tax at federal statutory rate		\$ (58,636)	\$ 25,689	\$ 19,532
Previously unbenefitted net operating losses		(150,842)	(23,601)	(19,339)
State taxes, net of federal benefit		660	4	506
Federal alternative minimum taxes		5,175	(1,300)	2,800
Reversal of valuation allowance		(111,570)	—	—
Purchased in-process research and development		170,913	—	—
Foreign losses at different rates		45,689	—	—
Foreign earnings at different rates		<u>3,081</u>	<u>508</u>	<u>636</u>
		<u><u>\$ (95,530)</u></u>	<u><u>\$ 1,300</u></u>	<u><u>\$ 4,135</u></u>

**GILEAD SCIENCES, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**DECEMBER 31, 2003**

**18. INCOME TAXES (Continued)**

The tax benefits associated with stock option exercises and the employee stock purchase plan resulted in a cumulative tax benefit of \$134.2 million during the year ended December 31, 2003. Such benefit was credited to additional paid-in capital when realized.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of our deferred tax assets and liabilities as of December 31, 2003 and 2002 are as follows (in thousands):

	<u>December 31,</u>	
	<u>2003</u>	<u>2002</u>
Net operating loss carryforwards	\$ 156,789	\$ 126,424
Research and other credits	63,329	43,700
Capitalized research and development expenses	6,961	14,923
Reserves and accruals not currently deductible	26,458	15,603
Other, net	<u>55,698</u>	<u>26,171</u>
Total deferred tax assets	309,235	226,821
Valuation allowance	<u>(59,174)</u>	<u>(226,821)</u>
Net deferred tax assets recognized	<u>\$ 250,061</u>	<u>\$ —</u>

The valuation allowance decreased by \$167.6 million for the year ended December 31, 2003 and increased by \$14.1 million for the year ended December 31, 2002.

In December 2003, based upon the level of historical taxable income and projections for future taxable income over the periods that our deferred tax assets are deductible, we determined that it was more likely than not that certain of our deferred tax assets will be realized and therefore released the related valuation allowance. The reversal of the valuation allowance resulted in a realization of income tax benefits of approximately \$111.6 million. The deferred tax asset attributable to the net operating loss carryforwards included tax benefits of \$129.5 million related to the exercise of employee stock options, which benefits were recorded directly to additional paid in capital. The reversal of the valuation allowance also resulted in the reduction of the remaining assembled workforce asset of \$3.2 million established upon the acquisition of Triangle. At December 31, 2003, we have a remaining valuation allowance of \$59.2 million against the net deferred tax asset as we have concluded, based on the standard set forth in SFAS No. 109, *Accounting for Income Taxes*, that it is more likely than not that we will not realize any benefits from the related deferred tax assets. We will assess the need for the valuation allowance at each quarter end based on all available evidence. Approximately \$11.0 million of the valuation allowance at December 31, 2003 relates to tax benefits of stock option deductions, which will be credited to additional paid-in capital when realized.

At December 31, 2003, we had U.S. federal net operating loss carryforwards of approximately \$444.1 million and state net operating loss carryforwards of approximately \$23.6 million. The federal net operating loss carryforwards will expire at various dates beginning in 2018 through 2022, if not utilized. The state net operating loss carryforwards will expire at various dates from 2004 through 2011, if not



**GILEAD SCIENCES, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**DECEMBER 31, 2003**

**18. INCOME TAXES (Continued)**

utilized. In addition, we had federal and state tax credit carryforwards of approximately \$56.0 million and \$11.3 million respectively, which expire in the years 2004 through 2022.

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

**19. RETIREMENT SAVINGS PLAN**

As of December 31, 2003, Gilead maintains one retirement savings plan under which eligible employees may defer compensation for income tax purposes under Section 401(k) of the Internal Revenue Code. Prior to January 1, 2001, Gilead maintained two separate retirement savings plans. One plan primarily covered former NeXstar employees (NeXstar Plan), and the other plan primarily covered Gilead's remaining eligible employees (Gilead Plan). At December 31, 2000, approximately \$0.6 million, representing 13,857 shares of Gilead common stock, was held by the NeXstar Plan in trust for plan participants. Effective January 2001, the NeXstar Plan was terminated and combined with the Gilead Plan. The shares of Gilead common stock held by the NeXstar Plan were subsequently liquidated and the proceeds were deposited into the various other investment options available under the Gilead plan. Under the Gilead Plan, employees may contribute up to 15% of their eligible annual compensation. Effective January 1, 2000, Gilead began making matching contributions under the Gilead Plan. We contribute up to 50% of an employee's first 6% of contributions up to an annual maximum match of \$2,500. Our total matching contribution for the Gilead Plan was \$1.4 million in 2003, \$1.2 million in 2002 and \$1.2 million in 2001.

**20. QUARTERLY RESULTS (UNAUDITED)**

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

	<u>1st Quarter</u>	<u>2nd Quarter</u>	<u>3rd Quarter</u>	<u>4th Quarter</u>
<b>2003 (1)(2)(3)</b>				
Total revenues	\$ 165,105	\$ 238,870	\$ 200,372	\$ 263,517
Gross profit on product sales	134,592	198,562	168,139	222,357
Total costs and expenses	598,702	131,098	121,199	175,540
Net income (loss)	(438,054)	100,372	73,096	192,583
Net income (loss) per common share—basic	<u>\$ (2.21)</u>	<u>\$ 0.50</u>	<u>\$ 0.36</u>	<u>\$ 0.94</u>
Net income (loss) per common share—diluted	<u>\$ (2.21)</u>	<u>\$ 0.46</u>	<u>\$ 0.33</u>	<u>\$ 0.85</u>

**GILEAD SCIENCES, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**DECEMBER 31, 2003**

**20. QUARTERLY RESULTS (UNAUDITED) (Continued)**

	<u>1st Quarter</u>	<u>2nd Quarter</u>	<u>3rd Quarter</u>	<u>4th Quarter</u>
<b>2002 (4)</b>				
Total revenues	\$ 78,416	\$ 109,363	\$ 133,984	\$ 145,027
Gross profit on product sales	58,669	76,070	99,789	119,627
Total costs and expenses	85,359	90,169	98,067	112,188
Net income (loss)	(3,850)	19,711	20,757	35,479
Net income (loss) per common share—basic	<u>\$ (0.02)</u>	<u>\$ 0.10</u>	<u>\$ 0.11</u>	<u>\$ 0.18</u>
Net income (loss) per common share—diluted	<u>\$ (0.02)</u>	<u>\$ 0.10</u>	<u>\$ 0.10</u>	<u>\$ 0.17</u>

- (1) In the first quarter of 2003, Gilead completed the acquisition of the net assets of Triangle and recorded a charge of \$488.6 million for in-process research and development.
- (2) In the third quarter of 2003, Gilead was reimbursed \$13.2 million of research and development expenses resulting from the settlement of a contractual dispute with a vendor.
- (3) In the fourth quarter of 2003, Gilead recorded non-cash impairment charges against certain long-lived assets of \$10.2 million and \$0.7 million related to other asset write-downs. In addition, we recorded an income tax benefit of \$111.6 million related to the reduction of the valuation allowance on certain of our net deferred tax assets.
- (4) In the third quarter of 2002, Gilead realized a \$16.0 million non-operating loss upon the sale of our remaining shares in OSI Pharmaceuticals, Inc.

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

	Balance at Beginning of  Period	Additions Charged to			Balance at  End of Period
		Expense	Charged to Other	Deductions	
Year ended December 31, 2003:					
Allowance for doubtful accounts	\$ 5,329	\$ 4,879	\$ 436	\$ —	\$ 10,644
Allowance for sales returns	5,032	4,698	—	733	8,997
Valuation allowance for deferred tax assets	226,821	—	—	167,647(1)	59,174
	<u>\$ 237,182</u>	<u>\$ 9,577</u>	<u>\$ 436</u>	<u>\$ 168,380</u>	<u>\$ 78,815</u>
Year ended December 31, 2002:					
Allowance for doubtful accounts	\$ 2,579	\$ 3,262	\$ —	\$ 512	\$ 5,329
Allowance for sales returns	678	4,902	—	548	5,032
Valuation allowance for deferred tax assets	212,700	—	14,121(2)	—	226,821
	<u>\$ 215,957</u>	<u>\$ 8,164</u>	<u>\$ 14,121</u>	<u>\$ 1,060</u>	<u>\$ 237,182</u>
Year ended December 31, 2001:					
Allowance for doubtful accounts	\$ 2,300	\$ 467	\$ —	\$ 188	\$ 2,579
Allowance for sales returns	581	569	—	472	678
Valuation allowance for deferred tax assets	228,600	—	—	15,900(3)	212,700
	<u>\$ 231,481</u>	<u>\$ 1,036</u>	<u>\$ —</u>	<u>\$ 16,560</u>	<u>\$ 215,957</u>

- (1) Charged against current tax expense and additional paid in capital.
- (2) Charged to deferred tax benefit.
- (3) Charged against current tax expense.

GILEAD SCIENCES, INC.

<div><div>/s/ GORDON E. MOORE</div><div>Gordon E. Moore</div></div>	Director	March 10, 2004
<div><div>/s/ GEORGE P. SHULTZ</div><div>George P. Shultz</div></div>	Director	March 10, 2004
<div><div>/s/ GAYLE E. WILSON</div><div>Gayle E. Wilson</div></div>	Director	March 10, 2004

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

**MASTER  
CLINICAL AND COMMERCIAL SUPPLY AGREEMENT  
AMONG  
GILEAD WORLD MARKETS, LIMITED  
AND  
GILEAD SCIENCES, INC.  
AND  
PATHEON INC.  
JANUARY 1, 2003**

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## MASTER CLINICAL AND COMMERCIAL SUPPLY AGREEMENT

**THIS MASTER CLINICAL AND COMMERCIAL SUPPLY AGREEMENT** (the “**Agreement**”) made as of the 1st day of January, 2003 (the “**Effective Date**”) among, on the one hand, Gilead World Markets, Ltd., a Cayman Company (“**Gilead World**”), whose registered address is Queensgate House, South Church Street, P.O. Box 1234GT, Grand Cayman, Cayman Islands, and Gilead Sciences, Inc., a Delaware corporation (“**Gilead Sciences**”) with its principal office located at 333 Lakeside Drive, Foster City, CA 94404 (Gilead World and Gilead Sciences collectively, “**Gilead**”), and, on the other hand, Patheon Inc., a Canadian corporation (“**Patheon**”) having its principal place of business at 7070 Mississauga Road, Suite 350, Mississauga, Ontario, Canada L5N 7J8. Gilead and Patheon are sometimes referred to herein individually as a “**Party**” and collectively as the “**Parties**”.

### WITNESSETH

**WHEREAS**, Gilead Sciences will require the manufacture and supply of Drug Products (as hereinafter defined) for clinical use and commercial distribution and sale in the Territory and Gilead World will require the manufacture and supply of Drug Products for commercial distribution and sale in the Territory; and

**WHEREAS**, Patheon possesses suitable facilities to manufacture, package and test Drug Products and will process, package and test Drug Products according to the terms and conditions set forth below; and

**WHEREAS**, Patheon is currently carrying out commercial manufacturing of Tenofovir DF Tablets (with the trade name Viread and the generic name tenofovir disoproxil fumarate) pursuant to that certain Commercial Supply Agreement dated August 1, 2001 between Gilead World Markets (which was assigned from Gilead Irish Holdings, Inc. by way of an Assignment of Agreement dated December 31, 2001) and Patheon Inc. (the “**Viread Agreement**”) and;

**WHEREAS**, the Parties now desire that this Agreement shall (i) replace the Viread Agreement such that the Viread Agreement shall be of no further force and effect for the Processing (as defined below) of new batches of tenofovir disoproxil fumarate tablets from and after the Effective Date, and (ii) govern the terms and conditions of clinical and commercial manufacturing of tenofovir disoproxil fumarate tablets and any additional Drug Products as may be agreed to between the Parties in writing from time to time as set forth below. For clarity, however, the Viread Agreement shall continue to have full force and effect only with respect to Tenofovir DF Tablets Processed between August 1, 2001 and December 31, 2002; and

**WHEREAS**, Gilead and Patheon now desire to contract for such manufacturing on the terms and conditions set forth herein;

**NOW, THEREFORE**, in consideration of the foregoing premises and the mutual covenants which are recited herein, the Parties agree as follows:

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

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## ARTICLE I

### DEFINITIONS AND SCHEDULES

#### 1.1 DEFINITIONS

In this Agreement, the following capitalized terms shall have the following meanings:

**“Act”** means the United States Food, Drug and Cosmetics Act of 1938 (21 C.F.R. Section 201 et seq.) and any legal requirement of Canada, the European Union or other jurisdiction within the Territory for any Drug Product, together with any regulation promulgated under any of the foregoing, including, without limitation, all Good Manufacturing Practices, in each case as amended from time to time.

**“Active Pharmaceutical Ingredient” or “API”** shall mean, for each Drug Product, the active drug substance of that Drug Product prior to Processing, as listed on Exhibit A of the Product-Specific Appendix hereto for that Drug Product.

**“Affiliate”** shall mean any person, firm or corporation which, directly or indirectly, through one or more intermediaries controls, is controlled by, or is under common control with, a Party to this Agreement. For purposes of this definition, “control” means the legal or beneficial ownership of fifty percent (50%) or more of the voting or equity interests, or the power or right to direct the management and affairs of the business (including acting as the general partner of a limited partnership). A Gilead Affiliate is an Affiliate of either or both of Gilead Sciences and Gilead World.

**“Annual API Cap”** shall mean, for each API, the value identified as such in Exhibit C of the applicable Product-Specific Appendix.

**“API Specifications”** shall mean, with respect to a given API, the Specifications for that API as set forth on Exhibit A of the Product-Specific Appendix hereto for the corresponding Drug Product.

**“Components”** shall mean, for each Drug Product, the labels, glue, product inserts and other packaging materials required to be used for the production of that Drug Product in accordance with the applicable Component Specifications.

**“Component Specifications”** shall mean, with respect to the Components for a given Drug Product, the Specifications for Components set forth on Exhibit A of the Product-Specific Appendix for that Drug Product.

**“Confidential Information”** shall have the meaning specified in Section 8.2.

**“Disposition Package”** shall mean, with respect to any shipment of Drug Product, the documentation and records defined pursuant to the relevant Quality Agreement (as defined in Section 2.8), which may include copies of the Certificate of Analysis, Certificate of Compliance, quality control documentation and manufacturing batch records for such shipment; written

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confirmation that such batch records have been reviewed and approved by Patheon quality assurance unit; and any other documentation required by law that is in Patheon's possession and required by Gilead for the release of the batch or batches of Drug Product in such shipment.

**"Drug Product"** shall mean a product set forth on Exhibit B of any Product-Specific Appendix.

**"Effective Date"** shall mean January 1, 2003.

**"Excipients"** shall mean, for each Drug Product, all materials other than the API and Components described in the Specifications for such Drug Product as a constituent part of such completed Drug Product.

**"Excipient Specifications"** shall mean, with respect to the Excipients for a given Drug Product, the Specifications for such Excipients set forth on Exhibit A of the Product-Specific Appendix hereto for such Drug Product.

**"Facility"** shall mean, for a given Drug Product, any Patheon manufacturing facility identified in Exhibit C of the Product-Specific Appendix for that Drug Product, or any other facility used for the Processing of that Drug Product that has been approved by Gilead, in writing.

**"FDA"** shall mean the United States government agency known as the Food and Drug Administration, or any successor thereto.

**"Gilead's Actual Standard API Costs"** shall mean, for a given API in a given Year, the amount established in accordance with Section 4.7.

**"Good Manufacturing Practices" or "cGMPs"** shall mean the current Good Manufacturing Practices for manufacturing finished products as set forth in the Act, and any other equivalent laws, rules or regulations or current good manufacturing practices specified by a Regulatory Authority, which are applicable to Patheon.

**"Intellectual Property"** shall mean any intellectual property rights including, without limitation, rights in patents, patent applications, formulae, trade-marks, trade-mark applications, trade secrets, Inventions, copyright, industrial designs and know-how.

**"Inventions"** shall mean any invention, innovation, improvement, development, discovery, computer program, device, trade secret, method, know-how, process, technique or the like, whether or not written or otherwise fixed in any form or medium, regardless of the media on which it is contained and whether or not patentable or copyrightable.

**"Inventory"** shall mean all inventories of Materials and work-in-process produced or held by Patheon in connection with the Processing of Drug Product but, for greater certainty, does not include any API.

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**“Master Batch Records”** shall mean, for a given Drug Product, the then-current procedures to be followed by Patheon with respect to the Processing, handling and storage of that Drug Product and the corresponding API, as contemplated in Exhibits A and B of the Product-Specific Appendix for that Drug Product.

**“Materials”** shall mean Excipients and Components as they are utilized in Processing.

**“Patheon Manufacturing Responsibilities”** shall have the meaning outlined in Section 3.2(a).

**“Processing”** shall mean the manufacturing, quality control, quality assurance and stability testing, packaging and related services, as contemplated in this Agreement, required to produce Drug Product from API and Materials. “Process,” “Processing” and “Processed” shall have analogous meanings.

**“Product-Specific Appendix”** shall have the meaning given such term in Section 2.1(a).

**“Regulatory Authority”** shall mean the FDA and any other governmental authority (whether national, federal, provincial and/or local) in the Territory that is a counterpart to the FDA or otherwise has jurisdiction over the manufacture or approval of any Drug Product.

**“Regulatory Filing”** shall mean any filing with or approval by a Regulatory Authority regarding a Drug Product or its manufacture.

**“Specifications”** shall mean, with respect to a Drug Product, the procedures, test results, requirements, standards and other data and documentation with respect to such Drug Product and the Excipients and Components therefor, as set forth in Exhibits A and B of the Product-Specific Appendix for that Drug Product, as may be revised from time to time in accordance with the terms set forth in Section 4.5 below.

**“Territory”** shall mean the geographical area set forth in Exhibit C of each Product-Specific Appendix hereto for a given Drug Product.

**“Third Party Rights”** shall mean the Intellectual Property of any third party.

**“Year”** shall mean, for each Drug Product, the period between the effective date of the Product-Specific Appendix for that Drug Product (as set forth in Exhibit C of the Product-Specific Appendix for such Drug Product) until December 31 of the year of such effective date, and thereafter, the twelve-month period commencing upon the completion of the immediately preceding Year.

**“Yearly Minimum Volume”** shall mean the yearly minimum volume of each Drug Product to be purchased by Gilead as more particularly set forth in Exhibit C of the applicable Product-Specific Appendix.

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## 1.2 SCHEDULES.

The following Schedules and Product-Specific Appendices as of the Effective Date are annexed hereto and form part of this Agreement:

<b>Schedule A :</b>	Yield Calculation Schedule
<b>Schedule B :</b>	Quality Agreements
<b>Schedule C-1 :</b>	Form of Product Specifications (Exhibit A to Appendix (•) of {Drug Name})
<b>Schedule C-2:</b>	Form of Finished Product Specifications and Testing Requirements (Exhibit B to Appendix (•) of {Drug Name})
<b>Schedule C-3 :</b>	Form of Pricing and API Schedule (Exhibit C to Appendix (•) of {Drug Name})

### APPENDIX 1 - TENOFOVIR DISOPROXIL FUMARATE

**Exhibit A to Appendix 1 - Tenofovir disoproxil fumarate** : Drug Substance, Excipient and Components Specifications

**Exhibit B to Appendix 1 - Tenofovir disoproxil fumarate** : Finished Product Specifications and Testing Requirements

**Exhibit C to Appendix 1 - Tenofovir disoproxil fumarate** : Pricing and API Schedules

### APPENDIX 2 - ADEFOVIR DIPIVOXIL

**Exhibit A to Appendix 2 – Adefovir dipivoxil** : Drug Substance, Excipient and Components Specifications

**Exhibit B to Appendix 2 - Adefovir dipivoxil** : Finished Product Specifications and Testing Requirements

**Exhibit C to Appendix 2 - Adefovir dipivoxil** : Pricing and API Schedules

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## ARTICLE II

### PURCHASE AND SUPPLY

#### 2.1 Purchase and Supply Agreement .

(a) This Agreement including the Schedules and Appendices annexed hereto shall serve as a master commercial supply agreement governing the manufacture, purchase and supply of Drug Products between the Parties. The Parties have agreed, as of the Effective Date, to product-specific terms governing the purchase and supply of two (2) Drug Products, Gilead's tenofovir disoproxil fumarate and adefovir dipivoxil products, as reflected in Appendices 1 and 2. Subject to Section 2.1(b), the Parties may agree to the manufacture, purchase and supply of additional drug products by agreeing to additional product-specific terms, each in the form of a new Appendix to this Agreement signed and delivered by a representative of the applicable Party, annexed hereto and incorporated herein once executed and delivered (each, a "**Product-Specific Appendix**"). Each Product-Specific Appendix shall be substantially in the form of Schedule C (e.g. C-1, C-2 and C-3) attached hereto, and shall include, at a minimum, the following for the applicable Drug Product: (a) an Exhibit A setting forth the API, API Specifications, Excipients, Excipient Specifications, Components, Component Specifications, and Disposition Package for the Drug Product covered by such Product-Specific Appendix; (b) an Exhibit B setting forth the finished product Specifications; and (c) an Exhibit C setting forth the pricing terms, Facility(ies), Territory, Yearly Minimum Volume, Drug Product costs and yields, effective date and initial term.

(b) Solely Gilead Sciences shall be Patheon's counterparty to Product-Specific Appendices for the [\*] supply of any Drug Product [\*] or for any [\*] supply of any Drug Product [\*]. Solely Gilead World shall be Patheon's counterparty to Product-Specific Appendices for the [\*] supply of any Drug Product [\*]. Solely Gilead Sciences will have the rights and obligations of Gilead hereunder to the extent pertaining to [\*] supply of Drug Products [\*] or for any [\*] supply of any Drug Product for [\*], in each case for which Gilead Sciences is party to the relevant Product-Specific Appendices. Solely Gilead World will have the rights and obligations of Gilead hereunder to the extent pertaining to [\*] supply of Drug Products for [\*] for which Gilead World is party to the relevant Product-Specific Appendices. Gilead World agrees to an obligation to provide to Patheon a written guarantee by Gilead Sciences, as Gilead World's ultimate parent company, of Gilead World's performance under this Agreement, and, in satisfaction of such obligation, Gilead Sciences hereby guarantees to Patheon the performance by Gilead World of Gilead World's obligations under this Agreement.

(c) Changes to the Product-Specific Appendices may only be made by prior written agreement of the Parties. If any Product-Specific Appendix conflicts with the body of this Agreement, the body of this Agreement shall control, except to the extent that such Product-Specific Appendix explicitly references particular Sections of the body of this Agreement that do not apply, or only partially apply, with respect to such Product-Specific Appendix, and describes the extent to which such Sections shall not apply. In such event, with respect to the subject matter covered by the explicitly referenced Sections of the body of this Agreement as applied to such Product-Specific Appendix, such Product-Specific Appendix and not the body of this Agreement shall control.

(d) During the Term (as such term is defined in Section 9.1) of this Agreement, Gilead agrees to buy, and Patheon agrees to supply, such quantities of each Drug Product for sale in the Territory as may be set forth on Firm Orders placed by Gilead in

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accordance with Section 2.4 at the prices set forth in Exhibit C of the applicable Product-Specific Appendices, as may be revised from time to time in accordance with Article IV hereof.

(e) **Minimum Volumes of Purchases.** Patheon acknowledges that Gilead may obtain a portion of its requirements for any Drug Product from third parties; provided, however, Gilead agrees to purchase from Patheon the Yearly Minimum Volume for each Drug Product as more particularly set forth in Exhibit C of the applicable Product-Specific Appendix.

**2.2 Drug Product And Materials Specifications And Testing .** Patheon shall, in Processing a Drug Product, use Excipients and Components that conform to the Excipient Specifications and Component Specifications, respectively, for such Drug Product. Such conformance will be verified in accordance with the testing standards and procedures specified therefor in the applicable Specifications. The Parties acknowledge that such Specifications and testing standards and procedures as set forth in Exhibits A or B of the applicable Product-Specific Appendix may need to be refined and modified with changes that are necessary or appropriate according to applicable Regulatory Authority requirements, or as otherwise requested by Gilead in writing. If such a change in the Specifications is needed or proposed, Section 4.5 shall apply.

**2.3 Orders and Forecasts .** Gilead shall provide Patheon with the following:

(a) concurrent with the execution of this Agreement for the first two (2) Drug Products and concurrent with the execution of any Product-Specific Appendix for an additional Drug Product, a written non-binding [\*] month forecast of the volume of each Drug Product that Gilead then anticipates will be required to be produced and delivered to Gilead during the following [\*] month period. Such forecast will be updated by Gilead monthly on a rolling [\*] month basis and updated forthwith upon Gilead determining that the volumes for the first [\*] months contemplated in the most recent of such forecasts has changed by more than [\*] ; and,

(b) on or before the [\*] day of each calendar month, firm written orders (“ **Firm Orders** ”) covering the supply for each Drug Product on the basis of [\*] units, to be produced and delivered to Gilead on a date not less than [\*] from the first day of the calendar month immediately following the date that the Firm Order is submitted.

(c) on or before [\*] , in each Year, a written non-binding [\*] forecast (broken down by calendar quarters for the [\*] of the forecast) of the volume for each Drug Product that Gilead anticipates will be required to be produced and delivered to Gilead during such [\*] period.

**2.4 Firm Orders .** The Firm Orders submitted to Patheon pursuant to Section 2.3 shall specify Gilead’s purchase order number, quantities, monthly delivery schedule and any other elements necessary to identify what must be delivered to fill such Firm Order. Unless mutually agreed upon by both Parties, the quantities of Drug Product ordered in such written orders shall be firm and binding on Gilead and shall not be subject to reduction, and shall only be subject to cancellation as set forth in Section 2.10.

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## **2.5 Materials Ordering and Stockpiles .**

(a) **Reliance by Patheon .** Gilead understands and acknowledges that Patheon will rely on the Firm Orders submitted pursuant to Section 2.3(b) in ordering the Materials required to meet such Firm Orders. In addition, Gilead understands that to ensure an orderly supply of such Materials and to achieve economies of scale in the costs therefor, it may be desirable for Patheon to purchase such Materials in sufficient volumes to meet the production requirements for each Drug Product during part or all of the forecasted periods referred to in Section 2.3(a), or such longer period as Patheon and Gilead may agree to. Accordingly, Gilead agrees that purchases may be made by Patheon in respect of the Materials for a given Drug Product to satisfy the production requirements for such Drug Product for the first [\*] months of the forecasted period, or such different period as may be identified opposite such Materials in the applicable Product-Specific Appendix or agreed in writing by the Parties. If any Materials ordered by Patheon in accordance with the foregoing sentence are not included in finished Drug Product purchased by Gilead within [\*] months after the forecasted month in respect of which such purchases have been made (or such longer period as the Parties may agree in writing), Gilead will pay to Patheon its actual costs to acquire such unused Materials and, in the event such Materials are incorporated into the Drug Product subsequently purchased by Gilead, Gilead will receive credit for any costs of such Materials previously paid to Patheon by Gilead.

(b) **Minimum Stockpiles .** Without limiting Patheon's ability to purchase and hold Materials as set forth in Section 2.5(a), Patheon shall at all times maintain an inventory of each Material sufficient to manufacture the relevant Drug Products to fill Gilead's Firm Orders and forecasts in the following [\*] months, or such different period of time as may be set forth for such Material in the applicable Product-Specific Appendix or otherwise agreed in writing by the Parties.

**2.6 Minimum Orders .** Each Drug Product to be Processed by Patheon may only be ordered in the minimum order quantities set out in Exhibit C of the Product-Specific Appendix for such Drug Product. As the Parties gain additional experience with the Processing of each Drug Product, they shall negotiate in good faith, upon request by Gilead, to revise the minimum order quantities in the applicable Exhibit C from time to time. If the Parties reach written agreement, following any necessary technical and cost review by Patheon in accordance with Section 4.5, they shall update the applicable Exhibit C to reflect the revised minimum order quantities.

**2.7 Excipients and Components .** All Materials shall be purchased (with the exception of those which are supplied by Gilead, which exceptions shall be identified in the applicable Product-Specific Appendix) and tested by Patheon at Patheon's expense in accordance with the applicable Specifications.

**2.8 Quality Agreements .** Each Party shall allocate, use and expend the resources necessary to perform the division of pharmaceutical responsibilities assigned to such Party as defined in the Quality Agreement(s) as set forth in Schedule B of this Agreement, to which such Party is a party, the terms of which, for clarity, are a part of this Agreement. Without limiting the generality of the foregoing sentence, the Parties' responsibilities relating to product

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complaints shall, at a minimum, include the following: (a) Patheon shall, as promptly as practicable after it becomes aware (but in any event, no later than [\*] business days thereafter), forward to Gilead or its designee, by phone and in writing, any and all complaints or problems relating to any Drug Product, and any information in its possession pertaining to such complaint or problem, including but not limited to: (i) Drug Product or its labeling may have been mistaken for or applied to another product; (ii) Drug Product may be affected by bacteriological contamination, significant chemical, physical or other change or deterioration or stability failures; (iii) Drug Product is the subject of a complaint by a Third Party, a Regulatory Authority or a customer relating to the quality of the Drug Product; (iv) a unit or batch of Drug Product supplied to or as directed by Gilead may not be in conformance with the applicable Specifications; or (v) a unit or batch of Drug Product supplied to or as directed by Gilead has not been Processed in accordance with the Patheon Manufacturing Responsibilities; (b) Gilead shall promptly inform Patheon, by phone and in writing, of any and all complaints that Gilead receives which implicate Patheon's Processing of Drug Product at the Facility; and (c) Patheon shall respond promptly to, and cooperate fully with Gilead regarding, any reasonable request by Gilead for assistance in resolving any and all complaints, in each case on a time frame sufficient to permit Gilead to comply with applicable laws, rules and regulations, as notified by Gilead. The Parties agree to negotiate in good faith to modify the Quality Agreement(s) to which they are respective parties, pursuant to Section 4.5, from time to time as necessary or appropriate in light of FDA or other regulatory requirements, or at Gilead's request. For clarity, either [\*], or Gilead Sciences may be party in place of Gilead World to a Quality Agreement relating to supply of Drug Product(s) to Gilead World.

**2.9 Technology Transfer** . Patheon shall facilitate, at Gilead's expense, any technology transfer to Gilead, its Affiliate or a third party in relation to the Processing of Drug Product(s) to the extent reasonably requested by Gilead.

**2.10 Cancellations** . Gilead may cancel any Firm Order previously accepted by Patheon by providing Patheon with prior written notice (the "**Notice**"); *provided* that if Gilead cancels any Firm Order and the Notice is received [\*] days or less prior to any scheduled delivery of Drug Product covered by such Firm Order, then Gilead shall reimburse Patheon for a percentage of the price that Patheon would have charged Gilead for the Firm Order, which amounts shall be calculated as follows:

(a) if Notice is received by Patheon less than [\*] days prior to any scheduled delivery of Drug Product covered by such Firm Order, then Gilead shall pay Patheon [\*] percent ( [\*] %) of the price that Patheon would have charged Gilead for the Firm Order if it had not been cancelled;

(b) if Notice is received by Patheon between [\*] to [\*] days prior to any scheduled delivery of Drug Product covered by such Firm Order, then Gilead shall pay Patheon [\*] percent ( [\*] %) of the price that Patheon would have charged Gilead for the Firm Order if it had not been cancelled; or

(c) if Notice is received by Patheon between [\*] to [\*] days prior to any scheduled delivery of Drug Product covered by such Firm Order, then Gilead shall pay Patheon

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[\*] percent ( [\*] %) of the price that Patheon would have charged Gilead for the Firm Order if it had not be cancelled.

This Section 2.10 shall not apply to mutually agreed changes in production or delivery schedules, or any cancellation for which alternative terms are mutually agreed upon by both Parties.

**2.11 Equipment .** If Gilead or a third party with a right to purchase Drug Product from Gilead supplies any equipment to Patheon for use in Processing any Drug Product:

(a) The Parties, or Patheon and such third party, as applicable, shall prepare a written inventory of such equipment, which inventory shall be signed by a representative of each Party, or a representative of Patheon and such third party, as applicable.

(b) Such inventory shall set forth where and under what conditions Patheon will locate and use such equipment. Gilead or such third party, as applicable, shall be responsible for validation of such equipment. In addition, Gilead or such third party, as applicable, shall be responsible for any costs for transportation, installation and training necessary to use such equipment.

(c) Such inventory shall set forth the routine preventative maintenance of such equipment that Patheon must perform, and Patheon shall perform such routine preventative maintenance in accordance with the terms and conditions of a separate agreement to be entered into by the Parties, or between Patheon and such third party, as applicable. For clarity, Patheon shall not be responsible to conduct major repairs to such equipment.

(d) Gilead or such third party will retain ownership of such equipment unless otherwise agreed to in writing by the Parties, or by Patheon and such third party, as applicable. Gilead or such third party, as applicable, will be responsible to maintain any insurance as to such equipment; provided, however, that if Gilead or such third party is unable to procure insurance to cover such equipment in Patheon's possession and requests Patheon to obtain such insurance, Patheon will use reasonable efforts to obtain such insurance at Gilead's or such third party's expense, as applicable.

### ARTICLE III

#### SUPPLY AND PROCESSING OF DRUG PRODUCT

##### 3.1 Supply Of API And Materials .

(a) For each Firm Order of Drug Product, Gilead, at its expense, shall deliver or cause to be delivered to the Facility, the number of kilograms of the applicable API(s) necessary for Patheon to Process the Drug Product(s) set forth on the relevant Firm Order.

(b) Patheon shall use commercially reasonable efforts to make the Facility and appropriate personnel available in order to complete the Processing of the relevant Drug

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Product(s) and make such Drug Product(s) available for delivery on the date specified in the relevant Firm Order. Within [\*] business days after Patheon's receipt of each Firm Order, Patheon shall notify Gilead in writing via electronic mail (in accordance with Section 10.5) whether Patheon accepts such Firm Order on the delivery schedule set forth therein. Patheon shall use commercially reasonable efforts to accept all Firm Orders on the delivery schedules that they specify, and in any event shall accept all Firm Orders to the extent not exceeding [\*] percent ( [\*] %) of the quantity of each Drug Product forecast in the applicable Last Forecasts (defined below) for the time period covered by the Firm Order, subject to reasonable scheduling of each delivery within the calendar month in which Gilead requests delivery in order to accommodate the specific timing of each applicable facility and Patheon personnel availability. For purposes of such [\*] percent ( [\*] %) limit, if [\*] percent ( [\*] %) of the quantity of a given Drug Product specified in a Last Forecast equals a fractional number of batches, then the minimum number of batches that Patheon must accept in a Firm Order shall be the next whole number of batches above the fractional number of batches that is equal to [\*] percent ( [\*] %). For example, [\*] . As used in this Section, "**Last Forecast**" shall mean the forecast provided under Section 2.3 (a) no later than [\*] months prior to the time that Gilead requests delivery in its Firm Order.

(c) Patheon shall, at its expense, purchase from a third party designated by Gilead from Patheon's preferred supplier list, or a supplier designated by Gilead, all Excipients to be used in the Processing of the Drug Product. Gilead may designate an Excipient supplier not on Patheon's preferred supplier list by written notice to Patheon, provided that Gilead shall pay for any increase in costs for such Excipients resulting from such purchase from a supplier not on Patheon's preferred supplier list. Each such notice shall specify either that (a) an audit of such supplier is not required by Gilead in which case Gilead will provide Patheon with all documentation required to support Gilead's qualification of such supplier; or (b) Gilead shall conduct an audit of such supplier at its own expense. All Excipients shall be tested in accordance with procedures specified by Gilead in the Excipient Specifications. If a particular supplier (from Patheon's preferred supplier list or as so designated by Gilead) is specified for a given Excipient in the applicable Specifications, then Patheon shall obtain such Excipient from such supplier. In addition, the Parties may provide in the relevant Product-Specific Appendix for Gilead to procure the required quantities of any of the Excipients for the relevant Drug Product.

(d) Patheon shall, at its expense, purchase all Components necessary to complete the Processing of Drug Products. All Components shall meet the applicable Component Specifications as described in Exhibit A of the Product-Specific Appendix for a given Drug Product, as amended or supplemented from time to time under the terms and conditions hereunder. In addition, the Parties may provide in the relevant Product-Specific Appendix for Gilead to procure the required quantities of any of the Component for the relevant Drug Product.

### 3.2 Processing Of Drug Product .

(a) Patheon will Process each Drug Product in accordance with the applicable Master Batch Records and Specifications, the Quality Agreement and any applicable federal, provincial and local laws and regulations, including without limitation cGMPs (hereinafter collectively the "**Patheon Manufacturing Responsibilities**"). Before, during and after each

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Processing of a Drug Product, Patheon shall monitor such Processing and the Processing environment and keep such records of the foregoing as are required by the applicable Master Batch Records and Specifications, and in accordance with cGMPs. In accordance with cGMPs and during the Term of this Agreement and as part of the Patheon Manufacturing Responsibilities, Patheon shall (i) take all commercially reasonable steps necessary to ensure that any Drug Product that may be Processed by it pursuant to this Agreement shall be free of cross-contamination from any fermentation, other manufacturing or similar activities and (ii) be responsible for the performance of validated cleaning and changeover procedures prior to Processing any Drug Product for Gilead.

(b) Patheon shall not manufacture or store any [\*] product (for example but without limitation, [\*] ) at, or otherwise introduce any of the foregoing to, any Facility where any API, Component, Excipient, or Drug Product is Processed or stored without Gilead's advance written consent. Gilead may withhold such consent in its sole discretion.

(c) Both Parties shall promptly notify each other of any new material instructions or specifications required by the Act and of other applicable laws, rules and regulations, and shall confer with each other with respect to the best means to comply with such requirements. The Parties shall allocate any costs of implementing such changes on an equitable basis in accordance with, and subject to the procedures set forth in, Section 4.5. If the proposed new instruction or specification policy relates to the production of a Drug Product solely, then any additional costs incurred by Patheon to produce such Drug Product shall be passed on to Gilead in accordance with, and subject to the procedures set forth in, Section 4.5.

(d) Upon prior written request, Patheon will permit duly authorized representatives of Gilead and Gilead's licensee(s) or distributor(s) for any Drug Product to observe the Processing of such Drug Product and to have access to any relevant records in connection with such Processing as more fully provided in Section 3.4 below; provided that representatives from Gilead's licensee(s) or distributor(s) for any Drug Product shall be granted access to Patheon's Facility at the same time and to the same extent as Gilead's representatives. Such representatives shall be bound by an obligation of confidentiality (comparable to that of Article VIII) with respect to information that such representatives may obtain during such visit to observe the Processing of Drug Product and will comply with all Patheon standard operating policies and procedures while within the Facility or other Patheon premises.

(e) Patheon shall supply Gilead with copies of Processing records, including batch records, as they relate to each Drug Product, for the purposes of assuring product quality and compliance with agreed-upon Processing procedures.

(f) All Processing of each Drug Product to be performed by Patheon under this Agreement shall be performed at the Facility(ies) for such Drug Product specified in the applicable Product-Specific Appendix.

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### 3.3 FDA And Regulatory Support .

(a) Patheon agrees to maintain a Site Master File (“**SMF**”) in accordance with the requirements of the FDA, if any, as well as any comparable files required by other Regulatory Authorities, and to provide Gilead with letters of access to such SMF (to the extent that they are required by the FDA or other related regulatory bodies) and comparable files and to further provide Gilead with all documents regarding the Processing of such Drug Product. Gilead shall be responsible for all other filings necessary for approval and export of each Drug Product. At Gilead’s reasonable cost, Patheon further agrees to assist Gilead, acting reasonably, in obtaining any government or agency approval which may be required for the marketing of any Drug Product in any country other than the United States. Gilead shall provide written notice of any additional regulatory requirements of countries, in accordance with Section 4.6.

(b) Patheon agrees to cooperate with any inspection by the FDA or other Regulatory Authority. Patheon specifically agrees to meet and confer with Gilead representatives in advance of the pre-approval inspections for any Drug Product and, at Gilead’s request, any other inspection of the Facility concerning any Drug Product, provided that Patheon receives advance notice of such inspection, and will provide Gilead with all necessary support in connection with each such inspection as may be reasonably required.

(c) Each Party shall notify the other Party immediately in writing in the event a Party learns of any action that has been or will be taken by the FDA or other Regulatory Authority which relates to the Facility and the Processing of any Drug Product, or which may delay or impair the ability to Process any Drug Product in accordance with this Agreement.

**3.4 cGMP Compliance and QA Audits .** Upon prior written request, Gilead shall have the right [\*] per Year to have its representatives and representatives from its licensee(s) and distributor(s) for any Drug Product visit the Facility during normal business hours on business days to audit Patheon’s manufacturing process, assess Patheon’s compliance with cGMPs and quality assurance standards, review records relating to the Processing of such Drug Product and discuss any related issues with manufacturing and management personnel as it relates to such Drug Product (such activities collectively, a “**cGMP/QA Audit**”). Notwithstanding the foregoing, if Gilead’s representatives and/or representatives from its licensee(s) and distributor(s) for any Drug Product require cGMP/QA Audits in addition to [\*] per Year, then they shall have the right to conduct such additional cGMP/QA Audits, in the presence of a Gilead representative, provided Gilead or such licensee(s) or distributor(s) shall pay Patheon’s reasonable costs for the conduct of such cGMP/QA Audits. Gilead’s representatives and representatives from its licensee(s) and distributor(s) for any Drug Product shall be bound by an obligation of confidentiality with respect to information that such representatives may obtain during such visit to inspect and audit Patheon’s manufacturing process and the Processing of Drug Product and will comply with all standard operating policies and procedures while within the Facility or other Patheon premises. Notwithstanding the foregoing, Gilead (and its licensee(s) and distributor(s) for any Drug Product) shall have the right to conduct a “For Cause” audit at any time, when requested as a reasonable response to a FDA or other regulatory agency audit notice or inquiry regarding a Drug Product, an unresolved deviation in Processing of Drug Product by Patheon, or customer complaints or adverse events regarding a Drug Product, and Gilead (or such licensees or distributors) shall bear Patheon’s expenses therefore unless as a

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result of such “For Cause” audit it is determined that there was non-compliance with the warranties in Section 6.2.

**3.5 Change in Manufacturing Process .** Patheon shall notify Gilead if Patheon wishes to make, and obtain Gilead’s prior written approval before Patheon implements, any of the following: (a) a major change (as defined in applicable regulations) including without limitation, major or regulatory changes relating to (i) the Facility that would constitute a change under cGMPs, would impact the validation status of the process, or would constitute noncompliance with the Patheon Manufacturing Responsibilities, (ii) the Materials, (iii) the Specifications, (iv) any quantitative formulae and any other aspect of Drug Product Processing, or (v) testing methods with respect to the Drug Product; and (b) changes that require regulatory submission, relating to the Materials, Specifications, Facility, equipment, process, testing methods or other procedures used to Process any Drug Product. Gilead’s consent with respect to such changes shall not be unreasonably withheld, or unduly delayed; provided, however, that with respect to such changes affecting a particular Drug Product, Patheon acknowledges that Gilead may be required to obtain its licensee’s consent to such changes prior to providing consent to Patheon.

**3.6 Compliance with Laws .** Patheon shall materially comply with all applicable orders, regulations, requirements and laws of any and all Regulatory Authorities including, without limitation, all laws and regulations applicable to (a) the transportation, storage, use, handling and disposal of hazardous materials, (b) the Processing of Drug Products and (c) Patheon’s performance of its obligations under this Agreement. Patheon specifically represents and warrants that it does not and will not use, in any capacity, the services of any person that is debarred under the provisions of the United States Generic Drug Diversion Act or applicable FDA regulations. Patheon represents and warrants to Gilead that it has and will maintain during the Term of this Agreement, all government permits, including without limitation, health, safety and environmental permits, legally required for the conduct of the actions and procedures that it undertakes pursuant to this Agreement. Unless otherwise provided in the Product-Specific Appendix for a given Drug Product, the Parties agree that Patheon shall be the quality representative for purposes of [\*] release of all Drug Products.

**3.7 Documentation .** Patheon shall keep complete, accurate and authentic accounts, notes, data and records of the Processing services performed under this Agreement including but not limited to all relevant information and records relating to the Processing of Drug Products under this Agreement which may be required from time to time to be provided to any Regulatory Authority pursuant to applicable laws and regulations, and all Process development information relating to the Drug Product (to the extent such information is in Patheon’s possession) (“**Documentation**”). Each Party shall maintain complete and adequate records in accordance with and to the full extent required by cGMP and the applicable Specifications pertaining to the methods and the Facility used for the Processing, holding and distribution of Drug Product. Upon written request by Gilead with reasonable notice, Patheon will provide to representatives of Gilead or its licensee(s) or distributor(s) for Drug Products, during normal business hours, reasonable access to Documentation, where such access is necessary or reasonably useful to permit Gilead or such distributor(s) or licensee(s) to comply with applicable laws, rules or

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regulations; subject to Section 3.4, the expense of such access shall be at the expense of Gilead or such licensee(s) or distributor(s). Patheon shall maintain Documentation until the later of (a) when such Documentation is no longer required by applicable law, rule or obligation to be maintained by Gilead or Patheon, or (b) for Drug Product supplied for (i) clinical trial supplies, the approval or withdrawal of all applications for approval included within Regulatory Filings for such Drug Product, or (ii) commercial supplies, one (1) year after expiration of the shelf life for the applicable batch.

**3.8 Reprocess and Rework** . Patheon shall not conduct any rework (meaning redressing or relabeling of Drug Product) or reprocessing (meaning repetition of any step in the manufacture of unlabeled Drug Product from API and Excipients) activities with respect to any Drug Product without prior written permission from Gilead. Patheon shall document appropriately all rework and reprocessing activities conducted under this Agreement.

**3.9 Variances** . Patheon shall notify Gilead within [\*] business days after its discovery of any Drug Product lot failure, or significant deviation from or variance in manufacturing procedures or standard operating procedures for such Drug Product. The Parties shall promptly discuss and mutually agree how to address any such deviation or variance. The Quality Agreement shall include a requirement that any deviation or variance be resolved within [\*] days after discovery or such longer period of time as may be agreed to between the Parties.

**3.10 Storage and Handling** . Patheon shall store and handle API and Materials as set forth in the applicable Master Batch Records and Specifications, and in accordance with cGMP, and shall conform to established safety practices and procedures set forth in Gilead's then-current material safety data sheet. In addition, Patheon shall take such actions as are reasonably necessary to protect API and Materials from damage and deterioration. If requested by Gilead in writing, Patheon shall return or destroy, at Gilead cost and expense, any unused API in accordance with Gilead's written instructions.

**3.11 Labels** . Unless otherwise agreed, Gilead, or a third party approved by Gilead, shall supply in a timely manner all necessary copy and art work to allow Patheon to procure Components for a Drug Product in accordance with the applicable Component Specifications. Patheon shall use such copy and art work to procure all necessary Components in accordance with the applicable Component Specifications and Gilead's written instructions, and in compliance with applicable regulatory requirements. Such Components shall be the only Components used for such Drug Product.

**3.12 Performance Indicators.** Within [\*] months after the Effective Date, the Parties shall confer to set a timeline for the development of a commercially reasonable system of performance indicators to evaluate the performance of Patheon in carrying out its obligations under this Agreement. Once the system of performance indicators is developed, the Parties shall evaluate the Processing of Drug Products by Patheon on a quarterly basis against such performance indicators.

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## ARTICLE IV

### PRICES AND PAYMENT

**4.1 Price .** Prices for each Drug Product shall be as set forth on Exhibit C of the Product-Specific Appendix for such Drug Product. Gilead shall be responsible for the payment of any sales and use taxes on Drug Product delivered by Patheon to Gilead or on API furnished by Gilead to Patheon. The fees listed on Exhibit C of each Product-Specific Appendix shall not be subject to change until the end of the first Year after the effective date of such Product-Specific Appendix, subject to the amendments to such fees provided for in Sections 4.3, 4.5 and 4.6. The prices for each Drug Product during each additional Year that this Agreement remains in force shall be agreed to between the Parties prior to the commencement of each such Year, in accordance with Section 4.4.

**4.2 Payment Terms .** All payments due hereunder to Patheon shall be paid not later than [\*] days following the date of the applicable invoice submitted by Patheon in accordance with Section 5.2(a); provided that if such invoice is received by Gilead more than [\*] business days after such date, Patheon will make reasonable allowances for any payments that are late due to such delay provided that Gilead uses commercially reasonable efforts to pay such invoice by the end of such [\*] days.

**4.3 Adjustments to Current Year's Pricing .** During any Year of this Agreement, the fees set out in Exhibit C of each Product-Specific Appendix shall be subject to adjustment in accordance with the following:

(a) **Minimum Order Quantity .** If at any time a Firm Order is for less than the minimum order quantity of any Drug Product specified in Exhibit C of the applicable Product-Specific Appendix (i.e., the smallest campaign size so specified, as either by batch size or a minimum number of batches or a combination of both of batch size and minimum number of batches) then Patheon shall be entitled to request an adjustment to the fee for Processing in respect of that Drug Product delivered under that Firm Order to reflect the increased costs that Patheon will incur as a result of manufacturing the lesser volume ordered by Gilead relative to the minimum order quantity for that Drug Product. For clarity, the minimum order quantity relates to the size of the manufacturing runs that Patheon will undertake to fill Gilead's orders, and not to overall or annual volume.

(b) **Materials and Component Costs .** If at any time market conditions result in Patheon's cost of Materials being greater than normal forecasted increases, then Patheon shall be entitled to request an adjustment to the fee for Processing in respect of any affected Drug Product to compensate it for such increased Materials costs. For the purposes of this Section 4.3(b), changes greater than normal forecasted increases shall be considered to have occurred only if (i) the cost of a Material for such Drug Product increases by [\*] percent ( [\*] %) of the cost for that Material upon which the fee quote was based or (ii) the aggregate cost for all Materials required to Process a Drug Product increases by [\*] percent ( [\*] %) of the total Material costs for such Drug Product upon which the fee quote was based. To the extent that Processing fees have been previously adjusted pursuant to this Section 4.3(b) to reflect an increase in the cost of one

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(1) or more Materials, the adjustments provided for in (i) and (ii) above shall operate based on the costs attributed to such Material (or Materials) at the time the last of such adjustments were made.

In connection with a fee adjustment request pursuant to this Section 4.3, Patheon shall deliver to Gilead a revised Exhibit C for each Drug Product for which it requests such fee adjustment and such budgetary pricing information, adjusted Material costs or other documentation sufficient to demonstrate that a fee adjustment is justified. Upon delivery of such request, each of Gilead and Patheon shall forthwith use all reasonable efforts to agree on a revised fee for the Processing in respect of each affected Drug Product.

**4.4 Adjustments to Subsequent Year's Pricing** . The fees for the Processing provided pursuant to the terms of this Agreement for any Drug Product during any Year after the first Year of this Agreement for that Drug Product shall be determined in accordance with the following:

(a) **Manufacturing Costs** . No later than [\*] months prior to the end of each Year for each Drug Product, Patheon shall be entitled to request an adjustment to the fees for the applicable Component costs and Processing fees in respect of such Drug Product for the increases in manufacturing costs based on the increase in the [\*] for July of the then current Year compared to the same month of the preceding Year, published by [\*] in respect of the immediately prior Year.

(b) **Pricing Basis** . Gilead acknowledges that the fee for the Processing in respect of a Drug Product in any Year is quoted based upon the minimum order quantity per Drug Product specified in Exhibit C of each Product-Specific Appendix for a given Drug Product and is subject to change as set forth above if the quantity ordered by Gilead in any Firm Order falls below the minimum order quantity for that Drug Product as specified in Exhibit C of the applicable Product-Specific Appendix or, if applicable, any revised minimum order quantity hereinafter agreed to by the Parties in writing; provided that Gilead orders such Drug Product in the time period covered by such Firm Order. For greater certainty, if Patheon and Gilead agree that the minimum order quantity in respect of a Drug Product shall be reduced and, as a result of such reduction, Patheon's costs relating to such Drug Product increase on a per unit basis, then Patheon shall be entitled to an increase in the fee for the Processing in respect of such Drug Product by an amount sufficient to absorb such increase. In addition, if Gilead will place orders for quantities permitting Patheon to manufacture in larger production runs, the Parties shall review the fee for the Processing of such Drug Product and shall reduce such fee on a per-unit basis by a reasonable amount to reflect savings in Patheon's costs relating to such Drug Product as a result of such increase if any.

In connection with a fee adjustment request pursuant to this Section 4.4, Patheon shall deliver to Gilead a revised Exhibit C for such Drug Product and such budgetary pricing information, adjusted Material costs for such Drug Product or other documentation sufficient to demonstrate that a fee adjustment is justified for such Drug Product, no later than [\*] prior to the end of the Year. Upon receipt of such a request, each of Gilead and Patheon shall forthwith use

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all reasonable efforts to agree on a revised fee for the Processing in respect of each affected Drug Product.

**4.5 Adjustments Due To Technical Changes** . Amendments to the Specifications for a given Drug Product, the Quality Agreement relating to Processing or the minimum order quantities for each Drug Product requested by Gilead will only be implemented following a technical and cost review by Patheon and are subject to Gilead and Patheon reaching agreement as to revisions, if any, to the fees specified in Exhibit C of the corresponding Product-Specific Appendix or otherwise necessitated by any such amendment. If Gilead accepts a proposed fee change, the proposed change in the Specifications, Quality Agreement or minimum order quantities shall be implemented, and the fee change shall become effective only with respect to those orders of such Drug Product that are Processed in accordance with such revision (s). The Parties acknowledge in Sections 2.2, 2.6 and 2.8 the potential need to refine or modify the Specifications, Quality Agreement or minimum order quantities for Drug Products, respectively. Accordingly, the Parties will negotiate in good faith to modify the applicable Specifications, Quality Agreement or minimum order quantities from time to time if requested by Gilead. Patheon will facilitate appropriate changes to the Exhibits, and shall implement any changes to the Specifications and/or Quality Agreement that are required by applicable legal requirements; provided that Gilead bears the costs of such changes to the extent relating solely to the Drug Product(s) or the Parties reach written agreement as to a different allocation of such increased costs. The Parties agree to allocate on an equitable basis any special costs of developing and implementing revised procedures, meaning that the cost of implementing any revised procedures shall be borne in full by Gilead in such cases where the changes are made solely for the benefit of Gilead, and the costs of other changes shall be allocated between the Parties on the basis of the extent to which such Party will be benefited by such change relative to the extent to which the other Party will be benefited by such change. In any event, Gilead agrees to purchase, at Patheon's cost, all Inventory for the relevant Drug Product utilized under any of the "old" Specifications and/or Quality Agreement and purchased or maintained by Patheon in order to fill Firm Orders for such Drug Product or in accordance with Section 2.5, to the extent that such Inventory can no longer be utilized under the revised Specifications and/or Quality Agreement. Open purchase orders for Materials no longer required under such revised Specifications and/or Quality Agreement that were placed by Patheon with suppliers in order to fill Firm Orders or in accordance with Section 2.5 shall be cancelled where possible, and where such orders are not subject to cancellation without penalty, shall be assigned to and satisfied by Gilead.

**4.6 Multi-Country Pricing** . If Gilead decides that it wishes to have Patheon Process a Drug Product for any country in addition to the Territory as stated in Exhibit C of the applicable Product-Specific Appendix, then Gilead shall inform Patheon of the packaging requirements for such Drug Product needed for this new country market and Patheon shall prepare a quotation for consideration by Gilead of the additional Component costs, if any, and the change over fees for such Drug Product destined for the new country market. The agreed additional packaging requirements and related packaging costs and change over fees shall be set out in a written amendment to Exhibit C of the applicable Product-Specific Appendix.

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**4.7 API Cost Adjustment .** Each Product-Specific Appendix when it is executed shall set forth Gilead's actual standard costs to acquire or manufacture the relevant API (" **Gilead's Actual Standard API Costs** ") in Exhibit C. The Parties recognize that such costs may fluctuate over time. Therefore, at the time of annual price adjustment pursuant to Section 4.4, Gilead shall determine an adjustment to Gilead's Actual Standard API Costs to reflect such costs in the [\*] month period prior to such adjustment. Such adjusted Gilead's Actual Standard API Costs shall apply solely on a prospective basis. Patheon shall have the right to audit the methodology employed by Gilead to determine an adjusted Gilead's Actual Standard API Costs.

## ARTICLE V

### DELIVERY AND ACCEPTANCE

**5.1 Quality Control Sample and Documentation .** Prior to the delivery of any batch of Drug Product, Patheon shall provide Gilead with a quality control sample of such batch for the purpose of confirming that such batch meets the Specifications (unless Gilead consents in writing that no such sample is required), and the Disposition Package for such batch. The quality control sample shall consist of Drug Product sampled so as to be representative of the batch. Patheon shall not deliver a shipment of Drug Product until it has been released by Gilead pursuant to Section 5.4(a) unless otherwise requested by Gilead in writing.

#### **5.2 Delivery and Title .**

(a) Unless otherwise agreed by the Parties in writing, all shipments shall be shipped [\*] (as such term is defined in Incoterms 2000) [\*] ; *provided*, however, that notwithstanding [\*] responsibility for customs clearance in accordance with [\*] as so defined in Incoterms 2000, [\*] shall be responsible to arrange for customs clearance for each shipment hereunder. The Parties shall reasonably cooperate to share any information for [\*] to fulfill its responsibilities to arrange for customs clearance. In accordance with delivery [\*] , [\*] shall bear all risk of loss or damage after the Drug Product [\*] . Patheon shall package Drug Product in accordance with the applicable Specifications. For each shipment of Drug Product, Patheon shall submit to Gilead the applicable Disposition Package pursuant to Section 5.1 together with an invoice for such shipment of Drug Product.

(b) Patheon shall consistently fulfill Firm Orders submitted to Patheon pursuant to Section 2.3 by supplying Drug Product with at least [\*] percent ( [\*] %) of initial shelf life remaining at the time of delivery, and Gilead shall have no obligation to accept or pay for any shipment of Drug Product delivered to Gilead with less than [\*] percent ( [\*] %) of initial shelf life remaining; provided, however, that if there is a delay in delivery due to investigation and resolution of a deviation that does not arise from Patheon's failure to manufacture Drug Product in accordance with the Patheon Manufacturing Responsibilities, then the deemed delivery date for purposes of calculating remaining shelf life under this Section 5.2(b) shall be the date preceding the actual delivery date by a number of days equal to the length of such delay, provided that Patheon has carried out its responsibilities in such investigation and resolution using commercially reasonable efforts, then Gilead shall be obligated to accept and pay for any shipment of Drug Product delivered to Gilead, subject to Gilead's rights pursuant to Section 5.4.

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In addition, Gilead may consent, in writing, to a shorter remaining shelf life at delivery of any Drug Product as follows: (i) where release of such Drug Product was delayed to enable a major deviation to be investigated and resolved; and (ii) provided that any such acceptance and utilization shall be subject to the written consent of any applicable third party purchasing Drug Product from Gilead, acting in good faith. In the circumstances outlined in the preceding sentence, Gilead shall be obligated to accept and pay for such shipment of Drug Product, subject to Gilead's rights pursuant to Section 5.4. Initial shelf life shall be measured and begin to expire commencing on the date that API and any Excipients are first combined. In all circumstances, Gilead shall use commercially reasonable efforts to promptly investigate and address any deviation or variance of the Drug Product.

(c) In the event of a deviation at any time during the Processing of a Drug Product, the Parties shall mutually agree upon procedures to rework, to the extent possible, such Drug Product in accordance with Section 3.8 so that such Drug Product will meet the applicable Specifications.

### 5.3 Late Delivery.

(a) Patheon agrees to use its commercially reasonable efforts to deliver Drug Products hereunder on the scheduled delivery dates as set forth in the relevant Firm Orders. It shall not be considered a breach of this Agreement if, for any batch for which Patheon has accepted a Firm Order, at least [\*] percent ( [\*] %) of Drug Product which conforms to the Specifications is made available for delivery within [\*] business days following the date originally agreed upon for delivery in such Firm Order (the “ **Scheduled Delivery Date** ”). However, it shall be deemed to be a late delivery if Patheon delivers a shipment of Drug Products later than [\*] business days after the relevant Scheduled Delivery Date (such date [\*] business days after the Scheduled Delivery Date, the “ **Late Delivery Date** ”).

(b) If Patheon has learned that any delivery of Drug Product may be expected to:

(i) have less than [\*] percent ( [\*] %) of the quantity stated in the relevant Firm Order; and/or

(ii) be delivered after the Late Delivery Date, according to Patheon's master delivery plan,

then Patheon shall: (1) as soon as practical, notify Gilead; (2) ensure that [\*] of this issue; and (3) develop and implement a [\*] to the extent reasonably practicable or any [\*] thereof.

(c) Notwithstanding the previous paragraph, Patheon will notify Gilead as promptly as practicable of such anticipated late or short delivery that is likely to occur despite Patheon's efforts (the “ **Notice** ”).

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(d) If, to the extent not caused by any of the events set forth in Section 5.3(h), during any period of [\*], Patheon delivers after the relevant Late Delivery Date [\*] (a “ **Delivery Default** ”), then at Gilead’s option, Gilead may request a meeting [\*]. The request for the meeting shall be given within [\*] from the date of Notice, and the meeting shall be held within [\*] from the date of the request.

(e) At the meeting, the Parties will negotiate diligently and in good faith to mutually agree upon [\*] for: (i) any [\*] of Drug Product occurring after [\*]; or (ii) any delivery of Drug Products having [\*] of the quantity stated [\*]. The Parties will, thereafter, enter into an amendment to this Agreement to reflect the mutually agreed resolutions (the “ **Amending Agreement** ”).

(f) If after entering the Amending Agreement and to the extent not caused by any of the events set forth in Section 5.3(h), there is another Delivery Default, then such default shall be deemed to be a material breach of this Agreement and Gilead may terminate this Agreement pursuant to Section 9.3(e).

(g) For purposes of determining a Delivery Default pursuant to Section 5.3(d), a batch shall not be counted as having been delivered after the Late Delivery Date if, with respect to such batch:

(i) the period between the day that Patheon provides the relevant Disposition Package to Gilead and the Scheduled Delivery Date is as long or longer than the release review period, which shall be [\*] or such other period as mutually agreed;

(ii) the batch has no deviations from the applicable Specifications or cGMPs that reasonably prevent Gilead from releasing such batch within the agreed release review period, which shall be [\*] or such other period as mutually agreed;

(iii) there are no deviations in the shipment of such batch that would form the basis of a Deficiency Notice pursuant to Section 5.4(b); and

(iv) Patheon actually makes such batch available for delivery within the agreed time frame following release by Gilead.

(h) Notwithstanding anything to the contrary in this Section 5.3, Patheon shall not be responsible for the failure to satisfy any Firm Order to the extent caused by any of the following events:

(i) Gilead’s failure to have delivered to Patheon adequate supplies of the applicable API;

(ii) Gilead’s failure to deliver forecasts pursuant to Section 2.3;

(iii) Gilead’s failure to timely deliver specifications or other technical information necessary to perform the Processing services;

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(iv) a Force Majeure event outlined in Section 10:10, provided that Patheon complies with its obligations to address any such Force Majeure event in accordance with Section 10.10;

(v) Gilead's failure to deliver the Firm Orders in accordance with Section 2.3(b); or

(vi) Gilead's changes to any Firm Orders.

#### **5.4 Product Deficiencies .**

(a) **Release.** Gilead or its designee shall review the Disposition Package for a potential shipment of Drug Product upon receipt of such Disposition Package thereof and test any quality control sample in its discretion and, within [\*], shall either release such shipment or shall give Patheon written notice (a **"Deficiency Notice"**) of all claims for Drug Product that deviates from the applicable Specifications or cGMPs, as determined by Gilead based on testing of any quality control sample or review of the Disposition Package. Any release by Gilead of a shipment of Drug Product shall be deemed to be an acceptance thereof, subject to Sections 5.4(b) and 5.4(f). Patheon shall have no liability for any deviations for which it has not received notice within such [\*] day period that should reasonably have been discovered within such time period by review of the Disposition Package of such shipment.

(b) **Inspection .** Gilead or its designee shall visually inspect shipments of Drug Product Processed by Patheon upon receipt thereof and, within [\*] days, shall give Patheon a Deficiency Notice of all claims for Drug Product that deviates from the applicable Specifications or cGMPs, or does not contain ordered quantities, as determined by Gilead based on such visual inspection. Such deviations may include, without limitation, Drug Product that has been cross-contaminated during Processing. Should Gilead fail to provide Patheon with a Deficiency Notice with respect to the delivery within [\*] days of receipt of a delivery of Drug Product, then the delivery shall be deemed to have been accepted by Gilead on the [\*] day after delivery. Patheon shall have no liability for any deviations for which it has not received notice within such [\*] day period that should reasonably have been discovered within such time period by inspection of such shipment.

Notwithstanding the foregoing provisions of this Section 5.4(b), for all shipments of Drug Product Processed by Patheon [\*] as specified in a Firm Order, the time period (i) for Gilead to provide Patheon with a Deficiency Notice with respect to such shipments, (ii) after which, if Gilead fails to provide Patheon with a Deficiency Notice with respect to such shipment, such shipment will be deemed accepted by Gilead, and (iii) after which, if Patheon has not received notice from Gilead, Patheon shall have no liability for any deviations with respect to such shipment that should reasonably have been discovered, shall be [\*] days ( [\*] days) of receipt of a delivery of such shipment.

(c) **Determination of Deficiency .** Upon receipt of a Deficiency Notice, Patheon shall have [\*] days to advise Gilead by notice in writing whether it disagrees with the contents of such Deficiency Notice. If Gilead and Patheon fail to agree within [\*] days after

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Patheon's notice to Gilead as to whether any Drug Product identified in the Deficiency Notice deviates from the applicable Specifications or cGMPs, then the Parties shall mutually select an independent laboratory to evaluate if such Drug Product deviates from the applicable Specifications or cGMPs. A sample of such Drug Product shall be submitted to the independent laboratory and such independent laboratory shall determine within [\*] days of receipt of the relevant sample (to the extent within the control of the Parties) whether such Drug Product meets the applicable Specifications and cGMPs. Such evaluation shall be binding on the Parties and if such evaluation certifies that any Drug Product deviates from the Specifications or cGMPs, Gilead may reject that Drug Product in the manner contemplated by Section 5.4(d) and, at Gilead's option, receive either a credit or a refund (to the extent previously paid by Gilead) for the amount that it was invoiced by Patheon for such shipment. If such evaluation does not so certify in respect of any such Drug Product, then Gilead shall be deemed to have accepted delivery of such Drug Product upon receipt by the Parties of the final determination in writing from the independent laboratory. The Party against whom the independent laboratory rules shall bear all costs of the testing.

**(d) Product Rejection and Replacement** . Subject to the provisions of Sections 5.4(a), (b), (c) and (f), Gilead has the right to reject and/or return, at the expense of Patheon, any portion of any shipment of Drug Product that deviates from the applicable Specifications or cGMPs, without invalidating any remainder of such shipment, to the extent that such deviation arises from Patheon's failure to provide the Processing services in accordance with Patheon Manufacturing Responsibilities. For such portion of any rejected and/or returned shipment, to the extent requested by Gilead, Patheon shall use commercially reasonable efforts to provide replacement quantities of the applicable Drug Product(s) to Gilead or its designee as soon as possible, but in any event, within [\*] days after the receipt by Patheon of a Deficiency Notice, regardless of whether Patheon agrees with the rejection. Subject to the provisions of Sections 7.3(a) and 7.3(b), Gilead shall supply quantities of the relevant API to permit such replacement manufacture, and shall bear the costs of replacement quantities of rejected Drug Product.

**(e) Disposition of Rejected Batches** . Gilead may destroy any batch of Drug Product without Patheon's consent in those cases where Patheon does not dispute that the batch fails to meet the applicable Specifications or cGMPs. To the extent that any deviation arises from Patheon's failure to Process the Drug Product in accordance with the Patheon Manufacturing Responsibilities, destruction of the Drug Product shall be made at Patheon's expense and Gilead shall provide evidence of such destruction.

**(f) Latent Defects** . Gilead shall notify Patheon promptly in writing if Gilead discovers a latent defect in any quantity of Drug Product resulting from nonconformance with the applicable Specifications or cGMPs at any time after such quantity has been accepted in accordance with this Section 5.4 and during its remaining shelf life, which defect should not reasonably have been discovered during the Disposition Package review conducted in accordance with Section 5.4(a) or the visual inspection conducted in accordance with 5.4(b) (a "Latent Defect "). Gilead's notice shall be deemed to be a Deficiency Notice, and the Parties

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shall address the Latent Defect in accordance with the provisions of Sections 5.4(c), 5.4(d) and 5.4(e).

## **5.5 API Yield .**

(a) **Yield-Related Reports .** Patheon shall submit yield-related reports for each Drug Product containing such information and at such times as described in the Yield Calculation Schedule.

(b) **Setting the [\*] Yield .** The Parties shall determine [\*] (as [\*] defined in the Yield Calculation Schedule which is attached hereto as Schedule B) for a particular Drug Product in accordance with the Yield Calculation Schedule. The Parties may, upon written agreement, adjust such [\*] on a Yearly basis to reflect further experience with Actual Yields (as defined in the Yield Calculation Schedule).

## **5.6 Responsibility for [\*] API in Non-Compliant Deliveries .**

(a) If (i) Patheon has failed to provide the Processing services in accordance with the Patheon Manufacturing Responsibilities for a delivery of Drug Product, (ii) the Drug Product in a delivery is not in compliance with the warranty made in Section 6.2, (iii) a delivery of Drug Product is properly rejected by Gilead pursuant to Section 5.4, or (iv) once a Target Yield has been set with respect to a given Drug Product, the [\*] Yield for any delivery of that Drug Product [\*] the applicable [\*] Yield, then subject to Section 7.3(a) Patheon shall [\*] the [\*] or the [\*] as calculated in accordance with the Yield Calculation Schedule for item (iv), in each case as calculated on [\*] . Within [\*] days after the end of each Year, the Parties shall determine whether Patheon is responsible for [\*] pursuant to this Section 5.6(a), and, if Patheon is responsible for [\*] , within [\*] days after the end of each Year, Gilead shall be [\*] either: (i) [\*] , or (ii) a [\*] of such [\*] .

(b) **Clarification of Relationship [\*] .** For clarity, the [\*] by Patheon to [\*] for a given Year that is [\*] the [\*] for such Year shall not in and of itself constitute a [\*] of this Agreement, however, whether a [\*] of this Agreement has occurred in any given instance shall depend on all relevant facts and circumstances. For example and without limitation, if the [\*] arises out of and is associated with a [\*] of Patheon to Process any Drug Product in accordance with the Specifications therefor, then such [\*] to Process in accordance with the Specifications may itself constitute [\*] of this Agreement, even though connected to a [\*] that in and of itself does not constitute [\*] .

## **ARTICLE VI**

### **REPRESENTATIONS AND WARRANTIES**

#### **6.1 Both Parties .** Each Party hereby represents and warrants to the other Party as follows:

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(a) **Existence and Power** . Such Party: (a) is duly organized, validly existing and in good standing under the laws of the jurisdiction in which it is organized; (b) has the power and authority and the legal right to own and operate its property and assets, to lease the property and assets it operates under lease and to carry on its business as it is now being conducted; and (c) is in compliance with all requirements of applicable law, except to the extent that any noncompliance would not materially adversely affect such Party's ability to perform its obligations under the Agreement.

(b) **Authorization and Enforcement of Obligations** . Such Party: (a) has the power and authority and the legal right to enter into the Agreement and to perform its obligations hereunder; and (b) has taken all necessary action on its part to authorize the execution and delivery of the Agreement and the performance of its obligations hereunder. The Agreement when duly executed and delivered on behalf of each Party, shall constitute a legal, valid, and binding obligation of the Parties.

(c) **No Conflict** . The execution and delivery of the Agreement and the performance of such Party's obligations hereunder: (a) do not materially conflict with or violate any requirement of applicable laws or regulations; and (b) do not materially conflict with, or constitute a material default or require any consent under, any material contractual obligation of such Party.

**6.2 Limited Warranty** . Patheon warrants that Drug Product delivered hereunder: (a) will be Processed in accordance with the Patheon Manufacturing Responsibilities and in material compliance with applicable rules and regulations, including, but not limited to, any regulations regarding use of the services of debarred persons; (b) will be Processed in accordance with the agreed-upon manufacturing procedures described in the applicable Master Batch Records supplied to Gilead and agreed upon by Gilead; and (c) will conform to the applicable Specifications set forth on Exhibits A and B of the applicable Product-Specific Appendix hereto at the time of delivery. The Parties agree that Sections 3.4 (with respect to "For Cause" audit costs), 5.4(c), 7.1(b) and 7.3(b) set forth the sole and exclusive remedy for Patheon's breach of the warranty in this Section 6.2. All other remedies that would otherwise be available at law or in equity are hereby explicitly excluded. The express warranties in Section 3.6 and this Section 6.2 are in lieu of all other warranties, express or implied, including, without limitation, the warranties of merchantability or fitness for a particular purpose.

**6.3 Non-Infringement** . Gilead covenants, represents and warrants that:

(a) the Specifications for each of the Drug Products are its or its Affiliate's property and that Gilead may lawfully disclose such Specifications to Patheon;

(b) any Intellectual Property embodied in the Specifications and which must be utilized by Patheon in order to Process Drug Products may be lawfully used as directed by Gilead without infringing any Third Party Rights;

(c) there are no actions or other legal proceedings, the subject of which is the infringement of Third Party Rights related to any of: (i) the Specifications; (ii) any of the API,

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and the Materials; or (iii) the sale, marketing, distribution and use or other disposition of any Drug Product; and

- (d) the Specifications for all Drug Products conform to all applicable cGMPs, laws and regulations.

The Parties agree that Article VII sets forth the sole and exclusive remedy for Gilead's breach of any of the representations and warranties in this Section 6.3. All other remedies that would otherwise be available at law or in equity are hereby explicitly excluded.

## ARTICLE VII

### INDEMNIFICATION

#### 7.1 Indemnity .

(a) Subject to Sections 7.2 and 7.3, and except to the extent the losses, liabilities, damages, costs, fees or expenses (including reasonable attorney's fees) (collectively, "**Losses**") resulting from any claim, suit, action, demand or cause of action brought by a third party (each a "**Third-Party Claim**") arise out of or result from any negligent or wrongful act or omission of any of Patheon and Patheon's directors, officers, employees, and agents, and the directors, officers, employees, and agents of any Patheon parent, subsidiary or related company (the "**Patheon Indemnitees**"), Gilead agrees to indemnify, hold harmless and defend the Patheon Indemnitees from and against any and all Losses resulting from any Third-Party Claim that arises or results from: (i) the possession or use of Drug Product by any person after delivery to Gilead or its designee; or (ii) any claim of infringement or alleged infringement of any Third Party Rights in respect of the Drug Product; or (iii) failure of Gilead to perform its obligations under this Agreement, including without limiting the generality of the foregoing, any Losses whatsoever with respect to death or injury to person or damage to property, provided that Patheon provides Gilead with prompt notice of any such Third-Party Claim and the exclusive ability to defend (with the reasonable cooperation of Patheon) or settle any such Third-Party Claim.

(b) Subject to Sections 7.2 and 7.3, and except to the extent the Losses resulting from any Third-Party Claim arise or result from any negligent or wrongful act or omission of any Gilead Indemnatee (defined below), Patheon agrees to indemnify, hold harmless and defend Gilead and Gilead's directors, officers, employees and agents, and the directors, officers, employees and agents of any Gilead parent, subsidiary, related company (collectively the "**Gilead Indemnitees**") from and against any and all Losses resulting from any Third Party Claim that results from or arises out of (i) Patheon's failure to Process any Drug Product in accordance with the Patheon Manufacturing Responsibilities, (ii) any injury to a person or damage to the Facility occurring in the course of Patheon's Processing hereunder, (iii) Patheon's breach of Section 6.2, (iv) Patheon's negligence or wrongful misconduct or (v) transportation, storage, use, handling and disposal of hazardous materials related to such Processing, including

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without limiting the generality of the foregoing, any Losses whatsoever with respect to death or injury to person or damage to property, provided that Gilead provides Patheon with prompt notice of any such Third Party Claim and the exclusive ability to defend (with the reasonable cooperation of Gilead) or settle any such Third Party Claim.

(c) In the event that the Parties cannot agree as to the application of Sections 7.1(a) and 7.1(b) above to any particular Third Party Claim, the Parties may conduct separate defenses of such Third Party Claim. Each Party further reserves the right to claim indemnity from the other in accordance with Sections 7.1(a) and 7.1(b) above upon resolution of the underlying claim, notwithstanding the provisions of Sections 7.1(a) and 7.1(b) above requiring the indemnified Party to tender to the indemnifying Party the exclusive ability to defend such Third Party Claim. The indemnified Party shall not compromise or settle any such Third Party Claim without the indemnifying Party's prior written consent. The indemnifying Party shall not compromise or settle any such Third Party Claim for any damages other than monetary damages without the indemnified Party's prior written consent. No such consent of an indemnified or indemnifying Party shall be unreasonably withheld.

**7.2 Consequential Damages .** UNDER NO CIRCUMSTANCES WHATSOEVER SHALL EITHER PARTY BE LIABLE TO THE OTHER IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY OR OTHERWISE FOR (A) ANY (DIRECT OR INDIRECT) LOSS OF PROFITS, OF PRODUCTION, OF ANTICIPATED SAVINGS, OF BUSINESS OR GOODWILL; OR (B) FOR ANY LIABILITY, DAMAGE, COSTS OR EXPENSE OF ANY KIND INCURRED BY THE OTHER PARTY OF AN INDIRECT OR CONSEQUENTIAL NATURE, EXCEPT TO THE EXTENT THAT A PARTY MAY BE REQUIRED TO INDEMNIFY THE OTHER PARTY UNDER SECTION 7.1 FOR AMOUNTS PAID TO A THIRD PARTY.

**7.3 Limitation Of Liability .**

(a) **Active Pharmaceutical Ingredients .**

(i) Patheon shall not be responsible for any loss or damage to any quantity of API, except where such loss or damage occurs while such materials are located on Patheon's premises and results from Patheon's negligence or intentional misconduct or failure by Patheon to provide the Processing services in accordance with the Patheon Manufacturing Responsibilities, or where Patheon [\*] on a [\*] basis as provided in Section 5.6(a). In such circumstances, Patheon's maximum liability shall be as outlined in Section 7.3(a)(iii).

(ii) For greater certainty, Gilead acknowledges that loss or damage of API in the course of technology transfer from Gilead to Patheon, or as part of failed regulatory, stability or test batches, shall not be regarded as lost due to the negligence or intentional misconduct of Patheon unless and to the extent that Patheon did not provide the Processing services in accordance with Patheon Manufacturing Responsibilities. Further, Patheon shall not be responsible for any loss or damage to any API where such loss or damage occurs during a batch implementing a new process or procedure (a “ **Development Batch** ”); provided, however, that both Parties shall agree, prior to commencement of manufacture of a batch, whether such

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batch shall be deemed a Development Batch. If the Parties do not agree in advance in writing that a given batch is a Development batch, then such batch shall not be deemed to be a Development Batch.

(iii) Patheon's maximum liability for loss or damage to any quantity of API for any reason whatsoever including, without limitation, those referred to in Section 7.3(a) (i) and (ii) shall be limited to the [\*] .

(b) **Drug Products** . Subject to Sections 5.4(c), 5.6 and 7.1(b), Patheon shall not be liable nor have any responsibility for any deficiencies in, or other liabilities associated with, any Drug Product manufactured by it, including, without limitation, any deficiencies or defects with respect to an Excipient which were not ascertainable by Patheon pursuant to Section 3.1(c); the Specifications; or the safety, efficacy or marketability of such Drug Product or any distribution thereof.

**7.4 Expenses** . No Party shall be required to pay over to another amounts called for under this Article VII until the final resolution of the claim, action, suit or proceeding from which the right to such payment arose.

## ARTICLE VIII

### CONFIDENTIAL INFORMATION

**8.1 Obligation** . During the Term of this Agreement and for a period of ten (10) years thereafter, the receiving Party (the "**Receiving Party** ") shall maintain in confidence all Confidential Information, as defined in Section 8.2 below, and shall not use, disclose or grant use of such Confidential Information except as expressly authorized by this Agreement. The Receiving Party may disclose Confidential Information, as authorized hereunder, only to those employees or consultants of the Receiving Party who agree to be bound by the terms of this Article VIII. The Receiving Party shall use the strictest standard of care which is practical to ensure that such employees do not disclose or make any unauthorized use of Confidential Information. The Receiving Party shall promptly notify the Disclosing Party (as defined in Section 8.2) upon discovery of any unauthorized use or disclosure of the Confidential Information.

**8.2 Definition** . As used in this Agreement, the term "Confidential Information" shall mean any information, either enabling or disabling, including but not limited to the terms of this Agreement, any batch record, any purchase order or other commercial relationship between the Parties, know-how, trade secret, research, data, process, technique, algorithm, program, design, drawing, formula, experimental design or test data relating to any research project, work in process, future development, scientific, manufacturing, marketing, business plan, financial or personnel matter relating to the disclosing party (the "**Disclosing Party** "), its present or future products, sales, suppliers, customers, employees, investors or business, or to any Invention that is the property of the Disclosing Party, whether in oral, written, graphic or electronic form disclosed by or on behalf of the Disclosing Party under this Agreement. The term "Confidential Information" shall include, without limitation: (i) the information contained in the batch records

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delivered to Gilead; (ii) any cost information related to the Processing of Drug Product, including the cost of the Materials or Processing; and (iii) the Specifications for Drug Product. All Confidential Information (as such term is defined in the Viread Agreement) disclosed pursuant to the Viread Agreement shall be deemed to be the Confidential Information under this Agreement of the Disclosing Party or, in the case of Gilead, of Gilead where the disclosing party was an Affiliate of Gilead Sciences or Gilead World.

**8.3 Exceptions .** Each of Patheon and Gilead shall be relieved of any and all of the obligations under Section 8.1 regarding Confidential Information which: (i) was known by the Receiving Party prior to receipt hereunder (unless it became so known to the Receiving Party under a separate agreement of confidentiality to the Disclosing Party in which case this exception shall not apply); (ii) at the time of disclosure, was generally available to the public, or which after disclosure hereunder becomes generally available to the public through no fault attributable to the Receiving Party; or (iii) is hereafter made available for use or disclosure from any third party having a right to do so.

**8.4 Permitted Disclosures .** Notwithstanding any other provision of this Agreement, each Party may disclose Confidential Information of the other Party:

(a) to the extent and to the persons and entities required by an applicable governmental law, rule, regulation or order; *provided, however* , that the Party required to disclose Confidential Information shall first have given prompt notice to the other Party hereto to enable it to seek any available exemptions from or limitations on such disclosure requirement and shall reasonably cooperate in such efforts by the other Party;

(b) to the extent and to the persons and entities required by rules of the National Association of Securities Dealers or other applicable securities laws, rules or regulations;

(c) to the extent and to the persons and entities required for purposes of making Regulatory Filings for any Drug Product;

(d) as necessary to file or prosecute patent applications, prosecute or defend litigation or otherwise establish rights or enforce obligations under this Agreement, but only to the extent that any such disclosure is necessary; and

(e) where such Confidential Information consists of Patheon batch records, protocols, validation reports or technical reports, to the extent and to the persons and entities solely as necessary for the purpose of controlling and setting process parameters relating to Drug Products, including but not limited to disclosure by Gilead to its bona fide third-party supplier(s) of processing services for Drug Products solely as necessary for such purpose, provided that any disclosure under this Section 8.4(e) may be made only under an agreement of confidentiality containing provisions as least as strict as those in this Article 8.

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## 8.5 Trademarks And Trade Names .

(a) Each Party hereby acknowledges that it does not have, and shall not acquire, any interest in any of the other Party's trademarks or trade names unless otherwise expressly agreed.

(b) Each Party agrees not to use any trade names or trademarks of the other Party, except as specifically authorized by the other Party in writing both as to the names or marks which may be used and as to the manner and prominence of use.

## 8.6 Improvements .

(a) Patheon acknowledges and agrees that it has no proprietary Intellectual Property in the current manufacturing process for any of the Drug Products, as set forth in the Specifications. The Parties acknowledge that Patheon, independently or jointly with Gilead, may develop improvements to the Specifications, inventions and other know-how (including without limitation data, information, processes, techniques, methods, and unpatentable inventions) in the course of fulfilling its obligations under this Agreement (“**Improvements**”). Patheon shall reasonably cooperate with Gilead in identifying any potential Improvements in the Processing of Drug Products and agrees to disclose any such Improvements to Gilead prior to implementing such Improvements in the Processing of the applicable Drug Product under this Agreement.

(b) All Improvements that relate solely to any API, any [\*] of an API, and/or Drug Product (or combination of any of the foregoing) shall be and remain the exclusive property of Gilead (collectively, the “**Product-Specific Improvements**”). Patheon hereby assigns its entire right, title and interest in the Product-Specific Inventions to Gilead. Patheon shall take all reasonable steps and execute and deliver all documents reasonably required for Gilead to evidence or record such assignment. Patheon shall only use in its performance under this Agreement, employees or consultants of Patheon who have agreed in writing to assign the Product-Specific Inventions to Patheon.

(c) All Improvements that relate to any API, [\*] an API or Drug Product, but also have application [\*] the API, [\*] or Drug Product, (collectively, the “**Broader Improvements**”) shall be and remain the exclusive property of Patheon. Patheon hereby grants to Gilead an irrevocable, nonexclusive, worldwide, royalty-free license, with the right to sublicense (through one or more tiers of sublicensees), under the Broader Improvements to research, develop, make, have made, use, sell, offer for sale, import and otherwise commercialize Gilead's (and its Affiliates' and licensees') products throughout the world.

(d) Patheon shall not use any of Patheon's patented or trade secret technology in its performance under this Agreement, without the prior written consent of Gilead, which consent shall not be unreasonably withheld or unduly delayed. The Parties shall agree, prior to the addition of each subsequent Product-Specific Appendix, whether Patheon shall use any such patented or trade secret technology in the Processing for the given Drug Product, and will set forth their agreement in such Product-Specific Appendix.

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## ARTICLE IX

### TERM; TERMINATION

**9.1 Term .** This Agreement shall commence on the Effective Date and shall remain in effect until the termination of all Product-Specific Appendices, unless terminated earlier by one of the Parties as provided herein (the “**Term**”). The initial term for each Product-Specific Appendix is set forth in Exhibit C of such Product-Specific Appendix (the “**Initial Term**”) and shall automatically continue for successive one (1) calendar year terms, unless either Party gives written notice to the other Party of its intention to terminate such Product-Specific Appendix at least [\*] months prior to the end of the then-current term.

**9.2 Surviving Obligations .** Termination or expiration of this Agreement shall not: (a) affect any other rights of either Party which may have accrued up to the date of such termination or expiration; or (b) relieve Gilead of its obligation to pay to Patheon sums due in respect of Drug Product delivered prior to termination or expiration of this Agreement. The provisions of Sections 3.6, 3.7, 6.2, 9.2, and 9.5, and Articles V, VI, VII, VIII, and X shall survive the termination or expiration of this Agreement.

### **9.3 Termination .**

(a) Either Party may terminate this Agreement upon written notice to the other Party if the other Party commits any material breach of this Agreement which the breaching Party fails to cure within [\*] days following written notice from the nonbreaching Party specifying such breach.

(b) Either Party may terminate this Agreement, effective immediately upon the giving of written notice, if the other Party shall file a petition for bankruptcy, or shall be adjudicated bankrupt, or shall take advantage of the insolvency laws of any state of the United States, or shall make an assignment for the benefit of creditors, or shall have a receiver, whether appointed by private instrument or court officer, appointed for its property.

(c) Any termination or expiration of this Agreement shall not affect any outstanding obligations or payments due hereunder prior to such termination or expiration, nor shall it prejudice any other remedies that the Parties may have under this Agreement.

(d) Patheon may terminate this Agreement upon [\*] prior written notice if Gilead assigns pursuant to Section 10.9 any of its rights under this Agreement to an assignee (excluding any Gilead Affiliates) that is, in the opinion of Patheon acting reasonably, not a credit worthy substitute for Gilead, is a competitor of Patheon within the field of pharmaceutical contract manufacturing services or pharmaceutical contract development services, or with whom Patheon has had prior materially negative business relations (e.g., Patheon having encountered uncured instances of non-payment of amounts due under a contract or other uncured material breaches) and has good cause to believe that any future business relations with such assignee will be similarly negative. Notwithstanding the foregoing, Patheon shall continue to supply the Drug Products pursuant to the terms of this Agreement until such time as Gilead is able to establish

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adequate alternative supply (i.e., its alternative supplier is regulatorily approved); provided that (i) Gilead shall use commercially reasonable efforts to promptly establish adequate alternative supply and (ii) Gilead remains liable hereunder.

**(e) Further Gilead Termination Rights.**

**(i)** If a Delivery Default has occurred pursuant to Section 5.3(d) and Patheon and Gilead cannot reach a satisfactory Amending Agreement pursuant to Section 5.3(e) within [\*] days, then Gilead, at its option, may either terminate this Agreement upon [\*] days written notice to Patheon (in which case Patheon shall have no right to cure the breach underlying such conditions) or refer the issue of the terms of such Amending Agreement to binding arbitration pursuant to Schedule D.

**(ii)** If a Delivery Default has occurred subsequent to an Amending Agreement being made by Patheon and Gilead which includes [\*], then Gilead may either terminate the Agreement or require Patheon to [\*] in accordance with the Amending Agreement. These remedies are mutually exclusive in respect to any Delivery Default and cannot be incurred concurrently or sequentially in respect of the same Delivery Default.

**9.4 Product Discontinuation/Withdrawal .** During the Term of this Agreement Gilead shall provide at least (a) [\*] advance notice if it intends to no longer order a Drug Product due to that Drug Product's discontinuation in the market and (b) [\*] advance notice if a Drug Product is withdrawn from the market pursuant to an order by the applicable Regulatory Authority. Upon the expiration of the applicable notice period in this Section 9.4, this Agreement shall terminate solely with respect to such Drug Product.

**9.5 Obligations on Termination.**

**(a)** If this Agreement expires or is terminated in whole or in part for any reason other than a material default by Patheon of its obligations under this Agreement, Gilead shall:

**(i)** purchase the Inventory, at such cost that Patheon had expended to acquire such Inventory, applicable to the Drug Product which was purchased, produced or maintained by Patheon in contemplation of filling Firm Orders or in accordance with Section 2.3 prior to notice of termination being given;

**(ii)** purchase all undelivered Drug Product which were Processed and/or packaged pursuant to a Firm Order, at the price in effect at the time the Firm Order was placed; and

**(iii)** satisfy the purchase price payable pursuant to Patheon's non-cancelable orders with suppliers of Materials, provided such orders were made by Patheon in reliance on Firm Orders or in accordance with Section 2.3.

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(b) If this Agreement is terminated as a result of a material default by Patheon of its obligations under this Agreement, Gilead agrees to purchase such of the items referred to in (a), (b) and (c) above as it determines, acting reasonably, that can be used by Gilead.

(c) The provisions of Article 5 will survive with respect to any purchases of Drug Product pursuant to this Section 9.5.

## ARTICLE X

### MISCELLANEOUS

**10.1 Recall .** In the event that Drug Product is recalled or that Gilead is required to disseminate information regarding such Drug Products, Gilead shall so notify Patheon and, not later than may be required to permit Gilead to meet such obligations, Patheon shall provide Gilead, at Gilead's cost, with such assistance in connection with such recall as may reasonably be requested by Gilead. If a Drug Product is recalled due to Patheon's negligence or failure to perform in accordance with the Patheon Manufacturing Responsibilities, Patheon shall be responsible for the costs reasonably required to effect such recall.

**10.2 Insurance .** Each Party shall maintain comprehensive general liability insurance, including blanket contractual liability insurance covering the obligations of that Party under this Agreement through the Term of this Agreement and for [\*] years thereafter, which insurance shall afford limits of not less than [\*] dollars (\$ [\*] ), for each occurrence, in the aggregate for bodily injury liability, personal injury liability, products liability, property damage liability, contractual liability and completed operations liability. Each Party will provide the other with a certificate of insurance evidencing the above and showing the name of the issuing company, the policy number, the effective date, the expiration date and the limits of liability. Each Party will provide at least [\*] days' written notice to the other Party of a cancellation of, or a material change in, the insurance of the first Party.

**10.3 Independent Parties .** The Parties are not employees, partners, or legal representatives of the other Party for any purpose. Neither Party shall have the authority to enter into any contracts in the name of or on behalf of the other Party.

**10.4 Governing Law .** This Agreement is made in accordance with, and shall be governed and construed under the laws of, the State of New York, excluding its choice of law rules. Both parties hereby consent to the exclusive jurisdiction and venue of the state and federal courts of competent subject matter jurisdiction located within the State of New York, and waive any defenses they may have to the personal jurisdiction and venue of such courts.

**10.5 Notice .** Unless otherwise provided in this Agreement, all notices, including notice of address change, required or permitted to be given under this Agreement shall be in writing and deemed to have been received: (a) when received if hand delivered; (b) four (4) days after being sent by first class U.S. mail, postage prepaid; (c) one (1) business day after being sent by overnight courier; (d) one (1) business day after facsimile transmission to the number(s) below, with receipt confirmed; or (e) one (1) business day after electronic mail transmission to

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the email address(es) below, with receipt confirmed, in each case addressed to the address set forth below.

If to Gilead:

Gilead Sciences, Inc.  
333 Lakeside Drive  
Foster City, CA 94044  
Attention: Vice President and General Counsel  
Facsimile: [\*]  
Email Address: [\*]

With a copy to:

Gilead Sciences, Inc.  
333 Lakeside Drive  
Foster City, CA 94044  
Attention: Director, Manufacturing  
Facsimile: [\*]  
Email Address: [\*]

If to Patheon:

Patheon Inc.  
7070 Mississauga Road, Suite 350  
Mississauga, Ontario L5N 7J8  
Attention: President  
Facsimile: [\*]  
Email Address: [\*]

**10.6 Severability** . In the event any provision of this Agreement is held to be invalid or unenforceable, the valid or enforceable portion thereof and the remaining provisions of this Agreement will remain in full force and effect.

**10.7 Waiver** . Any waiver (express or implied) by either Party of any breach of this Agreement shall not constitute a waiver of any other or subsequent breach.

**10.8 Entire Agreement** . This Agreement (including without limitation the schedules, appendices and the exhibits attached hereto) and the Viread Agreement constitutes the entire, final, complete and exclusive agreement between the Parties and supersedes all previous agreements or representations, written or oral, with respect to the subject matter of this Agreement. This Agreement may not be modified or amended except in writing signed by a duly authorized representative of each Party. Any term or condition in any order, confirmation

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or other document furnished by Gilead or Patheon which is in any way inconsistent with the terms set forth herein is hereby expressly rejected.

**10.9 Nonassignability: Binding on Successors** . Except in connection with any sale of all or substantially all of either Party's assets, whether by merger or otherwise, any attempted assignment of the rights or delegation of the obligations under this Agreement shall be void without the prior written consent of the nonassigning Party. In the case of any permitted assignment or transfer of or under this Agreement, this Agreement shall be binding upon, and inure to the benefit of, the successors, and permitted assigns of the Parties hereto.

**10.10 Force Majeure** . Neither Party shall be liable to the other for its failure to perform any of its obligations under this Agreement, except for payment obligations, during any period in which such performance is delayed or rendered impracticable or impossible due to circumstances beyond its reasonable control, including without limitation earthquakes, governmental regulations, riots, wars, acts of terrorism, fires, floods, storms, interruption of supply of API (to the extent beyond such Party's reasonable control), Excipients and Components, interruption of or delay in transportation (to the extent beyond such Party's reasonable control), civil disorder, acts of God, defective equipment (to the extent beyond such Party's reasonable control), lack of or inability to obtain fuel, power or Materials (to the extent beyond such Party's reasonable control), or compliance with any order or regulation of any government entity acting within color of right, provided that the Party experiencing the delay promptly notifies the other Party of the delay. Specifically excluded from this provision are the following circumstances that interfere, delay or render impossible the ability of Patheon to perform any of its obligations under this Agreement: (a) strike, lockout, or work or labor slowdowns at Patheon's Facility(ies), (b) governmental action to which Patheon's response is not reasonable, and (c) shutdowns due to Patheon's failure to make reasonable efforts to comply with government orders or regulations. With respect to any of the specifically excluded circumstances in the foregoing sentence, Patheon shall promptly inform Gilead of any such circumstance, its extent and duration, and any failure of Patheon to perform hereunder due to such an excluded circumstance shall constitute a breach of this Agreement.

**10.11 Publicity** . Neither Party will make any announcement nor other public statement concerning the existence or terms of this Agreement without the consent of the other Party, except as required by law. Notwithstanding the foregoing sentence, Patheon may, without Gilead's consent, disclose in presentations to groups consisting only of current or good faith potential investors or in small group meetings with groups consisting only of only current or good faith potential inventors that Gilead is a client of Patheon, but Patheon may not disclose any specific Drug Products or other products that are or are not manufactured for or supplied to Gilead or any other specific services that are or are not performed for Gilead.

**10.12 Captions** . The Parties agree that the headings in the Agreement are used for the convenience of the Parties only and are not intended to be used in the interpretation of the Agreement.

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**10.13 Reference to Patheon .** Drug Product shall be marketed without label reference to Patheon except to the extent required by law, in which case any label reference shall be to Patheon as a manufacturer only.

**10.14 Counterparts .** This Agreement may be executed in counterparts with the same force and effect as if each of the signatories had executed the same instrument.

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**10.15 Currency** . Unless otherwise indicated, all monetary amounts are expressed in this Agreement in the lawful currency of the United States of America.

**IN WITNESS WHEREOF** , the parties have executed this Agreement as of the Effective Date.

**GILEAD WORLD MARKETS, LIMITED**

By: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

**PATHEON INC.**

By: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

**GILEAD SCIENCES, INC.**

By: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

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## SCHEDULE A

### YIELD CALCULATION SCHEDULE

#### 1. Yield-Related Definitions:

- (a) “**Actual Yield**” shall mean, for a given API in each time period the [\*] .
- (b) “**[\*] Percentage**” shall mean the percentage of the [\*] Yield set out in Exhibit C of the Product-Specific Appendix hereto for the corresponding Drug Product.
- (c) “**[\*] Yield**” shall mean, for a given API, the [\*] Yield for such API, less the [\*] .
- (d) “**[\*]**” shall mean, for a given API in each time period, the total amount of that API [\*] the relevant Drug Product during such time period. The [\*] excludes API [\*] in Drug Product that is properly rejected under Section 5.4. For clarity, the [\*] of a given API includes quantities of such API [\*] delivered during the applicable time period under Section 7.3(b).
- (e) “**[\*]**” shall mean, for a given API in each time period, the total quantity of such API [\*] is calculated by adding the [\*] of the applicable API [\*] during the applicable time period to the [\*] API for such Drug Product held at the beginning of the such period, [\*] API held at the [\*] **Yield**” shall mean, for a given API in each time period, the end of such period.
- (f) “**[\*] Yield**” shall mean, for a given API in each time period, the [\*] in Section 3 below in this Yield Calculation Schedule.

2. **Yield-Related Reports:** Within [\*] days after the end of each calendar quarter during the Term of this Agreement, Patheon will submit to Gilead a report showing for each Drug Product (a) all API received during each calendar quarter, (b) the quantities of each API held in inventory, (c) all API contained in work-in-process and incorporated in finished Drug Product (including samples) as of the end of each month of such quarter and (d) the quantities of each Drug Product shipped during each month of such quarter. The report shall also indicate the actual conversion ratios experienced during each calendar month of such quarter.

3. **Setting the [\*] Yield:** Promptly after (and in any event, no more than [\*] days after) Patheon has completed a [\*] number of batches of a particular Drug Product at a given Facility pursuant to this Agreement (the “**Evaluation Batches**”), as set forth in the Product-Specific Appendix, the Parties shall determine a [\*] Yield and the [\*] Percentage for such Drug Product. Such [\*] Yield shall be (a) the [\*] Yield for the Evaluation Batches (excluding any failed batches) divided by the number of Evaluation Batches [\*], multiplied by (b) one hundred (100). The [\*] Percentage shall be determined by [\*] .

#### 4. Calculation of [\*] Yield for a given Drug Product:

$$\frac{[*] \text{ Yield}}{[*]} \times 100$$

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5. Calculation of [\*] Yield for a Given Drug Product:

[\*] Yield = [\*]

6. **Patheon’s [\*] Yield:** Once a [\*] Yield has been set with respect to a given Drug Product, if the [\*] Yield for a delivery of Drug Product [\*] the applicable [\*] Yield for that Year, then Patheon shall be [\*] for [\*] pursuant to Section 5.6(a) for the [\*] based on the following calculation:

[\*] = [\*] \* [\*] [\*] \* [\*]

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**SCHEDULE B**

**QUALITY AGREEMENT(S)**

**QUALITY AGREEMENT ON THE TASKS AND DIVISION OF RESPONSIBILITIES**

Defined roles and responsibilities of Patheon and Gilead are referenced in the attached agreement, effective January 1, 2003, as may be amended thereto from time to time through mutual written agreement of the Parties.

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**SCHEDULE C-1**

**FORM OF PRODUCT SPECIFICATIONS**

**EXHIBIT A to APPENDIX [\*] – [DRUG NAME]**

**DRUG SUBSTANCE, EXCIPIENT AND COMPONENT SPECIFICATIONS AND TESTING for**

All API, Excipient and Component testing shall be performed in accordance with the following Specifications, as may be amended from time to time by mutual written agreement of the Parties:

<u>DESCRIPTION</u>	<u>SPECIFICATION</u>
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**API**

**Excipients**

**Components**

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[\*] to any entity other than Gilead without Gilead's prior written consent. ]

**SCHEDULE C-2**

**FORM OF FINISHED PRODUCT SPECIFICATIONS AND TESTING REQUIREMENTS**

**EXHIBIT B TO APPENDIX [\*] [DRUG NAME]**

**SCHEDULE C-3**

**FORM OF PRICING AND API SCHEDULE**

**EXHIBIT C TO APPENDIX [\*] [DRUG NAME]**

**1. Launch Supplies**

Pricing for packaged                      prepared according to                      Kg batch sizes in preparation for launch are established according to the schedule below. This pricing reflects initial packaging as unlabeled bottles followed by subsequent labeling and cartoning with inserts.

**Minimum Order Quantity (units)**  
**Run Quantity (units)**  
**Price p/unit**

<b>USA Kg Brite Stock</b>	<b>USA Kg Brite Stock</b>	<b>USA Kg Brite Stock</b>
<b>30's</b>	<b>30's</b>	<b>30's</b>
<b>Bottles</b>	<b>Bottles</b>	<b>Bottles</b>
<b>[*]</b>	<b>[*]</b>	<b>[*]</b>

**Prices quoted in USD**



2. [\*] Product Pricing and [\*] Product Pricing:

Pricing for packaged are established according to the schedule below. This pricing reflects all manufacturing, primary packaging and secondary packaging as required for the [\*] .

	Price per 30's Bottle in USD
Pricing for kg Batch Size	
[*]	
[*]	
Minimum order quantity (Batches)	
Pricing for kg Batch Size	
[*]	
[*]	
Minimum order quantity (Batches)	

Conditions:

- 3. Gilead’s Actual Standard API Cost for 200(\*):
- 4. Patheon’s Annual API Cap:
- 5. Territory:
- 6. Facility(ies):
- 7. Yearly Minimum Volume for 200(\*):
- 8. [\*] Percentage for 200(\*):
- 9. Number of Evaluation Batches to Set [\*] Yield:
- 10. [\*] Yield for 200(\*):
- 11. [\*] Yield for 200(\*):
- 12. Appendix Effective Date:
- 13. Initial Term:

## SCHEDULE D

### ARBITRATION

(a) **Referable Issue** . Only the issue of the terms of an Amending Agreement under Sections 5.3(e) and 9.3(e)(i) ( **“Referable Issue”** ) may be submitted for resolution and finally determined under Schedule D. No other issues or disputes arising under this Agreement, shall be resolved as set forth in this Schedule D.

(b) **Finality of Decision** . The resolution of a Referable Issue made pursuant to this Schedule D shall be a final resolution and shall not be subsequently reviewable or justiciable in a court of law.

(c) **Selection of Industry Expert** . Within [\*] days after Gilead refers a Referable Issue for resolution under this Schedule D, each Party shall propose one (1) individual (i) having at least ten (10) years of significant management level experience with respect to manufacturing operations in the biopharmaceutical industry, (ii) that is not directly or indirectly affiliated with either Party or with either Party's Affiliates, sublicensees or business partners, and (iii) that does not have any direct or indirect interest of any kind in the resolution of the Referable Issue (a person having such characteristics, a **“Qualified Individual”** ). If the Parties are able to agree as to one of the Qualified Individuals proposed by a Party to resolve the Referable Issue within [\*] days after the date by which the Parties' notices to identify Qualified Individuals are due, then that person shall be the **“Industry Expert”** . If the Parties are unable to agree as to such a person within such [\*] day period, then within [\*] days after expiration of such [\*] day period, the two (2) Qualified Individuals chosen by the Parties shall select another Qualified Individual before whom such Referable Issue shall be resolved, and that person shall be the **“Industry Expert”** .

(d) **Resolution of Referable Issue** . Within [\*] days after the selection of the Industry Expert pursuant to Section (c) of this Schedule D, each Party shall submit to the other Party and to the Industry Expert a single, comprehensive, written proposal for the Amending Agreement, including without limitation the proposed Amending Agreement itself and any written materials in support of such proposal, with the entire submission of a Party not to exceed [\*] pages in a format substantially similar to this Agreement. Within [\*] days of the submission deadline for the proposals, the Industry Expert shall adopt in its entirety the single proposal of one of the Parties that the Industry Expert determines to be the more reasonable proposal. The Industry Expert shall have no authority to combine elements from one Party's proposal with elements from the other Party's proposal or to alter the terms of either Party's proposal. The Industry Expert shall determine the reasonableness of the Parties' proposals with respect to their terms based upon how well they reflect the following principles: (i) acceptability in the biopharmaceutical manufacturing sector as a commercially reasonable solution to the specific issues between the Parties; (ii) preservation of the Parties' ongoing manufacture and supply relationship for the Drug Products; (iii) ability under the proposal of each Party, through the use of commercially reasonable efforts, to attain the same economic profitability it could attain through performance in compliance with the original agreement; (iv) likelihood that the proposal

will incentivize each Party to perform its obligations as reflected in the original Agreement; (v) minimization of interruption of supply, prompt correction of prior shortages in supply and consistency of supply; and (vi) ease of administration and implementation. Promptly after selection of a proposal by the Industry Expert, the Parties shall execute and deliver the Amending Agreement included in the proposal selected by the Industry Expert. Such Amending Agreement shall have retroactive effect to the date of the Notice given pursuant to Section 5.3(c).

(e) **Interim Performance; Costs** . Until execution and delivery of an Amending Agreement pursuant to Section (d) of this Schedule D, the Parties shall continue to perform their obligations under this Agreement in good faith and make any applicable payments accordingly. The Parties shall bear all expenses and costs of the Industry Expert incurred pursuant to this Schedule D equally.

**APPENDIX 1 - TENOFOVIR DISOPROXIL FUMARATE**

**EXHIBIT A**

**DRUG SUBSTANCE, EXCIPIENT AND COMPONENT SPECIFICATIONS**

All API, Excipient and Component testing shall be performed in accordance with the following Specifications, as may be amended from time to time by mutual written agreement of the Parties:

<u>DESCRIPTION</u>	<u>CURRENT GILEAD PART NUMBER</u>	<u>CURRENT GILEAD SPECIFICATION</u>
API		
[*]	[*]	[*]
<u>Excipients</u>		
[*]		[*]
[*]		[*]
[*]		[*]
[*]		[*]
[*]		[*]
[*]		[*]
[*]		[*]
[*]		[*]
<u>Primary Components</u>		
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]

[\*]

**APPENDIX 1 –TENOFVIR DISOPROXIL FUMARATE**

**EXHIBIT B**

**FINISHED PRODUCT SPECIFICATIONS AND TESTING REQUIREMENTS FOR  
TENOFVIR DISOPROXIL FUMARATE TABLETS**

1. Specifications to conform with [\*] , effective [\*] and [\*] effective [\*] , as may be amended from time to time through mutual written agreement of the parties.
2. Testing to be performed by Patheon in accordance with the testing referenced in the above specification, according to the standard test methods listed or mutually qualified equivalent methods and as may be amended thereto from time to time through mutual written agreement of the parties.

APPENDIX 1 —TENOFVIR DISOPROXIL FUMARATE

EXHIBIT C

PRICING AND API SCHEDULE  
FOR 2003

1. Launch Supplies: [\*]

2. Product Pricing:

[\*]

[\*]  
[\*]  
[\*]

	[*]	[*]	[*]
	[*]	[*]	[*]
	[*]	[*]	[*]
	[*]	[*]	[*]

[\*]

[\*]

[\*]

	[*]	[*]
	[*]	[*]

## **Overall Manufacturing and Packaging Assumptions**

- a) Labeled packaging configuration includes: [\*]
- b) Unlabeled packaging configuration includes: [\*]
- c) Bulk packaging configuration includes: [\*]
- d) Unit pricing is based on [\*] . A [\*] will apply if [\*] .
- e) Unit pricing is based on [\*] . A [\*] will apply if [\*] .
- f) The minimum order quantity (Batches) can be packaged in [\*] . The [\*] campaign can [\*] .
- g) Conditions:
  - [\*]

## **Sub Lot Packaging[\*] Market Assumptions**

- a) Gilead is [\*] the packaging of a batch [\*] .
- b) For markets using the same packaging formats, the [\*] cost per unit applies with [\*] as noted. This requires inserts, cartons and labels to be essentially the same with text differences.
- c) Order quantities [\*] for each label will apply. The costs associate with the extra plates and dies are [\*] .
- d) [\*] are applicable for each time that the [\*] . No more than [\*] per batch will be allowed.
- e) For packaging configurations that represent different label, carton, or insert sizes or physical configurations, a separate quote will be issued.

3. **Gilead's Actual Standard API Cost for 2003:** [\*]
4. **Patheon's Annual API Cap:**  

[*] _____	[*] _____	[*] _____	[*] _____
[*]	[*]	[*]	[*]
5. **Territory:** [\*]
6. **Facility(ies):** [\*]  
[\*]
7. **Yearly Minimum Volume:** The Yearly Minimum Volume for Tenofovir Disoproxil Fumarate shall be the lesser of:  

(a) [\*] ; or  
(b) [\*]
8. **[\*] Percentage for 2003:** [\*]
9. **Number of Evaluation Batches to Set [\*] Yield:** [\*]
10. **[\*] Yield for 2003:** [\*]
11. **[\*] Yield for 2003:** [\*]
12. **[\*] Yield:** [\*]
13. **Appendix Effective Date:** January 1, 2003
14. **Initial Term:** January 1, 2003 to December 31, 2007



**APPENDIX 2 – ADEFOVIR DIPIVOXIL**

**EXHIBIT A**

**DRUG SUBSTANCE, EXCIPIENT AND COMPONENT SPECIFICATIONS**

All API, Excipient and Component testing shall be performed in accordance with the following Specifications, as may be amended from time to time by mutual written agreement of the Parties:

<u>DESCRIPTION</u>		<u>SPECIFICATION</u>	
[*]		[*]	
[*]		[*]	
[*]		[*]	
[*]		[*]	
[*]		[*]	
[*]		[*]	
<u>Primary Components</u>			
[*]		[*]	[*]
[*]		[*]	[*]
[*]			
[*]		[*]	[*]

[\*]

## **APPENDIX 2 – ADEFOVIR DIPIVOXIL**

### **EXHIBIT B**

#### **FINISHED PRODUCT SPECIFICATIONS AND TESTING REQUIREMENTS**

1. Specifications to conform with [\*], effective [\*], as may be amended from time to time through mutual written agreement of the parties.
2. Testing to be performed by Patheon in accordance with the testing referenced in the above specification, according to the standard test methods listed or mutually qualified equivalent methods and as may be amended thereto from time to time through mutual written agreement of the parties.

APPENDIX 2 – ADEFOVIR DIPIVOXIL

EXHIBIT C

**PRICING AND API SCHEDULE**

**FOR 2003**

1. **Launch Supplies:** [\*]

2. **Pricing**[\*]

	[*]	[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]	[*]

[\*]

**Pricing** [\*]

	[*]	[*]
[*]	[*]	[*]

## **Overall Manufacturing and Packaging Assumptions**

- a) Labeled packaging configuration includes: [\*]
- b) Unlabeled packaging configuration includes: [\*]
- c) Bulk packaging configuration includes: [\*]
- d) Unit pricing is based on [\*] . A [\*] will apply if [\*] .
- e) Unit pricing is based on [\*] . A [\*] will apply if [\*] .
- f) The minimum order quantity (Batches) can be packaged in [\*] . The minimum order quantity (Batches) for [\*] .
- g) Conditions:
  - [\*]

## **Sub Lot Packaging- Market Assumptions**

- a) .
- a) Gilead is [\*] the packaging of a batch [\*]
- b) For markets using the same packaging formats, the [\*] cost per unit applies with [\*] as noted. This requires inserts, cartons and labels to be essentially the same with text differences.
- c) Order quantities [\*] for each label will apply. The costs associate with the extra plates and dies are [\*] .
- d) [\*] are applicable for each time that the [\*] . No more than [\*] per batch will be allowed.
- e) For packaging configurations that represent different label, carton, or insert sizes or physical configurations, a separate quote will be issued.

3. **Gilead's Actual Standard Cost for 2003:** [\*]
4. **Annual API Cap** [\*]:  
  
[\*] [\*] [\*]
5. **Territory:** [\*]
6. **Facility(ies):** [\*]  
[\*]
7. **Yearly Minimum Volume** [\*]
8. **[\*] Percentage for 2003:** [\*]
9. **Number of Evaluation Batches to Set Target Yield:** [\*]
10. **[\*] Yield for 2003:** [\*]
11. **[\*] Yield for 2003:** [\*]
12. **[\*] Yield:** [\*]
13. **Appendix Effective Date:** January 1, 2003
14. **Initial Term:** January 1, 2003 to December 31, 2007

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

**Toll Manufacturing Agreement**

by and among

Gilead World Markets, Ltd  
Queensgate House  
South Church Street  
PO Box 1234 GT  
Grand Cayman  
Cayman Islands

Gilead Sciences, Inc.  
333 Lakeside Drive  
Foster City, CA 94404  
USA

and

ALTANA Pharma Oranienburg GmbH  
Lehnitzstr. 70-98  
16515 Oranienburg  
Germany

## TOLL MANUFACTURING AGREEMENT

This Amended And Restated Clinical and Commercial Supply Agreement (the “Agreement”) made and effective as of the 01 day of August, 2003 (the “Effective Date”) among, on the one hand, Gilead World Markets, Ltd., a Cayman Company (“**Gilead World**”), whose registered address is Queensgate House, South Church Street, P.O. Box 1234GT, Grand Cayman, Cayman Islands, and Gilead Sciences, Inc, a Delaware corporation (“**Gilead Sciences**”) with its principal office located at 333 Lakeside Drive, Foster City, CA 94404, USA (Gilead World and Gilead Sciences collectively, “**GILEAD**”), and, on the other hand, Altana Pharma Oranienburg GmbH, a German corporation (“**APO**”) having its principal place of business at Lehnitzstrasse 70-98, 16515 Oranienburg, Germany. Gilead and APO are sometimes referred to herein individually as a “Party” and collectively as the “Parties”.

WHEREAS, Gilead Sciences will require the manufacture and supply of Drug Products (as hereinafter defined) for clinical use in the Territory and Gilead World will require the manufacture and supply of Drug Products for commercial distribution and sale in the Territory; and

WHEREAS, GILEAD is a US biopharmaceutical company that discovers, develops and commercialises therapeutics to advance the care of patients suffering from life threatening diseases worldwide.

WHEREAS, GILEAD has developed the API tenofovir disoproxil fumarate (API, as hereinafter defined) and has filed patents thereto and commercializes the finished product under the trademark Viread® either by itself or through its Affiliates on a world-wide basis;

WHEREAS, GILEAD presently supplies the “**Finished Product**” (as hereinafter defined) produced by a Third Party manufacturer (“**Third Party Manufacturer**”) and its UK located affiliate GILEAD Sciences International Ltd. Cambridge is the holder of the Marketing Approval (Approval No.: [\*] ) pursuant to EU regulation 2309/93/EEC (as amended) or any implementation of it under the laws of any relevant EU member state where GILEAD markets the Finished Product;

WHEREAS, APO is the holder of the Manufacturing authorization pursuant to Directive 75/319/EEC (as amended) and any implementation of it under the laws of Germany for the manufacturing of products at its site at [\*] and it is interested in Manufacturing the Bulk Product (as hereinafter defined) for GILEAD;

NOW, THEREFORE, the Parties thereby agree as follows:

### DEFINITIONS

(A) “**Affiliate**” of a Party shall mean a corporation or other corporate entity that owns, is owned by or is under common direct or indirect ownership with such Party, where “own”, “owned” and “ownership” refer to ownership of over fifty percent (50%) of the voting shares or other voting interest of such entity or the ability to control or direct management of such entity.

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

- (B) “ **API** ” shall mean the active pharmaceutical ingredient tenofovir disoproxil fumarate to be used by APO in the Manufacture of the Bulk Product;
- (C) “[\*]” shall mean, for the API, the [\*] value identified as such in **Schedule “H”** that shall be subject to credit or reimbursement by APO pursuant to Section 2.7 [\*] .
- (D) “ **Bulk Product(s)** ” shall mean the API in its finished form as coated tablet(s) containing 300 mg of API in bulk, unlabelled after completion of all processing stages up to, but not including, final packaging as identified in **Schedule “A”** hereto, having the Specifications contained in **Schedule “C”** attached hereto;
- (E) “ **cGMPs** ” shall mean current Good Manufacturing Practices regulations promulgated by the EU Regulatory Agencies or the FDA, in respect of medicinal products as well as by the Quality Agreement, each in their respective current versions;
- (F) “ **Components** ” means, collectively, raw materials, excipients and ingredients, required to be used in order to produce the Bulk Product in accordance with the Specifications, other than the API, as set forth in **Schedule “D”** ;
- (G) “ **Confidential Information** ” shall have the meaning given such term in Section 15.1.
- (H) “ **Controlled** ” means, with respect to a patent, know-how or any other item of intellectual property, owned by or licensed to a Party with the ability to sublicense it to the other Party in accordance with this Agreement, without violating or breaching any agreement with any third party.
- (I) “ **EU Regulatory Agency** ” shall mean the Regulatory Agency of the European Union or their national equivalents;
- (J) “ **FDA** ” shall mean the U.S. Food and Drug Administration, or any successor agency.
- (K) “ **Finished Product(s)** ” shall mean the fully packaged Bulk Product with all necessary product information leaflets, i.e. SPC in the saleable form as approved by the relevant regulatory authority in the Territory
- (L) “ **Know-how** ” shall mean the information and know-how necessary for the Manufacturing of the Bulk Product to the exclusion, however, of the manufacturing know-how for the API;
- (M) “ **Inventory** ” means all inventories of Components and work-in-process produced or held by APO in connection with the Manufacture of the Bulk Product in accordance with the Specifications, but, for greater clarity, does not include the API;
- (N) “ **Manufacture** ” or “ **Manufacturing** ” shall mean the converting of API supplied by GILEAD or its appointee into Bulk Product by APO at the Manufacturing Location, including the required analyses and testing of API and such Bulk Products, and the bulk packing and dispatch labelling of such Bulk Product for shipment to GILEAD or its appointee, to the exclusion of the manufacture of API by APO;



- (O) “ **Manufacturing Location** ” shall mean the Manufacturing location for the Bulk Product of APO at [\*] ;
- (P) “ **Marketing Authorization** ” means the authorization to market Finished Product in a jurisdiction issued by the appropriate Regulatory Agency in such jurisdiction.
- (Q) “ **Release Documents** ” means the documentation specified pursuant to Sections 2.2.3 and 2.2.4 of the Quality Agreement that is required for GILEAD to release a batch of Bulk Product and authorize shipment thereof.
- (R) “ **Quality Agreement** ” shall mean the agreement on the pharmaceutical responsibilities of the Parties attached to this Agreement as **Schedule “B”** , with Gilead Sciences performing responsibilities for itself and on behalf of Gilead World.
- (S) “ **Specification(s)** ” shall mean all Manufacturing, (primary) packaging, quality assurance and release specifications in regards to Bulk Products set forth in **Schedule “C”** and in regards to API set forth in **Schedule “D”** attached hereto; such Specifications shall be supplied by GILEAD at its sole responsibility;
- (T) “ **Term** ” shall have the meaning set forth in Section 4;
- (U) “ **Territory** ” shall mean all the countries of the world in which GILEAD has notified APO that Finished Products shall be marketed;
- (V) “ **Year** ” shall mean the twelve month period commencing, in the case of the first Year (regarding the remaining months) of this Agreement, on the Effective Date, and thereafter commencing upon completion of the immediately preceding Year;
- (W) “ **Working Day(s)** ” shall mean any working day (with the exclusion of Saturday and Sunday) on which banks are normally open in USA, and in Germany for the transaction of business;

## **SECTION 1**

### **BULK PRODUCT SUPPLY COMMITMENTS**

**1.1 General.** During the term of this Agreement, APO shall Manufacture and supply to GILEAD the Bulk Product at the prices (the “ **Supply Price(s)** ”) indicated in **Schedule “A”** hereto (such prices being subject to adjustment in accordance with the terms hereof), and GILEAD agrees to purchase from APO the Bulk Products, subject to all other terms and conditions of this Agreement, at the Supply Prices provided for in **Schedule “A”** .

**1.2 Acceptance of Manufacturing Location by Regulatory Agencies in General.** Such supply and purchase obligations shall be conditional upon acceptance of the Manufacturing Location by the regulatory authorities of the Territory. With the effective date of [\*] , the EMEA has granted APO a manufacturing authorization to Manufacture the Bulk Product.

**1.3 Acceptance of Manufacturing Location by Regulatory Agencies of the European Community.** APO represents and warrants that it is the holder of the Manufacturing authorization pursuant to Directive 75/319/EEC (as amended) and any implementation of it under the laws of Germany for the manufacturing of certain solid pharmaceutical products at its Manufacturing Location.

**1.4 Manufacturing of Bulk Product for the United States of America .** GILEAD may elect to have APO Manufacturing Bulk Product also for the United States, upon which terms and conditions are to be agreed. In such case , GILEAD shall inform APO of such intention in writing and duly in advance; the Parties shall determine the possible consequences of the Manufacture of the Bulk Product for the US market, and they shall initiate the necessary steps to apply to the FDA for approval of Manufacture of the Bulk Product to be placed on the USA market and to comply with the applicable laws and regulations.

## **SECTION 2** **SUPPLY OF API**

**2.1 Supply of API by GILEAD.** GILEAD or an Affiliate of GILEAD shall supply, or arrange for the supply by their contract manufacturers of, API to APO for the Manufacture of Bulk Product and APO shall Manufacture Bulk Product exclusively from API supplied by GILEAD, an Affiliate of GILEAD, or a contract manufacturer thereof. In respect of the supply of API, the Parties agree as follows:

**2.2 Timely Supply.** GILEAD undertakes by itself or through an assignee to timely supply API directly to the Manufacturing Location as further provided hereinafter. APO shall be under no duty to Manufacture the Bulk Products (including validation batches), nor meet delivery dates provided in the Binding Orders, to the extent that GILEAD does not supply API in a timely fashion, whether said supply is provided by GILEAD or a permitted appointee of GILEAD.

**2.3 Conditions of Supply and Delivery.** GILEAD undertakes to supply API to APO [\*] . All the API provided by GILEAD shall be properly packed, marked, sealed and air-shipped [\*] (Incoterms 2000) in accordance with GILEAD's shipping and packing instructions and with APO's instructions for delivery, provided that at GILEAD's request and expense, APO will provide reasonable assistance in arranging for any necessary import clearance and licenses. Delivery of API shall be made at the Manufacturing Location between 9.00 a.m. and 4.00 p.m. during Working Days.

**2.4 Certification and Incoming Inspection of API.** The API delivered by GILEAD or its permitted appointee shall be in compliance with the Specifications and any other legal requirements and shall be accompanied by a Certificate of Analysis and a Certificate of Compliance. GILEAD will include the information about gross weight, net weight and tara on the label of each barrel of API. APO agrees to inspect the API delivered and to check it solely for identity, quantity and conformity with the bill of lading and, as far as reasonably possible, any damages suffered during shipping and any other obvious defects of the API delivered within [\*] following receipt. APO will check the gross weight of each barrel within such [\*] period and will confirm the net weight of each barrel in the course of performing the API weighing process for production orders.

**2.5. Failure of API to satisfy Incoming Inspection.** If the API delivered by GILEAD or its

permitted appointee to APO fails the inspections to be carried out during the [\*] following receipt as provided under Section 2.4 above, due to a discrepancy from the bill of lading due to lack of identity or a difference in gross weight, or to physical damages or other obvious defects, APO undertakes to notify GILEAD without undue delay in writing. GILEAD shall, upon receiving such written notice from APO, use commercially reasonable efforts to replace the rejected API as soon as reasonably possible; in any event, the provisions of Section 2.9 shall apply.

**2.6. Title to API.** All API (whether being held for Manufacture or in the process of Manufacture) supplied to APO by GILEAD or by a permitted appointee of GILEAD in accordance with this Agreement shall at all times be and remain the property of GILEAD, and shall be treated by APO in all respects as such, and shall be stored and handled in a manner to prevent contamination by other drugs and chemicals and in accordance with GILEAD's instructions as set forth in **Schedule "D"** hereto, which GILEAD may update from time to time with APO's approval, not to be unreasonably withheld.

**2.7 API Lost or Destroyed.** APO shall compensate GILEAD for any API lost or destroyed during the storage of API, or during the Manufacture or storage of the Bulk Product, which in any Year [\*] which will be set forth in accordance with **Schedule "H"** hereto, at the price as likewise set forth under such **Schedule "H"**, [\*]. In any event, it remains understood and agreed between the Parties that APO shall not be responsible for any loss or damage to the API, except where such loss or damage [\*] provided under Section 1.1 or is otherwise due to [\*]; and that APO's liability shall be limited to [\*] as likewise set forth under **Schedule "H"**. Upon a determination that API has been lost or destroyed such that APO is required to compensate GILEAD, APO shall [\*] GILEAD for the compensable amount.

**2.8. Defects of Bulk Product attributable to Defective API.** With respect to defects of the Bulk Product attributable to defective API, the provisions of Section 8.5 of this Agreement shall apply.

**2.9. Delays in Delivery of API or Replacement Deliveries of API pursuant to Section 2.4.** If GILEAD should fail to make timely delivery of API, or of a replacement delivery of API, to APO, the provisions of Section 2.1 hereof shall apply and APO shall not be liable for any breach of its obligations hereunder due to such events caused by GILEAD, *provided, however*, that APO shall be liable for any breach of its obligations due to failure to properly and timely inspect API pursuant to Section 2.4.

**2.10 Destruction of Defective API.** If API in the possession of APO is determined by the Parties to be defective, then APO will destroy it in compliance with GILEAD's instructions and applicable laws, rules and regulations, with GILEAD to bear the expenses thereof unless the defect was introduced after delivery to APO pursuant to Section 2.3.

### **SECTION 3** **MANUFACTURING LICENSE; MANUFACTURING BULK PRODUCT BY APO**

**3.1 Manufacturing License.** In relation to the grant of the Manufacturing license by GILEAD to APO for purposes of this Agreement, the Parties agree as follows:

**3.1.1 Grant of Manufacturing License.** GILEAD grants APO a non-exclusive, royalty-free, non-sublicensable, non-transferable license for the entire term of this Agreement, under all

patents Controlled by GILEAD that, but for the grant of this license, would be infringed by the Manufacture by APO of Bulk Product in accordance with this Agreement, and under all Know-how Controlled by GILEAD that is necessary or reasonably useful to the Manufacture by APO of Bulk Product in accordance with Agreement, to Manufacture the Bulk Product at the Manufacturing Location for the sole purpose of supply for the Territory of the Bulk Product so Manufactured to GILEAD, an Affiliate, or one of their contract manufacturers of Finished Product, indicated to APO in writing duly in advance, in accordance with the terms and provisions of this Agreement.

APO shall be responsible for the Manufacture of Bulk Product. Accordingly, GILEAD shall be responsible for the finishing of the Bulk Product into the Finished Product and, as holder of the Marketing Authorizations for the Territory, GILEAD shall release and place the Finished Product on the market.

**3.1.2 Transfer of Manufacturing and Quality Control Procedures.** To the extent reasonably necessary for the exercise by APO of the rights granted by GILEAD under Section 3.1.1 hereof and to the extent not already performed pursuant to Section 3.2 hereof, GILEAD shall make available to APO all Manufacturing and quality control procedures, including the related Know-How of GILEAD and all the other information, necessary to carry out the contracted operations correctly in accordance with the Marketing Authorisations and any other legal requirements.

**3.2 Validation and other Implementation Work Costs.** The validation of the manufacturing process of Bulk Product and of the analytical methods is already performed. If further validation work will be necessary, it will be charged to GILEAD based on the then-current daily rates; the daily rates will be those generally offered to APO's customers.

**3.3 Manufacturing Standards.** In the Manufacturing of the Bulk Product, APO agrees to adhere to (i) the quality standards and testing methods of GILEAD indicated in the Specifications; (ii) the Quality Agreement; (iii) any other condition provided under the Manufacturing Authorisation and the Marketing Authorisation; (iv) the cGMPs; as well as (v) any additional manufacturing standards agreed upon by the Parties in writing. Subject to what is provided under Section 10.2 below, APO agrees not to unreasonably withhold its consent to the implementation of any such additional manufacturing standards to the extent that GILEAD reimburses APO's out-of-pocket-costs, excluding overheads pertaining to the implementation of any such additional manufacturing standards.

**3.4 Manufacturing Capacity.** During the Term of this Agreement, APO agrees to use commercially reasonable efforts to allocate sufficient Manufacturing resources in order to meet GILEAD's requirements of the Bulk Product scheduled for delivery in accordance with Section 5 and 6 hereof. Nothing in this Section 3.4 is intended to negate APO's obligations to fulfil Binding Orders accepted pursuant to Section 6.3 or to prevent GILEAD from submitting aggregate Binding Orders that APO will accept, if otherwise properly submitted, for a calendar year for the applicable Yearly Minimum Volume.

**3.5 Quality Agreement, Change Control.** The pharmaceutical responsibilities of APO and GILEAD, in particular the procedures applicable in the event of any changes of the Specifications, and/or GILEAD's instructions for the packing and dispatch labelling of the Bulk Product, are set forth in the Quality Agreement attached hereto as **Schedule "B"**.

**SECTION 4**  
**TERM AND RENEWAL**

**4.1.Term.** Subject to any extension pursuant to Section 4.2. below, this Agreement shall commence on the Effective Date and shall run until [\*] (the “**Initial Term**”), unless it is terminated on an earlier date in accordance with Section 17 hereof.

**4.2 Extension.** GILEAD shall give written notice of its willingness to extend the duration of this Agreement to APO at least [\*] months before expiry of the Initial Term. The Parties will negotiate in good faith the conditions of the extension of the Agreement. Should the Parties not reach an agreement on such conditions within [\*] months of receipt of said written notice, then this Agreement shall expire at the end of its Initial Term.

**SECTION 5**  
**YEARLY MINIMUM VOLUMES OF PURCHASES**  
**LONG TERM FORECASTS FOR BULK PRODUCT**

**5.1. Minimum Volumes of Purchases.** GILEAD undertakes to guarantee the yearly minimum volumes of purchases of Bulk Products to be Manufactured by APO as set forth in **Schedule “I”** attached hereto (the “**Yearly Minimum Volumes**”). The Yearly Minimum Volumes shall be firm and binding on GILEAD and shall not be subject to reduction, *provided, however*, that if GILEAD orders an amount of Bulk Product for delivery in a calendar year that is less than the applicable Yearly Minimum Volumes, GILEAD shall not be in breach of this Section 5.1 if it exceeds the applicable Yearly Minimum Volume during any of the following Years by an amount equal to the shortfall from the Yearly Minimum Volume in the that prior calendar year.

**5.2. Long Term Rolling Forecast for Bulk Product.** Subject to what is provided under Section 5.1, for the entire term of the Agreement, within the first [\*] Working Days of each calendar month (“**M**”), GILEAD shall submit to APO its updated written long term rolling forecast for Bulk Product, (hereinafter the “**Long Term Rolling Forecast for Bulk Product**”) showing GILEAD’s estimated requirements for the Bulk Product to be produced and delivered to GILEAD during the following [\*] period beginning with such month M. The forecast for months M+ [\*] through M+ [\*] shall be non-binding.

**SECTION 6**  
**PURCHASE ORDERS**

**6.1 Binding Orders for Bulk Product.** Within the first [\*] Working Days of each month M, GILEAD shall submit to APO its written binding orders (the “**Binding Orders**”) for Bulk Product to be manufactured and delivered by APO in month M+ [\*] .

The Binding Orders submitted to APO shall specify GILEAD’s purchase order number, quantities of the Bulk Product, monthly delivery schedule and any other elements necessary to ensure the timely production and delivery of the Bulk Product by APO. The quantities of Bulk Product ordered in such written orders shall be firm and binding on GILEAD and shall not be subject to reduction.

**6.2 Binding Orders for Bulk Product in batch size.** Subject to what is provided under Section 3.4, GILEAD shall place with APO Binding Orders for the Bulk Product for a full batch size or multiples thereof, whereby it is understood that one (1) batch shall comprise approximately [\*] of the Bulk Product. It is furthermore understood by the Parties, that it is foreseen, that APO shall Manufacture the Bulk Product batches in campaigns of at least [\*] batches preferably in not more than [\*] campaigns per year which should be regularly distributed over the year. Therefore GILEAD shall consider this opportunity in its production planning and the following submission of its Binding Orders.

**6.3 Acceptance of Binding Orders for Bulk Product by APO.** APO is obliged to accept the Binding Orders placed by GILEAD pursuant to Sections 6.1 and 6.2 for as long as the quantities ordered do not exceed applicable Yearly Minimum Volume. APO shall use commercially reasonable efforts to supply Bulk Product in excess of the applicable Yearly Minimum Volume (subject to Section 3.4) and to supply Bulk Product in excess of [\*] of GILEAD's previous Long Term Rolling Forecast for Bulk Product for the applicable calendar year, but shall not be obligated to supply such quantities if it is not able to do so by use of commercially reasonable efforts, and APO shall be allowed to take into consideration in making its commercially reasonable decision to supply the quantity of the excess amounts APO's Manufacturing capacity and other manufacturing commitments.

**6.4 Addressee of Purchase Orders.** All purchase orders shall be sent by GILEAD with contemporaneous telephone notification, by email or to APO to the email or fax number set forth below or identified in writing by APO:

ALTANA Pharma Oranienburg GmbH  
Attention: [\*]  
email: [\*]  
Tel. No.: [\*]  
Fax No. : [\*]

APO will acknowledge and either accept or reject purchase orders within [\*]  
[\*] business days of receipt to the email or fax number set forth below:

Attention: [\*]  
Email: [\*]  
Tel. No.: [\*]  
Fax No.: [\*]

**6.5 Prevailing Terms.** To the extent the terms of any Binding Order or acknowledgement are inconsistent with the terms of this Agreement, the terms of this Agreement shall control, and any inconsistent terms are hereby expressly rejected.

**6.6 Reliance by APO.** GILEAD understands and acknowledges that APO will rely on the Binding Orders submitted pursuant to this Section 6 in ordering the Components required to meet such Binding Orders. In addition, GILEAD understands that to ensure an orderly supply of

such Components and to achieve economies of scale in the costs thereof, it may be desirable for APO to purchase such Components in sufficient volumes to meet the production requirements for the Bulk Product during part or all of the forecasted periods referred to in Section 5 or to meet the production requirements of any longer period as APO and GILEAD may agree to. Accordingly, GILEAD agrees that purchases may be made by APO in respect of the Components to satisfy the production requirements for the Bulk Product for forecasted periods to meet production requirements during such longer periods as may be agreed to in writing from time to time by GILEAD at the request of APO. If such Components are not included in the Bulk Products purchased by GILEAD within [\*] months after the forecasted month in respect of which such purchases have been made (or such longer period as the Parties may agree), GILEAD will pay to APO its costs thereof and, in the event such Components are incorporated into the Bulk Products subsequently purchased by GILEAD, GILEAD will receive credit for any costs of such Components previously paid to APO by GILEAD.

## **SECTION 7**

### **DELIVERY**

**7.1 Terms of Delivery of Bulk Product.** Prior to delivery and shipment of Bulk Product, APO will send the Release Documents to GILEAD at the following email or, with prior notification by telephone by fax, as follows:

Attention: [\*]

Address: Unit 13, Stillorgan Industrial Park, Blackrock, Co. Dublin, Ireland

email: [\*]

Fax no: [\*]

Tel. no: [\*]

APO will not deliver or ship until GILEAD has released the batch and authorized shipment. GILEAD will either release or reject a batch within [\*] business days of receipt of the Release Documents. Bulk Product Deliveries of the Bulk Product shall be made [\*] (as such term is defined in the Incoterms 2000) [\*], provided that APO [\*] (except as otherwise set forth below). Such title as APO has in the Bulk Products and risk of loss or of damage to the Bulk Products shall remain with APO until the Bulk Products are [\*] at which time title and risk of loss or damage shall transfer to GILEAD in accordance with the Incoterms 2000 [\*] clause. APO shall, in accordance with GILEAD's instructions, (i) arrange for shipping and insurance, to be paid by [\*] and (ii) at [\*] risk and expense, obtain any export licence or other official authorization and carry out all customs formalities necessary to export the Bulk Products. GILEAD, at its election, may select the freight carrier used by APO to ship the Bulk Products, informing APO of the name thereof reasonably in advance, and may monitor APO's shipping and freight practices as they pertain to this Agreement.

Transport conditions shall be based upon GILEAD's instructions for the transportation of the Bulk Products.

**7.2 Accompanying Documentation.** With each shipment of the Bulk Product, APO shall provide GILEAD with the appropriate documentation, including but not limited to bills of lading, certificate of analysis and certificate of compliance, and an invoice for such shipment. APO

undertakes, with prior notification by telephone, to email or fax to GILEAD a copy of each bill of lading to the attention of the following employee of GILEAD or as otherwise instructed by GILEAD in writing duly in advance:

Attention: [\*]

Address: Unit 13, Stillorgan Industrial Park, Blackrock, Co. Dublin, Ireland

email: [\*]

Fax no: [\*]

Tel. no: [\*]

**7.3 Short Deliveries.** Subject to what is provided under Section 8.2.4 below, acceptance by GILEAD of deliveries falling short of the quantities ordered and confirmed by APO shall be without prejudice to GILEAD's rights in relation to any such shortage.

## **SECTION 8**

### **DEFECTIVE BULK PRODUCT**

**8.1 Defective Bulk Products.** Quantities of the Bulk Product shall be deemed to be defective if such quantities do not comply with APO's warranties under Section 13.1 hereof (the "**Defective Bulk Product(s)**") and, in relation to any such non-compliance with APO's warranties under Section 13.1 (the "**Defect(s)**").

**8.2 GILEAD's Duties to inspect and confirm; Implied Waiver.** GILEAD agrees to inspect and confirm incoming shipments of Bulk Product as follows:

**8.2.1 Incoming Inspection.** GILEAD shall inspect, or cause its Affiliates or manufacturers to inspect, Bulk Product supplied by APO for transport damages, completeness, compliance as to quantity or timing as stated in the Binding Orders and, as far as reasonably possible, any other obvious defects within [\*] following receipt; GILEAD shall give APO written notice of all claims for any such obvious defect within such [\*] period.

**8.2.2 Additional Quality Control Procedures.** Thereafter, GILEAD may perform quality control procedures to be agreed between the Parties in writing with respect to Bulk Products supplied by APO no later than [\*] after receipt of the delivered Bulk Products in order to check if the delivered Bulk Product meet the Specifications.

**8.2.3 Notification of Defects.** GILEAD shall inform APO by prompt written communication (telex, fax) of any Defect as hereinafter defined, in any event such notice to be received by APO in case of defects due to a discrepancy from the bill of lading due to lack of identity or a difference in gross weight, or to physical damages, other obvious defects, or defects that reasonably should be detected by any additional quality control procedures that GILEAD may perform under Section 8.2.2 ("**Detectable Defects**"), within [\*] of receipt of the Bulk Product, and, in case of other Defects, i.e. those not reasonably detectable by the inspections in Section 8.2.1 or the procedures carried out pursuant to Section 8.2.2 ("**Non-Detectable Defects**"), within [\*] of discovery by GILEAD.



Any such notification of defects shall be made by notice given by courier under the following address, or, with contemporaneous telephone notification, by either fax to the number given below or email to the address below:

ALTANA Pharma Oranienburg GmbH  
Quality Control Dept.  
[\*]  
[\*]  
Germany

Attention: [\*]  
Tel. No.: [\*]  
Fax No.: [\*]  
Email: [\*]

**8.2.4 Implied Waiver.** Failure of GILEAD to inspect or to perform agreed quality control procedures, and to notify in writing APO in the relevant time periods specified in Sections 8.2.1, 8.2.2 and 8.2.3 above of any Detectable Defect, or to notify in writing APO within the pertaining time period specified in Section 8.2.3 above of any Non-Detectable Defect after its discovery, shall constitute a waiver of any rights relating to such Defects, unless otherwise agreed in writing.

**8.3 Disagreement as to Defects.** In the event of a disagreement between APO and GILEAD in respect of any Defects of the Bulk Product, GILEAD and APO shall conduct a joint investigation in accordance with GILEAD's and APO's quality control procedures governing the re-testing of the Bulk Product, in order to determine if any Bulk Product has a Defect. Should the Parties fail to agree within [\*] days after receipt of GILEAD's deficiency notice delivered to APO pursuant to Section 8.2.1 and/or Section 8.2.3 above as to whether any Bulk Product identified in such GILEAD's notice has a Defect, the Parties shall submit a representative sample of the rejected Bulk Product to an independent laboratory acceptable to both Parties for testing under GILEAD's quality control procedures. The findings of such third party laboratory shall be binding upon the Parties, and if such evaluation certifies that any Bulk Product is Defective, Sections 8.4, 8.5 and 8.6 below shall apply. The fees and expenses of such Third Party laboratory shall be borne by the Party against whom the finding is made.

**8.4 Remedies in relation to Defective Bulk Products.** Subject to Section 8.5 and subject to appropriate notification of GILEAD of potential Defects in Bulk Products in accordance with Section 8.2 above and to a confirmation of any such Defects in accordance with Section 8.3 above due to APO's failure to produce the Bulk Products in compliance with the Specifications and with any other warranties as specified in Section 13.1 below, APO shall forthwith after receiving written request thereof from GILEAD (i) in case of a visible Defect, sort the rejected Bulk Product from any non-rejected Bulk Product (ii) in case of any Defect, whether visible or not, replace the rejected Bulk Product in the next available campaign. GILEAD shall supply APO with the additional API for new batches at no additional costs for APO, provided that API quantities used to Manufacture such Defective Bulk Product shall be subject as applicable to the compensation provisions of Section 2.7. If GILEAD reasonably determines after consultation with APO that the timing of any projected replacement by APO of rejected Bulk Product during the next available campaign may cause GILEAD to have insufficient inventories of Finished

Product to meet its requirements for Finished Product, GILEAD shall have the right to have another supplier provide such replacement batch of Bulk Product. Subject to the other provisions of this Agreement, GILEAD's remedies under this Section 8.4 shall be cumulative with other remedies it may have under this Agreement.

**8.5 Defects of Bulk Product attributable to Deficiencies of API.** Subject to what is provided under Section 2 above, APO shall have no responsibility for any Defects in the Bulk Products which are due to deficiencies of API provided that such Defects are not attributable to APO's breach of its obligations to inspect the API delivered in accordance with Section 2.4 above.

**8.6 Limitation of Liability.** Except in the circumstances where APO has failed to comply with the Specifications and any other warranties as specified in Section 13.1 above, APO shall not be liable or have any responsibility for any deficiencies in, or other liabilities associated with, any Bulk Product manufactured by it, including, without limitation, any deficiencies contained in the formulae and procedures specified by GILEAD in the Specifications and effects deriving from compliance with legal requirements as specified in Section 13.1, or which are connected to the safety, efficacy or marketability of the Bulk Products or any distribution risk.

**8.7 Consequential Damages.** Neither Party shall be liable to the other for any consequential damages, except in the case of Party's gross negligence or intentional misconduct .

## **SECTION 9** **API OR BULK PRODUCT SHORTFALLS**

If at any time during the Initial Term and any extension of this Agreement, APO is or expects that it will be unable to satisfy GILEAD's requirements of Bulk Product, in full or in part, or GILEAD is or expects that it will be unable to satisfy APO's requirements of API, then that Party shall promptly notify the other Party, detailing the extent to which it will not meet such requirements. Nothing in this Section 9 is intended to relieve a Party of its other obligations under this Agreement.

## **SECTION 10** **PRICING AND CHANGES**

**10.1 Supply Price .** APO shall Manufacture and supply the Bulk Product to GILEAD at the Supply Price set forth in **Schedule "A"** . Subject to Section 10.2, the Supply Price shall be in force during the Initial Term of this Agreement.

**10.2 Changes in Manufacturing, Quality Control and Packaging of the Bulk Product.** With respect to any changes of the Manufacturing, quality control and packaging of the Bulk Product (hereinafter collectively referred to as "**Change(s)** "), the Parties agree with respect to the implication on the Supply Price as follows:

**10.2.1 Changes requested by GILEAD .** If GILEAD requests a Change which would result in an increase in APO's costs for Components or for manufacturing, controlling or packaging the Bulk Product, the Parties shall discuss in good faith what impact, if any, such Change will have on the Supply Price of the Bulk Product, and APO shall propose in good faith a proposal that

states the price change due to implementation of such a Change. If GILEAD should accept a proposed price change, the proposed Change shall be implemented, and the price change shall become effective only with respect to those orders of the Bulk Product which are manufactured in accordance with the revised Specifications. Unless a proposed Change would cause extreme disruption to APO's other operations at the Manufacturing Facility, APO will be obligated to implement such Change if GILEAD accepts APO's good faith proposal for a price change.

Notwithstanding any Change in the Specifications implemented in accordance with the terms of Art. 10.2.1 above, GILEAD agrees to purchase all the Bulk Product manufactured by APO based upon any Binding Order relying on "old" Specification at the "old" price for those Bulk Product. In addition, GILEAD agrees to purchase all Components and Inventory utilised under the "old" Specifications and purchased or maintained by APO in order to fulfil Binding Orders in accordance with Section 6 of the Agreement, to the extent that such Components and Inventory can no longer be utilised under the revised Specifications. Open purchase orders for Components no longer required under any revised Specification which were placed by APO with suppliers in order to fulfil Binding Orders in accordance with Section 6 of the Agreement shall be cancelled where possible, and where such orders are not subject to cancellation without penalty, shall be assigned to and satisfied by GILEAD.

**10.2.2 Other Required Changes.** In any event, should a Change become necessary in order to allow APO to guarantee the performance of the activities in a state of the art way or to comply with new provisions or compulsory requests of the regulatory authorities or, in any event, with APO's obligations under this Agreement, APO shall immediately inform GILEAD accordingly and the provisions set forth in Art. 10.2.1 above shall apply, *provided, however*, that if such Change is not specific to the Bulk Product but instead relates to compliance of the Manufacturing Facility or APO's general procedures with GMP, any increased costs to APO would be allocated equitably and consistently across all products manufactured by APO at the Manufacturing Facility.

## **SECTION 11**

### **PAYMENT**

**11.1 Invoicing.** APO shall issue invoices for the payment due from GILEAD for Bulk Product shipped to GILEAD, and all invoice amounts shall be expressed, and all payments made in Euros.

**11.2 Payment.** Payment shall be made by GILEAD to APO within [\*] days of the date of each invoice sent pursuant to Section 7.2.

**11.3 Currency.** Unless otherwise agreed, all monetary amounts are expressed in this Agreement in Euros.

## **SECTION 12**

### **GENERAL INFORMATION DUTIES**

**General Duties to inform.** Each Party to this Agreement shall keep the other Party fully informed of any notification or other information, whether received directly or indirectly which

might affect the marketability, safety or effectiveness of the finished drug product or which might result in the recall or seizure of the registration / market validation lots.

### **SECTION 13**

#### **WARRANTIES**

**13.1 Representations and Warranties of APO.** APO makes the following representations and warranties with respect to the Bulk Product sold hereunder: **(i)** the Bulk Product shall be of merchantable quality and shall fully comply with all Specifications; **(ii)** In Manufacturing the Bulk Product, APO shall adhere to **(a)** the quality standards and testing methods of GILEAD set forth in the Specifications; **(b)** the Quality Agreement; **(c)** any other condition provided under the Manufacturing Authorisation and the Marketing Authorisation; **(d)** the cGMPs; **(e)** any other applicable laws, rules and regulations applicable to manufacture of Bulk Product in territories where Finished Product is to be marketed, as notified by GILEAD; **(f)** any additional manufacturing standards agreed upon by the Parties; as well as **(g)** the Binding Orders.

**13.2 Limitation of Warranty.** The above stated warranty does not apply in the event of improper storage and/or improper handling of the Bulk Product by GILEAD or by any third party.

**13.3 Authority.** Each Party represents and warrants that it has the full right and authority to enter into this Agreement, and that it is not aware of any impediment that would inhibit its ability to perform its obligations hereunder.

**13.4 Formulae.** GILEAD represents and warrants that the Specifications for the Bulk Product are its property and that GILEAD may lawfully disclose such Specifications to APO. GILEAD further represents and warrants that any trademarks utilized by APO in connection with the Bulk Product are its property and may be lawfully used as directed by GILEAD. GILEAD further represents and warrants that the Specifications for the Bulk Product conform to all applicable laws and regulations, and that the Bulk Product if labelled and formulated in accordance with such Specifications and Manufactured in compliance with this Agreement (i) may be lawfully sold and distributed in every jurisdiction in which GILEAD markets the Bulk Product, (ii) will be fit for the purpose intended, and (iii) subject to labelling and application in accordance with applicable laws will be safe for human consumption.

### **SECTION 14**

#### **INDEMNIFICATION**

**14.1 Indemnification by APO.** APO shall indemnify, defend and hold harmless GILEAD, its officers, directors, agents, servants, and employees harmless against all losses, damages, judgments, liabilities, costs and expenses (including reasonable legal expenses) (“**Losses**”) resulting from third party claims, demands, actions, suits or proceedings (“**Third Party Claims**”), arising out of APO’s breach of this Agreement (including breaches of its warranties in Section 13.1) or APO’s negligence or willful misconduct in activities under this Agreement, except in each case to the extent GILEAD has an obligation of defense or indemnity with respect to such Loss or Third Party Claim pursuant to Section 14.2..

GILEAD shall not settle any such Third Party Claim without the prior written approval of APO, and APO shall have the right, if it so wishes, to conduct negotiations to settle, settle or to conduct any litigation arising out of, any such Third Party Claim. GILEAD shall provide prompt written notice of

any such Third Party Claim to APO and shall reasonably co-operate in the defence and/or settlement of any such Third Party Claim at APO's request and expense.

**14.2 Indemnification by GILEAD.** GILEAD shall indemnify, defend and hold harmless APO, its officers, directors, agents, servants, and employees harmless against all Losses resulting from Third Party Claims arising out of (i) GILEAD's breach of this Agreement (including breaches of its warranties in Section 13.4), (ii) for shipments of Bulk Product, the manufacture, use, import, offer for sale, sale, distribution, testing, handling, transport or disposal of Bulk Product or Finished Product following delivery of the relevant Bulk Product pursuant to this Agreement, or (iii) GILEAD's negligence or willful misconduct in activities under this Agreement, except in each case to the extent APO has an obligation of defense or indemnity with respect to such Loss or Third Party Claim pursuant to Section 14.1..

APO shall not settle any such Third Party Claim without the prior written approval of GILEAD, and GILEAD shall have the right, if it so wishes, to conduct negotiations to settle, settle or to conduct any litigation arising out of, any such Third Party Claim APO shall provide prompt written notice of any such Third Party Claim to GILEAD and shall reasonably co-operate in the defence and/or settlement of any such Third Party Claim at GILEAD's request and expense.

**14.3 Survival of Indemnification Obligations.** The indemnification obligations set forth in this Section 14 shall survive the expiration or termination of this Agreement.

## **SECTION 15** **CONFIDENTIALITY**

**15.1 General Principle.** “**Confidential Information**” shall mean confidential or proprietary information of a Party either disclosed orally or in writing to or otherwise learned by the other Party that should reasonably be known to be confidential or proprietary to the disclosing Party, including but not limited to such Party's: research, development, preclinical and clinical programs, data and results; pharmaceutical or biologic candidates and products; inventions, works of authorship, trade secrets, processes, conceptions, formulas, patents, patent applications, and licenses; business, product, marketing, sales, scientific and technical strategies, programs and results, including costs and prices; suppliers, manufacturers, customers, market data, personnel, and consultants. Each Party agrees to hold in strict confidence any and all Confidential Information of the other Party disclosed to it, to use such Confidential Information only for the purposes of this Agreement, and to restrict access to such Confidential Information to those persons entrusted to carry out the activities provided for hereunder and who are subject to the same secrecy obligation. Each Party will protect the confidentiality of Confidential Information of the other Party using the same level of effort it uses to protect its own confidential or proprietary information of a similar nature but in no event less than a commercially reasonable level of effort.

**15.2 Exceptions.** Excepted from the secrecy obligations in Section 15.1 shall be any Confidential Information: **(i)** which is in public domain at the time of disclosure; **(ii)** which is published or otherwise becomes part of the public domain through no fault of the receiving Party; **(iii)** which was in the possession of the receiving Party at the time of disclosure as shown by prior written records; **(iv)** which becomes available to the receiving Party without secrecy obligations from a third party

who has the right to disclose it without breach of any obligation to the other Party; (v) or, of which the receiving Party can clearly and convincingly prove that it was independently developed by employees of the receiving Party who had no access to the Confidential Information disclosed.

**15.3 Required Disclosure.** Notwithstanding any other provision of this Agreement, each Party may disclose Confidential Information of the other Party to the extent and to the persons or entities as required by applicable governmental law, rule, regulation or order (including to Regulatory Agencies for the purposes of this Agreement), provided that it first notifies the other Party of such disclosure requirement to enable it to seek any available Exception from this secrecy obligation shall further be Information or Know-How which has to be disclosed to the EU Regulatory Agencies for the purposes of this Agreement or which GILEAD is entitled to disclose according to this Agreement.

**15.4 Duration of Confidentiality Obligations.** The confidentiality obligations of the Parties shall survive this Agreement for a period of ten (10) years.

## **15.5 Improvements**

**15.5.1** APO acknowledges and agrees that it has no proprietary intellectual property rights in or to the current manufacturing process for the Finished Product, as set forth in the Specifications. APO shall not perform any Manufacturing other than for Manufacture of Finished Product for supply to Gilead pursuant to this Agreement, and APO shall not perform any process development or otherwise attempt to modify the Manufacturing process without Gilead's prior written consent.

**15.5.2** The Parties acknowledge that they, independently or jointly, may develop improvements to the Specifications, inventions and other know-how (including without limitation data, information, processes, techniques, methods, and unpatentable inventions) in the course of fulfilling their obligations under this Agreement ("Improvements"). Subject to Section 15.5.3, (i) APO shall own all right, title and interest in and to Improvements that are general manufacturing Improvements that have application beyond manufacture and processing of [\*] (including Finished Product and finished products incorporating [\*] to the [\*]) ("APO Improvements"), and (ii) Gilead shall own all, right, title and interest in and to all other Improvements ("Gilead Improvements"). Each Party hereby assigns its entire right, title and interest in Improvements that are to be owned by the other Party pursuant to this Section 15.5.2, and all patents and copyrights that may be obtained thereon and trade secrets and other intellectual property rights therein ("Improvements IP"), to the other Party, and each Party will take all reasonable steps and execute and deliver all documents reasonably required for the other Party to evidence or record such assignment as applicable. Each Party shall only use in its performance under this Agreement, its employees or consultants who have agreed in writing to assign Improvements to it.

**15.5.3** APO hereby grants to Gilead an irrevocable, nonexclusive, worldwide, royalty-free license under the APO Improvements and the APO Improvements IP to research, develop, make, have made, use, sell, offer for sale, import and otherwise commercialize Gilead's (and its Affiliates' and licensees') products throughout the world, with the right to sublicense (through one or more tiers of sublicensees to Affiliates of Gilead, licensees with exclusive or co-exclusive commercialization rights to such products to in one or more countries, and contract manufacturers).

**SECTION 16**  
**TERMINATION**

**16.1     Either Party's Right to terminate for Cause.** Either Party shall have the right to terminate this Agreement for cause in any of the following events:

**16.1.1     Termination for Material Breach.** Without prejudice to any remedy or claim it may have against the other Party for material breach or non-performance of this Agreement, either Party shall have the right to terminate this Agreement for cause in the event that the other Party fails to materially comply with or perform any material provision of this Agreement (the “**Breach**”) in accordance with the following provisions:

**16.1.1.1** The terminating Party shall notify the terminated Party of any such Breach in writing, specifying such Breach in reasonable detail and stating its intention to terminate this Agreement for cause (the “**Reminder**”).

**16.1.1.2** In the event that the terminated Party either (i) if the Breach is of such a nature that it can be reasonably expected to be cured within a [\*] day period (for example, as with an obligation to make payment of monies), fails to cure such Breach within a period of [\*] days following receipt by the terminated Party of such Reminder (the “**Remedy Period**”), or (ii) if the Breach is of such a nature that it cannot be reasonably expected to be cured within a [\*] day period, if the terminated Party fails to establish to the reasonable satisfaction of the terminating Party that it is diligently and actively pursuing a cure at the expiration of such Remedy Period, , the terminating Party shall be entitled to terminate this Agreement within a period of [\*] following the expiry of such Remedy Period with immediate effect by giving the terminated Party related written notice.

**16.1.1.3** In the event that the terminated Party, under the circumstances referred to under (ii) of Section 16.1.1.2 above, can establish to the reasonable satisfaction of the terminating Party that it is diligently and actively pursuing a cure at the expiration of the Remedy Period, then such Remedy Period shall be extended for so long as a cure is being diligently and actively pursued, such extension not to exceed [\*] days in the aggregate (the “**Extended Remedy Period**”). For clarity, the Remedy Period and the Extended Remedy Period together shall not exceed [\*] days.

**16.1.1.4** In the event that the terminated Party shall not have cured the Breach pursuant to Section 16.1.1.3 above at the end of such Extended Remedy Period, the terminating Party may exercise its termination right for Breach within a period of [\*] following the expiry of such Extended Remedy Period by giving the terminated Party related written notice.

**16.1.2     Termination for Reasons of Insolvency or Termination of Business Activities.** Either Party shall be entitled to terminate this Agreement if the other Party becomes insolvent or is subject of a petition in bankruptcy whether voluntary or involuntary or of any other proceeding under bankruptcy, insolvency or similar laws, or if this Agreement is assigned by such other Party for the benefit of creditors. Such termination right may be exercised within a term of [\*] following the date as of which the Party entitled to terminate receives knowledge of such insolvency or termination of business activities by the other Party, by giving the terminated Party

related written notice

**16.1.3 Termination for Medical or Regulatory Reasons.** GILEAD shall be entitled to terminate this Agreement in case of medical or regulatory reasons which prevent the use of Finished Product in humans or in case approval of Finished Product is rejected or withdrawn by EU or foreign Regulatory Agencies or in case of other serious safety reasons and GILEAD has undertaken serious attempts to remove the reasons therefore.

**16.2 Financial Consequences in Case of Termination.** Upon expiration or termination of this Agreement GILEAD shall, to the exclusion of other financial obligations of GILEAD except as specifically provided for herein: (i) purchase, at APO's cost, the Inventory applicable to the Bulk Product which was purchased, produced or maintained by APO in contemplation of filling Binding Orders and that is suitable for production of Bulk Product; (ii) purchase from APO all undelivered Bulk Products already firmly ordered in accordance with the ordering terms of Section 5.2, at the price in effect at the time the Binding Order was placed; and (iii) satisfy the purchase price payable pursuant to APO's orders with suppliers of Components, provided such orders were made by APO in reliance on Binding Orders. The provisions of this Agreement relating to delivery, acceptance, rejection and payment or and for Bulk Product shall govern delivery and purchase of such Bulk Product under (ii) and (iii).

If the Agreement is terminated by GILEAD pursuant to Section 16.1.1 as a result of a Breach by APO or pursuant to Section 16.1.3, GILEAD agrees to purchase such of the items referred to in (i), (ii) and (ii) above as it determines, acting reasonably, can be used by it.

**16.3 Return of Stocks of API.** In case of the expiration or termination of this Agreement for any reason whatsoever, APO shall, at GILEAD's request and option, return to GILEAD or its designee or destroy all stocks of API remaining at APO, the costs of transportation or destruction to be borne by GILEAD, or, in the case of a termination of this Agreement by GILEAD pursuant to Section 16.1.1 as a result of a Breach by APO or pursuant to Section 16.1.3, by APO.

**16.4 Termination of Manufacturing License.** Effective upon the expiration or termination of this Agreement for any reason whatsoever, the Manufacturing license granted by GILEAD to APO under Section 3.1 shall terminate, and the rights of each Party to Information and Know-How of the other Party shall expire with immediate effect. APO shall either, at GILEAD's option, return or destroy all Information and Know-How of GILEAD and all copies, extracts, summaries and derivatives thereof, in its possession and shall certify to GILEAD the completion thereof.

## **SECTION 17** **NOTICES**

Unless otherwise specified herein, any notice or other communication required or permitted to be given under this Agreement may be delivered personally or be sent by prepaid certified or registered post, courier or facsimile transmission (with receipt acknowledged or confirmed) addressed to the Party addressed as follows:

If to GILEAD:     [\*]



Gilead Sciences Inc.  
333 Lakeside Drive  
Foster City, CA 94404  
USA  
Fax No.: [\*]  
Tel. No.: [\*]  
Email: [\*]

with a copy to: Gilead Sciences, Inc.  
333 Lakeside Drive  
Foster City, CA 94404  
USA  
Attention: Vice President and General Counsel  
Fax No.: [\*]

and

if to APO: [\*]

Tel. No.: [\*]  
Fax No.: [\*]  
Email: [\*]

and any such notice or other communication shall be deemed to be effective upon receipt by the Party to which it is addressed if received during a Working Day or otherwise at the start of the next Working Day. Any Party may change the address to which notice is to be given as provided herein by giving the other Party related written notification.

## **SECTION 18**

### **DISPUTE RESOLUTION AND GOVERNING LAW**

**18.1 Disputes.** In the event of any dispute, claim, question or disagreement arising out of or relating to this Agreement (a “**Dispute**”), the Parties shall use all reasonable efforts to settle such Dispute by amicable negotiations within a period of [\*] days of one Party giving notice of the Dispute to the other Party.

**18.2 Arbitration.** Should the Parties not manage to settle the dispute by amicable negotiations within the such period of [\*] days, all disputes shall be finally settled under the rules of conciliation and arbitration of the International Chamber of Commerce (the “Rules”) by three arbitrators, reasonably fluent in English, one appointed by each of the Parties and the third one, who shall act as Chairman, by the other two arbitrators, or, in the event of their failure to reach agreement within [\*] days of the appointment, in accordance with the Rules.

The arbitration procedure will take place in Geneva and will be conducted in the English language.

The decision of the arbitrators will be final and binding upon the Parties.

**18.3 Governing law.** This Agreement shall be construed and enforced in accordance with the laws of Switzerland.

## **SECTION 19** **ASSIGNMENT AND SUBCONTRACT**

**19.1 Assignment.** This Agreement may be assigned by GILEAD provided that:

(i) GILEAD shall inform APO of said assignment in writing and in advance; and (ii) any assignee shall covenant in writing with APO to be bound by the terms of this Agreement.

APO may assign this Agreement to subsidiaries of APO only with prior written agreement by GILEAD which agreement shall not be unreasonably withheld.

**19.2 Subcontract.** APO may subcontract, in whole or in part, to third parties the performance of the activities contemplated under Section 3 above entrusted to it by this Agreement, provided that APO shall bear any additional costs possibly related to this appointment. In any event, before subcontracting the performance of the aforesaid activities to third parties, APO must first receive written consent from GILEAD.

**19.3** [\*] shall be APO's counterparty to for [\*] supplies of Bulk Product, and [\*] will have the rights and obligations of GILEAD hereunder to the extent pertaining to [\*] supplies of Bulk Products. [\*] shall be APO's counterparty to for [\*] supplies of Bulk Product and will have the rights and obligations of GILEAD hereunder to the extent pertaining to [\*] supplies of Bulk Products.

## **SECTION 20** **FORCE MAJEURE**

**20.1 Force Majeure.** Neither Party shall be liable for the failure to perform its obligations under this Agreement if such failure is occasioned by a cause or contingency beyond such party's reasonable control, including, but not limited to riots, wars, fires, floods, storms, strikes (excluding strikes and work slow-downs that affect APO but not the German pharmaceutical manufacturing sector generally), interruption of energy supply, or compliance with any order or regulation of any government entity which is not due to any failure or non-compliance of the Party affected. A Party claiming a right to excused performance under this Section 21 shall immediately notify the other Party in writing of the extent of its inability to perform, which notice shall specify the occurrence beyond its reasonable control that prevents such performance and shall indicate its consequences from the stand point of the fulfilment of contractual obligations.

The Party affected by an event of force majeure must use and continue to use every effort in order to continue to perform this Agreement and, subject to the following paragraph, if absolutely necessary the Parties shall co-operate in order to agree upon terms and conditions different from those contained herein, for the continuance of the Agreement itself for the entire period of time the event of force majeure continues.

Should the event of force majeure extend for more than [\*] months, each of the Parties shall be entitled to terminate this Agreement by giving [\*] days written notice thereof to the other Party. Such notice shall indicate, inter alia, the date provided for the termination of the Agreement.

## **SECTION 21**

### **WAIVER**

A waiver of any breach of any provision of this Agreement shall not be construed as a continuing waiver of other breaches of the same or other provisions of this Agreement.

The tolerance by either of the Parties, even if continued or repeated, of breaches by the other Party of provisions contained in any clause of this Agreement shall not constitute a waiver nor it may in any way affect the validity of the clause being breached, so long as the breach is contested within [\*] days of the date of the event by way of registered letter with return receipt.

## **SECTION 22**

### **NO PARTNERSHIP**

The relationship established hereby between GILEAD and APO is in all respects a commercial relationship. Nothing herein shall be construed as imposing any fiduciary obligations on either Party, or as establishing any partnership or joint venture between the Parties, or as rendering one Party an agent of the other.

## **SECTION 23**

### **ENTIRE AGREEMENT**

This Agreement constitutes the entire agreement between the Parties with reference to the subject matter hereof and supersedes any prior agreements with respect to such subject matter.

Any modification, amendment or supplement to this Agreement must be in writing and signed by authorised representatives.

The “WHEREAS” and the documents attached as Schedules to this Agreement form an integral and substantial part of this Agreement. The headings to the Sections of this Agreement are for convenience only and shall be disregarded in interpreting and construing this Agreement.

## **SECTION 24**

### **SEVERABILITY**

In the event of the invalidity of any provisions of this Agreement or of this Agreement containing any gaps, the Parties agree that such invalidity or gap shall not affect the validity of the remaining provisions of this Agreement. The Parties will in good faith replace an invalid provision or fill any gap with valid provisions, which most closely approximate the purpose and economic effect of the invalid provision or, in case of a gap, the Parties’ presumable intentions. In the event that the terms and conditions of this Agreement are materially altered as a result of

the preceding sentences, the Parties shall renegotiate the terms and conditions of this Agreement in order to resolve any inequities.

**SECTION 25**  
**SURVIVAL**

The termination or expiration of this Agreement for any reason whatsoever shall be without prejudice to any obligations or rights on the part of either Party which have accrued prior to such termination, and shall not affect or prejudice the following provisions of this Agreement which shall survive such termination or expiration: Title to API, Section 2.6; Destruction of Defective API, Section 2.10; Defective Bulk Product, Section 8; General Information Duties, Section 12; Warranties, Section 13; Indemnification, Section 14; Confidentiality, Section 15; Financial Consequences in Case of Termination, Section 16.2; Return of Stocks of API, Section 16.3; Termination of Manufacturing License, Section 16.4; Notices, Section 17; Dispute Resolution and Governing Law, Section 18; Waiver, Section 21; Entire Agreement, Section 23; Severability Section 24; and Survival, Section 25.

**SECTION 26**  
**EXECUTION BY COUNTERPART**

This Agreement may be executed by the Parties in two counterparts, each of which shall be deemed an original and all of which, taken together, shall constitute one and the same instrument.

IN WITNESS WHEREOF, this Agreement has been executed as of the date first above written by the parties' respective duly authorized representatives.

**Gilead World Markets, Ltd.**

**ALTANA Pharma Oranienburg GmbH**

\_\_\_\_\_  
Mark L. Perry, Director

\_\_\_\_\_  
Hans-Joachim Kaatz, General Manager

**Gilead Sciences, Inc.**

\_\_\_\_\_  
Mark L. Perry, Executive Vice President,  
Operations

\_\_\_\_\_  
Dr. Hans-Christian Meyer, Senior Director

**Schedules to this Agreement:**

<b>Schedule "A":</b>	Supply Price
<b>Schedule "B":</b>	Quality Agreement
<b>Schedule "C":</b>	Bulk Product Specifications
<b>Schedule "D":</b>	API and Excipient Specifications; Handling and Storage of API
<b>Schedule "E":</b>	Batch Coding System
<b>Schedule "F":</b>	Dispatch Labelling of APO
<b>Schedule "G":</b>	Shipment Instructions
<b>Schedule "H":</b>	Manufacturing Line [*] of API [*]
<b>Schedule "I":</b>	Yearly Minimum Volumes of Purchases

**Schedule “A”**  
**Toll Manufacturing Agreement**

**Supply Price**

**1. Supply Price coated tablets**

The Supply Price for [\*] shall correspond to [\*] . This price will be fixed till [\*] .

No later than [\*] the end of each year APO shall be entitled to request an adjustment to the fees for the applicable component costs and processing fees in respect of such drug product for increases in manufacturing costs based on the increases in the official index [\*] .

**Schedule “B”**  
**Toll Manufacturing Agreement**

**Quality Agreement**  
**for**  
**the Manufacturing and Supply of**  
**Products for Gilead Sciences, Inc.**

between

**Gilead Sciences, Inc.**

650 Cliffside Drive  
San Dimas, CA 91773

and

335 Lakeside Drive  
Foster City, CA 94404-1147

and

**Gilead Sciences Ltd.**

Unit 13, Stillorgan Industrial Park,  
Blackrock, Co., Dublin, Ireland  
as contract giver

and

**Altana Pharma Oranienburg GmbH**

[\*]

Germany  
as contract acceptor

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**Attachment A: PRODUCTS for MANUFACTURING**

**Attachment B: Contact Information**

**Attachment C: Responsibilities Matrix**



## Introduction

This Quality Agreement (hereinafter “AGREEMENT”) is a required and integral part of the Toll Manufacturing Agreement (hereinafter “Manufacturing Agreement”) between Gilead World Markets, Ltd. and Altana Pharma Oranienburg GmbH (hereinafter “APO”). This AGREEMENT defines the cooperation between Gilead Sciences, Inc., with offices in Foster City, California, and San Dimas, California, and Gilead Sciences Ltd., with offices in Dublin, Ireland, (hereinafter “GILEAD”) and APO with respect to Quality Assurance issues related to all such activities as may be required for the manufacture of those drug products set forth in Attachment A (hereinafter “PRODUCT”), including (as appropriate) the planning, purchasing, manufacture, processing, compounding, storage, filling, packaging, labeling, testing, sample retention, stability testing, release, and dispatch (hereinafter “MANUFACTURE” or “MANUFACTURING”).

Description of Roles between GILEAD sites:

GILEAD Foster City: [\*]

GILEAD San Dimas: [\*]

GILEAD Dublin: [\*]

In the event that there is a discrepancy between the provisions of the Manufacturing Agreement and the provisions of this AGREEMENT, the provisions of this AGREEMENT shall control with respect to terms governing the quality of the PRODUCT and the provisions of the Manufacturing Agreement shall control with respect to all other terms.

In all instances, “written authorization” shall mean communication written on official letterhead or other official forms of written correspondence and signed by the authoring party’s QA representative (as listed in Attachment A). In all instances, “procedures” shall mean company standard operating procedures approved through the change control process.

GILEAD and APO agree as follows:

### 1. Manufacturing of PRODUCT

#### 1.1. Manufacturing Procedures

- 1.1.1 APO shall manufacture the PRODUCT in accordance with principles of current Good Manufacturing Practice (cGMP) as described in the United States *Code of Federal Regulations* (CFR), Title 21, Part 211 and the most current edition of the Rules Governing Medicinal Products in the European Community, Volume IV, Good Manufacturing Practices for Medicinal Products.
- 1.1.2 GILEAD shall provide APO with all the information necessary to carry out the contracted operations correctly in accordance with the marketing authorizations, regulatory filings, and any other legal requirements via a PRODUCT-specific Contractor Manual. GILEAD shall ensure that APO is fully aware of any problems associated with the PRODUCT or the work that might pose a hazard to APO’s premises, equipment, personnel, and/or other materials and products.
- 1.1.3 APO shall manufacture the PRODUCT only in sites registered and/or approved by the US FDA and other applicable regulatory authorities for the manufacture of the PRODUCT.

- 1.1.4 APO shall not subcontract to a third party any part of the MANUFACTURING of the PRODUCT without GILEAD's prior evaluation and written authorization of the arrangements.
- 1.1.5 APO shall assure that the PRODUCT is manufactured, packaged, held, labeled, and tested according to approved procedures and specifications. APO is responsible for shipment of the PRODUCT to GILEAD (or designee) upon written authorization by GILEAD.
- 1.1.6 APO shall advise GILEAD Quality Assurance (QA) prior to implementing any Major change to the approved method of manufacture or specifications. "Major" has the same meaning as set forth in Section 506A (21 U.S.C. 356a) of the US Federal Food, Drug, and Cosmetic Act.
- 1.1.7 Where control of [\*] levels is required and included in the PRODUCT specifications, material specifications, and/or component specifications, APO shall control and monitor the facility environment, utilities and equipment used for the MANUFACTURING of the PRODUCT as per APO procedures.
- 1.1.8 APO shall refrain from any activity that may adversely affect the quality of the PRODUCT manufactured and/or analyzed for GILEAD.
- 1.2. Deviations
  - 1.2.1 APO shall document, justify, and, when appropriate, investigate whenever there is a manufacturing deviation (as defined in APO procedures) from approved procedures or specifications. Included is any suspect and confirmed out-of-specification (OOS) result for GILEAD-related raw material, components, intermediate, in-process specification or finished PRODUCT specification. This documentation shall be retained as part of the batch record(s) for the batch(es) affected.
  - 1.2.2 APO shall notify GILEAD of a manufacturing deviation with influence on the quality of the PRODUCT as defined in APO procedures within [\*] business days.
  - 1.2.3 Reprocessing shall be considered a deviation.
- 1.3. Rejection of Product
  - 1.3.1 APO shall include appropriate GILEAD personnel in any investigation concerning PRODUCT MANUFACTURING.
  - 1.3.2 In the event of rejection of PRODUCT, GILEAD and APO shall proceed per the Manufacturing Agreement.
- 1.4. Compendial Compliance
  - 1.4.1 APO is responsible for compliance to the Compendial methods, specifications, and testing of Compendial articles in the MANUFACTURING of PRODUCT and for control of the environment wherein MANUFACTURING occurs.
  - 1.4.2 GILEAD is responsible for compliance to the Compendial methods, specifications, and testing under its direct control and responsibility.
- 1.5. Materials
  - 1.5.1 APO shall purchase and receive from mutually agreed upon suppliers, inspect, test, release, store, and/or handle materials related to the MANUFACTURING of the PRODUCT, including components and excipients, in accordance with APO procedures and consistent with cGMPs.

- 1.5.2 GILEAD shall provide Active Pharmaceutical Ingredient (API) to APO with a GILEAD Certificate of Analysis.
- 1.5.3 APO shall receive, inspect, and test API from GILEAD.
- 1.5.4 APO shall audit and approve preferred suppliers of materials per APO procedures. GILEAD shall audit and approve GILEAD-specified suppliers, including suppliers of API, per GILEAD procedures.
- 1.5.5 APO shall maintain an approved GILEAD suppliers list in accordance with APO procedures for controlled materials purchased by APO for use in the PRODUCT.
- 1.5.6 APO shall store controlled materials according to specified storage requirements per APO procedures. APO shall have a system in place that ensures that stored material is re-sampled and tested according to specified re-test dates and discarded by specified expiration dates, as applicable.
- 1.5.7 APO shall assure that the potential for cross-contamination from any compound used at the APO facility is satisfactorily controlled via adequate cleaning procedures, dedicated equipment, and/or cleaning validation as appropriate.

#### 1.6. Labeling

GILEAD shall be responsible for, and provide APO with, copy content and artwork for all printed materials associated with the PRODUCT. This includes, but is not limited to, shipping container labels, cartons and inserts. GILEAD shall be responsible for compliance with federal, state, and local regulations and for obtaining regulatory approval for the PRODUCT labeling.

#### 1.7. Distribution

- 1.7.1 APO shall prepare orders and ship PRODUCT by appropriate freight forwarders to arrive in suitable condition at the premises designated by GILEAD.
- 1.7.2 Shipment of PRODUCT shall be conducted upon and according to GILEAD authorization, which shall include quantities and locations for shipment and all other pertinent information.
- 1.7.3 APO shall forward to GILEAD the following Inventory/Shipping documentation:
  - 1.7.3.1 API withdrawals and finished product completion from batch records (every transaction)
  - 1.7.3.2 Shipping Activity (every transaction)
  - 1.7.3.3 [\*]

#### 1.8. Qualification/Validation

- 1.8.1 APO shall qualify and maintain, consistent with cGMP according to APO protocols and procedures, the facilities, utilities, and equipment required to support the MANUFACTURING of the PRODUCT.
- 1.8.2 APO shall qualify cleaning processes for shared equipment in the facility for MANUFACTURING the PRODUCT as per APO protocols and procedures.
- 1.8.3 As specifically contracted by GILEAD (i.e., under separate purchase orders), related APO PRODUCT qualification/validation results shall be assembled in a validation report(s) and provided to GILEAD for review and approval. APO shall maintain original documentation in its site files and provide GILEAD with copies of the approved protocol(s) and report(s).

### 1.9. Reprocessing and Rework

APO shall obtain GILEAD approval prior to performing reprocessing and/or rework of the PRODUCT.

## 2. Testing of PRODUCT

### 2.1. Sampling , Inspection, and Testing of PRODUCT

2.1.1 The sampling, inspection, and testing of in-process material related to the PRODUCT shall be carried out by APO according to the product specifications and shall be appropriately documented.

2.1.2 APO shall sample the PRODUCT per APO procedures.

2.1.3 APO is responsible for quality control (QC) testing of the PRODUCT.

2.1.4 APO shall perform final PRODUCT testing per the test methods and specifications agreed upon between APO and GILEAD.

### 2.2. Batch Release

2.2.1 APO shall be responsible for release of PRODUCT [\*] .

2.2.2 Final release of the PRODUCT for clinical or commercial use shall be [\*] . GILEAD shall provide written [\*] to APO prior to [\*] of the PRODUCT to any [\*] .

2.2.2.1. Final release of PRODUCT for distribution in the EU is the sole responsibility of the Qualified Person at [\*] .

2.2.3 Subsequent to the successful completion of a mutually agreeable qualification exercise, APO shall forward to GILEAD the following documentation for each batch of the PRODUCT:

2.2.3.1. [\*]

2.2.3.2. [\*]

2.2.3.3. [\*]

2.2.3.4. [\*]

2.2.3.5. [\*]

2.2.3.6. [\*]

2.2.4 GILEAD may reduce the above requirements via written authorization to APO.

### 2.3. Stability Program

GILEAD is responsible for stability testing, primary data interpretation and reporting.

### 2.4. Annual Product Review

2.4.1 GILEAD shall perform PRODUCT annual product review per GILEAD procedures.

2.4.2 APO shall provide an annual product review summary to GILEAD per APO procedures.

2.4.3 GILEAD and APO shall periodically discuss quality issues related to the past MANUFACTURING of the PRODUCT with regards to the obligations and responsibilities as described in this AGREEMENT.

## 3. Retention of Samples

3.1. APO shall retain samples of raw materials (including API) per APO procedures.

3.2. GILEAD shall retain samples of PRODUCT according to GILEAD procedures.

## 4. Documentation

### 4.1. Manufacturing Records

- 4.1.1 Records related to the MANUFACTURING of the PRODUCT and/or materials used for the MANUFACTURING of the PRODUCT shall be mutually approved by APO and GILEAD prior to implementation.
- 4.1.2 Original Batch Records (i.e., MPRs) shall be made available for inspection and review by regulatory authorities at mutually agreeable times.

### 4.2. Records Retention

APO shall retain documentation specifically associated with the PRODUCT per APO procedures.

### 4.3. Change Control

- 4.3.1 APO shall process changes to documentation associated with the PRODUCT per APO procedures.
- 4.3.2 Upon approval and issuance, APO shall distribute copies of documentation associated with the MANUFACTURING of the PRODUCT to GILEAD.
- 4.3.3 Prior to manufacture of the next batch of the PRODUCT, APO shall notify GILEAD of any planned changes that have [\*], as defined in the US FDA Guidance for Industry “Changes to an Approved NDA or ANDA”. This includes changes to the [\*] to MANUFACTURE the PRODUCT.

### 4.4. Contractor Manual

- 4.4.1 GILEAD shall provide a current, controlled copy of each PRODUCT-specific Contractor Manual that includes GILEAD controlled documents critical to the MANUFACTURING of the PRODUCT.
- 4.4.2 APO shall distribute internally updated copies of documents contained in the Contractor Manual within an appropriate timeframe.

## 5. Information Flow

### 5.1. Communication

5.1.1 APO and GILEAD shall each employ a QA representative who shall be responsible for:

5.1.1.1. Approving the AGREEMENT

5.1.1.2. Ensuring that the terms of this AGREEMENT are complied with.

5.1.1.3. Ensuring that the terms of this AGREEMENT are performed in strict accordance with cGMPs.

5.1.1.4. Ensuring that the terms of this AGREEMENT are conducted in accordance with the regulatory filing(s) for the PRODUCT specified.

5.1.2 Attachment B identifies the contact individual(s) and areas of responsibility for APO and GILEAD. The parties may modify the individuals listed in Attachment B by notice in writing to the other parties.

### 5.2. Regulatory Inspections of Facilities and PRODUCT

5.2.1 APO shall notify GILEAD [\*] of any inspections or actions by regulatory agencies that [\*] the PRODUCT.

5.2.2 Prior to [\*] with regards to the PRODUCT, APO shall discuss the [\*] with GILEAD.

5.2.3 Prior to [\*] with regards to the MANUFACTURING of the PRODUCT, GILEAD shall discuss the [\*] with APO.

### 5.3. Access to Facility

GILEAD shall have the right to visit APO PRODUCT manufacturing and quality control testing site after reasonable notice and during normal business hours to review manufacturing operations and assess its compliance with cGMP and quality assurance standards and to discuss any related issues with manufacturing and management personnel as it relates to the MANUFACTURING of the PRODUCT.

### 5.4. Product Complaints

5.4.1 GILEAD shall provide a system to allow for the receipt of complaints associated with the PRODUCT (PRODUCT complaints). GILEAD shall receive, log, evaluate, and categorize each complaint received in accordance with GILEAD procedures.

5.4.2 As soon as possible, but not more than [\*] business days (unless a more urgent need is recognized) after receipt of a PRODUCT complaint from a source other than APO, GILEAD shall report the complaint in writing to APO QA (as required as a function of the complaint). GILEAD shall provide all information relative to the PRODUCT complaint to APO, including a description of the complaint and associated lot number(s) as stated from complainant. GILEAD shall forward to APO digital pictures of complaint subject and returned goods, as available. GILEAD shall send APO updates to the complaint as needed.

- 5.4.3 APO shall perform a thorough investigation of each PRODUCT complaint, and shall make every effort to provide GILEAD with appropriate written correspondence and/or final report documents for each PRODUCT complaint received within [\*] business days unless a more (or less) urgent need is recognized and mutually agreed to.
- 5.4.4 GILEAD shall maintain communication with the complainant to include the initial acknowledgement of the complaint received and the final results of the investigation conducted by APO.
- 5.4.5 GILEAD shall communicate to the complainants and/or regulatory authorities the results of the complaint investigation, if necessary. GILEAD shall notify APO of any regulatory action related to the MANUFACTURING of the PRODUCT taken by a regulatory authority.

#### 5.5. Product Recall

- 5.5.1 GILEAD shall have responsibility for initiating a PRODUCT recall or field corrections of the PRODUCT if the PRODUCT violates applicable laws, regulations or agreed specifications, or is deemed unacceptable for some other reason whether or not such action is requested by any government agency.
- 5.5.2 GILEAD shall notify APO of GILEAD's intent to initiate a PRODUCT recall in order to meet the standards of the US FDA and other regulatory authorities and shall review any potential PRODUCT recall with APO prior to taking any action.
- 5.5.3 During a PRODUCT recall, withdrawal, or field correction, APO shall fully cooperate with GILEAD to conduct necessary activities.

### 6. Duration

The term of this AGREEMENT shall be in force for a term to coincide with the Manufacturing Agreement and can be modified at anytime by agreement of the Parties. This AGREEMENT shall survive the expiration or termination of the Manufacturing Agreement until [\*] year after the expiration date of the last batch of PRODUCT manufactured hereunder.

### 7. Modifications to the AGREEMENT

Any modification to this AGREEMENT must be in writing and approved by both parties in order to be valid. Any such modifications shall form part of this AGREEMENT and shall be attached to this AGREEMENT. Attachments may be updated separately and appended to this AGREEMENT upon notice in writing to the other parties and mutual approval.

### 8. Approval Signatures

**For and on behalf of Gilead Sciences, Inc.**

Signed: \_\_\_\_\_  
[\*]

Signed: \_\_\_\_\_  
[\*]

Signed: \_\_\_\_\_  
[\*]

**For and on behalf of APO**

Signed: \_\_\_\_\_  
[\*]

Signed: \_\_\_\_\_  
[\*]

Signed: \_\_\_\_\_  
[\*]

Signed: \_\_\_\_\_  
[\*]

Signed: \_\_\_\_\_



Attachment A , Quality Agreement: PRODUCTS for MANUFACTURING

PRODUCT	TRADENAME	PRESENTATION	GILEAD CODE NO.	APO CODE NO.
[*]	[*]	[*]	[*]	[*]

**Attachment B , Quality Agreement: Contact Information**

**Gilead Sciences, Inc.**

<u>Area of Responsibility</u>	<u>Name</u>	<u>Address</u>	<u>Telephone</u>	<u>FAX</u>
Quality Assurance/ Product Complaints	[*]			
Quality Control	[*]	[*]	[*]	[*]
Materials/Planning	[*]	[*]	[*]	[*]
Pharmaceutical Manufacturing	[*]	[*]	[*]	[*]
Qualified Person, European Testing Site	[*]	[*]	[*]	[*]

**APO, Inc.**

<u>Area of Responsibility</u>	<u>Name</u>	<u>Address</u>	<u>Telephone</u>	<u>FAX</u>
Management	[*]		[*]	[*]
Quality Assurance	[*]	[*]	[*]	[*]
Quality Management	[*]		[*]	[*]
Manufacturing	[*]		[*]	[*]

**Attachment C , Quality Agreement: Responsibilities Matrix**

	<u>Contract Giver</u>	<u>Contract Acceptor</u>
Agreement with registration documents	[ <input checked="" type="checkbox"/> ]	[ <input type="checkbox"/> ]
<u>Active ingredients(s)</u>		
Specification	[ <input checked="" type="checkbox"/> ]	[ <input type="checkbox"/> ]
Supply/procurement	[ <input checked="" type="checkbox"/> ]	[ <input type="checkbox"/> ]
Testing (Full specification)	[ <input checked="" type="checkbox"/> ]	[ <input type="checkbox"/> ]
Testing (Identity on receipt of each container)	[ <input type="checkbox"/> ]	[ <input checked="" type="checkbox"/> ]
Reserve samples	[ <input type="checkbox"/> ]	[ <input checked="" type="checkbox"/> ]
<u>Other starting materials</u>		
Non-compendial material specifications	[ <input checked="" type="checkbox"/> ]	[ <input type="checkbox"/> ]
Compendial material specifications	[ <input type="checkbox"/> ]	[ <input checked="" type="checkbox"/> ]
Supply/procurement	[ <input type="checkbox"/> ]	[ <input checked="" type="checkbox"/> ]
Testing(1)	[ <input type="checkbox"/> ]	[ <input checked="" type="checkbox"/> ]
Reserve samples	[ <input type="checkbox"/> ]	[ <input checked="" type="checkbox"/> ]
<u>Bulk product</u>		
Specification	[ <input checked="" type="checkbox"/> ]	[ <input type="checkbox"/> ]
Manufacturing directions	[ <input checked="" type="checkbox"/> ]	[ <input type="checkbox"/> ]
In-process control requirements	[ <input checked="" type="checkbox"/> ]	[ <input type="checkbox"/> ]
Testing directions	[ <input checked="" type="checkbox"/> ]	[ <input type="checkbox"/> ]
Manufacture/manufacturing record	[ <input type="checkbox"/> ]	[ <input checked="" type="checkbox"/> ]
Quality control/testing record	[ <input type="checkbox"/> ]	[ <input checked="" type="checkbox"/> ]
Certificate of analysis	[ <input type="checkbox"/> ]	[ <input checked="" type="checkbox"/> ]

---

(1) Testing is performed per the complete specification unless otherwise specified.

**Schedule “C”**  
**Toll Manufacturing Agreement**

**Bulk Product Specifications**

APO has to test and release the Bulk Product in accordance to GILEAD test procedure No.: [\*] and [\*] (for clinical batches) in its current version.

The current versions are [\*] (effective date [\*] ) and [\*] (effective date [\*] ).

**Schedule “D”**  
**Toll Manufacturing Agreement**

**API and Excipient Specifications; Handling and Storage of API**

Active Pharmaceutical Ingredient provided by Gilead  
Starting materials (excipients) provided APO:

All API, Excipient and Component testing shall be performed in accordance with the following Specifications, as may be amended from time to time by mutual written agreement of the Parties:

<b><u>DESCRIPTION</u></b>	<b><u>SPECIFICATION</u></b>
<b><u>API</u></b>	
[*]	[*]
<b><u>Excipients</u></b>	
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]

[\*]

**Schedule “E”**  
**Toll Manufacturing Agreement**

**Batch Coding System**

Batch coding will consist of a unique alpha-numeric code of not more than 8 characters. APO will assign each lot number prior to manufacturing and reflect that number on the purchase order confirmation sent to Gilead for the batches requested at that time.

**Schedule “F”**  
**Toll Manufacturing Agreement**

**Dispatch Labelling of APO**

The labelling of the shipping carton of Products shall include the following information:

- [\*]

**Schedule “G”**  
**Toll Manufacturing Agreement**

**Shipment Instructions**

- [\*]



**Schedule “H”**  
**Toll Manufacturing Agreement**

**Manufacturing Line [\*]**

**[\*] of API [\*]**

**1. Manufacturing Line Loss (Yield)**

The Parties shall set forth and indicate in an *addendum* to this **Schedule “H”** the total [\*] of API allowable per [\*] period under the Manufacturing line [\*] after completion of the production of [\*] bulk. Other than in cases where APO has failed to comply with Section 3.3, APO shall not be required to [\*] GILEAD based on [\*] or API Manufacturing line [\*] for the first [\*] batches.

In addition, the following aspects have to be considered:

- Given that the API source might have an impact on the production process, no [\*] will be [\*] by APO for a special API-source before [\*] with the API-source were produced at APO.
- Each change of the manufacturing process, which requires a new validation and is of a nature that it is likely to change the Manufacturing line [\*] will lead to the same procedure and a new agreement concerning the acceptable [\*] as described in the addendum to Schedule “D”. In such event, the schedule of [\*] periods section (a) of the addendum shall not be changed unless it this would cause an inequitable result, in which case the parties will agree in good faith upon an equitable schedule. If the parties disagree as to whether a change is likely to change the Manufacturing line [\*], they will agree in good faith as to whether to reach a new agreement regarding acceptable line [\*] pursuant to Schedule “D”.

**Addendum to Schedule “H”**

(a) Initial Allowable Manufacturing Line [\*] per [\*] period: the initial allowable Manufacturing line [\*] shall be equal to [\*] not subject to deviation that are produced under this Agreement, minus the allowing [\*] :

[\*]

[\*] , then

[\*] Manufacturing Line [\*] : At the end of every [\*] period, the allowable manufacturing line [\*] shall be adjusted to be equal to [\*] not subject to deviation that are produced under this Agreement [\*] , minus the [\*] applicable at that time according to section (a).

(c) [\*] Arrangement: the [\*] arrangement will start with the first batch, that is produced after the allowable manufacturing line [\*] has been determined based on the [\*] initial batches pursuant to section (a).

(d) [\*] Procedure: the [\*] calculation will consider a period of time of up to [\*] months by the following procedure, using the allowable Manufacturing line [\*] determined pursuant to sections (a) or (b) as applicable:

- i. If the actual Manufacturing line [\*] for batches Manufactured during an initial [\*] month period is less than the allowed Manufacturing line [\*] , this period will [\*] .

- ii. If the actual Manufacturing line [\*] for batches manufactured during a [\*] month period is greater than allowed Manufacturing line [\*], [\*] will be due at that time. [\*] at the end of the next [\*] month period, the actual Manufacturing line [\*] shall be determined for batches Manufactured during the [\*] month period.
- iii. If the actual Manufacturing line [\*] for batches Manufactured during the [\*] month period is less than the allowed Manufacturing line [\*], [\*] for [\*] Manufacturing line [\*] will be [\*] pursuant to Section 2.7 for such [\*] month period.
- iv. If the actual Manufacturing line [\*] for batches Manufactured during the [\*] month period is [\*] the allowed Manufacturing line [\*], [\*] pursuant to Section 2.7 for the [\*] between the [\*] Manufacturing line [\*]. With [\*] for such [\*], a new period of time with reference to a [\*] will start.
- v. For every [\*], this [\*] is [\*] initially, based on an initial [\*] for [\*] API.
- vi. As the [\*] for API may fluctuate over time, on an annual basis GILEAD may determine an adjustment to the API [\*] to reflect such [\*] in the [\*] month period prior to such adjustment. Such adjusted API [\*] shall apply under this Schedule D solely on a prospective basis. APO shall have the right to audit the methodology employed by GILEAD to determine an adjusted [\*] for API.

**Schedule “I”**

**Toll Manufacturing Agreement**

**Yearly Minimum Volumes of Purchases**

Pursuant to what is provided under Section 5.1 and 3.7 of the Agreement, GILEAD undertakes to guarantee the following yearly minimum volumes of purchases of Bulk Products:

- For the Year 2003, GILEAD shall guarantee a minimum volume of purchase of [\*] of Bulk Product .
- For the Year 2004, GILEAD shall guarantee a minimum volume of purchase of [\*] of Bulk Product.
- For the Year 2005, GILEAD shall guarantee a minimum volume of purchase of [\*] of Bulk Product.

**It is agreed by APO that the specified minimum volume of purchases above are subject to a potential [\*] volume demand [\*] from GILEAD in a given year.** APO hereby confirms that GILEAD has the potential to discuss with APO additional volume requirements.

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

### **LICENSING AGREEMENT**

This LICENSING AGREEMENT ("Agreement"), effective as of March 31, 2000 (the "Effective Date"), by and among GILEAD SCIENCES, INC., a Delaware corporation with its principal office located at 333 Lakeside Drive, Foster City, CA 94404 ("Gilead Sciences"), and its wholly-owned subsidiary, NEXSTAR PHARMACEUTICALS, INC., a Delaware corporation (collectively with Gilead Sciences, "Gilead"), and EYETECH PHARMACEUTICALS, INC., a Delaware corporation with its principal offices located at 300 East 42nd Street, Third Floor, New York, New York 10017 ("EyeTech"). Unless otherwise defined in this Agreement, all capitalized terms shall have the meanings given to them in Section 1.1 of this Agreement.

### **RECITALS**

1. WHEREAS, Gilead owns certain patents and patent applications and related know-how for NX1838, and has made certain filings for regulatory approvals with respect to NX1838; and
2. WHEREAS, Gilead and EyeTech desire to enter into this Agreement and certain other agreements, including an agreement providing for the fill-and-finish manufacture of quantities of Product sufficient for the completion of Phase Ib clinical trials; and
3. WHEREAS, subject to the terms and conditions set forth in this Agreement, Gilead wishes to license to EyeTech and EyeTech wishes to license from Gilead all of Gilead's rights under patents, patent applications and know-how related to NX1838, and have access to all regulatory approvals with respect to NX1838; and
4. WHEREAS, subject to the terms and conditions set forth in this Agreement, Gilead also wishes to sell to EyeTech and EyeTech wishes to purchase from Gilead its inventory of NX1838.

NOW, THEREFORE, the Parties hereto, intending to be legally bound, hereby agree as follows:

### **SECTION 1** **DEFINITIONS**

- 1.1 Definitions. For purposes of this Agreement, the following terms shall have the meanings set forth below:

"Affiliate" shall mean any Person that, directly or indirectly, through one or more intermediaries, Owns, is Owned by or is under common Ownership with, a Party, where "Own" or "Ownership" means (a) direct or indirect possession of at least fifty percent (50%) of the outstanding voting securities of a corporation or a comparable ownership in any other type of Person, *provided, however*, that if the law of the jurisdiction in which such entity operates does not allow fifty percent (50%) or greater ownership by a Party, such ownership interest shall be at

least forty percent (40%) or (b) that a Person or group of Persons otherwise has the unilateral ability to control and direct the management of the entity, whether by contract or otherwise.

“Business Day” shall mean any day other than a Saturday, Sunday or banking holiday in New York City or San Francisco, California.

“Calendar Quarter” shall mean a calendar quarter (i.e., period of three (3) consecutive months) ending on March 31, June 30, September 30 or December 31.

“Calendar Year” shall mean any period of twelve (12) consecutive months ending on December 31.

“Competitive Product” shall mean a product competitive with a Product.

“Compulsory License” means a compulsory license under the Licensed Patents obtained by a Third Party through the order, decree, or grant of a governmental authority of competent jurisdiction, authorizing such Third Party to manufacture, use, sell, offer for sale or import a Competitive Product in one or more countries within the Territory.

“Control”, “Controls”, and “Controlled” shall mean, with respect to a particular item of information or intellectual property right, that the applicable Party owns or has a license to such item or right and has the ability to grant to the other Party access to and a license or sublicense (as applicable) under such item or rights as provided for in this Agreement without violating the terms of any agreement or other arrangement with any Third Party.

“Damages” shall mean any and all costs, losses, claims, liabilities, fines, penalties, damages and expenses, court costs, and reasonable fees and disbursements of counsel, consultants and expert witnesses incurred by a Party hereto (including any interest payments which may be imposed in connection therewith).

“Delivery Date” shall mean the date that is ten (10) days after the Effective Date.

“Effective Date” shall have the meaning given such term in the first sentence of this Agreement.

“EU” shall mean Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain, Sweden and the United Kingdom, and future members of the European Union (or its successor), upon their admission for full membership (with commercial rights and privileges substantially comparable to those of the foregoing countries).

“EyeTech Rights” shall mean any invention or inventions, patentable or not, know-how, information and/or data relating to the Product, including, without limitation, pre-clinical studies and clinical trial information, manufacturing processes, formulations, modes of delivery and/or data necessary for the manufacture, use or sale of the Product, which are Controlled by EyeTech during the term of this Agreement, and all Patents covering any of the foregoing which are Controlled by EyeTech during the term of this Agreement.

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

“FDA” shall mean the United States Food and Drug Administration, or any successor thereto.

“Field” shall mean the prevention and treatment of all human and other animal diseases and conditions, and expressly excluding in vivo and in vitro diagnostic applications.

“First Commercial Sale” shall mean, with respect to any particular country, the first sale of a Product in such country by EyeTech, or any of its Affiliates or sublicensees, after Regulatory Approvals in such country have been granted from the relevant Regulatory Authority in such country for such Product.

“GAAP” shall mean United States generally accepted accounting principles, consistently applied.

“Indemnified Party” shall have the meaning given in Section 7.2 hereof.

“Indemnifying Party” shall have the meaning given in Section 7.2 hereof.

“Know-How” shall mean all ideas, materials, inventions (whether patentable or not), trade secrets, data, instructions, processes, formulas, expert opinion and information, including, without limitation, the Manufacturing Information and biological, chemical, pharmacological, toxicological, physical and analytical, safety, manufacturing and quality control data and information, in each case within the Field, that, as of the Effective Date are (i) existing, and (ii) Controlled by Gilead as of the Effective Date, in each case which is necessary or useful for the development, manufacture, use, sale or commercialization of the Product in the Field. Excluded from Know-How are any Patents, the Licensed Patents and the Transferred Assets.

“License” shall mean the license granted by Gilead to EyeTech pursuant to Section 2.1.

“Licensed Patents” shall mean any Patents listed in Exhibit D (as updated from time to time pursuant to Section 5.6) which claim the manufacture, use, import, offer for sale or sale of Products in accordance with this Agreement and which now or at any time during the term of this Agreement are Controlled by Gilead or any Affiliate of Gilead.

“Major Countries” shall mean Canada, France, Germany, Italy, Japan, Spain, United Kingdom and the United States.

“Manufacturing Information” shall mean copies of all existing information in written and electronic form in Gilead’s possession or control as of the Effective Date, with respect to any Product existing as of the Effective Date, that relates to, in the Field: (1) processes for the production of NX1838, and intermediates in the preparation of a Product; (2) the in-process analytical controls for production of each of: (a) NX1838; and (b) a Product; (3) the process, formulation and development reports generated for the preparation of a Product; (4) the analytical methods and validation for the quality control release of each of: (a) NX1838; and (b) a Product; and (5) the stability protocols, stability indicating methods and stability data for each of: (a) NX1838; and (b) a Product.

“ NDA ” shall mean a New Drug Application filed with the FDA requesting market approval for a new drug product.

“ Net Sales ” shall mean, with respect to the Product, the gross amount billed or invoiced by EyeTech, its Affiliates or sublicensees, to unrelated Third Parties for the Products in finished product form, less the following deductions:

- (a) trade, quantity and cash discounts allowed, but expressly excluding discounts or allowances offered as part of a package of products that includes a Product sold by EyeTech, its Affiliates or sublicensees;
- (b) refunds, chargebacks and any other allowances which effectively reduce the net selling price;
- (c) actual product returns, credits and allowances;
- (d) rebates actually paid or credited to any governmental agency (or branch thereof) or to any Third Party payor, administrator or contractee;
- (e) discounts mandated by, or granted to meet the requirements of, applicable state, provincial or federal law, wholesaler, including required chargebacks and retroactive price reductions;
- (f) transportation, freight, postage charges and other charges such as insurance, relating thereto, in each case included as a specific line item on an invoice to such Third Parties; and
- (g) taxes, excises or other governmental charges upon or measured by the production, sale, transportation, delivery or use of goods, in each case included as a specific line item on an invoice to such Third Parties.

Notwithstanding the foregoing, amounts received by EyeTech, or its Affiliates or sublicensees, for the sale of Products among EyeTech and its Affiliates or sublicensees for resale shall not be included in the computation of Net Sales hereunder. Net Sales shall be determined from books and records maintained in accordance with GAAP. In the event the Product is sold as part of a combination product, or as part of bundled products or as part of a delivery system, the Net Sales from the combination product, bundled product or delivery system, for the purposes of determining royalty payments, shall be determined by multiplying the Net Sales (as defined without regard to this paragraph) of the combination product by the fraction,  $A/(A+B)$  where A is the average sale price of the Product when sold separately in finished form and B is the average sale price of the other product(s) or system sold separately in finished form, or, only if the value of B cannot be determined, where  $A+B$  is the average sales price of the product(s) and the delivery system together. If the value of B can be determined, in no event will the sales price of any combination product, bundled product or delivery system product be less than the sum of A and B. In the event that such average sale price cannot be determined for both the Product and such other product(s) or system in combination, the following calculation shall be substituted for the calculation recited in (ii) of the preceding sentence: the Net Sales (as defined without regard

to this paragraph) of the combination products shall be multiplied by the fraction  $C/(C+D)$  where C is EyeTech's cost of goods of the Product and D is EyeTech's cost of goods for the other product(s) or system, determined in accordance with the method of accounting normally employed by EyeTech in computing cost of goods, *provided, however*, that the minimum value of such fraction as used in the calculation of Net Sales shall be 0.9.

“ NX1838 ” shall mean Gilead's proprietary compound known as NX1838, as described in Exhibit A.

“ Party ” shall mean either Gilead or EyeTech, and “ Parties ” shall mean both of Gilead and EyeTech.

“ Patents ” shall mean patents and patent applications, both foreign and domestic, including without limitation, all extensions, reissues, renewals, reexaminations, patents of addition, supplementary protection certificates and inventors' certificates thereof, substitutions, provisionals, divisionals, continuations and continuations-in-part.

“ Person ” shall mean a natural person, a corporation, a partnership, a trust, a joint venture, a limited liability company, any governmental authority or any other entity or organization.

“ Pivotal Clinical Trial ” shall mean either (a) a trial on sufficient numbers of patients that is designed to establish that a pharmaceutical product is safe and efficacious for its intended use, and to define warnings, precautions and adverse reactions that are associated with the pharmaceutical product in the dosage range to be prescribed, and to support Regulatory Approval of such pharmaceutical product or label expansion of such pharmaceutical product, or (b) a clinical trial that began as a trial on sufficient numbers of patients that is designed to establish the safety and biological activity of a pharmaceutical product for its intended use, and to define warnings, precautions and adverse reactions that are associated with the pharmaceutical product in the dosage range to be prescribed, after such date as the U.S. Food and Drug Administration or its successor (or equivalent regulatory authority) has indicated that the applicable Party may reasonably continue such trials with the intention to establish that a pharmaceutical product is safe and efficacious for its intended use, and to define warnings, precautions and adverse reactions that are associated with the pharmaceutical product in the dosage range to be prescribed, and to support Regulatory Approval of such pharmaceutical product or label expansion of such pharmaceutical product.

“ Product ” shall mean any pharmaceutical composition containing NX1838 in any formulation, dosage concentration or volume, together with all label expansions, line extensions and improvements thereon, which may be included in any supplement, modification or addition to the filings for Regulatory Approval of the foregoing compound.

“ Product Data Package ” shall include the following information and data related to the Product in the possession or control of Gilead as of the Effective Date: (a) the Regulatory Documents; (b) pre-clinical and clinical development protocols, data, and reports; (c) manufacturing development technical reports; (d) toxicology reports; and (e) such other information and data specifically identified in Exhibit B attached hereto.



“Product Inventory” shall mean the NX1838 and Product inventory, in bulk or finished form, which Gilead Controls as of the Effective Date, as identified in Exhibit C attached hereto.

“Reasonable Diligence” shall mean commercially reasonable efforts to develop, obtain Regulatory Approval, and/or commercialize, as applicable, a Product in a country in the Territory, consistent with accepted business practices and legal requirements, and comparable to efforts in the pharmaceutical industry applicable to development, obtaining of Regulatory Approval for, or commercialization of human pharmaceutical products at an equivalent stage of development and similar market potential, profit potential and strategic value in view of conditions then prevailing.

“Regulatory Approval” shall mean (a) in the United States, approval by the FDA of an NDA, or equivalent application, for marketing approval and satisfaction of any related applicable FDA registration and notification requirements (if any) and (b) in any country other than the United States, all approvals (including any required marketing, pricing and reimbursement approvals) by the Regulatory Authority in such country of a single application or set of applications comparable to an NDA, enabling legal sale of a product in such country.

“Regulatory Authority” shall mean the FDA in the United States or the equivalent governmental agency having jurisdiction in any other country in the Territory.

“Regulatory Documents” shall mean the (a) United States investigational new drug application (the “IND”) #56503 (dated July 12, 1998), and all amendments and annual reports to same; (b) any pediatric data package or other exclusivity extensions relating to Products; and (c) any other regulatory filings with Regulatory Authorities relating to the Product.

“Royalty Term” shall mean, with respect to each country in which Product is sold, the period of time equal to the longer of (i) [\*] years from the date of First Commercial Sale of the Product in such country, or (ii) the expiration of the last-to-expire Licensed Patent in such country that claims the manufacture, use, and or sale of such Product as such activities are carried out pursuant to this Agreement.

“Territory” shall mean the world, unless the License terminates with respect to a country pursuant to Section 6.7, in which case the Territory shall exclude any country in which the License has so terminated.

“Third Party” shall mean a Person other than EyeTech, Gilead or their Affiliates.

“Transferred Assets” shall mean the Product Inventory and the Product Data Package.

**SECTION 2**  
**GRANT OF LICENSES AND TRANSFER AND DELIVERY OF TRANSFERRED**  
**ASSETS AND MANUFACTURING INFORMATION**

2.1 Grant of License. Subject to the terms and conditions of this Agreement, during the term of this Agreement, Gilead hereby grants to EyeTech an exclusive license under the Licensed Patents and Know How to make, have made, use, sell, offer to sell, import and export the Product within the Field throughout the Territory, with a right to sublicense to its Affiliates or (subject to Section 2.4) to any other Person.

2.2 Transferred Assets. As of the Effective Date, Gilead hereby assigns, transfers and conveys to EyeTech all of Gilead's right, title and interest in and to the Transferred Assets (subject to Section 4.5(c)), and EyeTech hereby accepts such assignment, transfer and conveyance. On or before the Delivery Date, Gilead shall have delivered to EyeTech all of the Transferred Assets and the Manufacturing Information. EyeTech shall have up to ten (10) days after such delivery to inventory the delivered Transferred Assets and Manufacturing Information and to give notice to Gilead of any Transferred Assets and Manufacturing Information that were not so delivered. If Gilead receives notice or otherwise learns after the Delivery Date that it has failed to deliver any Transferred Assets or Manufacturing Information to EyeTech, Gilead shall provide to EyeTech any such Transferred Assets or Manufacturing Information no later than five (5) Business Days after receipt of such notice or knowledge (or within such longer time as is mutually agreed by EyeTech and Gilead). The clinical data portion of the Product Data Package shall be provided to EyeTech in computer-readable format, where available, and otherwise in printed format. Gilead shall be under no obligation to convert to electronic format any portion of the Product Data Package that currently is available only in printed format. In the event that EyeTech is unwilling or unable to assume physical possession of the Transferred Assets and Manufacturing Information by the Effective Date, Gilead shall be entitled to charge EyeTech a reasonable fee for storage of the Transferred Assets and Manufacturing Information beyond the Effective Date. Gilead shall ship the Transferred Assets to EyeTech F.O.B. to EyeTech's designated facilities. For a period of 90 days following the receipt by EyeTech of the Transferred Assets and Manufacturing Information, Gilead personnel shall be reasonably available during Gilead's normal business hours to respond to technical inquiries of EyeTech regarding Products as is reasonably requested by EyeTech. EyeTech acknowledges that Gilead makes no representations or warranties with respect to the Transferred Assets or Manufacturing Information (other than as expressly set forth in Section 5 below) and that it accepts such Transferred Assets and Manufacturing Information "as is."

2.3 Negative Covenant of EyeTech. EyeTech shall not use or practice Licensed Patents or Know-How outside the Field or outside the Territory or for any other purpose except activities that it conducts in compliance with this Agreement.

2.4 Sublicenses. EyeTech shall have the right to sublicense the licenses granted to it by Gilead under this Agreement without the consent of Gilead; *provided* that (i) prompt notice and a copy of such sublicense shall be given by EyeTech to Gilead pursuant to Section 8.2 of this Agreement; (ii) EyeTech shall remain obligated at all times under this Agreement without regard to whether it has sublicensed its rights or whether EyeTech's sublicensee has performed; (iii) such sublicense shall name Gilead as a third party beneficiary of such sublicense; and (iv) any such sublicenses granted by EyeTech shall contain provisions providing for its termination or assignment to Gilead, at the option of Gilead, of EyeTech's interest therein upon termination of this Agreement, and shall further contain provisions which obligate such sublicensee to comply

with such terms, conditions, agreements and obligations that are consistent with the terms, conditions, agreements and obligations to which EyeTech is subject under this Agreement.

2.5 **Gilead Right of First Negotiation** . Except as otherwise provided in this Section 2.5, Gilead shall have a right of first negotiation with respect obtaining all rights with respect to any Product which is, or which can reasonably be expected to be, [\*] (a “Reversion Product”) as follows: Eyetech shall notify Gilead in writing if Eyetech intends to seek, negotiate, or solicit offers to license a Third Party to commercialize the Reversion Product for the treatment or prevention [\*] (the “Reversion Field”) and a specific territory (the “Reversion Territory”), prior to contacting any such potential Third Party licensees. Such written notice shall include sufficient detailed technical information concerning the Reversion Product as Gilead may reasonably require to evaluate its interest in such Reversion Product. Within thirty (30) days after receiving Eyetech’s notice as to the Reversion Product, Gilead shall notify Eyetech whether it is interested in negotiating with Eyetech the terms under which Gilead shall obtain a license from Eyetech to research, develop and commercialize Reversion Products as described herein. If Gilead provides such notice, the Parties shall negotiate exclusively and in good faith for a period of up to ninety (90) days after Eyetech receives Gilead’s notice of interest (the “Negotiation Period”) the terms of an agreement pursuant to which Eyetech will grant to Gilead and its Affiliates an exclusive, royalty-bearing, sublicensable license, under all Eyetech Know-How and Eyetech Patents relating to such Reversion Product, to research, develop, make, have made, use, import, offer for sale, sell and otherwise commercialize such Reversion Product within the Reversion Field within the Reversion Territory, and which agreement shall include commercially reasonable provisions for transfer of or access to relevant regulatory filings and technology to Gilead. Neither Gilead nor Eyetech shall have any obligation to actually enter into a license agreement with respect to such Reversion Product. If either Gilead does not respond to Eyetech’s notice of intent to license the Reversion Product within thirty (30) days after Gilead’s receipt thereof, or Gilead and Eyetech fail to agree upon the terms of a license under rights to the Reversion Product during the Negotiation Period, Eyetech shall be free to commercialize such Reversion Product by itself or through its Affiliates or Third Parties without further obligation to Gilead.

### **SECTION 3** **PAYMENTS AND DELIVERIES**

In consideration of the exclusive license granted herein and the transfer of ownership of the Transferred Assets, EyeTech shall pay the following amounts to Gilead:

#### 3.1 **Initial Payments and Deliveries** .

(a) On or before Tuesday, April 4, 2000, EyeTech shall pay to Gilead the sum of [\*] United States Dollars (US\$ [\*] ) by Federal Reserve electronic wire transfer in immediately available funds to an account designated by Gilead. Such amount shall be non-refundable and non-creditable, and shall not be subject to any counterclaim or set-off.

(b) On or before the Effective Date, EyeTech and Gilead Sciences shall enter into a Warrant Agreement (the “Warrant Agreement”) mutually satisfactory to both Parties

pursuant to which EyeTech shall issue to Gilead Sciences a warrant to purchase EyeTech Series B Preferred Stock.

(c) On or before the Delivery Date, Gilead shall deliver to EyeTech (i) all of the Transferred Assets pursuant to Section 2.2 of this Agreement; (ii) all of the Manufacturing Information pursuant to Section 2.2 of this Agreement; and (iii) a schedule (“Schedule of Transferred Assets and Manufacturing Information”) setting forth each of the Transferred Assets and Manufacturing Information being delivered to EyeTech at such time.

(d) Within ten (10) days of delivery of the Transferred Assets and the Manufacturing Information and of the Schedule of Transferred Assets and Manufacturing Information pursuant to Section 3.1(c) above, EyeTech shall inventory the delivered Transferred Assets and Manufacturing Information pursuant to Section 2.2 and shall either (i) deliver to Gilead a receipt acknowledging the receipt of each of the Transferred Assets and the Manufacturing Information set forth on the Schedule of Transferred Assets and Manufacturing Information or (ii) notify Gilead of any Transferred Assets or Manufacturing Information that Gilead did not deliver. If Gilead receives notice or otherwise learns after the Delivery Date that it has failed to deliver any Transferred Assets or Manufacturing Information to EyeTech, Gilead shall provide to EyeTech any such Transferred Assets or Manufacturing Information no later than five (5) Business Days after receipt of such notice or knowledge (or within such longer time as is mutually agreed by EyeTech and Gilead). Within ten (10) days of Gilead delivering such missing items to EyeTech following notice given by EyeTech pursuant to clause (ii) of this Section 3.1(d), EyeTech shall deliver the receipt described in clause (i) of this Section 3.1(d).

3.2 Milestone Payments. Within five (5) Business Days of EyeTech and/or its Affiliates or sublicensees achieving the first occurrence of each of the milestone events listed below with respect to any Product, EyeTech shall notify Gilead of such achievement and the date thereof, and within thirty (30) days of the date of such achievement, pay the one-time non-refundable fees specified below to Gilead by Federal Reserve electronic wire transfer in immediately available funds to an account designated by Gilead; provided, however, that in no event shall the following fees be payable more than once with respect to Products for any particular geographical area or Milestone:

Milestone	Fee
First [*] with respect to a Product	\$ [*]
First [*] with respect to a Product	\$ [*]
First [*] with respect to a Product	\$ [*]
First [*] with respect to a Product	\$ [*]
First [*] with respect to a Product	\$ [*]
First [*] with respect to a Product	\$ [*]

### 3.3 Royalties.

(a) Royalty on Products. EyeTech shall pay Gilead a royalty payment on Net Sales of Products that are made or sold during the Royalty Term and that are sold by EyeTech, its Affiliates or sublicensees (the “Royalty”) according to the following rates, as adjusted in accordance with Sections 3.3(b) below:

- (i) [\*] percent ( [\*] %) of Net Sales in the United States for the first [\*] dollars ( \$ [\*] ) in Net Sales in the United States in a given Calendar Year;
- (ii) [\*] percent ( [\*] %) of Net Sales in the United States for the next [\*] dollars ( \$ [\*] ), up to and including, [\*] dollars ( \$ [\*] ) in Net Sales during the same Calendar Year;
- (iii) [\*] percent ( [\*] %) of Net Sales in the United States in excess of [\*] dollars ( \$ [\*] ) during the same Calendar Year; and
- (iv) [\*] percent ( [\*] %) of Net Sales outside the United States in the same Calendar Year.

By way of example, if, in the year 2005, EyeTech Net Sales in the United States were equal to [\*] dollars ( \$ [\*] ), and [\*] dollars ( \$ [\*] ) outside the United States, then the Royalty payable to Gilead hereunder would equal [\*] dollars ( \$ [\*] ), calculated in the following manner:

<u>Amount of Net Sales</u>	<u>Royalty Rate</u>	<u>Royalty</u>
First \$ [*] (United States)	[*]%	\$ [*]
Next \$ [*] (United States)	[*]%	\$ [*]
Next \$ [*] (United States)	[*]%	\$ [*]
\$[*] (outside United States)	[*]%	\$ [*]
Total Royalty		\$ [*]

By way of further example, if, through the second Calendar Quarter in the year 2005, EyeTech Net Sales in the United States were equal to [\*] dollars ( \$ [\*] ), and [\*] dollars ( \$ [\*] ) outside the United States, then the Royalty payable to Gilead hereunder after such Calendar Quarter would equal [\*] dollars ( \$ [\*] ), calculated in the following manner:

<u>Amount of Net Sales</u>	<u>Royalty Rate</u>	<u>Royalty</u>
First \$ [*] (United States)	[*]%	\$ [*]
Next \$ [*] (United States)	[*]%	\$ [*]
\$[*] (outside United States)	[*]%	\$ [*]
Total Royalty		\$ [*]

(b) Offset. Notwithstanding the forgoing, on a country by country and Product by Product basis, EyeTech may credit against Net Sales [\*] percent ( [\*] %) of any royalties it must pay to any Third Party on any Product: (1) pursuant to any licenses necessary to practice the License; or (2) resulting from any litigation (including settlement thereof) under

Section 6.16; provided, however, for purposes of this Section 3.3(b) that the applicable royalty rates used for calculation of Royalties payable to Gilead shall not be reduced to less than [\*] percent ( [\*] %) of the royalty rates(s) otherwise applicable pursuant to Section 3.3(a).

3.4 Payment; Report. All Royalties payable to Gilead under this Agreement shall be paid in U.S. dollars within sixty (60) days of the end of each Calendar Quarter or as otherwise specifically provided herein by Federal Reserve electronic wire transfer in immediately available funds to an account designated by Gilead. At the time of payment of Royalties, EyeTech shall send to Gilead a statement with respect to the applicable Calendar Quarter, country by country and Product by Product, for EyeTech, its Affiliates and sublicensees, of the amount of aggregate worldwide gross sales and Net Sales, the amount of gross sales during such Calendar Quarter, an itemized calculation of Net Sales showing deductions provided for in the definition of Net Sales and in Section 3.3(b), and, on a cumulative basis for the current Calendar Year, the amount of Royalties or other payments due on such sales.

3.5 Exchange Rate; Manner and Place of Payment.

(a) All payments due hereunder from time to time shall be paid in U.S. Dollars. For purposes of computing such payments, the Net Sales of Product in countries other than the United States shall be converted into U.S. Dollars as computed using the average monthly rate of exchange at the time for such currencies as the rate applicable to the transfer of funds arising from payments as published in the Wall Street Journal (New York edition). The currency conversion system used by EyeTech shall be subject to audit by Gilead as described in Section 3.6 and, if not determined to be a system reflecting the fair market value of the currencies in question, shall be modified as necessary to effect currency conversion at fair market value.

(b) Notwithstanding the provisions of Section 3.5(a), if by reason of any restrictive exchange laws or regulations, EyeTech shall be unable to convert to U.S. Dollars the amount, determined as above, equivalent to the amount due by EyeTech hereunder, then EyeTech shall so notify Gilead promptly and provide an explanation of the circumstances. In such event, EyeTech shall make all such payments or the balance thereof due hereunder and which is not paid in foreign currency as provided below, in U.S. Dollars as soon as reasonably possible after and to the extent that such restrictive exchange laws or regulations are lifted so as to permit EyeTech to pay amounts due under this Section 3.5 in U.S. Dollars. EyeTech shall promptly notify Gilead if such restrictions are so lifted. At its option Gilead shall meanwhile have the right to request the payment (to it or to its nominee), and, upon request, EyeTech shall pay or cause to be paid amounts due (or such portions thereof as are specified by Gilead) in the currency of any other country designated by Gilead and legally available to EyeTech under the then-existing laws of regulations. Any payments shall be payable to Gilead by wire transfer at such bank in the United States as Gilead Sciences shall specify from time to time. Not less than one (1) Business Day prior to such wire transfer, the remitting party shall telefax the receiving party advising it of the amount and of the payment to be made.

3.6 Audits. EyeTech and its Affiliates and sublicensees shall keep full and accurate books and records relating to the financial performance of the Product. During the term of this

Agreement plus four (4) years after termination or expiration of this Agreement, Gilead shall have the right, during regular business hours and upon reasonable advance notice, to have such books and records audited by an independent certified accountant so as to verify the accuracy of the information previously reported to Gilead. Such information shall be deemed to be Proprietary Information of EyeTech and, as such, subject to confidentiality obligations pursuant to Section 6.3. The independent certified account shall keep confidential any Proprietary Information obtained during such audit and shall report to Gilead only the amounts of Royalties due and payable. The cost of such audit shall be borne by Gilead; however, in the event such audit reveals that the Royalties to Gilead constitute an underpayment of five percent (5%) or more from that revealed by the audit to be actually owed, the cost of the audit shall be borne by EyeTech. EyeTech shall include in all sublicenses granted as permitted under Section 2.4 an audit provision substantially similar to the foregoing requiring the sublicensee to keep full and accurate books and records relating to the Product and granting Gilead the right to audit the accuracy of the information reported by the sublicensee in connection therewith on the same terms as apply to an audit of EyeTech's records hereunder. The terms of this Section 3.6 shall survive any termination or expiration or termination of this Agreement for a period of four (4) years.

3.7 Withholding Taxes. Any and all taxes levied on account of royalty payments paid or owed from a country in which provision is made in the law or by regulation for withholding will be deducted from royalty payments paid Gilead hereunder. EyeTech shall cooperate with Gilead to claim exemption from such deductions or withholdings under any double taxation or similar agreement in force from time to time.

3.8 Sublicensee Obligations. In the event EyeTech sublicenses its right to sell a Product, such sublicense shall include an obligation for the sublicensee to account for and report its Net Sales of Products and provide that Gilead shall have audit rights therefor pursuant to this Section 3 on the same basis as if such sales were Net Sales of Products by EyeTech, and EyeTech shall pay royalty payments to Gilead as if the Net Sales of the sublicensee were Net Sales of EyeTech.

3.9 Late Payments. Any amounts not paid by EyeTech when due under this Agreement shall be subject to interest from and including the date payment is due through and including the date upon which Gilead has collected immediately available funds in an account designated by Gilead at a rate equal to the sum of two percent (2%) plus the prime rate of interest quoted in the Money Rates section of The Wall Street Journal, calculated daily on the basis of a 360-day year, or similar reputable data source. No special notice by Gilead to EyeTech of such interest due shall be required.

3.10 Compulsory License. If either Party learns that a Third Party has obtained a Compulsory License in any country in the Territory, such Party shall promptly notify the other Party of such occurrence. If the royalty rate payable by the grantee of the Compulsory License is less than the royalty rates applicable in such country set forth in Section 3.3 of this Agreement, then the applicable royalty rates set forth in Section 3.3 of this Agreement shall be reduced to the lower royalty rates applicable in such country pursuant to such Compulsory License for so long

as sales of a Competitive Product are made by any Third Party pursuant to the Compulsory License.

#### **SECTION 4**

##### **TERM OF AGREEMENT; TERMINATION**

4.1 Term. The term of this Agreement shall commence upon the Effective Date and, unless sooner terminated as provided in this Section 4, expire on the expiration of all Royalty Terms for all Products.

4.2 Licenses upon Expiration. In the event that the Agreement expires as set forth in Section 4.1 above without early termination, the License shall automatically become, at EyeTech's election made at least 90 days prior to such expiration, either (i) an exclusive, irrevocable, royalty-bearing license, subject to the surviving provisions of the Agreement, to use and/or sublicense the use of Know How to make, have made, use, import, have imported, offer for sale, sell, and have sold Product(s) in the Field in the Territory as it exists at the time of such expiration, subject to payment by EyeTech to Gilead of a royalty equal to [\*] percent ( [\*] %) of Net Sales of Products made pursuant to the license under this Section 4.2(i) after the expiration of this Agreement, or (ii) a non-exclusive, irrevocable, royalty-free, paid-up license, subject to the surviving provisions of this Agreement, to use and/or sublicense the use of Know How to make, have made, use, import, have imported, offer for sale, sell, and have sold Product(s) in the Field in the Territory as it exists at the time of such expiration.

4.3 Termination for Breach. Each Party shall have the right to terminate this Agreement and its obligations hereunder for material breach by the other Party, which breach remains uncured for sixty (60) days after written notice is provided to the breaching Party, or in the case of an obligation to pay royalty payments or other amounts owing under this Agreement, which breach remains uncured for thirty (30) days after written notice to the breaching Party; provided, however, that non-payment of any royalty amounts or other payments owing under this Agreement, for which the non-paying Party reasonably disputes the obligation or amounts not paid, shall not be deemed a breach of an obligation to pay royalty payments or other amounts owing under this Agreement, provided that the non-paying Party has paid all such amounts not in reasonable dispute.

4.4 Termination in Event of Patent Challenge. Gilead shall have the right to terminate this Agreement if EyeTech challenges the validity of the Licensed Patents within any country in the Territory, effective thirty (30) days after EyeTech's receipt of written notice of such termination by Gilead.

4.5 Reversion of Product Rights.

(a) Termination of Agreement. In the event that this Agreement is terminated pursuant to Sections 4.3 or 4.4 above, other than for Gilead's material breach of this Agreement, the License shall terminate immediately upon such termination.



(b) Loss of License Rights in Country. In the event that EyeTech permanently loses its right to use and sell Products in any country other than by reason of any action or failure to act on the part of Gilead or any party acting on behalf of Gilead, the License shall terminate with respect to such country.

(c) Transfer of Rights. With respect to any and all countries in which EyeTech's license rights are terminated pursuant to Sections 4.5(a), 4.5(b), or 6.7(b): (i) such country(ies) shall automatically be removed from the Territory; (ii) EyeTech hereby grants to Gilead an exclusive, freely sublicensable license under the EyeTech Rights, which license shall be royalty-free and paid-up, subject to Section 4.5(d), to make, have made, use, import, offer for sale, sell and otherwise research, develop and commercialize formulations of the NX1838 in such countries, and Gilead covenants not to practice such license until the actual termination of EyeTech's license rights as to such countries pursuant to Sections 4.5(a) or (b); (iii) EyeTech shall assign all of its right, title and interest in and to, and shall cooperate in the transfer of all of, the following related to Products to the extent that EyeTech Controlled such during the term of this Agreement: (A) INDs and Regulatory Approvals, (B) all pre-clinical and clinical development protocols, data, and reports and other information and data (with any clinical data to be in computer-readable format, where available, and otherwise in printed format, with no obligation of EyeTech to convert to electronic format any portion of such clinical data that currently is available only in printed format), (C) manufacturing development technical reports, (D) toxicology reports, and (E) such other information and data specifically identified in Exhibit B or of such type (the preceding (A), (B), (C), (D) and (E) constituting the "Updated Product Data Package"), (iv) EyeTech shall deliver to Gilead copies of all information, records and data that it Controls that are reasonably necessary for the research, development and commercialization of Products, including without limitation all clinical data relating to Products, forward to Gilead samples of all chemical and biological materials acquired, made, cloned, synthesized, first discovered or collected as a result of research development or commercialization of Products and reasonable necessary to continue the research, development and commercialization of Products, and take such other actions and execute such other instruments, assignments and documents as may be necessary to effect the transfer of rights and materials hereunder to Gilead; and (v) EyeTech shall provide assistance reasonably requested by Gilead for a period of ninety (90) days following the date of notice of termination to facilitate the exercise of the license granted to Gilead in Section 4.5(c)(ii).

(d) Royalties. Any license granted to Gilead pursuant to Section 4.5(c) shall be subject to payment of a royalty to EyeTech on a country-by-country basis at a rate equal to: (i) if such license is granted after initiation of Pivotal Clinical Trials for a Product applicable to such country, [\*] percent ( [\*] %) of Gilead's net sales of Products in such country, or (ii) if such license is granted on or after the first Regulatory Approval of Product in such country, [\*] percent ( [\*] %) of Gilead's net sales of Products in such country.

4.6 Accrued Rights and Obligations; Survival. Termination or expiration of this Agreement for any reason shall be without prejudice to any rights which shall have accrued to the benefit of either Party prior to such termination or expiration, including damages arising from any breach hereunder. The following provisions of this Agreement shall survive the expiration or termination of this Agreement: Sections 2.3, 4.2, 4.6, 5, 6.3, 6.4, 6.5, 6.9, 6.11(a), 6.12, 6.18,

7, 8. The following provisions of this Agreement shall survive the expiration of this Agreement to the extent that the license granted to EyeTech pursuant to Section 4.2 is in effect: Sections 3.4 through 3.9, 4.3, 4.5, 6.2, 6.7(d), 6.7(f), 6.8, 6.11(b), 6.11(c), 6.11(d), 6.13, 6.16 and 6.17(a).

## **SECTION 5**

### **REPRESENTATIONS AND WARRANTIES**

5.1 Corporate Existence and Power. As of the Effective Date, each Party represents and warrants to the other that it (a) is a corporation duly organized, validly existing and in good standing under the laws of the state in which it is incorporated, and (b) has full corporate power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement, including, without limitation, the right to grant the licenses granted hereunder.

5.2 Authority and Binding Agreement. As of the Effective Date, each Party represents and warrants to the other that it (a) has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder, (b) has taken all necessary corporate action on its part required to authorize the execution and delivery of the Agreement and the performance of its obligations hereunder, and (c) the Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid and binding obligation of such Party and is enforceable against it in accordance with its terms.

5.3 Title. As of the Effective Date, each Party represents and warrants to the other that it has sufficient legal and/or beneficial title under its intellectual property rights necessary to perform activities contemplated under this Agreement and to grant the licenses contained in this Agreement and other ownership rights conveyed pursuant to this Agreement

5.4 No Conflict. Each Party represents and warrants to the other that it has not entered, and will not enter, into any agreement with any Third Party which is in conflict with the rights granted to the other Party under this Agreement, and has not taken and will not take any action that would in any way prevent it from granting the rights granted to the other Party under this Agreement, or that would otherwise materially conflict with or adversely affect the rights granted to the other Party under this Agreement.

5.5 No Approvals or Consents Required. Each Party represents and warrants to the other that all necessary consents, approvals and authorizations of all governmental authorities and other persons or entities required to be obtained by such Party in order to enter into this Agreement have been obtained.

5.6 Patents. Gilead represents and warrants to EyeTech that in Exhibit D, Gilead has in good faith supplied a complete list of all Patents it Controls as of the Effective Date, that, but for the grant of the License, would be infringed by the manufacture, use or sale of Products in the Field. If EyeTech reasonably determines that any Patent Controlled by Gilead or any Affiliate of Gilead as of the Effective Date should be added to Exhibit D because EyeTech's manufacture, use or sale of Products would infringe such Patent, then there shall be no deemed breach of Gilead's representations and warranties in this Section 5.6 until after the parties negotiate in

good faith regarding the addition of any such Patent to Exhibit D without any additional financial obligation and are unable to reach agreement on such addition of such Patent.

5.7 No Conflict . Each Party represents and warrants to the other that the execution and delivery of the Agreement by such Party and the performance of such Party's obligations hereunder (a) do not conflict with or violate any requirement of applicable law or regulation or any provision of articles of incorporation or bylaws of such Party in any material way, and (b) do not conflict with, violate or breach or constitute a default or require any consent under, any contractual obligation or court or administrative order by which such Party is bound.

5.8 Regulatory Documents . Gilead represents and warrants to EyeTech that:

- (a) Gilead has furnished EyeTech with access to a complete copy of the United States Regulatory Documents for the Product, including all material amendments and supplements thereto;
- (b) the Regulatory Documents have been accepted by, and Gilead has received no notice that the Regulatory Documents are not in good standing with, the relevant Regulatory Authorities;
- (c) to its knowledge, Gilead has filed with the relevant Regulatory Authorities all required notices, supplemental applications and annual or other reports, including adverse experience reports, with respect to the Regulatory Documents which are material;
- (d) Gilead has received no written notice of any regulatory action by the relevant Regulatory Authorities which may reasonably be expected to have a material adverse effect on the ability of a Party to obtain Regulatory Approval for Products based upon the Regulatory Documents.

5.9 Manufacturing Information . Gilead represents and warrants that, it has delivered or shall by the Delivery Date deliver to EyeTech all of the Transferred Assets and the Manufacturing Information.

5.10 Product Quality . Gilead hereby represents and warrants that all Product Inventory that is provided to EyeTech pursuant to the terms of this Agreement has been manufactured in compliance with all laws, rules and regulations (including without limitation, all applicable IND applications) applicable to the conduct of Gilead's Phase I clinical trial for a Product.

5.11 Implied Warranties . EXCEPT AS EXPRESSLY PROVIDED IN THIS SECTION 5, GILEAD MAKES NO REPRESENTATION OR WARRANTY AS TO THE PATENTS, LICENSED PATENTS, KNOW-HOW, THE TRANSFERRED ASSETS, PRODUCTS, ITS INVENTORY OF PRODUCTS OR NX1838, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT OF THIRD PARTY RIGHTS, OR OTHERWISE, AND GILEAD SPECIFICALLY DISCLAIMS ANY AND ALL IMPLIED OR STATUTORY WARRANTIES.

Without limiting the foregoing, EyeTech acknowledges that it has not and is not relying upon any implied warranty, including without limitation implied warranties of merchantability, fitness for a particular purpose, non-infringement of third party rights, or upon any representation or warranty whatsoever as to the prospects (financial, regulatory or otherwise), or the validity or likelihood of success, of any Product after the Effective Date.

## **SECTION 6**

### **ADDITIONAL COVENANTS AND AGREEMENTS OF THE PARTIES**

6.1 **Governmental Filings**. Gilead and EyeTech each agree to prepare and file whatever filings, requests or applications are required to be filed with any governmental authority in connection with this Agreement and to cooperate with one another as reasonably necessary to accomplish the foregoing. Without limiting the generality of the foregoing, prior to, or within five (5) Business Days following, the assignment, transfer and conveyance by Gilead to EyeTech of the Transferred Assets pursuant to Section 2.2, Gilead shall have submitted to the relevant Regulatory Authorities the information required of a former owner of regulatory filings with respect to the Product, and EyeTech shall submit to the relevant Regulatory Authorities the information required of a new owner of regulatory filings with respect to the Product.

6.2 **Compliance with Law**. EyeTech shall comply with all supranational, national, federal, state, provincial and other local laws and regulations applicable to EyeTech's manufacture, use, development, marketing and sale of the Product. Without limiting the generality of the foregoing sentence, EyeTech shall not promote the Product in any manner in conflict with any applicable laws or regulations.

6.3 **Proprietary Information; Exceptions**. Each Party will maintain all Proprietary Information received by it under this Agreement in trust and confidence and will not disclose any such Proprietary Information to any Third Party or use any such Proprietary Information for any purposes other than those necessary or permitted for performance under this Agreement. In particular, EyeTech shall not use any Know How for the manufacture or sale of any product other than a Product in the Field. Each Party may use such Proprietary Information only to the extent required to accomplish the purposes of this Agreement. Proprietary Information shall not be used for any purpose or in any manner that would constitute a violation of any laws or regulations, including without limitation the export control laws of the United States. Proprietary Information shall not be reproduced in any form except as required to accomplish the intent of this Agreement. No Proprietary Information shall be disclosed to any employee, agent, consultant, Affiliate, or sublicensee who does not have a need for such information. To the extent that disclosure is authorized by this Agreement, the disclosing Party will obtain prior agreement, from its employees, directors, agents, consultants, Affiliates, sublicensees or clinical investigators to whom disclosure is permitted to be made, to obligations to hold in confidence and not make use of such information for any purpose other than those permitted by this Agreement, that are at least as restrictive as those of this Section 6.3. Each Party will use at least the same standard of care as it uses to protect its own Proprietary Information of a similar nature to ensure that such employees, agents, consultants and clinical investigators do not disclose or make any unauthorized use of such Proprietary Information, but no less than reasonable care.

Each Party will notify the other within two (2) Business Days upon discovery of any unauthorized use or disclosure of the Proprietary Information.

Proprietary Information shall not include any information which, as shown by competent proof:

- (a) is now, or hereafter becomes, through no act or failure to act on the part of the receiving Party, its employees or contractors in breach hereof, generally known or available;
- (b) is known by the receiving Party at the time of receiving such information, as evidenced by its contemporaneous written records;
- (c) is hereafter furnished to the receiving Party by a Third Party, as a matter of right and without restriction on disclosure;
- (d) is independently developed by the receiving Party without any breach of this Agreement, as shown by independent, contemporaneous, written records; or
- (e) is the subject of a prior, express, written permission to disclose provided by the disclosing Party.

Notwithstanding any other provision of this Section 6.3, (i) the Parties agree that they shall issue a press release promptly after close of NASDAQ trading on Monday, April 3, 2000, which shall include key financial terms for this Licensing Agreement and the Warrant Agreement, including the initial payment under Section 3.1(a), the aggregate milestone payments under Section 3.2, the number and class of shares issuable upon exercise of the warrant pursuant to the Warrant Agreement and the price per share of such shares, but excluding the royalty rates in Section 3.3 and elsewhere in this Agreement, and (ii) either Party may disclose such terms to bona fide potential corporate partners, to the extent required or contemplated by this Agreement, and to financial underwriters and other Third Parties with a need to know such information, provided that all such disclosures shall be made only to such Third Parties under an obligation of confidentiality and appropriately limited use.

6.4 Authorized Disclosure. Notwithstanding any other provision of this Agreement, each Party may disclose Proprietary Information if such disclosure:

- (a) is in response to a valid order of a court or other governmental body of the United States or a foreign country, or any political subdivision thereof; provided, however, that the receiving Party shall first have given notice to the other Party hereto and shall have made a reasonable effort to obtain a protective order requiring that the Proprietary Information so disclosed be used only for the purposes for which the order was issued;
- (b) is otherwise required by governmental law, rule or regulation, including without limitation rules or regulations of the U.S. Securities and Exchange Commission, or by rules of the National Association of Securities Dealers; or

(c) is otherwise necessary to file or prosecute patent applications, prosecute or defend litigation or comply with applicable governmental regulations or otherwise establish rights or enforce obligations under this Agreement, but only to the extent that any such disclosure is necessary. Under no circumstances will EyeTech disclose publicly proprietary features of Gilead manufacturing technology for NX1838; provided, however, that Gilead shall cooperate with EyeTech to disclose such information to the extent required to provide EyeTech with reasonable protection from liability by reason of this prohibition on disclosure.

6.5 Return of Proprietary Information. In the event that the License terminates or expires, EyeTech shall promptly return all Proprietary Information received by it from Gilead.

6.6 Expenses. Gilead and EyeTech shall each bear their own direct and indirect expenses incurred in connection with the negotiation and preparation of this Agreement and, except as set forth in this Agreement, the performance of the obligations contemplated hereby.

6.7 Efforts.

(a) EyeTech shall use Reasonable Diligence to develop, obtain Regulatory Approval for, and commercialize Product(s) in the Territory and shall be solely responsible for all related development, regulatory and commercialization efforts and costs; *provided, however*, with respect to countries in the Territory that are not Major Countries (such countries, "Non-Major Countries"), EyeTech shall have the right to determine, on a country by country basis using its reasonable discretion not to pursue Regulatory Approval in such Non-Major Country because commercialization of the Product is not economically feasible for EyeTech. EyeTech shall provide Gilead with written notice of all decisions by EyeTech to not pursue development, Regulatory Approval or commercialization in a country in the Territory for a Product in the Field for any reason within thirty (30) days of such decision.

(b) In the event EyeTech or its sublicensees fail to undertake Reasonable Diligence in developing, obtaining Regulatory Approval of, and/or commercializing Products in one or more Major Countries in the Territory, such failure shall (i) automatically cause the License to terminate with respect to such Major Country(ies) and have the consequences set forth in Section 4.5(c) with respect to any such Major Country(ies); and (ii) shall entitle Gilead to terminate this Agreement for material breach under Section 4.3 if there have been such failures of diligence applying to four (4) or more Major Countries, with the consequences set forth in Section 4.5(c); provided in each case that EyeTech (or its sublicensee) does not cure such failure within ninety (90) days of written notice from Gilead specifying its belief that such failure has occurred and the reasons therefor. Gilead shall not be entitled to exercise the foregoing termination rights if EyeTech reasonably disputes Gilead's contention that EyeTech has failed in such Reasonable Diligence until after the Parties have first completed dispute resolution procedures pursuant to Section 8.9.

(c) EyeTech's Responsibilities. EyeTech shall be responsible, at its sole expense, for all development of, regulatory activities relating to, and commercialization of Products in the Territory beginning on the Effective Date, including performing clinical development of Products within the Territory using standard pharmaceutical industry practices,

and making all regulatory filings necessary to obtain Regulatory Approvals of Products in the Territory. Within thirty (30) days of the Effective Date, EyeTech shall provide to Gilead a formal clinical development plan for Products in the Field in the Territory (the "Development Plan"), pursuant to which EyeTech will carry out development of Products under this Agreement, which shall be reasonably satisfactory to Gilead. The Development Plan shall be subject to amendment by EyeTech from time to time, with notice and copy of such amended Development Plan to Gilead; provided, however, (i) Gilead shall have the right to review such proposed amendment prior to its adoption; (ii) EyeTech shall in good faith consider any reasonable comments and considerations raised by Gilead within five (5) Business Days of Gilead's receipt of such proposed amendment; and (iii) such proposed amendment is consistent with EyeTech's obligations of Reasonable Diligence pursuant to Sections 6.7(a) and (b).

(d) Regulatory Filings and Matters. EyeTech will file such regulatory filings as may be necessary to obtain Regulatory Approvals of Products within the Territory. EyeTech will be responsible for all communications with all supranational, regional, federal, state, provincial or other local regulatory agencies, department, bureaus and other governmental authorities with jurisdiction over Regulatory Approvals in connection with such filings. EyeTech will keep Gilead informed of the status of such filings in each country, and will provide Gilead with at least sixty (60) days advance notice of the final submission of an application for Regulatory Approval in any country of the Territory. EyeTech will promptly advise Gilead each time that it obtains Regulatory Approval of Products in a country of the Territory. EyeTech shall be responsible for the reporting of adverse events related to the use of Products marketed by EyeTech, its Affiliates or sublicensees in the Territory.

(e) Reporting; Meetings. Prior to February 1, May 1, August 1 and November 1 of each Calendar Year, EyeTech will submit to Gilead, written reports summarizing the status and progress of the clinical development, marketing and commercialization efforts for each Product in sufficient detail so as to allow Gilead to monitor EyeTech's compliance with Section 6.7(a). During March and September of each Calendar Year, senior executive and scientific personnel of EyeTech will meet with Gilead representatives to report on the status of development and commercialization of Products and to consult as to modifications in the development plan referenced in Section 6.7(c).

6.8 Pricing. EyeTech shall determine, in its sole discretion, the pricing, discounting policy and other commercial terms relating solely to Products. EyeTech agrees that EyeTech, its Affiliates and its sublicensees shall not subject the selling price of Products to abnormal discounts taken against Products in order to achieve sales of other products.

6.9 Export Control. This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States of America or other countries which may be imposed upon or related to Gilead or EyeTech from time to time. Each Party agrees that it will not export, directly or indirectly, any technical information acquired from the other Party under this Agreement or any products using such technical information to a location or in a manner that at the time of export requires an export license or other governmental approval, without first obtaining the written consent to do so from the appropriate agency or other governmental entity.

6.10 Inability to Develop or Commercialize. EyeTech represents that it has, and covenants that it will maintain adequate resources and expertise to fulfill its obligations under this Agreement. During the term of this Agreement, EyeTech shall provide such information that Gilead may request that is reasonably necessary for Gilead to verify that EyeTech has adequate resources and expertise to fulfill its obligations under this Section 6.10.

6.11 Compliance with Laws; Cooperation; Maintenance of Original Documents.

(a) Each Party shall carry out its activities pursuant to this Agreement in compliance with all applicable supranational, national, state, provincial and local laws, rules, regulations and guidances.

(b) Gilead and EyeTech each agree to use all commercially reasonable efforts to take, or cause to be taken, all actions and to do, or cause to be done, all things necessary or proper to make effective the transactions contemplated by this Agreement, including such actions as may be reasonably necessary to obtain approvals and consents of governmental Persons and other Persons (including, without limitation, all applicable drug listing and notifications to the relevant Regulatory Authority identifying EyeTech as the licensee of the Product), in each case as reasonably necessary to allow EyeTech to develop, obtain Regulatory Approvals for, and commercialize Products as provided in this Agreement; provided that no Party shall be required in connection with such activities to (1) make any payment (other than as expressly required pursuant to this Agreement), or (2) assume any other material obligation not otherwise required to be assumed by this Agreement.

(c) For so long as EyeTech, its Affiliates or sublicensees is making, using or selling Products, Gilead shall store and maintain all original Manufacturing Information in a secure location in accordance with practices customary for Gilead and the pharmaceutical industry for regulatory documents and in compliance with applicable laws and regulations, and, upon proper notice from a Regulatory Authority of competent jurisdiction over Products, shall make such Manufacturing Information reasonably available to such Regulatory Authority.

(d) EyeTech shall store and maintain all original Updated Product Data Package in a secure location in accordance with practices customary for EyeTech and the pharmaceutical industry for regulatory documents and in compliance with applicable laws and regulations.

6.12 Cooperation. If either Party shall become engaged in or participate in any investigation, claim, litigation or other proceeding with any Third Party, including any proceeding before a Regulatory Authority, relating in any way to the Product or any of the Licensed Patents the other Party shall cooperate in all reasonable respects with such Party in connection therewith, including, without limitation, using its reasonable efforts to make available to the other Party such Party's employees who may be helpful with respect to such investigation, claim, litigation or other proceeding, provided that, for purposes of this provision, reasonable efforts to make available any employee shall be deemed to mean providing a Party with reasonable access to any such employee at no cost for a period of time not to exceed 24 hours (e.g., three 8-hour Business Days). Thereafter, any such employee shall be made available for



such time and upon such terms and conditions (including, but not limited to, compensation) as the Parties may mutually agree.

6.13 Exclusive Rights. The licenses granted under this Agreement to EyeTech are exclusive, and no Person, including without limitation Gilead, shall have any right with respect to such licenses during the term of this Agreement, except as otherwise permitted under this Agreement. Except as otherwise permitted by this Agreement, Gilead shall refrain from granting any right to any Third Party relating to NX1838, the Licensed Patents or the Transferred Assets that would, in any manner, violate the terms of or conflict with the rights granted to EyeTech pursuant to this Agreement.

6.14 Patent Prosecution and Maintenance.

(a) Prosecution of Patents. Licensed Patents shall be prosecuted and maintained in the Territory by Gilead using diligent efforts, at Gilead's expense, except as otherwise provided in this Section 6.14(a). If Gilead reasonably determines that it has no material or commercially useful application for a Licensed Patent, then EyeTech shall have the right to have Gilead prosecute and maintain such Licensed Patents or file for such patent term extension therefor at EyeTech's sole expense. EyeTech shall bear all reasonable costs of any inter partes patent proceeding, including without limitation oppositions, interferences or contested re-examinations, which proceeding shall be conducted under the control of Gilead.

(b) EyeTech shall assist Gilead in obtaining patent extensions and supplementary protection certificates, and provide such other assistance as reasonably requested by Gilead in connection with the prosecution and maintenance of the Licensed Patents in any part of the Territory at EyeTech's sole expense.

6.15 Infringement of Licensed Patents.

(a) Notice. Each Party shall promptly notify the other in writing of any alleged infringement by Third Parties of any Licensed Patent within the Territory and provide any information available to that Party relating to such alleged infringement or misappropriation. EyeTech shall have no rights with respect to any infringement of Licensed Patents that occurs outside of the Field and/or outside the Territory except the right to receive notice pursuant to this Section 6.15(a).

(b) Enforcement of Licensed Patents against Competitive Products. If any Licensed Patent is infringed by a Third Party in connection with the manufacture, use, sale, offer for sale or import of a Competitive Product within the Field and within the Territory ("Competitive Product Infringement"), EyeTech shall have the primary right, but not the obligation, to initiate, prosecute and control any action with respect to such infringement in the Territory, by counsel of its own choice, to secure the cessation of the infringement or to enter suit against the infringer. Gilead shall have the right to participate in any such action with respect to the Licensed Patents and to be represented by counsel of its own choice. If EyeTech fails to bring an action or proceeding to enforce a Licensed Patent within a period of one hundred twenty (120) days after having knowledge of infringement of such Licensed Patent, then Gilead

shall have the right to bring and control any such action by counsel of its own choice, and EyeTech shall have the right to participate in such action and be represented by counsel of its own choice. If a Party brings any such action or proceeding under this Section 6.15(b), the other Party agrees to be joined as a party plaintiff and to give the first Party reasonable assistance and authority to control, file and prosecute the suit as necessary. The costs and expenses of the Party bringing suit under this Section 6.15(b) (including the internal costs and expenses specifically attributable to such suit) shall be reimbursed first out of any damages or other monetary awards recovered in favor of the Parties, and any remaining damages shall be treated as Net Sales of EyeTech in its Territory if EyeTech controlled the action or allocated between the parties in accordance with their economic interest in the profitability of Products if Gilead controlled the action. No settlement or consent judgment or other voluntary final disposition of a suit under this Section 6.15(b) relating to a Licensed Patent may be entered into without the consent of Gilead, not to be unreasonably withheld.

(c) Enforcement of Licensed Patents against Non-Competitive Products. With respect to any infringement of Licensed Patents within the Field and within the Territory that is not a Competitive Product Infringement, Gilead shall have the primary right, but not the obligation, to initiate, prosecute and control any action with respect to such infringement, by counsel of its own choice, to secure the cessation of the infringement or to enter suit against the infringer and shall be the "Lead Party" and EyeTech shall be the "Secondary Party". The Secondary Party shall have the right to participate in any such action with respect to its Patents and to be represented by counsel of its own choice. If the Lead Party fails to bring an action or proceeding to enforce a Licensed Patent within a period of one hundred twenty (120) days after having knowledge of infringement of such Licensed Patent, then the Secondary Party shall have the right to bring and control any such action by counsel of its own choice, and the Lead Party shall have the right to participate in such action and be represented by counsel of its own choice. If a Party brings any such action or proceeding hereunder, the other Party agrees to be joined as a party plaintiff and to give the first Party reasonable assistance and authority to control, file and prosecute the suit as necessary. The costs and expenses of the Party bringing suit under this Section 6.15(c) (including the internal costs and expenses specifically attributable to such suit) shall be reimbursed first out of any damages or other monetary awards recovered in favor of the Parties, and any remaining damages shall be paid to Gilead if Gilead controlled the action, or paid to each Party in proportion to their expenditures in such action, if EyeTech controlled the action. No settlement or consent judgment or other voluntary final disposition of a suit under this Section 6.15(c) relating to a Licensed Patent may be entered into without the consent of Gilead, not to be unreasonably withheld.

#### 6.16 Infringement of Third Party's Rights.

(a) If the practice of the Licensed Patents through the manufacture, use or sale of Products by EyeTech, its Affiliates or sublicensees results in a claim for patent infringement against EyeTech, its Affiliates or sublicensees, the Party to this Agreement first having notice of that claim shall promptly notify the other Party in writing. The notice shall set forth the facts of the claim in reasonable detail.

(b) If a Third Party asserts that a patent or other right owned by or licensed to it is infringed by the practice of the Licensed Patents through the manufacture, use or sale of Products by EyeTech, its Affiliates or sublicensees pursuant to the License, EyeTech may attempt to resolve the problem raised by the asserted infringement. The matter shall be deemed resolved if EyeTech obtains: (a) a license permitting EyeTech to manufacture, use and sell Products in that country on a royalty-free or royalty-bearing basis; (b) a statement or representation from the Third Party that: (1) no action will be taken against EyeTech, its Affiliates or its sublicensees, or (2) that the patent or other right is not infringed by the manufacture, use or sale of Products by EyeTech, its Affiliates or its sublicensees; or (c) a final judgment by a court of competent jurisdiction from which no appeal has or can be taken that the Third Party's patent(s) alleged to be infringed is invalid, or the Third Party's patent(s) or other right(s) are unenforceable or not infringed by the manufacture, use or sale of Products by EyeTech, its Affiliates or sublicensees. EyeTech shall have the primary right to defend any such claim. Gilead shall have the right, but not the obligation, to participate in any such suit at its sole option and at its own expense. Each Party shall reasonably cooperate with the Party conducting the defense of the claim. Neither Party shall enter into any settlement that affects the other Party's rights or interests without such other Party's prior written consent, not to be unreasonably withheld. If EyeTech makes a payment to any Third Party in the course of defending or settling any claim brought by a Third Party pursuant to this Section 6.16, EyeTech shall be entitled to offset a percentage of all such amounts against royalties due to Gilead hereunder as provided in Section 3.3(b).

6.17 Manufacturing.

(a) EyeTech shall be solely responsible for the manufacture of Product following the Effective Date, including without limitation for clinical trials and commercialization.

(b) The Parties shall enter into an agreement dated as of the Effective Date (the "Manufacturing Agreement") obligating the Parties to enter into a clinical supply agreement providing for the fill and finish of sufficient quantities of Product Inventory to complete a Phase Ib trial investigating the use of NX1838 for the treatment of age-related macular degeneration.

6.18 Use of Names, Logos or Symbols. No Party hereto shall use the name, trademarks, logos, physical likeness, employee names or owner symbol of the other Party hereto for any purpose, including, without limitation, in connection with any private or public securities placements, without the prior written consent of the affected Party, such consent not to be unreasonably withheld or delayed so long as such use of name is limited to objective statements of fact, rather than for endorsement purposes. Nothing contained herein shall be construed as granting either Party any rights or license to use any of the other Party's trademarks or trade names without separate, express written permission of the owner of such trademark or trade name.

**SECTION 7**  
**INDEMNIFICATION**

7.1 Indemnification.

(a) Gilead shall indemnify, defend and hold EyeTech (and its directors, officers, employees, consultants, Affiliates and sublicensees) (each, an “EyeTech Indemnitee”) harmless from and against any and all Damages incurred or suffered by an EyeTech Indemnitee as a result of Third Party claims, actions or proceedings (collectively, “EyeTech Claims”) to the extent such EyeTech Claims are a consequence of:

- (1) the breach or alleged breach of any representation or warranty by Gilead hereunder, or
- (2) the negligence or misconduct of Gilead in connection with its activities under this Agreement;

except to the extent such EyeTech Claims are a consequence any of the items in Sections 7.1(b)(1), (2) or (3).

(b) EyeTech shall indemnify, defend and hold Gilead (and its directors, officers, employees, consultants and Affiliates) (each, a “Gilead Indemnitee”) harmless from and against any and all Damages incurred or suffered by a Gilead Indemnitee as a result of Third Party claims, actions or proceedings (collectively, “Gilead Claims”) to the extent such Gilead Claims are a consequence of:

- (1) the breach or alleged breach of any representation or warranty by EyeTech hereunder;
- (2) the negligence or willful misconduct of EyeTech in connection with its activities under this

Agreement;

- (3) the possession, research, development, manufacture, use, offer for sale, sale, administration, storage or transport of NX1838 or Products by EyeTech or its Affiliates or sublicensees;

except to the extent such Gilead Claims are a consequence any of the items in Sections 7.1(a)(1) or (2).

7.2 Mechanics. If a Party or its Affiliate has a right to be indemnified under this Section 7 (the “Indemnified Party”), such Party or Affiliate (i) shall give prompt notice of such EyeTech Claim or Gilead Claim, as the case may be (as applicable, a “Claim”), to the other Party (the “Indemnifying Party”) and (ii) subject to Sections 6.15 and 6.16 of this Agreement, will have the first right to defend any Claims for which it is entitled to indemnification from the other Party under Section 7.1, with the cooperation and at the expense of such other Party, provided that it will not settle any such Claim without the prior written consent of the Indemnifying Party, which consent shall not be unreasonably withheld. If the Indemnified Party is defending a

Claim, the Indemnifying Party shall have the right to be present in person or through counsel at substantive legal proceedings. In the event that the Parties cannot agree as to the application of Section 7.1 to any Damages or Claim, the Parties may conduct separate defenses of such claim. Each Party further reserves the right to claim indemnity from the other in accordance with Section 7.1 upon resolution of the underlying claim.

7.3 Insurance Coverage. Each Party represents and warrants that it is covered and will continue to be covered by a comprehensive general liability insurance program which covers all of each Party's activities and obligations hereunder in accordance with reasonable pharmaceutical industry standards. Each Party will provide the other Party with written notice at least fifteen (15) days prior to any cancellation or material change in such insurance program. Each Party will maintain such insurance program, or other program with comparable coverage, beyond the expiration or termination of this Agreement during the period in which any Product is being commercially distributed or sold, and for a commercially reasonable period thereafter.

7.4 Indemnification Payment Adjustments. The amount of any Damages for which indemnification is provided under this Section 7 shall be reduced to take account of any net tax benefit and shall be increased to take account of any net tax detriment arising from the incurrence or payment of any such Damages or from the receipt of any such indemnification payment and shall be reduced by the insurance proceeds received and any other amount recovered, if any, by the Indemnified Party with respect to any Damages; provided, however, that an Indemnified Party shall not be subject to an obligation to pursue an insurance claim relating to any Damages for which indemnification is sought hereunder. If any Indemnified Party shall have received any payment pursuant to this Section 7 with respect to any Damages and shall subsequently have received insurance proceeds or other amounts with respect to such Damages, then such Indemnified Party shall pay to the Indemnifying Party an amount equal to the difference (if any) between (1) the sum of the amount of those insurance proceeds or other amounts received and the amount of the payment by such Indemnifying Party pursuant to this Section 7 with respect to such Damages and (2) the amount necessary to fully and completely indemnify and hold harmless such Indemnified Party from and against such Damages; provided, however, in no event will such Indemnified Party have any obligation pursuant to this sentence to pay to such Indemnifying Party an amount greater than the amount of the payment by such Indemnifying Party pursuant to this Section 7 with respect to such Damages.

7.5 Indemnification Payment. Upon the final determination of liability and the amount of the indemnification payment under this Section 7, the appropriate Party shall pay to the other in immediately available funds, within thirty (30) Business Days after such determination, the amount of any claim for indemnification made hereunder.

7.6 Survival. The provisions of this Section 7 shall survive any termination of this Agreement with respect to actions of the Parties during the term of the Agreement or the term of any license to EyeTech, whichever occurs later. Each Indemnified Party's rights under this Section 7 shall not be deemed to have been waived or otherwise affected by such Indemnified Party's waiver of the breach of any representation, warranty, agreement or covenant contained in or made pursuant to this Agreement, unless such waiver expressly and in writing also waives any or all of the Indemnified Party's right under Section 7.

**SECTION 8**  
**MISCELLANEOUS**

8.1 Successors and Assigns.. This Agreement shall be binding upon and shall inure to the benefit of the Parties hereto and their respective successors and assigns; provided, however, that neither Gilead nor EyeTech may assign any of its rights, duties or obligations hereunder without the prior written consent of the other, which consent may be withheld in the other's sole discretion, except that no prior written consent shall be required in the event that a Third Party acquires substantially all of the assets or outstanding shares of, or merges with, EyeTech or Gilead, as the case may be. No assignment of this Agreement or of any rights hereunder shall relieve the assigning Party of any of its obligations or liability hereunder. Any attempted assignment not in compliance with this Section 8.1 shall be of no force or effect.

8.2 Notices.. All notices or other communications required or permitted to be given hereunder shall be in writing and shall be deemed to have been duly given if delivered by hand, prepaid telex, cable, telegram or facsimile and confirmed in writing, or mailed first class, postage prepaid, by registered or certified mail, return receipt requested (mailed notices and notices sent by telex, cable or telegram shall be deemed to have been given on the date received) as follows:

If to Gilead, as follows:

Gilead Sciences, Inc.  
333 Lakeside Drive,  
Foster City, CA 94404  
Facsimile: (650) 522-5488  
Attn: Chief Executive Officer

With a copy to:

Gilead Sciences, Inc.  
333 Lakeside Drive,  
Foster City, CA 94404  
Facsimile: (650) 522-5537  
Attn: General Counsel

If to EyeTech, as follows:

EyeTech Pharmaceuticals, Inc.  
300 East 42nd Street  
Third Floor  
New York, N.Y. 10017  
Facsimile: (212) 883-8883  
Attn: Chief Executive Officer

With a copy to:

Duval & Stachenfeld LLP  
300 East 42nd Street  
Third Floor  
New York, N.Y. 10017  
Facsimile: (212) 883-8883  
Attn: Harsha Murthy

or in any case to such other address or addresses as hereafter shall be furnished as provided in this Section 8.2 by any Party hereto to the other Party.

8.3 Waiver; Remedies. Any term or provision of this Agreement may be waived at any time by the Party entitled to the benefit thereof by a written instrument executed by such Party. No delay on the part of Gilead or EyeTech in exercising any right, power or privilege hereunder shall operate as a waiver thereof, nor shall any waiver on the part of either Gilead or EyeTech of any right, power or privilege hereunder operate as a waiver of any other right, power or privilege hereunder nor shall any single or partial exercise of any right, power or privilege hereunder preclude any other or further exercise thereof or the exercise of any other right, power or privilege hereunder.

8.4 Survival of Representations. Each of the representations and warranties made in this Agreement shall survive the expiration or termination of this Agreement only with respect to activities conducted or events occurring prior to the expiration or termination of the Agreement.

8.5 Entire Agreement. This Agreement, together with all exhibits hereto and the Warrant Agreement and the Manufacturing Agreement, constitute the entire agreement between the Parties with respect to the subject matter hereof and supersedes all prior agreements or understandings of the Parties relating thereto.

8.6 Amendment. This Agreement may be modified or amended only by written agreement of the Parties hereto.

8.7 Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original but all of which together shall constitute a single instrument.

8.8 Governing Law. This Agreement shall be governed and construed in accordance with the laws of the State of California, excluding its choice of law rules, except for the application of the Federal Arbitration Act pursuant to Section 8.9(c)(ii).

8.9 Dispute Resolution.

(a) The Parties recognize that disputes as to certain matters may from time to time arise during the term of this Agreement which relate to either party's rights and/or obligations hereunder or thereunder. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by

mutual cooperation and without resort to litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in this Section 8.9 if and when a dispute arises under this Agreement. In the event of disputes between the Parties, a Party seeking to resolve such dispute will, by written notice to the other Party, have such dispute referred to their respective executive officers designated below or their successors, for attempted resolution by good faith negotiations within fourteen (14) days after such notice is received. Said designated officers are as follows:

For EyeTech:	Chief Executive Officer
For Gilead:	Chief Executive Officer

In the event the designated executive officers are not able to resolve such dispute, either party may at any time after the 14 day period invoke the provisions of Section 8.9(b) hereinafter.

(b) Following settlement efforts pursuant to Section 8.9(a), any dispute, controversy or claim arising out of or relating to the validity, construction, enforceability or performance of this Agreement, including disputes relating to alleged breach or to termination of this Agreement under Section 4, other than disputes which are expressly prohibited herein from being resolved by this mechanism, shall be settled by binding Alternative Dispute Resolution (“ADR”) in the manner described below:

(i) If a party intends to begin an ADR to resolve a dispute, such party shall provide written notice (the “ADR Request”) to counsel for the other party informing such other party of such intention and the issues to be resolved. From the date of the ADR Request and until such time as any matter has been finally settled by ADR, the running of the time periods contained in Section 4.3 as to which party must cure a breach of this Agreement shall be suspended as to the subject matter of the dispute.

(ii) Within ten (10) business days after the receipt of the ADR Request, the other party may, by written notice to the counsel for the party initiating ADR, add additional issues to be resolved.

(iii) Disputes regarding the scope, validity and enforceability of Patents shall not be subject to this Section 8.9, except for Section 8.9(a), and shall be submitted to a court of competent jurisdiction.

(c) The ADR shall be conducted pursuant to Comprehensive Rules for Commercial, Real Estate and Construction Disputes then in effect, except that notwithstanding those rules, the following provisions shall apply to the ADR hereunder:

(i) The arbitration shall be conducted by a panel of three arbitrators (the “Panel”). The Panel shall be selected from a pool of retired independent federal judges to be presented to the Parties by JAMS.

(ii) The time periods set forth in the JAMS rules shall be followed, unless a party can demonstrate to the Panel that the complexity of the issues or other reasons



warrant the extension of one or more of the time tables. In such case, the Panel may extend such time tables, but in no event shall the time tables being extended so that the ADR proceeding extends more than 18 months from its beginning to the Award. In regard to such time tables, the Parties (i) acknowledge that the issues that may arise in any dispute involving this Agreement may involve a number of complex matters and (ii) confirm their intention that each party will have the opportunity to conduct complete discovery with respect to all material issues involved in a dispute within the framework provided above. Within such time frames, each party shall have the right to conduct discovery in accordance with the Federal Rules of Civil Procedure. The Panel shall not award punitive damages to either party and the Parties shall be deemed to have waived any right to such damages. The Panel shall, in rendering its decision, apply the substantive law of the State of California, without regard to its conflict of laws provisions, except that the interpretation of and enforcement of this Section 8.9(c)(ii) shall be governed by the Federal Arbitration Act. The Panel shall apply the Federal Rules of Evidence to the hearing. The proceeding shall take place in San Francisco, San Mateo or Santa Clara Counties, California. The fees of the Panels and JAMS shall be paid by the losing Party which shall be designated by the Panel. If the Panel is unable to designate a losing party, it shall so state and the fees shall be split equally between the Parties.

(iii) The Panel is empowered to award any remedy allowed by law, including money damages, multiple damages, prejudgment interest and attorneys' fee, and to grant final, complete, interim, or interlocutory relief, including injunctive relief but excluding punitive damages.

(iv) Except as set forth in Section 8.9(c)(ii), above, each party shall bear its own legal fees. The Panel shall assess its costs, fees and expenses against the party losing the ADR unless it believes that neither party is the clear loser, in which case the Panel shall divide such fees, costs and expenses according to the Panel's sole discretion.

(v) The ADR proceeding shall be confidential and the Panel shall issue appropriate protective orders to safeguard each party's Proprietary Information. Except as required by law, no party shall make (or instruct the Panel to make) any public announcement with respect to the proceedings or decision of the Panel without prior written consent of each other party. The existence of any dispute submitted to ADR, and the award, shall be kept in confidence by the Parties and the Panel, except as required in connection with the enforcement of such award or as otherwise required by applicable law.

(d) The Parties agree that judgment on any arbitral award issued pursuant to this Section 8.9 shall be entered in the United States District Court for the Northern District of California or, in the event such court does not have subject matter jurisdiction over the dispute in question, such judgment shall be entered in the Superior Court of the State of California, in the County of San Mateo, and each Party agrees to the co-exclusive personal jurisdiction of such courts for the purpose of entry of such a judgment.

8.10 Captions. All section titles or captions contained in this Agreement, in any Exhibit referred to herein and the table of contents, if any, to this Agreement are for convenience

only, shall not be deemed a part of this Agreement and shall not affect the meaning or interpretation of this Agreement.

8.11 No Third Party Rights or Obligations. Except as expressly provided in Section 7, no provision of this Agreement shall be deemed or construed in any way to result in the creation of any rights or obligation in any Person not a Party to this Agreement.

8.12 Severability. If any provision of this Agreement is found or declared to be invalid or unenforceable by any court or other competent authority having jurisdiction, such finding or declaration shall not invalidate any other provision hereof, and this Agreement shall thereafter continue in full force and effect. In the event any such provision is so declared invalid or unenforceable, the Parties shall negotiate an alternative provision that closely approximates the Parties' intent, to the extent allowable under law.

8.13 Attachments. All Exhibits and other attachments to this Agreement are by this reference incorporated herein and made a part of this Agreement.

8.14 Disclaimer of Agency. This Agreement shall not constitute any Party the legal representative or agent of another, nor shall any Party have the right or authority to assume, create, or incur any Third Party liability or obligation of any kind, express or implied, against or in the name of or on behalf of another except as expressly set forth in this Agreement.

8.15 Interpretation. This Agreement has been jointly prepared by the Parties and their respective legal counsel and shall not be strictly construed against either Party.

8.16 Force Majeure. Each of the Parties hereto shall be excused from the performance of its obligations hereunder (except the payment of money) in the event such performance is prevented by force majeure, provided that the non-performing Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so long as the condition constituting force majeure continues and the non-performing Party makes and continues to make reasonable efforts to remove or overcome the condition. For the purposes of this Agreement, force majeure shall mean any act of God, fire, casualty, flood, war, earthquake, strike, failure of public utilities, any act, exercise, assertion or requirement of governmental authority, accident, epidemic, destruction of facilities, or such other similar occurrences beyond the control of the Party whose performance is affected.

8.17 Limitation of Liability. IN NO EVENT SHALL EITHER PARTY OR ITS RESPECTIVE AFFILIATES AND PERMITTED SUBLICENSEES BE LIABLE FOR SPECIAL, EXEMPLARY, CONSEQUENTIAL OR PUNITIVE DAMAGES, WHETHER IN CONTRACT, WARRANTY, TORT, STRICT LIABILITY OR OTHERWISE, EXCEPT TO THE EXTENT SUCH PARTY MAY BE REQUIRED TO INDEMNIFY THE OTHER PARTY FROM SUCH DAMAGES CLAIMED BY THIRD PARTIES UNDER SECTION 7.

8.18 No Assumption of Obligations. Except as expressly provided in this Agreement: (i) neither Party is assuming any of the other Party's responsibilities, duties (including, without limitation, compliance with all applicable laws and regulations), obligations (including payment obligations), claims, Damages, liabilities, burdens and problems of any nature whatsoever

(collectively, “Obligations”), whether by operation of law or otherwise, and (ii) without limiting the foregoing, EyeTech is not assuming any of Gilead’s Obligations with respect to Transferred Assets.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be duly executed and delivered as of the day and year first above written.

GILEAD SCIENCES, INC.

EYETECH PHARMACEUTICALS, INC.

By: /s/ Mark L. Perry  
Mark L. Perry  
Senior Vice President, Operations

By: /s/ David Guyer  
David Guyer  
Chief Executive Officer

NEXSTAR PHARMACEUTICALS, INC.

By: /s/ Mark L. Perry  
Mark L. Perry  
Chief Financial Officer

## EXHIBIT A

**NX1838**

The compound NX1838, is [\*]

A-1

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## EXHIBIT B

### PRODUCT DATA PACKAGE INFORMATION AND DATA

#### Regulatory

- IND
- Pre-IND submissions
- IND correspondence
- IND supplements

#### Clinical

- Case Report Forms by site
- 1838 Project Files
- Investigator Files by Site

#### Manufacturing (API)

- Synthesis Batch Records
- Accompanying Analytical Data
- Records of Failed Lots

#### Manufacturing (DP)

- Master Production Records
- Bills of Materials
- Assay methods
- Finished Product Specifications

EXHIBIT C

PRODUCT INVENTORY

DESCRIPTION	PART NUMBER	LOT NUMBER	QUANTITY	UNITS OF MEASUREMENT
[*]				
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**EXHIBIT D**

**LICENSED PATENTS**

[illegible]



## AMENDMENT NO. 1 TO LICENSING AGREEMENT

THIS AMENDMENT NO. 1 (the "Amendment") is entered into as of the 9th day of May, 2000, by and among GILEAD SCIENCES, INC., a Delaware corporation, NEXSTAR PHARMACEUTICALS, INC., a Delaware corporation (these two parties collectively referred to herein as "Gilead") and EYETECH PHARMACEUTICALS, INC., a Delaware corporation (hereinafter "EyeTech"), to amend the Licensing Agreement made effective as of March 31, 2000 (the "Agreement") by and among Gilead and EyeTech, whereby Gilead licensed EyeTech to further clinically develop and commercialize Gilead's proprietary compound NX 1838. Capitalized terms used and not otherwise defined herein shall have the meanings given them in the Agreement.

## RECITALS

WHEREAS, the Parties desire to amend the Agreement to define the term "Proprietary Information" which was employed but not defined in the Licensing Agreement, and to set the term of survival for the confidentiality, nondisclosure and nonuse obligations pertaining to such Proprietary Information.

NOW, THEREFORE, in consideration of the foregoing and the covenants and promises contained in this Amendment, and the Parties hereby amend the Agreement as follows:

1. Section 1.1 is hereby amended to insert the following defined term and definition immediately following the definition for Product Inventory:

"Proprietary Information" shall mean, subject to Section 6.3 of the Agreement, any Know-How, patent applications or other confidential information of a Party disclosed by such Party to another Party in the course of negotiating or performing under this Agreement or any other written agreement between the Parties entered into on or prior to May 9, 2000. Proprietary Information shall be deemed to include the terms of this Agreement and the terms of any other written agreement between the Parties entered into on or prior to May 9, 2000.

2. Section 6.3 is hereby amended to add the following new paragraph to the end of such section:

The obligations of confidentiality, nondisclosure and nonuse contained in this Section 6.3 shall survive any expiration or termination of this Agreement for a period of five (5) years.

3. The Agreement, as amended by this Amendment, shall remain in full force and effect according to its terms.

4. This Amendment may be executed in any number of counterparts, each of which shall be deemed an original, and all of which taken together shall constitute one and the same instrument.

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5. This Amendment shall be effective as of the date first written above.

IN WITNESS WHEREOF, the parties hereto have duly executed this Amendment effective as of the date first written above.

GILEAD SCIENCES, INC.

By: /s/ Mark L. Perry

Name: Mark L. Perry

Title: Senior Vice President, Operations

EYETECH PHARMACEUTICALS, INC.

By: /s/ David Guyer

Name: David Guyer

Title: Chief Executive Officer

NEXSTAR PHARMACEUTICALS, INC.

By: /s/ Mark L. Perry

Name: Mark L. Perry

Title: Chief Financial Officer

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## AMENDMENT NO. 2 TO LICENSING AGREEMENT

THIS AMENDMENT NO. 2 (“the Second Amendment”) is entered into as of December 4, 2001, by and between EyeTech Pharmaceuticals, Inc. a Delaware corporation (“EyeTech”) and Gilead Sciences, Inc., a Delaware corporation (“Gilead”), to amend that certain Licensing Agreement dated as of March 31, 2000, as amended by Amendment No. 1 to Licensing Agreement dated as of May 9, 2000 (the “Agreement”) by and between EyeTech and Gilead (as successor in interest to NeXstar Pharmaceuticals, Inc.). Capitalized terms used and not otherwise defined herein shall have the meanings given them in the Agreement.

WHEREAS, EyeTech desires to obtain access to notebooks of Gilead relating or potentially relating to the compound NX1838;

WHEREAS, Gilead is willing to provide such access to EyeTech personnel if the information in such notebooks is kept confidential by EyeTech and its personnel under the terms of the Agreement;

WHEREAS, in support of EyeTech’s activities under the Agreement, Gilead would like to provide to EyeTech, and EyeTech would like to receive from Gilead, certain of Gilead’s inventory of VEGF aptamer and potentially a reference standard possessed by Gilead, as determine by Gilead (“Materials”).

NOW, THEREFOR, in consideration of the foregoing and the covenants herein, EyeTech and Gilead hereby agree, and the Agreement is hereby amended, as follows:

1. All information learned, received, extracted or copied by EyeTech from notebooks or other documents or records of Gilead, or excerpts thereof, that Gilead provides or makes available to EyeTech after the date hereof shall be deemed to be Proprietary Information of Gilead and subject to provisions in the Agreement pertaining to Proprietary Information of Gilead.
  2. Nothing in this Second Amendment shall be construed as creating any obligation of Gilead to provide or make available to EyeTech any notebooks or other documents or records of Gilead, or excerpts thereof, beyond any such obligation of Gilead currently existing under the Agreement.
  3. Gilead will deliver the materials to EyeTech within fifteen (15) days after the date hereof.
  4. EyeTech shall not and shall not permit any person or entity to (a) administer any Materials to humans under any circumstances; or (b) administer any Materials to animals except in compliance with U.S. National Institutes of Health guidelines and all other applicable laws, rules, and regulations.
  5. Nothing in this Amendment shall be construed to grant either Party any right or license beyond those set forth in the Agreement.
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6. GILEAD PROVIDES THE MATERIALS “AS IS”, WITH NO WARRANTY, EXPRESS, IMPLIED OR STATUTORY, INCLUDING WITHOUT LIMITATION WARRANTIES OF MERCHANTABILITY, TITLE, NON-INFRINGEMENT, EXCLUSIVITY, OR FITNESS FOR A PARTICULAR PURPOSE.

7. Solely for purposes of Section 7.1(b) of the Agreement, the Materials will be deemed to be included within NX1838.

8. The Agreement, as amended by this Second Amendment, shall remain in full force and effect according to its terms.

9. This Second Amendment may be executed in any number of counterparts, each of which shall be deemed an original, and all of which taken together shall constitute one and the same instrument.

10. This Second Amendment shall be effective as of the date first written above.

IN WITNESS WHEREOF, the parties hereto have duly executed this Second Amendment effective as of the date first written above.

EYETECH PHARMACEUTICALS, INC.

By: /s/ Harsha Murthy

Name: Harsha Murthy

Title: V.P. - Business Development & General Counsel

GILEAD SCIENCES, INC.

By: /s/ Nicole Onetto

Name: Nicole Onetto

Title: SVP Medical Affairs

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CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

### **AMENDMENT NO. 3 TO LICENSING AGREEMENT**

This Amendment No. 3 to Licensing Agreement (the “Third Amendment”) amends, effective August 30, 2002, the LICENSING AGREEMENT, itself effective as of March 31, 2000 and previously amended first as of May 9, 2000 and second as of December 4, 2001 (as so twice amended, the “Agreement”) originally by and among GILEAD SCIENCES, INC., a Delaware corporation with its principal office located at 333 Lakeside Drive, Foster City, CA 94404 (“Gilead”), and its wholly-owned subsidiary, NEXSTAR PHARMACEUTICALS, INC., a Delaware corporation, on the one hand, and EYETECH PHARMACEUTICALS, INC., a Delaware corporation with its principal office as of the date hereof located at 500 Seventh Avenue, 18<sup>th</sup> Floor, New York, New York 10018 (“EyeTech”), on the other hand, and currently between Gilead and EyeTech. All capitalized terms used herein and not otherwise defined shall have the meanings given in the Agreement. All references to “Sections” and “Articles” are to sections and articles of the Agreement unless otherwise specified below.

The Parties hereby amend the Agreement as follows:

1. The definition of Net Sales is deleted in its entirety and replaced with the following:

“‘ Net Sales ’ shall mean, with respect to the Product, the gross amount billed or invoiced by EyeTech, its Affiliates or sublicensees to Third Parties for Products and Combination Products (defined below), less the following deductions to the extent included in such billed or invoiced or credited amounts:

- (a) trade, quantity and cash discounts allowed, but expressly excluding discounts or allowances offered as part of a package of products that includes a Product sold by EyeTech, its Affiliates or sublicensees;
- (b) refunds, chargebacks and any other allowances which effectively reduce the net selling price;
- (c) actual product returns, credits and allowances allowed to customers;
- (d) rebates actually paid or credited to any governmental agency (or branch thereof) or to any Third Party payor, administrator or contractee;
- (e) discounts mandated by, or granted to meet the requirements of, applicable state, provincial or federal law, wholesaler, including required chargebacks and retroactive price reductions;
- (f) transportation, freight, postage charges and other charges such as insurance, relating thereto, in each case included as a specific line item on an invoice to such Third Parties; and
- (g) taxes, excises or other governmental charges upon or measured by the production, sale, transportation, delivery or use of goods, in each case included as a specific line item on an invoice to such Third Parties.

If any such sales to Third Parties are made in transactions that are not at arm’s length between the buyer and the seller, then the gross amount to be included in the calculation of Net Sales shall be the amount that would have been invoiced had the transaction been conducted at arm’s length. Such amount that would have been invoiced shall be determined, wherever possible, by reference to the average selling price of the relevant Product in arm’s-length transactions in the relevant country.

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If EyeTech, its Affiliate or sublicensee sells a Product in unfinished form to a Third Party for resale, then the gross amount to be included in the calculation of Net Sales arising from such sale shall be the amount invoiced by the Third Party upon resale, in lieu of the amount invoiced by EyeTech, its Affiliates or sublicensee when selling the Product in unfinished form. Otherwise, where EyeTech, its Affiliate or sublicensee sells a Product in finished form to a Third Party that does not require a sublicense under the Licensed Patents for further resale (a distributor) (each such Third Party hereinafter a “Distributor”), the amount to be included in the calculation of Net Sales shall be the price invoiced from EyeTech or its Affiliate or sublicensee to the Third Party, not the amount invoiced by the Third Party upon resale.

If, in addition to or in lieu of a transfer price paid for quantities of Product supplied, any Distributor provides consideration to EyeTech, its Affiliate or sublicensee in connection with any Product or the Distributor’s rights or relationship with EyeTech, its Affiliate or sublicensee in relation thereto, then such consideration shall be included in the calculation of Net Sales in the calendar quarter in which it becomes due to EyeTech or its Affiliate or sublicensee (as applicable).

Notwithstanding the foregoing, amounts received by EyeTech, or its Affiliates or sublicensees, for the sale of Products among EyeTech and its Affiliates or sublicensees for resale shall not be included in the computation of Net Sales hereunder.

Net Sales shall be determined from books and records maintained in accordance with GAAP, consistently applied throughout the organization and across all products of the entity whose sales of Product are giving rise to Net Sales.

If any Product (i) contains or is sold with a therapeutically active ingredient other than NX1838 (such therapeutically active ingredient an “Other Active”), regardless of whether they are coformulated or physically packaged together, or (ii) is sold with a mechanical or pharmacological delivery system for the delivery of such Product (such system, a “Delivery System), (such a Product including and together with the Other Active or Delivery System, a “Combination Product”) then Net Sales from the Combination Product shall be determined by multiplying the Net Sales of the Combination Product (as determined without reference to the calculations of this paragraph ) by the fraction  $A/(A+B)$ , where A is the average sale price of a Product of the same formulation and dosage when not sold as part of a Combination Product, and B is the average sale price of the Other Active or Delivery System when sold separately, or, only if the value of B cannot be determined, where  $A+B$  is the average sales price of the Combination Product. If A and B can be determined, in no event will the sales price of the Combination Product be less than the sum of A and B. If both A and B, and  $A+B$ , cannot be determined, then  $C/(C+D)$  shall be substituted for  $A/(A+B)$  in such calculation, where C is EyeTech’s cost of goods of the Product and D is EyeTech’s cost of goods for the Other Active or Delivery System, determined in accordance with the method of accounting normally employed by EyeTech in computing cost of goods sold (which must be in accordance with GAAP consistently applied throughout EyeTech), *provided, however*, that the minimum value of such fraction as used in the calculation of Net Sales shall be 0.9. All average prices, for purposes of this paragraph, shall be determined on a country-by-country and product-by-product basis.

For clarity and without limiting the generality of the foregoing, the inclusion of PEG (polyethylene glycol) in a Product, because PEG is not a therapeutically active molecule, will not in itself be deemed to result in a Combination Product for purposes of the foregoing paragraph.”

2. The phrase “with a right to sublicense to its Affiliates or (subject to Section 2.4) to any other Person” in Section 2.1 is deleted and replaced with the following: “with a right (subject to Section 2.4) to sublicense to its Affiliates or to any other Person.”
3. In Section 2.5, the phrase “EyeTech Know-How and EyeTech Patents” in the nineteenth (19<sup>th</sup>) line is deleted and replaced with the following: “EyeTech Rights.”

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

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4. The following words are included in the sentence that is the text of Section 2.3, at the end of the sentence: “within the scope of the license granted EyeTech in Section 2.1.”
5. Section 3.3(b) is deleted in its entirety and replaced with the following:

“Offset. Notwithstanding the foregoing, on a country-by-country and Product-by-Product basis, EyeTech may credit against Royalties otherwise due hereunder on Net Sales of such Product in such country [\*] percent in any calendar quarter ( [\*] %) of any royalties it must pay to any Third Party on sales of such Product in such country in such calendar quarter: (1) pursuant to any licenses necessary to practice the License; or (2) resulting from any litigation (including settlement thereof) under Section 6.16; *provided, however* , for purposes of this Section 3.3(b) that the applicable royalty rates used for calculation of Royalties payable to Gilead shall not be reduced to less than [\*] percent ( [\*] %) of the royalty rate(s) otherwise applicable pursuant to Section 3.3(a).”
6. The following is inserted between the first and second sentences of Section 3.7: “EyeTech shall promptly remit any amounts so withheld to the appropriate governmental authority and provide Gilead with written evidence of such payment.”
7. Section 4.6 is deleted in its entirety and replaced with the following:

“Accrued Rights and Obligations; Survival. Termination or expiration of this Agreement for any reason shall be without prejudice to any rights which shall have accrued to the benefit of either Party prior to such termination or expiration, including damages arising from any breach hereunder. The following provisions of this Agreement shall survive any expiration or termination of this Agreement: Sections 2.3, 3.6, 4.2, 4.6, 5, 6.3, 6.4, 6.5, 6.9, 6.11(a), 6.12, 6.18, 7, and 8. In addition, the following provisions of this Agreement shall survive the expiration of this Agreement to the extent that the license granted to EyeTech pursuant to Section 4.2 is in effect: Sections 3.4 through 3.9, 4.3, 4.5, 6.2, 6.7(c)-(e), 6.8, 6.9, 6.11(b), 6.11(c), 6.11(d), 6.13, 6.16 and 6.17(a).”
8. The last sentence of Section 6.13 is deleted in its entirety and changed to read as follows: “Except as otherwise permitted by this Agreement or required by law, Gilead shall refrain from granting any right to any Third Party relating to NX1838, the Licensed Patents or the Transferred Assets that would, in any manner, violate the terms of or conflict with the rights granted to EyeTech pursuant to this Agreement.
9. The phrase “distribution,” is inserted immediately prior to “administration” in the second (2<sup>nd</sup>) line of Section 7.1(b)(3).
10. Section 8.2, “Notices” is changed to show EyeTech’s address as follows: EyeTech Pharmaceuticals, Inc., 500 Seventh Avenue, 18<sup>th</sup> Floor, New York, New York 10018, Facsimile: 212-997-9251, attn: Chief Executive Officer.
11. The Agreement, as amended by this Third Amendment, remains in full force and effect according to its terms.
12. Article 18 shall apply to this Third Amendment as if set forth herein in its entirety.

IN WITNESS WHEREOF, the Parties have caused this Third Amendment to be duly executed and delivered as of the day and year first above written.

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GILEAD SCIENCES, INC.

By: /s/ Gregg Alton

Gregg Alton

Vice President and General Counsel

EYETECH PHARMACEUTICALS, INC.

By: /s/ David Guyer

David Guyer

Chief Executive Officer

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GlaxoSmithKline Letterhead

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

Gilead World Markets Limited  
Queensgate House  
South Church Street  
PO Box 1234GT'  
Grand Cayman  
Cayman Islands

19 May 2003

Dear Sirs,

**Licensing Agreement dated 26 April 2002 made by and between (1) Glaxo Group Limited and (2) Gilead World Markets Limited ("Agreement")**

We refer to the Agreement and hereby confirm that with effect from 28 April 2003 Exhibit E of the Agreement (Safety Data Exchange Protocol) ("SDEP") has been replaced with a revised SDEP the terms of which are attached as Appendix 1 hereof.

We would be grateful if you could execute and return to us the duplicate copy of this letter which is enclosed herewith to acknowledge and confirm your acceptance of its terms.

Yours faithfully,

/s/ Victoria Llewellyn  
Glaxo Group Limited  
Victoria Llewellyn  
Assistant Secretary

Gilead World Markets Limited

By: /s/ Gregg H. Alton  
Gregg H. Alton, Director

Date: 5/23/03

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## **EXHIBIT E**

### **SAFETY DATA EXCHANGE PROTOCOL**

Safety monitoring of adefovir dipivoxil  
between  
Global Clinical Safety & Pharmacovigilance, GlaxoSmithKline  
And  
Global Drug Safety, Gilead Sciences

This Safety Data Exchange Protocol is agreed by Glaxo Group Limited and Gilead World Markets, Limited in connection with the Licensing Agreement between them dated as of April 2002 (“Licensing Agreement”) and will govern safety data exchange for adefovir dipivoxil by them or by their Affiliates. “Gilead” shall refer to Gilead World Markets, Limited or its Affiliates performing safety data exchange under this Protocol; “GlaxoSmithKline” shall refer to Glaxo Group Limited or its Affiliates performing safety data exchange under this Protocol. Capitalized terms used but not otherwise defined herein shall have the meanings given such terms in the Licensing Agreement to the extent defined therein.

#### **1. DEFINITIONS (CONSISTENT WITH ICH GUIDELINE E2A)**

[\*]

#### **2. LANGUAGE AND MEANS OF EXCHANGE**

[\*]

#### **3. SAFETY DATABASE**

[\*]

#### **4. CORE SAFETY INFORMATION**

[\*]

#### **5. EXPEDITED REPORTING**

[\*]

#### **6. PERIODIC REPORTING**

[\*]

#### **7. REGULATORY ENQUIRIES**

[\*]

#### **8. GENERAL MANAGEMENT OF SAFETY**

[\*]

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**9. REVIEW AND REVISIONS**

[\*]

**10. TERMINATION OF THE SDE PROTOCOL**

[\*]

**11. CONTACTS**

[\*]

For Gilead  
[\*]

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## GlaxoSmithKline Letterhead

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

Gilead World Markets Limited  
Queensgate House  
South Church Street  
PO Box 1234GT'  
Grand Cayman  
Cayman Islands

9 January 2004

Dear Sirs,

**Licensing Agreement dated 26 April 2002 made by and between (1) Glaxo Group Limited and (2) Gilead World Markets Limited ("Agreement")**

We refer to the Agreement and to the letter agreement dated 19 May 2003 and hereby confirm that with effect from the date hereof, Exhibit E of the Agreement (Safety Data Exchange Protocol) ("SDEP") has been replaced with the revised SDEP the terms of which are attached as Appendix 1 hereof.

We would be grateful if you could execute and return to us the duplicate copy of this letter which is enclosed herewith to acknowledge and confirm your acceptance of its terms.

Yours faithfully,

/s/ Victoria Llewellyn  
\_\_\_\_\_  
Glaxo Group Limited  
Victoria Llewellyn  
Assistant Secretary

Gilead World Markets Limited

By: /s/ Gregg H. Alton  
\_\_\_\_\_  
Gregg H. Alton, Director

Date: 1/27/04  
\_\_\_\_\_

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**EXHIBIT E**  
**SAFETY DATA EXCHANGE PROTOCOL**

Safety monitoring of adefovir dipivoxil  
between  
Global Clinical Safety & Pharmacovigilance, GlaxoSmithKline  
And  
Global Drug Safety, Gilead Sciences

This Safety Data Exchange Protocol is agreed by Glaxo Group Limited and Gilead World Markets, Limited in connection with the Licensing Agreement between them dated as of April 2002 (“Licensing Agreement”) and will govern safety data exchange for adefovir dipivoxil by them or by their Affiliates. “Gilead” shall refer to Gilead World Markets, Limited or its Affiliates performing safety data exchange under this Protocol; “GlaxoSmithKline” shall refer to Glaxo Group Limited or its Affiliates performing safety data exchange under this Protocol. Capitalized terms used but not otherwise defined herein shall have the meanings given such terms in the Licensing Agreement to the extent defined therein.

**1. DEFINITIONS (CONSISTENT WITH ICH GUIDELINE E2A)**

[\*]

**2. LANGUAGE AND MEANS OF EXCHANGE**

[\*]

**3. SAFETY DATABASE**

[\*]

**4. CORE SAFETY INFORMATION**

[\*]

**5. EXPEDITED REPORTING**

[\*]

**6. PERIODIC REPORTING**

[\*]

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**7. REGULATORY ENQUIRIES**

[\*]

**8. GENERAL MANAGEMENT OF SAFETY**

[\*]

**9. REVIEW AND REVISIONS**

[\*]

**10. TERMINATION OF THE SDE PROTOCOL**

[\*]

**11. CONTACTS**

For GlaxoSmithKline

[\*]

For Gilead

[\*]

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**SUBSIDIARIES OF GILEAD SCIENCES, INC.**

<u>Name of Subsidiary</u>	<u>Country or State of Incorporation</u>
Gilead Sciences Limited	Ireland
Gilead World Markets, Ltd.	Cayman Islands
Gilead International, Ltd.	Cayman Islands
Gilead International Holdings, Ltd.	Cayman Islands
Gilead Sciences GmbH	Germany
Gilead Sciences Sarl	France
Gilead Sciences S.r.l.	Italy
Gilead Sciences, S.L.	Spain
Gilead Sciences, Lda.	Portugal
Gilead Sciences Ltd.	United Kingdom
Gilead Sciences International Ltd.	United Kingdom
Gilead Sciences Canada, Inc.	Canada
Gilead Sciences PTY Limited	Australia
Gilead Sciences (NZ)	New Zealand
Gilead Sciences B.V.	Netherlands
Gilead Sciences Hellas EPE	Greece
Gilead Vintage Park, L.L.C.	Delaware

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

We consent to the incorporation by reference in the Registration Statements (Form S-8 Nos. 333-08085, 333-08083, 333-47520, 333-58893, 333-64628, 333-84713, 333-84719, 333-102911 and 333-102912) pertaining to the 1991 Stock Option Plan, Employee Stock Purchase Plan, and the 1995 Non-Employee Directors' Stock Option Plan of Gilead Sciences, Inc., the NeXstar Pharmaceuticals, Inc. 1993 Incentive Stock Plan, NeXstar Pharmaceuticals, Inc. 1995 Director Option Plan, Vestar, Inc. 1988 Stock Option Plan, Triangle Pharmaceuticals, Inc. 1996 Stock Incentive Plan, and the Option Agreement, dated August 5, 2002, between Triangle Pharmaceuticals, Inc. and Daniel G. Welch, and the Registration Statements (Form S-3 Nos. 333-103871 and 333-111451) of Gilead Sciences, Inc. and in the related Prospectuses, as applicable, of our report dated January 23, 2004, 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, 2003.

/s/ ERNST & YOUNG LLP

Palo Alto, California  
March 10, 2004

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**CERTIFICATIONS**

I, John C. Martin, certify that:

1. I have reviewed this annual report on Form 10-K of Gilead Sciences, Inc.;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
  - b) intentionally omitted
  - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures as of the end of the period covered by this report based on such evaluation;
  - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting; and
6. The registrant's other certifying officers and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 10, 2004

/s/ JOHN C. MARTIN

John C. Martin

*President and Chief Executive Officer*

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**CERTIFICATIONS**

I, John F. Milligan, certify that:

1. I have reviewed this annual report on Form 10-K of Gilead Sciences, Inc.;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
  - b) intentionally omitted
  - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures as of the end of the period covered by this report based on such evaluation; and
  - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting; and
6. The registrant's other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 10, 2004

/s/ JOHN F. MILLIGAN

John F. Milligan

*Executive Vice President and Chief Financial Officer*

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**CERTIFICATION**

Pursuant to the requirements set forth in Rule 13a 14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. § 1350, as adopted), John C. Martin, the Chief Executive Officer of Gilead Sciences, Inc. (the "Company"), and John F. Milligan, the Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

**1.** The Company's Annual Report on Form 10-K for the period ended December 31, 2003, to which this Certification is attached as Exhibit 32 (the "Annual Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and

**2.** The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods covered by the Annual Report.

**In Witness Whereof**, the undersigned have set their hands hereto as of the 10th day of March, 2004.

Dated: March 10, 2004

/s/ JOHN C. MARTIN

John C. Martin

*Chief Executive Officer*

/s/ JOHN F. MILLIGAN

John F. Milligan

*Chief Financial Officer*

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Gilead Sciences, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

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