



**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

**FORM 8-K**

**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934**

**DATE OF REPORT (DATE OF EARLIEST EVENT REPORTED):**  
**June 23, 2005**

**GILEAD SCIENCES, INC.**

(Exact name of registrant as specified in its charter)

**DELAWARE**  
(State or other jurisdiction of  
incorporation or organization)

**0-19731**  
(Commission File Number)

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

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

**94404**  
(Zip Code)

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFD 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))



## SECTION 8 – OTHER EVENTS

### Item 8.01 Other Events

On September 27, 1996, Gilead Sciences, Inc., a Delaware corporation (“Gilead”), entered into a Development and License Agreement (the “1996 Agreement”) with F. Hoffmann-La Roche Ltd, a Swiss corporation (“Roche Ltd”), and Hoffmann-La Roche Inc., a New Jersey corporation (“Roche US” and together with Roche Ltd, “Roche”), to develop and commercialize therapies to treat and prevent viral influenza. Tamiflu® (oseltamivir phosphate), an antiviral pill for the treatment and prevention of influenza, was co-developed by Gilead and Roche. Under the 1996 Agreement, Roche has the exclusive right to manufacture and sell Tamiflu worldwide, subject to its obligation to pay Gilead a percentage of the net revenues that Roche generates from Tamiflu sales, subject to reduction for certain defined manufacturing costs. On June 23, 2005, Gilead delivered a notice of termination to Roche for material breach of the 1996 Agreement. If, and when, Gilead’s notice of termination becomes effective, all licenses granted to Roche under the 1996 Agreement would terminate and revert to Gilead. The 1996 Agreement was filed as Exhibit 10.42 to the Report on Form 10-Q for the quarter ended September 30, 1996. A copy of the press release announcing the notice of termination is attached as Exhibit 99.1 to this report and a copy of the notice of termination that was delivered to Roche on June 23, 2005 is attached as Exhibit 99.2 to this report.

## SECTION 9 – FINANCIAL STATEMENTS AND EXHIBITS

### Item 9.01 Financial Statements and Exhibits

(c) Exhibits

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release, issued by Gilead Sciences, Inc. on June 23, 2005.
99.2	Letter dated June 23, 2005 from Gilead Sciences, Inc. to F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc.



### SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**GILEAD SCIENCES, INC.**

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(Registrant)

/s/ John F. Milligan

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John F. Milligan  
Executive Vice President and  
Chief Financial Officer

Date: June 23, 2005



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**Exhibit  
Number**    **Description**

- 99.1    Press Release, issued by Gilead Sciences, Inc. on June 23, 2005.
- 99.2    Letter dated June 23, 2005 from Gilead Sciences, Inc. to F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc.



**Exhibit 99.1**



**CONTACTS:** Susan Hubbard, Investors  
(650) 522-5715

Amy Flood, Media  
(650) 522-5643

**For Immediate Release**

**GILEAD DELIVERS TERMINATION NOTICE TO ROCHE FOR TAMIFLU®  
DEVELOPMENT AND LICENSING AGREEMENT**

**FOSTER CITY, CA – June 23, 2005** – Gilead Sciences, Inc. (Nasdaq: GILD) today announced that it has delivered a notice of termination to F. Hoffmann-La Roche Ltd (Roche) for material breach of the parties’ 1996 Development and License Agreement for Tamiflu® (oseltamivir phosphate), an antiviral pill for the treatment and prevention of influenza. Through this action, Gilead is seeking to terminate the 1996 agreement, which would result in the rights to Tamiflu held by Roche reverting to Gilead.

Tamiflu is the only antiviral pill that has demonstrated activity against the most common strains of the virus and is approved for both the treatment and prevention of influenza infection. Ensuring that Tamiflu is made as widely available as possible is necessary for the protection of public health. Gilead intends to provide physicians, public health officials and consumers with greater access to and information about Tamiflu.

“Despite our repeated communication of concerns over the last several years, Roche has not adequately demonstrated the requisite commitment to Tamiflu since its launch in the United States nearly six years ago, nor has it allocated the necessary resources to realize the potential of the product as a treatment and preventive for influenza,” said John C. Martin, PhD, President and Chief Executive Officer, Gilead Sciences. “Gilead is taking this action in the interest of our shareholders and, importantly, because it is essential for public health that healthcare professionals and consumers have improved access to information about Tamiflu, as well as to the product itself.”

Gilead’s notice of termination describes material breaches of obligations by Roche under the 1996 Agreement in the following areas: (1) Roche’s failure to use best efforts to commercialize Tamiflu by adequately and sustainably promoting and marketing the product in all significant markets, including the failure to launch in a number of markets where the product has been approved; (2) Roche’s failure to use best efforts to commercialize Tamiflu as evidenced by past problems with the manufacturing process that led to shortages in product supply; and (3) Roche’s failure to properly calculate and pay the royalties fairly owed to Gilead.

“As the inventor of this novel product, Gilead’s commitment to the healthcare community, to governments, consumers and to the product itself remains unwavering,” continued Dr. Martin. “The development and delivery of therapeutic advancements like Tamiflu is at the heart of our mission as a company, and Gilead will make every effort to ensure ongoing education about, access to and supply of this important antiviral.”

- more -

Gilead Sciences, Inc. 333 Lakeside Drive Foster City, CA 94404 USA  
phone 650 574 3000 facsimile 650 578 9264

[www.gilead.com](http://www.gilead.com)



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**Conference Call**

At 4:30 p.m. Eastern Time today, Gilead will webcast a conference call live on the company's website to discuss this announcement. To access the live webcast or the archive via the internet, log on to [www.gilead.com](http://www.gilead.com). Please connect to the company's website at least 15 minutes prior to the conference call to ensure adequate time for any software download that may be needed to hear the webcast.

Alternatively, please call 800-299-0148 (U.S.) or 617-801-9711 (international) and dial the participant passcode 12249097 to access the call. Telephone replay is available approximately two hours after the call through 6:30 p.m. Eastern Time, June 26, 2005. To access the replay, please call 888-286-8010 (U.S.) or 617-801-6888 (international) and dial the participant passcode 45968715. The webcast will be archived on [www.gilead.com](http://www.gilead.com) for one year.

**About Influenza**

In a typical flu season, approximately 5-15 percent of the population develops upper respiratory infections that are caused by the influenza virus. These annual epidemics are believed to result in 3-5 million cases of severe illness and 250-500,000 deaths worldwide. In the United States alone, up to 40 million Americans develop the flu, more than 200,000 people are hospitalized and 36,000 people die as a result of the flu and its complications during the average flu season.

While influenza is a significant public health issue in a typical year, the outbreak of pandemic influenza has the potential to cause tens of millions of deaths around the world. The Centers for Disease Control and Prevention (CDC) predict that an influenza pandemic in the United States would cause 20-47 million illnesses, 730,000 hospitalizations and 89-207,000 deaths.

**About Tamiflu**

Tamiflu is indicated for the treatment and prevention of the most common strains of influenza (types A and B). The medication targets one of the two major surface structures of the influenza virus, the neuraminidase protein. The neuraminidase site is virtually the same in the most common strains of influenza, types A and B. Tamiflu attacks the influenza virus and is thought to work by stopping it from spreading inside the body.

Tamiflu is generally well tolerated. In treatment studies in adults, the most frequently reported adverse events were mild-to-moderate transient nausea or vomiting. Other events reported more frequently than with placebo were bronchitis, insomnia and vertigo. In prophylaxis studies in patients aged 13 and older, adverse events were qualitatively similar to those seen in the treatment studies despite a longer duration of dosing. Events reported more frequently in subjects receiving Tamiflu compared to subjects receiving placebo in prophylaxis studies included nausea, vomiting, diarrhea, abdominal pain, dizziness, insomnia, headache, vertigo and fatigue.

In pediatric treatment studies, the most frequently reported adverse event was vomiting. Other events reported more frequently by pediatric patients treated with Tamiflu included abdominal pain, epistaxis, ear disorder and conjunctivitis. These events generally occurred once and resolved despite continued dosing. In a prophylaxis study, which included pediatric patients aged one to 12 years, gastrointestinal events were most frequently reported, particularly vomiting.

Efficacy of Tamiflu in the treatment of subjects with chronic cardiac disease and/or respiratory disease has not been established.

Vaccination is considered the first line of defense against influenza.

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**About Gilead Sciences**

Gilead Sciences is a biopharmaceutical company that discovers, develops and commercializes innovative therapeutics in areas of unmet medical need. The company's mission is to advance the care of patients suffering from life-threatening diseases worldwide. Headquartered in Foster City, California, Gilead has operations in North America, Europe and Australia.

**Securities Safe Harbor Under the Private Securities Litigation Reform Act of 1995**

This press release contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements involve known and unknown risks and uncertainties, which may cause actual results to differ materially from those set forth in such statements. Such forward-looking statements include, without limitation, statements relating to: Gilead's intent to terminate the 1996 Development and Licensing Agreement; Gilead's rights to, and intentions regarding, the Tamiflu product; the benefits to physicians, public health officials, consumers and others of Gilead's full control of Tamiflu; Gilead's ability to provide Tamiflu with additional support and resources and the potential benefits thereof; Gilead's efforts to provide ongoing education about, access to and supply of Tamiflu; Gilead's beliefs regarding Roche, and Gilead's statements regarding Roche's action and inaction, as well as Gilead's basis for determining that Roche is in breach of the 1996 Development and License Agreement; and the CDC's predictions regarding the effects of an influenza pandemic in the United States. Forward-looking statements also include other statements of management's opinion or expectations, such as statements containing the words "believes," "expects," "anticipates" or words of similar import. No forward-looking statement can be guaranteed, and actual results may differ materially from those projected due to, among other things, Roche's response to the notice of termination issued by Gilead, including its ability to cure such breaches pursuant to the terms of the 1996 Development and Licensing Agreement, the outcome of any potential arbitration or litigation relating to Tamiflu or to the 1996 Development and License Agreement, Gilead's ability to timely and efficiently assume the management of the Tamiflu manufacturing and supply process, as well as changes in economic, business, competitive, technological or regulatory factors and trends. All forward-looking statements in this document are made as of the date hereof, based on information available to Gilead as of the date hereof and Gilead undertakes no obligation to publicly update any forward-looking statement in order to reflect events or circumstances that arise after the date of this release. Forward-looking statements in this press release should be evaluated together with, and actual results may be affected by, the many uncertainties that affect Gilead's business, particularly those mentioned in Gilead's Form 10-K for the year ended December 31, 2004, and in periodic reports on Form 10-Q and Form 8-K, including but not limited to those described in Gilead's Form 10-Q for the quarterly period ended March 31, 2005 under the captions "Forward-Looking Statements and Risk Factors."

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*For more information on Gilead Sciences, please visit the company's web site at [www.gilead.com](http://www.gilead.com) or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000.*



**Exhibit 99.2**



June 23, 2005

F. Hoffmann-La Roche Ltd.  
Grenzacherstrasse 124  
CH-4070 Basel  
Switzerland  
Attention: Corporate Law Department  
VIA OVERNIGHT MAIL AND TELEFACSIMILE  
Facsimile: 41-61-688 13 96

Hoffmann-La Roche Inc.  
340 Kingsland Street  
Nutley, NJ 07110  
Attention: Corporate Secretary  
VIA PERSONAL SERVICE AND TELEFACSIMILE  
Facsimile: 973/ 235-7605

Re: Notice of Termination for Breach of 1996 Development and License Agreement

Dear Sirs:

This letter serves as a notice of termination for breach pursuant to Article 9.3 of the 1996 Development and License Agreement by and between Gilead Sciences, Inc. and F. Hoffmann-La Roche Ltd. and Hoffmann-La Roche Inc. (the "Agreement").

Roche's poor performance under the parties' Agreement has been the subject of extensive discussions and correspondence between our two companies for the past five years. Gilead is now taking action to protect the interests of our shareholders and, as importantly, because it is essential for global public health that healthcare professionals and patients have improved access to information about Tamiflu and access to the product itself. We can no longer accept Roche's consistent record of inactivity and neglect with respect to this important product.

**BACKGROUND**

As you are aware, Gilead's long-standing concerns have been discussed by our companies at both the operational level and among senior executives. As early as August 2000, we expressed concerns regarding Roche's reluctance to market Tamiflu aggressively in Europe. Noting that the clinical data for Tamiflu met or exceeded both parties' original expectations, we stressed: "It is our expectation that you will aggressively market Tamiflu in Europe after approval. The nature of the royalty arrangement with Gilead should not, in our view, negatively affect the effort Roche puts



behind the product on a worldwide basis.” We expressed concerns regarding Roche’s calculation of royalties as early as April 2002. At that time, we also expressed concerns regarding marketing strategies, promotional efforts, and manufacturing problems during our meetings with Roche.

The early concerns expressed in these letters and our face-to-face meetings culminated in a letter from John Milligan to Urs Foelml in March 2003, stating that Gilead was concerned that Roche was not meeting its contractual obligations to devote its “Best Efforts” to commercialize Tamiflu. Gilead identified concerns regarding Roche’s (1) inadequate promotional and marketing efforts, (2) manufacturing, supply and logistical problems, and (3) improper reporting of financials to Gilead and calculation of royalties.

In the ensuing two years, in extensive correspondence and meetings, Gilead has continued to communicate its concerns over Roche’s failure to expend meaningful resources in fulfillment of the Best Efforts obligation. As Gilead’s concerns have grown, Roche’s efforts have diminished. It has now become clear that either Roche will not, or likely cannot, satisfy the contract’s requirements over the long term. As a result, this important product will not achieve its potential either commercially or in terms of protecting the public health unless Gilead exercises its contractual right to resume control of Tamiflu’s development and distribution.

### **ROCHE’S BREACH OF THE 1996 DEVELOPMENT AND LICENSE AGREEMENT**

In Article 4.1 of the Agreement, Roche agreed to “devote its Best Efforts to commercialize Tamiflu in substantially all markets in the world.” That section goes on to clarify that “Best Efforts” means “Roche is performing its obligations in a sustained manner consistent with the efforts major pharmaceutical companies devote to significant general practice products of similar market potential derived from internal research programs.”

Beginning in May 2001 and continuing to the present, Roche’s breach has manifested itself in at least the following areas of Roche’s performance: (1) Roche’s failure to use Best Efforts to commercialize Tamiflu by adequately and sustainably promoting and marketing the product in all significant markets, including the failure to launch in a number of markets where the product has been approved; (2) Roche’s failure to exercise its Best Efforts in the manufacture of Tamiflu, including, without limitation, failing to address problems with the manufacturing process that led to product recalls and shortages in product supply; and (3) Roche’s failure to properly calculate and pay the royalties fairly owed to Gilead under the Agreement, resulting in an underpayment of more than \$18.2 million through December 31, 2003 alone.



### 1. Roche's Breach of Article 4: Promotion and Marketing

As expressed in our letter to you of March 26, 2003, we believe Roche has failed to fulfill the Best Efforts standard in both the United States and international markets in promoting and marketing Tamiflu.

**The United States.** Roche has failed to satisfy the Best Efforts standard in the United States in at least the following respects:

**Commercial Product Support.** Roche launched Tamiflu in the United States in late 1999. Not even two years later, around the time that Roche announced a widely publicized change of corporate focus to emphasize specialty practice products, its commercial support for Tamiflu began to drop precipitously. First, in 2001, Roche greatly reduced its general medical practice sales force in the United States. Based on our review of available data, Roche's field sales efforts quickly fell below industry standards, both in the quantity of visits made to doctors and in the qualitative targeting of which doctors to visit. Since then, the size of the Roche sales force has continued to diminish.

Subsequently, during or prior to November 2002, Roche shifted Tamiflu to the company's "Mature Products Group," despite the fact that this innovative product has patent protection until 2017. In Roche's Mature Products Group, Tamiflu no longer had access to the full complement of resources appropriate for commercial support of a novel product of substantial market potential and relevance for the public health. The move to the Mature Products Group was particularly disturbing as Roche at that time had not yet even launched Tamiflu in the European markets. Gilead just recently learned that, in connection with pandemic demand preparations, Roche intends to shift Tamiflu back from the Mature Products Group to a "Lifecycle Team." Notwithstanding Roche's contractual obligations to Gilead, it has taken the spotlight of a global crisis to resurrect Roche's interest in this product.

**Continuing Medical Education/Physician Outreach.** Despite the clear imperative of physician outreach for building awareness and experience with this innovative product, beginning in 2001, Roche abruptly curtailed its continuing medical education (CME) programs involving Tamiflu and severely limited its outreach to the medical profession through medical conferences, post-marketing clinical studies and relevant medical scholarship.

**Direct to Consumer (DTC) Advertising.** Despite Roche's acknowledgement that DTC advertising was "essential" to building the market for Tamiflu, Roche inexplicably slashed the product's advertising budget to woefully inadequate levels, reaching a nadir of roughly \$200,000 in 2002-03.



In response to Gilead's repeated expressions of concern, Roche offered assurances that it has pursued the most appropriate strategy for marketing Tamiflu. Roche has stressed that Tamiflu is "unique." In Roche's opinion, Tamiflu cannot be cost-effectively marketed using "traditional" field force driven approaches that rely on heavy, sustained resourcing. Rather, Roche has argued that the focus must be on public relations, DTC advertising, key account management, and insight gained from "FluStar," Roche's internal influenza surveillance system. Gilead has remained extremely concerned over Roche's failure to allocate adequate resources to support Tamiflu, but, until now, we have relied on Roche's assurances and reserved judgment in order to evaluate the professed strategy based on actual performance.

Based on a thorough review of Roche's strategy over the last three flu seasons, we have now concluded that Gilead's concerns regarding Roche's commitment and capabilities are, indeed, well-founded. Contrary to repeated assurances, the FluStar surveillance program has not resulted in either efficient or adequate targeting of Tamiflu details. Instead, data sources show Roche's targeting efforts fall consistently below industry averages. Not only has Roche failed to exercise its Best Efforts in a sustained manner as required by the Agreement, Roche has failed to execute the marketing strategies it set for itself. This situation was made particularly clear during the flu season of 2004-05, when the public was alarmed due to a dramatic shortage of influenza vaccine. At that critical juncture, Roche did virtually nothing to build awareness of, and appreciation for, Tamiflu as an available treatment option. .

**International Markets.** Roche has failed to market Tamiflu in "all significant markets" as required under the Agreement. Whereas Roche has received approval for Tamiflu in 64 countries, it has failed to launch the product in 43 countries, including Italy, Spain, China, Israel, and most of Latin America. In Europe, Roche's efforts have been hampered by its inability to achieve favorable pricing and characterized by long delays and poor penetration. Roche did not launch Tamiflu in Europe until 2002. When it ultimately did launch Tamiflu in several European markets, it failed to adequately promote and market the product. This has resulted in poor penetration in Europe's leading markets.

Moreover, we continue to be concerned, as we first expressed in August 2000, with Roche's pricing and reimbursement strategies for Tamiflu in the European Union. We appreciate the challenges that all providers of medicine confront in Europe as member countries implement healthcare cost containment programs. We do not believe, however, that Roche has responded adequately to meet these challenges. Roche has failed to engage health and regulatory officials in Europe effectively concerning the important public health benefits of Tamiflu.

Beyond Roche's failure to market Tamiflu adequately, it has also neglected an even more fundamental obligation: to protect the public health by ensuring that medical professionals, especially physicians, have a clear understanding of Tamiflu and its benefits. Experts point out that physicians' understanding of Tamiflu outside of the



United States and Japan is virtually nonexistent. In a recent article titled “What’s in the Medicine Cabinet” by A. Abbott and published in the journal *Nature*, Professor Fred Hayden of the University of Virginia noted, “[i]t would be very good for physicians in these other countries to have experience with the drug [Tamiflu] before a pandemic arrives, so they learn how best to treat patients.”

Roche is required under the contract to promote Tamiflu in “substantially all the markets in the world,” yet over the past five years it has limited itself to minimal efforts in just a handful of major markets. The consequence is that most treating physicians do not understand the benefits Tamiflu can provide or how to use it properly. Despite impressive clinical results documenting the efficacy of Tamiflu in both the treatment and prevention of the flu, Roche has failed to penetrate the market effectively. The result is that a product with important public health benefits, which has the potential of saving many lives, is not reaching those in need. This has materially compromised global public health.

## 2. Roche’s Breach of Article 6: Manufacturing

Roche has failed to exercise its Best Efforts in the manufacture of Tamiflu.

Article 6.2 provides that “Roche shall be solely and exclusively responsible at its own expense for commercial manufacture of Products, either itself or through third parties.” As demonstrated by the following incidents, Roche has failed to manufacture Tamiflu consistent with its contractual obligations.

- In April 2002, traces of two other products were found in Tamiflu powder bound for Japan. The discovery led to a Class 2 product recall of all Tamiflu capsules in the United States. Roche subsequently added a purification step to the manufacturing process and expressed “confidence” that this would not happen again.
- Three months later, in July 2002, an inspection of a Japanese shipment of the pediatric form of Tamiflu, the liquid formulation, revealed the presence of “yellow dots.” Roche’s Japanese affiliate (“Roche-Japan”) was unable to use any of the product in this shipment, resulting in a shortage for the Japanese market. Roche-Japan issued a public apology.
- In October 2002, traces of glass were found in a European batch of liquid formulation Tamiflu. As a result, Roche shipped lesser quantities of the liquid formulation to the EU than it had previously planned were necessary for the product launch in 2002.
- In November 2003, Roche-Japan again discovered problems in its liquid formulation supplies and had to recall its product from the Japanese market.



- In December 2003, Roche-Japan discovered evidence of another “carry-over” product in its liquid formulation supplies, leading to further product shortages during the 2003-04 flu season.

These repeated missteps have created concern over Roche’s ability to manufacture Tamiflu in the manner necessary to secure the level of public acceptance required for the product to deliver its potential public health benefits. Moreover, we believe Roche has not attempted to achieve the manufacturing process efficiencies and economies of scale that generally permit pharmaceutical manufacturers to lower manufacturing costs for growth products over time. To the contrary, Roche’s own schedules reveal that between 2000 and 2003 Roche claimed an increase of 33 percent in Tamiflu’s Actual Manufacturing Costs. These cost inefficiencies are likely to have a further chilling effect on the global public’s ability to avail itself of Tamiflu. The unavoidable conclusion is that Roche has breached its Best Efforts obligation by failing to address problems with the manufacturing process that led to shortages in product supply.

Roche has previously acknowledged that the manufacturing procedures for Tamiflu have not been “robust.” We believe the problem is far more serious. Roche’s efforts with respect to manufacturing Tamiflu violate the contractual standards under Article 4.1. As a result, Roche lost sales (and Gilead lost royalties) in the impacted flu seasons undermined Tamiflu’s reputation at a critical stage in the brand’s lifecycle. The loss of public confidence in Roche, coupled with its lack of cost-efficient manufacturing and affordable pricing, drastically restricts the likely ability of Tamiflu, if it remains under Roche’s control, to achieve its full potential in protecting the public health from the threat of influenza.

### 3. Roche’s Breach of Article 5: Calculation of Royalties

Roche has failed to properly calculate and pay the royalties owed to Gilead under the Agreement, resulting in an underpayment of more than \$18.2 million through December 31, 2003 alone. As a result, Roche has breached its obligations under Article 5 of the Agreement.

Gilead first expressed concern regarding Roche’s calculation of royalties in April 2002, and again, in a letter to you dated March 23, 2003. Because Roche did not offer satisfactory explanations to address Gilead’s concerns, Gilead subsequently requested that Roche prepare a set of abstracts of relevant business records to be reviewed by Gilead’s independent certified public accountants in accordance with Article 8.3. In response, Roche proposed instead that Gilead conduct a formal audit. Gilead accepted Roche’s proposal. Accordingly, Gilead engaged PriceWaterhouse Coopers (PWC) to investigate and analyze the royalty payments made to Gilead under the Agreement during the years 2001-03. The audit included on-site visits to Roche’s facilities in Basel, Switzerland; Nutley, New Jersey; and Tokyo Japan, as well as numerous communications with Roche representatives by phone and email. According to PWC, Roche cooperated in the audit without objection.



The audit is now concluded. PWC has identified four different categories of underpayment that comprise the \$18.2 million in unpaid royalties: (1) Cost of Goods Sold adjustments, (2) United States rebates, (3) United States government pricing concerns and (4) Japanese rebates. We will forward under separate cover a copy of the report for your review.

### CONCLUSION

In a typical flu season, approximately 5-15 percent of the population develops upper respiratory infections that are caused by the influenza virus. These annual epidemics are believed to result in 3-5 million cases of severe illness and 250,000-500,000 deaths worldwide. In the United States alone, more than 200,000 people are hospitalized and 36,000 people die as a result of the flu during the average flu season.

Prior to Tamiflu's development, influenza treatments were limited due to a lack of efficacy against all influenza strains, adverse side effects, and rapid development of viral resistance. Tamiflu is the first and only approved neuraminidase inhibitor available for the treatment and prevention of all common strains of influenza, types A and B. It is also the only neuraminidase inhibitor approved for the treatment of influenza infection in patients as young as one year old.

As a result of Roche's ongoing neglect of the product, Tamiflu's potential for both the treatment and prevention of influenza has not been realized. Roche's deliberate decision to deemphasize Tamiflu in its product portfolio and its simultaneous reduction in marketing and sales resources dedicated to the product resulted in a breakdown in the education of global medical professionals regarding Tamiflu's unique potential to prevent and remedy the effects of influenza. In addition, Roche's history of manufacturing problems leading to Tamiflu supply shortages has undermined public confidence in both the product and in Roche's ability to manufacture the product in the future. Moreover, Roche's inadequate processes for manufacturing Tamiflu have resulted in cost inefficiencies that defy the normal course of cost reductions over time, and that make it more difficult for populations around the world to avail themselves of Tamiflu in an affordable manner. Finally, despite Gilead's efforts over the last several years to assist Roche in remedying its poor performance, Roche has failed to take the steps necessary to live up to its obligations under the 1996 Agreement. The result is that despite Tamiflu's proven efficacy, its use in the United States and international markets has been severely compromised.



Accordingly, Gilead hereby provides this notice of termination for breach of the Agreement under Article 9.3.

Sincerely,

John C. Martin, Ph.D.  
President and Chief Executive Officer  
Gilead Sciences, Inc.