

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

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**FORM 10-Q**

**/x/ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE  
ACT OF 1934**

For the period ended March 31, 2001

or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File No. 0-19731

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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)

**650-574-3000**

(Registrant's telephone number, including area code)

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

Number of shares outstanding of the issuer's common stock, par value \$.001 per share, as of April 30, 2001: 94,696,787

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## PART I. FINANCIAL INFORMATION

### ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

#### GILEAD SCIENCES, INC. CONDENSED CONSOLIDATED BALANCE SHEETS (in thousands, except share and per share amounts)

	March 31, 2001	December 31, 2000
	(unaudited)	(Note)
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 77,403	\$ 197,292
Marketable securities	406,407	315,586
Accounts receivable	51,187	48,814
Inventories	20,537	20,562
Prepaid expenses and other	14,844	11,544
Total current assets	570,378	593,798
Property, plant and equipment, net	54,975	55,174
Other noncurrent assets	32,192	29,127
	\$ 657,545	\$ 678,099
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 9,908	\$ 11,605
Accrued clinical and preclinical expenses	11,010	9,925
Accrued compensation and employee benefits	9,908	9,995
Other accrued liabilities	18,608	19,324
Deferred revenue	2,914	4,355
Long-term obligations due within one year	2,854	3,034
Total current liabilities	55,202	58,238
Long-term deferred revenue	10,578	10,730
Accrued litigation settlement expenses	5,484	5,769
Long-term obligations due after one year	1,941	2,238
Convertible subordinated notes	250,000	250,000
Commitments and contingencies		
Stockholders' equity:		
Common stock, par value \$.001 per share; 500,000,000 shares authorized; shares issued and outstanding: 94,451,768 shares at March 31, 2001 and 94,287,602 shares at December 31, 2000	94	94
Additional paid-in capital	859,572	857,942
Accumulated other comprehensive income (loss)	2,405	(901)
Deferred compensation	(2)	(3)
Accumulated deficit	(527,729)	(506,008)

Total stockholders' equity	334,340	351,124
	<u>\$ 657,545</u>	<u>\$ 678,099</u>

Note: The condensed consolidated balance sheet at December 31, 2000 has been derived from audited financial statements at that date but does not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements.

See accompanying notes.

**GILEAD SCIENCES, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
(unaudited)  
(in thousands, except per share amounts)

	Three Months Ended March 31,	
	2001	2000
<b>Revenues:</b>		
Product sales, net	\$ 45,064	\$ 36,340
Royalty revenue, net	6,182	8,042
Contract revenue	6,437	840
Contract revenue—SAB 101	153	2,490
Total Revenues	57,836	47,712
<b>Costs and expenses:</b>		
Cost of products sold	10,581	7,947
Research and development	51,146	26,246
Selling, general and administrative	21,911	17,970
Total costs and expenses	83,638	52,163
Loss from operations	(25,802)	(4,451)
Interest income	7,383	3,945
Interest expense	(3,533)	(1,537)
Loss before provision for income taxes, equity in loss of unconsolidated affiliate and cumulative effect of change in accounting principle	(21,952)	(2,043)
Provision for income taxes	470	307
Equity in loss of unconsolidated affiliate	390	921
Loss before cumulative effect of change in accounting principle	(22,812)	(3,271)
Cumulative effect of change in accounting principle	1,089	(13,670)
Net loss	\$ (21,723)	\$ (16,941)
<b>Basic and diluted net loss per common share:</b>		
Loss before cumulative effect of change in accounting principle	\$ (0.24)	\$ (0.04)
Cumulative effect of change in accounting principle	0.01	(0.15)
Net loss	\$ (0.23)	\$ (0.19)
Common shares used to calculate basic and diluted net loss per common share	94,349	88,680

See accompanying notes.

**GILEAD SCIENCES, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(unaudited)  
(in thousands)

	Three Months Ended March 31,	
	2001	2000
<b>OPERATING ACTIVITIES:</b>		
Net loss	\$ (21,723)	\$ (16,941)
Adjustments to reconcile net loss to net cash used in operating activities:		
Net effect of change in accounting principle	(1,089)	11,180
Depreciation and amortization	3,445	2,893
Equity in loss of unconsolidated affiliate	390	921
Net unrealized loss on foreign currency transactions	1,135	1,211
Other non-cash transactions	83	94
Changes in assets and liabilities:		
Accounts receivable	(6,030)	(2,439)
Inventories	25	(27)
Prepaid expenses and other assets	(3,436)	2,926
Accounts payable	(1,600)	(2,868)
Accrued liabilities	145	(3,241)
Deferred revenue (excluding net effect of change in accounting principle)	(1,593)	732
Net cash used in operating activities	(30,248)	(5,559)
<b>INVESTING ACTIVITIES:</b>		
Purchases of marketable securities	(157,796)	(59,657)
Sales of marketable securities	34,592	5,990
Maturities of marketable securities	35,456	46,278
Capital expenditures	(3,254)	(3,724)
Investment in unconsolidated affiliate	—	(2,450)
Net cash used in investing activities	(91,002)	(13,563)
<b>FINANCING ACTIVITIES:</b>		
Proceeds from issuances of common stock	1,900	9,996
Repayments of long-term debt	(477)	(913)
Net cash provided by financing activities	1,423	9,083
Effect of exchange rate on cash	(62)	324
Net decrease in cash and cash equivalents	(119,889)	(9,715)
Cash and cash equivalents at beginning of period	197,292	47,011
Cash and cash equivalents at end of period	\$ 77,403	\$ 37,296
<b>NON-CASH ACTIVITIES:</b>		
Common stock issued upon the conversion of convertible subordinated notes	\$ —	\$ 25

See accompanying notes.

## 1. Summary of Significant Accounting Policies

### *Basis of Presentation*

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information. The financial statements include all adjustments (consisting only of normal recurring adjustments) that the management of Gilead Sciences, Inc. ("Gilead," the "Company" or "we") believes is necessary for fair presentation of the balances and results for the periods presented. These interim financial results are not necessarily indicative of results to be expected for the full fiscal year.

Preparing financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses. Examples include provisions for sales returns, bad debts and accrued clinical and preclinical expenses. Actual results may differ from these estimates. The accompanying consolidated financial statements include the accounts of the Company and its wholly and majority-owned subsidiaries. Significant intercompany transactions have been eliminated. Certain prior period amounts have been reclassified to conform to the current presentation. The accompanying financial information should be read in conjunction with the audited financial statements for the fiscal year ended December 31, 2000 included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC").

### *Basic and Diluted Net Loss Per Common Share*

For all periods presented, both basic and diluted net loss per common share are computed by dividing the net loss by the number of weighted average common shares outstanding during the period. Stock options, warrants and convertible subordinated notes could potentially dilute basic earnings per share in the future, but were excluded from the computation of diluted net loss per common share as their effect is antidilutive for the periods presented. All share and per share amounts for all periods presented have been restated to reflect the two-for-one stock split, effected in the form of a 100% stock dividend, completed on February 22, 2001.

## 2. Cumulative Changes in Accounting Principles

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 the cumulative effect of a change in accounting principle. See Note 3, "Derivative Financial Instruments." Effective in the first quarter of 2000, Gilead adopted the SEC's Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements*, and the change was also accounted for as the cumulative effect of a change in accounting principle.

## 3. Derivative Financial Instruments

On January 1, 2001, Gilead adopted SFAS 133, *Accounting for Derivative Instruments and Hedging Activities*. The standards require that Gilead recognize all derivatives as either assets or liabilities measured at fair value. If the derivative is designated as, and meets the definition of, a fair value hedge, the changes in the fair value of the derivative and of the hedged item attributable to the hedged risk are recognized in earnings. If the derivative is designated as, and meets the definition of, a cash flow hedge, the effective portions of changes in the fair value of the derivative are recorded in other comprehensive income ("OCI") and are recognized in the income statement when the hedged item

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affects earnings. Ineffective portions of changes in the fair value of cash flow hedges are recognized in earnings immediately. SFAS 133 also requires that warrants to purchase capital stock of a non-public company, which include a net exercise feature, are to be recorded in the balance sheet at fair value with an offsetting amount recorded in the results of operations. The fair value of the warrants are required to be remeasured at each balance sheet date, with changes in the fair value of the warrants recorded in results of operations.

Gilead has forward currency contracts with maturities of 12 months or less related to its foreign currency denominated accounts receivable and to its forecasted future foreign currency denominated raw material purchases. These forward currency contracts have been designated as and qualify as cash flow hedges. 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 unrecognized firm commitments and forecasted foreign currency cash flows associated with accounts receivable are designated and documented at the inception of the respective hedge as cash flow hedges and evaluated for effectiveness quarterly. As the terms of the forward contract and the underlying transaction are matched at inception, forward contract effectiveness is calculated by comparing the fair value of the contract to the change in the forward value of the underlying hedged item, with the effective portion of the gain or loss on the derivative instrument reported as a component of OCI in stockholders' equity and reclassified into earnings in the same period or periods during which the hedged transaction affects earnings. All values reported in OCI will be reclassified to earnings within 12 months. Any residual change in fair value of the instruments or other ineffectiveness is recognized immediately in selling, general and administrative expense. Ineffectiveness in the first quarter of 2001 was not significant. Additionally, Gilead has a warrant to purchase stock in a non-public company. This warrant has a net exercise feature and accordingly, is considered a derivative instrument under SFAS 133.

Upon adoption of SFAS 133 on January 1, 2001, Gilead recognized an increase in other assets of approximately \$1.7 million representing \$1.1 million in the fair value of a warrant and \$0.6 million for the unrealized gain on forward hedge contracts along with an increase in OCI of \$0.6 million. In addition, Gilead recognized an aggregate credit to the results of operations recorded as a cumulative change in accounting principle of \$1.1 million representing the fair market value of the warrant.

During the three months ended March 31, 2001, a \$0.4 million loss on hedging contracts had been recognized in the income statement and a \$0.6 million reduction in the fair value of derivatives was recognized in OCI. At March 31, 2001, fair value gains and losses on the balance sheet were not material.

## 4. Inventories

Inventories are summarized as follows (in thousands):

	March 31, 2001	December 31, 2000
Raw materials	\$ 9,866	\$ 9,647
Work in process	4,113	7,781
Finished goods	6,558	3,134
Total inventories	\$ 20,537	\$ 20,562

## 5. Collaborative Arrangements and Contracts

In January 2001, Gilead entered into an agreement with Cubist Pharmaceuticals, Inc. ("Cubist") relating to Cubist's antibacterial compound daptomycin, including Cidecin™, an intravenous formulation of the compound that is currently in Phase III clinical trials for treatment of bacterial infections. Under

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the terms of the agreement, Gilead paid Cubist an upfront license fee of \$13.0 million and received exclusive commercial rights to the compound in sixteen European countries ("Gilead's territory") as well as the right to develop the compound for commercialization in this territory. Research and development expense has been charged for \$10.6 million of the \$13.0 million payment. The \$2.4 million balance is included in Other noncurrent assets because if, prior to January 2002, Gilead terminates its rights under the agreement with respect to a preclinical oral formulation of daptomycin being developed by Cubist, or if Cubist discontinues development of that oral formulation, Gilead would be entitled to receive a refund of this amount from Cubist. Subsequent to January 2002, this refundable amount is reduced ratably on a monthly basis over a four year period and will be amortized to research and development expense. Cubist will continue to be responsible for worldwide clinical development of Cidecin and the preclinical oral formulation. Gilead will be responsible for both regulatory filings and marketing and selling of the product within Gilead's territory. Gilead may make additional payments to Cubist of up to \$31.0 million if certain clinical and regulatory milestones related to Cidecin and the oral formulation are reached. In April 2001, one of these milestones had been met and Gilead agreed to pay the \$1.25 million related to that milestone. Additionally, if Cidecin is successfully commercialized in Gilead's territory, Gilead will pay Cubist a royalty on net sales of the product.

## 6. Comprehensive Loss

Following are the components of comprehensive loss (in thousands):

	Three months ended March 31,	
	2001	2000
Net loss	\$ (21,723)	\$ (16,941)
Net foreign currency translation gain (loss)	282	(196)
Net unrealized gain (loss) on available-for-sale securities	3,073	(276)
Net unrealized loss on cash flow hedges	(49)	—
Comprehensive loss	\$ (18,417)	\$ (17,413)

## 7. Disclosures about Segments of an Enterprise and Related Information

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

Product sales consisted of the following (in thousands):

	Three months ended March 31,	
	2001	2000
AmBisome®	\$ 41,901	\$ 34,586
Other	3,163	1,754
Consolidated total	\$ 45,064	\$ 36,340

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

	Three months ended March 31,	
	2001	2000
United States	\$ 12,735	\$ 6,566
United Kingdom	7,743	5,843
Germany	4,768	5,393
Switzerland	4,500	6,716
Italy	4,534	4,348
Spain	4,536	3,577
Other European countries	14,769	10,178
Other countries	4,251	5,091
Consolidated total	\$ 57,836	\$ 47,712

Product sales to one distributor accounted for approximately 13% of total revenues for the first three months of 2001 and approximately 12% of total revenues for the same period of 2000. For the quarter ended March 31, 2001, sales to and royalties from Fujisawa Healthcare, Inc. ("Fujisawa") were 15% of total revenue. Revenues from Fujisawa were less than 10% of sales during the first three months of 2000.

## 8. Increase in Authorized Shares of Common Stock

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

## ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

### Overview

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

Gilead completed a two-for-one stock split, effected in the form of a 100% stock dividend, on February 22, 2001. Accordingly, all share and per share amounts for all periods presented have been restated to retroactively reflect the split.

In the quarter ended March 31, 2001, Gilead adopted SFAS 133, *Accounting for Derivative Instruments and Hedging Activities*, which resulted in a cumulative effect of change in accounting principle.

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. Our actual results could differ materially from those discussed in any forward-looking statements. Some of the factors that could cause or contribute to these differences are listed below. You should also read the "Risk Factors" included in our Annual Report on Form 10-K for the year ended December 31, 2000 for more detailed information regarding these and other risks and uncertainties that can affect our actual financial and operating results. All forward-looking statements are based on information currently available to Gilead, and we assume no obligation to update any such forward-looking statements.

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

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

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

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

*Foreign Currency Fluctuations.* A significant majority of our product sales is denominated in foreign currencies. Increases in the value of the U.S. Dollar against these foreign currencies in the past have reduced, and in the future may reduce, our U.S. Dollar return on these sales and negatively impact our financial condition. We do not hedge our exposure to the impact of fluctuating foreign exchange rates on forecasted sales. We do hedge accounts receivable balances denominated in foreign currencies, which minimizes but does not eliminate our exposure to currency fluctuations between the date a sale is recorded and the date that cash is collected.

*Uncertain Financial Results.* We expect that our financial results will continue to fluctuate from quarter to quarter and that such fluctuations may be substantial. The fluctuations can be caused by many factors that are beyond our control, including the risk factors listed above. We have never been profitable on a full-year basis and we may never achieve or sustain profitability. As of March 31, 2001, our accumulated deficit was \$527.7 million.

## **Results of Operations**

### *Revenues*

We had total revenue of \$57.8 million for the quarter ended March 31, 2001 compared with \$47.7 million for the quarter ended March 31, 2000. Included in total revenue are net product sales, royalty income and contract revenue, including research and development collaborations.

Net product sales were \$45.1 million for the first quarter of 2001 compared with \$36.3 million for the first quarter of 2000. Sales of AmBisome accounted for 93% of revenues from product sales in the first quarter of 2001 and 95% in the first quarter of 2000. Sales of AmBisome for the first quarter of 2001 increased 21% over the first quarter of 2000. Excluding the impact of the decline in foreign currencies relative to the U.S. Dollar in 2001, sales of AmBisome would have increased 29% in the first quarter of 2001 over the comparable period in 2000. In addition, Gilead recorded product sales of \$2.1 million and \$1.0 million from the sale of VISTIDE and DaunoXome, respectively, during the first quarter of 2001. A significant majority of Gilead's product sales is denominated in foreign currencies. We do not hedge our exposure to the impact of fluctuating foreign exchange rates on forecasted sales. We do hedge accounts receivable balances denominated in foreign currencies, which minimizes but does not eliminate our exposure to currency fluctuations between the date a sale is recorded and the date that cash is collected.

Net royalty revenue was \$6.2 million for the first quarter of 2001 compared with \$8.0 million for the comparable quarter in 2000. Royalties in the first quarter of 2001 included \$3.8 million from

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Fujisawa for sales of AmBisome in the United States, \$2.1 million from Roche for sales of Tamiflu worldwide and \$0.3 million for VISTIDE sales by Pharmacia Corporation ("Pharmacia") outside the United States. First quarter 2000 royalties included \$5.4 million from Roche for Tamiflu, \$2.2 million from Fujisawa for AmBisome and \$0.4 million for VISTIDE sales by Pharmacia. Higher sales of AmBisome in the United States resulted in the \$1.6 million increase in Fujisawa royalty payments. We record royalties from Roche in the quarter following the quarter in which the related Tamiflu sales occur. The \$3.3 million decline in Tamiflu royalties resulted from the 2000-2001 flu season being the lightest in terms of the number of reported cases in at least six years.

Total contract revenue was \$6.4 million for the quarter ended March 31, 2001 and \$0.8 million for the comparable quarter in 2000. Contract revenue for the first quarter of 2001 included a \$2.0 million milestone payment from Roche, \$2.5 million from marketing agreements, and recognition of \$1.7 million of the up-front license fee received from EyeTech Pharmaceuticals, Inc. ("EyeTech") in March 2000. Contract revenue in the first quarter of 2000 included \$0.4 million for development expense reimbursements from Roche.

Additionally, first quarter 2001 contract revenue included \$0.2 million related to a previously recognized initial license fee from Pharmacia that was deferred upon adoption of SAB 101 in January 2000 and will be recognized on a straight-line basis over the next twelve years. Included in contract revenue for the first quarter of 2000 was \$2.5 million related to previously recognized initial license fees received from Sumitomo Pharmaceuticals Co., Ltd., Roche and Pharmacia. The up-front fees were deferred upon adoption of SAB 101, and \$2.5 million is the portion of the fees that was subsequently recognized in contract revenue in the first quarter of 2000.

### *Cost of Product Sales*

Cost of products sold was \$10.6 million, or 23% of net product sales, for the quarter ended March 31, 2001, and \$7.9 million, or 22% of net product sales, for the quarter ended March 31, 2000. In connection with most of our European product sales, we price our products in the currency of the country into which the products are sold. A significant majority of our manufacturing cost is in U.S. Dollars. A decline in the value of these foreign currencies relative to the U.S. Dollar will negatively impact gross margins since our manufacturing costs will remain approximately the same while our revenues, which are reported in U.S. Dollars, will decline. In addition, we increased our sales of AmBisome sales to Fujisawa. Under the terms of our agreement with Fujisawa, Gilead supplies AmBisome at manufacturing cost.

Except for the potential impact of unpredictable and uncontrollable changes in payment currencies relative to the U.S. Dollar and the impact of direct sales to Fujisawa, we expect that cost of sales as a percentage of sales revenues for the full year 2001 to be materially consistent with the 22% amount reported for the year 2000. In future periods, changes in the nature or mix of our product sales could impact this relationship.



## *Operating Expenses*

Research and development ("R&D") expenses were \$51.1 million for the first quarter of 2001, up 95% from \$26.2 million for the first quarter of 2000. R&D expenses included for the first quarter of 2001 \$10.6 million of the \$13.0 million upfront license fee paid to Cubist for daptomycin. In addition, Gilead's expenses associated with the Phase III clinical programs for tenofovir DF for HIV and adefovir dipivoxil for HBV increased significantly during the quarter, including the initiation of an early access program and clinical supply costs for tenofovir DF. We expect R&D expenses for the full year 2001 to be approximately 20% to 30% higher than 2000 levels due to increased spending on the continued late stage development of tenofovir DF for HIV and adefovir dipivoxil for HBV as well as the up-front daptomycin license fee.

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Selling, general and administrative ("SG&A") expenses were \$21.9 million for the first quarter of 2001, compared to \$18.0 million for the first quarter of 2000. The increase was due to sales and marketing and related activities necessary to prepare for the anticipated U.S. and European commercial launch of tenofovir DF. We expect SG&A expenses for the year 2001 to be approximately 25% to 40% higher than 2000 levels due primarily to commercialization expenses related to tenofovir DF.

## *Interest Income and Interest Expense*

We reported interest income of \$7.4 million for the quarter ended March 31, 2001, up from \$3.9 million for the quarter ended March 31, 2000. The increase is primarily due to significantly higher investment balances in 2001. At March 31, 2001, we had cash, cash equivalents and marketable securities of \$483.8 million, up from \$291.8 million at March 31, 2000.

Interest expense was \$3.5 million for the quarter ended March 31, 2001, up from \$1.5 million for the quarter ended March 31, 2000. The largest component of interest expense in the first quarter of 2001 was interest on our \$250.0 million 5% convertible subordinated notes issued in December 2000. Interest expense for the first quarter of 2000 was principally the interest on the \$79.5 million outstanding balance of 6.25% subordinated debentures, which were subsequently converted to common stock in August 2000.

## *Equity in Loss of Unconsolidated Affiliate*

For the first quarter of 2001, we recorded \$0.4 million as our equity in the loss of Proligo L.L.C. ("Proligo"), representing our 49% share of Proligo's losses for its fiscal quarter ended March 31, 2001. For the first quarter of 2000, we recorded equity losses of Proligo of \$0.9 million representing our portion of Proligo's loss for its first fiscal quarter ended February 29, 2000. During the fourth quarter of 2000, Proligo changed its fiscal year-end to December 31 from November 30. Our investment in Proligo is reported in other noncurrent assets on the balance sheet, and was \$6.6 million at March 31, 2001. We have no commitments to provide additional funding to Proligo.

## **Liquidity and Capital Resources**

Cash, cash equivalents and marketable securities totaled \$483.8 million at March 31, 2001, down from \$512.9 million at December 31, 2000. Cash was used primarily to fund operating activities.

Our accounts receivable balance at March 31, 2001 was \$51.2 million compared to a balance of \$48.8 million at December 31, 2000. The \$2.4 million growth in accounts receivable is due primarily to an increase in net product sales. In certain countries where payments are typically slow, primarily Greece, Spain and Italy, our accounts receivable balances are significant. At March 31, 2001, our past due accounts receivable for Greece, Spain and Italy totaled approximately \$19.5 million, of which \$9.2 million was more than 120 days past due. This compares to past due receivables of approximately \$19.3 million at December 31, 2000 for these same countries, of which \$10.9 million was more than 120 days past due. To date, we have experienced only modest losses with respect to the collection of our accounts receivable and believe that the past due accounts receivable for Greece, Spain and Italy are collectible.

Other significant changes in working capital during the three months ended March 31, 2001 included a \$3.4 million increase in prepaid expenses and other assets due primarily to the \$2.0 million milestone payment due from Roche and a \$0.5 million increase in prepaid insurance. Accounts payable decreased in the three months ended March 31, 2001 primarily due to accrued contract obligations at December 31, 2000 that have since been paid. The decrease in current deferred revenue is primarily due to the \$1.7 million amortization of the EyeTech up-front license fee.

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The primary elements of the increase in other assets was the \$2.4 million unrecognized portion of the \$13.0 million license fee payment to Cubist and the \$1.1 million valuation of a warrant to purchase stock in EyeTech recognized in accordance with SFAS 133.

Through April 2001 we maintained a \$10.0 million unsecured line of credit with a major financial institution bearing interest at a floating rate. Under the terms of the line of credit, we were required to maintain certain financial ratios and there were limitations on our ability to incur additional debt or to engage in certain significant transactions. As of March 31, 2001, we had no outstanding borrowings under the line. The line of credit, which included a foreign exchange facility, expired on April 16, 2001. We renewed the foreign exchange facility but did not renew the line of credit. Under the terms of the new foreign exchange facility we will be required to maintain a minimum cash investment balance with the financial institution. Our cash investment balance with that institution presently exceeds the minimum balance. There are no required financial ratios or limitations on debt or other transactions under the foreign exchange facility.

We believe that our existing capital resources, supplemented by net product sales, contract and royalty revenues will be adequate to satisfy our capital needs for the foreseeable future. As of March 31, 2001, we are entitled to additional cash payments of up to \$9.6 million from Roche, if and when Roche achieves specific additional Tamiflu developmental and regulatory milestones. We are also entitled to additional cash payments from EyeTech of up to \$25.0 million, if and when EyeTech achieves certain NX 1838 milestones. We cannot be assured that any of these milestones will be met. Our future capital requirements will depend on many factors, including:

- the progress of our research and development efforts,

- the success of our partners' research and development efforts and commercialization of their products,
- the scope and results of preclinical studies and clinical trials,
- the cost, timing and outcome of regulatory reviews,
- the rate of technological advances,
- determinations as to the commercial potential of our products under development,
- the commercial performance of AmBisome and any of our products in development that receive marketing approval,
- regulatory approval of tenofovir DF and if approved, its commercial performance,
- administrative expenses,
- the status of competitive products,
- the establishment of manufacturing capacity or third-party manufacturing arrangements,
- the expansion of sales and marketing capabilities,
- our possible geographic expansion, and
- the establishment of additional collaborative relationships with other companies.

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

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### ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As of March 31, 2001, our \$250.0 million convertible subordinated notes had a fair value of \$169.0 million. There have been no other significant changes in our market risk compared to the disclosures in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2000.

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## PART II. OTHER INFORMATION

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

A Special Meeting of Stockholders was held on February 2, 2001 in Redwood City, California. Of the 94,171,488 shares of Gilead Common Stock entitled to vote at the meeting, 75,664,638 shares were represented at the meeting in person or by proxy, constituting a quorum. The stockholders approved an amendment to Gilead's Certificate of Incorporation to increase the authorized number of shares of Common Stock from 100,000,000 shares to 500,000,000 shares. There were 59,152,774 votes cast for the proposal, 16,451,600 votes cast against, 60,264 abstentions and there were no broker non-votes.

### ITEM 5. OTHER MATTERS

In early May 2001, Gilead submitted a New Drug Application with the U.S. Food and Drug Administration and a Marketing Authorisation Application to the European Agency for the Evaluation of Medicinal Products for marketing approval of tenofovir disoproxil fumarate (tenofovir DF), an investigational reverse transcriptase inhibitor in development for the treatment of HIV infection.

### ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a)

Exhibits

No. 10.42 Marketing, Distribution, and Development Agreement between Cubist Pharmaceuticals, Inc. and the Registrant.\*

(b) Reports on Form 8-K

None.

\*

Confidential treatment requested as to specific portions, which portions are omitted and filed separately with the Securities and Exchange Commission.

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## 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 thereunto duly authorized.

GILEAD SCIENCES, INC.

(Registrant)

Date: May 14, 2001

/s/ JOHN C. MARTIN

John C. Martin  
President and Chief Executive Officer

Date: May 14, 2001

/s/ SHARON A. SURREY-BARBARI

Sharon A. Surrey-Barbari  
Vice President and Chief Financial Officer  
(Principal Financial and Accounting Officer)

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**MARKETING, DISTRIBUTION AND DEVELOPMENT AGREEMENT**

**BY AND BETWEEN**

**GILEAD SCIENCES, INC.**

**AND**

**CUBIST PHARMACEUTICALS, INC.**

**January 6, 2001**

**[\*]=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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**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.**

## **MARKETING, DISTRIBUTION AND DEVELOPMENT AGREEMENT**

**THIS MARKETING, DISTRIBUTION AND DEVELOPMENT AGREEMENT** (the "Agreement") is made effective as of the 6th day of January, 2001 (the "Effective Date") by and between **GILEAD SCIENCES, INC.**, a Delaware corporation having its principal place of business at 333 Lakeside Drive, Foster City, CA 94404 ("Gilead"), and **CUBIST PHARMACEUTICALS, INC.**, a Delaware corporation having its principal place of business at 24 Emily Street, Cambridge, Massachusetts 02139 ("Cubist"). Cubist and Gilead are sometimes referred to herein individually as a "Party" and collectively as the "Parties", and references to "Gilead" and "Cubist" shall include their respective Affiliates.

### **RECITALS**

**WHEREAS**, Cubist has in-licensed and continues to develop a proprietary compound known under the generic name of daptomycin;

**WHEREAS**, Cubist is currently conducting clinical trials of an intravenous formulation of daptomycin for the treatment of various gram-positive bacterial infections in humans, and is evaluating an oral formulation of daptomycin in preclinical studies;

**WHEREAS**, Gilead possesses extensive capabilities in the development, promotion and marketing of anti-infective pharmaceutical products in Europe and desires to seek regulatory approval for and market daptomycin in Europe; and

**WHEREAS**, Gilead desires to obtain the exclusive right to develop and commercialize daptomycin in the European Community and certain additional countries, and Cubist desires to grant Gilead such rights in such countries all as set forth below;

**NOW THEREFORE**, based on the foregoing premises and the mutual covenants and obligations set forth below, the Parties agree as follows:

### **ARTICLE 1 DEFINITIONS**

The following terms shall have the following meanings as used in this Agreement:

**1.1 "Affiliate"** shall mean, except as provided below, an entity that, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with Cubist or Gilead.

**1.2 "Bacteremia"** shall mean the treatment of a blood-borne infection caused by any bacteria.

**1.3 "CAP"** shall mean the treatment of community acquired pneumonia.

**1.4 "Change in Control"** shall mean that a Third Party shall have become the beneficial owner of securities representing **[\*]** or more of the aggregate voting power of the then outstanding voting securities of Cubist, or any sale by Cubist of all or substantially all of Cubist's assets.

**1.5 "Clinical Transfer Price"** shall have the meaning assigned such term in Section 7.2.

**1.6 "Commercial Launch"** shall mean the first sale of a Licensed Product to a Third Party in a given country.

**1.7 "Commercialize"** shall have the meaning assigned such term in Section 5.1 and "Commercialization" shall be interpreted accordingly.

**1.8 "Commercially Reasonable Efforts"** shall mean, with respect to a Party's obligation under this Agreement to develop or commercialize Licensed Product, the level of efforts required to carry out such obligation in sustained manner consistent with the efforts a similarly situated biopharmaceutical company devotes to a product of similar market potential, profit potential or strategic value resulting from its own research efforts, based on conditions then prevailing.

**1.9 "Compulsory License"** shall mean a compulsory license under any Cubist Patent 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 product competitive with a Licensed Product in one or more countries within the Gilead Territory.

**1.10 "Confidential Information"** shall mean all Information, and other information and materials, received by either Party from the other Party pursuant to this Agreement, other than that portion of such information or materials which:

- (a) is publicly disclosed by the disclosing Party, either before or after it becomes known to the receiving Party;
- (b) was known to the receiving Party, without obligation to keep it confidential, prior to when it was received from the disclosing Party;



(c) is subsequently disclosed to the receiving Party by a Third Party lawfully in possession thereof without obligation to keep it confidential;

(d) has been publicly disclosed other than by the disclosing Party and without breach of an obligation of confidentiality with respect thereto; or

(e) has been independently developed by the receiving Party without the aid, application or use of Confidential Information, as demonstrated by competent written proof.

**1.11 "Control"** shall mean possession of the ability to grant a license or sublicense as provided for herein without violating the terms of any agreement or other arrangement with any Third Party.

**1.12 "Core IV Products"** shall mean those IV Products whose primary therapeutic indication is CAP or cSST.

**1.13 "Core Licensed Products"** shall mean those Licensed Products whose primary therapeutic indication is CAP or cSST.

**1.14 "Core Trials"** shall mean the clinical trials listed on Exhibit A under the title "Core Trials."

**1.15 "CPMP"** shall mean the Committee for Proprietary Medicinal Products, which represents the medicine authorities of the European Community member states.

**1.16 "cSST"** shall mean the treatment of complicated skin and soft tissue bacterial infection.

**1.17 "Cubist Development Plan"** shall have the meaning assigned such term in Section 3.1.

**1.18 "Cubist Diligence Obligation"** shall have the meaning assigned such term in Section 3.5.

**1.19 "Cubist Know-How"** shall mean all Information which is [\*]. Notwithstanding anything herein to the contrary, Cubist Know-How shall exclude Information [\*].

**1.20 "Cubist Marks"** shall mean (i) all [\*] listed at Exhibit B; (ii) the [\*]; and (iii) any other [\*] that the Parties may agree in writing to designate for [\*].

**1.21 "Cubist Patent"** shall mean any Patent which (i) covers [\*]; and (ii) is [\*], including [\*].

**1.22 "Cubist Technology"** shall mean all Cubist Patents and Cubist Know-How.

**1.23 "cUTI"** shall mean the treatment of complicated urinary tract infections.

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**1.24 "Daptomycin"** shall mean the compound set forth and identified as the primary daptomycin molecule on Exhibit C, [\*] of such compound, which [\*], and all [\*] of such primary daptomycin molecule, [\*].

**1.25 "Daptomycin Product"** shall mean any pharmaceutical composition containing Daptomycin, but only if such pharmaceutical composition is formulated for use for oral delivery [\*] or for delivery via injection [\*], and that [\*]; *provided, however*, that in any event, [\*] is developing pursuant to its [\*] for development of [\*] shall be deemed to be a Licensed Product.

**1.26 "Daptomycin-Derived Product"** shall mean any pharmaceutical composition [\*] and that [\*], but excluding Daptomycin Products.

**1.27 "Development Subcommittee"** shall have the meaning assigned such term in Section 2.3(a).

**1.28 "Diligence Obligation"** shall mean the Gilead Diligence Obligation and/or the Cubist Diligence Obligation.

**1.29 "Directly Competitive Product"** shall mean any antibiotic in any formulation marketed and sold (i) primarily for [\*] (*provided that this clause (i) shall apply solely for the purpose of determining whether a product is competitive with [\*] Licensed Product and shall not apply for the purpose of determining whether a product is competitive with any Licensed Product other than [\*]*), (ii) primarily to [\*] in humans, and (iii) for [\*] approved by a Regulatory Authority in the Gilead Territory including, as the primary indication for the product, an indication that is also included on the label approved by a Regulatory Authority in the Gilead Territory for any Licensed Product. The Parties shall, at the time Cubist or Gilead commences Phase III Clinical Trials for an Oral Product that is a Licensed Product, modify this definition by mutual agreement to accommodate products competitive with such Oral Product, considering the terms of this Section 1.29 as guiding principles (it being understood that [\*] of such Oral Product may not necessarily be [\*]). If the Parties do not agree, the issue shall be submitted for resolution [\*] as provided in Section 15.4.

**1.30 "Dollar"** shall mean a United States dollar, and "\$" shall be interpreted accordingly.

**1.31 "Drug Approval Application"** shall mean an application for Regulatory Approval required before commercial sale or use of a Licensed Product as a drug in a regulatory jurisdiction, including without limitation an NDA filed in the United States.

**1.32 "EC"** shall mean the European Community.

**1.33 "EMA"** shall mean the European Medicines Evaluation Agency, or any successor thereto, which coordinates the scientific review of human pharmaceutical products under the centralized licensing procedures of the European Community.

**1.34 "Endocarditis"** shall mean the treatment of inflammation of the heart and/or its valves resulting from a bacterial infection.

**1.35 "Enterococcal Infection"** shall mean the treatment of enterococcal bacterial infections.

**1.36 "FDA"** shall mean the United States Food and Drug Administration, or any successor thereto.

**1.37 "Force Majeure"** shall mean any event beyond the control of the relevant Party, including, without limitation, fire, flood, earthquakes, riots, strikes, epidemics, war (declared or undeclared and including the continuance, expansion or new outbreak of any war or conflict now in existence), embargoes and governmental actions or decrees.

**1.38 "Free Sales Certificate"** shall mean market approval sufficient for the manufacture, distribution, use and sale of Licensed Products outside of the United States which can be obtained primarily on the basis of U.S. FDA, EMEA or other European Regulatory Approval and without the conduct of additional clinical trials, and shall include both market approvals referred to commonly as

"free sales certificates" and similar market approvals or certificates referred to by other names, provided that such similar market approvals or certificates do not impose a substantially greater burden on the applicant than those market approvals commonly referred to as "free sales certificates."

**1.39 "Gilead Development Plan"** shall have the meaning assigned such term in Section 3.2.

**1.40 "Gilead Diligence Obligation"** shall have the meaning assigned such term in Section 5.6.

**1.41 "Gilead Indemnifiable Technology"** shall have the meaning assigned such term in Section 9.6(d)(ii).

**1.42 "Gilead Indemnifiable Technology Losses"** shall have the meaning assigned such term in Section 9.6(d)(ii).

**1.43 "Gilead Marks"** shall mean (i) all [\*] listed at Exhibit D as it may be updated from time to time; (ii) any [\*] in connection with Licensed Products in the Gilead Territory; and (iii) any other [\*] that the Parties may agree in writing to designate for [\*].

**1.44 "Gilead Project Know-How"** shall mean all Information that (i) Gilead [\*], (ii) covers the [\*] and (iii) is [\*]. Gilead Project Know-How shall exclude Information [\*]. Gilead Project Know-How shall include any [\*] that the Parties agree in writing to include in the Gilead Project Know-How [\*].

**1.45 "Gilead Project Patent"** shall mean any Patent that (i) claims [\*] (ii) covers the [\*], (iii) is [\*], and (iv) is [\*]. Gilead Project Patents include Gilead's interest in [\*] that the Parties agree in writing to include in the Gilead Project Patents [\*].

**1.46 "Gilead Project Technology"** shall mean the Gilead Project Know-How and Gilead Project Patents.

**1.47 "Gilead Territory"** shall mean the countries listed in Exhibit E and any other country that is added to the Gilead Territory pursuant to Section 6.5(a), and the possessions and territories of each such country.

**1.48 "HAP"** shall mean the treatment of hospital-acquired pneumonia.

**1.49 "Incremental Product Development Costs"** shall mean the costs attributed to the implementation of a Proposed Modification, as determined by the Steering Committee pursuant to Section 3.4.

**1.50 "IND"** shall mean an Investigational New Drug Application as defined in the United States Food, Drug and Cosmetic Act and applicable regulations promulgated thereunder by the FDA or the equivalent application to the equivalent agency in any other country or group of countries, the filing of which is necessary to commence clinical testing of Licensed Product in humans in a particular jurisdiction.

**1.51 "Information"** shall mean (i) techniques and data specifically relating to development, manufacture, use or sale of Licensed Products, including, but not limited to, inventions, practices, methods, knowledge, know-how, skill, experience, test data including pharmacological, toxicological and clinical test data, analytical and quality control data, regulatory submissions, correspondence and communications, marketing, pricing, distribution, cost, sales, manufacturing, patent and legal data or descriptions and (ii) compositions of matter, assays and biological materials specifically relating to development, manufacture, use or sale of Licensed Products.

**1.52 "Infringement"** shall have the meaning assigned in Section 9.5.

**1.53 "IV Product"** shall mean any Daptomycin Product formulated for intravenous delivery, including without limitation the formulation described by the specifications set forth in a letter that Cubist has provided to Gilead prior to the Effective Date.

**1.54 "Joint Invention"** shall have the meaning assigned in Section 9.1.

**1.55 "Joint Patent"** shall have the meaning assigned such term in Section 9.2.

**1.56 "Licensed Product"** shall mean all Daptomycin Products, and all Daptomycin—Derived Products that become Licensed Products pursuant to Section 6.5(b).

**1.57 "Lilly"** shall mean Eli Lilly and Company.

**1.58 "Lilly License"** shall mean that certain Licensing Agreement between Cubist and Lilly dated October 6, 2000, which restated the prior agreement between such parties dated November 7, 1997, as amended.

**1.59 "Loss"** shall have the meaning assigned such term in Section 11.1.

**1.60 "MAA"** shall mean an application filed with the EMEA for regulatory approval to market and sell Licensed Products in the European Union, or an application filed through the mutual recognition procedures in the European Union having a similar purpose to the NDA in the United States.

**1.61 "Marketing Subcommittee"** shall have the meaning assigned such term in Section 2.3(b).

**1.62 "MSL"** shall mean a Cubist employee serving as a medical science liaison for commercialization of Licensed Products, as provided in Section 5.4.

**1.63 "NDA"** shall mean a New Drug Application for Regulatory Approval filed in the United States.

**1.64 "Necessary"** shall have the meaning assigned such term in Section 6.8(a).

**1.65 "Net Sales"** shall mean, with respect to a particular time period, the amount billed by Gilead, its Affiliates and Permitted Sublicensees for sales of Licensed Products made in such time period to a Third Party less:

- (i) discounts, including cash and quantity discounts, charge-back payments and rebates granted to managed health care organizations or to federal, state and local governments, their agencies, purchasers and reimbursers or to trade customers;
- (ii) credits or allowances actually granted upon claims, damaged goods, rejections or returns of such Licensed Products, including recalls;
- (iii) freight, postage, shipping, transportation and insurance charges actually allowed or paid for delivery of Licensed Products; and
- (iv) taxes (other than income taxes), duties or other governmental charges levied on, absorbed or otherwise imposed on sale of such Licensed Products, including without limitation value-added taxes, or other governmental charges otherwise measured by the billing, as adjusted for rebates and refunds.

If Gilead sells Licensed Products in the form of a combination product containing one or more active ingredients in addition to Daptomycin (which may be either combined in a single formulation or packaged as separate formulations sold as a single package), Net Sales for such combination product will be calculated by multiplying actual Net Sales of such combination product by the fraction  $A/(A+B)$  where A is the invoice price of the Licensed Product if sold separately, and B is the total invoice price of the other active ingredient or ingredients in the combination, if sold separately. If, on a country-by-country basis, the other active ingredient or ingredients in the combination are not sold separately in said country, Net Sales for the purpose of determining royalties of the combination product shall be calculated by multiplying actual Net Sales of such combination product by the fraction  $A/C$  where A is the invoice price of the Licensed Product if sold separately, and C is the invoice price of the combination product. If, on a country-by-country basis, the Licensed Product is not sold

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separately in said country, Net Sales for the purposes of determining royalties of the combination product shall be determined by the Steering Committee in good faith on the basis of the fair market value of the Licensed Product.

Notwithstanding the foregoing, amounts received by Gilead, its Affiliates or Permitted Sublicensees for the sale of Licensed Products among Gilead, its Affiliates and Permitted Sublicensees for resale shall not be included in the computation of Net Sales hereunder.

For purposes of this definition and the other provisions of this Agreement, no distributor of Gilead that sells a Licensed Product shall be deemed to be a Permitted Sublicensee of Gilead unless expressly so agreed in writing by the Parties. If any distributor of Licensed Products makes any payment to Gilead, its Affiliates or Permitted Sublicensees in consideration of being a distributor of any Licensed Product, which payment would not, but for the provisions of this sentence, be included in the definition of Net Sales, then the amount of such payment to Gilead, its Affiliates or Permitted Sublicensees shall be included in Net Sales in the quarter in which Gilead, its Affiliates or Permitted Sublicensees received such payment for purposes of calculating the royalty due to Cubist pursuant to Article 8.

**1.66 "Oral Product"** shall mean any Daptomycin Product formulated for oral delivery, [\*].

**1.67 "Oral Product Fee"** shall have the meaning assigned such term in Section 8.1(b).

**1.68 "Other Licensee"** shall mean any Third Party to whom Cubist has granted or grants a license and/or sublicense to develop or commercialize a Licensed Product.

**1.69 "Patent"** shall mean (i) unexpired letters patent (including inventor's certificates) which have not been held invalid or unenforceable by a court of competent jurisdiction from which no appeal can be taken or has been taken within the required time period, including without limitation any substitution, extension, registration, confirmation, reissue, re-examination, renewal or any like filing thereof and (ii) pending applications for letters patent, including without limitation any provisional, converted provisional, continued prosecution application, continuation, divisional or continuation-in-part thereof.

**1.70 "Permitted Sublicense"** shall have the meaning assigned such term in Section 6.11.

**1.71 "Phase I Clinical Trial"** shall mean those trials on sufficient numbers of normal volunteers and patients that are designed to establish that a pharmaceutical product is safe for its intended use, and to support its continued testing in Phase II Clinical Trials.

**1.72 "Phase II Clinical Trial"** shall mean those trials on sufficient numbers of patients that are designed to establish the safety, dosage 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.

**1.73 "Phase III Clinical Trials"** means those trials on sufficient numbers of patients that are designed to establish that a drug is safe and efficacious for its intended use, and to define warnings, precautions and adverse reactions that are associated with the drug in the dosage range to be prescribed, and supporting Regulatory Approval of such drug or label expansion of such drug.

**1.74 "Phase IIIB Clinical Trials"** means product support clinical trials of a Licensed Product (i.e., a clinical trial which is not required for receipt of Regulatory Approval but which may be useful in providing additional drug profile data) commenced before receipt of Regulatory Approval in the

country where such trial is being conducted.

**1.75 "Phase IV Clinical Trials"** means product support clinical trials of a Licensed Product commenced after receipt of Regulatory Approval in the country where such trial is being conducted.

**1.76 "Price Approval"** shall mean, with respect to any country in which the price at which Gilead sells Licensed Product must be approved by a governmental authority for reimbursement or payment purposes, the receipt of approval by the applicable governmental authority with respect to such price.

**1.77 "Primary Endpoint"** shall mean, with respect to a clinical trial, the point at which equivalence to the comparator agent has been achieved with respect to a clinical or microbiological outcome as specified in the protocol for such trial as set forth in Exhibit A, unless otherwise agreed by the Parties in writing.

**1.78 "Refund Event"** shall have the meaning assigned such term in Section 8.1(c).

**1.79 "Regulatory Approval"** shall mean any approvals (including supplements, amendments, pre- and post-approvals and Price Approvals), licenses, registrations or authorizations of any national, supra-national (e.g., the European Commission or the Council of the European Union), regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity, necessary for the manufacture, distribution, use or sale of Licensed Products in a regulatory jurisdiction.

**1.80 "Regulatory Authority"** shall mean a foreign counterpart of the FDA.

**1.81 "Related Gilead Know-How"** shall mean all Information [\*] (i) which is [\*], (ii) is [\*] and (iii) relates to [\*].

**1.82 "Related Gilead Project Patent"** shall mean any Patent other than a Gilead Project Patent which (i) covers [\*]; and (ii) is [\*], including Gilead's interest in [\*].

**1.83 "Related Gilead Technology"** shall mean the Related Gilead Know-How and Related Gilead Project Patents.

**1.84 "ROFR Territory"** shall mean those countries listed at Exhibit F and their territories and possessions. The ROFR Territory shall also include [\*], but shall exclude [\*] and with respect to which [\*]; *provided, however*, that any such country that is not included in the ROFR Territory [\*] shall be included in the ROFR Territory upon and from the date [\*].

**1.85 "Steering Committee"** shall mean the committee formed as described in Section 2.2.

**1.86 "Supply Agreement"** shall have the meaning assigned such term in Section 7.1.

**1.87 "Term"** shall mean the term of this Agreement.

**1.88 "Third Party Royalties"** shall mean royalties payable to any Third Party as a result of the manufacture, use or sale of Licensed Products pursuant to, and in accordance with, the provisions of this Agreement or the Supply Agreement, including without limitation royalties due under the Lilly License.

**1.89 "Third Party"** shall mean any entity other than Cubist or Gilead or an Affiliate of either of them.

**1.90 "Transfer Price"** shall mean the price to Gilead for supply of a unit of Licensed Product manufactured by or for Cubist, which shall be determined annually in accordance with Section 7.2.

**1.91 "Valid Claim"** shall mean (i) an unexpired claim of an issued patent within Cubist Patents which has not been found to be unpatentable, invalid or unenforceable by a court or other authority in the subject country, from which decision no appeal is taken or can be taken; or (ii) a claim of a pending application within the Cubist Patents, which application claims a first priority no more than [\*] prior to the date upon which pendency is determined.

## ARTICLE 2 MANAGEMENT

**2.1 General.** The Parties desire to establish a committee that will oversee the Parties' activities under this Agreement, and establish two (2) or more subcommittees to exchange information regarding, and to discuss the Parties' development and commercialization of, Licensed Products both within and outside of the Gilead Territory. Such committee and subcommittees shall have the responsibilities and authority set forth in this Article 2 and in other provisions of this Agreement.

### 2.2 Steering Committee.

**(a) Formation.** Within thirty (30) days after the Effective Date, Cubist and Gilead shall establish the Steering Committee, which shall have overall responsibility for the success of the Parties' efforts under this Agreement. The purposes of the Steering Committee shall be (i) to coordinate the [\*], (ii) to coordinate the Parties' activities hereunder, (iii) to resolve issues that the subcommittees of the Steering Committee cannot resolve, and (iv) to approve [\*], all based on the principles of prompt and diligent development of the Licensed Products in the Gilead Territory consistent with good pharmaceutical practices and the maximization of long-term profits derived from the sale of Licensed Products in the Gilead Territory.

**(b) Membership.** Cubist and Gilead each shall designate three (3) representatives with appropriate expertise to serve as members of the

Steering Committee. Each Party shall select one (1) person appointed by it to the Steering Committee to serve as co-chair. Either Party may designate substitutes for its committee representatives to participate if one or more of such Party's designated representatives is unable to be present at a meeting. A Party may replace its representatives serving on the Steering Committee from time to time by written notice to the other Party specifying the prior representative(s) to be replaced and the replacement(s) therefor. The Steering Committee will have the power to form subcommittees in addition to the Development Subcommittee and the Marketing Subcommittee expressly provided for in this Agreement, or working groups with appropriate representation from Cubist, Gilead, their Affiliates, and appropriate Third Parties. The co-chairpersons shall be responsible for calling meetings, preparing and circulating an agenda in advance of each meeting, and preparing and issuing minutes of each meeting within [\*] days thereafter.

**(c) Meetings.** The Steering Committee shall hold meetings at such times as it elects to do so, but in no event shall such meetings be held less frequently than once every [\*]. The Steering Committee shall meet alternately at Cubist's facilities in Cambridge, Massachusetts and Gilead's facilities in Foster City, California, or at such locations as the Parties may otherwise agree. With the consent of the representatives of each Party serving on the Steering Committee, other representatives of each Party or of Third Parties involved in the manufacture, development or commercialization of the Licensed Products may attend meetings of the Steering Committee as nonvoting participants. Meetings of the Steering Committee may be held by audio or video teleconference with the consent of each Party, provided that at least one (1) meeting per year shall be held in person. Each Party shall be responsible for all of its own expenses of participating in the Steering Committee. Meetings of the Steering Committee shall be effective only if at least two (2) representatives of each Party are present or participating. The co-chairpersons will alternate responsibility for preparing minutes of each meeting of the Steering Committee, which minutes will not be finalized until the co-chairperson that did not prepare such minutes reviews and confirms the accuracy of such minutes in writing.

**(d) Specific Responsibilities.** In addition to its overall responsibility for overseeing the Parties' activities under this Agreement, the Steering Committee shall in particular:

(i) review and comment upon [\*], and review and comment upon the [\*];

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(ii) review strategies for [\*];

(iii) review [\*] as it becomes available;

(iv) review and discuss the Parties' [\*];

(v) review the Parties' [\*] with respect to Licensed Products;

(vi) approve the implementation of [\*], and the allocation of [\*] for any approved [\*];

(vii) review and discuss the Parties' [\*] relating to Licensed Products; and

(viii) perform such other functions as appropriate to further the purposes of this Agreement as determined by the Parties, including the periodic evaluation of the Parties' performance under this Agreement.

**(e) Limited Authority; Decision-Making.**

(i) Except with respect to the matters set forth in Section 3.4, the role of the Steering Committee shall be [\*]. The Steering Committee shall serve as a forum for the sharing of information and for the purpose of preventing, or informally resolving, disputes between the Parties. However, the Parties intend to operate [\*] in developing and commercializing Licensed Products in their respective territories. The rights and responsibilities of each Party shall be governed by this Agreement, including the exhibits hereto, and the Steering Committee shall not have [\*].

(ii) The Steering Committee shall operate by consensus. With respect to matters to be discussed by the Steering Committee, the representatives of each Party shall present a unified position on behalf of such Party. In the absence of consensus of Steering Committee members with respect to any matter before the Steering Committee, such matter shall be deemed not to have been approved by the Steering Committee, and the Parties shall be free to proceed independently as they see fit (subject always to compliance by the Parties with their respective obligations under this Agreement). Specifically, in the absence of consensus of Steering Committee members for [\*] that requires Steering Committee approval, such approval shall be deemed not to have been granted, and the Parties shall have the rights to proceed independently with respect to [\*].

**(f) Meeting Agendas.** Each Party will disclose to the other Party its final agenda items along with appropriate related Information at least [\*] in advance of each meeting of the Steering Committee.

**2.3 Formation of Subcommittees.**

**(a) Development Subcommittee.** Within [\*] after the Effective Date, the Parties shall form a subcommittee of the Steering Committee to address development issues relating to Licensed Products as provided below in Article 3 (the "Development Subcommittee").

**(b) Marketing Subcommittee.** At a time designated by the Steering Committee in advance of Commercial Launch, the Parties shall form a subcommittee of the Steering Committee to address marketing issues relating to Licensed Products in the Gilead Territory (the "Marketing Subcommittee").

**(c) Additional Subcommittees.** The Steering Committee may form such additional subcommittees of the Steering Committee as it may deem to be desirable to address other aspects of Licensed Product development and commercialization.

**(d) Membership.** Cubist and Gilead each shall designate three (3) representatives with appropriate expertise to serve as members of each of the subcommittees formed under this

Section 2.3. One (1) of each Party's members of the Development Subcommittee shall also be one of such Party's members of the Marketing Subcommittee and shall have expertise in the area of marketing pharmaceutical products. One of each Party's members of the Marketing Subcommittee shall also be one of such Party's members of the Development Subcommittee and shall have expertise in the area of developing pharmaceutical products. Each Party shall select one (1) person appointed by it to each such subcommittee to serve as co-chair. Either Party may designate substitutes for its committee representatives to participate if one or more of such Party's designated representatives is unable to be present at a meeting. A Party may replace its representatives serving on a subcommittee from time to time by written notice to the other Party specifying the prior representative(s) to be replaced and the replacement(s) therefor. The co-chairpersons shall be responsible for calling meetings, preparing and circulating an agenda in advance of each meeting, and preparing and issuing minutes of each meeting within [\*] thereafter.

**(e) Meetings.** Each subcommittee shall hold meetings at such times as it elects to do so, but in no event shall such meetings be held less frequently than once every [\*]. Each subcommittee shall meet alternately at Cubist's facilities in Cambridge, Massachusetts and Gilead's facilities in Foster City, California, or at such locations as the Parties may otherwise agree. With the consent of the representatives of each Party serving on a subcommittee, other representatives of each Party or of Third Parties involved in the manufacture, development or commercialization of Licensed Products may attend meetings of the Steering Committee as nonvoting participants. Meetings of each subcommittee may be held by audio or video teleconference with the consent of each Party, provided that at least [\*] shall be held in person. Each Party shall be responsible for all of its own expenses of participating in the subcommittees. Meetings of each subcommittee shall be effective only if at least two (2) representatives of each Party are present or participating. The co-chairpersons will alternate responsibility for preparing minutes of each meeting of each subcommittee, which minutes will not be finalized until the co-chairperson that did not prepare such minutes reviews and confirms the accuracy of such minutes in writing.

**(f) Specific Responsibilities of the Development Subcommittee.** In addition to its overall responsibility for overseeing the Parties' development activities under this Agreement, the Development Subcommittee shall in particular:

- (i) review and comment upon the [\*], review and comment upon the [\*], discuss the requirements for [\*] and review any [\*];
- (ii) work to achieve [\*] by coordinating efforts with the Marketing Subcommittee;
- (iii) evaluate the Parties' [\*] to provide for sufficient [\*]; and
- (iv) perform such other functions as appropriate to further the purposes of this Agreement as determined by the Steering Committee.

**(g) Specific Responsibilities of the Marketing Subcommittee.** In addition to its overall responsibility for overseeing the Parties' marketing and commercialization activities under this Agreement, the Marketing Subcommittee shall in particular:

- (i) consider and discuss [\*];
- (ii) work to achieve a [\*] by coordinating efforts with the Development Subcommittee, including without limitation coordinating the Parties' efforts with respect to [\*];
- (iii) evaluate the Parties' needs for [\*];
- (iv) consider and discuss the Parties' efforts to [\*]; and
- (v) perform such other functions as appropriate to further the purposes of this Agreement as determined by the Steering Committee.

#### **(h) Limited Authority; Decision-Making.**

(i) The role of each subcommittee shall be [\*], with the goal of serving as [\*]. However, the parties intend to operate [\*] in developing and commercializing Licensed Products in their respective territories. The rights and responsibilities of each Party shall be governed by this Agreement, including the exhibits hereto, and no subcommittee shall have any power to amend, modify or waive compliance with this Agreement.

(ii) Each subcommittee shall operate by consensus. With respect to matters to be discussed by the subcommittee, the representatives of each Party shall present a unified position on behalf of such Party. Any disagreement among the members of a subcommittee will be submitted for resolution by the Steering Committee.

(i) **Meeting Agendas.** Each Party will disclose to the other Party its final agenda items along with appropriate related Information at least [\*] in advance of each meeting of each subcommittee.

**2.4 Project Coordinators.** Each Party will, promptly after the formation of each subcommittee pursuant to Section 2.3, assign an appropriately expert and experienced individual to the other Party to facilitate communication and coordination of activities relating to the development and commercialization of Licensed Products and to provide support and guidance to the subcommittee (the "Project Coordinator"). Each Project Coordinator shall be experienced in project management.

#### **2.5 Collaboration Guidelines.**

**(a) General.** In all matters relating to this Agreement, the Parties shall seek to comply with good pharmaceutical and environmental practices.

**(b) Independence.** Subject to the terms of this Agreement, the activities and resources of each Party shall be managed by such Party, acting independently and in its individual capacity. The relationship between Cubist and Gilead is that of independent contractors and neither Party shall have the power to bind or obligate the other Party in any manner, other than as is expressly set forth in this Agreement.

**2.6 Accounting.** Each Party shall determine Incremental Product Development Costs and all other costs and expenses that may be shared with or reimbursed to a Party under this Agreement or the Supply Agreement (including without limitation the amounts Gilead shall pay to Cubist for supply of Licensed Products pursuant to the Supply Agreement), if any, using its standard accounting procedures, consistently applied, to the maximum extent practical as if such Licensed Product were a solely owned product of the determining Party, except as specifically provided in this Agreement. The Parties also recognize that such procedures may change from time to time and that any such changes may affect the definition of Incremental Product Development Costs and such other costs and expenses. The Parties agree that, where such changes are economically material to either Party, adjustments shall be made to compensate the affected Party in order to preserve the same economics as reflected under this Agreement under such Party's accounting procedures in effect as of the Effective Date.

## ARTICLE 3 DEVELOPMENT

### 3.1 Cubist Development, Development Plan, and Diligence Obligation.

**(a) Development Obligation.** Subject to the limitations and other provisions set forth in this Section 3.1, the Parties intend that during the Term, Cubist shall continue to develop Licensed Products by conducting the Core Trials to support Regulatory Approval of Core IV Products in the United States. Additionally, subject to the limitations and other provisions set forth in this

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Section 3.1, Cubist shall use Commercially Reasonable Efforts to conduct (A) a [\*] for the treatment of [\*]; (B) a [\*] for the treatment of [\*]; (C) [\*] in such territories and for such indications [\*], having reasonably [\*] of the Development Subcommittee; and (D) such additional clinical trials and preclinical studies for the IV Product and such additional formulations of Licensed Products as Cubist determines to conduct, [\*] having reasonably [\*] that the Development Subcommittee may make.

**(b) Development Plan.** The development activities, including both preclinical and clinical development activities, that Cubist will conduct for Licensed Products shall be covered by a development plan that Cubist shall prepare and submit to the Development Subcommittee for review [\*] after the Effective Date (such plan, the "Cubist Development Plan"). The Cubist Development Plan shall include at least the [\*] in clauses (A), (B) and (C) above in Section 3.1(a). The Cubist Development Plan shall [\*]. Subject to its overall diligence obligations contained in this Section 3.1, Cubist reserves the right to change or modify the Cubist Development Plan (except with respect to the [\*]) or any of the preclinical studies or clinical trials (other than the [\*]) described in the Cubist Development Plan in response to (i) [\*], (ii) [\*], (iii) [\*] or (iv) [\*]. Cubist additionally reserves the right to change or modify any Core Trial (1) [\*] such trial in accordance with the then-current protocol therefor as a result of [\*], or (2) in response to any [\*]; *provided, however*, that Cubist recognizes that Gilead's efforts to [\*] will depend upon [\*] and further provided that the foregoing ability to change or modify a Core Trial shall not contravene Cubist's obligations to provide [\*]. Accordingly, if Cubist has the right to change or modify a Core Trial pursuant to the foregoing sentence, it shall so notify Gilead, the Parties shall discuss any proposed modification to the Core Trial at issue or other alternative arrangement to address the reason giving rise to Cubist's right to change or modify the Core Trial while providing for [\*] from Cubist to [\*], and Cubist shall implement any such proposed modification or alternative arrangement to which the Parties mutually agree. Cubist shall modify the Cubist Development Plan from time to time to reflect timing or protocol changes to the Core Trials or any other trials, and to reflect additional trials that Cubist conducts or trials Cubist terminates for any Licensed Product during the Term. Cubist shall also revise the Cubist Development Plan from time to time to reflect each new indication for or formulation of Licensed Products that Cubist is developing or plans to develop. Additionally, [\*], Cubist shall update the Cubist Development Plan no later [\*] and submit such plan to the Development Subcommittee for review and comment. Cubist acknowledges that [\*]. Accordingly, Cubist shall use Commercially Reasonable Efforts to obtain Regulatory Approval of Core IV Products in the United States.

**(c) Conduct of Clinical Trials Described in Development Plan.** Subject to the provisions of the next sentence and solely with respect to clinical trials that are not Core Trials, Cubist shall use Commercially Reasonable Efforts to conduct, and to continue to conduct, if not already begun as of the Effective Date, all of the clinical trials of Licensed Products described in the Cubist Development Plan. Gilead acknowledges that it may be consistent with Commercially Reasonable Efforts for Cubist to suspend or terminate a clinical trial (other than a Core Trial) or activity referred to in the Cubist Development Plan [\*] including without limitation [\*].

**(d) Cubist Trials in Gilead Territory.** Any clinical trials conducted by Cubist may be run at sites within the Gilead Territory, *provided* that Cubist first confers with Gilead on the design of any such trials that begin after the Effective Date, and that the data generated in any such trial shall be used by Cubist, its Affiliates and Other Licensees solely to support Regulatory Approval or marketing of Licensed Products outside of the Gilead Territory.

**(e) Oral Product Development.** Anything to the contrary in Section 3.1(b) and 3.1(c) notwithstanding, Cubist's diligence obligation with respect to the development of Oral Products shall be as described in this Section 3.1(e). Until the Oral Product enters the clinical development phase, Cubist's diligence obligation hereunder with respect to Oral Products shall be [\*] with

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respect to the development of the Oral Product; and Cubist shall provide Gilead with [\*] updates regarding its preclinical development of the Oral Product, whenever possible, in advance of the Development Subcommittee meetings so that the Development Committee may discuss such updates. From the date, if ever, that Cubist decides to commence clinical development of an Oral Product, Cubist's diligence obligation with respect to such Oral Product shall be to use Commercially Reasonable Efforts to clinically develop and seek Regulatory Approval for the Oral Product [\*] and to provide Gilead with a clinical data package sufficient to support Regulatory Approval of the Oral Product in the Gilead Territory.

**(f) Determination.** Determination of whether Cubist has met its development diligence obligations pursuant to this Section 3.1 shall be

determined solely in accordance with Section 3.5.

**3.2 Gilead Development Plan.** Gilead may, but shall not be obligated to, conduct [\*] for Licensed Products, and such other development activities that Gilead, in its discretion, deems desirable to [\*] for Licensed Products for which Regulatory Approval has been obtained. Such studies may also include [\*] on Licensed Products. Any development activities that Gilead may conduct for the Licensed Products shall be set forth in a development plan which Gilead shall prepare and submit to the Steering Committee for review promptly after Gilead has designed such trial, but in no event later than the date provided in Section 3.4 for submission of a protocol for consideration by the Steering Subcommittee (such plan, the "Gilead Development Plan"). Gilead shall modify the Gilead Development Plan from time to time to reflect changes to the timing or protocol for the clinical trials described therein, or to reflect trials that Gilead determines, in its sole discretion, to conduct or terminate during the Term. Any clinical trials that Gilead conducts under this Section 3.2 may be run at sites outside of the Gilead Territory, *provided* that Gilead confers with Cubist on the design of any such trial, and that the data generated therein shall be used by Gilead, its Affiliates or Permitted Sublicensees solely to support Regulatory Approval in the Gilead Territory. Gilead shall update the Gilead Development Plan [\*] and submit such plan to the Development Subcommittee for review and comment. [\*] shall [\*] in connection with any of the activities reflected in the Gilead Development Plan, except as otherwise provided in Section 3.4.

**3.3 Responsibilities of the Development Subcommittee during Development.** The Development Subcommittee will review the overall strategy for and design of all programs under the Cubist Development Plan and the Gilead Development Plan. The Development Subcommittee shall review and make recommendations to the Steering Committee whether to approve any proposals by one Party to modify clinical trials being planned by the other Party, as described in Section 3.4 and prepare initial estimates and budgets for shared Incremental Product Development Costs as may be required under Section 3.4.

#### **3.4 Modification of Clinical Trials; Incremental Product Development Costs.**

**(a) Notice.** Each Party shall have the right to propose modifications to a clinical trial for Licensed Products being conducted by the other Party as provided in this Section 3.4. Each Party shall notify the other Party at least [\*] days before commencing any clinical trial not commenced prior to or on the Effective Date to support Regulatory Approval of a Licensed Product in such Party's territory (i.e., the Gilead Territory for Gilead, and all countries outside the Gilead Territory for Cubist). If such Party giving notice with respect to a clinical trial it is planning to commence (the "Conducting Party") has not previously disclosed in the Gilead Development Plan or Cubist Development Plan, as applicable, the protocol for such trial pursuant to Section 3.1 or 3.2, then such notice shall be accompanied by such protocol. Thereafter, the Conducting Party shall, upon request by the other Party (the "Non-Conducting Party"), provide such relevant information as the Non-Conducting Party may reasonably request within [\*] days after receiving notice from the Conducting Party under this Section 3.4 to enable the Non-Conducting Party to determine its

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interest in using data obtained in such clinical trial to support a filing for Regulatory Approval of or another regulatory filing for Licensed Products in the Non-Conducting Party's territory.

**(b) Response.** If the Non-Conducting Party is interested in so using such data, and if the Non-Conducting Party desires to propose a modification to a protocol for a clinical trial to be conducted by the Conducting Party, the Non-Conducting Party shall so notify the Conducting Party and specify the proposed modification to such protocol (the "Proposed Modification") within [\*] days of receiving all information the Conducting Party is required to provide the Non-Conducting Party pursuant to the foregoing sentence.

**(c) Steering Committee Role; Agreement.** The Steering Committee shall confer regarding such Proposed Modification promptly after the Conducting Party receives such notice, and the Steering Committee shall, within [\*] after the Conducting Party receives such notice, meet to determine whether implementation of such Proposed Modification is acceptable to the Parties, and the costs attributable to implementing the Proposed Modification (the "Incremental Product Development Costs"). The Steering Committee may request that the Development Subcommittee develop a budget for implementation of the Proposed Modification and total Incremental Product Development Costs therefor, and that the Development Subcommittee make a recommendation of the allocation of such Incremental Product Development Costs between the Parties based upon [\*], assuming a [\*] of such trial. The Development Subcommittee shall also evaluate the possibility of [\*]. If the Steering Committee approves the Proposed Modification and agrees upon the appropriate allocation of Incremental Product Development Costs between the Parties, the Parties may enter into a written agreement as to the details of the Proposed Modification and Incremental Product Development Costs associated with such Proposed Modification providing for the Conducting Party to modify the protocol for the relevant clinical trial to incorporate the Proposed Modification and amend its development plan hereunder to reflect such change. If the Steering Committee does not approve the Proposed Modification, or the Parties do not enter into such an agreement within [\*] after the Steering Committee approves the Proposed Modification, then the Conducting Party shall have no obligation to modify the protocol for the relevant clinical trial to incorporate the Proposed Modification and the Non-Conducting Party shall have no obligation to pay the Incremental Product Development Costs if the Conducting Party does nonetheless implement the Proposed Modification. Any such agreement between the Parties may provide for the Steering Committee to, at least [\*], review the Incremental Product Development Costs actually incurred and to be incurred in connection with a relevant clinical trial and modify the budget for such Incremental Product Development Costs as appropriate to reflect the Parties' progress with respect to such clinical trial.

**(d) Oral Products.** In accordance with the rest of this Section 3.4 above, the Parties recognize that Gilead may request Proposed Modifications to clinical trials of Oral Products for the purpose of obtaining data to support Regulatory Approval therefor in the Gilead Territory, and the Parties may enter into an agreement pursuant to Section 3.4(c). Any agreement between the Parties with respect to a Proposed Modification of an Oral Product clinical trial may include [\*] with respect to the Oral Product if [\*] will be required [\*] the Proposed Modification pursuant to such Agreement.

**3.5 Determination of Cubist Diligence.** If Gilead believes that Cubist is not meeting its diligence obligation pursuant to Section 3.1 (such obligation, the "Cubist Diligence Obligation") with respect to any Licensed Product, Gilead shall notify Cubist. Cubist shall respond in writing to Gilead's notice as to Cubist's activities that it believes meets the Cubist Diligence Obligation with respect to such Licensed Product as well as the circumstances surrounding Cubist's development of the Licensed Products within [\*] of Cubist's receipt of such notice from Gilead. Gilead shall reply to Cubist within [\*] after receiving such written response from Cubist whether, in light of such response, Gilead continues to believe that Cubist has not met the Cubist Diligence Obligation with respect to such



Licensed Product. If, after following the foregoing procedures in this Section 3.5, the Parties continue to disagree whether Cubist has met the Cubist Diligence Obligation with respect to such Licensed Product, the Parties shall [\*] to be convened within [\*] of such reply from Cubist. [\*] shall examine and discuss for [\*] Cubist's efforts to develop such Licensed Product [\*]. After such examinations and discussions:

- (a) If the Parties are [\*] the Cubist Diligence Obligation with respect to such Licensed Product, then Cubist shall [\*] its development of such Licensed Product [\*].
- (b) If Cubist [\*] to meet the Cubist Diligence Obligation with respect to such Licensed Product, then Cubist shall [\*] with respect to such Licensed Product as promptly as is reasonably practicable under the circumstances [\*]; *provided* that if Gilead [\*]. If, after following such procedure, the Parties are in disagreement as to whether Cubist has met the Cubist Diligence Obligation with respect to such Licensed Product, then Section 3.5(c) shall apply.
- (c) If, after having followed the procedure set forth in Sections 3.5(a) and 3.5 (b), the Parties disagree as to whether [\*] describes [\*] the Cubist Diligence Obligation with respect to a particular Licensed Product, then the Parties shall submit the issue of whether the [\*] is sufficient to meet the Cubist Diligence Obligation with respect to such Licensed Product to [\*] by [\*]. Such [\*] shall determine whether Cubist has met the Cubist Diligence Obligation with respect to such Licensed Product or whether a [\*] is sufficient to enable Cubist to meet the Cubist Diligence Obligations with respect to such Licensed Product. If such [\*] determines that Cubist has met such Cubist Diligence Obligation, then Cubist shall be free to proceed with the development of such Licensed Product [\*]; otherwise, such [\*] shall formulate [\*] to enable Cubist to meet such Cubist Diligence Obligation and Cubist shall use Commercially Reasonable Efforts to perform under such [\*].
- (d) In no event shall Cubist be deemed to breach the Cubist Diligence Obligation with respect to any Licensed Product if any delay, omission or action by Gilead has contributed to Cubist's delay or failure.

## ARTICLE 4 REGULATORY

**4.1 General.** Gilead shall devote Commercially Reasonable Efforts to file for and obtain Regulatory Approval for those Licensed Products in the Gilead Territory for which Cubist obtains Regulatory Approval in the United States and regarding which Cubist provides Gilead with clinical data sufficient to support Regulatory Approval in the Gilead Territory. Notwithstanding anything in this Agreement to the contrary, Gilead shall not be required pursuant to this Agreement, but may elect, to [\*]. In recognition that Gilead's efforts to obtain Regulatory Approval for Licensed products in the Gilead Territory will depend upon its ability to use data relating to Licensed Products generated by Cubist outside of the Gilead Territory in making regulatory filings within the Gilead Territory, Cubist shall devote Commercially Reasonable Efforts to obtain clinical data to support, file for and obtain Regulatory Approval for Core Licensed Products outside the Gilead Territory in accordance with the provisions of Article 3.

### **4.2 Free Sales Certificates; Ownership of Regulatory Approvals.**

(a) Cubist shall apply for and use Commercially Reasonable Efforts to obtain Free Sales Certificates for Licensed Products in all countries within the Gilead Territory where such certificates are available and Gilead requests in writing that Cubist obtain them. Gilead shall cooperate in all such efforts [\*]. Gilead shall [\*] in seeking such Free Sales Certificates. Once Cubist obtains any Free Sales Certificates for Licensed Products in the Gilead Territory, to the extent permitted by law, Cubist shall transfer them to Gilead and Gilead shall thereafter assume all responsibility for communication with Regulatory Authorities and compliance with law in each

case in relation to the Free Sales Certificates. In any country in which transfer of a Free Sales Certificate to Gilead is not permitted by law, Cubist shall maintain such Free Sales Certificate and reasonably cooperate with Gilead to effect communications with Regulatory Authorities in connection therewith to the extent desired and requested by Gilead.

(b) In all other countries of the Gilead Territory, Gilead shall [\*] Drug Approval Applications and Regulatory Approvals for Licensed Products, and shall be [\*] responsible for all communications with regulatory authorities in such countries.

(c) Gilead shall apply for and use Commercially Reasonable Efforts to obtain Free Sales Certificates for Licensed Products in all countries outside the Gilead Territory where such certificates are available and Cubist requests in writing that Gilead obtain them. Cubist shall cooperate in all such efforts [\*]. Cubist shall [\*] in seeking such Free Sales Certificates. Once Gilead obtains any Free Sales Certificates for Licensed Products outside the Gilead Territory, to the extent permitted by law, Gilead shall transfer them to Cubist and Cubist shall thereafter assume all responsibility for communication with regulatory authorities and compliance with law in each case in relation to the Free Sales Certificates. In any country in which transfer of a Free Sales Certificate to Cubist is not permitted by law, Gilead shall maintain such Free Sales Certificate and reasonably cooperate with Cubist to effect communications with Regulatory Authorities in connection therewith to the extent desired and requested by Cubist.

### **4.3 Gilead Access to Cubist and Other Licensee Information.**

(a) **Regulatory Data as of the Effective Date.** Cubist will, as soon as possible after the Effective Date, provide Gilead copies of all regulatory filings, including without limitation the IND for the IV Product in the United States, and the results of all clinical and non-clinical testing of IV Products performed by or on behalf of Cubist or Other Licensees (subject to applicable restrictions on disclosure of such Information) to the extent that such filings or information existing prior to the Effective Date has not already been provided to Gilead prior to the Effective Date.

(b) **Regulatory Data Generated After the Effective Date.** During the Term, Cubist will provide to Gilead for use in Gilead's development efforts relating to Licensed Products all Information owned or Controlled by Cubist regarding Licensed Products necessary or useful for making regulatory filings for, or marketing of, Licensed Products in the Gilead Territory as such Information becomes available.

**(c) Other Licensee Permission.** Cubist shall attempt to obtain from any Other Licensees permission for Cubist to provide to Gilead any information relating to Licensed Products that is necessary for Gilead to make regulatory filings for Licensed Products in the Gilead Territory and that, if such information were owned or Controlled by Cubist, would be Information that Cubist must provide to Gilead pursuant to Section 4.3(a) or (b). Cubist shall require Other Licensees to allow Cubist to disclose to Gilead all information relating to adverse events that Cubist must report pursuant to Section 4.5. Gilead shall not provide any Information it receives from Cubist pursuant to this Article 4 (other than Information relating to adverse events provided by Cubist pursuant to Section 4.5) to any Permitted Sublicensee unless and until such Permitted Sublicensee permits Gilead to provide to Cubist any and all information owned or Controlled by such Permitted Sublicensee that, if such information were owned or Controlled by Gilead, would be Information that Gilead must provide to Cubist pursuant to Section 4.4.

**(d) Gilead Use of Information.** Gilead shall have a right of access, a right of reference and the right to use and incorporate all information provided to it pursuant to this Section 4.3 in its Drug Approval Applications for Regulatory Approvals of Licensed Products within the Gilead Territory. The Parties shall discuss, via their participation in the Steering Committee, the form in which the Parties shall exchange Information pursuant to this Section 4.3 and Section 4.4.

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#### 4.4 Cubist and Other Licensee Access to Gilead Information.

**(a) Provision to Cubist.** During the Term, Gilead will provide to Cubist for use in Cubist's development efforts relating to Licensed Products all Information in Gilead's possession regarding Licensed Products necessary or useful for making regulatory filings for Licensed Products outside the Gilead Territory as such Information becomes available. Cubist shall have a right of access, a right of reference and the right to use and incorporate all Information provided it pursuant to the foregoing sentence in Drug Approval Applications in Licensed Products outside of the Gilead Territory. Such rights shall be transferable solely as provided in Section 4.4(b).

**(b) Sublicensee Permission; Transferability to Sublicensees.** Gilead shall attempt to obtain from any Permitted Sublicensees permission for Gilead to provide to Cubist any information relating to Licensed Products that is necessary for Cubist to make regulatory filings for Licensed Products in the Cubist Territory and that, if such information were owned or Controlled by Gilead, would be Information that Gilead must provide to Cubist pursuant to Section 4.4(a). Gilead shall require its Permitted Sublicensees to allow Gilead to disclose to Cubist all information that Gilead must report pursuant to Section 4.5. Cubist shall not provide any Information it receives from Gilead pursuant to this Article 4 (other than Information relating to adverse events provided by Gilead pursuant to Section 4.5) to any Other Licensee unless and until such Other Licensee permits Cubist to provide to Gilead any and all information owned or Controlled by such Other Licensee that, if such information were owned or Controlled by Cubist, would be Information that Cubist must provide to Gilead pursuant to Section 4.3.

**4.5 Adverse Event Reporting.** The Parties shall report, and take other actions in relation to, adverse events with Licensed Products to each other in accordance with a reporting protocol that will be substantially in the form of the protocol used by Gilead under its relationship with [\*].

**4.6 Communications.** Except as may be required by law or as contemplated pursuant to Section 4.2, Cubist shall not communicate regarding any Licensed Product with any Regulatory Authority having jurisdiction in the Gilead Territory unless requested to do so by Gilead.

**4.7 Applications for Regulatory Exclusivity.** The Parties recognize that exclusivity rights granted or provided for under regulatory laws of the countries in the Gilead Territory are likely to be [\*] to Licensed Products. To the extent permitted by law, Gilead shall have the exclusive right to file for, request and maintain any regulatory exclusivity rights for Licensed Products in the Gilead Territory, including without limitation regulatory exclusivity rights based upon an orphan drug designation of a Licensed Product, and to conduct and prosecute any proceedings or actions to enforce such regulatory exclusivity rights, and Cubist shall reasonably cooperate with Gilead in such actions [\*]. In countries where Gilead is not entitled to take one or more of the actions described in the foregoing sentence, then Cubist shall take such actions as instructed by Gilead and for the benefit of Gilead, [\*]. Gilead shall own any regulatory exclusivity rights in the Gilead Territory where permitted by law. Cubist hereby grants Gilead the exclusive right to market Licensed Products in the Gilead Territory under any regulatory exclusivity rights that must be granted directly to Cubist in a given country in the Gilead Territory.

**4.8 Recalls and Voluntary Withdrawals.** The Parties shall exchange their internal standard operating procedures ("SOPs") as to product recalls reasonably in advance of Commercial Launch of any Licensed Product in the Gilead Territory. If either Party becomes aware of information about any Licensed Product indicating that it may not conform to the specifications for Licensed Product then in effect pursuant to the Supply Agreement, or that there are potential adulteration, misbranding and/or other issues regarding safety or effectiveness, it shall promptly so notify the other Party. The Steering Committee shall meet to discuss such circumstances and to consider appropriate courses of action, which courses of action with respect to each recall shall be consistent with the internal SOP of the Party having the right to control such recall pursuant to this Section 4.8. Gilead shall have the right to

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control, [\*], a recall of the Licensed Product in the Gilead Territory, unless such recall is caused by a Manufacturing Defect (as defined by the Supply Agreement), in which case [\*] shall [\*] associated with the recall. Cubist shall control, [\*], all recalls of Licensed Product outside the Gilead Territory. Gilead shall maintain complete and accurate records of any recall for such periods as may be required by legal requirements, but in any event for no less than [\*].

**4.9 Label.** To the extent permitted by law, Gilead shall identify Cubist as the manufacturer or licensor of each Licensed Product on the outside of the packaging for such Licensed Product in each country of the Gilead Territory in a manner approved in advance in writing by Cubist, such consent not to be unreasonably withheld.

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## COMMERCIALIZATION; DILIGENCE

**5.1 Right.** Gilead shall have the exclusive right to market and commercialize, including, without limitation, by conducting pre-marketing, advertising and promotion activities, and sponsoring medical education events, exhibits and symposia (collectively, "Commercialize") Licensed Products in all countries of the Gilead Territory during the Term, for its own account (subject to the [\*] under this Agreement), [\*] and subject to the participation of the Cubist MSLs as provided below in Section 5.4.

**5.2 Responsibilities of the Marketing Subcommittee during Commercialization.** The Marketing Subcommittee will review and comment upon the overall strategy and design of Gilead's marketing efforts under its Marketing Plans.

**5.3 Marketing Plan.** No later than [\*] before Gilead anticipates the first Commercial Launch of a Licensed Product anywhere in the Gilead Territory, Gilead will submit a plan detailing Gilead's projected activities to commercialize Licensed Products in the Gilead Territory including anticipated budgets (the "Marketing Plan"), to the Marketing Subcommittee. Thereafter, on or before each anniversary of the date of the first Commercial Launch of a Licensed Product, Gilead shall update, revise, and present to the Marketing Subcommittee the Marketing Plan. The Marketing Plan shall include a description of any anticipated activities of the MSLs. Cubist may comment upon each version of the Marketing Plan via its participation in the Marketing Subcommittee. Gilead reserves the right to modify its Marketing Plan at any time in response to (i) changes in [\*], (ii) [\*], (iii) the feasibility of [\*], (iv) changes in the [\*] or (v) any failure [\*], subject only to [\*] to comment upon such changes and [\*].

### 5.4 Activities by MSLs in Gilead Territory.

**(a) MSLs.** During the [\*] (as defined in Section 5.4(d)), Cubist shall have a limited right to participate with Gilead in support of certain of Gilead's Commercialization activities for Licensed Products in the Gilead Territory, solely as described and permitted in this Section 5.4. Cubist may provide up to [\*] MSLs to participate in such activities throughout the Gilead Territory at any one time during the [\*]; *provided, however,* that Cubist's rights to so participate shall expire on a country-by-country basis as provided in Section 5.4(d), and *further provided* that Gilead shall have the right, in its discretion, to allocate the MSLs to participate in such activities in such country or countries of the Gilead Territory as Gilead may decide. Cubist shall notify Gilead on or before [\*] of each calendar year during the [\*] how many MSLs it will make available in the next calendar year, subject to the limitations set forth in this Section 5.4. Gilead shall provide to the Cubist MSLs access to particular facilities in the Gilead Territory for the purposes of conducting meetings with Gilead representatives, but shall not be required to provide [\*]. Such [\*] by Cubist [\*] to Gilead in the Gilead Territory, and Cubist shall be [\*], subject to and in accordance with the requirements of the country in which each Cubist MSL is employed. Each Cubist MSL shall have language skills appropriate for conducting his or her responsibilities under this Section 5.4 in the country of the Gilead Territory in which Gilead elects to place them, and other educational and professional training appropriate for the conduct of his or her responsibilities in such country. Gilead shall have the [\*] Cubist MSLs proposed by Cubist, and Cubist shall, upon Gilead's request, [\*]. Each [\*] shall execute [\*] in the form provided by [\*].

**(b) Role of Cubist MSLs.** The Cubist MSLs shall, [\*] relating to Licensed Products: (i) to [\*] of Licensed Products conducted by or on behalf of Gilead in the Gilead Territory; (ii) to [\*] in the Gilead Territory, and [\*] in the Gilead Territory, to the extent consistent with the efforts of Gilead's MSLs providing [\*] in such country; and (iii) to [\*], concerning the Licensed Products and their characteristics. During the [\*], Gilead shall provide to each of the Cubist MSLs a more detailed description of the scope of their [\*], and may update such detailed description from time to time using its [\*] judgment, provided that all activities set forth in any such detailed description

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shall be consistent with this Section 5.4. Except to the extent Gilead specifically directs in the detailed description of permitted MSL activities provided pursuant to this Section 5.4(b), Cubist MSLs shall not [\*] of Licensed Products in the Gilead Territory, perform any activities in connection [\*], provide any [\*] with respect to Licensed Products, [\*] in the Gilead [\*] in connection with Licensed Products, or perform any [\*] or other activities in relation to Licensed Products in the Gilead Territory. Cubist shall not directly or indirectly [\*] set forth therein. The Cubist MSLs shall [\*] conducted in connection with Licensed Products, [\*] with respect to Licensed Products to a designated Cubist representative who shall in turn provide reports of MSL activities to each of the Development Subcommittee and the Marketing Subcommittee, and provide to [\*] of Licensed Products. Gilead shall have the right to [\*] from time to time upon [\*] notice to Cubist.

**(c) Payment.** Gilead shall pay Cubist [\*] per MSL [\*] to Gilead in the Gilead Territory during each calendar year during the [\*]. Such amount shall be payable [\*] each due within [\*] after the end of [\*] during the [\*], with the first such payment due within [\*] after the end of the [\*] in which the [\*] commenced. For any MSL that Cubist provides pursuant to this Section 5.4 for less than an entire calendar year, Gilead shall pay Cubist a prorated portion of the foregoing [\*] amount to reflect the portion of such calendar year during which Cubist [\*] such MSL to Gilead (the "Partial Year"), with such amounts payable in [\*] due at the end of [\*] during which such MSL was [\*] to Gilead during such Partial Year.

**(d) Termination of [\*].** The "[\*]" shall commence [\*] prior to the anticipated date (as determined by the Steering Committee) that the [\*] in the Gilead Territory (the "Commencement Date") and shall expire [\*] after [\*] in the Gilead Territory in which Gilead [\*] of Licensed Product (the "Expiration Date"); *provided, however,* that the [\*], and *further provided* that the [\*] shall terminate [\*]. Additionally, during the [\*], Cubist's right to provide MSLs to support Commercialization of Licensed Products shall [\*] of a Licensed Product in the [\*] in the Gilead Territory. Anything to the contrary in this Agreement notwithstanding, (i) Gilead shall [\*] in Commercialization of Licensed Products in each country in the Gilead Territory pursuant to this Section 5.4 [\*] and (ii) Gilead shall [\*].

**5.5 Diligence Obligation.** The Parties agree that the primary focus of their efforts to develop Licensed Products shall be upon IV Products and Oral Products. Gilead shall use Commercially Reasonable Efforts to Commercialize in the Gilead Territory both the IV Product, and an Oral Product if Cubist obtains Regulatory Approval for such a product in the United States and provides a clinical data package relating thereto that is sufficient to support Regulatory Approval in the Gilead Territory, in each case following Regulatory Approval of such Licensed Products in the Gilead Territory. Gilead shall require its Permitted Sublicensees in the Gilead Territory to use Commercially Reasonable Efforts to Commercialize such Licensed Products in the Gilead Territory following Regulatory Approval of such Licensed Products in the Gilead Territory. Whether Gilead is meeting such Diligence Obligation shall be determined with respect to each Licensed Product based upon all relevant factors, which may include without limitation the following factors:

**(a)** the level of [\*] of such Licensed Product in the [\*] in a given calendar year relative to (i) the level of [\*] in the preceding calendar year for such Licensed Product, and (ii) the level of [\*];

- (b) the [\*] for such Licensed Product, including whether there is [\*];
- (c) the [\*] in the Gilead Territory for such Licensed Product;
- (d) the [\*] for such Licensed Product in the [\*];
- (e) the level of [\*] Licensed Product in the Gilead Territory relative to the level of [\*] Licensed Product outside the Gilead Territory, taking into account differences in Licensed Product [

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\*, the incidence of [\*] in such regions, as well as differences in [\*] between the different regions, and such other factors as may be appropriate under the circumstances;

- (f) whether [\*] with respect to such Licensed Product;
- (g) the [\*] for such Licensed Product in a country [\*]; and
- (h) Gilead's efforts with respect to [\*] in the Gilead Territory and each of the foregoing factors with respect to the [\*].

In no event shall Gilead's Diligence Obligation with respect to any Licensed Product be deemed to include a requirement that Gilead [\*] in any country.

**5.6 Determination of Gilead's Diligence.** If Cubist believes that Gilead is not meeting its diligence obligation pursuant to Section 5.5 (such obligation, the "Gilead Diligence Obligation") with respect to any Licensed Product, Cubist shall notify Gilead. The Parties shall then proceed as provided in Sections 5.6(a) through (d) to determine Gilead's diligence in Commercializing Licensed Products. Gilead shall [\*] to Cubist's notice [\*] with respect to such Licensed Product as well as [\*] of such Licensed Products within [\*] of Gilead's receipt of such notice from Cubist. Cubist shall [\*] with respect to such Licensed Product. If, after following the foregoing procedures in this Section 5.6, the Parties continue to disagree whether Gilead has met the Gilead Diligence Obligation with respect to such Licensed Product, the Parties shall [\*] Gilead's efforts to Commercialize such Licensed Product in the Gilead Territory (the "Discussion Period"). After such [\*]:

- (a) If the Parties are in agreement that Gilead is meeting the Gilead Diligence Obligation with respect to such Licensed Product, then Gilead shall continue its Commercialization of the Licensed Product without being required to alter its approach.
- (b) If Gilead [\*] with respect to such Licensed Product, then [\*] after the end of the Discussion Period, and shall use [\*]; *provided* that if [\*] with respect to such Licensed Product, then the Parties shall follow the procedure set forth in the first paragraph of this Section 5.6. If, after following such procedure, the Parties are in disagreement as to whether Gilead has met the Gilead Diligence Obligation with respect to such Licensed Product, then Section 5.6(c) shall apply.
- (c) If, after having followed the procedure set forth in Sections 5.6(a) and (b), the Parties [\*] with respect to such Licensed Product, then the Parties shall submit the issue of whether Gilead's plan is sufficient to meet such Diligence Obligation to dispute resolution [\*] pursuant to Section 15.4. Such [\*] shall [\*]. If such [\*] determines that [\*] of such Licensed Product pursuant to its Marketing Plan; otherwise, such [\*] shall [\*].
- (d) In no event shall Gilead be deemed to breach the Gilead Diligence Obligation with respect to any Licensed Product if any delay, omission or action by Cubist or any Cubist MSL has contributed to Gilead's delay or failure.

#### 5.7 Diversion of Resources for Directly Competitive Product.

- (a) If Gilead Commercializes a Directly Competitive Product in the Gilead Territory (which Gilead [\*]), Gilead shall, within [\*] of the commercial launch of such product, provide to Cubist a statement showing [\*] of [\*] the date of the Commercial Launch of such Directly Competitive Product (the "First Statement"), and shall provide Cubist a statement on [\*] thereafter showing the amount of [\*] (each such report a "Subsequent Statement").
- (b) If Cubist disputes the accuracy of the First Statement or any Subsequent Statement for Licensed Products, the Parties shall confer to determine [\*] for such First Statement or Subsequent Statement. If the Parties cannot agree on [\*] for the relevant statement within [\*] after beginning to confer, the [\*] for the purpose of making a determination hereunder.

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(c) If any Subsequent Statement (including any statement that is modified by agreement between Gilead and Cubist, or any that is modified [\*] shows that Gilead has [\*] from the First Statement, then Gilead shall [\*] with respect to the relevant Licensed Product(s) and Cubist shall [\*] with respect to such Licensed Product(s), with such Licensed Product(s) [\*].

(d) This Section 5.7 has been agreed upon solely to address Cubist's concern that Gilead may reduce its commitment to Commercializing Licensed Product(s) if Gilead is also selling a Directly Competitive Product in the Territory. Accordingly, this Section 5.7 and its provisions, approach, reasoning, terms, and percentages shall apply and have relevance only if Gilead is Commercializing a Directly Competitive Product in the Territory and may not be referred to or relied upon by either Party, or any court or dispute resolution body, for purposes of interpreting Gilead's obligations under any other section of this Agreement, including, without limitation, for determining if Gilead has met the Gilead Diligence Obligation in Section 5.6.

**5.8 Discounting.** Neither Gilead, its Affiliates nor Permitted Sublicensees shall discount the price of Licensed Products in consideration of any price increase on, or the receipt of any payment in connection with, a product other than a Licensed Product, or shall enter into any agreement for such purpose.

**5.9 Gilead Compliance.** In connection with any development activities undertaken by Gilead in connection with any Licensed Product, Gilead shall comply with all applicable laws and regulations regarding the care and use of experimental animals, as such laws and regulations are in effect where such development activities are undertaken. All animals used by Gilead to evaluate Daptomycin or any Licensed Product shall be provided humane care and treatment in accordance with the most acceptable veterinary practices.

## **ARTICLE 6**

### **LICENSE; RIGHTS OF FIRST REFUSAL; EXCLUSIVITY**

**6.1 Patent Licenses to Gilead.** Subject to the terms and conditions of this Agreement, Cubist grants to Gilead an exclusive (even as to Cubist except to the extent provided below) license under the Cubist Patents: (i) [\*] Licensed Products on a worldwide basis for the [\*] Licensed Products in the Gilead Territory; (ii) to [\*] Licensed Products in the Gilead Territory; and (iii) to develop (by conducting preclinical and clinical studies) Licensed Products on a worldwide basis for the [\*] of Licensed Products within the Gilead Territory; *provided, however,* that Cubist shall retain the right, including the right to grant licenses and sublicenses, [\*] Licensed Products on a worldwide basis for the [\*] of Licensed Products outside of the Gilead Territory and, solely pursuant to this Agreement, in the Gilead Territory, and to develop Licensed Products on a worldwide basis for the [\*] of Licensed Products outside of the Gilead Territory and, solely pursuant to this Agreement, in the Gilead Territory. Gilead may grant sublicenses under the foregoing license under Cubist Patents (A) for the purpose of [\*] Licensed Products on a worldwide basis for the [\*] of Licensed Products in the Gilead Territory, and (B) for such other purposes as Cubist may agree pursuant to Section 6.11. All such sublicenses are subject to the terms and conditions of this Agreement. In addition to any rights expressly retained by Cubist in the foregoing provisions of this Section 6.1, Cubist shall retain any and all rights in and to the Cubist Patents that are not expressly granted to Gilead pursuant to this Section 6.1.

**6.2 Patent Licenses to Cubist.** Subject to the terms and conditions of this Agreement, Gilead grants to Cubist a non-exclusive license under the Gilead Project Patents: (i) to make and have made Licensed Products on a worldwide basis for the use, sale, offering for sale and importation of Licensed Products outside of the Gilead Territory and, solely pursuant to this Agreement including without limitation the Supply Agreement, in the Gilead Territory; (ii) to use, sell, offer for sale and import Licensed Products outside of the Gilead Territory and, solely pursuant to this Agreement including without limitation the Supply Agreement, in the Gilead Territory; and (iii) to develop Licensed

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Products on a worldwide basis for the use, sale, offering for sale and importation of Licensed Products outside of the Gilead Territory and, solely pursuant to this Agreement including without limitation the Supply Agreement, within the Gilead Territory. Cubist may grant sublicenses under the foregoing license under Gilead Project Patents. All such sublicenses are subject to the terms and conditions of this Agreement. Gilead shall retain any and all rights in and to the Gilead Project Patents that are not expressly granted to Cubist pursuant to this Section 6.2.

**6.3 Nonexclusive Know-How License to Gilead.** Subject to the terms and conditions of this Agreement, Cubist grants Gilead a [\*] to use Cubist Know-How solely for the purposes of: (i) making and having made (solely as provided in Article 7 and the Supply Agreement) Licensed Products on a worldwide basis for the use, sale, offering for sale and importation of Licensed Products in the Gilead Territory; (ii) using, selling, offering for sale and importing Licensed Products in the Gilead Territory; and (iii) developing (by conducting preclinical and clinical studies) Licensed Products on a worldwide basis for the use, sale, offering for sale and importation of Licensed Products in the Gilead Territory. Gilead may grant sublicenses under the foregoing license under Cubist Know-How for the purpose of making and having made (solely as provided in Article 7 and the Supply Agreement) Licensed Products on a worldwide basis for the use, sale, offering for sale and importation of Licensed Products in the Gilead Territory and for such other purposes as Cubist may agree pursuant to Section 6.11. All such sublicenses are subject to the terms and conditions of this Agreement. Cubist shall retain any and all rights in and to the Cubist Know-How that are not expressly granted to Gilead pursuant to this Section 6.3.

**6.4 Nonexclusive Know-How License to Cubist.** Subject to the terms and conditions of this Agreement, Gilead grants Cubist a royalty-free, non-exclusive, worldwide license, to use Gilead Know-How solely for purposes of (i) making and having made Licensed Products on a worldwide basis for the use, sale, offering for sale and importation of Licensed Products outside of the Gilead Territory and, solely pursuant to this Agreement, including without limitation the Supply Agreement, in the Gilead Territory; (ii) using, selling, offering for sale and importing Licensed Products outside the Gilead Territory and, solely pursuant to this Agreement, including without limitation the Supply Agreement, in the Gilead Territory; and (iii) developing Licensed Products on a worldwide basis for the use, sale, offering for sale and importation of Licensed Products outside of the Gilead Territory and, solely pursuant to this Agreement, including without limitation the Supply Agreement, within the Gilead Territory. Cubist may grant sublicenses under the foregoing license under Gilead Project Know-How. All such licenses are subject to the terms and conditions of this Agreement. Gilead shall retain any and all rights in and to the Gilead Project Know-How that are not expressly granted to Cubist pursuant to this Section 6.4.

#### **6.5 Rights of First Refusal and Negotiation.**

**(a) ROFR for Licensed Product in the ROFR Territory.** Gilead desires to have a right of first refusal to develop and Commercialize Licensed Products in the countries included in the ROFR Territory, which are countries of [\*]. Accordingly, Cubist hereby grants Gilead a right of first refusal for [\*] Licensed Products in the ROFR Territory as follows: if Cubist intends to [\*] to [\*] in any country [\*], Cubist shall so [\*] prior to entering into an agreement with such Third Party with respect to [\*] and shall first [\*] with respect to such [\*] upon the same [\*] with respect to such [\*], on the other terms and conditions set forth in this Agreement, prior to entering into such [\*]. If, within [\*] after Cubist shall have made such offer to Gilead, Gilead shall not have agreed in writing to [\*] with respect to such Licensed Product upon such [\*], then Cubist shall be free to enter into such agreement with such Third Party on such [\*] and shall have no further obligation under this Section 6.5(a) to offer or grant such terms to Gilead in each case for a period of [\*] after the earlier of [\*]. Without limiting the generality of the foregoing, this Section 6.5(a) shall apply if [\*] with a Third Party for the [\*] in any country within the ROFR Territory during the Term. If Gilead accepts [\*] pursuant to this Section 6.5(a), then such country shall be included in

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the Gilead Territory and excluded from the ROFR Territory for the remainder of the Term. For purposes of this Section 6.5(a), [\*].

**(b) ROFN for [\*].** Cubist hereby grants Gilead a right of first negotiation for [\*] in the Gilead Territory and ROFR Territory on the following terms: If Cubist wishes to contract with a Third Party [\*], Cubist shall so notify Gilead, such notice to reference the relevant [\*]. If Gilead

requests within [\*] after its receipt of such notice to discuss with Cubist the terms upon which Cubist would grant Gilead the right to include such [\*] within the definition of Licensed Product (and therefore the licenses of Sections 6.1 and 6.3 pursuant to this Agreement) and Commercialize, or to otherwise grant Gilead the right to Commercialize, such [\*], then the Parties shall negotiate in good faith for a period of [\*] such terms. If the Parties are unable to agree upon such terms within such [\*] period, Cubist shall be free for a period of [\*] after the end of the Parties' good faith negotiation period to contract with a Third Party [\*]; *provided, however*, that in no event shall Cubist enter into an agreement with a Third Party relating to such [\*] (i) prior to the expiration of such [\*] period if Gilead has not notified Cubist of its interest prior to such date, or (ii) prior to expiration of such [\*] period, if the Parties do not reach written agreement prior to such date. If the Parties reach agreement as to such terms pursuant to this Section 6.5(b), then the Parties may either agree in writing to include such [\*] within the definition of Licensed Product hereunder or enter into a separate agreement pursuant to which Cubist would grant Gilead the right to Commercialize such [\*] in the Gilead Territory. Without limiting the generality of the foregoing, this Section 6.5(b) shall apply if [\*] with a Third Party for the [\*] in any country within the Gilead Territory or ROFR Territory.

## **6.6 Exclusivity.**

**(a) Gilead.** In each country of the Gilead Territory, Gilead shall not market, sell or otherwise distribute any Directly Competitive Product prior to the [\*] anniversary of the Commercial Launch of the Licensed Product with which such Directly Competitive Product is competitive in such country. Gilead shall not develop, promote, sell or offer for sale Licensed Products (except in connection with clinical trials of Licensed Product) outside of the Gilead Territory. Gilead shall require [\*] to make a covenant similar that provided in this Section 6.6(a) with respect to Licensed Products. Gilead shall be free to manufacture Licensed Products outside the Gilead Territory solely to the extent permitted in Article 7 and the Supply Agreement.

**(b) Cubist.** Cubist shall not promote, sell, or offer for sale Licensed Products for use (except in connection with clinical trials of Licensed Product) within the Gilead Territory. Cubist shall be free to manufacture Licensed Products in the Gilead Territory in a manner consistent with the licenses granted to it in Article 6. Cubist shall require [\*] to make a covenant similar to that provided in this Section 6.6(b) with respect to Licensed Products.

**6.7 Trademark License.** Cubist hereby grants Gilead an exclusive, royalty-free license under its entire right, title and interest in and to the Cubist Marks to use and display the Cubist Marks in connection with the Commercialization of Licensed Products within the Gilead Territory. Gilead hereby grants Cubist an exclusive, royalty-free license under its entire right, title and interest in and to the Gilead Marks to use and display the Gilead Marks in connection with the Commercialization of Licensed Products outside of the Gilead Territory. Each Party shall provide the other Party with copies of any materials containing such other Party's trademarks prior to using or disseminating such materials, and shall reasonably consider all comments made by such other Party regarding the use of its trademarks. Neither Party shall use the other Party's trade names and/or marks in a way which would be confusing or otherwise adversely affect their value. [\*].

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## **6.8 Third Party Technology.**

**(a) Required.** [\*] under all intellectual property rights (including without limitation rights in Patents and trade secrets) that are [\*] that may be brought by a Third Party in connection with the manufacture of Licensed Product by or for supply to [\*], or [\*] by [\*] in the [\*], except that [\*] shall have no obligation under this Section 6.8(a) to the extent that such claims arise or would arise solely out of the practice of [\*], and shall [\*], including without limitation [\*] due pursuant to such licenses. [\*], its Affiliates, Permitted Sublicensees and distributors as described in more detail in Section 9.6(d) against any losses arising from [\*] to obtain or maintain any such license.

**(b) Desirable.** For each intellectual property right that is [\*], either Party may propose that the Steering Committee consider (i) whether the Parties should seek a license thereunder to allow either or both Parties to practice such right in connection with the development, manufacture, use sale, offer for sale or import of Licensed Products, (ii) how to allocate the costs of obtaining and maintaining such license between the Parties (taking into account the Parties' relative interests therein inside and outside of the Gilead Territory) and (iii) how the Parties should proceed to seek such license. If the Steering Committee is unable to reach consensus with respect to the seeking of such license, either Party shall be free to itself seek a license under such right at its sole cost and expense, with no obligation to make such license or right available to the other Party.

## **6.9 Sublicensed Technology.**

**(a) Generally.** The licenses granted under this Article 6, to the extent they include sublicenses of Third-Party technology, shall be subject to the terms and conditions of the license agreement pursuant to which the sublicense is granted; *provided, however*, that if either Party enters into any Third Party license relevant to the development or commercialization of Licensed Products during the Term for technology that is desirable for the development and commercialization of Licensed Products, such Party shall faithfully and timely perform and discharge its obligations under such Third Party license and shall not permit any action to be taken or event to occur, in each case, within such Party's reasonable control, which would give such Third Party the right to terminate such Third Party license. [\*]. If the Party that enters into any such Third Party license [\*] or otherwise [\*], it shall promptly notify the other Party. The Parties shall promptly confer regarding an [\*] within [\*] by [\*]. If the Party that entered into any such Third Party license [\*] within [\*], then the [\*] may [\*] for [\*] for [\*] and [\*] shall be [\*]. If a good faith dispute between a Third Party and the Party that entered into a license with such Third Party about the interpretation of any provision of the agreement governing such Third Party license, the other Party shall use its Commercially Reasonable Efforts to ensure that its actions, if any, under this Section 6.9 do not detrimentally affect the ability of the breaching Party to contest the interpretation advanced by such Third Party.

### **(b) Lilly License.**

**(i)** Cubist shall, for the benefit of Gilead, faithfully and timely perform and discharge its obligations under the Lilly License and shall not permit any action to be taken or event to occur, in each case, within Cubist's reasonable control, which would give Lilly the right to terminate the Lilly License. Notwithstanding the provisions of the foregoing sentence, [\*]. If Cubist is notified or otherwise becomes aware of its material breach of the Lilly License, it shall promptly notify Gilead. [\*]. If Cubist does not perform the agreed upon remedy of such breach within the designated time, [\*].

(ii) It is agreed and acknowledged that in the event of termination of the Lilly License, [\*].

(c) **Grants Back by Other Licensees.** Cubist shall attempt to obtain the agreement of each of the Other Licensees to grant to Cubist the ability to grant Gilead a license under such Other

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Licensee's Patents and Know-How [\*] for Gilead's activities under this Agreement. Gilead shall attempt to obtain the agreement of its Permitted Licensees to grant to Gilead the ability to grant Cubist a license under such sublicensee's Patents and Know-How [\*] to make, have made, use, sell, offer for sale, import or export Licensed Products outside of the Gilead Territory. If either Party[\*], as the case may be, [\*] agreement with the Other Licensee or Permitted Sublicensee, as the case may be; *provided, however*, that neither Party shall be [\*] in connection with such efforts.

#### 6.10 Related Gilead Technology.

(a) Gilead shall inform Cubist of any Related Gilead Know-How (i) that Gilead is aware is being used by [\*] to [\*] in or for use in [\*], or (ii) that Gilead wishes for Cubist and its Affiliates and Third Party manufacturers [\*], in the case of clause (ii), as the Parties intend to further provide for in the Supply Agreement.

(b) Gilead shall inform Cubist in writing of any [\*] (i) that Gilead is aware covers the [\*] in or for use in [\*], or (ii) that covers an invention that Gilead wishes for Cubist and its Affiliates and Third Party manufacturers [\*], in the case of clause (ii), as the Parties intend to further provide for in the Supply Agreement.

(c) If Cubist desires to include within the definition of [ \* ] thereunder pursuant to [\*], as applicable, any particular [\*] of which [\*], then Cubist shall so [\*] pursuant to [\*] and the Parties shall, to the extent that [\*] for a period of [\*] upon which [\*]. If the Parties [\*] for any particular [\*] then such [\*] shall be included in the definitions of [\*], as applicable, subject to such agreed [\*]. If the Parties [\*], then [ \* ].

**6.11 Sublicensing.** In addition to Gilead's rights to sublicense certain of its rights included in its licenses under the Cubist Patents and the Cubist Know-How pursuant to Sections 6.1 and 6.3 as provided for in such sections, [\*] pursuant to this Section 6.11 shall be referred to herein as a "Permitted Sublicensee".

**6.12 Use of Patents and Know-How.** Each Party covenants to the other that it will not practice the Patents or Know-How of the other Party except as expressly permitted in the licenses granted to it in this Article 6.

**6.13 Field.** Notwithstanding anything in this Agreement to the contrary, it is acknowledged and agreed by the Parties that the licenses granted by Cubist to Gilead under this Agreement with respect to the Cubist Patents and Cubist Know-How that are licensed to Cubist pursuant to the Lilly License shall be solely for application to the treatment of [\*].

### ARTICLE 7 MANUFACTURE AND SUPPLY

**7.1 Supply by Cubist.** As of the Effective Date, Cubist has established manufacturing arrangements for bulk Daptomycin and finished IV Products through Third Party suppliers (such Third Parties and any other Third Party supplier of Licensed Products to Cubist shall be referred to collectively as the "Cubist Suppliers"). Cubist shall supply to Gilead, and Gilead shall purchase from Cubist, (i) [\*] in the Gilead Territory during the first five (5) years of the Term, and (ii) [\*] of [\*] in the Gilead Territory after the first [\*] of the Term, in both cases on the terms and conditions to be set forth in a Supply Agreement to be added to this Agreement by addendum, which the Parties shall use their reasonable efforts in good faith to negotiate, execute and deliver within [\*] days after the Effective Date (the "Supply Agreement"). Attached hereto as Exhibit G is a term sheet that sets forth certain of the terms that the Parties have agreed to incorporate into the Supply Agreement. Upon execution and delivery by the Parties of the Supply Agreement, the Supply Agreement shall supersede all of the terms and provisions of such term sheet.

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#### 7.2 Transfer Price.

(a) Gilead shall pay to Cubist a transfer price for (i) clinical supply of Licensed Product to Gilead by Cubist equal to the Clinical Transfer Price, and (ii) commercial supply of Licensed Product by Cubist to Gilead equal to the Transfer Price, in each case as determined in accordance with this Section 7.2.

(b) [\*] 2001, a "Clinical Transfer Price" for units of Licensed Product for clinical supply delivered by Cubist to Gilead and a "Transfer Price" for units of Licensed Product for commercial supply delivered by Cubist to Gilead, in each case to apply for the following [\*], shall be determined as provided in Sections 7.2(c) and (e) based upon Cubist's [\*], for Licensed Product in the [\*] period preceding the time the Transfer Price and Clinical Transfer Price are determined. The "Clinical Manufacturing Cost" shall be equal to [\*], calculated in accordance with reasonable cost accounting methods that comply with generally accepted accounting principles. The "Manufacturing Cost" shall be equal to [\*], calculated in accordance with reasonable cost accounting methods that comply with generally accepted accounting principles. For quantities of Licensed Product Cubist acquires from a Third Party, Cubist's [\*] the calculations of the Clinical Manufacturing Cost and Manufacturing Cost. The Transfer Price and Clinical Transfer Price shall [\*].

(c) No later than [\*] and no later than [\*] thereafter, Cubist shall notify Gilead in writing of the dollar figures that Cubist proposes to be the Clinical Transfer Price and Transfer Price, respectively, for units of Licensed Product delivered in the [\*] following the date of such notice. Cubist's notice as to the Clinical Transfer Price and Transfer Price it proposes shall include [\*] upon which [\*], and shall include a [\*]. Within [\*] of receiving such notice from Cubist, Gilead shall respond in writing as to whether it (i) [\*] manufactured by Cubist and/or its Affiliates to be [\*], or (ii) [\*]. Additionally within such time frame, [\*].

(d) If Gilead does not dispute the Clinical Transfer Price or the Transfer Price proposed by Cubist, then the amounts proposed by Cubist shall be the Clinical Transfer Price and Transfer Price, respectively, for all units of Licensed Product manufactured by or for Cubist and/or

its Affiliates and delivered to Gilead in the [\*] following the date of the Parties' notices pursuant to Section 7.2(c).

(e) Within [\*] after the end of each [\*] in which Cubist has delivered Licensed Product to Gilead, Cubist shall notify Gilead in writing of Cubist's actual Clinical Manufacturing Cost for quantities of Licensed Product delivered to Gilead as clinical supply in such [\*]. If Gilead does not dispute the Clinical Manufacturing Cost as calculated by Cubist, then [\*] any difference between the Clinical Transfer Price and the Clinical Manufacturing Cost shall, within [\*] after the end of such [\*], pay [\*] by wire transfer of immediately available funds to an account designated by such other Party. If Gilead disputes the Clinical Manufacturing Cost as calculated by Cubist, then such values shall be determined pursuant to Section 7.2(f) and [\*] any such discrepancy shall, within [\*] after the Independent Accounting Firm as defined in Section 7.2(f) makes its calculation of such value known to the Parties, pay [\*] by wire transfer of immediately available funds to an account designated by such other Party.

(f) If Gilead disputes an amount proposed by Cubist to be the Clinical Transfer Price, Transfer Price, Clinical Manufacturing Price or Manufacturing Price, then the Steering Committee shall discuss the issues for a period of [\*]. If, after such discussions by the Steering Committee, the Parties continue to disagree on such issue, then the Parties shall submit the issue to Cubist's independent auditor (currently, Pricewaterhouse Coopers) (the "Independent Accounting Firm"). The Independent Accounting Firm, using personnel other than those who perform regular accounting services for Cubist, shall calculate the disputed value in accordance with the basis specified in Section 7.2(b) based on [\*]. The Parties shall use their commercially reasonable efforts

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to cause the Independent Accounting Firm to render its calculation of the disputed value to the Parties within [\*] of the date the Parties submit such calculation to the Independent Accounting Firm. Neither Party shall [\*] the Independent Accounting Firm. The Parties shall [\*] the Independent Accounting Firm for the purposes described in this Section 7.2(f). The Independent Accounting Firm's calculation of the disputed value [\*].

(g) If Cubist is to supply Gilead with multiple Licensed Products in a given [\*], then Clinical Transfer Prices, Transfer Prices, Clinical Manufacturing Costs and Manufacturing Costs shall be determined separately for each Licensed Product in accordance with this Section 7.2.

(h) The Supply Agreement shall [\*].

## ARTICLE 8 COMPENSATION

### 8.1 License Fee.

(a) Within [\*] after the Effective Date, Gilead shall pay a license fee for the IV Product of [\*] to Cubist by wire transfer of immediately available funds into an account designated by Cubist. This license fee shall be nonrefundable and noncreditable.

(b) Within [\*] after the Effective Date, Gilead shall pay a license fee for the Oral Product of [\*] to Cubist by wire transfer of immediately available funds into an account designated by Cubist (the "Oral Product Fee"). The Oral Product Fee shall be subject to [\*] in accordance with the provisions of Section 8.1(c).

(c) If (I) this Agreement is [\*] by Gilead with respect to the Oral Product pursuant to the provisions of Section 14.2 at any time prior to the [\*] anniversary of the Effective Date, (II) Cubist shall have [\*] its [\*] with respect to the Oral Product for a period exceeding [\*] (other than on account of a Force Majeure) at any time prior to the [\*], or (III) Cubist has been determined pursuant to Section 3.5 to have [\*] with respect to the Oral Product at any time [\*] in accordance with the following schedule:

(i) If a [\*] occurs prior to the [\*] anniversary of the Effective Date, [\*].

(ii) If a [\*] occurs on or after the [\*] anniversary of the Effective Date but prior to the [\*] anniversary of the Effective Date, [\*] between [\*], prorated based upon the number of months after the [\*] anniversary of the Effective Date such event occurs (as examples, if such event occurs [\*] after the Effective Date, [\*]; if such event occurs [\*] after the Effective Date, [\*]).

Additionally, Gilead shall not [\*] with respect to the development of an Oral Product [\*], subject to Section 8.1(d).

(d) If the [\*] leading to a [\*] pursuant to Section 8.1(c) was the [\*] referred to in clause (I) of such Section, then Gilead shall have [\*] to the Oral Product. If the [\*] leading to a [\*] pursuant to Section 8.1(c) was the [\*] referred to in clause (II) or clause (III) of such Section, then Cubist shall [\*] with respect to Oral Products, but Gilead shall [\*] pursuant to this Agreement. If at any time after a [\*] referred to in the foregoing sentence Cubist wishes to resume development of an Oral Product, Cubist shall so notify Gilead in writing [\*] development of an Oral Product. In such event, Gilead shall be [\*] with respect to an Oral Product [\*] after the Resumption Date, but shall have [\*].

**8.2 Milestone Payments.** Subject to Section 14.2, in consideration for the licenses and exclusive rights of this Agreement, Gilead shall make milestone payments to Cubist based on achievement of IV Product development milestones as set forth in Section 8.2(a), and based on the achievement of Oral

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Product development milestones as set forth in Section 8.2(b). Gilead shall pay the amounts set forth below within [\*] after Gilead's receipt of notice from Cubist of the first achievement of the relevant milestone for an IV Product or an Oral Product, as documented by appropriate written and/or other materials. Each milestone payment by Gilead to Cubist hereunder shall be paid only once, and shall be noncreditable and nonrefundable.

#### (a) IV Product Development Milestone Payments.



	Milestone Event	Payment Amount (in millions)
1.	[*] in the following clinical trials included in Exhibit A (defined as [*] for cSST; and either of the [*] for CAP.	[*]
2.	[*], Protocol Number [*].	[*]
3.	[*], Protocol Number [*]	[*]
4.	[*], Protocol Number [*].	[*]
5.	[*], Protocol Number [*].	[*]
6.	[*] for Endocarditis	[*]
7.	[*] for Endocarditis.	[*]
8.	Completion of the [*] of the following trials: • [*] for UTI • [*] for Bacteremia • [*] for Enterococcal Infection	[*]
9.	[*] for the IV Product.	[*]
10.	[*]	[*]
11.	Patent issuing from [*] in a country within the Gilead Territory.	[*]

**Total Potential IV Product Development Milestone Payments** [\*]

The Parties recognize that the clinical trials, protocol numbers and Primary Endpoints listed in the milestone events above may change as otherwise permitted pursuant to this Agreement. The milestone events as defined above shall be interpreted to apply to the modified clinical trial, protocol number and/or Primary Endpoint replacing that set forth above.

**(b) Oral Product Development Milestone Payments.**

	Milestone Event	Payment Amount (in millions)
1.	[*] for an Oral Product.	[*]
2.	[*] of an Oral Product.	[*]
3.	[*] of an Oral Product.	[*]
4.	[*] of an Oral Product.	[*]
5.	[*]	[*]

**Total Potential Oral Product Development Milestone Payments** [\*]

**8.3 Royalties.**

**(a) Royalty.** Subject to the other terms and conditions of this Agreement, Gilead shall pay Cubist a royalty equal to [\*] (the "Royalty Rate") of Net Sales of each Licensed Product sold during each calendar quarter by Gilead, its Affiliates, or Permitted Sublicensees, less the [\*] paid by Gilead for supply of units of such Licensed Product that are (i) [\*] or (ii) [\*], but in the case of clause (ii), [\*] Licensed Products, and in each case by Gilead, its Affiliates or Permitted Sublicensees in such calendar quarter, subject to adjustment pursuant to this Section 8.3.

**(b) Royalty Where There Is No Exclusivity.** The Royalty Rate shall be reduced by [\*] with respect to Net Sales in any country in the Gilead Territory in which (i) there is [\*] of Licensed Products, or [\*] covering [\*]; and (ii) there is [\*] in such country.

**(c) Compulsory License.** If Gilead learns that a Third Party is seeking a Compulsory License in any country in the Gilead Territory, Gilead shall use commercially reasonable efforts to oppose the granting of such Compulsory License. If either Party learns that a Third Party has obtained a Compulsory License in any country in the Gilead Territory, such Party shall promptly notify the other Party of such occurrence. If the [\*] by the grantee of the Compulsory License is [\*] than the [\*] applicable in such country [\*], then the applicable [\*] applicable in such country pursuant to such Compulsory License for so long as such Compulsory License remains in effect.

**8.4 Term of Royalties.** Cubist's right to receive royalties under Section 8.3 shall expire on a country-by-country and product-by-product basis upon the later of (i) [\*] from the Commercial Launch of such Licensed Product in such country; or (ii) expiration of the last to expire issued Cubist Patent containing a Valid Claim which would be infringed by the manufacture, use or sale in the Gilead Territory by Gilead of Licensed Product absent the license granted hereunder.

**8.5 Third Party Royalties and Other Payments.** The royalties payable by Gilead to Cubist under Section 8.3 shall be [\*] arising from license or other agreements entered into by Cubist prior to the Effective Date relating the manufacture, use, sale, offer for sale or importation of the Licensed Products, including without limitation [\*]; *provided, however*, that nothing in this Section 8.5 shall limit the obligation of Gilead to [\*] as contemplated by the Supply Agreement.

**8.6 Royalty Payments and Reports.** All amounts payable to Cubist under this Agreement shall be paid in Dollars within [\*] of the end of each calendar quarter except as otherwise specifically provided herein. Each payment of royalties owing to Cubist shall be accompanied by a statement, [\*] of Licensed Product, [\*] showing deductions provided for in Section 1.65 during such quarter, the [\*] of Licensed Product and Net Sales during such quarter and on a [\*] and the amount of royalty due on such sales. If any royalty reductions are claimed by Gilead under this Agreement from the full royalty rates set forth in Section 8.3, then the report shall set forth in detail the claimed reduction and the related facts.

**8.7 Taxes.** Subject to the provisions of Section 8.7(b), Cubist shall be responsible for any and all taxes levied on account of amounts it

receives under this Agreement.

**(a) Payment Procedure.** If Gilead is required by law, rule or regulation to withhold taxes from such types of payments due Cubist hereunder, Gilead will (i) deduct those taxes from the remittable amount, (ii) pay the taxes to the proper taxing authority, and (iii) send evidence of the obligation together with proof of payment to Cubist within [\*] following that payment.

**(b) Gross-Up for Taxes Resulting from Assignment.** If as a result of any assignment of this Agreement from Gilead to an Affiliate of Gilead, or from an Affiliate of Gilead to another Affiliate of Gilead, including, without limitation, assignments pursuant to Section 16.6 (collectively, "Gilead Affiliate Assignment"), the [\*] under this Agreement [\*].

**8.8 Blocked Currency.** In any country where conversion of the local currency is blocked and such currency cannot be removed from the country, Gilead shall pay Cubist in local currency by deposit in a local bank designated by Cubist.

**8.9 Foreign Exchange.** For the purpose of computing the Net Sales for Licensed Products sold in a currency other than Dollars, such currency shall be converted into Dollars as computed in the central Gilead currency conversion system using the average monthly rate of exchange at the time for such currencies as retrieved from the on-line edition of the Wall Street Journal (at <http://www.interactive.wsj.com>). The currency conversion system used by Gilead shall be subject to audit by Cubist as described in Section 12.1, and, if not determined to be a system reflecting a reasonable

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average exchange rate of the currencies in question, shall be modified as necessary to effect currency conversion at a reasonable average exchange rate.

**8.10 Payments to or Reports by Affiliates.** Any payment required under any provision of this Agreement to be made to either Party or any report required to be made by any Party shall be made to or by an Affiliate of that Party if designated in writing by that Party as the appropriate recipient or reporting entity.

**8.11 Late Payments.** Any amounts not paid by Gilead 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 made a wire transfer of immediately available funds into an account designated by Cubist at a rate equal to [\*] quoted in the Money Rates section of the on-line edition of the Wall Street Journal (at <http://www.interactive.wsj.com>) calculated daily on the basis of a 365-day year, or similar reputable data source, or, if lower, the highest rate permitted under applicable law.

## ARTICLE 9 INTELLECTUAL PROPERTY

**9.1 Ownership of Inventions.** Each Party shall own any inventions made solely by its employees or agents in their activities hereunder. Inventions hereunder made jointly by employees or agents of each Party shall be owned jointly by the parties ("Joint Inventions"). Inventorship shall be determined in accordance with U.S. patent laws.

### 9.2 Prosecution of Patents.

**(a) Cubist Patents.** Cubist shall be responsible for the prosecution and maintenance of the Cubist Patents at [\*]. Gilead shall have the right to review and comment upon such prosecution by Cubist of the Cubist Patents in the jurisdictions of the Gilead Territory. To that end, Cubist shall furnish Gilead with copies of each draft submission regarding a Cubist Patent to a patent authority of any jurisdiction of the Gilead Territory no later than [\*] prior to the date such submission is proposed to be made, in the state that such submission is reasonably in at such time (which may, for example, be in the form of descriptions of experiments and experimental data that may be used to demonstrate an actual reduction to practice of the relevant invention, which experiment may be ongoing) and will [\*] thereon. If Gilead does not provide Cubist with reasonably timely comments, Cubist shall be free to proceed with its submission or other contemplated action. Cubist will make reasonable efforts to provide Gilead an update to such draft prior to filing to enable Gilead to monitor progress and further comment on the draft and shall provide Gilead with a copy of each submission to a patent authority of a jurisdiction within the Gilead Territory regarding a Cubist Patent [\*] after making such filing. If Cubist determines in its sole discretion to abandon or not maintain any claim or patent application within the Cubist Patents anywhere in the Gilead Territory, then Cubist shall provide Gilead with [\*] prior written notice of such determination and shall provide Gilead with the opportunity to prosecute and maintain such claim or patent application in the Gilead Territory on behalf of Cubist [\*]. Cubist shall inform Gilead of any patents, information or proceeding of which Cubist becomes aware that relate to Cubist Patents that may adversely impact the validity, title or enforceability of Cubist Patents in the Gilead Territory.

**(b) Gilead Project Patents.** Gilead shall be responsible for the prosecution and maintenance of the Gilead Project Patents [\*]. Cubist shall have the right to review and comment upon Gilead's prosecution of the Gilead Project Patents in the jurisdictions outside the Gilead Territory. To that end, Gilead shall furnish Cubist with copies of each draft submission regarding a Gilead Project Patent to the patent authority of any jurisdiction outside the Gilead Territory no later than [\*] prior to the date such submission is proposed to be made, in the state that such draft submission is reasonably in at such time (which may, for example, be in the form of descriptions of experiments

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and experimental data that may be used to demonstrate an actual reduction to practice of the relevant invention, which experiment may be ongoing) and will [\*] thereon. If Cubist does not provide Gilead with reasonably timely comments, Gilead shall be free to proceed with its submission or other contemplated action. Gilead will make reasonable efforts to provide Cubist an update to such draft prior to filing to enable Cubist to monitor progress and further comment on the draft and shall provide Cubist with a copy of each submission made to a patent authority outside the Gilead Territory regarding a Gilead Project Patent reasonably promptly after making such filing. If Gilead determines in its sole discretion to abandon or not maintain any claim or patent application within the Gilead Project Patents anywhere outside the Gilead Territory, then Gilead shall provide Cubist with [\*] prior written notice of such determination and shall provide Cubist with the opportunity to prosecute and maintain such claim or patent application outside the Gilead Territory on behalf of Gilead at [\*]. Gilead shall

inform Cubist of any patents, information or proceeding of which Gilead becomes aware that relate to Gilead Project Patents that may adversely impact the validity, title or enforceability of Gilead Project Patents outside the Gilead Territory.

**(c) Joint Patents.** With respect to Joint Inventions, the Parties shall [\*] covering such Joint Invention (any such patent application and any patents issuing therefrom a "Joint Patent"). If either Party prosecutes a patent application covering a Joint Invention, such Party shall [\*], except as provided in the final sentence of this paragraph. Except to the extent either Party is restricted by the licenses granted to the other Party, and covenants contained, herein, and to the extent permitted by law, each Party shall be entitled to [\*]. Either Party may disclaim its interest in any particular Patent or patent application covering a Joint Invention, in which case (i) the disclaiming Party shall assign its ownership interest in such Patent or patent application to the other Party for no additional consideration, (ii) the Party which is then the sole owner shall be solely responsible for all future costs of such patent or patent application, and (iii) the disclaiming Party shall hold no further rights thereunder.

**9.3 Patent Term Extensions.** Cubist will, [\*], after discussing its strategy with Gilead and [\*], in each country in the Gilead Territory, determine for which, if any, of the Patents within the Cubist Patents, Gilead Project Patents and Joint Patents, the Parties will apply to extend the patent term with respect to Licensed Products, as provided for in patent term extension laws or regulations in the Gilead Territory similar to the Patent Term Restoration Act or other similar laws and regulations affording an extension or restoration of patent terms in the United States, which similar laws and regulations shall include without limitation any Supplementary Protection Certificates. Cubist shall act with reasonable promptness in light of the development stage of Licensed Products to apply for any such extension. Gilead shall not make any submissions, filings or other communications with any governmental agency with respect to patent term restoration (or other similar grant of a monopoly right with respect to any Licensed Product) for any Patents within the Cubist Patents, Gilead Project Patents or Joint Patents in the Gilead Territory without Cubist's express consent. Gilead will cooperate fully with Cubist in making such filings [\*] which may include without limitation, making available regulatory data and information.

**9.4 Non-Patent Regulatory Exclusivity.** Gilead shall have the right to apply for regulatory exclusivity for the Licensed Products as provided in Section 4.7.

### **9.5 Infringement of Patents by Third Parties.**

**(a) Notification.** Each Party shall promptly notify the other Party in writing of any alleged or threatened infringement of the Cubist Patents and Gilead Project Patents of which it becomes aware (such infringement, "Infringement", and "Infringe" shall be interpreted accordingly).

**(b) Infringement of Cubist Patents in the Gilead Territory [\*].** If the Infringement of Cubist Patents involves or would involve a [\*] in the Gilead Territory only and not Licensed Products outside of the Gilead Territory, Gilead shall have the right, but not the obligation, to bring, [\*], an

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appropriate action against the person or entity engaged in such Infringement directly or contributorily. If Gilead does not bring such action within [\*] of notification thereof to or by Cubist pursuant to Section 9.5(a) or within [\*] of the date upon which notification thereof to Cubist should have been given by Gilead pursuant to Section 9.5(a) hereof, Cubist shall have the right, but not the obligation, to bring [\*], such appropriate action. The Party not bringing an action under this paragraph (b) shall be entitled to separate representation in such matter by counsel of its own choice and at its own expense, but such Party shall cooperate fully with the party bringing such action.

**(c) Other Infringement of Cubist Patents.** For all Infringement of Cubist Patents that involves or would involve a product that is [\*] other than Infringement described in Section 9.5(b), Cubist shall have the [\*] right, but not the obligation, to bring, [\*], an appropriate action against any person or entity engaged in such Infringement directly or contributorily. If Cubist does not bring such action within [\*] of notification thereof to or by Gilead pursuant to Section 9.5(a) or within [\*] of the date upon which notification thereof to Gilead should have been given by Cubist pursuant to Section 9.5(a) hereof, Gilead shall have the right, but not the obligation, to bring [\*], such appropriate action; *provided, however*, that such appropriate action is brought [\*] and is limited only to [\*] and not to[\*] or otherwise to [\*]. The Party not bringing an action under this paragraph (c) shall be entitled to separate representation in such matter by counsel of its own choice and at its own expense, but such Party shall cooperate fully with the Party bringing such action.

**(d) Joint Patents.** With respect to Third Party Infringement of Joint Patents other than that Infringement described in Sections 9.5(b) and 9.5(c), the Parties shall confer and take such action, and allocate expenses and recoveries, in such manner as they shall agree.

**(e) Infringement of Gilead Project Patents Outside the Territory by [\*] Infringement.** In the event the Infringement of a Gilead Project Patent involves or would involve a [\*] outside of the Gilead Territory, Cubist shall have the right, but not the obligation, to bring, [\*], an appropriate action against the person or entity Infringing a Gilead Project Patent (including any Joint Patent) directly or contributorily. If Gilead does not bring such action within [\*] in the case of an action brought under the Hatch-Waxman Act) of notification thereof to or by Gilead, Cubist shall have the right, but not the obligation, to bring [\*], such appropriate action. The Party not bringing an action under this Section 9.5(e) shall be entitled to separate representation in such matter by counsel of its own choice and at its own expense, but such Party shall cooperate fully with the party bringing such action.

**(f) Other Infringement of Gilead Project Patents.** For all Infringement other than that described in Section 9.5(e) that involves a Gilead Project Patent that is not a Joint Patent, Gilead shall have the exclusive right, but not the obligation, to bring, [\*], an appropriate action against any person or entity Infringing a Gilead Project Patent directly or contributorily.

**(g) Settlement; Allocation of Proceeds.** Cubist shall not settle a claim brought under this Section 9.5 involving Gilead Project Patents or Joint Patents, or a claim brought under this Section 9.5 involving Cubist Patents that would [\*], in either case without the prior written consent of Gilead (which consent shall not be unreasonably withheld or delayed). Gilead shall not settle a claim brought under this Section 9.5 involving Cubist Patents or Joint Patents, or a claim brought under this Section 9.5 involving Gilead Project Patents that would [\*], in either case without the prior written consent of Cubist (which consent shall not be unreasonably withheld or delayed). In the event of any recovery of monetary damages from the Third Party in an action brought under this Section 9.5, [\*], such recovery shall be allocated [\*], and any remaining amounts shall be split as follows: (i) the portion of any such remaining amounts that represents recovery

such remaining amounts are recovered in an action brought by Cubist pursuant to Section 9.5(b) hereof in which case the portion of any such remaining amounts that represents recovery for Infringement that involves or would involve a product that [\*], (ii) the portion of any such remaining amounts that represents recovery for Infringement that involves or would involve a product that [\*] for Cubist and (iii) the portion of any such remaining amounts that represents recovery for Infringement in an action brought pursuant to Section 9.5(d) shall be split [\*] to Gilead and [\*] to Cubist unless Gilead and Cubist shall have agreed to a different allocation.

#### 9.6 Infringement of Third Party Rights.

**(a) Notice.** If any Licensed Product manufactured, used or sold by either Party, its Affiliates, licensees or sublicensees under this Agreement becomes the subject of a Third Party claim, or there is the potential for a claim, of patent infringement relating to the manufacture, use, sale, offer for sale or importation of Licensed Product, the Party first having notice of the claim shall promptly notify the other Party, and the Parties shall promptly meet to consider the claim and the appropriate course of action.

**(b) Defense.** Except as provided herein, the Party against which such Third Party infringement claim is brought shall defend against such claim at its sole expense and the other Party shall have the right, but not the obligation, to participate in any such suit, at its sole option and at its own expense. Such other Party shall reasonably cooperate with the Party conducting the defense of the claim, including if required to conduct such defense, furnishing a power of attorney. Notwithstanding the foregoing provisions of this Section 9.6(b), [\*].

**(c) Settlement.** Neither Party shall enter into any settlement that affects the other Party's rights or interests without such other Party's written consent, which consent shall not be unreasonably withheld or delayed.

#### **(d) Indemnification.**

**(i)** Subject to the provisions of this Section 9.6(d), Cubist shall Indemnify (as defined in Section 11.1) Gilead and the Gilead Indemnitees (as defined in Section 11.1) from and against any and all Losses arising from the [\*] of any Third Party intellectual property right (all such Losses, "Section 9.6(d) Losses") by the manufacture, use, sale, offer for sale or importation of Licensed Products by Gilead and its Affiliates, Permitted Sublicensees and distributors; *provided* that Cubist shall not be obligated to Indemnify Gilead or the Gilead Indemnitees pursuant to this Section 9.6(d)(i) to the extent that (i) the alleged infringement arises out of Gilead's breach or non-compliance with any of the provisions of this Agreement (including without limitation the Supply Agreement), or (ii) such Section 9.6(d) Losses are Gilead Indemnifiable Technology Losses. If Cubist is unable to procure any license from a Third Party owning or controlling rights that would be infringed or misappropriated by the development, manufacture, use or sale of Licensed Products in the Gilead Territory on commercially reasonable terms, Cubist shall so notify Gilead and Gilead shall discontinue manufacturing, using and selling such Licensed Product; *provided* that prior to being required to cease such activities, (i) the Parties shall first confer in good faith as promptly as practicable as to whether to alter their approach to the infringing activities with respect to the Licensed Product that would avoid such infringement without adversely affecting their rights under this Agreement or return from the Commercialization of Licensed Product in the Gilead Territory, (ii) the Third Party owning such technology shall have refused to grant a license to Cubist on commercially reasonable terms, and (iii) Cubist shall have afforded Gilead an opportunity to seek such Third Party license and, within sixty (60) days of being given such opportunity, such Third Party [\*]. Notwithstanding the foregoing, Cubist shall not be required to obtain any such license and Cubist shall not be obligated to [\*] that would cause [\*]. Gilead may in its sole discretion agree to [\*] in order to allow Cubist to achieve [\*].

**(ii)** If Cubist desires to incorporate or utilize any Gilead Project Know-How or invention claimed by any Gilead Project Patent in or in connection with the [\*]. If Gilead agrees in writing, after such discussions by the Development Subcommittee, that any such Gilead Project Technology shall be so incorporated or utilized and shall be deemed "Gilead Indemnifiable Technology" hereunder, then Gilead shall indemnify Cubist pursuant to the last sentence of this Section 9.6(d)(ii). If Gilead does not so agree in writing, Cubist shall be entitled to make such incorporation or utilization in connection with the practice of the licenses set forth in Sections 6.2 and 6.4, but such Gilead Project Technology shall not be Gilead Indemnifiable Technology and Gilead shall not be obliged to indemnify Cubist as provided in such sentence. Gilead Indemnifiable Technology shall also include any technology owned or Controlled by Gilead (other than Cubist Technology or Joint Patents) that Gilead uses (but that is not being used by Cubist, its Affiliates or sublicensees in connection with Licensed Products outside the Gilead Territory) in the development, manufacture, use, sale offer for sale or import of Licensed Products in the Gilead Territory. Subject to the last sentence of this Section 9.6(d), Gilead shall Indemnify Cubist and the Cubist Indemnitees (as defined in Section 11.1) from and against any and all Losses to the extent arising from the infringement or misappropriation of any Third Party intellectual property right (all such Losses, "Gilead Indemnifiable Technology Losses") by the practice of Gilead Indemnifiable Technology in the manufacture, use, sale, offer for sale or importation of Licensed Products by or for Gilead and its Affiliates, Permitted Sublicensees and distributors as otherwise permitted hereunder; *provided* that Gilead shall not be obligated to Indemnify Cubist pursuant to this Section 9.6(d)(ii) to the extent that (i) the alleged infringement or misappropriation arises out of Cubist's breach or non-compliance with any of the provisions of this Agreement, including without limitation the Supply Agreement, or (ii) such Losses arise from the infringement or misappropriation of Third Party intellectual property by the practice of Cubist Technology.

**(iii)** If Gilead is obligated to indemnify Cubist pursuant to Section 9.6(d)(ii) with respect to the practice of Gilead Indemnifiable Technology outside of the Gilead Territory, and in connection with such obligation is unable to procure any license from a Third Party owning or Controlling rights that would be infringed or misappropriated by the development, manufacture, use or sale of Licensed Products outside of the Gilead Territory with respect to the Gilead Indemnifiable Technology on commercially reasonable terms, Gilead shall so notify Cubist and [\*], (i) the Parties shall [\*], (ii) the Third Party owning such technology shall have [\*], and (iii) Gilead shall have afforded Cubist an [\*]. The provisions of this Section 9.6(d) and Sections 9.7 and 11.6 state [\*] in respect of liability for infringement or misappropriation of any Third Party's intellectual property right by the manufacture, use, sale, offer for sale or importation of any Licensed Product.

**9.7 Royalty Reduction.** If Gilead is required (either by final judgment from a court of competent jurisdiction or pursuant to the terms of any settlement that complies with the provisions of Section 9.6(c) above) to pay a Third Party a royalty or make any payment of any kind for the right to practice the Cubist Technology in a particular country in the Gilead Territory and Cubist is required, [\*], an amount [\*] in respect of the [\*]; *provided, however*, that nothing in this Section 9.7 shall relieve Cubist or Gilead from its obligations under Section 9.6 hereof.

**9.8 Patent Marking.** Licensed Products marketed and sold by Gilead hereunder shall be marked with appropriate patent numbers or indicia at Cubist's request to the extent permitted by law, in those countries in which such markings have notice value as against infringers of patents.

**9.9 Selection and Registration of Product Trademarks.** Gilead may select and own its own trademarks for use in connection with the sale of Licensed Products within the Gilead Territory, in addition to the Cubist-owned trademarks to which Gilead has a license pursuant to Section 6.7. Each Party shall be responsible for registering and maintaining its own trademarks, at its own expense.

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**9.10 Infringement of Trademarks by Third Parties.** With respect to Licensed Products within the Gilead Territory, each Party shall notify the Steering Committee promptly upon learning of any actual, alleged or threatened infringement of any trademark or of any unfair trade practices, trade dress imitation, passing off of counterfeit goods, or like offenses, or any such claims brought by a Third Party against a Licensed Product (hereinafter "TM Infringement"). Upon learning of such TM Infringement, the Steering Committee [\*]. In the absence of other agreement [\*], to bring an action to address such TM Infringement, in which case such Party [\*].

#### **9.11 Patent Oppositions.**

**(a) Third Party Patent Rights.** If either Party desires to bring an opposition, action for declaratory judgment, nullity action, interference, reexamination or other attack upon the validity, title or enforceability of a Patent owned or Controlled by a Third Party that covers the manufacture, use or sale of any Licensed Product, such Party shall so notify the other Party and the Parties shall promptly confer to determine whether to bring such action or the manner in which to settle such action. Cubist shall have the first right, but not the obligation, to bring at its own expense and in its sole control such action outside the Gilead Territory. Gilead shall have the first right, but not the obligation, to bring at its own expense and in its sole control such action in the Gilead Territory. If Gilead does not bring such action within [\*] of notification thereof pursuant to this Section 9.11(a) (or earlier, if required by the nature of the proceeding), Cubist shall have the right, but not the obligation, to bring at Cubist's expense and in its sole control, such action. The Party not bringing an action under this Section 9.11(a) shall be entitled to separate representation in such proceeding by counsel of its own choice and at its own expense, and shall cooperate fully with the Party bringing such action. Any awards or amounts received in bringing any such action shall be first allocated to [\*].

**(b) Parties' Patent Rights.** If a Cubist Patent or a Gilead Project Patent becomes the subject of any proceeding commenced by a Third Party in connection with an opposition, reexamination request, action for declaratory judgment, nullity action, interference or other attack upon the validity, title or enforceability thereof, then the Party owning or Controlling such Patent shall control such defense at its sole cost; *provided* that if such action relates to a Joint Patent, the Parties shall confer and determine which Party shall control such action. The controlling Party will permit the non-controlling Party to participate in the proceeding to the extent permissible under law, and to be represented by its own counsel in such proceeding, at the non-controlling Party's expense. If either Party decides that it does not wish to defend against such action, then the other Party shall have a backup right to assume defense of such Third Party action at its own expense. Any awards or amounts received in defending any such Third Party action shall be allocated [\*].

**(c) Noncontravention.** Nothing in this Section 9.11 shall be deemed to relieve either Party of its obligations under Section 9.6(d) or Article 11.

**9.12 Lilly License.** Notwithstanding the foregoing, the Parties' rights and obligations under this Article 9 shall be subject to limitations imposed by the Lilly License, *provided* that the Parties shall work to address such limitations in a manner that permits Gilead to exercise its rights under this Agreement to the fullest extent reasonably possible.

### **ARTICLE 10 REPRESENTATIONS AND WARRANTIES**

**10.1 Mutual Representations and Warranties.** Each Party hereby represents and warrants to the other Party as follows:

**(a) Corporate Existence and Power.** It is a corporation duly organized, validly existing and in good standing under the laws of the state in which it is incorporated, and has full corporate power

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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.

**(b) Authority and Binding Agreement.** As of the Effective Date, (a) it has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (b) it 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 that is enforceable against it in accordance with its terms.

**(c) No Conflict.** It has not entered, and will not enter, into any agreement with any Third Party that 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. Its performance and execution of this Agreement will not result in a breach of any other contract to which it is a Party.

**(d) Regulatory Data.** The regulatory data it provides to the other Party shall be complete and accurate in all material respects.

**(e) No Misappropriation.** It has not and shall not misappropriate the trade secret of another in its activities to develop or commercialize Licensed Products.

**(f) No Debarment.** Each Party represents and warrants that in the course of the development of Licensed Products, such Party shall not have used, during the term of this Agreement, any employee or consultant that has been debarred by the FDA or Regulatory Authorities, or, to the best of such Party's knowledge, is the subject of debarment proceedings by the FDA or Regulatory Authorities.

**10.2 Cubist.** Cubist represents and warrants to Gilead as follows:

**(a) Non-Infringement of Cubist Technology by Third Parties.** As of the Effective Date, Cubist is unaware of any activities by Third Parties which would constitute infringement or misappropriation of the Cubist Technology.

**(b) Lilly License.** Cubist is in full compliance with the Lilly License as of the Effective Date, and has received no notices of default under the Lilly License.

**(c) Regulatory Data.** Cubist is not aware of any data or information given to Gilead relating to Licensed Products that is untrue or inaccurate in any material respect or of any other data or information that is necessary to make the data and information provided to Gilead complete and not misleading in all material respects.

**(d) Oral Product Rights.** Cubist owes no obligation [\*] which would conflict with the rights granted Gilead herein, including without limitation the exclusive license with respect to all Licensed Products (including without limitation Oral Products) that Gilead continues pursuant to this agreement to enjoy even after a [\*] described by clause (II) or (III) of Section 8.1(c).

**(e) Rights in Technology.** As of the Effective Date, Cubist has sufficient right in and to the Cubist Technology, free and clear of any liens or encumbrances, to grant the rights set forth in this Agreement.

**(f) Non-infringement of Third Party Rights.** As of the Effective Date, Cubist is unaware of any Patents or trade secret rights owned or controlled by a Third Party, which would be infringed

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or misappropriated by the manufacture, use, sale, offer for sale or importation of Daptomycin Products, and has received no, and has reason to believe that it would receive any, written claims relating to any claims of such infringement or misappropriation.

**10.3 Disclaimer.** Gilead understands that Licensed Products are the subjects of ongoing clinical research and development and that Cubist cannot assure the safety or usefulness of Licensed Products. Cubist makes no warranty except as set forth in this Article 10 concerning its Patents or Know-How.

**10.4 No Other Representations.** THE EXPRESS REPRESENTATIONS AND WARRANTIES STATED IN THIS ARTICLE 10 ARE IN LIEU OF ALL OTHER REPRESENTATIONS AND WARRANTIES, EXPRESS, IMPLIED, OR STATUTORY, INCLUDING WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS.

## ARTICLE 11 INDEMNIFICATION

**11.1 Indemnification by Cubist.** Cubist hereby agrees to defend, hold harmless and indemnify (collectively "Indemnify") Gilead and its Affiliates, agents, directors, officers and employees (the "Gilead Indemnitees") from and against any and all suits, claims, actions, demands, liabilities, expenses and/or losses, including without limitation reasonable legal expenses and attorneys' fees (collectively "Losses") resulting directly or indirectly from (i) a breach of any of Cubist's representations and warranties pursuant to Article 10; (ii) any claims resulting directly or indirectly from the secondment of a Cubist MSL in the Gilead Territory other than to the extent arising directly from an action taken by a Cubist MSL in accordance with Gilead's specific instructions; or (iii) the development, use, sale, offer for sale or importation of Licensed Products by Cubist or its Affiliates, licensees or sublicensees; *provided, however*, that Cubist shall not be required pursuant to this Section 11.1 to indemnify the Gilead Indemnitees for any Section 9.6(d) Losses. Cubist's obligation to Indemnify the Gilead Indemnitees pursuant to this Section 11.1 shall not apply to the extent of any Losses (i) that arise from the negligence or intentional misconduct of any Gilead Indemnitee; (ii) from Gilead's breach of this Agreement, including without limitation the Supply Agreement; or (iii) for which Gilead is obligated to Indemnify the Cubist Indemnitees pursuant to Section 11.2 or the Supply Agreement. Cubist's obligations to indemnify Gilead with respect to the manufacture and supply of Licensed Product are set forth in the Supply Agreement.

**11.2 Indemnification by Gilead.** Gilead hereby agrees to Indemnify Cubist and its Affiliates, agents, directors, officers and employees (the "Cubist Indemnitees") from and against any and all Losses resulting directly or indirectly from (i) a breach of any of Gilead's representations and warranties pursuant to Article 10; or (ii) the development, use, sale, offer for sale or importation of Licensed Products by Gilead or its Affiliates or sublicensees. Gilead's obligation to Indemnify the Cubist Indemnitees pursuant to the foregoing sentence shall not apply to the extent of any Losses (i) that arise from the negligence or intentional misconduct of any Cubist Indemnitee, (ii) for which Cubist is obligated to Indemnify the Gilead Indemnitees pursuant to Section 11.1, or (iii) from any breach by Cubist of this Agreement, including without limitation the Supply Agreement. Gilead's obligations to indemnify Cubist with respect to the manufacture and supply of Licensed Products are set forth in the Supply Agreement.

**11.3 Procedure.** If either Party is seeking indemnification under Section 11.1 or 11.2 in connection with a Third Party claim, it shall inform the indemnifying Party of such Third Party claim giving rise to the obligation to indemnify pursuant to such section as soon as reasonably practicable after receiving notice of the claim. The indemnifying Party shall have the right to assume the defense of any such Third Party claim for which it is obligated to indemnify the indemnified Party under Section 11.1 or

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11.2. The indemnified Party shall cooperate with the indemnifying Party (and its insurer) as the indemnifying Party may reasonably request, and at the indemnifying Party's sole cost and expense. The indemnified Party shall have the right to participate, at its own expense and with counsel of its choice, in the defense of any claim or suit that has been assumed by the indemnifying Party. Neither Party shall have any obligation to indemnify the other Party in connection with any settlement made without the indemnifying Party's written consent, *provided* that the indemnifying Party does not unreasonably withhold or delay any such written consent. If the Parties cannot agree as to the application of Sections 11.1 or 11.2 to any Third Party claim, the Parties may conduct separate defenses of such claims, with each Party retaining the right to claim indemnification from the other in accordance with Section 11.1 or 11.2 upon resolution of the underlying claim.

**11.4 Insurance.** Each Party shall procure and maintain insurance or self-insurance, including product liability insurance, adequate to cover its obligations hereunder and which are consistent with normal business practices of prudent companies similarly situated at all times during which any Licensed Product is being clinically tested with human subjects or commercially distributed or sold by Gilead. It is understood that such insurance shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under this Article 11. Each Party shall provide the other with written evidence of such insurance (or financial information that describes the amounts available under any self-insurance facility) upon request. Each Party shall provide the other with written notice at least [\*] prior to the cancellation, non-renewal or material change in such insurance or self-insurance which materially adversely affects the rights of the other Party hereunder.

**11.5 No Application to Third Party Infringement Claims.** Except for the provisions of Section 11.4 above and Section 11.6 below, the provisions of this Article 11 shall not apply to any claims by a Third Party for infringement of such Third Party's patents or other intellectual property or to any Losses suffered or incurred by either Party arising from, or related to, any such claims by a Third Party. The indemnification rights and obligations of both Parties with respect to any such claims by a Third Party are provided for in Section 9.6(d) hereof.

**11.6 Limitation of Liability.** EXCEPT AS EXPRESSLY PROVIDED IN THIS AGREEMENT, INCLUDING WITHOUT LIMITATION IN THIS ARTICLE 11, AND EXCEPT FOR INFRINGEMENT BY EITHER PARTY OF THE OTHER PARTY'S INTELLECTUAL PROPERTY RIGHTS OR BREACH OF CONFIDENTIALITY OBLIGATIONS UNDER ARTICLE 13, NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR LOST PROFITS OR FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, PUNITIVE OR EXEMPLARY DAMAGES OF THE OTHER PARTY IN CONNECTION WITH THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED BY THIS AGREEMENT, HOWEVER CAUSED, UNDER ANY THEORY OF LIABILITY (COLLECTIVELY, "*OTHER DAMAGES*"). IN NO EVENT SHALL EITHER PARTY BE LIABLE FOR OTHER DAMAGES IN EXCESS OF [\*] (THE "*SECTION 11.6 CAP*"). IT IS EXPRESSLY UNDERSTOOD THAT THE OBLIGATION OF EITHER PARTY UNDER ARTICLE 11 TO INDEMNIFY FOR AMOUNTS THAT THE OTHER PARTY ACTUALLY PAYS TO A THIRD PARTY SHALL NOT BE LIMITED BY THE SECTION 11.6 CAP.

## ARTICLE 12 RECORDS; PUBLICATIONS

**12.1 Records.** Each Party shall keep or cause to be kept such records as are required to determine, in a manner consistent with generally accepted accounting principles in the United States, the sums or credits due under this Agreement, including, but not limited to Incremental Product Development Expenses, Transfer Prices and Net Sales. At the request (and expense) of either Party, the other Party and its Affiliates and licensees and sublicensees shall permit an independent certified public accountant appointed by such Party and reasonably acceptable to the other Party, accompanied by representatives of the financial department of the audited Party at reasonable times, upon reasonable notice and no

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more frequently than once per calendar year, to examine only those records as may be necessary to determine, with respect to any calendar year ending not more than [\*] prior to such Party's request, the correctness or completeness of any report or payment made under this Agreement. Results of any such examination shall be (i) limited to information relating to the Licensed Products, (ii) made available to both Parties, and (iii) subject to Article 13. The Party requesting the audit shall bear the full cost of the performance of any such audit, unless such audit discloses a variance of more than [\*] from the amount of the original report, royalty or payment calculation. In such case, the Party being audited shall bear the full cost of the performance of such audit.

**12.2 Publications.** Neither Party shall publish or present the results of studies carried out under this Agreement without the opportunity for prior review by the other Party. Subject to Section 13.2, each Party agrees to provide the other Party the opportunity to review any proposed abstracts, manuscripts or presentations (including verbal presentations) which relate to any Licensed Product at least [\*] prior to their intended submission for publication and agrees, upon request, not to submit any such abstract or manuscript for publication, or to make such presentation, until the other Party is given a reasonable period of time to secure patent protection for any material in such publication or presentation which it believes to be patentable. Both Parties understand that a reasonable commercial strategy may require delay of publication or presentation of information or filing of patent applications. The Parties agree to review and consider delay of publication or presentation and filing of patent applications under certain circumstances. The Steering Committee will review such requests and recommend subsequent action. Neither Party shall have the right to publish or present Confidential Information of the other Party, and each Party shall remove the Confidential Information of the other Party from any proposed publication or presentation upon request by such other Party. Nothing contained in this Section 12.2 shall prohibit the inclusion of information necessary to file a patent application with a government authority, except for Confidential Information of the non-filing Party, provided the non-filing Party is given a reasonable opportunity to review the information to be included prior to submission of such patent application. Notwithstanding the foregoing, the Parties recognize that independent investigators have been engaged, and will be engaged in the future, to conduct clinical trials of Licensed Products. Independent investigators that have been engaged by a Party or both Parties prior to or on the Effective Date may release information regarding such studies in a manner consistent with academic standards within the scope of such investigator's agreement with the relevant Party. Independent investigators that are engaged by a Party or both Parties after the Effective Date are understood to operate in an academic environment and shall be allowed to release information regarding such studies in a manner consistent with academic standards; *provided, however*, that the Party in privity with such investigators shall discourage such disclosures if detrimental to the collaboration.

## ARTICLE 13 CONFIDENTIALITY

**13.1 Treatment of Confidential Information.** The Parties agree that during the Term, and for a period of [\*] after this Agreement expires or terminates, a Party receiving Confidential Information of the other Party shall (i) maintain in confidence such Confidential Information to the same

extent such Party maintains its own proprietary industrial information of similar kind and value (but at a minimum each Party shall use commercially reasonable efforts to maintain Confidential Information in confidence); (ii) not disclose such Confidential Information to any Third Party without prior written consent of the disclosing Party, except for disclosures made in confidence to any Third Party pursuant to a plan approved by the Steering Committee or to its licensees or sublicensees who agree to be bound by obligations of non-disclosure and non-use at least as stringent as those contained in this Article 13; and (iii) not use such Confidential Information for any purpose except those purposes permitted by this Agreement.

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**13.2 Authorized Disclosure.** 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 or regulation or court 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;

(c) 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. In particular, the Parties acknowledge that Cubist and/or Gilead may be obligated to file a copy of this Agreement with the U.S. Securities and Exchange Commission with its next quarterly report on Form 10-Q, annual report on Form 10-K or current report on Form 8-K or with any registration statement filed with the U.S. Securities and Exchange Commission (the "SEC") pursuant to the Securities Act of 1933, as amended. In the event of any such filing, the Parties agree to cooperate and work together to request confidential treatment pursuant to, and in accordance with, the rules and regulations of the SEC; or

(d) as required by the Lilly License.

**13.3 Publicity.** The Parties agree that the joint public announcement of the execution of this Agreement shall be substantially in the form of the press release attached as Exhibit H. Any other publication, news release or other public announcement relating to this Agreement or to the performance hereunder, shall first be reviewed and approved by both Parties, which approval shall not be unreasonably withheld.

## **ARTICLE 14 TERM AND TERMINATION**

**14.1 Term.** This Agreement shall become effective on the Effective Date and shall remain in effect, unless earlier terminated pursuant to this Article 14 with respect to each Licensed Product until the expiration of the last royalty obligation relating to sales of such Licensed Product as provided in Article 8.

**14.2 Termination by Gilead.** Gilead shall have, [\*], the right to terminate this Agreement [\*] upon [\*] written notice to Cubist. If Gilead terminates this Agreement [\*] Licensed Product pursuant to this Section 14.2, (i) Gilead shall provide Cubist with all reasonable assistance during the [\*] notice period to effect the transfer of all regulatory activities, regulatory filings and Regulatory Approvals in the Gilead Territory for Licensed Product(s) as to which such termination is effective to Cubist, (ii) Cubist shall promptly wind down its efforts under any Proposed Modification to a protocol for a clinical trial being conducted by Cubist for such Licensed Product(s) pursuant to Section 3.4 that the Steering Committee approves, to the extent reasonably practicable without adversely affecting the value of the data to be obtained from such clinical trial to Cubist or compromising patient safety, and (iii) Gilead shall wind down its efforts to develop and commercialize such Licensed Product(s) in the Gilead Territory. Gilead shall continue to [\*] pursuant to its [\*] as to which this Agreement is terminated that is ongoing as of the date upon which Gilead provides a termination notice for such Licensed Product(s) pursuant to this Section 14.2, but Gilead shall not be responsible for [\*] with respect to the Licensed Product(s) that are the subject of such trial. The Steering Committee shall oversee any such wind down efforts. Additionally, after termination of this Agreement pursuant to this Section 14.2, [\*] with respect to which this Agreement is terminated prior to the effective date of such termination, but not for [\*].

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### **14.3 Termination for Breach.**

(a) **Notice.** If either Party believes that the other is in material breach of this Agreement with respect to one or more Licensed Products, then the Party holding such belief (the "Non-breaching Party") may deliver notice of such breach to the other Party (the "Notified Party"). Other than as explicitly provided for in Sections 3.5 or 5.6, a breach by either Party of its Diligence Obligation shall not be deemed to be a material breach of this Agreement. The Notified Party shall have [\*] to either cure such breach or, if cure cannot be reasonably effected within such [\*] period, to deliver to the Non-breaching Party a plan to cure such breach within a timeframe that is reasonably prompt in light of the circumstances then prevailing. Following delivery of such plan, the notified Party shall use Commercially Reasonable Efforts to carry out the plan and cure the breach.

(b) **Failure to Cure.** If the Notified Party fails to cure such breach as provided for in Section 14.3(a), the Non-breaching Party may terminate this Agreement either in its entirety or with respect to one or more Licensed Products upon written notice to the Notified Party; *provided, however,* that alleged breaches by either Party of its Diligence Obligations pursuant to Section 3.1 or 5.5 shall be handled initially as provided in Section 3.5 or 5.6.

(c) **Disputes.** If a Party gives notice of termination under this Section 14.3 and the other Party disputes whether such termination is proper under this Section 14.3, then the issue of whether this Agreement may properly be terminated upon expiration of the notice period (unless such breach is cured as provided in Section 14.3(a)) shall be resolved in accordance with Article 15. If as a result of such dispute resolution process it is determined that the notice of termination was proper, then such termination shall be deemed to have been effective



[\* ] following the date of the notice of termination. If as a result of such dispute resolution process it is determined that the notice of termination was improper, then no termination shall have occurred and this Agreement shall remain in effect.

**(d) Termination as to Certain Licensed Products.** Notwithstanding the foregoing provisions of this Section 14.3, either Party may exercise its right to terminate the Agreement pursuant to this Section 14.3 with respect to one or more particular Licensed Products as to which the other Party has breached its obligations under this Agreement, rather than with respect to the entire Agreement, in which case the notice provided by such Party pursuant to Section 14.3(a) shall specify that the Agreement is being terminated pursuant to this Section 14.3 only with respect to certain Licensed Products listed in such notice. If either Party makes such an election under this Section 14.3(d), then subsections (a) through (c) shall be deemed to refer to termination of the Agreement only with respect to those Licensed Products set forth in the notice provided pursuant to Section 14.3(a).

**14.4 Cubist Rights upon Certain Terminations of the Agreement or as to Certain Licensed Products.** If Cubist terminates this Agreement in its entirety or with respect to one or more Licensed Product(s) pursuant to Section 14.3, or Gilead terminates this Agreement in its entirety or with respect to any Licensed Products pursuant to Section 14.2 (such Licensed Products as to which Gilead or Cubist has terminated Gilead's rights, or all Licensed Products if the Agreement is terminated in its entirety, "Reverted Products"), then:

**(a)** Gilead hereby grants to Cubist a nonexclusive, royalty-free license, with the right to grant sublicenses, to use the Gilead Marks in connection with the commercialization of Reverted Products (collectively "Permitted Uses"). Promptly after any such termination of this Agreement in its entirety or Gilead's rights with respect to certain Licensed Products, Gilead shall execute any documents required in the reasonable opinion of Cubist for Cubist to be entered as a "registered user" or recorded licensee of the Gilead Marks for Permitted Uses, or for Gilead to be removed as registered user or licensee thereof.

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**(b)** Gilead shall transfer to Cubist all Drug Approval Applications and Regulatory Approvals for Reverted Products that Gilead holds as of the time of such termination. In such event, Gilead shall take all actions reasonably necessary to effect such transfer of such Drug Approval Applications and Regulatory Approvals for Reverted Products to Cubist.

**(c)** The licenses granted by Cubist and by Gilead under Article 6 shall terminate with respect to Reverted Products. Gilead shall grant to Cubist a nonexclusive, worldwide, royalty-free, license, with the right to grant sublicenses, under the Gilead Project Technology to develop, make, use, sell, offer for sale and import Reverted Products.

**(d)** Upon termination of this Agreement for any reason with respect to any or all Licensed Products and, if applicable, after the sell-out period set forth in Section 14.5 hereof has expired, Gilead shall discontinue making any representation regarding its status as a licensee of or distributor for Cubist in the Gilead Territory for all Reverted Products, and shall cease conducting any activities with respect to the marketing, promotion, sale or distribution of the Reverted Product in the Gilead Territory.

**14.5 Gilead Rights upon Certain Terminations.** If Gilead terminates this Agreement pursuant to Section 14.3 in its entirety or with respect to one or more Licensed Product(s), then [\*] with respect to [\*] for which [\*], shall [\*] for so long as [\*], except that [\*] shall [\*], without [\*], and Gilead shall have no further obligations under this Agreement with respect to any such Licensed Product(s) other than [\*], which shall last [\*] as required by [\*], and any other [\*] that [\*]. In addition, each Party's [\*] with respect to [\*] shall [\*]. Gilead shall [\*].

**14.6 Survival.** The following provisions shall survive any expiration or termination of this Agreement for the period of time specified: Articles 11 (other than Section 11.4, and, subject to Section 14.5, only with respect to actions arising with respect to periods prior to termination), 12, 14, 15 and 16, and Sections 4.3 (but solely as necessary to effect the exchange of adverse events information in conjunction with Section 4.5), 4.5, 6.7 (but solely as to marks used in connection with Licensed Products during the Term), 7.2(e) (but only for [\*] beyond the end of the Term), 8.6 (but only for [\*] and in relation to Net Sales made during the Term), 9.6(d) (subject to Section 14.5, with respect to actions arising with respect to periods prior to termination), 13.1 and 13.2, and in the case of any of the foregoing and other Section that by their terms explicitly survive beyond the Term, each such Section shall survive beyond the Term only for the length of time specified in such Section. The foregoing provisions that survive in the event of any expiration or termination of this Agreement shall survive in addition to those that survive any termination under Section 14.4 or 14.5, as specifically provided in such sections. Termination of this Agreement shall not relieve the Parties of any liability which accrued hereunder prior to the effective date of such termination nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement nor prejudice either Party's right to obtain performance of any obligation. The remedies provided in this Article 14 are not exclusive of any other remedies a Party may have in law or equity.

**14.7 Clarification with respect to Supply Agreement.** Upon The Parties' execution of the Supply Agreement, references to the Agreement in Sections 14.2, 14.3, 14.4, 14.5 and 14.6 shall be interpreted to apply to this Agreement and to the Supply Agreement as if they were one agreement.

**14.8 Repurchase of Inventory.** Upon any termination of this Agreement by Gilead, Cubist shall have the obligation, upon request of Gilead, to repurchase all of the inventory of the Licensed Product held by Gilead or its sublicensees in the Gilead Territory, *provided* such inventory is in resalable condition. The price for such inventory shall be [\*]. Gilead shall notify Cubist within [\*] days after termination if Gilead wishes to have Cubist repurchase inventory and Cubist shall issue a return authorization to Gilead and Gilead shall ship the Licensed Product to Cubist [\*]. If Gilead does not

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exercise its right to have Cubist repurchase inventory pursuant to this Section 14.8, Gilead shall have the right to sell out its inventory for a period of [\*] from the date of termination.

## ARTICLE 15 DISPUTE RESOLUTION

**15.1 Disputes.** 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. 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 15.1 if and when a dispute arises under this Agreement. All disputes arising under this Agreement shall be discussed first by the Steering Committee. If the Steering Committee is unable to resolve any dispute within [\*] after such dispute is submitted to it, either Party may, 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 [\*] after such notice is received. Such designated officers are as follows:

**For Gilead:** Chief Executive Officer

**For Cubist:** Chief Executive Officer

If the designated officers are not able to resolve such dispute within such [\*] period, either Party may at any time thereafter pursue any legal or equitable remedy available to it.

**15.2 Governing Law; Judicial Resolution.** Resolution of all disputes arising out of or related to this Agreement or the performance, enforcement, breach or termination of this Agreement and any remedies relating thereto, shall be governed by and construed under the substantive laws of the State of New York, as applied to Agreements executed and performed entirely in the State of New York by residents of the State of New York, without regard to conflicts of law rules. Any dispute arising under this Agreement shall be submitted to a state or federal court of competent jurisdiction, except as otherwise expressly provided in this Agreement.

**15.3 Patent and Trademark Dispute Resolution.** Any dispute, controversy or claim relating to the scope, validity, enforceability or infringement of any patent rights covering the manufacture, use or sale of any Licensed Product or of any trademark rights relating to any Licensed Product shall be submitted to a court of competent jurisdiction in the territory in which such patent or trademark rights were granted or arose.

**15.4 [\*] Resolution of Certain Disputes.** Issues relating to whether either Party is meeting its Diligence Obligations designated for resolution by a [\*] pursuant to Section 3.5 or 5.6, modification of Section 1.29 with respect to Directly Competitive Product of an Oral Product, and whether Gilead has properly determined the amount of Promotional Resources under Section 5.7, shall be finally determined as set forth in this Section 15.4. Within [\*] after a Party proposes to submit an issue for resolution by a [\*], each Party shall [\*]. Neither of such [\*] may be [\*], and neither of such [\*]. Within [\*] days after expiration of such [\*] period, the [\*] shall [\*] the issue(s) presented by the Parties. [\*]. Each Party shall submit written materials to the other Party and to [\*] relating to the matters in issue within [\*] after [\*]. Each Party shall then have [\*] to submit a written rebuttal to the other Party's materials to the other Party [\*]. The [\*] shall decide the issue presented to them pursuant to Section 5.6, within [\*] after they receive all such written materials from each Party. The [\*] shall have the discretion to [\*]. Each Party shall cooperate with [\*]. The [\*] determination shall be dispositive of all issues presented to it and such determination shall be given retroactive effect. Until such determination is delivered to the Parties, the Parties shall continue to perform their obligations under

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this Agreement in good faith and make any applicable payments accordingly. The Parties shall bear all expenses incurred pursuant to this Section 15.4 equally.

## **ARTICLE 16 MISCELLANEOUS**

**16.1 Entire Agreement; Amendment.** This Agreement, including the Exhibits hereto, sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto and supersedes and terminates all prior agreements and understandings between the Parties. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

**16.2 Force Majeure.** Both Parties shall be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented by force majeure and the nonperforming 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 nonperforming Party uses reasonable efforts to remove the condition. For purposes of this Agreement, force majeure shall include conditions beyond the control of the Parties, including without limitation, an act of God, voluntary or involuntary compliance with any regulation, law or order of any government, war, civil commotion, labor strike or lock-out, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe; *provided, however*, the payment of invoices due and owing hereunder shall not be delayed by the payor because of a force majeure affecting the payor.

**16.3 Notices.** Any notice required or permitted to be given under this Agreement shall be in writing, shall specifically refer to this Agreement and shall be deemed to have been sufficiently given for all purposes if mailed by first class certified or registered mail, postage prepaid, express delivery

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service or personally delivered, or if sent by facsimile, electronic transmission confirmed. Unless otherwise specified in writing, the mailing addresses of the Parties shall be as described below.

For Gilead: Gilead Sciences, Inc.  
333 Lakeside Drive,  
Foster City, CA 94404  
Attn: Vice-President of Corporate Development  
Fax: (650) 522-5488  
cc: General Counsel  
Fax: (650) 522-5537

With a Copy to: Cooley Godward LLP  
Five Palo Alto Square  
3000 El Camino Real  
Palo Alto, CA 94306  
Fax: (650) 849-7400  
Attention: Robert L. Jones, Esq.

For Cubist: Cubist Pharmaceuticals, Inc.  
24 Emily Street  
Cambridge, Massachusetts 02139  
Attention: Head of Corporate Development and Licensing  
Fax: (617) 234-5592

With a Copy to: Bingham Dana LLP  
150 Federal Street  
Boston, Massachusetts 02492  
Attention: Julio E. Vega, Esq.  
Fax: (617) 951-8736

**16.4 Maintenance of Records.** Each Party shall keep and maintain all records required by law or regulation with respect to Licensed Products and shall make copies of such records available to the other Party upon request.

**16.5 No Strict Construction.** This Agreement has been prepared jointly and shall not be strictly construed against either Party.

**16.6 Assignment.** Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other, except that a Party may make such an assignment without the other Party's consent to Affiliates or to a successor to substantially all of the business of such Party, whether in a merger, sale of stock, sale of assets or other transaction, and except to the extent provided in Section 10.06 of the Lilly License. Any permitted successor or assignee of rights and/or obligations hereunder shall, in a writing to the other Party, expressly assume performance of such rights and/or obligations. The Cubist Technology and the Gilead Project Technology shall exclude any intellectual property held or developed by a permitted successor of the relevant Party not in connection with Daptomycin Products. Any permitted assignment shall be binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this Section 16.6 shall be null and void and of no legal effect.

**16.7 Performance by Affiliates.** Each of Cubist and Gilead acknowledge that obligations under this Agreement may be performed by Affiliates of Cubist and Gilead. Each of Cubist and Gilead guarantee performance of this Agreement by its Affiliates. Wherever in this Agreement the Parties delegate responsibility to Affiliates or local operating entities, the Parties agree that such entities may not make

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decisions inconsistent with this Agreement, amend the terms of this Agreement or act contrary to its terms in any way.

**16.8 Counterparts.** This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

**16.9 Further Actions.** Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

**16.10 Severability.** If any one or more of the provisions of this Agreement is held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

**16.11 Headings.** The headings for each article and section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular article or section.

**16.12 No Waiver.** Any delay in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, except with respect to an express written and signed waiver relating to a particular matter for a particular period of time.

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**IN WITNESS WHEREOF,** the Parties have executed this Agreement in duplicate originals by their proper officers as of the Effective Date.

**CUBIST PHARMACEUTICALS, INC.**

**GILEAD SCIENCES, INC.**

By: /s/ S. M. Rocklage

By: /s/ John C. Martin

Date: January 6, 2001

Date: January 6, 2001

**EXHIBIT A**

## CUBIST CLINICAL TRIALS

Core Trials	Protocol Number and Trial Phase	Country(ies) in which conducted	Primary Endpoint
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
Other Trials			
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]

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## EXHIBIT B

## CUBIST MARKS

[illegible]

[\*]  
[\*]  
[\*]  
[\*]  
[\*]

[\*]      [\*]      [\*]  
[\*]      [\*]      [\*]  
[\*]      [\*]      [\*]  
[\*]      [\*]      [\*]  
[\*]      [\*]      [\*]

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**EXHIBIT C**

**PRIMARY DAPTOMYCIN MOLECULE**

[\*]

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**EXHIBIT D**

**GILEAD MARKS**

[\*]

D-1

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**EXHIBIT E**

**COUNTRIES OF THE GILEAD TERRITORY**

[\*]

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**EXHIBIT F**

**COUNTRIES OF THE ROFR TERRITORY**

[\*]

F-1

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**EXHIBIT G**

**SUPPLY AGREEMENT  
SUMMARY OF TERMS**

[\*]

(4 pages of continuous text omitted here)

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**EXHIBIT H**

**JOINT PRESS RELEASE**



[CUBIST PHARMACEUTICALS LOGO]

**Contacts:**

Cubist Pharmaceuticals, Inc.

Jennifer LaVin

Senior Director, Corporate Communications  
(617) 576-4258

jlavin@cubist.com

Noonan/Russo Communications

Renee Connolly, Media

(212) 696-4455 ext. 227

renee@noonanrusso.com

Gilead Sciences, Inc.

Susan Hubbard, Investors

(650) 522-5715

Amy Flood, Media  
(650) 522-5643

**CUBIST PHARMACEUTICALS AND GILEAD SCIENCES ANNOUNCE  
EUROPEAN COMMERCIALIZATION AGREEMENT FOR  
INVESTIGATIONAL ANTIBACTERIAL AGENT CIDECIN™**

**Cambridge, MA and Foster City, CA, January 7, 2001**—Cubist Pharmaceuticals, Inc. (Nasdaq: CBST) and Gilead Sciences, Inc. (Nasdaq: GILD) today jointly announced the signing of a licensing agreement for the exclusive rights to commercialize Cubist's investigational antibacterial drug Cidecin™ (daptomycin for injection) and an oral formulation of daptomycin in 16 European countries following regulatory approval.

Gilead has agreed to pay Cubist an up-front licensing fee of \$13 million, and Cubist is entitled to receive additional cash payments of up to \$31 million upon achievement of certain clinical and regulatory milestones. Gilead will also pay Cubist a fixed royalty on net sales. Cubist will continue to be responsible for worldwide clinical development of Cidecin, while Gilead will be responsible for any regulatory filings in the covered territories. Gilead's sales force will market the products in Europe. Cubist will provide European Medical Science Liaisons (MSLs) who will support the product by providing medical education services to infectious disease specialists and other international opinion leaders.

"We believe Gilead to be the ideal European marketing partner for Cubist," said Scott M. Rocklage, Ph.D., Chairman, President and CEO of Cubist. "With its international sales force, Gilead is already calling on the identical target market for Cidecin. We believe this will be a synergistic relationship given that Gilead's product AmBisome and Cidecin are complementary in therapeutic focus, allowing for targeted marketing efforts to the same physician audiences. In addition, Gilead's

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proven track record of sales performance and experience with European regulatory authorities provides us with confidence in the company's ability to successfully market Cidecin to the European hospital community."

Daptomycin is the first in a new class of investigational drugs called lipopeptides. Cubist is currently developing IV and oral formulations of daptomycin to treat serious bacterial infections. *In vitro* data show daptomycin has the ability to rapidly kill virtually all Gram-positive bacteria, including those resistant to current therapies. Cubist has multiple ongoing Phase III clinical trials of Cidecin, the IV formulation, to evaluate the efficacy and safety in the treatment of complicated skin and soft tissue infection (cSST), community-acquired pneumonia (CAP) and complicated urinary tract infection (cUTI). Phase II trial are also ongoing to investigate the treatment of bacteremia (BAC) and resistant infections (RRC). Cubist recently announced that it had completed enrollment in its international Phase III cSST trial and expects to announce clinical results during the second quarter of 2001. An oral version of daptomycin is currently in pre-clinical development.

"Cidecin is an important addition to our portfolio of products for unmet medical needs," said John C. Martin, Ph.D., President and Chief Executive Officer of Gilead. "We believe Cidecin possesses a strong worldwide market potential and are pleased that Cubist has chosen Gilead as its European commercialization partner."

Gilead markets AmBisome® (liposomal amphotericin B) for injection in 42 countries worldwide for the treatment of life-threatening systemic fungal infections. Since the product's European introduction in 1990, Gilead has successfully grown the market for AmBisome throughout the world. With total 1999 sales of \$173 million, AmBisome is the second largest-selling injectable antifungal product worldwide. Much of the product's growth can be attributed to Gilead's efforts to increase the number of territories in which AmBisome is marketed, expand the product label through additional regulatory filings and inclusion of head-to-head competitive data, and maintain its well established marketing relationships.

Cubist Pharmaceuticals is focused on becoming a global leader in the research, development and commercialization of novel antimicrobial drugs to combat serious and life-threatening bacterial and fungal infections. Cubist is evaluating the safety and efficacy of Cidecin™ (daptomycin for injection) in the EDGE™ (Evaluation of Daptomycin against Gram-positive Entities) clinical trial program and is engaged in multiple, strategic partnerships, including Novartis Pharma AG, Merck & Co and Schering-Plough for the discovery and development of novel anti-infectives. Cubist recently completed the acquisition of TerraGen Discovery Inc., a private, natural products discovery company with operations in Vancouver, BC, Canada and Slough, UK.

Gilead Sciences, headquartered in Foster City, CA, is an independent biopharmaceutical company that seeks to provide accelerated solutions

for patients and the people who care for them. The Company discovers, develops, manufactures and commercializes proprietary therapeutics for challenging infectious diseases (viral, fungal and bacterial infections) and cancer. Gilead maintains research, development or manufacturing facilities in Foster City, CA, Boulder, CO, San Dimas, CA, and Cambridge, UK, and sales and marketing organizations in the United States, Europe and Australia.

Statements contained herein that are not historical fact may be forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, that are subject to a variety of risks and uncertainties. There are a number of important factors that could cause actual results to differ materially from those projected or suggested in any forward-looking statements made by Cubist or Gilead. These factors include, but are not limited to: (i) the ability of Cubist to successfully complete product research and development, including pre-clinical and clinical studies and commercialization; (ii) the ability of Cubist and Gilead to obtain required governmental approvals; (iii) the ability of Cubist to attract and/or maintain manufacturing, sales, distribution and marketing partners; (iv) the ability of Cubist to develop and commercialize its

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products before its competitors; and (v) the ability of Gilead to grow or maintain the market for AmBisome particularly in light of the anticipated introduction of competitive products. Additional factors that would cause actual results to differ materially from those projected or suggested in any forward-looking statements are contained in each company's filings with the Securities and Exchange Commission, including those factors discussed under the caption "Risk Factors" for Cubist on Annual Report on Form 10-K/A (file No. 000-21379) filed on April 3, 2000 and for Gilead on Form 10-K for the year ended December 31, 1999.

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For additional information, visit either of the companies' web sites at  
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