

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON D.C. 20549  
FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 1998

OR

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

Commission file number 0-12477

AMGEN INC.  
(Exact name of registrant as specified in its charter)

Delaware	95-3540776
-----	-----
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

One Amgen Center Drive, Thousand Oaks, California	91320-1789
-----	-----
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (805) 447-1000

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

As of March 31, 1998, the registrant had 254,070,280 shares of Common Stock, \$.0001 par value, outstanding.

AMGEN INC.

INDEX

Page No.

PART I FINANCIAL INFORMATION

Item 1. Financial Statements.....3

Condensed Consolidated Statements of  
Operations - three months  
ended March 31, 1998 and 1997.....4

Condensed Consolidated Balance Sheets -  
March 31, 1998 and December 31, 1997.....5

Condensed Consolidated Statements of  
Cash Flows - three months  
ended March 31, 1998 and 1997.....6 - 7

Notes to Condensed Consolidated Financial  
Statements.....8

Item 2. Management's Discussion and Analysis  
of Financial Condition and Results of  
Operations.....15

PART II OTHER INFORMATION

Item 1. Legal Proceedings.....23  
Item 5. Other Information.....24  
Item 6. Exhibits and Reports on Form 8-K.....24  
Signatures .....25  
Index to Exhibits .....26

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

The information in this report for the three months ended March 31, 1998 and 1997 is unaudited but includes all adjustments (consisting only of normal recurring accruals) which Amgen Inc. ("Amgen" or the "Company") considers necessary for a fair presentation of the results of operations for those periods.

The condensed consolidated financial statements should be read in conjunction with the Company's financial statements and the notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 1997.

Interim results are not necessarily indicative of results for the full fiscal year.

## AMGEN INC.

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In millions, except per share data)  
(Unaudited)

	Three Months Ended March 31,	
	1998	1997
	-----	-----
Revenues:		
Product sales .....	\$566.8	\$536.0
Corporate partner revenues .....	22.6	27.4
Royalty income .....	16.0	12.1
	-----	-----
Total revenues .....	605.4	575.5
	-----	-----
Operating expenses:		
Cost of sales .....	79.0	72.0
Research and development .....	152.5	147.7
Marketing and selling .....	66.8	68.1
General and administrative .....	46.3	44.4
Loss of affiliates, net .....	6.2	8.5
	-----	-----
Total operating expenses .....	350.8	340.7
	-----	-----
Operating income .....	254.6	234.8
	-----	-----
Other income (expense):		
Interest and other income .....	15.2	15.9
Interest expense, net .....	(2.2)	(0.3)
	-----	-----
Total other income (expense) .....	13.0	15.6
	-----	-----
Income before income taxes .....	267.6	250.4
Provision for income taxes .....	80.3	70.1
	-----	-----
Net income .....	\$187.3	\$180.3
	=====	=====
Earnings per share:		
Basic .....	\$0.73	\$0.68
Diluted .....	\$0.71	\$0.65
Shares used in calculation of earnings per share:		
Basic .....	256.2	265.2
Diluted .....	264.1	278.1

See accompanying notes.

AMGEN INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(In millions, except per share data)  
(Unaudited)

	March 31, 1998	December 31, 1997
	-----	-----
ASSETS		
Current assets:		
Cash and cash equivalents .....	\$ 104.6	\$ 239.1
Marketable securities .....	775.5	787.4
Trade receivables, net .....	289.2	269.0
Inventories .....	118.1	109.2
Other current assets .....	124.3	138.8
	-----	-----
Total current assets .....	1,411.7	1,543.5
Property, plant and equipment at cost, net	1,277.5	1,186.2
Investments in affiliated companies.....	119.6	116.9
Other assets.....	272.7	263.6
	-----	-----
	\$3,081.5	\$3,110.2
	=====	=====
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable .....	\$ 114.8	\$ 103.9
Accrued liabilities .....	674.1	608.0
Current portion of long-term debt .....	36.0	30.0
	-----	-----
Total current liabilities .....	824.9	741.9
Long-term debt.....	223.0	229.0
Put warrants.....	3.7	-
Contingencies		
Stockholders' equity:		
Preferred stock; \$.0001 par value; 5 shares authorized; none issued or outstanding .....	-	-
Common stock and additional paid-in capital; \$.0001 par value; 750 shares authorized; outstanding - 254.1 shares in 1998 and 258.3 shares in 1997 .....	1,240.9	1,196.1
Retained earnings .....	789.0	943.2
	-----	-----
Total stockholders' equity .....	2,029.9	2,139.3
	-----	-----
	\$3,081.5	\$3,110.2
	=====	=====

See accompanying notes.

AMGEN INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In millions)  
(Unaudited)

	Three Months Ended	
	March 31,	
	1998	1997
	-----	-----
Cash flows from operating activities:		
Net income .....	\$187.3	\$180.3
Depreciation and amortization .....	36.1	36.4
Loss of affiliates, net .....	6.2	8.5
Cash provided by (used in):		
Trade receivables, net .....	(20.2)	18.9
Inventories .....	(8.9)	(3.0)
Other current assets .....	15.3	16.8
Accounts payable .....	10.9	1.6
Accrued liabilities .....	66.1	(27.4)
	-----	-----
Net cash provided by operating activities .....	292.8	232.1
	-----	-----
Cash flows from investing activities:		
Purchases of property, plant and equipment .....	(127.4)	(102.5)
Proceeds from maturities of marketable securities .....	-	149.3
Proceeds from sales of marketable securities .....	180.1	184.6
Purchases of marketable securities .....	(169.0)	(205.7)
Increase in investments in affiliated companies .....	(0.4)	-
Increase in other assets .....	(12.3)	(3.4)
	-----	-----
Net cash (used in) provided by investing activities .....	(129.0)	22.3
	-----	-----

See accompanying notes.

(Continued on next page)

AMGEN INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Continued)

(In millions)  
(Unaudited)

	Three Months Ended	
	March 31,	
	1998	1997
	-----	-----
Cash flows from financing activities:		
Repayment of long-term debt .....	\$ -	\$(78.2)
Net proceeds from issuance of common stock upon the exercise of stock options .....	34.4	24.3
Tax benefits related to stock options ....	13.4	8.6
Repurchases of common stock .....	(337.8)	(101.7)
Other .....	(8.3)	(11.9)
	-----	-----
Net cash used in financing activities ..	(298.3)	(158.9)
	-----	-----
(Decrease) increase in cash and cash equivalents .....	(134.5)	95.5
Cash and cash equivalents at beginning of period .....	239.1	169.3
	-----	-----
Cash and cash equivalents at end of period	\$104.6	\$264.8
	=====	=====

See accompanying notes.

AMGEN INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 1998

1. Summary of significant accounting policies

Business

Amgen Inc. ("Amgen" or the "Company") is a global biotechnology company that discovers, develops, manufactures and markets human therapeutics based on advances in cellular and molecular biology.

Principles of consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries as well as affiliated companies for which the Company has a controlling financial interest and exercises control over their operations ("majority controlled affiliates"). All material intercompany transactions and balances have been eliminated in consolidation. Investments in affiliated companies which are 50% or less owned and where the Company exercises significant influence over operations are accounted for using the equity method. All other equity investments are accounted for under the cost method. The caption "Loss of affiliates, net" includes Amgen's equity in the operating results of affiliated companies and the minority interest others hold in the operating results of Amgen's majority controlled affiliates.

Inventories

Inventories are stated at the lower of cost or market. Cost is determined in a manner which approximates the first-in, first-out (FIFO) method. Inventories are shown net of applicable reserves and allowances. Inventories consist of the following (in millions):

	March 31, 1998	December 31, 1997
Raw materials .....	\$ 17.5	\$ 18.7
Work in process ....	56.3	53.6
Finished goods .....	44.3	36.9
	-----	-----
	\$118.1	\$109.2
	=====	=====



## Product sales

Product sales consist of three products, EPOGEN(R) (Epoetin alfa), NEUPOGEN(R) (Filgrastim) and INFERGEN(R) (Interferon alfacon-1).

The Company has the exclusive right to sell Epoetin alfa for dialysis, diagnostics and all non-human uses in the United States. The Company sells Epoetin alfa under the brand name EPOGEN(R). Amgen has granted to Ortho Pharmaceutical Corporation, a subsidiary of Johnson & Johnson ("Johnson & Johnson"), a license relating to Epoetin alfa for sales in the United States for all human uses except dialysis and diagnostics. Pursuant to this license, Amgen does not recognize product sales it makes into the exclusive market of Johnson & Johnson and does recognize the product sales made by Johnson & Johnson into Amgen's exclusive market. Sales in Amgen's exclusive market and adjustments thereto are derived from Company shipments and from third-party data on shipments to end users and their usage (see Note 4, "Contingencies - Johnson & Johnson arbitrations").

## Foreign currency transactions

The Company has a program to manage foreign currency risk. As part of this program, it has purchased foreign currency option and forward contracts to hedge against possible reductions in values of certain anticipated foreign currency cash flows generally over the next 12 months, primarily resulting from its sales in Europe. At March 31, 1998, the Company had option and forward contracts to exchange foreign currencies for U.S. dollars of \$49.9 million and \$18.2 million, respectively, all having maturities of nine months or less. The option contracts, which have only nominal intrinsic value at the time of purchase, are designated and effective as hedges of anticipated foreign currency transactions for financial reporting purposes and accordingly, the net gains on such contracts are deferred and recognized in the same period as the hedged transactions. The forward contracts do not qualify as hedges for financial reporting purposes and accordingly, are marked-to-market. Net gains on option contracts (including option contracts for hedged transactions whose occurrence are no longer probable) and changes in market values of forward contracts are reflected in "Interest and other income". The deferred premiums on option contracts and fair values of forward contracts are included in "Other current assets".

The Company has additional foreign currency forward contracts to hedge exposures to foreign currency fluctuations of certain receivables and payables denominated in foreign currencies. At March 31, 1998, the Company had forward contracts to exchange foreign currencies, primarily Swiss francs, for U.S. dollars of \$22.4 million, all having maturities of two months or less. These contracts are designated and effective as hedges and accordingly, gains and losses on these forward contracts are recognized in the same period the offsetting gains and losses of hedged assets and liabilities are realized and recognized. The fair values of the forward contracts are included in the corresponding captions of the hedged assets and liabilities. Gains and losses on forward

contracts, to the extent they differ in amount from the hedged receivables and payables, are included in "Interest and other income".

#### Income taxes

Income taxes are accounted for in accordance with Statement of Financial Accounting Standards ("SFAS") No. 109 (Note 3).

#### Stock option and purchase plans

The Company's stock options and purchase plans are accounted for under Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees".

#### Earnings per share

Basic earnings per share is based upon the weighted-average number of common shares outstanding. Diluted earnings per share is based upon the weighted-average number of common shares and dilutive potential common shares outstanding. Potential common shares are outstanding options under the Company's stock option plans which are included under the treasury stock method.

The following table sets forth the computation for basic and diluted earnings per share (in millions, except per share information):

	Three Months Ended	
	March 31,	
	1998	1997
	-----	-----
Numerator for basic and diluted earnings per share - net income .	\$187.3	\$180.3
	=====	=====
Denominator:		
Denominator for basic earnings per share - weighted-average shares .....	256.2	265.2
Effect of dilutive securities - employee stock options .....	7.9	12.9
	-----	-----
Denominator for diluted earnings per share - adjusted weighted-average shares .....	264.1	278.1
	=====	=====
Basic earnings per share .....	\$0.73	\$0.68
	=====	=====
Diluted earnings per share .....	\$0.71	\$0.65
	=====	=====

#### Use of estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make

estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results may differ from those estimates.

#### Basis of presentation

The financial information for the three months ended March 31, 1998 and 1997 is unaudited but includes all adjustments (consisting only of normal recurring accruals) which the Company considers necessary for a fair presentation of the results of operations for these periods. Interim results are not necessarily indicative of results for the full fiscal year.

#### Reclassification

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

## 2. Debt

As of March 31, 1998, the Company had \$259 million of unsecured debt securities outstanding. Long-term debt consists of the following (in millions):

	March 31, 1998	December 31, 1997
Debt securities .....	\$259.0	\$259.0
Less current portion .....	(36.0)	(30.0)
	-----	-----
	\$223.0	\$229.0
	=====	=====

The Company has established a \$500 million debt shelf registration statement under which the Company has issued \$100 million of debt securities (the "Notes") and established a \$400 million medium term note program. The Company may offer and issue medium term notes from time to time with terms to be determined by market conditions. The Notes bear interest at a fixed rate of 6.5% and mature in 10 years. The Company's other outstanding debt includes \$100 million of debt securities that bear interest at a fixed rate of 8.1% and mature in 2097 and \$59 million of notes that bear interest at fixed rates averaging 5.8% and have remaining maturities of less than six years.

The Company also has a commercial paper program which provides for unsecured short-term borrowings up to an aggregate of \$200 million. No commercial paper was outstanding under this program at March 31, 1998. In April 1998, the Company replaced this program with a new commercial paper program which provides for the same amount of aggregate short-term borrowings and issued commercial paper with a face amount of \$100 million. These borrowings had maturities

of less than three months and had effective interest rates averaging 5.6%.

As of March 31, 1998, \$150 million was available under the Company's line of credit for borrowing.

### 3. Income taxes

The provision for income taxes consists of the following (in millions):

	Three Months Ended	
	March 31,	
	1998	1997
	-----	-----
Federal(including U.S. possessions) .	\$74.9	\$65.1
State .....	5.4	5.0
	-----	-----
	\$80.3	\$70.1
	=====	=====

The increase in the effective tax rate in the current year is the result of a provision in the federal tax law which caps tax benefits associated with the Company's Puerto Rico operations at the 1995 income level.

### 4. Contingencies

Johnson & Johnson arbitrations

Epoetin alfa

In September 1985, the Company granted Johnson & Johnson's affiliate, Ortho Pharmaceutical Corporation, a license relating to certain patented technology and know-how of the Company to sell a genetically engineered form of recombinant human erythropoietin, called Epoetin alfa, throughout the United States for all human uses except dialysis and diagnostics. Johnson & Johnson sells Epoetin alfa under the brand name PROCRI(R). A number of disputes have arisen between Amgen and Johnson & Johnson as to their respective rights and obligations under the various agreements between them, including the agreement granting the license (the "License Agreement").

A dispute between Amgen and Johnson & Johnson that is the subject of a current arbitration proceeding relates to the audit methodology currently employed by the Company for Epoetin alfa sales. The Company and Johnson & Johnson are required to compensate each other for Epoetin alfa sales which either party makes into the other party's exclusive market, sometimes referred to as "spillover". Spillover occurs when, for example, a hospital or other purchaser buys one brand for use in both dialysis and non-dialysis indications. The Company has established and is employing an audit methodology to assign the

proceeds of sales of EPOGEN(R) and PROCRIT in the Company's and Johnson & Johnson's respective exclusive markets. On September 12, 1997, the arbitrator in this matter (the "Arbitrator") issued an opinion adopting the Company's audit methodology. For the free standing dialysis center segment of the Epoetin alfa market, which accounts for about two-thirds of the Company's EPOGEN sales, the Arbitrator ruled that the Company's audit accurately determined that all Epoetin alfa sales to free standing dialysis centers are made for dialysis. For the other segments of the Epoetin alfa market, the Arbitrator ruled that the detailed methodology used by Amgen accurately measured and allocated Epoetin alfa sales for all but the Hospital and Home Health Care segments, for which he ordered certain adjustments to the results of the audit for the 1991-94 time period. The Arbitrator also ruled that no payments are due for the 1989-90 period. Subject to further guidance from the Arbitrator to clarify his opinion, the Company estimated that the effect of the opinion would be a net spillover payment to Johnson & Johnson which, after benefit of income tax effects, was \$78 million for the 1991-94 period and interest in the amount of \$18 million after tax. As a result of the opinion, the Company took a charge of \$0.35 per share in the third quarter of 1997 for the spillover payment and interest.

A hearing before the Arbitrator was held on October 27, 1997 to clarify, among other issues, the calculation for the amount of the spillover payment due to Johnson & Johnson for the 1991-94 time period. As a result of that hearing, the Company will pay an additional amount to Johnson & Johnson for the 1991-94 period which is covered by amounts previously provided for by the Company. An additional hearing relating to the Company's entitlement to attorneys' fees and costs and audit costs as well as the calculation of spillover payments, if any, that may be due to the Company or Johnson & Johnson for 1995, 1996 and 1997 was held on January 7, 1998. On April 14, 1998, the Arbitrator issued his final order which confirmed that the Company was the successful party in the arbitration and, as a result, Johnson & Johnson has been ordered to pay to the Company all costs and expenses, including reasonable attorney's fees, that the Company incurred in the arbitration as well as one-half of the audit costs. The Company currently estimates that it will submit a bill for such costs incurred over an eight year period of approximately \$100 million; however, the actual amount of the Company's recovery will be determined by the Arbitrator. The Order also confirms that for the period 1995 forward, the estimates of usage of Epoetin alfa in the Hospital segment of the Company's audit methodology shall be applied without adjustment, subject to the right of either party to challenge the Hospital survey results for 1995 and certain subsequent years. The Company does not expect that any such challenges, if made, would result in any payments to Johnson & Johnson which would be material to the Company.

Both parties have filed motions seeking reconsideration of certain aspects of the Arbitrator's final order. Due to remaining uncertainties, the Company has not taken any benefit for the possible recovery of attorneys' fees and costs or audit costs and has retained spillover reserves. If, as a result of these further arbitration rulings or challenges, any adjustments to the results of the Company's

audit yield results that are different from the results of the audit currently employed by the Company, the Company may be required to pay additional compensation to Johnson & Johnson for sales during 1995, 1996 and 1997, or Johnson & Johnson may be required to pay compensation to the Company for such prior period sales.

The Company has filed a demand in the arbitration to terminate Johnson & Johnson's rights under the License Agreement and to recover damages for breach of the License Agreement. Johnson & Johnson disputes the Arbitrator's jurisdiction to decide the Company's demand. The Company has requested a hearing before the Arbitrator on the Company's termination demand. No trial date on this matter has been set.

On October 2, 1995, Johnson & Johnson filed a demand for a separate arbitration proceeding against the Company before the American Arbitration Association ("AAA") in Chicago, Illinois. Johnson & Johnson alleges in this demand that the Company has breached the License Agreement. The demand also includes allegations of various antitrust violations. In this demand, Johnson & Johnson seeks an injunction, declaratory relief, unspecified compensatory damages, punitive damages and costs. On October 27, 1995, the Company filed a complaint in the Circuit Court of Cook County, Illinois seeking an order compelling Johnson & Johnson to arbitrate the Company's claim for termination before the Arbitrator as well as all related counterclaims asserted in Johnson & Johnson's October 2, 1995 AAA arbitration demand. The Company is unable to predict at this time the outcome of the demand for termination or when it will be resolved. The Company has filed a motion to stay the AAA arbitration pending the outcome of the existing arbitration proceedings before the Arbitrator discussed above. The Company has also filed an answer and counterclaim denying that AAA has jurisdiction to hear or decide the claims stated in the demand, denying the allegations in the demand and counter claiming for certain unpaid invoices.

#### NESP

On June 5, 1997, Johnson & Johnson filed a demand for arbitration against Kirin-Amgen, Inc. ("Kirin-Amgen"), an affiliate of the Company, before the AAA. The demand alleges that Amgen's novel erythropoiesis stimulating protein ("NESP") is covered by a license granted by Kirin-Amgen to Johnson & Johnson in 1985 for the development, manufacture and sale of Epoetin alfa in certain territories outside the United States, Japan and China (the "K-A License"). In 1996 Kirin-Amgen acquired exclusive worldwide rights in NESP from Amgen. Kirin-Amgen, in turn, transferred certain rights in NESP to Kirin and certain rights to Amgen. Johnson & Johnson alleges that the K-A License effectively grants Johnson & Johnson the same right to develop, manufacture and sell NESP as granted under the K-A License with respect to Epoetin alfa. Kirin-Amgen filed its answer to Johnson & Johnson's complaint on January 12, 1998, denying that Johnson & Johnson has rights to NESP. Kirin-Amgen also asserted a counterclaim for the recovery of certain royalty payments which Kirin-Amgen asserts were improperly withheld. These same disputes exist between the Company and Johnson & Johnson under the License Agreement

and the parties have agreed that the resolution of these issues in this arbitration will be binding upon them with respect to the License Agreement. The trial in this matter is scheduled to commence in July 1998.

While it is not possible to predict accurately or determine the eventual outcome of the above described legal matters or various other legal proceedings (including patent disputes) involving Amgen, the Company believes that the outcome of these proceedings will not have a material adverse effect on its annual financial statements.

#### 5. Stockholders' equity

During the three months ended March 31, 1998, the Company repurchased 6.2 million shares of its common stock at a total cost of \$337.8 million under its common stock repurchase program. In October 1997, the Board of Directors authorized the Company to repurchase up to an additional \$1 billion of common stock through December 31, 1998. At March 31, 1998, \$374.4 million of this authorization remained. Stock repurchased under the program is retired.

#### 6. Comprehensive income

As of January 1, 1998, the Company adopted Statement of Financial Accounting Standards ("SFAS") No. 130, "Reporting Comprehensive Income". SFAS No. 130 establishes new rules for the reporting and display of comprehensive income and its components. SFAS No. 130 requires unrealized gains and losses on the Company's available-for-sale securities and foreign currency translation adjustments to be included in other comprehensive income. During the three months ended March 31, 1998 and 1997, total comprehensive income was \$184.3 million and \$178.3 million, respectively.

### Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

#### Liquidity and Capital Resources

Cash provided by operating activities has been and is expected to continue to be the Company's primary source of funds. During the three months ended March 31, 1998, operations provided \$292.8 million of cash compared with \$232.1 million during the same period last year. The Company had cash, cash equivalents and marketable securities of \$880.1 million at March 31, 1998, compared with \$1,026.5 million at December 31, 1997.

Capital expenditures totaled \$127.4 million for the three months ended March 31, 1998, compared with \$102.5 million for the same period a year ago. The Company anticipates spending approximately \$400 million to \$500 million in 1998 on capital projects and equipment to expand the Company's global operations. Thereafter, over the next few

years, the Company anticipates that capital expenditures will average in excess of \$400 million per year.

The Company receives cash from the exercise of employee stock options. During the three months ended March 31, 1998, stock options and their related tax benefits provided \$47.8 million of cash compared with \$32.9 million for the same period last year. Proceeds from the exercise of stock options and their related tax benefits will vary from period to period based upon, among other factors, fluctuations in the market value of the Company's stock relative to the exercise price of such options.

The Company has a stock repurchase program primarily to offset the dilutive effect of its employee stock option and stock purchase plans. During the three months ended March 31, 1998, the Company purchased 6.2 million shares of its common stock at a cost of \$337.8 million compared with 1.7 million shares purchased at a cost of \$101.7 million during the same period last year. In October 1997, the Board of Directors authorized the Company to repurchase up to an additional \$1 billion of common stock through December 31, 1998. At March 31, 1998, \$374.4 million of this authorization remained.

To provide for financial flexibility and increased liquidity, the Company has established several sources of debt financing. The Company established a \$500 million debt shelf registration statement and in December 1997, pursuant to such registration statement, the Company issued \$100 million of debt securities that bear interest at a fixed rate of 6.5% and mature in 10 years (the "Notes"). As of March 31, 1998, the Company had \$259 million of unsecured debt securities outstanding. This amount includes the Notes, \$59 million of debt securities that bear interest at fixed rates averaging 5.8% and have remaining maturities of less than six years and \$100 million of debt securities that bear interest at a fixed rate of 8.1% and mature in 2097. The Company also has a commercial paper program which provides for short-term borrowings up to an aggregate face amount of \$200 million. In April 1998, the Company replaced this program with a new commercial paper program which provides for the same amount of aggregate short-term borrowings and issued commercial paper with a face amount of \$100 million. These borrowings had maturities of less than three months and had effective interest rates averaging 5.6%. The Company has a \$150 million revolving line of credit for borrowings and to support the commercial paper program. As of March 31, 1998, no amounts were outstanding under the line of credit.

The primary objectives for the Company's investment portfolio are liquidity and safety of principal. Investments are made to achieve the highest rate of return to the Company, consistent with these two objectives. The Company's investment policy limits investments to certain types of instruments issued by institutions with investment grade credit ratings and places restrictions on maturities and concentration by type and issuer. The Company invests its excess cash in securities with varying maturities to meet projected cash needs.



The Company believes that existing funds, cash generated from operations and existing sources of debt financing are adequate to satisfy its working capital and capital expenditure requirements for the foreseeable future, as well as to support its stock repurchase program. However, the Company may raise additional capital from time to time.

## Results of Operations

### Product sales

Product sales were \$566.8 million during the three months ended March 31, 1998, an increase of \$30.8 million or 6% over the same period last year.

#### EPOGEN(R) (Epoetin alfa)

EPOGEN(R) sales were \$304.4 million for the three months ended March 31, 1998, an increase of \$12.8 million or 4% over the same period last year. This increase was primarily due to growth in the U.S. dialysis patient population and certain dialysis providers using a different method of anemia measurement, hemoglobin, instead of hematocrit. EPOGEN(R) sales continued to be adversely affected by reimbursement changes (the "HCFA Policy Changes") implemented on September 1, 1997 by the Health Care Financing Administration ("HCFA"). Prior to the HCFA Policy Changes, fiscal intermediaries under contract with HCFA were authorized to pay reimbursement claims for patients whose hematocrits exceeded 36 percent, the top of the suggested target hematocrit range in the Company's labeling, if deemed medically justified. Under the HCFA Policy Changes, medical justification was not accepted for payment of claims of hematocrits that exceeded 36 percent and, if the current month's hematocrit were greater than 36 percent and the patient's hematocrit exceeded 36.5 percent on an historical 90-day "rolling average" basis, reimbursement for the current month would be denied in full. Beginning in the second quarter of 1997, the Company has experienced a decline in the growth rate of EPOGEN(R) sales as dialysis providers attempted to lower hematocrits by lowering or withholding EPOGEN(R) doses in order to avoid or minimize claim denials under the HCFA Policy Changes. However, in March 1998, HCFA announced the easing of restrictions on reimbursement that had been instituted under the HCFA Policy Changes.

In March 1998, HCFA issued two revisions (the "HCFA Revisions") to the HCFA Policy Changes in a program memorandum. The first revision provides that, for a month in which the three month "rolling average" hematocrit exceeds 36.5 percent, HCFA will pay the lower of 100 percent of the actual dosage billed for that month, or 80 percent of the prior month's allowable EPOGEN(R) dosage. The second revision re-establishes authorization to make payment for EPOGEN(R) when a patient's hematocrit exceeds 36 percent when accompanied by documentation establishing medical necessity. Dialysis providers are currently in the process of understanding the HCFA Revisions, revising their protocols and discerning how fiscal intermediaries will implement the HCFA Revisions. The Company believes that fiscal intermediaries are likely to implement the HCFA Revisions at variable rates which may have an impact on dialysis providers' practice pattern changes and the rate of change. The Company believes that, compared with the HCFA Policy Changes, the HCFA Revisions may result in fewer doses being withheld and that physicians generally are not likely to reduce doses by more than 20 percent from the previous

month's level. Accordingly, it is difficult to predict what effect the HCFA Revisions will have on EPOGEN(R) sales.

#### NEUPOGEN(R) (Filgrastim)

Worldwide NEUPOGEN(R) sales were \$261.2 million for the three months ended March 31, 1998, an increase of \$16.8 million or 7% over the same period last year. This increase was primarily due to the impact of wholesaler stocking, and to a lesser extent, an increase in underlying demand, which includes price changes. Unfavorable foreign currency effects and European Union ("EU") government initiatives to lower health care expenditures reduced growth in reported sales. In addition, the Company believes that the use of protease inhibitors as a treatment for AIDS continues to reduce sales of NEUPOGEN(R) for off-label use as a supportive therapy in this setting. NEUPOGEN(R) is not approved or promoted for such use, except in Australia and Canada.

Cost containment pressures in the U.S. health care marketplace have contributed to the slowing of growth in domestic NEUPOGEN(R) usage over the past several quarters. These pressures are expected to continue to influence growth for the foreseeable future. In addition, quarterly NEUPOGEN(R) sales volume is influenced by a number of factors including underlying demand and wholesaler inventory management practices.

The growth of the colony stimulating factor ("CSF") market in the EU in which NEUPOGEN(R) competes has slowed, principally due to EU government pressures on physician prescribing practices in response to ongoing government initiatives to reduce health care expenditures. Additionally, the Company faces competition from another granulocyte CSF product. Amgen's CSF market share in the EU has remained relatively constant over the last several quarters, however, the Company does not expect the competitive intensity to subside in the near future.

#### Other product sales

INFERGEN(R) (Interferon alfacon-1) sales were \$1.2 million for the three months ended March 31, 1998. INFERGEN(R) was launched in October 1997 for the treatment of chronic hepatitis C virus infection. There are existing treatments for this infection against which INFERGEN(R) competes, and the Company cannot predict the extent to which it will penetrate this market.

#### Cost of sales

Cost of sales as a percentage of product sales was 13.9% and 13.4% for the three months ended March 31, 1998 and 1997, respectively. In 1998, cost of sales as a percentage of product sales is expected to be slightly higher than 1997.

#### Research and development

During the three months ended March 31, 1998, research and development expenses increased \$4.8 million or 3% compared with the

same period last year. This increase is primarily due to higher clinical and preclinical expenses, including staff-related costs, necessary to support ongoing product development activities. In 1998, annual research and development expenses are expected to increase, but at a substantially lower rate than 1997. This increase is planned for internal development of product candidates, and for discovery and licensing efforts.

#### Marketing and selling/General and administrative

Marketing and selling expenses decreased \$1.3 million or 2% during the three months ended March 31, 1998 compared with the same period last year. This decrease was primarily due to lower expenses related to the Johnson & Johnson arbitration and lower European marketing expenses partially offset by higher U.S. marketing costs.

General and administrative expenses increased \$1.9 million or 4% during the three months ended March 31, 1998 compared with the same period last year. This increase is primarily due to higher staff-related expenses, partially offset by lower legal fees.

In 1998, marketing and selling expenses combined with general and administrative expenses are expected to have little growth.

#### Income taxes

The Company's effective tax rate for the three months ended March 31, 1998 was 30.0% compared with 28.0% for the same period last year. The increase in the effective tax rate in the current year is due to a provision in the federal tax law which caps tax benefits associated with the Company's Puerto Rico operations at the 1995 income level.

#### Foreign currency transactions

The Company has a program to manage certain portions of its exposure to fluctuations in foreign currency exchange rates arising from international operations. The Company generally hedges the receivables and payables with foreign currency forward contracts, which typically mature within six months. The Company uses foreign currency option and forward contracts which generally expire within 12 months to hedge certain anticipated future sales and expenses. At March 31, 1998, outstanding foreign currency option and forward contracts totaled \$49.9 million and \$40.6 million, respectively.

#### Year 2000

The Year 2000 issue results from computer programs that do not differentiate between the year 1900 and the year 2000 because they were written using two digits rather than four to define the applicable year; accordingly, computer systems that have time-sensitive calculations may not properly recognize the year 2000. The Company has conducted an initial review of its computer systems, devices, applications and manufacturing equipment (collectively, "Computer Systems") to identify those areas that could be affected by Year 2000 noncompliance. Additionally, the Company has appointed a

program manager for Year 2000 compliance and is presently assessing in detail the affected Computer Systems and is developing plans to address the required modifications. The Company presently intends to utilize internal and external resources to identify, correct or reprogram and test its Computer Systems for Year 2000 compliance. The total cost associated with Year 2000 compliance is not known at this time. The Company has not communicated with many of its suppliers, service providers, distributors, wholesalers and other entities with which it has a business relationship (collectively, "Third Party Businesses") regarding compliance with Year 2000 requirements, although the Company does intend to communicate with key Third Party Businesses. In addition, the Company has not determined the impact, if any, on its operations if Third Party Businesses fail to comply with Year 2000 requirements. While the Company has developed plans to complete modifications of its business critical Computer Systems prior to the year 2000, if modifications of such business critical Computer Systems, or Computer Systems of key Third Party Businesses are not completed in a timely manner, the Year 2000 issue could have a material adverse effect on the operations and financial position of the Company. The Company may also be affected by the failure of state, federal and private payors or reimbursers to be Year 2000 compliant if such entities are unable to make timely, proper or complete payments to sellers of the Company's products. The Company cannot predict the extent of any such impact.

#### Financial Outlook

Future NEUPOGEN(R) (Filgrastim) sales growth is dependent primarily upon further penetration of existing markets, the timing and nature of additional indications for which the product may be approved and the effects of competitive products. Although not approved or promoted for use in Amgen's domestic or foreign markets, except for Australia and Canada, the Company believes that approximately 5%-10% of its worldwide NEUPOGEN(R) sales are from off-label use as a supportive therapy to various AIDS treatments. Changes in AIDS therapies, including protease inhibitors that may be less myelosuppressive, are believed to have adversely affected and are expected to continue to adversely affect such sales. NEUPOGEN(R) usage is expected to continue to be affected by cost containment pressures on health care providers worldwide. In addition, reported NEUPOGEN(R) sales will continue to be affected by changes in foreign currency exchange rates and government budgets.

The Company expects a high single digit sales growth rate for EPOGEN(R) in 1998. Although HCFA announced revisions to its EPOGEN(R) reimbursement policy in March 1998 (see, "Results of Operations - Product sales - EPOGEN(R) (Epoetin alfa)"), the timing and magnitude of any EPOGEN(R) sales growth due to increases in dose cannot be predicted principally due to the timing and variety of dialysis providers' and fiscal intermediaries' reaction to the HCFA Revisions; however, the Company believes that increases in the U.S. dialysis patient population will continue to grow EPOGEN(R) sales in the near term and long term. Patients receiving treatment for end stage renal disease are covered primarily under medical programs

provided by the federal government. Therefore, EPOGEN(R) sales may also be affected by future changes in reimbursement rates or a change in the basis for reimbursement by the federal government. The previously disclosed report of the Office of the Inspector General has been issued, recommending a 10% reduction in the Medicare reimbursement rate for EPOGEN(R). The Company believes the recommendation would primarily affect dialysis providers and that it is difficult to predict the impact on Amgen.

INFERGEN(R) (Interferon alfacon-1) was launched in October 1997 for the treatment of chronic hepatitis C virus infection. There are existing treatments for this infection against which INFERGEN(R) competes, and the Company cannot predict the extent to which it will penetrate this market. The Company is presently engaged in certain litigation related to INFERGEN(R), as described in "Part I, Item 3. Legal Proceedings - INFERGEN(R) litigation" in the Company's Annual Report on Form 10-K for the year ended December 31, 1997.

The Company anticipates a single digit total product sales growth rate for 1998. Without giving effect to the 1997 legal assessment, earnings per share in 1998 is expected to grow at a rate between high single and low double digits. Estimates of future product sales and earnings per share, however, are necessarily speculative in nature and are difficult to predict with accuracy.

Following an approximate six-month period, during which Amgen considered a number of corporate partnering alternatives for its inflammation program in Boulder, Colorado, Amgen has decided to pursue separate paths with its inflammation product development programs and its inflammation discovery research program. Amgen will retain its principal inflammation product candidates, STNFr-1 and IL-1ra, and relocate the related development programs to Thousand Oaks, California. Amgen will not continue the Boulder inflammation discovery research program; employees are seeking investment capital in order to continue this research in a new company. If those efforts are successful, Amgen expects to receive equity in exchange for its intellectual property. However, there can be no assurance these efforts will be successful or that an exchange could be negotiated on acceptable terms.

Except for the historical information contained herein, the matters discussed herein are by their nature forward-looking. Investors are cautioned that forward-looking statements or projections made by the Company, including those made in this document, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Reference is made in particular to forward-looking statements regarding product sales, earnings per share and expenses. Amgen operates in a rapidly changing environment that involves a number of risks, some of which are beyond the Company's control. Future operating results and the Company's stock price may be affected by a number of factors, including, without limitation: (i) the results of preclinical and clinical trials; (ii) regulatory approvals of product candidates, new indications and manufacturing facilities; (iii) reimbursement for Amgen's products by governments and private payors; (iv) health care

guidelines relating to Amgen's products; (v) intellectual property matters (patents) and the results of litigation; (vi) competition; (vii) fluctuations in operating results and (viii) rapid growth of the Company. These factors and others are discussed herein and in the sections appearing in "Item 1. Business - Factors That May Affect the Company" in the Company's Annual Report on Form 10-K for the year ended December 31, 1997, which sections are incorporated herein by reference and filed as an exhibit hereto.

#### Legal Matters

The Company is engaged in arbitration proceedings with one of its licensees and various other legal proceedings. For a discussion of these matters, see Note 4 to the Condensed Consolidated Financial Statements.

## PART II - OTHER INFORMATION

### Item 1. LEGAL PROCEEDINGS

The Company is engaged in arbitration proceedings with one of its licensees. For a discussion of these and other matters, see Note 4 to the Condensed Consolidated Financial Statements, "Contingencies". Other legal proceedings are also reported in Note 4 to the Condensed Consolidated Financial Statements and in the Company's Form 10-K for the year ended December 31, 1997, with material developments since that report described below. While it is not possible to predict accurately or to determine the eventual outcome of these matters, the Company believes that the outcome of these proceedings will not have a material adverse effect on the annual financial statements of the Company.

#### Transkaryotic Therapies and Hoechst litigation

On April 15, 1997, Amgen filed suit in the United States District Court in Boston, Massachusetts against Transkaryotic Therapies Inc. ("TKT") and Hoechst Marion Roussel alleging infringement of several U.S. patents owned by Amgen that claim an erythropoietin product and processes for making erythropoietin. The suit seeks an injunction preventing the defendants from making, importing, using or selling erythropoietin in the U.S. On July 9, 1997, the court denied TKT's motion to dismiss the lawsuit on the pleadings. On April 15, 1998, the court issued an order granting the defendants' motion for summary judgment of non-infringement on the grounds that defendants' activities to date were protected by the clinical trial exemption. The court also ruled that Amgen's motion for summary judgment for infringement would be administratively closed. Although the matter is administratively closed, it may be re-opened upon motion of either party for good cause shown.

Item 5. Other Information

The Company's 1999 Annual Meeting of Stockholders will be held on May 13, 1999.

Item 6. Exhibits and Reports on Form 8-K

- (a) Reference is made to the Index to Exhibits included herein.
- (b) Reports on Form 8-K  
None



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.

Amgen Inc.  
(Registrant)

Date: 5/12/98  
-----

By: /s/ Kathryn E. Falberg  
-----

Kathryn E. Falberg  
Vice President, Finance,  
Chief Financial Officer and  
Chief Accounting Officer

AMGEN INC.

INDEX TO EXHIBITS

Exhibit No.	Description
3.1	Restated Certificate of Incorporation as amended. (19)
3.2	Amended and Restated Bylaws. (23)
4.1	Indenture dated January 1, 1992 between the Company and Citibank N.A., as trustee. (8)
4.2	Forms of Commercial Paper Master Note Certificates. (10)
4.3	First Supplement to Indenture, dated February 26, 1997 between the Company and Citibank N.A., as trustee. (16)
4.4	Officer's Certificate pursuant to Sections 2.1 and 2.3 of the Indenture, as supplemented, establishing a series of securities "8-1/8% Debentures due April 1, 2097." (18)
4.5	8-1/8% Debentures due April 1, 2097. (18)
4.6	Form of stock certificate for the common stock, par value \$.0001 of the Company. (19)
4.7	Officer's Certificate pursuant to Sections 2.1 and 2.3 of the Indenture, dated as of January 1, 1992, as supplemented by the First supplemental Indenture, dated as of February 26, 1997, each between the Company and Citibank, N.A., as Trustee, establishing a series of securities entitled "6.50% Notes Due December 1, 2007". (22)
4.8	6.50% Notes Due December 1, 2007 described in Exhibit 4.7. (22)
4.9*	Corporate Commercial Paper - Master Note between and among Amgen Inc., as Issuer, Cede & Co., as nominee of The Depository Trust Company and Citibank, N.A. as Paying Agent.
10.1	Company's Amended and Restated 1991 Equity Incentive Plan. (23)
10.2	Company's Amended and Restated 1984 Stock Option Plan. (14)
10.3	Shareholder's Agreement of Kirin-Amgen, Inc., dated May 11, 1984, between the Company and Kirin Brewery Company, Limited (with certain confidential information deleted therefrom). (1)
10.4	Amendment Nos. 1, 2, and 3, dated March 19, 1985, July 29, 1985 and December 19, 1985, respectively, to the Shareholder's Agreement of Kirin-Amgen, Inc., dated May 11, 1984 (with certain confidential information deleted therefrom). (3)
10.5	Product License Agreement, dated September 30, 1985, and Technology License Agreement, dated, September 30, 1985 between the Company and Ortho Pharmaceutical Corporation (with certain confidential information deleted therefrom). (2)
10.6	Product License Agreement, dated September 30, 1985, and Technology License Agreement, dated September 30, 1985 between Kirin-Amgen, Inc. and Ortho Pharmaceutical

- Corporation (with certain confidential information deleted therefrom). (3)
- 10.7 Company's Amended and Restated Employee Stock Purchase Plan. (14)
- 10.8 Research, Development Technology Disclosure and License Agreement PPO, dated January 20, 1986, by and between the Company and Kirin Brewery Co., Ltd. (4)
- 10.9 Amendment Nos. 4 and 5, dated October 16, 1986 (effective July 1, 1986) and December 6, 1986 (effective July 1, 1986), respectively, to the Shareholders Agreement of Kirin-Amgen, Inc. dated May 11, 1984 (with certain confidential information deleted therefrom). (5)
- 10.10 Assignment and License Agreement, dated October 16, 1986, between the Company and Kirin-Amgen, Inc. (with certain confidential information deleted therefrom). (5)
- 10.11 G-CSF European License Agreement, dated December 30, 1986, between Kirin-Amgen, Inc. and the Company (with certain confidential information deleted therefrom). (5)
- 10.12 Research and Development Technology Disclosure and License Agreement: GM-CSF, dated March 31, 1987, between Kirin Brewery Company, Limited and the Company (with certain confidential information deleted therefrom). (5)
- 10.13 Company's Amended and Restated 1988 Stock Option Plan. (14)
- 10.14 Company's Amended and Restated Retirement and Savings Plan. (14)
- 10.15 Amendment, dated June 30, 1988, to Research, Development, Technology Disclosure and License Agreement: GM-CSF dated March 31, 1987, between Kirin Brewery Company, Limited and the Company. (6)
- 10.16 Agreement on G-CSF in Certain European Countries, dated January 1, 1989, between Amgen Inc. and F. Hoffmann-La Roche & Co. Limited Company (with certain confidential information deleted therefrom). (7)
- 10.17 Partnership Purchase Agreement, dated March 12, 1993, between the Company, Amgen Clinical Partners, L.P., Amgen Development Corporation, the Class A limited partners and the Class B limited partner. (9)
- 10.18\* Amgen Inc. Supplemental Retirement Plan (As Amended and Restated Effective January 1, 1998).
- 10.19 Promissory Note of Mr. Kevin W. Sharer, dated June 4, 1993. (11)
- 10.20 Amgen Performance Based Management Incentive Plan. (17)
- 10.21 Credit Agreement, dated as of June 23, 1995, among Amgen Inc., the Borrowing Subsidiaries named therein, the Banks named therein, Swiss Bank Corporation and ABN AMRO Bank N.V., as Issuing Banks, and Swiss Bank Corporation, as Administrative Agent. (12)
- 10.22 Promissory Note of Mr. George A. Vandeman, dated December 15, 1995. (13)
- 10.23 Promissory Note of Mr. George A. Vandeman, dated December 15, 1995. (13)
- 10.24 Promissory Note of Mr. Stan Benson, dated March 19, 1996. (13)
- 10.25 Amendment No. 1 to the Company's Amended and Restated Retirement and Savings Plan. (14)

- 10.26 Amendment Number 5 to the Company's Amended and Restated Retirement and Savings Plan dated January 1, 1993. (17)
- 10.27 Amendment Number 2 to the Company's Amended and Restated Retirement and Savings Plan dated April 1, 1996. (17)
- 10.28 First Amendment to Credit Agreement, dated as of December 12, 1996, among Amgen Inc., the Borrowing Subsidiaries named therein, and Swiss Bank Corporation as Administrative Agent. (17)
- 10.29 Fourth Amendment to Rights Agreement, dated February 18, 1997 between Amgen Inc. and American Stock Transfer and Trust Company, Rights Agent. (15)
- 10.30 Preferred Share Rights Agreement, dated February 18, 1997, between Amgen Inc. and American Stock Transfer and Trust Company, Rights Agent. (15)
- 10.31 Consulting Agreement, dated November 15, 1996, between the Company and Daniel Vapnek. (17)
- 10.32 Agreement, dated May 30, 1995, between the Company and George A. Vandeman. (17)
- 10.33 First Amendment, effective January 1, 1998, to the Company's Amended and Restated Employee Stock Purchase Plan. (20)
- 10.34 Third Amendment, effective January 1, 1997, to the Company's Amended and Restated Retirement and Savings Plan dated April 1, 1996. (20)
- 10.35 Heads of Agreement dated April 10, 1997, between the Company and Kirin Amgen, Inc., on the one hand, and F. Hoffmann-La Roche Ltd, on the other hand (with certain confidential information deleted therefrom). (20)
- 10.36 Binding Term Sheet, dated August 20, 1997, between Guilford Pharmaceuticals Inc. ("Guilford") and GPI NIL Holdings, Inc., and Amgen Inc. (with certain confidential information deleted therefrom). (21)
- 10.37 Promissory Note of Ms. Kathryn E. Falberg, dated April 7, 1995. (23)
- 10.38 Promissory Note of Mr. Edward F. Garnett, dated July 18, 1997. (23)
- 10.39 Fourth Amendment to the Company's Amended and Restated Retirement and Savings Plan as amended and restated effective April 1, 1996. (23)
- 10.40 Fifth Amendment to the Company's Amended and Restated Retirement and Savings Plan as amended and restated effective April 1, 1996. (23)
- 10.41 Company's Amended and Restated 1987 Directors' Stock Option Plan. (17)
- 10.42\* Amended and Restated Agreement on G-CSF in the EU between Amgen Inc. and F. Hoffmann-La Roche Ltd (with certain confidential information deleted therefrom).
- 10.43 Collaboration and License Agreement, dated December 15, 1997, between the Company, GPI NIL Holdings, Inc. and Guilford Pharmaceuticals Inc. ("Guilford") (with certain confidential information deleted therefrom). (24)
- 27\* Financial Data Schedule.
- 99\* Sections appearing under the heading "Business - Factors That May Affect Company" in the Company's Annual Report on Form 10-K for the year ended December 31, 1997.

\* Filed herewith.

- (1) Filed as an exhibit to the Annual Report on Form 10-K for the year ended March 31, 1984 on June 26, 1984 and incorporated herein by reference.
- (2) Filed as an exhibit to Quarterly Report on Form 10-Q for the quarter ended September 30, 1985 on November 14, 1985 and incorporated herein by reference.
- (3) Filed as an exhibit to Quarterly Report on Form 10-Q for the quarter ended December 31, 1985 on February 3, 1986 and incorporated herein by reference.
- (4) Filed as an exhibit to Amendment No. 1 to Form S-1 Registration Statement (Registration No. 33-3069) on March 11, 1986 and incorporated herein by reference.
- (5) Filed as an exhibit to the Form 10-K Annual Report for the year ended March 31, 1987 on May 18, 1987 and incorporated herein by reference.
- (6) Filed as an exhibit to Form 8 amending the Quarterly Report on Form 10-Q for the quarter ended June 30, 1988 on August 25, 1988 and incorporated herein by reference.
- (7) Filed as an exhibit to the Form 8 dated November 8, 1989, amending the Annual Report on Form 10-K for the year ended March 31, 1989 on June 28, 1989 and incorporated herein by reference.
- (8) Filed as an exhibit to Form S-3 Registration Statement dated December 19, 1991 and incorporated herein by reference.
- (9) Filed as an exhibit to the Form 8-A dated March 31, 1993 and incorporated herein by reference.
- (10) Filed as an exhibit to the Form 10-Q for the quarter ended March 31, 1993 on May 17, 1993 and incorporated herein by reference.
- (11) Filed as an exhibit to the Form 10-Q for the quarter ended September 30, 1993 on November 12, 1993 and incorporated herein by reference.
- (12) Filed as an exhibit to the Form 10-Q for the quarter ended June 30, 1995 on August 11, 1995 and incorporated herein by reference.
- (13) Filed as an exhibit to the Annual Report on Form 10-K for the year ended December 31, 1995 on March 29, 1996 and incorporated herein by reference.
- (14) Filed as an exhibit to the Form 10-Q for the quarter ended September 30, 1996 on November 5, 1996 and incorporated herein by reference.
- (15) Filed as an exhibit to the Form 8-K Current Report dated February 18, 1997 on February 28, 1997 and incorporated herein by reference.
- (16) Filed as an exhibit to the Form 8-K Current Report dated March 14, 1997 on March 14, 1997 and incorporated herein by reference.
- (17) Filed as an exhibit to the Annual Report on Form 10-K for the year ended December 31, 1996 on March 24, 1997 and incorporated herein by reference.
- (18) Filed as an exhibit to the Form 8-K Current Report dated April 8, 1997 on April 8, 1997 and incorporated herein by reference.
- (19) Filed as an exhibit to the Form 10-Q for the quarter ended March 31, 1997 on May 13, 1997 and incorporated herein by reference.
- (20) Filed as an exhibit to the Form 10-Q for the quarter ended June 30, 1997 on August 12, 1997 and incorporated herein by reference.

- (21) Filed as exhibit 10.47 to the Guilford Form 8-K Current Report dated August 20, 1997 on September 4, 1997 and incorporated herein by reference.
- (22) Filed as an exhibit to the Form 8-K Current Report dated and filed on December 5, 1997 and incorporated herein by reference.
- (23) Filed as an exhibit to the Annual Report on Form 10-K for the year ended December 31, 1997 on March 24, 1998 and incorporated herein by reference.
- (24) Filed as Exhibit 10.40 to the Guilford Form 10-K for the year ended December 31, 1997 and incorporated herein by reference.



EXHIBIT 4.9

CORPORATE COMMERCIAL PAPER - MASTER NOTE  
BETWEEN AND AMONG AMGEN INC., AS ISSUER,  
CEDE & CO., AS NOMINEE OF THE DEPOSITORY TRUST COMPANY  
AND CITIBANK, N.A. AS PAYING AGENT

Date of Issuance

AMGEN INC. (Issuer), for value received, hereby promises to pay Cede & Co., as nominee of The Depository Trust Company, or to registered assigns: (i) the principal amount, together with unpaid accrued interest thereon, if any, on the maturity date of each obligation identified on the records of Issuer (the Underlying Records) as being evidenced by this Master Note, which Underlying Records are maintained by CITIBANK, N.A. (Paying Agent); (ii) interest on the principal amount of each such obligation that is payable in installments, if any, on the due date of each installment, as specified on the Underlying Records; and (iii) the principal amount of each such obligation that is payable in installments, if any, on the due date of each installment, as specified on the Underlying Records. Interest shall be calculated at the rate and according to the calculation convention specified on the Underlying Records. Payments shall be made by wire transfer to the registered owner from Paying Agent without the necessity of presentation and surrender of this Master Note.

REFERENCE IS HEREBY MADE TO THE FURTHER PROVISIONS OF THIS MASTER NOTE SET FORTH ON THE REVERSE HEREOF.

This Master Note is a valid and binding obligation of Issuer.  
Not Valid Unless Countersigned for Authentication by Paying Agent.

CITIBANK, N.A.

AMGEN INC.

By: /s/ Wafaa Orfy  
Authorized Countersignature

By: /s/Larry A. May  
Authorized Signature

Guarantor

By: /s/  
Authorized Signature

1

At the request of the registered owner, Issuer shall promptly issue and deliver one or more separate note certificates evidencing each obligation evidenced by this Master Note. As of the date any such note certificate or certificates are issued, the obligations which are evidenced thereby shall no longer be evidenced by this Master Note.

-----  
FOR VALUE RECEIVED, the undersigned hereby sells, assigns, and transfers unto

(Name, address and Taxpayer Identification Number of Assignee)

the Master Note and all rights thereunder, hereby irrevocably constituting and appointing attorney to transfer said Master Note on



the books of Issuer with full power of substitution in the premises.

Dated:

Signature(s) Guaranteed: (Signature)

Notice: The Signature on this assignment must correspond with the name as written upon the face of this Master Note, in every particular, without alteration or enlargement or any change whatsoever.

-----  
Unless this certificate is presented by an authorized representative of The Depository Trust Company, a New York corporation (DTC), to Issuer or its agent for registration of transfer, exchange, or payment, and any certificate issued is registered in the name of Cede & Co. or in such other name as is requested by an authorized representative of DTC (and any payment is made to Cede & Co. or to such other entity as is requested by an authorized representative of DTC), ANY TRANSFER, PLEDGE, OR OTHER USE HEREOF FOR VALUE OR OTHERWISE BY OR TO ANY PERSON IS WRONGFUL inasmuch as the registered owner hereof, Cede & Co., has an interest herein.

FORM OF LEGEND FOR  
PRIVATE PLACEMENT MEMORANDUM AND NOTES

THE NOTES HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE ACT), OR ANY OTHER APPLICABLE SECURITIES LAW, AND OFFERS AND SALES THEREOF MAY BE MADE ONLY IN COMPLIANCE WITH AN APPLICABLE EXEMPTION FROM THE REGISTRATION REQUIREMENTS OF THE ACT AND ANY APPLICABLE STATE SECURITIES LAWS. BY ITS ACCEPTANCE OF A NOTE, THE PURCHASER WILL BE DEEMED TO REPRESENT THAT IT HAS BEEN AFFORDED AN OPPORTUNITY TO INVESTIGATE MATTERS RELATING TO THE ISSUER AND THE NOTES, THAT IT IS NOT ACQUIRING SUCH NOTE WITH A VIEW TO ANY DISTRIBUTION THEREOF AND THAT IT IS EITHER (A) AN INSTITUTIONAL INVESTOR OR SOPHISTICATED INDIVIDUAL INVESTOR THAT IS AN ACCREDITED INVESTOR WITHIN THE MEANING OF RULE 501(a) UNDER THE ACT (AN INSTITUTIONAL ACCREDITED INVESTOR OR SOPHISTICATED INDIVIDUAL

ACCREDITED INVESTOR, RESPECTIVELY) AND THAT EITHER IS PURCHASING NOTES FOR ITS OWN ACCOUNT, IS A U.S. BANK (AS DEFINED IN SECTION 3(a)(2) OF THE ACT) OR A SAVINGS AND LOAN ASSOCIATION OR OTHER INSTITUTION (AS DEFINED IN SECTION 3(a)(5)(a) OF THE ACT) ACTING IN ITS INDIVIDUAL OR FIDUCIARY CAPACITY OR IS A FIDUCIARY OR AGENT (OTHER THAN A U.S. BANK OR SAVINGS AND LOAN) PURCHASING NOTES FOR ONE OR MORE ACCOUNTS EACH OF WHICH IS SUCH AN INSTITUTIONAL ACCREDITED INVESTOR OR SOPHISTICATED INDIVIDUAL ACCREDITED INVESTOR (i) WHICH ITSELF POSSESSES SUCH KNOWLEDGE AND EXPERIENCE OR (ii) WITH RESPECT TO WHICH SUCH PURCHASER HAS SOLE INVESTMENT DISCRETION; OR (B) A QUALIFIED INSTITUTIONAL BUYER (QIB) WITHIN THE MEANING OF RULE 144A UNDER THE ACT WHICH IS ACQUIRING NOTES FOR ITS OWN ACCOUNT OR FOR ONE OR MORE ACCOUNTS, EACH OF WHICH IS A QIB AND WITH RESPECT TO EACH OF WHICH THE PURCHASER HAS SOLE INVESTMENT DISCRETION; AND THE PURCHASER ACKNOWLEDGES THAT IT IS AWARE THAT THE SELLER MAY RELY UPON THE EXEMPTION FROM THE REGISTRATION PROVISIONS OF SECTION 5 OF THE ACT PROVIDED BY RULE 144A. BY ITS ACCEPTANCE OF A NOTE, THE PURCHASER THEREOF ALSO SHALL ALSO BE DEEMED TO AGREE THAT ANY RESALE OR OTHER TRANSFER THEREOF WILL BE MADE ONLY (A) IN A TRANSACTION EXEMPT FROM REGISTRATION UNDER THE ACT, EITHER (1) TO THE ISSUER OR TO GOLDMAN, SACHS & CO. OR ANOTHER PERSON DESIGNATED BY THE ISSUER AS A PLACEMENT AGENT FOR THE NOTES (COLLECTIVELY, THE PLACEMENT AGENTS), NONE OF WHICH SHALL HAVE ANY OBLIGATION TO ACQUIRE SUCH NOTE, (2) THROUGH A PLACEMENT AGENT TO AN INSTITUTIONAL ACCREDITED INVESTOR, SOPHISTICATED INDIVIDUAL ACCREDITED INVESTOR OR A QIB, OR (3) TO A QIB IN A TRANSACTION THAT MEETS THE REQUIREMENTS OF RULE 144A AND (B) IN MINIMUM AMOUNTS OF \$250,000.



AMGEN INC.  
SUPPLEMENTAL RETIREMENT PLAN  
(As Amended and Restated Effective January 1, 1998)

ARTICLE I  
INTRODUCTION AND PLAN PURPOSE

The Amgen Supplemental Retirement Plan (the "Plan") was established by Amgen Inc. (the "Company") effective as of January 1, 1993 and was amended and restated effective January 1, 1998. The purpose of this Plan is to provide benefits to employees of the Company and certain of its affiliates whose Matching Contributions and Core Contributions are limited under the Amgen Inc. Retirement and Savings Plan (the "Retirement Plan"). The Company intends that the Plan will aid in retaining and attracting employees of exceptional ability by providing them with these benefits.

ARTICLE II  
DEFINITIONS

For the purposes of this Plan, the following terms, when capitalized, have the following meanings, and, except as provided otherwise below, the terms defined in the Retirement Plan shall have the meanings provided in the Retirement Plan.

2.1 Account means the Account maintained by the Company in accordance with Article IV with respect to Matching Credits, Core Credits and Earnings.

2.2 Beneficiary means the person, persons or entity entitled under Article VI to receive Plan benefits payable in the event of your death.

2.3 Board means the Board of Directors of the Company.

2.4 Code means the Internal Revenue Code of 1986, as amended.

2.5 Committee means the Compensation Committee of the Company's Board.

2.6 Company means Amgen Inc. or any subsidiary or affiliate of Amgen Inc. selected by the Board or the Committee to participate in the Plan.

2.7 Compensation has the same meaning as such term has under the Retirement Plan, except that, for purposes of this Plan, Compensation is not limited by the Salary Cap and Compensation for purposes of this Plan will not include any foreign assignment differential, that is, an amount paid to you to compensate for costs unique to an overseas assignment.

2.8 Core Credit means the amount credited to your Account under Section 4.2(a) of the Plan.

1

2.9 Deferral Commitment means the election to defer "Participant Elected Contributions" under the Retirement Plan.

2.10 Earnings means the amount credited to your Account under Article IV.

2.11 Matching Credit refers to amounts credited to your Account under Section 4.2(b) of the Plan.

2.12 Normal Retirement Date means the first day of the month coincident with or next following your attainment of age 65.

2.13 Participation Agreement means the agreement you file with the Committee acknowledging the terms of the Plan and enrolling in the Plan.

2.14 Retirement Plan means the Amgen Inc. Retirement and Savings Plan.

2.15 Salary Cap means the highest level of compensation that can be considered for the purpose of calculating benefits under Section 401(a)(17) of the Code (\$160,000 for 1998).

2.16 Spouse means your wife or husband who is lawfully married to the you at the time of your death.

ARTICLE III  
ELIGIBILITY AND PARTICIPATION

3.1 Eligibility. You are eligible to participate in the Plan if you are an employee of the Company whose compensation for a particular year is in excess of the Salary Cap.

3.2 Participation. If you are eligible, you may elect to participate in the Plan with respect to any calendar year by submitting a Participation Agreement to the Committee by the last day of the calendar year in which you are eligible and wish to participate. Your participation in the Plan will continue unless and until you submit a new Participation Agreement changing or canceling your participation.

ARTICLE IV  
CREDITS TO YOUR ACCOUNT

4.1 Account. For record keeping purposes only, an Account will be maintained for you. Your Account will be used solely to determine the amounts to be paid to you under the Plan. Your Account will not constitute or be treated as a trust fund for your benefit.

4.2 Credits. As of the last day of each calendar month, the Company will credit your Account with your share of Matching Credits and Core Credits

(a) Core Credits. The amount of Core Credits to be credited to your account will be determined by calculating first what you would have received as a Core Contribution under the Retirement Plan without

considering the Salary Cap, less the amount of core contributions that were actually contributed on your behalf to the Retirement Plan.

(b) Matching Credits. The amount of Matching Credits to be credited to your account will be the amount of matching contributions that would have been made on your behalf under the Retirement Plan as if the Salary Cap were not in effect, based on your Deferral Commitment in effect at the time the Salary Cap is reached for the year (provided that you demonstrate to the Company that you have set aside for investment an amount equal to the amount you were prevented from deferring because of the Salary Cap) less the amount of matching contributions that were actually contributed on your behalf to the Retirement Plan.

4.3 Earnings. On the last day of each calendar month, your Account will be credited with Earnings with respect to the investments of the Core and Matching Credits credited to your Account. Notwithstanding the foregoing, if you terminate service as a result of Normal Retirement, death or Disability (as defined in the Retirement Plan), you will be entitled to Earnings up to the date of distribution of your Account. Earnings will be credited at the rate declared by the Committee, acting in its sole discretion, after taking into account the investment performance of the investment vehicles selected by the Committee, or, if the Committee permits, selected by you from among the investment vehicles available under the Retirement Plan.

4.4 Vesting of Your Account. Your Account will become fully vested upon termination of employment with the Company on or after (1) your Normal Retirement Date, (2) the date you become disabled (as determined under the terms of the Retirement Plan), or (3) your death. If your employment with the Company is terminated for any other reason, your Account will be vested in accordance with the following schedule:

Years of Service	Vested Percentage
Less than 5	0%
5 but less than 6	50%
6 but less than 7	60%
7 but less than 8	70%
8 but less than 9	80%
9 but less than 10	90%
10 or more	100%

However, your entire Account will be subject to the creditors of the Company in the event of the insolvency of the Company.

4.5 Determination of Accounts. Your Account will consist of all your credited Matching Credits, Core Credits, and Earnings.

4.6 Statement of Accounts. Prior to March 1 of each year or at such other time as determined by the Committee, the Committee will distribute statements to you showing the balance of your Account.

ARTICLE V  
DISTRIBUTIONS

5.1 Distributions. Following the termination of your employment with the Company, the Company will pay you the vested balance in your Account. The payments will be made to you in cash and may be paid either in a lump sum or in periodic installments at such time and in such form as determined by the Committee. If you are paid in periodic installments, the amount of each installment will be equal to the vested balance in your Account divided by the number of remaining installments that you are to receive. Any unpaid balance will continue to receive Earnings. In the event of your death prior to receiving your full distribution, the unpaid balance will be paid to your Beneficiary at such times and in such form as the Committee determines in its sole discretion.

5.2 Withholding; Payroll Taxes. The Company will withhold any taxes required to be withheld from payments made from the Plan to satisfy any federal, state, or local requirements regarding tax withholding.

5.3 Payment to Guardian. If a Plan benefit is payable to a minor, a person declared incompetent or a person incapable of handling the disposition of property, the Committee may direct payment of such Plan benefit to the guardian, legal representative or person having the care and custody of such minor, incompetent or person. The Committee may require proof of incompetency, minority, incapacity or guardianship as may be appropriate prior to distribution of the Plan benefit. Such distribution completely discharges the Committee and the Company from all liability with respect to such benefit.

ARTICLE VI  
BENEFICIARY DESIGNATION

6.1 Beneficiary Designation. Your Beneficiary under the Plan will be the same Beneficiary you select under the Retirement Plan. If you change your Beneficiary designation made under the Retirement Plan you will automatically change the Beneficiary designation under the Plan.

6.2 No Beneficiary Designation. If you fail to designate a Beneficiary under the Retirement Plan, or if the Beneficiary you designate dies before you or before complete distribution of your benefits, your designated Beneficiary will be the first of the following classes in which there is a survivor:

- (a) your surviving Spouse;
- (b) your children, except if any of the children predecease you but leave surviving issue, then such issue will take by right of representation the share the parent would have taken if living;
- (c) your estate.

6.3 Effect of Payment. The payment to the Beneficiary completely discharges Company's obligations under this Plan.

ARTICLE VII  
ADMINISTRATION

7.1 Committee; Duties. This Plan is administered by the Committee. The Committee is responsible for making such rules, interpretations and computations as may be appropriate. Any decision of the Committee with respect to the Plan including, without limitation, any determination of eligibility to participate in the Plan and any calculation of Plan benefits, is conclusive and binding on all persons. The Committee may appoint a panel consisting of any number of individuals, who may or may not be employees of the Company, to carry out the Committee's duties and responsibilities under the Plan.

7.2 Agents. The Committee may employ other agents and delegate to them such administrative duties as it sees fit, and may from time to time consult with counsel who may be counsel to the Company.

7.3 Binding Effect of Decisions. The decisions or actions of the Committee with respect to any question arising out of or in connection with the administration, interpretation or application of the Plan and the rules or regulations promulgated hereunder will be final, conclusive and binding upon all persons having any interest in the Plan.

7.4 Indemnity of Committee. The Company will indemnify and hold harmless the members of the Committee against any and all claims, loss, damage, expense or liability arising from any action or failure to act with respect to this Plan, except in the case of the Committee's gross negligence or willful misconduct.

7.5 Claims Procedure. The Claims Procedure under the Plan is the same as that under the Retirement Plan, except that the Committee will be substituted for the Review Panel.

ARTICLE VIII  
AMENDMENT AND TERMINATION OF PLAN

8.1 Amendment. The Committee may at any time amend the Plan in whole or in part. No amendment may decrease or restrict the amount accrued in any Account maintained under the Plan through the date of Amendment.

8.2 Company's Right to Terminate. The Board may at any time partially or completely terminate the Plan if, in its judgment, the tax, accounting, or other effects of the continuance of the Plan, or potential payments thereunder, would not be in the best interests of the Company.

ARTICLE IX  
MISCELLANEOUS

9.1 Unfunded Plan. This Plan is intended to be an unfunded plan for tax law purposes and for purposes of Title I of the Employee Retirement Income Act of 1974, as amended ("ERISA"), maintained primarily to provide benefits for a select group of management or



highly compensated employees. This Plan is not intended to create an investment contract, but to provide tax planning opportunities and retirement benefits to eligible individuals who have elected to participate in the Plan. Eligible individuals are members of management who, by virtue of their position with the Company, are uniquely informed as to the Company's operations and have the ability to materially affect the Company's profitability and operations.

9.2 Unsecured General Creditor. Neither you nor your Beneficiaries, heirs, successors and assigns will have any legal or equitable rights, interest or claims in any property or assets of Company, nor will they be Beneficiaries of, or have any rights, claims or interests in any life insurance policies, annuity contracts or the proceeds therefrom owned or which may be acquired by Company. Such policies or other assets of Company will not be held under any trust for your benefit or that of your Beneficiaries, heirs, successors or assigns, or held in any way as collateral security for the fulfilling of the obligations of Company under this Plan. Any and all of Company's assets and policies will be, and remain, the general, unpledged, unrestricted assets of Company. Company's obligation under the Plan will be that of an unfunded and unsecured promise of Company to pay money in the future.

9.3 Trust Fund. The Company will pay all Plan benefits. At its discretion, the Company may establish one or more trusts, with such trustees as the Board may approve, for the purpose of providing for the payment of such benefits. Such trust or trusts may be irrevocable, but the assets thereof will be subject to the claims of the Company's creditors. To the extent any benefits provided under the Plan are actually paid from any such trust, the Company will have no further obligation with respect thereto, but to the extent not so paid, such benefits will remain the obligation of, and paid by, the Company.

9.4 Nonassignability. Neither you nor any other person may commute, sell, assign, transfer, hypothecate or convey in advance of actual receipt the amounts, if any, payable hereunder, or any part thereof, which are expressly declared to be nonassignable and nontransferable. No part of the amounts payable will, prior to actual payment, be subject to seizure or sequestration for the payment of any debts, judgments, alimony or separate maintenance owed by you or any other person (other than amounts owed to the Company's creditors in the event of the Company's insolvency), nor be transferable by operation of law in the event of the bankruptcy or insolvency of you or any other person (other than the Company). Notwithstanding the above, benefits will be payable to an individual other than you under this Plan upon the determination by the administrative committee of the Retirement Plan that a domestic relations order is a Qualified Domestic Relations Order (as such term is defined in Code Section 414(p)).

9.5 Not a Contract of Employment. The terms and conditions of this Plan may not be construed to constitute a contract of employment between you and the Company and you (or your Beneficiary) will have no rights against the Company except as otherwise specifically provided herein. Moreover, nothing in this Plan will be deemed to give you the right to be retained in the service of the Company or to interfere with the right of the Company to discipline or discharge you at any time.

9.6 Cooperation. You are required to cooperate with the Company by furnishing any and all information requested by the Company in order to facilitate the payment of benefits hereunder.

9.7 Terms. Whenever words are used in this Plan in the masculine they will be construed as though they were used in the feminine in all cases where they would so apply; and whenever any words are used in this Plan in the singular or in the plural, they will be construed as though they were used in the plural or the singular, as the case may be, in all cases where they would so apply.

9.8 Captions. The captions of the articles, sections and paragraphs of this Plan are for convenience only and do not control or affect the meaning or construction of any of its provisions.

9.9 Governing Law. The provisions of this Plan is to be construed and interpreted according to the laws of the State of California to the extent that they have not been preempted by federal law.

9.10 Validity. In case any provision of this Plan is found to be held illegal or invalid for any reason, said illegality or invalidity will not affect the remaining parts hereof, but this Plan will be construed and enforced as if such illegal and invalid provision had never been inserted herein.

Adopted this 16th day of February, 1998.

/s/ Edward F. Garnett  
Edward F. Garnett  
Vice President, Human Resources



ASTERISKS (\*) INDICATE CONFIDENTIAL INFORMATION OMITTED AND FILED SEPARATELY WITH THE SEC

EXHIBIT 10.42

AMENDED AND RESTATED  
AGREEMENT  
ON G-CSF IN THE EU  
BETWEEN  
AMGEN INC.  
AND  
F. HOFFMANN-LA ROCHE LTD

TABLE OF CONTENTS

ARTICLE	PAGE
1. DEFINITIONS	1
2. GRANTS AND OBLIGATIONS	6
3. COLLABORATION IN CLINICAL RESEARCH DEVELOPMENT, REGISTRATION & MARKETING	14
4. OWNERSHIP, PREPARATION AND FILING OF CPMP, NDA's and MA/V's	19
5. SUPPLY	22
6. MARKETING	28
7. COMPENSATION	34
8. REPORTS AND PAYMENTS	36
9. WARRANTIES AND INDEMNIFICATION	38
10. PATENT AND TRADEMARK INFRINGEMENT	39
11. TERM AND TERMINATION	40
12. MISCELLANEOUS	42

AMENDED AND RESTATED  
AGREEMENT  
ON G-CSF IN THE EU

This Agreement is made and effective as of the 10th day of April 1997 ("Effective Date") by and between AMGEN INC., a Delaware corporation located at Thousand Oaks, California, USA (hereinafter "AMGEN") and F. HOFFMANN-LA ROCHE LTD, a corporation organized and existing under the laws of Switzerland located at Basel, Switzerland (hereinafter "ROCHE").

WHEREAS, AMGEN possesses rights in and to a pharmaceutical product known as G-CSF;

WHEREAS, AMGEN and ROCHE have entered into a contractual relationship regarding G-CSF in the European Union;

WHEREAS, AMGEN and ROCHE have agreed to modify their present relationship as set forth herein.

NOW, THEREFORE, for and in consideration of the mutual covenants contained herein, ROCHE and AMGEN hereby agree as follows:

ARTICLE 1  
DEFINITIONS

1.01 "Affiliate" shall mean:

- (a) An organization which owns, directly or indirectly, a controlling interest in AMGEN or ROCHE by stock ownership or otherwise; or
- (b) An organization in which AMGEN or ROCHE or its stockholders own, directly or indirectly, a controlling interest by stock ownership or otherwise; or

(c) An organization having its majority ownership directly or indirectly common to the majority ownership of AMGEN or ROCHE.

1.02 "KIRIN" shall mean, collectively, KIRIN BREWERY INC., a Japanese company and KIRIN-AMGEN, INC., a California corporation, fifty percent (50%) owned by AMGEN, as the case may be in the context used in a particular section of this Agreement.

1.03 "Territory" shall mean all countries which are currently members of the European Union ("EU") together with those countries that join the EU during the Term of this Agreement.

As soon as any EU member country may withdraw or become excluded from the EU, then as from the effective date of such withdrawal or exclusion, such country shall automatically be considered as a country of the territory of the Agreement on G-CSF in Certain European Countries dated as of the first day of January 1989.

1.04 "G-CSF" shall mean a polypeptide of 174 or 175 amino acids, with an amino acid sequence according to positions +1 to 174 of Table VII of International Patent Application Publication No. WO 87/01132 with possibly an additional N-terminal methionine, obtained by recombinant DNA technology, having the biological properties of naturally-occurring pluripotent granulocyte colony-stimulating factor.

1.05 "Product" shall mean: (1) any product consisting of or containing as an active ingredient G-CSF or (2) a Second Generation Product, if any, that becomes a Product pursuant to the provisions of Section 2.03 hereof. For illustration, the term Product shall include, without limitation, bulk forms of the Product ("Bulk Product") and/or finished and packaged dosage units of the Product ("Finished Product").

1.06 "Patents" shall mean all patents (including inventor's certificates) and applications therefor owned and/or controlled by AMGEN in the countries of the Territory, including without limitation any substitutions, extensions, reissues, renewals, divisions, continuations or continuations-in-part thereof or therefor covering G-CSF or a Product or inventions, arising from or made during the course of this Agreement.

Notwithstanding the foregoing, the term "Patents" shall have the following meaning in reference to a Second Generation Product that becomes a Product pursuant to Section 2.03: "Patents" shall mean all patents (including inventor's certificates) and applications therefor owned and/or controlled by AMGEN or ROCHE or in which either party has any interest (including but not limited to the \*\*\*\*\* Patents) in the countries of the Territory, including without limitation any substitutions, extensions, reissues, renewals, divisions, continuations or continuations-in-part thereof or therefore covering a Product or inventions, arising from or made during the course of this Agreement."

1.07 "Term of this Agreement" shall mean the period commencing on the Effective Date of this Agreement and ending, unless terminated sooner or prolonged in accordance with this Agreement, on December 31, 2010, or until the date of \*\*\*\*\* in which either party has any right or interest claiming a Product approved for sale in the EU, \*\*\*\*\* . If, however, \*\*\*\*\* , the term of this Agreement \*\*\*\*\* until the \*\*\*\*\* . The latest of any of the dates in this Section 1.07 is hereinafter referred to as the "Scheduled Termination Date".

1.08 "Confidential Information" shall mean information which relates to G-CSF or a Product, including financial statements, costs and expense data, marketing, distribution and consumer data, production data, know-how, trade secrets, secret processes and formulae, technical data and reports including gene technology, biochemical, toxicological, pharmacokinetic, manufacturing and formulation data, clinical data, regulatory correspondence or any other information which is not generally ascertainable from public or published information, regardless of whether such information was provided pursuant to the terms of this Agreement, by request of the other party or in any other manner.

By way of illustration, Confidential Information shall include without limitation, all information developed or to be developed by a party to this Agreement, its Affiliates, and/or clinicians, and all material and information submitted to and/or filed with a governmental regulatory agency or any other equivalent agency covering a Product. Confidential Information shall also include without limitation all information related to G-CSF or a Product contained in all documents submitted in connection with INDs (Investigational New Drug), NDAs (New Drug Application), CTCs (Clinical Trial Certificate), AMM (Authorisation de Mise au Marche) and other regulatory submissions throughout the world covering a Product.

1.09 "Trademark" shall mean the trademark NEUPOGEN(R) owned by AMGEN and all other trademarks, if any, adopted, used and/or owned by AMGEN in connection with a Product.

- 1.10 "CPMP" shall mean either (i) the Committee for Proprietary Medical Products, (ii) its procedures, including its "bio/high tech" concertation procedures or (iii) the marketing authorization applications as per such procedures as the case may be in the context used in a particular section of this Agreement.
- 1.11 "Net Sales" shall mean the gross invoice price billed for Product to third parties by AMGEN or ROCHE and/or each of its Affiliates (but not including invoices relating to transactions between and/or among AMGEN, ROCHE, and/or each of its Affiliates) with respect to a Product in the Territory, less those deductions normally made under generally accepted accounting principles and described in detail in the Supplementary Agreement.
- 1.12 "Operating Profit or Loss" shall mean the combined profit or loss of both companies resulting from the activities described in this Agreement and described in detail in the Supplementary Agreement.
- 1.13 "Operating Costs and Expenses" shall mean those costs and expenses which are included in the calculation of Operating Profit or Loss. They are described in detail in the Supplementary Agreement.
- 1.14 "Supplementary Agreement" shall mean the supplementary agreement attached hereto as Appendix 1.14, which is hereby modified effective as of the Effective Date to (1) change all references therein from Swiss francs to U.S. Dollars to reflect the change in the functional currency of this Agreement from Swiss francs to U.S. Dollars and (2) apply mutatis mutandis except where the context requires otherwise. It is the intent of the parties to revise the Supplementary Agreement as soon as practicable following the execution of this Agreement in order to memorialize previously agreed alterations thereto.
- 1.15 "Scheduled Termination Date" shall have the meaning set forth in Section 1.07.
- 1.16 "EMEA" shall mean either (i) the European Agency for the Evaluation of Medicinal Products, (ii) its procedures and approval systems, including its centralized approval procedure or (iii) the marketing authorization applications as per such procedures as the case may be in the context used in a particular section of this Agreement.



1.17 "Second Generation Product" shall mean any product consisting of or containing as an active ingredient any of the following

\*\*\*\*\* (other than G-CSF) which  
\*\*\*\*\*:

(i) \*\*\*\*\*  
\*\*\*\*\*;

(ii) \*\*\*\*\*  
\*\*\*\*\*;

(iii) \*\*\*\*\*;

(iv) \*\*\*\*\*  
\*\*\*\*\*;

(v) \*\*\*\*\*  
\*\*\*\*\*; and

(vi) \*\*\*\*\*  
\*\*\*\*\*.

1.18 "Current GMP Requirements" shall mean those current practices, as amended from time to time, related to the manufacture of biotechnology products and their precursors laid down in guidelines and regulations such as the GMP rules of the World Health Organization, the United States Code of Federal Regulations, the Guide to Inspection of Bulk Pharmaceutical Chemicals (U.S. Department of Health and Human Services, Revised September 1991), the Pharmaceutical Inspection Convention, and the European Community Guide to Good Manufacturing Practice in the production of pharmaceutical products.

1.19 In the terms defined herein, the singular shall include the plural and vice versa.

ARTICLE 2  
GRANTS AND OBLIGATIONS

2.01 (a) AMGEN hereby grants to ROCHE and its Affiliates, under the Patents and Trademarks and the conditions herein imposed, the \*\*\*\*\* right to formulate and fill Finished Product in any country of the Territory or in Switzerland, \*\*\*\*\*.

By mutual agreement between parties hereto, ROCHE shall have the right to have formulated and/or filled Finished Product by a particular independent third party in any country of the Territory or in Switzerland.

All rights of ROCHE and its Affiliates under this subsection (a) shall terminate with regard to each country (including with respect to all Products sold in each such country) on the respective dates set forth in Appendix 2.01 (a) and AMGEN shall formulate and fill each Finished Product itself.

(b) AMGEN hereby grants to ROCHE and its Affiliates, under the Patents and the conditions herein imposed, the \*\*\*\*\* right to use and sell (including the right to promote and detail) each Finished Product in the Territory, \*\*\*\*\*; provided, however, that AMGEN and ROCHE have agreed to certain other terms relating to Spain and Italy which are set forth in Appendix 2.01, which terms shall supplement (and if in conflict shall supersede) all other terms of this Agreement. All rights and obligations specified in Appendix 2.01 shall also apply to any Second Generation Product that becomes a Product pursuant to the terms of Section 2.03.

It is, however, understood that AMGEN shall retain the right to \*\*\*\*\* with \*\*\*\*\* in the Territory as further described hereinbelow.

All rights of ROCHE and its Affiliates under this subsection (b) to use and sell (but not the right to \*\*\*\*\* ) shall terminate for each Product with regard to the countries and upon the respective dates set forth in Appendix 2.01 (b).

(c) AMGEN and ROCHE shall each have the right and obligation to co-develop each Product to be promoted, detailed and sold in all countries of the Territory, as set forth in more detail hereinbelow.

(d) During the Term of this Agreement, AMGEN shall not either, directly or indirectly or expressly or by implication,

\*\*\*\*\*  
\*\*\*\*\*.

(i) \*\*\*\*\*  
\*\*\*\*\* in any country in the Territory or in Switzerland, or

(ii) \*\*\*\*\*  
\*\*\*\*\* in any country of the Territory, except where such arrangements are made primarily for the provision of logistic or related services or back-up supply.

e) AMGEN hereby grants to ROCHE and ROCHE to AMGEN a \*\*\*\*\* right and license in each country in the Territory to that portion of their respective Confidential Information, \*\*\*\*\*, as is necessary to perform their respective obligations as set forth in this Agreement, such right and license to continue in each country of the Territory until the Scheduled Termination Date.

(f) AMGEN hereby grants to ROCHE a \*\*\*\*\* right and license in each country of the Territory to AMGEN's Trademark for use as set forth in this Agreement in connection with each Product to which such Trademark is applicable, such right and license to continue in each country of the Territory until the Scheduled Termination Date.

Except as necessary to perform ROCHE's obligations set forth in this Agreement, ROCHE's right and license under this subsection (f) shall terminate for each Product with regard to the countries and upon the respective dates set forth in Appendix 2.01 (b).

2.02 It shall be a material obligation of each party hereunder to act in accordance with accepted business practices and all material legal requirements in carrying out its rights and responsibilities hereunder.

2.03 Second Generation Product.

(a) General

It is the desire of the parties to develop and commercialize a Second Generation Product for the Territory, subject to and in accordance with the rights, obligations and conditions set forth in this Agreement. Any future decision by AMGEN and



(b) \*\*\*\*\* License

If the agreed upon Second Generation Product includes any technology claimed in or covered by the \*\*\*\*\* PATENTS (as defined in the \*\*\*\*\* License and hereinafter referred to as the "\*\*\*\*\* Patents") in the "\*\*\*\*\* License", ROCHE will grant AMGEN an \*\*\*\*\* sublicense for the Territory under any rights ROCHE may have with respect to the \*\*\*\*\* Patents under the \*\*\*\*\* License. ROCHE shall not \*\*\*\*\* any of its rights under the \*\*\*\*\* License. ROCHE and its Affiliates will commercialize a Second Generation Product in the Territory only under rights granted by AMGEN.

(c) AMGEN Products

\*\*\*\*\*  
\*\*\*\*\*  
\*\*\*\*\*  
\*\*\*\*\*  
\*\*\*\*\*  
\*\*\*\*\*  
\*\*\*\*\*  
\*\*\*\*\* This paragraph shall not apply to G-CSF (Neupogen(R)) or a Second Generation Product which AMGEN or its licensee/partner brings to the Territory in a cell therapy, ex-vivo expansion application.

(d) ROCHE Products

\*\*\*\*\*  
\*\*\*\*\*  
\*\*\*\*\*  
\*\*\*\*\*  
\*\*\*\*\*  
\*\*\*\*\*  
\*\*\*\*\*

(e) Development Costs

As from the Effective Date, AMGEN and ROCHE shall share, in accordance with the then current profit split in Article 7, \*\*\*\*\* in the Territory for a Second Generation Product or a Product, including:

-  
\*\*\*\*\*  
\*\*\*\*\*; and  
9

\*\*\*\*\*  
\*\*\*\*\* License. Such costs shall include \*\*\*\*\* payable to \*\*\*\*\* as follows:

i) \*\*\*\*\* of the NET SALES (as defined in the \*\*\*\*\* License) of the \*\*\*\*\* product described and claimed by \*\*\*\*\* in the \*\*\*\*\* Patents as \*\*\*\*\* (the "\*\*\*\*\* Product"), provided, however, that in the event that

(1) certain \*\*\*\*\* have to be paid to a third party due to a patent issue, in such case the \*\*\*\*\* payable to \*\*\*\*\* shall be \*\*\*\*\*; or

(2) the \*\*\*\*\* Product shall face significant competition from a third party \*\*\*\*\* the \*\*\*\*\* payable to \*\*\*\*\* in any such country shall be \*\*\*\*\*;

provided further that the total deduction in the aggregate from (1) and (2) shall not cause the \*\*\*\*\* payable to \*\*\*\*\* to be less than \*\*\*\*\*.

If both (1) and (2) are applicable, the calculation in (1) shall be made first and then (2) shall be calculated.

ii) For a Second Generation Product other than the \*\*\*\*\* Product the making, using, selling, offering for sale, or importing of which would, but for \*\*\*\*\* License, infringe one or more valid issued claims included in the \*\*\*\*\* Patents, all \*\*\*\*\* as per i) will be \*\*\*\*\*.

iii) For a Second Generation Product the making, using, selling, offering for sale or importing of which does not infringe one or more valid issued claims included in the \*\*\*\*\* Patents, all \*\*\*\*\* as per i) will be \*\*\*\*\*.

iv) The \*\*\*\*\* under iii) above shall be payable so long as the \*\*\*\*\* License is in full force and effect.

Such costs shall also include the \*\*\*\*\* payable to \*\*\*\*\* as follows:

(1)\*\*\*\*\*

\*\*\*\*\* shall be payable no later than \*\*\*\*\*

(2)\*\*\*\*\*

\*\*\*\*\* shall be payable \*\*\*\*\* after the first entry of a patient in a \*\*\*\*\* with a

Second Generation Product in any EU country or the \*\*\*\*\* as agreed to in the time and events schedule in the Clinical R&D Plan (to be established after the completion of the Evaluation Plan), whichever is earlier.

(3)\*\*\*\*\*

\*\*\*\*\* shall be payable \*\*\*\*\* after 50% of patients have been enrolled in a \*\*\*\*\* with a Second Generation Product in any EU country, or to \*\*\*\*\* as agreed to in the time and events schedule of Clinical R&D Plan, whichever occurs earlier.

(4)\*\*\*\*\*

\*\*\*\*\* shall be payable \*\*\*\*\* after the submission of the first Second Generation Product license \*\*\*\*\* to the Authority in \*\*\*\*\* or the \*\*\*\*\* as agreed to in the time and events schedule in the Clinical R&D Plan, whichever is earlier.

(5)With respect to

\*\*\*\*\* of (3) above and \*\*\*\*\* of (4) above, shall be creditable against the payment of \*\*\*\*\* payable to \*\*\*\*\*.

(f) \*\*\*\*\* of Second Generation Products

\*\*\*\*\*  
\*\*\*\*\*  
\*\*\*\*\*  
\*\*\*\*\*

\*\*\*\*\*  
\*\*\*\*\*  
\*\*\*\*\*  
\*\*\*\*\*  
\*\*\*\*\*  
\*\*\*\*\*  
\*\*\*\*\*  
\*\*\*\*\*  
\*\*\*\*\*  
\*\*\*\*\*  
\*\*\*\*\*  
\*\*\*\*\*  
\*\*\*\*\*  
\*\*\*\*\*  
\*\*\*\*\*  
\*\*\*\*\*  
\*\*\*\*\*

i) \*\*\*\*\*  
\*\*\*\*\*  
\*\*\*\*\*

ii) \*\*\*\*\*  
\*\*\*\*\*  
\*\*\*\*\*

iii) \*\*\*\*\*  
\*\*\*\*\*

iv) \*\*\*\*\*  
\*\*\*\*\*  
\*\*\*\*\*

v) \*\*\*\*\*  
\*\*\*\*\*  
\*

(g) Manufacturing



If the agreed upon Second Generation Product is the \*\*\*\*\* Product, \*\*\*\*\* shall have the rights to manufacture the bulk form of the Product for the Territory and supply and deliver it DDP (Incoterms 1990) at a price equal to \*\*\*\*\* (as defined in the \*\*\*\*\* License) of the Product in the Territory. Until such \*\*\*\*\* is available, the Product shall be delivered at the expected average \*\*\*\*\* in the Territory to be agreed by the parties and \*\*\*\*\* . All Second Generation Products other than the \*\*\*\*\* Product will be manufactured, formulated and filled by AMGEN for the Territory.

(h) Miscellaneous

There is nothing in the Kirin-AMGEN Agreements that restricts AMGEN from fulfilling its obligations under this Agreement regarding any Second Generation Product in the Territory.

There is nothing in this Agreement that restricts any party from commercializing in the ROE \*\*\*\*\* and ROW (throughout the world, \*\*\*\*\* a Second Generation Product that is not being commercialized in the EU.

(i) Applicability of Other Provisions of this Agreement

If and when a Second Generation Product becomes a "Product" pursuant to this Section 2.03, then in addition to the provisions of this Section 2.03 the other provisions of this Agreement shall also apply with respect to such Product.

2.04 AMGEN shall have sole ownership of the G-CSF Product and all related rights during the Term and following expiration or termination thereof.

With respect to any Second Generation Product that becomes a Product pursuant to Section 2.03:

(1) if the Product is the \*\*\*\*\* Product or is otherwise covered by the \*\*\*\*\* Patents, then AMGEN shall have the rights described in Section 2.03(b) for the Term and the parties shall \*\*\*\*\* under the \*\*\*\*\* License (taking into account ROCHE's obligations to \*\*\*\*\* ) following expiration or termination of this Agreement;

(2) if the Product is covered by any ROCHE Patents, then ROCHE shall have sole ownership of the Product and all related rights during the Term and following expiration or termination thereof but AMGEN shall have an  
\*\*\*\*\*  
\*\*\*\*\* license to the Product for the Term and the parties shall

\*\*\*\*\* following expiration or termination of this Agreement; and

(3) if the Product is covered by any AMGEN Patents, then AMGEN shall have sole ownership of the Product and all related rights during the Term and following expiration or termination thereof but the parties shall  
\*\*\*\*\* following expiration or termination of this Agreement.

ARTICLE 3  
COLLABORATION IN CLINICAL RESEARCH, DEVELOPMENT,  
REGISTRATION AND MARKETING

3.01 AMGEN and ROCHE shall cooperate in reasonable ways to develop and exchange data and information about each Product so as to obtain the authorization and to develop the ability to formulate, ship and sell the Product in the Territory. Pursuant to the terms of this Agreement, the parties shall use reasonably diligent efforts consistent with prudent business practice to

(i) optimally develop each Product,

(ii) obtain rapidly the necessary governmental authorization and approval to sell each Product in commercial quantities, and

(iii) sell each Product in all countries in the Territory.

3.02 (a) The parties shall each appoint two (2) authorized representatives ("Coordinators") between whom communications will be directed with regard to each Product. Each party will notify the other as to the name of the individuals so appointed. Each party may replace its Coordinators at any time, upon written notice to the other party.

The four (4) Coordinators shall form a joint committee ("Product Management Committee") and shall confer regularly to discuss and to coordinate the effective performance of the terms of this Agreement.

The Product Management Committee is expected to meet regularly to

- (i) review pertinent information and data
  - (ii) approve the budgets proposed by the sub-teams and the countries.
  - (iii) resolve differences of opinion within the sub-teams, if any.
  - (iv) harmonize and coordinate all efforts in view of obtaining authorization and ability to market each Product in each country in the Territory and to further develop, promote and detail each Product in each country of the Territory pursuant to Article 6.
- (b) The Product Management Committee shall establish one or more operating dedicated sub-teams for the whole Territory directed by the Product Management Committee and consisting of representatives of each party which will meet regularly at mutually agreeable times and locations.

3.03 (a) One of the sub-teams of subsection 3.02(b), the joint international clinical development team ("Product Clinical Team") shall consist of two (2) permanent representatives of each AMGEN and ROCHE. Each party may replace its representatives at any time, upon written notice to the other party.

(b) The Product Clinical Team will be responsible to discuss and coordinate the generation and exchange of information and data necessary to obtain and maintain approval of each Product in each country of the Territory, and formulate the strategies, the plans and the programs that should be implemented to most effectively and efficiently obtain such approvals. Illustratively, the Product Clinical Team shall:

- (i) formulate and coordinate plans for the development of data and information necessary to obtain governmental approvals of each Product in each country of the Territory, taking into consideration, if applicable, AMGEN's development plans for the USA and AMGEN's results elaborated in the USA, and
- (ii) coordinate the preparation and the filing of all governmental applications for approvals necessary to distribute and market each Product in each country of the Territory, taking into consideration, if applicable, and using to the extent reasonably possible, AMGEN's clinical development plans as well as any data and submissions to the FDA on each Product.

(c) The Product Clinical Team shall create and execute a Joint Clinical Research and Development Plan for the Territory ("Clinical R&D Plan") which shall describe the clinical program necessary for the preparation and filing of

the first as well as subsequent NDA's in the Territory and any additional studies and/or programs required to support NDA claims and/or to generate scientific publications with due regard for the overall international plan created by AMGEN with input from ROCHE and KIRIN and consideration of pre-clinical and clinical data.

The Clinical R&D Plan will include the description of:

- (i) clinical strategies, rationale, objectives, general program and study designs, location of studies, principal investigator name, time schedules, number of patients planned, status of studies and program, responsibility for monitoring and data handling and any critical issues and recommendations relative to the clinical development of each Product, and
- (ii) strategies, plans and status of IND, NDA and MAA (or equivalent documents, including EMEA) preparation and submission to governmental authorities to obtain authorization to carry out clinical studies and to obtain from all necessary governmental authorities marketing approval of each Product in each country of the Territory.
- (iii) estimates of costs of implementing the approved Clinical R&D Plan and the AMGEN and ROCHE personnel and external personnel and resources required to execute the approved Clinical R&D Plan.
- (d) The Product Clinical Team shall, inter alia, be responsible for the following issues:
  - (i) assuring that the clinical program is carried out to mutually acceptable levels of Good Clinical Practice procedures,
  - (ii) preparing and approving individual study protocols, case record forms, final study reports and any other official clinical research documents,
  - (iii) establishing and maintaining a compatible international computerized database on an AMGEN-based computer to which ROCHE and AMGEN shall have terminal access.
  - (iv) the appropriate collection and transfer of reportable adverse event data to satisfy governmental agencies and post-marketing surveillance throughout the world, and
  - (v) creating and proposing to the Product Management Committee a detailed clinical budget, monitoring actual expenditures versus budget and proposing appropriate revisions to this budget.

(vi) reviewing and approving the promotional materials of each country in the Territory to ensure compliance with approved labeling.

(vii) creating an environment in which the clinical development of each Product can be harmoniously and efficiently carried out.

(e) The provisions of the Clinical R&D Plan and any other R&D matters shall be agreed to by the Product Clinical Team and

approved by the Product Management Committee, and if the Product Clinical Team cannot reach a consensus agreement, then the matter(s) in dispute shall be referred to the Product Management Committee.

(f) In the event that the Product Management Committee is unable to reach a consensus decision on any R&D matter, the President of AMGEN shall be entitled to make the final determination.

3.04 (a) The other of the sub-teams of subsection 3.02(b), the joint marketing team ("Product Marketing Team") shall also consist of two (2) permanent members of each AMGEN and ROCHE. Each party may replace its representatives at any time, upon written notice to the other party.

(b) The Product Marketing Team shall have the responsibility for the marketing functions as set forth in Article 6 of this Agreement.

(c) All items regarding the marketing functions shall be agreed to by the Marketing Team and approved by the Product Management Committee, and if the Product Marketing Team cannot reach a consensus agreement, then the matter(s) in dispute shall be referred to the Product Management Committee.

(d) In the event that the Product Management Committee is unable to reach a consensus decision on marketing matters, the President of AMGEN shall be entitled to make the final determination.

3.05 AMGEN and ROCHE shall promptly furnish each other with all Confidential Information in its possession and control with respect to each Product in the Territory, which has not been previously furnished to the other and which may aid the other in performing its responsibilities under this Agreement.

Moreover, the parties will provide each other, through the Product Clinical Team, with the results of all of its pre-clinical and clinical studies on G-CSF throughout the world, and with

- (i) quarterly status reports and data on its clinical development efforts with respect to G-CSF outside the Territory to which the other party may not have access otherwise;
- (ii) data and information on animal and human studies relative to G-CSF known to it; and
- (iii) information and data regarding G-CSF which was submitted or will be submitted by ROCHE or its Affiliates, AMGEN or its Affiliates, or KIRIN (to the extent possible

according to contractual relations) to governmental authorities throughout all countries of the world outside the Territory to obtain authorization to initiate investigational use in humans and/or to obtain approval to market G-CSF in commercial quantities in such countries, including but not limited to control, pre-clinical and clinical information and data.

- 3.06 The results of all clinical studies and experiments with respect to each Product conducted in connection with this Agreement, and related technical information, shall be delivered promptly to AMGEN by ROCHE and to ROCHE by AMGEN, and may be used by each and its Affiliates, as well as KIRIN, in connection with further development and marketing of each Product and applications to governmental authorities throughout the world.
- 3.07 In accordance with the Clinical R&D Plan, AMGEN (or in the case of a Second Generation Product that becomes a Product, either AMGEN or ROCHE, as mutually agreed by the parties) shall supply quantities of each Product in a form suitable for clinical trials which would enable the parties to continue to analyze each Product and to initiate and to continue tests including, but not limited to, pharmacological, toxicological, microbiological, and clinical tests on each Product as well as material for formulation tests on the Product which in both the Product Clinical Team's as well as in the Product Marketing Team's reasonable judgment may be necessary to obtain the authorization and the ability to formulate the Finished Product in any country of the Territory as well as to ship and sell each Product in the Territory.
- 3.08 AMGEN and ROCHE will promptly seek and use its best efforts to obtain all necessary FDA, EMEA and other applicable governmental authorizations throughout the world required for the party supplying each Product pursuant to Section 3.07 to manufacture, ship and export each Product from the USA (or other country of export) to all countries in the Territory and in Switzerland for the parties to be able to conduct pre-clinical and clinical trials.

3.09 During the Term of this Agreement, each party shall promptly furnish the other party with information concerning unexpected side effects, injury, toxicity or sensitivity reactions or unexpected incidence and severity thereof associated with animal or clinical uses, studies, investigations or tests with each Product, whether or not determined to be attributable to each Product.

3.10 Each party, free of charge, shall also permit a reasonable number of representatives of the other party to this Agreement or its Affiliates at reasonable time and upon reasonable notice, to observe, review, make copies of, and/or

discuss the results of studies and/or submissions (except studies or submissions relating to manufacturing the Bulk Product to the extent not necessary for seeking marketing approval) to the governmental authorities concerning each Product with scientists or clinicians employed by it (or its Affiliates) or doing research under its auspices, at any location mutually agreeable to the parties hereto.

ARTICLE 4  
OWNERSHIP, PREPARATION AND FILING OF  
EMEA, CPMP, NDA's and MA/V's

4.01 In connection with its tasks contained in Section 3.03 hereinabove, the Product Clinical Team shall prepare and complete a marketing application and variations for new indications and new galenical forms pursuant to the CPMP/EMEA "bio/high tech" concertation procedure ("MA/V Filing") with respect to each Product for use in each country of the Territory.

Such MA/V shall contain all data and information deemed necessary to obtain and maintain approval of the respective marketing authorizations (including variations) in each country of the Territory ("Country MA/V") with respect to the indications of each Product agreed upon by the Product Clinical Team.

Notwithstanding the foregoing, if applicable, the MA/V Filing shall instead be made pursuant to the centralized approval procedure of the EMEA (or other then applicable and appropriate procedure) in order to obtain and maintain approval of the centrally approval marketing authorization (including variations) for the EU (the "EU MA/V").

4.02 All data, information, results, etc., including Confidential Information, contained in the  
\*\*\*\*\*  
\*\*\*\*\*, provided, however, that  
\*\*\*\*\*  
\*\*\*\*\* and all data, information, results, etc., including Confidential Information, as is necessary for ROCHE to perform its duties as set forth in this Agreement and the  
\*\*\*\*\* License.

4.03 (a) \*\*\*\*\* shall have the \*\*\*\*\* in the preparation and filing of the  
\*\*\*\*\*  
\*\*\*\*\*  
\*\*\*\*\*, respectively, with the respective authorities of the rapporteur country of the Territory and lodged with the CPMP/EMA secretariat.  
\*\*\*\*\*  
\*\*\*\*\*  
respectively, with the respective authorities in each country of the Territory, \*\*\*\*\*.

(b) \*\*\*\*\*, respectively, subject to consultation with and approval by the Product Clinical Team, shall be responsible for filing responses to questions and comments received from governmental authorities with respect to Country MA/V's and for filing reports necessary to maintain Country MA/V's.

In carrying out such responsibilities, AMGEN and its Affiliates, and ROCHE and its Affiliates shall advise the Product Clinical Team of all communications by them with governmental authorities that may be considered significant and shall, if requested by the Product Clinical Team, submit for prior review all proposed filings.

4.04 (a) AMGEN and ROCHE shall, in principle, attend all meetings, if any, with CPMP, EMA and other drug regulatory personnel of the EU. AMGEN shall have the lead role in making presentations in such meetings.

(b) AMGEN and its Affiliates, respectively, subject to consultation with and approval by the Product Clinical Team, shall be responsible for responding to questions and comments received from governmental authorities.

(c) In the event that the Product Clinical Team or the parties are unable to reach a consensus decision on any regulatory matter, AMGEN shall be entitled to make the final determination.



4.05 (a) With regard to the countries and upon the respective dates set forth in Appendix 2.01 (b):

(i) the rights and obligations of \*\*\*\*\* in Sections 4.03 (a) and (b) shall terminate and thereafter the following shall apply in lieu thereof with respect to each Product: \*\*\*\*\* shall have the lead role in preparation and filing of the \*\*\*\*\* and shall file the \*\*\*\*\* in its \*\*\*\*\* with the EMEA (or other than applicable regulatory agency). The parties shall mutually agree on the method

of the filing(s), if any, necessary to enable \*\*\*\*\* and \*\*\*\*\* to sell each Product in the Territory pursuant to the terms of this Agreement. \*\*\*\*\* shall be the holder of each \*\*\*\*\* and \*\*\*\*\* , respectively, subject to consultation with and the approval by the Product Clinical Team, shall be responsible for filing responses to questions and comments received from any and all regulatory authorities with respect to the \*\*\*\*\* . Following receipt of the \*\*\*\*\* or \*\*\*\*\* will file reports necessary to maintain the MA/V or EU MA/V and respond to inquiries and comments from any and all regulatory authorities. In carrying out such responsibilities, \*\*\*\*\* shall advise the Product Clinical Team of all communications by them with governmental authorities that may be considered significant and shall, if requested by the Product Clinical Team, submit for prior review all proposed filings.

(ii) all data and documents with respect to a \*\*\*\*\* shall be handed over by \*\*\*\*\* to \*\*\*\*\* , which shall be entitled to use such data and documents for its own purposes and for the purposes of this Agreement.

(iii) \*\*\*\*\* shall cooperate with \*\*\*\*\* on a timely basis and in every proper way to \*\*\*\*\* to \*\*\*\*\* and \*\*\*\*\* shall seek, and use its best efforts to obtain, the necessary authorization from the pertinent governmental authorities \*\*\*\*\*

(iv) to the extent necessary, applicable governmental authorizations and approvals in the country shall be \*\*\*\*\* to the extent permitted by laws and regulations, from \*\*\*\*\* to \*\*\*\*\* for such transfer shall be charged to the \*\*\*\*\* provided for hereunder.

Notwithstanding the foregoing, ROCHE shall retain its rights and obligations under this Article 4 with respect to Italy (ROCHE-Trademark) (Granulokine(R)) until the Scheduled Termination Date.

ARTICLE 5  
SUPPLY

- 5.01 With respect to the Territory, AMGEN shall supply ROCHE, \*\*\*\*\* and under the terms of this Agreement, with requirements of Finished Product for clinical purposes and Bulk Product for all developmental and commercial purposes for all countries of the Territory and shall obtain authorization from the FDA to manufacture, ship and export from the USA Bulk Product and Finished Product for clinical purposes in and to any appropriate countries of the Territory or Switzerland.
- 5.02 (a) For the whole Territory, the Product Marketing Team shall provide AMGEN (i) within \*\*\*\*\* of signing this Agreement a preliminary \*\*\*\*\* forecast of the total requirements for Bulk Product, and (ii) at least \*\*\*\*\* before the beginning of each calendar year with a \*\*\*\*\* forecast of the total requirements for the Bulk Product in the respective calendar year.
- (b) Thereafter, a revised estimate of the requirements will be given prior to each calendar quarter for the subsequent four calendar quarters.
- (c) Within \*\*\*\*\* before the date ROCHE requires to receive the amount of Bulk Product as per subsections (a) and (b) of this Section 5.02, ROCHE shall place firm orders setting forth the quantities of Bulk Product to be supplied by AMGEN.

(d) ROCHE's firm orders shall specify reasonable delivery dates and instructions for shipping and packaging as aforesaid. If there is any inconsistency between any of the terms and conditions of a ROCHE order and the terms and conditions of this Agreement, the terms and conditions of this Agreement shall prevail.

5.03 AMGEN will manufacture Bulk Product and ROCHE will formulate and fill Finished Product strictly

(i) in accordance with established written manufacturing procedures and Finished Product specifications according to Current GMP Requirements,

(ii) which will meet the requirements set forth in accordance with applicable laws and regulations for shipment of the Bulk Product into any of the countries of the Territory or into Switzerland, and

(iii) which will meet the requirements set forth in all governmental submissions filed by ROCHE or AMGEN with regulatory agencies for the manufacture of the Bulk Product into Finished Product.

Each party shall promptly advise the other party of any new instructions or specifications required by the foreign regulatory agencies and the parties shall confer with respect to the best mode of compliance with such requirements.

5.04 (a) AMGEN will provide ROCHE with a certificate of analysis for each lot of Product produced. In order to comply with Current GMP Requirements, ROCHE requests and AMGEN agrees to supply ROCHE with all procedures, including SOP's, allowing ROCHE to perform:

(i) The analyses of the Product upon arrival at ROCHE's designated facility(ies), and

(ii) The analyses of the finished pharmaceutical form before ROCHE supplies to the trade or the Clinical Research Centers.

(b) On receipt of a delivery of the Bulk Product ordered, ROCHE shall check whether it complies with the specifications. Any discernible non-compliance has to be reported in writing to AMGEN immediately, together with all test data, at the latest within \*\*\*\*\* after receipt of the delivery. At the same time ROCHE sends the written notification, ROCHE shall also send to AMGEN a sample of the Bulk Product delivered. Otherwise, it will be assumed that

the Bulk Product delivered has been approved. In the event of a duly claimed and justified notice of non-compliance, AMGEN shall make good the order by delivering new material.

- 5.05 AMGEN will use its best efforts to comply with the sales forecasts, estimates and orders provided for under this Article and to ship Bulk Product in accordance with ROCHE's firm orders, and ROCHE will use its best efforts to formulate and fill Product promptly and efficiently so as to ensure that a sufficient supply of Product is available to commence and continue distribution of the Product in each country of the Territory as soon as reasonably practicable with reasonably adequate inventory. The Bulk Product shall be shipped "DDP (Incoterms 1990)" to ROCHE's facility. In

addition, AMGEN shall use its best efforts to have \*\*\*\*\* to it which can produce an amount of Bulk Product which is at least \*\*\*\*\* over the Product Marketing Team sales estimates for the forthcoming year.

- 5.06 Should, at any future time, ROCHE's requirements of Bulk Product exceed the anticipated requirements for a calendar year, ROCHE shall provide AMGEN, as soon as practicable, with reasonable written notice to this effect with an indication of the total amount of such excess requirements. AMGEN shall use its best efforts to supply such excess requirements and shall, within \*\*\*\*\* from the receipt of such notice, advise ROCHE in writing as to AMGEN's ability to provide such supply.

- 5.07 (a) AMGEN shall furnish ROCHE full descriptions and instructions concerning the methods, formulae and standards to be employed by ROCHE to formulate and fill Finished Product, including such written procedures, flow sheets, specifications for raw materials, packaging materials and finished dosage units as well as in-process control procedures and other process and control data necessary for the formulation and filling of the Finished Products. AMGEN shall provide ROCHE from time to time during the Term of this Agreement with any modifications or supplements to the information previously furnished to ROCHE.

(b) As far as possible AMGEN is ready, at the request of ROCHE, to temporarily delegate AMGEN manufacturing experts to give advice to ROCHE concerning the analytical methods, formulation and filling of the Finished Product and to instruct its personnel.

5.08 In the event that the Bulk Product cannot be exported out of the USA and into any of the countries of the Territory or Switzerland to a facility of ROCHE's designation, AMGEN shall be responsible, at its cost, for arranging non-U.S. manufacture and shipping of Bulk Product to ROCHE for commercial purposes.

(a) In the event that AMGEN is unable or unwilling to supply an adequate quantity of Bulk Product from its own facilities or third party facilities, ROCHE will make its manufacturing facilities available to AMGEN for manufacture of Bulk Product with priority equal to its other products.

(b) Subsection (a) of this Section 5.08 shall apply mutatis mutandis if ROCHE is unable or unwilling to formulate and/or fill or have formulated or filled Finished Product.

5.09 AMGEN will use its best efforts to arrange for shipment of Bulk Product to ROCHE. If other sources or Product for clinical trials are unavailable, ROCHE will make its

manufacturing facilities to AMGEN for manufacture of Product for clinical trials.

5.10 (a) All of ROCHE's rights and obligations under this Section 5 shall terminate with regard to the countries and upon the respective dates given in Appendix 2.01 (a) and, as from such dates, AMGEN shall manufacture, fill, formulate, ship and otherwise supply and invoice all Finished Product in such countries. Notwithstanding the foregoing, ROCHE shall continue to invoice the Finished Product in Italy (ROCHE-Trademark (Granulokine(R)) only) until the Scheduled Termination Date and in Greece until the time, if any, that AMGEN assumes primary responsibility for marketing the Product in Greece.

As from the respective dates and countries in Appendix 2.01

(a) the following provisions shall apply:

(i) ROCHE's overall bulk supply forecasts and delivery schedules shall be adjusted to exclude Product amounts targeted for the country;

(ii) ROCHE shall terminate formulating and filling of Finished Product intended to be sold in the country and ROCHE's inventory of Finished Product targeted for such country shall be handled as agreed by the parties;

(iii) Sales revenues and/or out of pocket expenses as well as direct and indirect internal costs for the country, accrued until such date but not yet received or paid by ROCHE, shall be considered to be outstanding.

(b) The parties have agreed that AMGEN will supply requirements for Italy and Greece with formulated, filled and Finished Product on the respective dates set forth in Appendix 2.01 (a), provided that: (1) AMGEN's production and distribution facility in The Netherlands must have been approved as a distribution and production site to the extent required by regulatory requirements in Italy or Greece, as the case may be; (2) Finished Product for Greece and Finished Product (ROCHE - Trademark) (Granulokine(R)) for Italy with ROCHE make-up in accordance with regulatory requirements in Italy or Greece, as the case may be, shall be delivered by AMGEN to ROCHE (CIP) (Incoterms 1990) (ROCHE's warehouse Basel, Switzerland) for shipping and invoicing by ROCHE to customers in Italy or Greece, as the case may be; (3) Finished Product (Neupogen(R)) for Italy with make-up in accordance with regulatory requirements in Italy shall be supplied, delivered, shipped and invoiced by AMGEN as required by arrangements, if any, between AMGEN and any distributor in Italy; and (4) any changes to the then current pack, its size and dimensions, its text on the product, pack and enclosures (i.e.: SmPC and PIL) or other like changes

must have been approved in compliance with regulatory requirements in Italy or Greece. In addition, as from AMGEN assuming such supply requirements in Italy (ROCHE-Trademark) (Granulokine(R)) or Greece, the following terms shall apply:

- (i) The Finished Product will be manufactured, formulated and filled according to Current GMP Requirements and will conform to the lot release specifications accepted by the appropriate regulatory authorities and contained in the Country MA/V or EU MA/V (the "Specifications"). ROCHE shall notify AMGEN of any changes to the Specifications required by the rules, regulations or requirements of the appropriate regulatory authorities.
- (ii) AMGEN will provide ROCHE with a certificate of analysis for each lot of Finished Product produced. In order to comply with Current GMP Requirements, ROCHE requests and AMGEN agrees to supply ROCHE with all procedures, including SOP's, allowing ROCHE to perform the analysis of the Finished Product upon arrival at ROCHE's designated warehouse.
- (iii) On receipt of a delivery of the Finished Product ordered, ROCHE shall check whether it complies with the Specifications. Any discernible noncompliance has to be reported in writing to AMGEN immediately, together with all test data, at the latest within six (6) weeks after receipt of the delivery. At the same time ROCHE sends the written notification, ROCHE shall also send to AMGEN a sample of the Finished Product delivered. Otherwise, it will be assumed that

the Finished Product delivered has been approved. In the event of a duly claimed and justified notice of non-compliance, AMGEN shall make good the order by delivering new material.

- (iv) AMGEN will use its best efforts to supply Finished Product promptly and efficiently so as to ensure that a sufficient supply of Finished Product is available for distribution as soon as reasonably practicable with reasonably adequate inventory.
- (v) In order to facilitate AMGEN's supply planning, ROCHE shall provide AMGEN during the first month of every calendar quarter with the estimate of ROCHE's requirement of the Finished Product for the next twenty-four (24) months. ROCHE shall furnish AMGEN firm purchase orders for its planned requirements not later than sixty (60) days prior to the requested

shipdate. AMGEN may supply but shall not be obligated to supply in any one month more than fifty percent (50%) of ROCHE's quarterly estimate.

- (vi) Pricing for the Finished Product delivered by AMGEN to ROCHE will be established annually by the parties, but shall include \*\*\*\*\* and \*\*\*\*\* for the \*\*\*\*\*. Freight and insurance will be paid for by AMGEN but included in AMGEN's variable costs. ROCHE's payment for Finished Product shall be made not later than \*\*\*\*\* following ROCHE's receipt of delivery.

5.11 Notwithstanding anything in this Article 5 and in lieu of the foregoing provisions, the following shall apply to the supply of any Second Generation Product that becomes a Product pursuant to the terms of Section 2.03 hereof:

- (a) Clinical Supply. The clinical supply of the Product shall be manufactured and supplied at cost by AMGEN or ROCHE as mutually agreed and shall be subject to provisions of Section 3.07 and 3.08.
- (b) Commercial Supply. If the Product is the \*\*\*\*\* Product, the parties shall negotiate an agreement with \*\*\*\*\* pursuant to which \*\*\*\*\* will enter into a definitive agreement with either AMGEN or ROCHE to manufacture the Bulk Product for the Territory and supply it to AMGEN for formulation, filling, labeling and packaging by AMGEN into Finished Product. If the Product is not the \*\*\*\*\* Product, AMGEN shall manufacture, formulate, fill, label and package into Finished Product. In either case, AMGEN shall invoice (except as specified in Section 2.03(f)) and distribute the Finished Product.

(c) Standards of Supply. Bulk Product will be manufactured and Finished Product formulated and filled strictly:

(i) in accordance with established written manufacturing procedures and Finished Product specifications according to Current GMP Requirements,

(ii) which will meet the requirements set forth in accordance with applicable laws and regulations for shipment of the Bulk Product or Finished Product into any countries of the Territory or into Switzerland, and

(iii) which will meet the requirements set forth in all governmental submissions by AMGEN with regulatory agencies for the manufacture of the Bulk Product into Finished Product.

ARTICLE 6  
MARKETING

6.01 (a) ROCHE and AMGEN shall use best efforts consistent with accepted pharmaceutical business practices and legal requirements to deploy their sales forces to promote and detail each Product in the Territory on a country-by-country basis in such manner and with such expedition as they would have adopted in launching, promoting, detailing, selling and marketing a pharmaceutical product of their own innovation and consistent with the approved country Marketing Plan.

(b) AMGEN shall use its best efforts consistent with accepted pharmaceutical business practices and legal requirements:

(i) to build a new organization in particular countries of the Territory which can perform AMGEN's responsibilities hereunder;

(ii) to promote, detail, sell and market each Product in each country in the Territory in which it has a sales force.

6.02 (a) In developing a marketing strategy, the Product Marketing Team will review and approve the promotion, detailing and marketing plans of the Product in the Territory and the strategies and programs to maximize sales of each Product in each country of the Territory.



Illustratively, the Product Marketing Team shall

- (i) using any AMGEN core program as a guide, review and approve the prelaunch activities and the launch plans of each Product in each country in the Territory; and
- (ii) make suggestions for continuing promotion and detailing efforts with respect to each Product in the Territory, taking into account AMGEN's experience inside and outside the Territory;
- (iii) ensure the exchange of promotional material and experiences, both within and outside the Territory.

(b) In each country of the Territory, on a country-by-country basis, ROCHE will have the final responsibility, with the cooperation and assistance of AMGEN, over marketing matters provided however, after \*\*\*\*\* and upon \*\*\*\*\* notice to ROCHE prior to the beginning of a \*\*\*\*\* , AMGEN may assume such final responsibility and control for such

\*\*\*\*\* and \*\*\*\*\* thereafter in Greece or any new EU country.

ROCHE's rights and obligations to assume final responsibility and control over marketing matters for each Product has or will terminate with regard to the countries and upon the respective dates set forth Appendix 6.02 (b) and AMGEN has or shall therefore assume such final responsibility and control in such countries and as of such dates, however ROCHE shall continue to participate in the Product Marketing Team as it has done before except that ROCHE will not have final responsibility and control thereover.

(c) The Product Marketing Team shall meet annually in the Territory or in Switzerland in order to review marketing plans for specified periods for the Territory ("Marketing Plan").

A Marketing Plan generally consists of the following elements:

- (i) Prerequisites
  - Product Profile
  - Patent Status
  - Trade Mark
  - Price and Reimbursement
  - Packaging
  - Manufacturing and Logistics

(ii) Targets

- Unit Sales
- Market Share

(iii) Strategy/Objectives

- Positioning (in therapy)
- Target Audience
- Media Selection
- Marketing Investment

(iv) Implementation

- Priority in Relation to Other Products
- Time Table
- Field Staff (training, sales-time, incentives)
- Medical Marketing and Publications
- Congresses, Symposia, Round-Tables
- Sampling
- Journal Advertising
- Direct Mail
- Public Relations

(v) Budget

(d) The provisions of the Marketing Plan shall be reviewed by the Product Marketing Team and approved by the Product Management Committee, and if the Product Marketing Team cannot reach a consensus agreement, then the matters in dispute shall be referred to the Product Management Committee.

(e) ROCHE shall have the final responsibility for the Marketing Plan; provided, however, that after \*\*\*\*\* and upon \*\*\*\*\* notice to ROCHE prior to the beginning of a \*\*\*\*\*, AMGEN may assume such final responsibility and control over the Marketing Plan for each Product for such \*\*\*\*\* and \*\*\*\*\* thereafter in Greece or any new EU country.

All of ROCHE's rights and obligations to assume final responsibility for the Marketing Plan for each Product has or will terminate with regard to the countries and upon the respective dates given in Appendix 6.02 (b) and AMGEN has or shall therefore assume such final responsibility and control in such countries and on such dates, however ROCHE shall continue to participate in developing and formulating the Marketing Plan in that country as it has done before except that ROCHE will not have final responsibility and control thereover.

(f) Notwithstanding who has final responsibility or control, a party shall have the right to comment upon and make marketing recommendations to the other party regarding the other party's activities under this Agreement, which recommendations the other party shall thoroughly evaluate and consider, taking into account the other party's expertise and experience.

6.03 In each country in the Territory and subject to any other provision of this Agreement, each party will provide the other with all information helpful for the detailing and promotion of each Product within a reasonable time after such information becomes known to the party, provided such information is not received under a secrecy obligation to a third party or is otherwise restricted.

6.04 \*\*\*\*\* in which  
\*\*\*\*\* ,  
ROCHE and AMGEN shall create and develop through the Product Marketing Team and under the guidance and supervision of the Product Management Committee, respectively, core sales and promotional materials relating to each Product for distribution to independent third parties of the medical and

health community in the Territory. In so doing, any AMGEN core program shall be considered.

AMGEN and ROCHE may each develop promotional or sales training materials intended to be used outside the Territory and, if such materials are used (or adapted for use) in the Territory with the prior approval of the Product Marketing Team, charge an appropriate portion of the related costs to the Operating Profit and Operating Loss account hereunder. To the extent that materials developed for the Territory are modified and used outside the Territory, the party using such materials outside the Territory shall pay or reimburse to the AMGEN/ROCHE Operating Profit or Loss ten percent (10%) of the costs incurred in developing such materials for the Territory.

ROCHE's Affiliates are requested to use such core materials as much as possible but are free to adapt them as they see fit. With just cause, ROCHE's Affiliates can develop their own materials which will be submitted for review to the Product Marketing Team.

ROCHE shall provide AMGEN through the Product Marketing Team and the Product Management Committee, respectively, with such materials, in amounts which are reasonable under the terms of the Marketing Plan for the promotion and detailing by AMGEN in cooperation with ROCHE in a given country to members of

the medical and health community. It is understood that AMGEN shall supply, \*\*\*\*\* to ROCHE samples of sales and promotional material which AMGEN intends to use outside the Territory so that ROCHE, with the assistance and cooperation of AMGEN through the Product Marketing Team and the Product Management Committee, respectively, may at its discretion modify or have modified the material and distribute it to members of the medical and health community in the Territory; the same applies to samples of promotional material being created by ROCHE outside the Territory.

This Subsection 6.04 shall apply mutatis mutandis should AMGEN assume final responsibility in a country.

- 6.05 Neither party shall have any responsibility for the hiring, firing or compensation of the other party's employees or for any employee benefits. No employee or representative of a party shall have any authority to bind or obligate the other party to this Agreement for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other party without said party's authorized written approval.
- 6.06 All of the transition dates referenced in Appendices 2.01 (a) and (b) shall apply as from such dates regardless of any delay or inability to transfer any government authorizations or approvals on or prior to any such dates; provided, however, that in the event that any required MA/V's cannot be transferred as of any such dates through no fault of ROCHE, then AMGEN shall defend ROCHE, its agents, directors, officers and employees ("Representatives") at its cost and expense, and will indemnify and hold harmless ROCHE and its Representatives from and against any and all claims for losses, costs, damages, fees or expenses incurred by ROCHE as the MA/V holder to the extent they arise out of or in connection with any action or failure to act by AMGEN. Any such claim shall be controlled by the provisions of Section 9.02 (c) hereof.

As from the Effective Date, ROCHE's sales force shall continue active participation at a reduced level. The parties shall, as part of the annual budget process, determine the specific participation and role of the ROCHE sales force on a country-by-country basis. If the parties are unable to reach a consensus determination, the President of AMGEN shall be entitled to make the final determination. The parties have agreed to the level of ROCHE's sales force participation for 1997 and 1998, with a copy of the 1998 participation set forth in Appendix 6.06. Beginning in 1998 and thereafter, the level of ROCHE's sales force participation in the Territory

as a whole (aggregating the ROCHE sales forces for all Products in all countries in the Territory) shall roughly approximate ROCHE's then current profit participation in Article 7; provided however, that the ROCHE sales force participation for all Products shall not exceed the level already established for 1997 on a country-by-country basis.

Notwithstanding the foregoing, following a proposal by ROCHE to AMGEN of reasonable proposed plans acceptable to AMGEN (with acceptance by AMGEN not to be withheld arbitrarily) to include a sales force non-billable to the Operating Profit or Loss for any Product in any country of the Territory, ROCHE shall be entitled to have a sales force for any such Product in any country in the Territory if and for so long as: (1) it bears all of the costs (direct and indirect) associated therewith (i.e. - such costs are not included in the Operating Profit or Loss), (2) the activities of such sales force are consistent with the approved applicable country Marketing Plans and (3) any and all sales of each such Product by such sales force are included in the Operating Profit or Loss.

Notwithstanding anything in this Agreement, with regard to the participation rights conferred upon ROCHE in Articles 2 through 6 of this Agreement neither AMGEN nor the Operating

Profit or Loss shall bear any direct or indirect costs (i.e. - such costs are not included in the Operating Profit or Loss) relating to or in connection with any of such rights, except those costs reasonably necessary to support the agreed ROCHE sales force charged to the Operating Profit or Loss.

6.07 The following provisions of Sections 6.07 (a) and (b) shall apply on a country-by-country basis only with respect to and during the period in which ROCHE maintains a sales force in that country billable to the Operating Profit or Loss (or non-billable if AMGEN agrees that such provisions shall not apply) and in all other countries each Product shall be presented solely as an AMGEN product:

(a) With respect to each Product, AMGEN and ROCHE will be presented and described, by each party hereto, to the medical and paramedical communities, investors, the press and the trade as joining in the development, detailing and promotion of each Product in the Territory, and all written information (including, but not limited to, educational materials, journal advertisements, direct mail, sales pieces and other promotional material) and, to the extent practicable, all oral information, disseminated or presented, respectively, to such communities and trade regarding the detailing and promoting of each Product in the Territory will state this

collaboration. Neither party shall distribute or have distributed any such information which bears the name of the other without the prior written approval of the other, which approval shall not be unreasonably withheld. Major public announcements, especially those of regulatory filing and approvals, will include the names of both AMGEN and ROCHE and will recognize the innovative role of AMGEN, the important contributions of ROCHE and the joint AMGEN/ROCHE efforts to complete registration and launch. Each Product shall be represented solely as an AMGEN/ROCHE product.

(b) When packaged, and to the extent permitted under the law of each country of the Territory, each Product will bear the Trademark and the label of AMGEN/ROCHE.

(c) Each party at its option may issue press releases or other public announcements relating to each Product or the Agreement contemplated by this Agreement, provided, however, that without the prior approval of the other party, neither party shall issue a press release or public announcement which has, as a major focus, either the joint development, detailing and promotion of any Product in the Territory or such agreement, which approval shall not be unreasonably withheld. Moreover, neither party may issue a press release or other public announcement which mentions the other party by name, without the prior written approval of the other

party, which approval shall not be unreasonably withheld. Notwithstanding the foregoing, either party may issue such press releases or make such public disclosures as may be required by law or regulation.

ARTICLE 7  
COMPENSATION

7.01 (a) In each calendar year during the Term of this Agreement, AMGEN and ROCHE shall share on the  
\*\*\*\*\*  
\*\*\*\*\*, the \*\*\*\*\* or \*\*\*\*\* for each Product for such calendar year for each country in the Territory.

\*\*\*\*                    \*\*\*\*\*                    \*\*\*\*\*  
  
\*\*\*\*                    \*\*                                    \*\*  
\*\*\*\*                    \*\*                                    \*\*  
\*\*\*\*                    \*\*                                    \*\*  
\*\*\*\*\*                    \*\*                                    \*\*  
\*\*\*\*\*  
\*\*\*\*\*

(b) "\*\*\*\*\*" or "\*\*\*\*\*" for each Product in a country is determined and further defined in the Supplementary Agreement and shall be calculated and converted into Swiss francs prior to the Effective Date and shall be calculated and converted into U.S. Dollars thereafter.

(c) In determining \*\*\*\*\* or \*\*\*\*\* be considered an \*\*\*\*\* with respect to G-CSF shall mean \*\*\*\*\* on account of \*\*\*\*\* in a country in the Territory in a calendar year, which \*\*\*\*\* is payable by \*\*\*\*\* for the calendar year to \*\*\*\*\* in respect of the making, use or sale of G-CSF in or for any country in the Territory. \*\*\*\*\* with respect to a Second Generation Product that becomes a Product pursuant to Section 2.03 shall mean \*\*\*\*\* on account of \*\*\*\*\* in the case the Product is the \*\*\*\*\* Product) in a country in the Territory in a calendar year, which \*\*\*\*\* is payable by \*\*\*\*\* or \*\*\*\*\* (including the \*\*\*\*\* payable to \*\*\*\*\* set forth in Section 2.03 (e) necessary to \*\*\*\*\* under the \*\*\*\*\* License) to any \*\*\*\*\* in respect of the making, use or sale of the Product for any country in the Territory.

The \*\*\*\*\* paid prior to the Effective Date (specified as a percentage of \*\*\*\*\*) included the following:

Party	*****
*****	****
*****	**
*****	***

The \*\*\*\*\* payable on and after the Effective Date shall include, but not be limited to, the following \*\*\*\*\* (specified as a percentage of \*\*\*\*\*):

Party	*****
*****	*****
*****	*****
*****	*****
*****	****
*****	**

ASTERISKS (\*) INDICATE CONFIDENTIAL INFORMATION OMITTED AND FILED SEPARATELY WITH THE SEC

Notwithstanding the foregoing, no other \*\*\*\*\* payable to \*\*\*\*\* shall be considered \*\*\*\*\* included in \*\*\*\*\* (i.e. \*\*\*\*\* not to exceed \*\*), unless otherwise negotiated between the parties pursuant to Sections 2.03 (c) or 2.03 (d).

Each party will provide documentation satisfactory to the other to confirm to such other party's reasonable satisfaction that the \*\*\*\*\* payments to such \*\*\*\*\* for a calendar year are required pursuant to agreements in respect of the making, use or sale of each Product in or for any country in the Territory in the given calendar year. \*\*\*\*\* .

(d) As from the Effective Date, in determining \*\*\*\*\* shall be \*\*\*\*\* incurred by \*\*\*\*\* in the Territory (and outside the Territory to the extent benefiting potential sales reasonably expected by both parties of the Product in the Territory) for all indications of each Product. Included in such \*\*\*\*\* shall be the following \*\*\*\*\* incurred after the Effective Date, some of which were previously considered \*\*\*\*\* .

\*\*\*\*\* shall consult with \*\*\*\*\* prior to incurring any \*\*\*\*\* in connection with formulation and fill and supply activities.

#### ARTICLE 8 REPORTS AND PAYMENTS

8.01 During the Term of this Agreement, each party shall provide to the other party the necessary information so that \*\*\*\*\* may be calculated. Each local ROCHE Affiliate or AMGEN Affiliate, respectively, will send to ROCHE and AMGEN, respectively, the \*\*\*\*\* . ROCHE and AMGEN, respectively, will each calculate the \*\*\*\*\* . The respective \*\*\*\*\* by Affiliate and total \*\*\*\*\* will be exchanged within one hundred and twenty (120) days after the end of each calendar year between AMGEN and ROCHE. AMGEN/ROCHE \*\*\*\*\* will be \*\*\*\*\* and approved by the party not responsible for \*\*\*\*\* within \*\*\*\*\* upon receipt thereof.



Resulting estimated \*\*\*\*\*  
calculated in accordance with Section 7.01 will be settled  
and paid according to the following schedule:

(a) \*\*\*\*\* settlements will be made based on  
\*\*\*\*\* based on the pro  
rata budget for said quarter, as determined by party  
responsible for reporting. A respective country will be  
settled on a \*\*\*\*\* basis if the country's  
\*\*\*\*\* do not exceed significantly the  
\*\*\*\*\* of all countries in the  
Territory. Cash transfer in connection with the \*\*\*\*\*  
settlements will take place \*\*\*\*\* after the end of  
each \*\*\*\*\*.

(b) \*\*\*\*\* will be made based on  
the \*\*\*\*\* as outlined in the Supplementary  
Agreement and will consider the prevailing \*\*\*\*\*  
settlements. Cash transfer in connection with the  
\*\*\*\*\* will take place within  
\*\*\*\*\* after \*\*\*\*\* and \*\*\*\*\* of the respective  
calendar year.

8.02 As from the Effective Date, all sums due to a party under  
this Agreement will be payable by the other party in U.S.  
Dollars to the following address:

For AMGEN:  
AMGEN INC.  
1840 DeHavilland Drive  
Thousand Oaks, California 91320 U.S.A.

For ROCHE:  
F. HOFFMANN-LA ROCHE LTD  
Grenzacherstrasse 124  
CH-4070 Basel, Switzerland

or any other place or bank account as AMGEN or ROCHE may  
designate in writing. Since sales may be made in another  
currency, conversion of sales and Operating Costs and  
Expenses to Swiss francs prior to the Effective Date and U.S.  
Dollars thereafter shall be at rates determined in  
accordance with the Supplementary Agreement calculated by  
ROCHE through the 1997 calendar year and AMGEN thereafter,  
provided that such rates and methodology shall be subject to  
both parties reasonable approval.

8.03 Further, if a law or governmental regulation should require withholding of taxes, said taxes will be deducted from such remitted amount and will be paid to the proper taxing authority, and proof of payment will be secured and sent to the party receiving the amount as evidence of such payment in such form as required by the tax authorities have in jurisdiction thereover.

8.04 Auditing of ROCHE's books and records will be accomplished by ROCHE's internal auditors and will be documented by means of certification from the internal audit staff. In addition, the workpapers of the AMGEN/ROCHE consolidation will be available to AMGEN's auditors.

Auditing of AMGEN's books and records will be accomplished by AMGEN's internal auditors and will be documented by means of certification from the internal audit staff. In addition, the workpapers of the AMGEN/ROCHE consolidation will be available to ROCHE's auditors.

ARTICLE 9  
WARRANTIES AND INDEMNIFICATION

9.01 Each party warrants and represents to the other that it has the full right and authority to enter into this Agreement, and that it is not aware of any impediment that would inhibit its ability to perform its obligations under this Agreement.

9.02 (a) During the Term of this Agreement, each party will provide through self insurance or a combination of self insurance and commercially placed insurance coverage in

respect of product liability. The terms of any insurance coverage shall include insurance against the obligations assumed by the parties hereunder. Evidence of the existence and continuation of such insurance shall be provided, upon written request, to the other party annually and at such other times as the other party may reasonably request. A party shall notify the other of any cancellation of or material change in any such insurance arrangements prior, if possible, to such cancellation or material change, but in any event, as soon as possible.

(b) ROCHE shall defend AMGEN, its agents, directors, officers and employees at its cost and expense, and will indemnify and hold harmless AMGEN, its agents, directors, officers and employees from and against any and all claims for losses, costs, damages, fees or expenses to the extent they arise out of or in connection with ROCHE's manufacture or distribution of each Product and/or delivery of the Product to AMGEN, provided that the foregoing indemnity shall not apply to the extent that any actual or alleged losses, costs, damages, fees or expenses are specifically and proximately due to AMGEN's failure to properly manufacture and/or delivery the

Bulk Product. In the event of any such claim against AMGEN or any agent, director, officer or employee, AMGEN shall promptly notify ROCHE in writing of the claim and ROCHE shall manage and control, at its sole expense, the defense of the claim and its settlement. AMGEN shall cooperate with ROCHE and may, at its option an expense, be represented in any such action or proceeding. ROCHE shall not be liable for any litigation costs or expenses incurred be AMGEN without ROCHE's written authorization.

(c) AMGEN shall defend ROCHE, its agents, directors, officers and employees at its cost and expense, and will indemnify and hold harmless ROCHE, its agents, directors, officers and employees from and against any and all claims for losses, costs, damages, fees or expenses to the extent they arise out of or in connection with AMGEN's manufacture or distribution of each Product and/or delivery of the Product to ROCHE. In the event of any such claim against ROCHE or any agent, director, officer or employee, ROCHE shall promptly notify AMGEN in writing of the claim and AMGEN shall manage and control, at its sole expense, the defense of the claim and its settlement. ROCHE shall cooperate with AMGEN and may, at its option and expense, be represented in any such action or proceeding. AMGEN shall not be liable for any litigation costs or expenses incurred be ROCHE without AMGEN's written authorization.

ARTICLE 10  
PATENT AND TRADEMARK INFRINGEMENT

10.01 (a) In the event that AMGEN or ROCHE become aware of any infringement by a third party of any Trademark or Patents,

each party shall inform the other in writing of all available evidence and details available concerning said infringement. AMGEN and ROCHE shall then consult with each other as to the best manner in which to proceed. AMGEN shall have the sole right but not the obligation to bring, defend, maintain any appropriate suit or action or to control the conduct thereof against the infringer. If ROCHE agrees to equally share all expenses, ROCHE shall also share the recoveries due to any such action. If ROCHE does not agree to share all expenses, AMGEN will receive all recoveries due to any such action. If AMGEN requests ROCHE to join AMGEN in such suit or action, ROCHE shall execute all papers and perform such other acts as may be reasonably required. Should AMGEN lack standing to bring any such action, then AMGEN may ask ROCHE to do so. If ROCHE elects to bring suit, AMGEN shall cooperate with ROCHE in conducting the suit and the parties shall share expenses and recoveries equally.

(b) If AMGEN fails to bring legal action or terminate an infringing activity within nine (9) months of notification of infringing activity, ROCHE shall have the right but not the obligation to bring suit against the infringer in the country of the Territory. If ROCHE elects to bring suit, AMGEN shall cooperate with ROCHE in conducting the suit and the parties shall share expenses and recoveries equally.

10.02 In the event that AMGEN and/or ROCHE are sued or threatened with suit by a third party who claims that the manufacture, use or sale of any Product is an infringement of one or more claims of a patent owned by the third party, the parties shall consult with each other as to the best manner to proceed. ROCHE and AMGEN agree to equally share the costs of such suit or threatened suit. If the settlement of a lawsuit or threatened lawsuit or other action requires any payments or license in order to manufacture, use or sell any Product, AMGEN and ROCHE agree to equally share any such payments and/or license fees including royalties.

ARTICLE 11  
TERM AND TERMINATION

11.01 Either party may terminate this Agreement for "Good Cause" (as defined in Section 11.03 below), on a country-by-country basis, effective at any time after providing \*\*\*\*\* written notice; provided that the other party shall have an opportunity to cure any defect or omission during such \*\*\*\*\* period. Should such cure

be effected, such notice with respect to such Good Cause shall be null and void.

Should the Agreement be terminated in a country by \*\*\*\*\* for Good Cause,

(i) \*\*\*\*\* shall receive its share of \*\*\*\*\* or pay its share of \*\*\*\*\* for that country under Section \*\*\*\* for the calendar year in which termination occurs,

(ii) For subsequent years, \*\*\*\*\* shall receive or pay the \*\*\*\*\* it would have received for that country in accordance with Section \*\*\*\*\* if \*\*\*\*\*.

Should the Agreement be terminated in a country by \*\*\*\*\* for Good Cause,

- (i) \*\*\*\*\* shall receive the amount in U.S. Dollars in that country up to and including the \*\*\*\*\* ,
- (ii)\*\*\* shall receive \*\*\*\*\* for that country.

11.02(a) "Good Cause" shall include

- (i) the failure of the other party to comply with any of its material obligations contained in this Agreement in a country of the Territory;
- (ii)any action or proceeding before any court or governmental agency or other regulatory or administrative agency or commission, by any governmental or other regulatory or administrative agency or commission or by any other person, successfully challenging this Agreement or the relationship or actions of the parties contemplated hereby or otherwise materially and adversely affecting the business or property (including the goodwill and business reputation and character) of a party hereto;
- (iii)termination (a) by ROCHE or Hoffmann-La Roche Inc. for any reason, or (b) by AMGEN due to the failure of ROCHE or any Affiliate of ROCHE (including but not limited to Hoffmann-La Roche Inc.) to comply with any of its or their material obligations contained therein, of either of the License Agreements of even date herewith with respect to the \*\*\*\*\*; or
- (iv)(a) ROCHE's failure to obtain \*\*\*\*\* consent to the sublicense referred to in Section 2.03 (b) ; or
- (b) ROCHE's subsequent termination of such sublicense; or
- (c) termination of the \*\*\*\*\* License by ROCHE; or
- (d) termination of the \*\*\*\*\* License by \*\*\*\*\* due to the failure of ROCHE or any Affiliate of ROCHE to comply with any of its or their material obligations thereunder through no fault of AMGEN; provided, however, that in such event termination of this Agreement shall not effective until fault is established or mutually agreed, but if it is established or agreed that AMGEN is not at fault then termination shall be effective retroactive to the date AMGEN provided ROCHE with notice of termination and ROCHE shall receive only its share of Operating Profit or Loss up to and including the calendar month of the date of notice of termination.

11.03 Any other provision of this Agreement notwithstanding, termination of this Agreement for Good Cause shall be without prejudice to

- (i) any remedies which either party may then or thereafter have hereunder or at law; and
- (ii) either party's right to obtain performance of any obligations provided for in this Agreement which survive termination by their terms or by a fair interpretation of this Agreement.

ARTICLE 12  
MISCELLANEOUS

12.01(a) This Agreement shall be governed by and interpreted under the laws of England and the regulations of the EU.

(b) In the event of any controversy or claim arising out of or relating to any provision of this Agreement or the breach thereof, the parties shall try to settle those conflicts amicably between themselves.

(c) Should they fail to agree, any controversy, dispute or claim which may arise out of or in connection with this Agreement, or the breach, termination or validity thereof, shall be settled by final and binding arbitration pursuant to the Rules of Conciliation and Arbitration of the International Chamber of Commerce (Paris) as hereinafter provided:

(i) The Arbitration Tribunal shall consist of three arbitrators. Each party shall nominate in the request for arbitration and the answer thereto one arbitrator and the two arbitrators so named will then jointly appoint the

third arbitrator as chairman of the Arbitration Tribunal. If one party fails to nominate its arbitrator or, if the parties' arbitrators cannot agree on the person to be named as chairman within sixty (60) days, the Court of Arbitration of the International Chamber of Commerce shall make the necessary appointments for arbitrator or chairman.

(ii) The place of arbitration shall be in London, England, and the arbitration procedure shall be held in English. The procedural law of the place of arbitration shall apply where the said Rules are silent.

(iii) The award of the Arbitration Tribunal shall be final and judgment upon such an award may be entered in any competent court or application may be made to any competent court for judicial acceptance of such an award and order of enforcement.

12.02 For a period commencing September 26, 1988 and ending  
\*\*\*\*\* from the termination or expiration of this  
Agreement:

(a) each party agrees not to use Confidential Information  
furnished by the other party for any purpose inconsistent  
with this Agreement; and

(b) each party will treat Confidential Information furnished  
by the other party as if it were its own proprietary  
information and will not disclose it to any third party other  
than its Affiliates or consultants without the prior written  
consent of the other party who furnished such information;  
provided, however, that such Confidential Information may be  
disclosed if in the reasonable opinion of recipient's counsel  
such disclosure is necessary to comply with the requirements  
of any law, governmental order (including a court order) or  
regulation. Recipient shall notify and consult with the  
disclosing party prior to such disclosure of information.  
Prior to the oral or written presentation or submission for  
publication of any data or information with respect to a  
Product or Second Generation Product being evaluated,  
developed or commercialized for the Territory, each party  
will provide a copy of the proposed presentation or  
publication to the other party for review. If the data or  
information relates to the \*\*\*\*\* Product or is covered by the  
\*\*\*\*\* Patents then it shall also be submitted to  
\*\*\*\*\* for review. The proposed manuscript, presentation  
outline or other information shall be submitted to the  
reviewing party as soon as practicable but in no event less  
than fifteen (15) days prior to the proposed presentation or  
publication. The parties will cooperate and, if necessary,  
delay the publication or presentation to permit patent filing

and any other protections to be instituted to protect any  
such proposed disclosure before the disclosure occurs. Upon  
request, the presenting or publishing party will remove any  
Confidential Information belonging to the other party from  
any presentation or publication.

12.03 A party shall be relieved of any and all of the  
obligations of Section 12.02 with respect to a specific item  
of Confidential Information if:

(a) such Confidential Information was known to the party  
receiving the Confidential Information prior to receipt from  
the disclosing party; or

(b) such Confidential Information was at the time of  
disclosure to the party receiving the Confidential  
Information generally available to the public or which became

generally available to the public through no fault  
attributable to the party receiving the Confidential  
Information; or

(c) such Confidential Information was made available to the  
party receiving the Confidential Information for its use or  
disclosure from any third person who was at the time of  
transmitting such Confidential Information not under a non-  
disclosure obligation to the other party.

- 12.04 During the Term of this Agreement and for \*\*\*\*\*  
thereafter, for a period of \*\*\*\*\* immediately  
after voluntary or involuntary termination of an employee who  
was involved in promoting or detailing each Product for a  
party to this Agreement, the other party to the Agreement  
shall not engage such former employee in any work or other  
activity (whether as consultant, employee or otherwise),  
involving promoting, detailing or marketing each Product for  
such other party, without the prior written approval of the  
party who was the employer of the former employee.
- 12.05 This Agreement shall be binding upon, and shall inure to  
the benefit of successors to a party hereto, provided  
however, that neither this Agreement nor any of the rights or  
obligations hereunder shall be assignable without the prior  
written consent of both parties.
- 12.06 Any notice required to be given hereunder shall be  
considered properly given if sent by certified mail, return  
receipt requested, to the respective address of each party as  
follows:

F. Hoffmann-La ROCHE Ltd  
Grenzacherstrasse 124

CH-4070 Basel, Switzerland  
Attention: Corporate Law Department

and

AMGEN Inc.  
1840 DeHavilland Drive  
Thousand Oaks, California 91320 U.S.A.  
Attention: Corporate Secretary

with a copy to:

AMGEN (Europe) AG  
Alpenquai 30  
6002 Luzern, Switzerland  
Attention: Vice President, Europe



or such other address as the addressee shall have last furnished in writing in accordance with this provision to the addresser.

12.07 If any provision of this Agreement is held to be invalid, such invalidity shall not affect the validity of the remaining provisions.

12.08 In the event that either party is prevented from performing or is unable to perform any of its obligations under this Agreement due to any act of God, fire, casualty, flood, war, strike, lockout, failure of public utilities, injunction or any act, exercise, assertion or requirement of governmental authority, including any governmental law, order, regulation permanently or temporarily prohibiting or reducing the level of research, development or production work hereunder or the manufacture, use or sale of Product, epidemic, destruction of production facilities, riots, insurrection, inability to procure or use materials, labor, equipment, transportation or energy sufficient to meet experimentation or manufacturing needs; or any other cause beyond the reasonable control of the party invoking this Section 12.08 provided such party shall have used its best efforts to avoid such occurrence; such party shall give notice to the other party in writing promptly, and thereupon the affected party's performance shall be excused and the time for performance shall be extended for the period of delay or inability to perform due to such occurrence.

12.09 The waiver by either party of a breach or a default of any provision of this Agreement by the other party shall not be construed as a waiver of any succeeding breach of the same or any other provision, nor shall any delay or omission on the part of either party to exercise or avail itself of any right, power or privilege that it has or may have hereunder operate as a waiver of any right, power or privilege by such party.

12.10 In the event that any provision of this Agreement is held by a court of competent jurisdiction to be unenforceable because it is invalid or in conflict with any law of any relevant jurisdiction, the validity of the remaining provisions shall not be affected, and the rights and obligations of the parties shall be construed and enforced as if the Agreement did not contain the particular provisions held to be unenforceable.

12.11 All captions hereunder are for convenience only and shall not be interpreted as having any substantive meaning.

12.12 All covenants, agreements, representations and warranties made hereunder shall be deemed to have been relied upon notwithstanding any investigation heretofore or hereafter made and shall survive the execution of this Agreement.

12.13 This Agreement (including all Appendices attached hereto which shall be considered part of this Agreement) constitutes the complete and final agreement between the parties hereto with respect to the within subject matter for the Territory and cancels and supersedes all prior negotiations, correspondence, understanding and agreements, whether written or oral, respecting the subject matter thereof. This Agreement may be changed only in writing signed by properly authorized representatives of AMGEN and ROCHE. Any inconsistency between this Agreement and the Supplementary Agreement shall be construed in favor of this Agreement.

12.14 This Agreement may be executed in any number of counterparts, each of which need not contain the signature of more than one party but all such counterparts taken together shall constitute one and the same agreement.

12.15 This Agreement is not intended to create a partnership and except as expressly set forth herein neither party shall have the power or authority to bind or obligate the other party.

IN WITNESS WHEREOF, AMGEN INC. AND F. HOFFMANN-LA ROCHE LTD, have caused this Agreement to be duly executed by their authorized representatives, in duplicate on the dates written herein below.

Thousand Oaks, California, AMGEN INC.

January 26 , 1998 By: /s/Kevin Sharer

Its: President

Basel, Switzerland, F. HOFFMANN-LA ROCHE LTD

January 26 , 1998 By: /s/Erich Platzer

Its: Business Manager, Oncology  
46

SUPPLEMENTARY AGREEMENT TO  
AGREEMENT ON G-CSF IN THE EC  
BETWEEN  
AMGEN INC.  
AND  
F. HOFFMAN-LA ROCHE & CO. LIMITED COMPANY

This document is the Supplementary Agreement regarding the definition of Operating Profit or Operating Loss referred to in Articles 1.18, 1.19 and 7.01(a) of the Agreement on G-CSF in the EC (European Community) between F. Hoffmann-LaRoche & Co. Limited Company (Roche) and Amgen Inc. (Amgen), dated September 26, 1988. In addition, this supplementary agreement covers the financial planning, accounting policies and procedures to be followed in determining the Operating Profit and or Loss and related sharing of profit and expenses. For purposes of this agreement the consolidated accounting of operations will be referred to as AMRO.

1. Principles of Reporting

The presentation of results of operations will follow the Roche format of presentation used for distribution to management, which is as follows:

Sales  
Sales Deductions  
Cost of Goods Sold  
  
Fixed Production Costs  
Commercial Services  
Research and Development  
  
Other Operating Inc./Exp.  
Technical Services  
Administration  
  
Operating Profit (Loss)

Amgen will make the appropriate adjustments to its financial statements to conform to the Roche format of reporting results of operations.

2. Frequency of Reporting

Reporting of AMRO will be done twice a year, at the end of 6 months and the end of 12 months. The fiscal year of the venture will be a calendar year.

On an interim basis Roche will supply Amgen with certain information:

Sales in units, local currency and Swiss francs will be reported monthly by country.

Key events such as -  
Start of clinical trials;  
Seminars/Congresses attended or held;  
Filings of regulatory documents;  
Approvals by regulatory agencies;  
will be reported as they occur.

Amgen's European Chief Financial Officer or designee will meet regularly with Roche's designated financial controller to review:

Performance Information  
Actual Results  
Latest Estimates

Consolidated results of operations will be prepared in accordance with the calendar of financial reporting used by Roche.

### 3. Budgeting

The financial responsibility for the budget will rest with the G-CSF Clinical team and G-CSF Marketing team with final approval by the G-CSF Management Committee. The timing of planning will conform to Roche's planning cycle. In broad terms a preliminary budget will be due at \*\*\*\*\* headquarters in \*\*\*\*\* on \*\*\*\*\*. Consolidation will be completed in November and budget approved in December.

Budgets will be prepared on an annual basis. Sales will be the only element of the financial plan which will be planned on a monthly basis.

Budgets will be supplemented with detailed business plans for clinical trials, registrations applications, and detailed plans for product introduction.

Budget variances and performance analysis will be done in the local currency of the country in question. Budgets, as stated in local currency, cannot be exceeded without formal approval by the G-CSF Management Committee.

The Management Committee may adjust the budget during the course of the year.

#### 4. Definitions

##### Sales -

Amounts invoiced to third parties  
Less: Returns and credits  
    Rebates  
    Volume discounts  
    Sales taxes/other taxes related to sales

##### Sales deductions -

Consists of direct and variable expenses incurred in the distribution of goods and services sold. Which includes:

    Outward freight (all outward expenses for freight in connection with the distribution of goods sold)  
    Transportation insurance  
    Packing materials (for dispatch of goods sold such as boxes, drums, etc.)  
    Other direct distribution expenses

##### Cost of Goods Sold -

Cost of goods sold consists of the direct production costs which include the following:

    Raw materials  
    Packaging materials  
    Auxiliary materials  
    Outside contractors  
    Personnel costs (Salary and Wages)  
    Energy (Variable cost)  
    Workshop (Repairs and maintenance)  
        (Variable cost primarily preventative maintenance)  
    Quality control (Variable cost-related to product testing)  
    Waste disposal (Variable cost)

##### Fixed Production Costs -

Fixed production costs will include those manufacturing costs which are period costs and do not vary based on production volume. These costs include the following:

    Production management and planning  
    Equipment depreciation & rental  
    Building depreciation & rental  
    Energy (Boiler rooms, general consumption of utilities, fixed costs)

Workshop (repairs and maintenance) (major replacement not dependent on volume, fixed costs)  
Quality control (fixed costs - process testing)  
Waste disposal (fixed costs)

Commercial Services -

Commercial Services consists of two major areas:

Marketing  
Commercial Services Infrastructure  
(In Amgen books and records this area is referred to as Marketing)

Marketing consists of all activities which are focused on the introduction, promotion and selling of pharmaceutical products. Within the scope of this area will be:

Field staff -

Field staff comprises all the costs of the entire field staff including its management and support (training, record files, etc.)

Internal Marketing Services -

Internal marketing services comprises the entire marketing organization with the exception of the field staff and infrastructure.

Activities included in this area are as follows:

Market Research  
Pricing  
Regional Coordination and Documentation  
Product Management  
Technical Promotion  
Medical Information Services  
Marketing Clinicals Studies

C-CSF product specific costs will be chargeable to the operations of the Product.

The types of costs or expenses to be included in this area shall be:

Sales and promotional materials  
Seminars, exhibits, and conventions  
Advertising in journals, mailings and other media  
Post-marketing surveillance

Costs related to institutional promotion, or promotion of the company which is not product specific, will not be chargeable to the operations of the Product.

Commercial Services Infrastructure -

Costs in this area include:

Commercial Service Manager (G-CSF Team Manager) and Secretary  
Registration  
Strategic and Operational Planning  
Marketing Administration  
Health Economics  
Other staff reporting to the Commercial Services Manager

Attached to this agreement are the current charts of accounts for Roche and Amgen concerning Commercial Services (Exhibit I), and Marketing (Exhibit V), respectively.

Account definitions, where available, are included in Exhibit III.

Research and Development -

Those expenses, direct and indirect, required to obtain the authorization and/or ability to manufacture, formulate, fill, ship and/or sell the Product in commercial quantities to third Parties in the Territory.

Such expense shall include but not limited to:

Costs of research, proposals or studies on the toxicological, pharmaceutical, formulation or clinical aspects of the Product conducted internally or by individual investigators, hospitals or medical centers, or clinical research organizations, or consultants necessary for the purpose of obtaining and/or maintaining approval of the Product by a government organization in a country in the Territory. In

addition, costs for preparing, submitting, reviewing or developing data or information for the purpose of submission to a governmental authority to obtain and/or maintain approval of the Product in a country.

These costs shall include expenses for data management, statistical designs and studies, document preparation, and other similar expenses associated with the clinical testing program.

ASTERISKS (\*) INDICATE CONFIDENTIAL INFORMATION OMITTED AND FILED SEPARATELY WITH THE SEC

It is understood that obtaining FDA authorization to ship product from the USA into the territory or Switzerland shall be at \*\*\*\*\* sole expense.

Attached to this agreement as Exhibit II and Exhibit IV are the current charts of accounts for Roche and Amgen, respectively. In addition, account definitions, where available, are included in Exhibit III.

Other Income/Expense -

Other Income/Expense will include the following items:

- Bad debt expenses
- Inventory write-offs
- Cash discounts
- Royalty expense

Technical Services -

Technical services includes the following functions:

- Technical Services Admin.
- Engineering
- Technical Safety & Environment Protection
- Materials Management

Costs relating to the Product in this area will be limited to allocations to support manufacturing.

Administration -

Administration shall consist of the following:

- Personnel
- Data Processing
- General Services - (This cost area covers the internal postal system, the telephone exchange, the microfilm office, the in-house printing shop and central reprography service, etc.)

Costs relating to the Product in this area will be limited to expenses that are directly related to the functional areas of Manufacturing, Commercial Services and Research and Development.

5. Manufacturing Costs and Cost of Goods Sold -

The elements and characterization of manufacturing costs will conform to Roche's accounting policies and practices. To the extent that Amgen has cost elements included in manufacturing



costs that do not conform to Roche's accounting practices such costs will be accounted for as per the category of costs normally used by Roche.

In order to achieve a proper and acceptable accounting for manufacturing costs for the Product, standard costs per unit for direct manufacturing costs and fixed production costs will be established. Such standards will be established annually; variances from standard will not be charged or credited to Cost and Goods Sold.

In addition, annually, a standard cost for samples and clinical requirements will be developed.

6. Bulk Transfer of Product

Pricing for bulk G-CSF shipped by Amgen to Roche will be at a cost based on a standard set \*\*\*\*\*. The bulk transfer price will be the \*\*\*\*\*.

Payments for bulk shipments will be made on a \*\*\*\*\*.

Freight and insurance will be paid for by Amgen and included in the standard cost of the bulk Product.

Samples required by local Amgen companies will be provided by local Roche companies and will be billed at cost.

Roche will maintain one inventory to service all bulk inventory requirements on a worldwide basis.

7. Foreign Exchange -

The functional currency for accounting for operating profit will be Swiss francs.

Amgen will bill shipments of bulk Product in Swiss francs.

Roche will maintain the bulk inventory of Product in Swiss francs.

Roche affiliates will account for inventory in local currency.

Each statement of operations will be translated into Swiss francs on an average rate for the reporting period, except for sales which is translated on a monthly weighted average.

8. Auditing of Accounts -

Auditing of Roche's books and records will be accomplished by Roche's internal auditors and will be documented by means of certification from the internal audit staff. In addition, the workpapers of the AMRO consolidation will be available to Amgen's auditors.

Amgen will request that its public accounting firm, Arthur Young and Co., review its financial records and accountings of AMRO activities and provide a "comfort letter" to Roche concerning the accuracy, consistency, and adherence to the accounting agreement.

9. Interim Compensation Payments of Partners -

Compensation payments for operating income and expense will be made \*\*\*\*\* between the partners based on budget. Such payments will be made \*\*\*\*\* after each fiscal quarter. At the end of each \*\*\*\*\* period a settlement will be made to adjust budgeted income and expense to actual. Such a settlement will take into consideration quarterly operating income and expense compensation, and payments made for transfer of bulk Product. Settlement payments will be made as soon as the actual operating expense and income are consolidated and approved by the partners, but in no event later than \*\*\*\*\* after \*\*\*\*\* and \*\*\*\*\*.

10. Responsibility for Reporting -

The responsibility for accounting shall be placed with the company responsible for distribution and invoicing of customers.

11. Amgen Accounting for Internal R&D and Marketing -

To the extent that Amgen establishes departments that are wholly dedicated to G-CSF in Europe, such operating costs will be charged to the operating results of the Product based on actual, limited by the prevailing budget.

If resources are provided by departments which are not wholly dedicated to G-CSF Europe, then an hourly rate for that department will be developed, and applied to time reported by staff working in that department, to account for internal operating costs of that department for the purposes of this agreement. The hourly rate will be based on the current Amgen budget, adjusted for inflation.

12. Allocation of Technical Services and Administration -

Roche will conduct an annual study to determine the total percentage relationship of Technical Services to COGS. The percentage of Administrative Expense to the total of Commercial Services and Research and Development will be calculated similarly.

Amgen will determine a similar percentage of Administration to the total of Marketing and Research and Development. Amgen may review the percentage after the initial year to determine its appropriateness. Amgen will not charge operations of the Product with "start-up" costs for its European operations. In addition, administration expenses associated with operations in the United States will not be charged to the expenses of the Product.

These percentages will be applied to actual and budgeted Commercial Services (Marketing) and Research and Development expenses to determine Technical Services (Roche only) and Administration expense for the consolidated statement of operations and budget.

Third party legal expenses or product liability insurance will not be permitted in the calculation of an administrative percentage.

13. Definition of Net Sales for Royalty Calculations -

Net Sales for purposes of calculating royalties shall be Sales, as defined in part 4 of this agreement, less any cash discounts charged to other income and expenses.

14. Start of Operations -

Operation of AMRO will commence \*\*\*\*\*. Costs incurred, and approved by the Management Committee will be charged to AMRO operations after \*\*\*\*\*. Costs incurred prior to \*\*\*\*\* are not chargeable to AMRO.

Costs for \*\*\*\*\* that are in progress at \*\*\*\*\* and directed towards supporting filing in

Europe can be charged to the AMRO operation after approval by the G-CSF Clinical Team.

15. Guidelines for Charging Costs to AMRO -

- I. If an element of cost is \*\*\*\*\* to the development or commercialization of G-CSF as a product \*\*\*\*\* , then \*\*\*\* of that element will be chargeable \*\*\*\*\* on the basis agreed to by the partners.
  
- II. If an expense to a \*\*\*\*\* is \*\*\*\*\* to the development or commercialization of G-CSF as a product within \*\*\*\*\* then:
  - a) If the amount of that element of cost utilized in the development or commercialization of G-CSF \*\*\*\*\* \*\*\*\*\* \*\*\*\*\* then the amount used may be charged \*\*\*\*\*.
  
  - b) Upon approval by the Management Committee of an activity or expense which benefits G-CSF in cases where there is \*\*\*\*\* available, then:
    - i) If \*\*\*\*\* expense is determined by the partners to be utilized in the development or commercialization of G-CSF, then \*\*\*\* of the element may be charged \*\*\*\*\*.
  
    - ii) If \*\*\*\*\* of the expense is determined by the partners to be utilized in the development or commercialization of G-CSF, then \*\*\* of the element may be charged \*\*\*\*\*.
  
    - iii) If there is \*\*\*\*\* in the development or commercialization G-CSF, but it is also \*\*\*\*\* , then \*\* of that expense may be charged \*\*\*\*\*.

Attest:

AMGEN INC.

By /s/ Robert D. Weist

By /s/ Lowell E. Sears

Date 1/19/89

Date 1/19/89

F. HOFFMAN-LA ROCHE & CO.,  
LIMITED COMPANY

By /s/ Stephan C.J. Walsh

Date 24 January 1989

By /s/[illegible]

Date 24 January 1989

Exhibit I

AMRO  
Roche  
Commercial Services  
Chart of Accounts

COST TYPE	TITLE
4219.01	TEMPORARY HELP (from temporary agencies)
4223.02	TRAINING
4311.01	TRAVEL COSTS
4311.51	VISITORS' COSTS
4312.01	RENT - REAL ESTATE, OFFICES
4312.04	LEASING - EDP EQUIPMENT
4314.01	DEPRECIATION
4350.01	ADVERTISING - PRINTING
4350.04	SLIDES, PHOTOS
4350.05	CONGRESSES, CONVENTIONS
4350.15	MARKET RESEARCH
4350.16	AGENCY, CONSULTING EXPENSES
4350.18	OTHER ADVERTISING EXPENSES
4350.19	OTHER MARKETING EXPENSES
4361.03	OUTSIDE PRINTING, PHOTOS
4361.21	ASSOCIATION DUES
4361.54	REGISTRATION FEES - AUTHORITIES
4371.21	BOOKS, PERIODICALS
4371.22	OUTSIDE PROGRAMMING - EDP
4371.31	OP/APPL SOFTWARE
4371.41	SPECIAL SHIPPING COSTS
4371.91	OTHER OUTSIDE WORK
6001.96	SAMPLES
6112.95	ENERGY
6011.02	SALARIES & BENEFITS
6011.03	SALARIES & BENEFITS (Temporaries employed by Roche on Roche P/R)

Exhibit II

AMRO  
Roche  
Clinical Research and Development  
Chart of Accounts

COST TYPE	TITLE
4111.32	CHEMICALS
4219.01	TEMPORARY HELP (from Temporary Agencies)
4223.02	TRAINING
4311.01	TRAVEL COSTS
4311.51	VISITORS' COSTS
4312.07	RENT - REAL ESTATE, OFFICES
4312.04	LEASING-EDP EQUIPMENT
4314.01	DEPRECIATION
4331.02	FEES & GRANTS
4331.03	EXPENSES FOR BIOMETRY (Statistical evaluation of clinical trials by Third Party)
4361.03	OUTSIDE PRINTING, PHOTOS
4371.21	BOOKS, PERIODICALS
4371.31	OP/APPL SOFTWARE
4371.41	SPECIAL SHIPPING COSTS
4371.91	OTHER OUTSIDE WORK
6001.16	TECHNICAL ARTICLES
6001.95	AUXILIARY MATERIALS
6001.96	SAMPLES
6001.96	SALARIES (Full-time employees)
6011.03	SALARIES (TEMPS) - (Temporaries employed by Roche on Roche P/R)
6111.95	REPAIR MATERIALS
6112.95	ENERGY
6113.95	QUALITY CONTROL

Exhibit III

Account No.

Description: Personnel Expenses

6011.02  
6011.03  
4219.01

Definition:

Personnel expenses include all payments made to employees in the form of wages and salaries. Also included, are expenses related to pensions, welfare and other employee benefits.

Description: Wages and Salaries

6011.02  
6011.03  
4219.01

Definition:

This position includes all remuneration paid to employees in the form of:

- Salaries
- Wages
- Overtime pay
- Shift, holiday and other premiums
- Disability payments to employees
- Vacations and other paid absences
- Employee awards and bonuses
- Salesmen's commissions and other employee commissions.

The above payments made to temporary personnel, summer employees, etc., are included under this position. Also included are wages and salaries paid to outside agencies providing temporary workers and employees.

Payments made to former employees (pensioners) are not included under this position.

Description: Pension, Welfare and Other Employee Benefits

6011.02  
6011.03

Definition:

This position includes all costs incurred for employee benefits, other than direct remuneration to the employee. Expenses reported under this position include:

- Company paid insurance premiums (life insurance, hospital insurance, medical insurance, etc.)



- Workmen's compensation insurance
- Payments to pension fund, trust or other social institutions
- Payments to retirement plans and matching contributions to savings plans

Account No.

Description: Energies

6112.95

Definition:

This position represents the consumption of purchased energies such as electricity, natural gas, gasolines, diesel fuel, oil, coal, pressurized gases, etc., as well as any other related charges.

Description: Repairs and Maintenance

6111.95

Definition:

Minor repairs and maintenance expenditures required throughout the economic life of an asset in order to keep it in efficient operating condition. The distinguishing characteristics of such expenditures are that they do not add to the value or extend the useful life of property.

Repairs and maintenance have to be considered as current period expenses and should not be deferred over subsequent periods. This account contains only invoiced costs for repairs and maintenance from third parties (incl. material).

Also to be included here are expenses for material for which no inventory-accounts are kept.

In addition, any expenditure of a fixed asset nature, which by local tax regulations may be regarded as a deductible expense, could be included here.

Description: Rent and Leasehold

6116.95  
4312.04

Definition:

Expenses included in this category are rental and non-capitalized leasing costs incurred by the company for:

- Property, buildings and plants

- Machinery and equipment
- Office equipment, furniture and fixtures
- EDP equipment and software licensing
- Parking lots rented for personnel
- Other rental or leasing expenses

Account No.

Description: Travel and Entertainment Expenses

4311.01  
4311.51

Definition:

This position includes all costs incurred by employees (including field staff) while traveling on company business and/or entertaining business associates.

Exceptional entertainment expenses (such as company anniversary celebrations) should be reported as non-operating expenses.

Description: Advertising and Promotion

4350.01  
4350.04  
4350.05  
4350.15  
4350.18  
4350.19

Definition:

Items classified in this category include all costs paid to third parties for advertising and promotion of company products and/or services. Types of advertising and promotion include:

- Radio and television advertising
- Samples distributed to outsiders
- Journal advertising
- Promotional material
- Material and space for conventions and exhibitions

Self-produced and distributed samples are not to be included here.

If however, inventory accounts for all or certain promotion materials are maintained, the corresponding expense should appear under "Material and Merchandise Expense."

Account No.

Description: Outside Services for Research and  
Development

4111.32  
4331.02  
4331.03  
4361.02  
4371.91

Definition:

This account includes Third Party expenses directly related to research and development, such as:

- Fees and grants
- Research chemicals
- Clinical trials
- Test animals (including inward freight, transportation, insurance, etc.)
- Animal feed
- Printing, photocopying, photography, etc.
- All other expenses directly related to the research activity.

Note:

Under outside expenses, we understand expenses paid to third party only.

Description: Depreciation of Property, Plant and  
Equipment

4314.01

Definition:

Depreciation is a systematic charge against income which distributes the cost or other basic values of fixed assets over the estimated useful life of the asset. Depreciation expense for the year is that portion of the decrease in book value of the asset charged during the current period (cost value and revaluation value).

Account No.

Description: Other Outside Services

4371.21  
4223.02  
4371.31  
4371.41  
4361.21  
4361.03  
4361.54  
4371.91  
4350.16

Definition:

This account includes all other operational expenses that cannot be assigned to one of the above mentioned positions. Expenses in this category include:

Office Supplies

Office supplies are charged directly to operating expenses. If however, inventory accounts for all of certain office supplies are maintained, the corresponding expense should appear under "Material and Merchandise Expense."

Books and Periodicals

All expenses for books, professional literature, magazines and newspapers.

Printing, Photocopying, etc.

All outside expenses for printing, photocopying and other reprographic services except those pertaining directly and exclusively to either research and development or sales and promotion activities.

Translations

Fees and expenses for translations performed by outsiders except those pertaining directly and exclusively to sales and promotion activities.

Telephone, Cable and Telex Expense

All regular and incidental (including installation) expenses for telephone, cable and telex services.

Postage

All outside postage costs, except those relating to sales and promotion activities (sending out samples, sales literature, etc.). These are to be recorded under "Advertising and Promotion."

Account No.

Description: Other Outside Services (cont.)

Definition: (cont.)

Association and Membership Dues

Items such as dues paid to trade, industry and employers' associations, and membership fees paid to private clubs on behalf of certain employees.

Management Consultancy Expenses

Apart from the usual items, this account should also include software development services in connection with electronic data processing.

Not to be included are payments made to or received from the other parties as a result of the outcome of such proceedings. These payments are to be shown under non-operating income and/or expenses.

Notarial and Registration Fees

All notarial and registration fees and expenses incurred in connection with verifications, attestations, etc. Examples of such costs are the legitimization of contracts.

Public Permits and Dues

Building, driving, road, radio and other such permits or dues which are issued or levied by public authorities.

Outside Contractors' Fees

All fees and expenses by outside manufacturers for work performed on saleable goods.

Other Personnel Expenses

Outside expenses in connection with: hiring of staff, recruitment and relocation of personnel, personnel training, welfare activities and staff relations, contract transport for daily conveyance of employees to and from work and payments or provisions for dismissal indemnities.

Miscellaneous

Such general outside service expenses that cannot be charged to one of the above accounts.

Description: Royalty Expense - Third Parties

Definition:

This position represents expenses charged against the current operating period for amounts paid or payable to third parties in the form of license fees or royalties for the use of patents, trademarks, copyrights, and other similar intangible rights.

Description: Cash Discounts

Definition:

This position represents cash discounts granted to third parties customers upon payment of their account(s) within a stipulated period.

Description: Bad Debt Expense

Definition:

This position represents the total amount of write-offs or amounts reserved against future write-offs of trade accounts or notes receivable or other short-term receivables, which the company records as expense during the current operating period. Bad debt expense is charged with specific accounts that have been written off during the year, as well as after establishing the new balances for the allowance for doubtful accounts with third parties.

Description: Inventory Write-Offs

Definition:

This position represents the total current period inventory write-offs that should not be charged to production cost. The various types of inventory adjustments are obsolescence (e.g. inventory which exceeds quality control expiration date and represents not further value), book-to-physical adjustments, damages occurred in warehouses and other similar reasons.

When inventory adjustments occur as a direct result of production activity, these adjustments would normally be charged to production cost. The position here would usually include only those inventory adjustments which cannot be related to manufacturing or other direct activities of the current operating period.

AMRO  
Amgen  
Chart of Accounts  
Research and Development

Type of Expense

Salaries and Wages (included Temporaries)

Overtime

Employee Benefits

Employer taxes, Workers Comp. Ins.  
and Annual Leave

Health insurance, other benefits

Recruiting and Relocation

R&D Operating Expense

Chemicals and reagents

Supplies

Animal Studies

Maintenance and repair

Equipment rental

Contract filling

Chemical analysis

Contract services

Internal lectures

Professional meetings

Society memberships

R&D consulting

Misc. supplies and expenses

Cost of sales absorption

Technology rights

Library

Grants

SAB expenses

Clinical and pre-clinical expenses

Data processing

Occupancy

Travel and entertainment

Telephone

Depreciation

Other expenses (Business Insurance)

Functions included in R&D:

Research

Pilot plant operations

Quality assurance

Process development

Regulatory affairs

Clinical affairs



AMRO  
Amgen

Major Cost Elements  
Marketing

Type of Expense

Salaries and Wages (included Temporaries)

Overtime

Employee Benefits

Employer taxes, Workers Comp. Ins.  
and Annual Leave

Health insurance, other benefits

Recruiting and Relocation

Occupancy

Travel and entertainment

Telephone

Depreciation

Marketing -

Advertising

Direct mail

Literature preparation

Medical education

Symposium/Lectures

Trade shows/exhibits

Sales training

Market research

Marketing consultants

Functions included in Marketing -

Marketing staff

Sales management

Detailing staff

Customer service

Order entry

Training

Appendix 2.01  
Certain Other Rights in Spain and Italy

I. Spain

1. General Understanding

In addition to what is set forth in the Agreement AMGEN grants to ROCHE the right to have marketed the Product in Spain under a trademark owned by ROCHE (for the time being, ROCHE intends to use the trademark GRANULOKINE(R)) (hereinafter referred to as the "ROCHE-Trademark") and the right to sublicense such right to market the Product in Spain to Laboratorios Pensa, Av. Mare de Deu de Montserrat, Barcelona, Spain (hereinafter referred to as "PENSA") under the ROCHE-Trademark, in accordance with the terms herein.

2. Marketing by ROCHE Under the Trademark

ROCHE shall have the right to market the Product under the Trademark in Spain until the Scheduled Termination Date (as defined in the Agreement).

3. Sublicense to PENSA

a) AMGEN hereby grants ROCHE the limited right as set forth herein to enter into a co-marketing agreement with PENSA for the Product in Spain. Such co-marketing agreement will consist of a license agreement between Productos ROCHE, S.A., Carretera de Carabanchel a la de Andalucia s/n, E-28025 Madrid, Spain (hereinafter referred to as "ROCHE-Spain") and PENSA ("License Agreement") and a supply agreement between ROCHE and PENSA ("Supply Agreement") as well as a trademark license agreement ("ROCHE-Trademark Agreement") (the License Agreement, the Supply Agreement and the ROCHE-Trademark Agreement are collectively referred to as the "ROCHE-PENSA Agreements") copies of which have been provided to AMGEN.

b) ROCHE and ROCHE-Spain will obtain AMGEN's written consent with respect to the ROCHE-PENSA Agreements prior to entering into such ROCHE-PENSA Agreements and, with respect to any future amendments or waivers under ROCHE-PENSA Agreements, prior to any such amendment or waiver. ROCHE and AMGEN agree that AMGEN is a third party beneficiary of the ROCHE-PENSA Agreements. ROCHE agrees to indemnify and hold AMGEN harmless from any damages suffered by AMGEN by reason of any action taken by ROCHE or ROCHE-Spain or any failure of ROCHE or ROCHE-Spain to act other than in accordance with the terms hereof or the ROCHE-PENSA Agreements, respectively.

c) PENSA will market the Product under the ROCHE-Trademark for the term of the ROCHE-PENSA Agreements. The term of the ROCHE-PENSA Agreements shall last from January 1, 1992 until December 31, 1997. During such term the following shall apply:

(i) While PENZA markets the Product under the ROCHE-Trademark in Spain, the proceeds from the sale of the Product under

the ROCHE-Trademark will be included in the calculation of Operating Profit or Loss.

(ii) ROCHE will send all reports as further described in Art. 6.1 of the ROCHE-PENZA License Agreement to AMGEN promptly upon receipt by ROCHE or ROCHE-Spain.

(iii) ROCHE herewith declares that in the event ROCHE notifies PENZA as per Art. 5.2 of the ROCHE-PENZA Supply Agreement to interrupt the supply of the Product, ROCHE will appoint AMGEN as the third party supplier as described in said Art. 5.2 of the ROCHE-PENZA Supply Agreement, should AMGEN so request.

(iv) With regard to Art. 3.2.9 Sections c) and d) of the ROCHE-PENZA License Agreement, AMGEN will be accorded all the rights and titles resulting from clinical trials as per said Art. 3.2.9 Section c) and d) of the ROCHE-PENZA License Agreement as anticipated in the EC-Agreement.

(v) ROCHE agrees that prior to the release of confidential information by PENZA to third party collaborators under Art. 7.1 of the ROCHE-PENZA License Agreement, PENZA will receive written consent from ROCHE and ROCHE will receive prior written consent from AMGEN, which will not be unreasonably withheld.

(vi) ROCHE hereby warrants and represents that ROCHE-Spain and PENZA will not modify the ROCHE-PENZA Agreements without AMGEN's prior written consent, and that ROCHE will cause ROCHE-Spain to perform its obligations contemplated herein and as set forth in the ROCHE-PENZA Agreements.

(vii) \*\*\*\*\*  
\*\*\*\*\*  
\*\*.

d) Upon the termination of the ROCHE-PENZA Agreements on December 31, 1997, the following shall apply:

(i) PENZA's right to use the ROCHE-Trademark will immediately cease and PENZA will immediately transfer to ROCHE all rights in the ROCHE-Trademark, including all goodwill associated therewith;

(ii) ROCHE's right to use the ROCHE-Trademark in the Territory will immediately cease;

(iii) ROCHE will grant to AMGEN all of ROCHE's rights in the ROCHE-Trademark including all goodwill associated therewith;

(iv) ROCHE will have no rights whatsoever to use the ROCHE-Trademark in the Territory.

(v) AMGEN shall have the sole right to market the Product in Spain under the Trademark.

(vi) Notwithstanding Section 2.01(d) of the Agreement, AMGEN shall grant to PENZA the rights set forth in Section I.3 (a) of this Appendix 2.01 for a term of \*\*\*\*\*.

The net proceeds received by AMGEN from the sale of the Product by PENZA (or any subsequently appointed distributor or AMGEN) will be included in the calculation of Operating Profit and Operating Loss for the Term of the Agreement.

\*\*\*\*\*  
\*\*\*\*\*  
\*\*\*\*\*

Notwithstanding anything to the contrary contained in the foregoing, ROCHE will continue to supply PENZA with the Product until April 13, 1998 by extending its Supply Agreement with PENZA until such date. The supply price between January 1, 1998 and April 13, 1998 shall be agreed by ROCHE, PENZA and AMGEN. Subject to the exception contained in this provision (v), Section 2.01 (d) of the Agreement shall remain in full force and effect.

## II. Italy

### 1. General Understanding

In addition to what is set forth in the Agreement AMGEN grants to ROCHE the right to market the Product in Italy (as used herein Italy shall include the Vatican City and the Republic of San Marino) under a trademark owned by ROCHE and the right to sublicense such right to market the Product in Italy to Dompe Biotech, S.p.A. Via S. Lucia, 4-20122 Milano, Italy, (hereinafter referred to as "DOMPE") under the Trademark, in accordance with the terms hereof.

### 2. Marketing by ROCHE Under ROCHE-Trademark

a) ROCHE will market the product under a trademark (for the time being, ROCHE intends to use the trademark GRANULOKINE(R) owned by ROCHE (hereinafter referred to as "ROCHE-Trademark").

b) ROCHE shall market the Product under the ROCHE-Trademark in Italy until the Scheduled Termination Date (as defined in the Agreement).

c) The Operating Profit or Loss from the sales of the Product under the ROCHE-Trademark in Italy will be apportioned as set forth in Art. 7.01(a) of the Agreement.

d) The parties agree to discuss revisions of the terms of the Agreement in the event of any new indications or dosage forms which significantly expand clinical and marketing resources needed to adequately market and sell the Product under the ROCHE-Trademark in Italy.

e) Following the termination of the marketing of the Product by ROCHE under the ROCHE-Trademark in Italy, ROCHE will transfer the ROCHE-Trademark to AMGEN or an Affiliate of AMGEN.

f) With respect to the marketing or promotion of the Product in Italy by ROCHE (1) ROCHE shall provide AMGEN with all information reasonably requested by it; (2) the Marketing Plan for the Product shall be generally consistent with the Marketing Plans in the other countries of the Territory; and (3) ROCHE may (but shall not be obligated to) provide at least the comparable level of marketing and promotion effort then being provided by other companies distributing similar products in Italy, provided that such right shall not change the level of ROCHE's billable sales force participation in the Territory as a whole.

### 3. Sublicense to DOMPE

a) AMGEN hereby grants ROCHE the limited right as set forth herein to enter into a co-marketing agreement with DOMPE for the Product in Italy. Such co-marketing agreement will consist of a license agreement between Prodotti ROCHE S.p.A., Piazza Durante 11. I-20131 Milano (hereinafter referred to as "ROCHE-Italy") and DOMPE ("License Agreement") and a supply agreement between ROCHE and DOMPE ("Supply Agreement") (both the License Agreement and the Supply Agreement are collectively referred to as the "ROCHE-DOMPE Agreements"), copies of which have been provided to AMGEN.

b) ROCHE and ROCHE-Italy will obtain AMGEN's written consent with respect to the ROCHE-DOMPE Agreements prior to entering into such ROCHE-DOMPE Agreements and, with respect to any future amendments or waivers under the ROCHE-DOMPE Agreements, prior to any such amendment or waiver. ROCHE and AMGEN agree that AMGEN is a third party beneficiary of the ROCHE-DOMPE Agreements. ROCHE agrees to indemnify and hold AMGEN harmless from any damages suffered by AMGEN by reason of any action taken by ROCHE or ROCHE-Italy or any failure of ROCHE or ROCHE-Italy to act other than in accordance with the terms hereof or the ROCHE-DOMPE Agreements, respectively.

c) DOMPE will market the Product under the Trademark for the term of the ROCHE-DOMPE Agreements. The ROCHE-DOMPE Agreements shall terminate effective as from December 31, 1997.

Upon the termination of the ROCHE-DOMPE Agreements, AMGEN will have the sole right to market the Product in Italy under the Trademark.

d) Upon the termination of the ROCHE-DOMPE Agreements, the following shall apply:

(i) DOMPE's rights to use the Trademark will immediately cease and DOMPE will immediately transfer to ROCHE all rights in

the Trademark, including all goodwill associated therewith;

(ii) ROCHE's right to use the Trademark in the Territory will immediately cease;

(iii) ROCHE will grant to AMGEN all of ROCHE's rights in the Trademark including all goodwill associated therewith; and

(iv) ROCHE will have no rights whatsoever to use the Trademark in the Territory.

e) While DOMPE markets the Product under the Trademark in Italy, the proceeds from the sale of the Product under the Trademark will be included in the calculation of Operating Profit or Operating Loss.

f) Notwithstanding Section 2.01(d) of the Agreement, following termination of the ROCHE-DOMPE Agreements on December 31, 1997, AMGEN shall grant to DOMPE rights to distribute the Product in Italy under the Trademark. Similar to the prior arrangements under the ROCHE-DOMPE agreements,

\*\*\*\*\* shall be included in the calculation of Operating Profit and Operating Loss for the Term of the Agreement.

g) The \*\*\*\*\* paid by DOMPE to ROCHE-Italy under the ROCHE-DOMPE License Agreement will be included in the calculation of Operating Profit or Operating Loss. Such \*\*\*\*\* paid by DOMPE (or any other third party licensee or distributor) to AMGEN after December 31, 1997 shall also be included in the calculation of Operating Profit or Operating Loss. If no such \*\*\*\*\* is paid, AMGEN shall contribute the financial equivalent of such royalty to the Operating Profit.

h) ROCHE will send all reports as further described in Art. 7.2 and 6.1 of the ROCHE-DOMPE License Agreement to AMGEN promptly upon receipt by ROCHE or ROCHE-Italy.

i) ROCHE agrees that prior to the release of confidential information by DOMPE to third party collaborators under Art. 8.1 of the ROCHE-DOMPE License Agreement, DOMPE will receive written consent from ROCHE and ROCHE will receive prior written consent from AMGEN, which will not be unreasonably withheld.

j) The parties agree that at the end of the ROCHE-DOMPE Agreements, ROCHE-Italy will promptly appoint AMGEN or its designee as the transferee of the official registration for the











Appendix 6.02 (b)  
Assumption of Marketing Responsibility by AMGEN

\*\*\*\*\*

\*\*\*\*\*  
\*\*\*\*\*  
\*\*\*\*\*  
\*\*\*\*\*  
\*\*\*\*\*  
\*\*\*\*\*  
\*\*\*\*\*  
\*\*\*\*\*  
\*\*\*\*\*  
\*\*\*\*\*  
\*\*\*\*\*  
\*\*\*\*\*

\*\*\*\*\*

\*\*\*\*\*  
\*\*\*\*\*

\*\*\*\*\*

\*\*\*\*\*

\*\*\*\*\*

\*\*\*\*\*

\*\*\*\*\*

\*\*\*\*\* \* \*\* \*\* \*\*\*\*\* \*\*\*\*\*  
\*\*\*\*\* \*\* \*\* \*\* \*\*\*\*\* \*\*\*\*\*  
\*\*\*\*\* \* \*\* \*\* \*\*\*\*\* \*\*\*\*\*  
\*\*\*\*\* \* \*\* \*\* \*\*\*\*\* \*\*\*\*\*  
\*\*\*\*\* \* \* \* \*\*\*\*\* \*\*\*\*\*  
\*\* \* \* \* \*\*\*\*\* \*\*\*\*\*  
\*\*\*\*\* \* \* \* \*\*\*\*\* \*\*\*\*\*  
\*\*\*\*\* \* \* \* \*\*\*\*\* \*\*\*\*\*  
\*\*\*\*\* \* \* \* \*\*\*\*\* \*\*\*\*\*  
\*\*\*\*\* \* \* \* \*\*\*\*\* \*\*\*\*\*  
\*\*\*\*\* \* \* \* \*\*\*\*\* \*\*\*\*\*  
\*\*\*\*\* \* \* \* \*\*\*\*\* \*\*\*\*\*  
\*\*\*\*\* \* \* \* \*\*\*\*\* \*\*\*\*\*  
\*\*\*\*\* \* \* \* \*\*\*\*\* \*\*\*\*\*  
\*\*\*\*\* \* \* \* \*\*\*\*\* \*\*\*\*\*

\*\*\*\*\* \*\*\*\* \*\* \*\*\*\*\* \*\*\*\*\*  
\*\*\*\*\* \*\*\*\*\* \* \*\*\*\*\* \*\*\*\*\*  
\*\*\*\*\* \*\*\*\*\* \*\* \*\*\*\*\* \*\*\*\*\*



THIS SCHEDULE CONTAINS SUMMARY FINANCIAL INFORMATION EXTRACTED FROM THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS CONTAINED IN THE COMPANY'S QUARTERLY REPORT ON FORM 10-Q FOR THE QUARTER ENDED MARCH 31, 1998 AND IS QUALIFIED IN ITS ENTIRETY BY REFERENCE TO SUCH FINANCIAL STATEMENTS.

1,000,000

3-MOS		
	DEC-31-1998	
	JAN-01-1998	
	MAR-31-1998	105
		776
		304
		15
		118
	1,412	1,794
		516
	3,082	
825		223
0		0
		0
	2,030	
3,082		567
	605	79
		79
	272	
	0	
	2	
	268	
	80	
0		0
	0	
	0	
		0
	187	
	.73	
	.71	

FACTORS THAT MAY AFFECT THE COMPANY

Factors That May Affect the Company

Amgen operates in a rapidly changing environment that involves a number of risks, some of which are beyond the Company's control. The following discussion highlights some of these risks and others are discussed elsewhere herein.

Product development

The Company intends to continue an aggressive product development program. Successful product development in the biotechnology industry is highly uncertain, and only a small minority of research and development programs ultimately result in the commercialization of a product. Of the candidates that are selected for product development, all will not be successfully commercialized. Product candidates that appear promising in the early phases of development may fail to reach the market for numerous reasons, including, without limitation, results indicating lack of effectiveness or harmful side effects in clinical or preclinical testing, failure to receive necessary regulatory approvals, uneconomical manufacturing costs, the existence of third party proprietary rights, failure to be cost effective in light of existing therapeutics, or other factors. There can be no assurance that the Company will be able to produce future products that have commercial potential. Additionally, success in preclinical and early clinical trials does not ensure that large scale clinical trials will be successful. For example, the Company has previously announced product development failures in connection with BDNF (for subcutaneous injection for ALS), a product candidate that did not produce acceptable clinical results in a specific indication with a specific route of administration after a Phase III trial; although this product candidate had demonstrated acceptable preclinical and earlier clinical trial results sufficient to warrant advancement to a later stage clinical trial. Further, clinical results are frequently susceptible to varying interpretations which may delay, limit or prevent further clinical development or regulatory approvals. The length of time necessary to complete clinical trials and receive approval for product marketing by regulatory authorities varies significantly by product and indication and is often difficult to predict. See "- Regulatory approvals".

Regulatory approvals

The Company's research and development, preclinical testing, clinical trials, facilities, manufacturing, pricing, and sales and marketing of its products are subject to extensive regulation by numerous state and federal governmental authorities in the U.S., such as the FDA, HCFA, as well as by foreign countries, including the EU. The success of the Company's current products and future product candidates will depend in part upon obtaining and maintaining regulatory approval to market products in approved indications. The regulatory approval process can be both a long and complex process, both in the U.S. and in foreign countries, including countries in the

1

EU. Even if regulatory approval is obtained, a marketed product and its manufacturer are subject to continued review. Later discovery of previously unknown problems with a product or manufacturer may result in restrictions on such product or manufacturer, including withdrawal of the product from the market. Failure to obtain necessary approvals, or the restriction, suspension or revocation of any approvals or the failure to comply with regulatory requirements could have a material adverse effect on the Company.

Reimbursement; Third party payors

In both domestic and foreign markets, sales of the Company's products are dependent in part on the availability of reimbursement from third party payors such as state and federal governments (for example, under Medicare and Medicaid programs in the United States) and private insurance plans. In certain foreign markets, pricing and

profitability of prescription pharmaceuticals are subject to government controls. In the United States, there have been, and the Company expects there to continue to be, a number of state and federal proposals to implement price controls. In addition, an increasing emphasis on managed care in the United States has and will continue to increase the pressure on pharmaceutical pricing and usage. Further, significant uncertainties exist as to the reimbursement status of newly approved therapeutic products and current reimbursement policies for existing products may change. Changes in reimbursement or failure to obtain reimbursement may reduce the demand for, or the price of, the Company's products which could have a material adverse effect on the Company including results of operations. For example, patients in the U.S. receiving EPOGEN(R) in connection with treatment for end stage renal disease are covered primarily under medical programs provided by the federal government. Therefore, EPOGEN(R) sales may be affected by future changes in reimbursement rates or the basis for reimbursement by the federal government. As the Company previously announced, in early 1997, HCFA instituted a reimbursement change for EPOGEN(R) which has adversely affected the Company's EPOGEN(R) sales. See "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations - Results of Operations - Product Sales - EPOGEN(R) (Epoetin alfa)".

#### Guidelines

In addition to government agencies that promulgate regulations and guidelines directly applicable to the Company and its products, professional societies, practice management groups, private health/science foundations and organizations involved in various diseases may also publish, from time to time, guidelines or recommendations to the health care and patient communities. These organizations may make recommendations that affect the usage of certain therapies, drugs or procedures, including the Company's products. Such recommendations may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Recommendations or guidelines that are followed by patients and health care providers and that result in, among other things, decreased use of the Company's products could have a material adverse effect on the Company's results of operations. In addition, the perception that such recommendations or guidelines will be followed could adversely affect prevailing market prices for the Company's common stock.



## Intellectual property and legal matters

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and often involve complex legal, scientific and factual questions. To date, there has emerged no consistent policy regarding breadth of claims allowed in such companies' patents. Accordingly, there can be no assurance that patents and patent applications relating to the Company's products and technologies will not be challenged, invalidated or circumvented or will afford protection against competitors with similar products or technology. Patent disputes are frequent and can preclude commercialization of products. The Company currently is, and may in the future be, involved in patent litigation. Such litigation, if decided adversely, could subject the Company to competition and/or significant liabilities, could require the Company to enter into third party licenses or could cause the Company to cease using the technology or product in dispute. In addition, there can be no assurance that such licenses will be available on terms acceptable to the Company, or at all.

The Company is currently involved in arbitration proceedings with Ortho Pharmaceutical Corporation, a subsidiary of Johnson & Johnson ("Johnson & Johnson"), relating to a license granted by the Company to Johnson & Johnson for sales of Epoetin alfa in the United States for all human uses except dialysis and diagnostics. See Note 4 to the Consolidated Financial Statements, "Contingencies - Johnson & Johnson arbitrations".

## Competition

Amgen operates in a highly competitive environment. The Company competes with pharmaceutical and biotechnology companies, some of which may have technical or competitive advantages for, among other things, the development of technologies and processes and the acquisition of technology from academic institutions, government agencies and other private and public research organizations. There can be no assurance that the Company will be able to produce or acquire rights to products that have commercial potential. Even if the Company achieves product commercialization, there can be no assurance that one or more of the Company's competitors will not achieve product commercialization earlier than the Company, receive patent protection that dominates or adversely affects the Company's activities, or have significantly greater marketing capabilities.

## Fluctuations in operating results

The Company's operating results may fluctuate from period to period for a number of reasons. Historically the Company has planned its operating expenses, many of which are relatively fixed in the short term, on the basis that revenues will continue to grow. Accordingly, even a relatively small revenue shortfall may cause a period's results to be below Company expectations. Such a revenue shortfall could arise from any number of factors, including, without limitation, lower than expected demand, changes in wholesaler buying patterns, changes in product pricing strategies, increased competition from new and existing products, fluctuations in foreign currency exchange rates, changes in government or private reimbursement, transit interruptions, overall economic conditions or natural disasters (including earthquakes).

## Rapid growth

The Company has adopted an aggressive growth plan that includes substantial and increased investments in research and development and investments in facilities that will be required to support significant growth. This plan carries with it a number of risks, including a higher level of operating expenses and the complexities associated with managing a larger and faster growing organization.

## Stock price volatility

The Company's stock price, like that of other biotechnology companies, is subject to significant volatility. The stock price may be affected by, among other things, clinical trial results and other product development related announcements by Amgen or its competitors, regulatory matters, announcements in the scientific and research community, intellectual property and legal matters, changes in reimbursement policies or medical practices or broader industry and market trends unrelated to the Company's performance. In addition, if revenues or earnings in any period fail to meet the investment community's expectations, there could be an immediate adverse impact on the Company's stock price.

