FORM 10-Q

Quarterly report pursuant to sections 13 or 15(d)

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FILER

INTERMUNE INC

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SECURITIES AND EXCHANGE COMMISSION
Washington, D. C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2001

Commission File Number 0-29801

InterMune, Inc.

(Exact name of registrant as specified in its charter)

DELAWARE	**94-3296648**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

3280 Bayshore Blvd., Brisbane, California 94005
(Address of principal executive offices)

(415) 466-2200
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Stock, $.001 par value	**NASDAQ National Market System**

Securities registered pursuant to Section 12(g) of the Act:
None

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 filing requirements for the past 90 days. Yes /x/ No / /

As of August 1, 2001, there were 28,273,298 outstanding shares of Common Stock, par value $.001 per share, of InterMune Pharmaceuticals, Inc.

This report on Form 10-Q contains 16 pages.

INTERMUNE, INC.
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PART I–FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

INTERMUNE, INC.
CONDENSED BALANCE SHEETS
(Unaudited, in thousands, except share and per share data)

	June 30, 2001	December 31, 2000
ASSETS		
Current assets:		
Cash and cash equivalents	$ 21,314	$ 48,191
Short-term investments, available for sale	123,165	146,329
Accounts receivable, net	1,873	1,800
Inventories	2,650	1,049
Product revenue rights from Connetics	–	2,633
Other current assets and prepaid expenses	2,260	552
Total current assets	151,262	200,554
Property and equipment, net	5,000	845

Acquired product rights, net	32,059	–
Restricted cash balance	1,675	250
	$ 189,996	$ 201,649

LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 8,705	$ 3,874
Accrued payroll	1,291	638
Other accrued liabilities	1,928	424
Payable to Amgen	8,000	–
Payable to Connetics	–	912
Total current liabilities 19,924	5,848	
Deferred rent	95	–
Commitments		
Stockholders' equity:		
Convertible preferred stock, $0.001 par value; 5,000,000 shares authorized; no shares issued and outstanding at June 30, 2001 and December 31, 2000, respectively	–	–
Common stock, $0.001 par value, 45,000,000 shares authorized; 23,972,702 and 23,897,954 shares issued and outstanding at June 30, 2001 and December 31, 2000, respectively	24	24
Additional paid-in capital	240,425	239,620
Notes receivable from stockholder	(65)	(95)
Deferred stock compensation	(4,943)	(7,188)
Accumulated other comprehensive (loss) income	(14)	107
Accumulated deficit	(65,450)	(36,667)
Total stockholders' equity	169,977	195,801
	$ 189,996	$ 201,649

See accompanying notes to Condensed Financial Statements.

INTERMUNE, INC.
CONDENSED STATEMENTS OF OPERATIONS
(Unaudited, in thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2001	2000	2001	2000
Product sales, net:				
Actimmune	$ 7,278	$ 3,027	$ 12,207	$ 3,133
Other	750	–	1,363	–
Total net product sales	$ 8,028	$ 3,027	$ 13,570	$ 3,133

Costs and expenses:				
Cost of goods sold	3,084	1,885	6,599	1,940
Amortization of acquired product rights	1,057	1,220	3,175	1,220
Research and development	10,453	3,838	17,228	8,065
Selling, general and administrative	8,306	5,137	14,759	7,000
Acquired in-process research and development	5,400	–	5,400	–
Total costs and expenses	28,300	12,080	47,161	18,225
Loss from operations	(20,272)	(9,053)	(33,591)	(15,092)
Other income (expense):				
Interest income	2,058	2,198	4,838	2,695
Interest expense	–	(44)	(30)	(134)
Net loss	$ (18,214)	$ (6,899)	$ (28,783)	(12,531)
Preferred stock accretion				(269)
Deemed dividend on redeemable preferred stock				(27,762)
Net loss applicable to common stockholders				$ (40,562)
Historical basic and diluted net loss per common share	$ (0.79)	$ (0.33)	$ (1.25)	$ (3.42)
Weighted average shares used in computing historical basic and diluted net loss per common share	23,173	20,736	23,102	11,875
Pro forma basic and diluted net loss per common share	$ (0.79)	$ (0.33)	$ (1.25)	$ (2.30)
Weighted average shares used in computing pro forma basic and diluted net loss per common share	23,173	20,736	23,102	17,537

See accompanying notes to Condensed Financial Statements.

INTERMUNE, INC.
CONDENSED STATEMENTS OF CASH FLOWS
(Unaudited, in thousands)

	Six Months Ended June 30,	
	2001	**2000**
Cash flows used for operating activities:		
Net loss	$ (28,783)	$ (12,531)
Adjustments to reconcile net loss to net cash used for operating activities:		
Amortization of deferred stock compensation	2,245	3,070
Issuance of equity instruments for non-cash benefits	435	879
Accretion of long-term obligations payable to Connetics	–	87
Accretion of current obligation payable to Connetics	30	–
Amortization of acquired product rights	541	–

Acquired in-process research and development	5,400	–
Depreciation and amortization	171	36
Deferred rent	95	–
Changes in operating assets and liabilities:		
Accounts receivable	(73)	(1,145)
Inventories	(1,601)	474
Restricted cash	(1,425)	–
All other assets	(1,708)	(3,743)
Accounts payable	6,031	(1,252)
All other liabilities	957	(875)
Payable to Connetics	1,691	(1,395)
Net cash used for operating activities	(15,994)	(16,395)
Cash flows from investing activities:		
Purchases of property and equipment	(4,326)	(690)
Acquisition of product rights	(30,000)	–
Purchases of available-for-sale securities	(180,639)	(56,802)
Sales and maturities of available-for-sale securities	203,682	24,179
Net cash used for investing activities	(11,283)	(33,313)
Cash flows from financing activities:		
Return of capital to parent (Connetics)	–	(1,000)
Proceeds from issuance of common stock, net	370	115,466
Repayment of notes receivable from stockholder	30	–
Proceeds from redeemable preferred stock, net	–	26,176
Net cash provided by financing activities	400	140,642
Net increase (decrease) in cash and cash equivalents	(26,877)	90,934
Cash and cash equivalents at beginning of period	48,191	3,772
Cash and cash equivalents at end of period	$ 21,314	$ 94,706
Supplemental disclosure of cash flow information:		
Short-term obligation return on capital (Connetics)	–	$ 500
Deferred stock compensation	–	$ 8,583
Accrued product rights payable to Amgen	$ 8,000	–

See accompanying notes to Condensed Financial Statements.

INTERMUNE, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
(Unaudited)

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of presentation

In the opinion of the management of InterMune, Inc., ("InterMune," "we," "our," or "us"), the accompanying unaudited financial statements contain all adjustments, consisting only of normal recurring adjustments, necessary to present fairly our financial position, results of operations and cash flows for the periods presented. The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Certain information and footnote disclosures usually included in financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted. These financial statements should be read in conjunction with our annual report filed on Form 10-K for the year ended December 31, 2000 and our filings of periodic reports on Form 10-KA, 10-Q and 8-K. The results of operations for the interim periods presented are not necessarily indicative of results that may be expected for any other interim period or for the full fiscal year.

Revenue recognition

Revenues from product sales are recognized upon shipment when title passes to the customer, net of allowances for estimated returns, rebates and chargebacks. We are obligated to accept from customers the return of pharmaceuticals that have reached their expiration date. We monitor product ordering cycles and actual returns, product date codes and wholesale inventory levels to estimate potential product return rates. We believe that our product return reserves are adequate, and we have not experienced any significant returns of expired product. Royalty revenues will be recognized as earned under the terms of the applicable agreement.

Cash, cash equivalents and short-term investments

Cash and cash equivalents consist of highly liquid investments with original maturities when purchased of less than three months. We consider investments with maturities beyond three months at the date of acquisition and that mature within one year from the balance sheet date to be short-term investments. Cash equivalents and short-term investments are carried at fair value, with unrealized gains and losses, net of tax, as a separate component of stockholders' equity. The cost of securities sold is based on the specific identification method.

Cash in excess of immediate requirements is invested with regard to liquidity and return and, wherever possible, we seek to minimize the potential effects of concentration and degrees of risk.

Investment securities are classified as available-for-sale and unrealized holding gains and losses are included in comprehensive income (loss). In accordance with Statement of Financial Standards (SFAS) No. 115, Accounting for Certain Investments in Debt and Equity Securities, realized gains or losses, calculated based on the specific identification method, were not material for any period. Unrealized losses total $14,000 at June 30, 2001 and unrealized gains of $107,000 at December 31, 2000.

Foreign currency risk

InterMune purchases clinical supplies from a foreign vendor and pays the vendor in a foreign currency. This exposes us to foreign currency exchange rate risk, which is monitored by us as part of our overall risk management program. There are no other significant sources of foreign currency exchange risk.

Inventories

Inventories consist principally of raw material and finished good products and are stated at the lower of cost or market. Cost is determined by the first-in, first-out (FIFO) method.

	June 30, 2001	December 31, 2000

	(in thousands)	
Raw materials	$ 1,132	$ –
Finished goods	1,518	1,049
	$ 2,650	$ 1,049

Comprehensive income (loss)

InterMune has adopted Statement of Financial Accounting Standards No. 130, "Reporting Comprehensive Income." The only component of other comprehensive income is unrealized gains and losses on available-for-sale securities. During the three-month periods ended June 30, 2001 and 2000, total comprehensive loss amounted to $18,341,000 and $6,928,000, respectively, and for the six-month periods ended June 30, 2001 and 2000, total comprehensive loss amounted to $28,904,000 and $12,563,000, respectively.

Net loss per share

In accordance with SFAS No. 128, Earnings Per Share, and SEC Staff Accounting Bulletin (or SAB) No. 98, basic net income (loss) per share is computed by dividing the net income (loss) for the period by the weighted average number of common shares outstanding during the period. Shares subject to repurchase are deducted from the outstanding shares in arriving at the weighted average shares outstanding. Diluted net income (loss) per share is computed by dividing the net income (loss) for the period by the weighted average number of common and common equivalent shares outstanding during the period. We excluded potentially dilutive securities, composed of incremental common shares issuable upon the exercise of stock options and common shares issuable on conversion of preferred stock, from historical diluted loss per share because of their anti-dilutive effect.

Pro forma net loss per share has been computed as described above and also gives effect to common equivalent shares arising from preferred stock that automatically converted upon the closing of our initial public offering on March 24, 2000 (using the as-if converted method from original date of issuance). The pro forma net loss per share for the six months ended June 30, 2000, includes the impact of the deemed preferred stock dividend and excludes the preferred stock accretion.

The calculation of historical and pro forma basic and diluted net loss per share is as follows (in thousands, except per share data):

	Three months ended June 30,		Six months ended June 30,	
	2001	2000	2001	2000
Historical basic and diluted:				
Net loss	$ (18,214)	$ (6,899)	$ (28,783)	$ (12,531)
Preferred stock accretion	–	–	–	(269)
Deemed dividend to preferred shareholders	–	–	–	(27,762)
Net loss allocable to common stockholders	$ (18,214)	$ (6,899)	$ (28,783)	$ (40,562)
Weighted-average shares of common stock outstanding	23,956	21,914	23,935	13,089
Less: weighted-average shares subject to repurchase	(783)	(1,178)	(832)	(1,214)
Weighted-average shares used in computing basic and diluted net loss per common share	23,173	20,736	23,102	11,875

Basic and diluted net loss per common share	$ (0.79)	$ (0.33)	$ (1.25)	$ (3.42)
Pro forma basic and diluted:				
Net loss allocable to common stockholders	$ (18,214)	$ (6,899)	$ (28,783)	$ (40,562)
Add: Preferred stock accretion	–	–	–	269
Net loss before preferred stock Accretion	$ (18,214)	$ (6,899)	$ (28,783)	$ (40,293)
Shares used above	23,173	20,736	23,102	11,875
Pro forma adjustment to reflect weighted average effect of assumed conversion of preferred stock	–	–	–	5,662
Weighted-average shares used in computing pro forma basic and diluted net loss per common share	23,173	20,736	23,102	17,537
Pro forma basic and diluted net loss per common share	$ (0.79)	$ (0.33)	$ (1.25)	$ (2.30)

Product acquisition costs

Initial payments for the acquisition of products that, at the time of acquisition by InterMune, are already marketed or are approved by the FDA for marketing are typically capitalized and amortized ratably over the estimated life cycle of the products, typically ten years. At the time of acquisition, the product life cycle is estimated based upon the term of the agreement, the patent life of the product and management's assessment of future sales and profitability of the product. This estimate is assessed regularly during the amortization period, and the asset value or useful life would be adjusted when appropriate. Accumulated amortization of these costs was $541,000 at June 30, 2001.

New accounting standards

In July 2001, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards No. 141("SFAS 141"), "Business Combinations." SFAS 141 requires the purchase method of accounting for business combinations initiated after June 30, 2001 and eliminates the pooling-of-interests method. The Company does not believe that the adoption of SFAS 141 will have a significant impact on its financial statements.

In July 2001, the FASB issued Statement of Financial Accounting Standards No. 142 ("SFAS 142"), "Goodwill and Other Intangible Assets", which is effective January 1, 2002. SFAS 142 provides for, among other things, the discontinuance of goodwill amortization. In addition, the standard includes provisions for the reclassification of certain existing recognized intangibles as goodwill, reassessment of the useful lives of

existing recognized intangibles, reclassification of certain intangibles out of previously reported goodwill and the identification of reporting units for purposes of assessing potential future impairments of goodwill. SFAS 142 also requires the Company to complete a transitional goodwill impairment test six months from the date of adoption. The Company does not believe that the adoption of SFAS 142 will have a significant impact on its financial statements.

Product acquisition activity and new agreements

In May 2001, we entered into a joint development and commercialization agreement for Moli1901 with MoliChem Medicines, Inc. We paid an upfront fee of $1.5 million to MoliChem and we are obligated to pay MoliChem one-time payments on certain milestones. The parties will jointly fund the development and commercialization of Moli1901 for all diseases worldwide, starting with cystic fibrosis, sharing profits on

any resulting products in proportion to the parties' financial contribution to their development and commercialization. MoliChem will lead the development efforts, and we will lead the commercialization efforts for Moli1901.

In June 2001, we entered into a licensing and commercialization agreement with Amgen Inc. to obtain an exclusive license in the United States and Canada to Infergen®, and the rights to an early stage program to develop a pegylated form of Infergen for a total consideration of $29 million, plus development milestones and royalties. Under the agreement, we also have the exclusive right to develop Infergen for other indications in the United States and Canada. The in-process research and development program for pegylated Infergen is in its early stages, has not reached technological feasibility and has no foreseeable alternative future use. Based upon an independent appraisal, the fair value of the in-process research and development program for pegylated Infergen was $5.4 million. The remainder of the purchase price of approximately $23.6 million was allocated to developed technology and will be amortized over ten years. (We will evaluate our intangible assets for impairment on a regular basis.) The valuation was based on a discounted cash flow methodology, and the estimates used in the valuation were based upon assumptions we believe to be reasonable but which are inherently uncertain and unpredictable. Our assumptions may be incomplete or inaccurate, and no assurance can be given that unanticipated events and circumstances will not occur. Accordingly, actual results may vary from the projected results.

Financing activities and subsequent events

On July 5, 2001, we completed a secondary public offering of 4,295,896 shares of common stock, including 545,896 shares issued pursuant to the underwriters' exercise in full of their over-allotment option, at a price of $32.00 per share, raising $137.5 million in gross proceeds. We received net proceeds of approximately $129.0 million after deducting placement agent fees of $7.9 million and estimated related expenses of $0.6 million.

Concurrent with the secondary public offering, we also completed a public offering of $149.5 million aggregate principal amount of 5.75% convertible subordinated notes due 2006, including $19.5 million principal amount of the notes issued pursuant to the underwriters' exercise of their over-allotment option. The notes are convertible at the option of the note holders into our common stock at a conversion rate of $38.40 per share subject to adjustment in certain circumstances. Interest on the notes is paid semi-annually in arrears in January and July. We can redeem the notes on or after July 15, 2004. We received net proceeds of approximately $144.4 million after deducting placement agent fees of $4.5 million and estimated related expenses of $0.6 million.

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

The discussion in this report on Form 10-Q contains forward-looking statements that involve risks and uncertainties. The statements contained in this report that are not purely historical are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding our expectations, beliefs, intentions or strategies regarding the future, such as those in the discussions about:

our strategy;

governmental regulation and approval;

sufficiency of our cash resources;

revenues from existing and new collaborations;

product development;

our research and development expenses and other expenses; and

our operational and legal risks.

All forward-looking statements included in this document are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements. Our actual results could differ materially from those described in our forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in this report and those discussed under the heading "Additional Risk Factors," "Business," or "Management's Discussion and Analysis of Financial Condition of Operations" in our annual report filed on Form 10-K for the year ended December 31, 2000, and our filings of periodic reports on Forms 10-KA, 10-Q and 8-K.

Overview

We are developing and commercializing innovative products for the treatment of serious pulmonary and infectious diseases and cancer. We have three marketed products, growing product revenues and advanced-stage clinical programs addressing a range of diseases with attractive commercial markets. In the United States, we market our lead product, Actimmune®, for the treatment of chronic granulomatous disease and severe, malignant osteopetrosis. We are currently conducting a Phase III pivotal clinical trial with Actimmune for the treatment of idiopathic pulmonary fibrosis, which we estimate to have a maximum U.S. market opportunity of $2.5 billion per year. We are also conducting or planning clinical trials of Actimmune for the treatment of multidrug-resistant tuberculosis, ovarian cancer, atypical mycobacterial infections, cryptococcal meningitis, cystic fibrosis, liver fibrosis and non-Hodgkin's lymphoma. We believe that these clinical programs also represent significant commercial opportunities for Actimmune. The active ingredient of Actimmune is interferon gamma-1b. We plan to independently develop and commercialize Actimmune for multiple diseases in the United States, Canada and Japan. In addition, through our strategic partnership with Boehringer Ingelheim International GmbH, we plan to develop and commercialize Imukin®, Boehringer Ingelheim's tradename for interferon gamma-1b, for multiple diseases in Europe and other major markets of the world. We recently acquired rights to Infergen®, which has been approved by the FDA and which is marketed in the United States and Canada for the treatment of chronic hepatitis C infections. We also market Amphotec® worldwide for the treatment of invasive aspergillosis.

In June 2001, we entered into a licensing and commercialization agreement with Amgen Inc. to obtain an exclusive license in the United States and Canada to Infergen, and the rights to an early stage program to develop a pegylated form of Infergen for a total consideration of $29 million plus development milestones and royalties. Under the agreement, we also have the exclusive right to develop Infergen for other indications in the United States and Canada.

In May 2001, we entered into a joint development and commercialization agreement for Moli1901 with MoliChem Medicines, Inc. We paid an upfront fee of $1.5 million to MoliChem and we are obligated to pay MoliChem one-time payments on certain milestones. The parties will jointly fund the development and commercialization of Moli1901 for all diseases worldwide, starting with cystic fibrosis, sharing profits on any resulting products in proportion to the parties' financial contribution to their development and commercialization. MoliChem will lead the development efforts, and we will lead the commercialization efforts for Moli1901.

In March 2001, we formed an international strategic partnership with Boehringer Ingelheim International GmbH, to develop and commercialize interferon gamma-1b under Boehringer Ingelheim's trade name, Imukin®, in all countries outside of the United States, Canada and Japan. Indications to be developed include idiopathic pulmonary fibrosis (IPF), tuberculosis, systemic fungal infections, chronic granulomatous disease (CGD) and osteopetrosis. Under the agreement, InterMune will fund and manage clinical and regulatory development of interferon gamma-1b for all indications. Boehringer Ingelheim has an option to exclusively promote Imukin® and we may opt to promote the product where Boehringer Ingelheim does not do so. Furthermore, both companies will share in the profits from commercializing interferon gamma-1b through a specified royalty schedule.

On January 5, 2001, we acquired worldwide rights to Amphotec® from ALZA Corporation. The transaction terms included an upfront license fee of $9.0 million, milestone payments based upon sales levels and the development of Amphotec® in combination with Actimmune®, and royalties payable upon net sales levels. Amphotec® is an FDA-approved lipid-complexed form of amphotericin B indicated for the treatment of invasive aspergillosis, a life-threatening fungal infection.

We have sustained losses on a quarterly and an annual basis since inception. As of June 30, 2001, we had an accumulated deficit of $65.5 million. Our net losses from operations were $33.6 million for the six-month period ended June 30, 2001, and $15.1 million for the same period in 2000. These losses resulted from significant costs incurred in the development and marketing of our products and acquired in-process research and development charges.

Our expenses have consisted primarily of costs incurred in research and development, sales and marketing and from general and administrative costs associated with our operations. We expect our research and development expenses to increase as we continue to commercialize our products and expand of our operations worldwide. As a result, we expect to incur losses for the foreseeable future.

We have a limited history of operations and anticipate that our quarterly results of operations will fluctuate for the foreseeable future due to several factors, including market acceptance of current or new products, patent conflicts, the introduction of new products by our competitors, the timing and extent of our research and development efforts, and the timing of significant orders. Our limited operating history makes accurate prediction of future operating results difficult or impossible.

Total sales of Actimmune were $12.2 million and $5.0 million for the six-month periods ended June 30, 2001 and 2000, respectively. Sales for the three-month period ended March 31, 2000, were reported by us on a net basis (equivalent to zero). Product sales as reported by InterMune for either the three or six-month periods ended June 30, 2001 or 2000, respectively, are not necessarily indicative of product sales for any future period.

Results of Operations

Three Months Ended June 30, 2001 and 2000

Revenue. Total revenues were $8.0 million and $3.0 million for the three month-periods ended June 30, 2001 and 2000, respectively. The 2001 revenues represent all sales of Actimmune in the United States and worldwide sales of Amphotec for the period and sales of Infergen in the United States for the

period from June 15, 2001 (the date we acquired the marketing rights to Infergen) to June 30, 2001. The 2000 revenues consist of only sales of Actimmune in the United States for the period.

Cost of goods sold. We recognized a total of $3.1 million and $1.9 million for the three-month periods ended June 30, 2001 and 2000, respectively. Cost of goods sold includes all product cost of goods sold including manufacturing costs, royalties and distribution costs associated with our revenues.

Amortization of acquired product rights. We recorded a total of $1.1 million and $1.2 million for the three-month periods ended June 30, 2001 and 2000, respectively. Effective April 1, 2000, we purchased rights to all of the Actimmune revenues and related expenses that we had

previously transacted for Connetics. The amortization of those rights is expensed based upon product units shipped under the previous contractual unit baseline for the year 2001. This amounted to $741,000 for the second quarter in 2001. In addition, we recognized a total of $316, 000 for the amortization of other acquired product rights.

Research and development expenses. Research and development expenses increased by $6.7 million or 172%, to $10.5 million for the threemonth period ended June 30, 2001, compared to $3.8 million for the three-month period ended June 30, 2000. The increase was due primarily to increased costs for clinical trial expenses for Actimmune in new disease indications and increased staffing and related expenses necessary to manage the expansion of our operations. We expect research and development expenses to increase significantly over the next several years.

Selling, general and administrative expenses. Selling, general and administrative expenses were $8.3 million and $5.1 million for the three-month periods ended June 30, 2001 and 2000, respectively, representing an increase of 62%. This increase is attributable primarily to increased staffing and related expenses necessary to manage the expansion of our operations. We believe that selling, general and administrative expenses will continue to increase in absolute dollars as a result of the anticipated expansion of our sales and administrative staff, increased marketing and selling expenses for our products in their approved diseases and the expenses associated with expansion of our operations worldwide.

Acquired in-process research and development. We recorded a one-time charge for acquired in-process research and development of $5.4 million and $0 for the three-month periods ended June 30, 2001, and 2000, respectively. In June 2001, we entered into a licensing and commercialization agreement with Amgen Inc. to obtain an exclusive license in the United States and Canada to Infergen, (a therapeutic approved by the FDA for the treatment of hepatitis C infections), and the rights to an early stage program to develop a pegylated form of Infergen for a total consideration of $29 million, plus development milestones and royalties. Under the agreement, we also have the exclusive right to clinically develop Infergen for other indications in the United States and Canada. We do not expect the pegylated Infergen program, which is currently in its early stages (approximately 10% completed), to reach the FDA approval stage until 2006 at the earliest, if at all. Based upon a preliminary independent appraisal, the fair value of the in-process research and development program for pegylated Infergen was $5.4 million. The remainder of the purchase price of approximately $23.6 million, was allocated to developed technology and will be amortized over ten years. We will evaluate our intangible assets for impairment on a regular basis.

The value assigned to acquired in-process research and development was determined by estimating the costs to develop Amgen's purchased in-process research and development into a commercially viable product, currently estimated to be approximately $56 million including development milestones, estimating the resulting net cash flows from the project and discounting the net cash flows to their present value. A discount rate of 33% was used for valuing the in-process research and development and is intended to be commensurate with our corporate maturity and the uncertainties in the economic estimates described above. However, there is risk associated with the completion of this project, which includes the inherent difficulties and uncertainties of an early stage drug development program such as lack of efficacy and inability to obtain FDA approval as well as risks related to intellectual property and the impact of potential

changes in future target markets. There is no assurance that the project will meet either technological or commercial success. The technology under development has no foreseeable alternative future use.

The estimates used by the Company in valuing in-process research and development were based upon assumptions the Company believes to be reasonable but which are inherently uncertain and unpredictable. The Company's assumptions may be incomplete or inaccurate, and no assurance can be given that unanticipated events and circumstances will not occur. Accordingly, actual results may vary from the projected results.

Interest income. Interest income decreased to $2.1 million for the three-month period ended June 30, 2001, compared to $2.2 million for the three-month period ended June 30, 2000. The decrease in interest income was due to a decrease in funds available for investments as a result of funding our operating loss and product acquisitions made during 2001.

Interest expense. Interest expense was $0 for the three-month period ended June 30, 2001, compared to $44,000 for the threemonth period ended June 30, 2000. The decrease in interest expense was due to repayment of the entire balance due to Connetics in the first quarter of 2001.

Six Months Ended June 30, 2001 and 2000

Revenue. Total revenues were $13.6 million and $3.1 million for the six-month periods ended June 30, 2001 and 2000, respectively. The revenues in 2001 represent all sales of Actimmune in the United States for the period, worldwide sales of Amphotec for the period from January 5, 2001 (the date we acquired the marketing rights to Amphotec) to June 30, 2001 and sales of Infergen in the United States for the period from June 15, 2001 (the date we acquired the marketing rights to Infergen) to June 30, 2001. The sales in 2000 represent only those sales of Actimmune related to a supply arrangement outside the United States for the three months ended March 31, 2000, and all sales of Actimmune for the three months ended June 30, 2000. Sales for the three-month period ended March 31, 2000 were transacted for Connetics Corporation under the Transition Agreement that was subsequently terminated by the Revenue Adjustment Agreement. The Transition Agreement established an annual contractual baseline for Actimmune sales that has been terminated. Sales transacted for Connetics below the annual contractual baseline were recorded on a net basis, which was zero, and we paid to Connetics any amounts in excess of net revenues less costs to produce and market.

Cost of goods sold. We recognized a total of $6.6 million and $1.9 million for the six-month periods ended June 30, 2001 and 2000, respectively. Cost of goods sold includes all product cost of goods sold including manufacturing costs, royalties and distribution costs associated with our revenues.

Amortization of acquired product rights. We recorded a total of $3.2 million and $1.2 million for the six-month periods ended June 30, 2001 and 2000, respectively. Effective April 1, 2000, we purchased remaining rights to Actimmune revenues and related expenses that we had previously transacted for Connetics. The amortization of those rights is expensed based upon product units shipped under the previous contractual unit baseline for the year 2001. This amounted to $2.6 million and $1.2 million for the six-month periods ended June 30, 2001 and 2000, respectively. In addition, we recognized a total of $541,000 for the amortization of other acquired product rights.

Research and development expenses. Research and development expenses increased by $9.1 million or 114%, to $17.2 million for the six-month period ended June 30, 2001, compared to $8.1 million for the six-month period ended June 30, 2000. The increase was due primarily to increased costs for clinical trial expenses for Actimmune in new disease indications and increased staffing and related expenses necessary to manage the expansion of our operations. We expect research and development expenses to increase significantly over the next several years.

Selling, general and administrative expenses. Selling, general and administrative expenses were $14.8 million and $7.0 million for the six-month periods ended June 30, 2001 and 2000, respectively, representing an increase of 111%. This increase is attributable primarily to increased staffing and related expenses necessary to manage the expansion of our operations. We believe that selling, general and administrative expenses will continue to increase in absolute dollars as a result of the anticipated expansion of our sales and administrative staff, increased marketing and selling expenses for our products in their approved diseases and the expenses associated with expansion of our operations worldwide.

Acquired in-process research and development. We recorded a one-time charge for acquired in-process research and development of $5.4 million and $0 for the six-month periods ended June 30, 2001, and 2000, respectively. The acquired in-process research and development related to the acquisition of the early stage research pegylation program acquired from Amgen in the second quarter of 2001 (discussed above).

Interest income. Interest income increased to $4.8 million for the six-month period ended June 30, 2001, compared to $2.7 million for the same period in 2000. The increase in interest income was due to an increase in the average funds available for investments generated from financing activities in the year 2000.

Interest expense. Interest expense decreased to $30,000 for the six-month period ended June 30, 2001, compared to $134,000 for the six-month period ended June 30, 2000. The decrease in interest expense was due to lower liability balances to Connetics and Genentech during the period in 2001.

Deemed dividend upon issuance of convertible preferred stock. We recorded a deemed dividend of $27.8 million in January 2000, upon the issuance of 4,966,361 shares of Series B redeemable preferred stock. At the dates of issuance, we believed the per share price of $5.59 represented the fair value of the preferred stock and was in excess of the deemed fair value of our common stock. Subsequent to the commencement of our initial public offering process, we re-evaluated the deemed fair value of our common stock as of January 2000 and determined it to be $12.60 to $14.40 per share. Accordingly, the incremental fair value is deemed to be the equivalent of a preferred stock dividend. We recorded the deemed dividend at the date of issuance by offsetting charges and credits to additional paid in capital of $27.8 million without any effect on total stockholders' equity. The amount increased the loss applicable to common stockholders in the calculation of basic net loss per share for the six-month period ended June 30, 2000.

Liquidity and Capital Resources

For the six-month period ended June 30, 2001, cash expenditures for operating activities were $16.0 million. In addition to cash expenditures for operating activities, we used $4.3 million of cash for the acquisition of leasehold improvements and equipment for our new corporate headquarters located in Brisbane, California. We anticipate that expenditures for operating activities will increase significantly in future periods.

On January 10, 2001, we paid in cash an upfront license fee totaling $9.0 million to ALZA Corporation for the acquisition of worldwide rights to Amphotec.

On March 27, 2001, we repaid in full a total of $942,000 to Connetics Corporation as part of the Revenue Adjustment Agreement effective April 1, 2000. The present value of this obligation was included in our current liabilities at December 31, 2000 as $912,000.

On June 15, 2001, we paid in cash an upfront license fee totaling $21.0 million to Amgen Inc. for the acquisition of rights to Infergen in the United States and Canada and an early stage pegylated interferon product candidate, and are obligated to pay another $8 million under the terms of this agreement.

At June 30, 2001, we had available cash, cash equivalents and available-for-sale securities of $144.5 million. Our cash reserves are held in a variety of interest-bearing instruments including high-grade

corporate bonds, commercial paper and money market accounts. Cash in excess of immediate requirements is invested with regard to liquidity and return and, wherever possible. We seek to minimize the potential effects of concentration and degrees of risk.

We believe our existing cash, cash equivalents and short-term investments, together with cash flows will be sufficient to fund our currently planned operating expenses, debt obligations and capital requirements through at least the end of 2003. However, our capital requirements may increase in future periods. As a result, we may require additional funds and may attempt to raise additional funds through equity or debt financings, collaborative arrangements with corporate partners or from other sources. We have no commitments for any additional financings, additional funding may not be available to finance our operations when needed or, if available, the terms for obtaining such funds may not be favorable or may result in dilution to our stockholders.

Quantitative and Qualitative Disclosures about Market Risk

Our exposure to market risk is confined to our cash and investments. We maintain an investment portfolio of depository accounts, master notes and liquidity optimized investment contracts. The securities in our investment portfolio are not leveraged, are classified as available-for-sale and are, due to their very short-term nature, subject to minimal interest rate risk. We currently do not hedge interest rate exposure. Because of the short-term maturities of our investments, we do not believe that a change in market rates would have a significant negative impact on the value of our investment portfolio.

PART II–OTHER INFORMATION
INTERMUNE, INC.

ITEM 4. Submission of Matters to a Vote of Securities Holders.

We held our annual meeting of stockholders on May 8, 2001.

The stockholders elected the board of director nominees for director by the votes indicated:

Nominee	Votes in favor	Votes withheld
Wayne T. Hockmeyer	15,928,995	13,185
Jay P. Shepard	15,928,995	13,185

The stockholders approved the proposal to ratify the selection of Ernst & Young LLP as our independent auditors for the fiscal year ending December 31, 2001 with 15,940,995 affirmative votes, 800 negative votes, 385 abstentions and zero broker non-votes.

ITEM 6. Exhibits and Reports on Form 8-K.

(a) The following exhibits are included herein:

3.4 Certificate of Ownership and Merger, dated as of April 26, 2001.

*10.39 License and Commercialization Agreement, dated as of June 15, 2001, with Amgen Inc.

*

Confidential treatment requested with respect to certain portions of this exhibit. Omitted protions have been filed separately with the Securities and Exchange Commission.

(b) Reports on Form 8-K

On April 27, 2001, we filed a report on Form 8-K related to the name change of the company to InterMune, Inc.

On June 18, 2001, we filed a report on Form 8-K related to the issuance of three press releases announcing: (1) our license agreement with Amgen Inc. for Infergen, (2) updated financial guidance and (3) the amendment of our Form S-3 registration statement adding a concurrent offering of $125 million of convertible subordinated notes.

On June 29, 2001, we filed a report on Form 8-K updating our risk factors in connection with our public equity and subordinated debenture offerings.

INTERMUNE, INC.
SIGNATURES

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

Date: August 3, 2001

InterMune, Inc.

/s/ TIMOTHY P. LYNCH

By: Timothy P. Lynch
Chief Financial Officer and
Vice President of Finance
and Administration
(Principal Financial and Accounting
Officer and Duly Authorized Officer)

Exhibit 3.4

CERTIFICATE OF OWNERSHIP AND MERGER

MERGING

INTERMUNE, INC.,
a Delaware Corporation

INTO

INTERMUNE PHARMACEUTICALS, INC.
a Delaware Corporation

Pursuant to Section 253 of the
General Corporation Law of the State of Delware

InterMune Pharmaceuticals, Inc., a corporation organized and existing under the General Corporation Law of the State of Delaware (the "Corporation"),

DOES HEREBY CERTIFY:

FIRST: That the Corporation owns all of the outstanding shares of InterMune, Inc., a corporation organized and existing under the General Corporation Law of the State of Delaware.

SECOND: That the Corporation, by the following resolutions of its Board of Directors, duly adopted by Unanimous Written Consent pursuant to Section 141(f) of the General Corporation Law of the State of Delaware on the 18th of April, 2001, determined to merge InterMune, Inc. into itself on the terms and conditions set forth in such resolutions:

RESOLVED, that InterMune, Inc. be merged with and into the Corporation and that the Corporation be the surviving corporation in such merger;

FURTHER RESOLVED, that the merger shall become effective upon the date and time of the filing of a Certificate of Ownership and Merger with the Secretary of State of the State of Delaware;

FURTHER RESOLVED, that upon the effectiveness of the merger, the Corporation shall assume all of the liabilities and obligations of InterMune, Inc.; and

FURTHER RESOLVED, that upon the effectiveness of the merger, the name of the Corporation shall be changed to "InterMune, Inc." and Article I of the Amended and Restated Certificate of Incorporation of the Corporation shall be amended to read as follows:

"ARTICLE I. The name of this corporation is InterMune, Inc."

IN WITNESS WHEREOF, this Certificate of Ownership and Merger is hereby executed on behalf of the surviving corporation, InterMune Pharmaceuticals, Inc.

Dated as of April 26, 2001

INTERMUNE PHARMACEUTICALS, INC.

By: /s/ W. Scott Harkonen

W. Scott Harkonen
President, Chairman of the Board and
Chief Executive Officer

QuickLinks

Exhibit 3.4

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Exhibit 10.39

LICENSE AND COMMERCIALIZATION AGREEMENT

BY AND BETWEEN

AMGEN INC.

AND

INTERMUNE, INC.

June 15, 2001

TABLE OF CONTENTS

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

LICENSE AND COMMERCIALIZATION AGREEMENT

This License and Commercialization Agreement (the "Agreement") is made effective as of the 15th day of June, 2001 (the "Effective Date") by and between **Amgen Inc.**, a Delaware corporation having its principal place of business at One Amgen Center Drive, Thousand Oaks, CA 91320-1799 ("Amgen") and **InterMune, Inc.,** a Delaware corporation having its principal place of business at 1710 Gilbreth Road, Suite 310, Burlingame, CA 94010-1317 ("InterMune"). Amgen and InterMune are sometimes referred to herein individually as a "Party" and collectively as the "Parties", and references to "InterMune" and "Amgen" shall include their respective Affiliates.

Recitals

Whereas, Amgen has bioengineered, developed, obtained regulatory approval for, and currently markets in the United States and Canada a pharmaceutical composition containing a novel, non-naturally occurring Type 1 interferon, sold under the trademark Infergen®;

Whereas, InterMune has clinically developed and currently markets an interferon-gamma product in the United States, and therefore has both clinical development experience and a sales force that may be particularly well suited to market and further develop a product such as Infergen;

Whereas, InterMune desires to obtain, and Amgen wishes to grant InterMune, the exclusive license to commercialize and further develop Infergen in the United States and Canada on the terms and conditions set forth herein; and

Whereas, Amgen is willing to supply InterMune, and InterMune wishes to be supplied by Amgen, with quantities of Infergen (as such term is defined below) on the Supply Terms (as defined below);

Now Therefore, based on the foregoing premises and the mutual covenants and obligations set forth below, the Parties agree as follows:

ARTICLE 1
DEFINITIONS

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

1.1 "Active Component" shall mean any product other than the Licensed Product which **[*]** therapeutic or prophylactic function when combined with the Licensed Product.

1.2 "Affiliate" shall mean, except as provided below, a Person that, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with Amgen or InterMune. For purposes of this definition, "control" shall mean the possession, direct or indirect, of the power to cause the direction of the management and policies of a Person, whether through ownership of fifty percent (50%) or more of the voting securities of such Person, by contract or otherwise. Affiliate **[*]** shall **[*]**

1.3 "Amgen Know-How" shall mean the following information: (1) information disclosed in the BLA for Infergen as of the Effective Date, (2) information disclosed as of the Effective Date in any BLA supplements for Infergen, (3) all Amgen-sponsored investigator-driven clinical trial results, and the results of the Ongoing Clinical Trials, (subject to any contractual confidentiality obligations of Amgen to Third Parties regarding such results); (4) Infergen sales and marketing training materials; (5) any regulatory data which Amgen provides to InterMune pursuant to Section 4.3; (6) **[*]**; (7) the safety and clinical database referenced in Section 4.8; and (8) Formulating Know-How (as defined in Section 12.1 of Exhibit F).

1.4 "Amgen Trademarks" shall mean the registered trademarks listed at **Exhibit A**, all trademark applications listed at **Exhibit A** and all trademarks issuing from such applications, together with any renewals, modifications or extensions thereto.

1.5 "Amgen Patent" shall mean **[*]**

1.6 "Amgen Technology" shall mean all Amgen Patents, Amgen Know-How and Amgen Trademarks.

1.7 "BLA" shall mean a Biological License Application for Regulatory Approval filed in the United States.

1.8 "CMC" shall mean the Chemistry Manufacturing Control section of a BLA.

1.9 "Combination Product" shall have the meaning assigned such term pursuant to Section 6.6.

1.10 "Commercialize" or "Commercialization" shall mean those activities relating to the promotion, marketing and sale of Licensed Products and shall include without limitation, Phase IV Clinical Trials or equivalent clinical trials conducted following Regulatory Approval to market a pharmaceutical product.

1.11 "Commercially Reasonable Efforts" shall mean the level of efforts and resources required to Commercialize a Licensed Product in a sustained manner consistent with the efforts a similarly situated biopharmaceutical company would typically devote to a product of similar market potential, profit potential or strategic value resulting from its own research efforts, based on conditions then prevailing. Commercially Reasonable Efforts shall be determined on a country-by-country (each country including its territories) basis for a particular Licensed Product, and it is anticipated that the level of effort will change over time reflecting changes in the status of the Licensed Product and the country (including its territories) involved.

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

(a) is publicly disclosed by the disclosing Party, either before or after it becomes known to the receiving Party;

(b) was known to the receiving Party, without obligation to keep it confidential, prior to when it was received from the disclosing Party;

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

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

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

1.13 "Control" shall mean possession of the ability to grant a license or sublicense as provided for herein under such intellectual property right without violating the terms of any agreement or other arrangement with any Third Party.

1.14 "Default" shall mean with respect to either Party (i) that any representation or warranty of such Party set forth herein shall have been untrue in any material respect when made or (ii) such Party, such Party's Affiliate or such Party's sublicensee shall have failed to materially perform any material obligation set forth herein.

1.15 "Directly Competitive Product" shall mean any pharmaceutical product that contains **[*]** or **[*]** of such **[*]** and that **[*]** with **[*]** in **[*]** such Licensed Product **[*]**

1.16 "Dollar" shall mean a United States dollar, and "$" shall be interpreted accordingly.

1.17 "Drug Approval Application" shall mean an application for Regulatory Approval required before commercial sale or use of a Licensed Product as a drug or to treat a particular indication in a regulatory jurisdiction, including without limitation applications to expand the label of an approved drug.

1.18 "Existing License" shall mean that certain Agreement between **[*]**

1.19 "Existing License Patents" shall mean the Patents under which Amgen has a license pursuant to the Existing License, a copy of which has been provided to InterMune.

1.20 "Existing Licensor" shall mean **[*]**

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

1.22 "Force Majeure" shall mean any occurrence beyond the reasonable control of a Party that prevents or substantially interferes with the performance by the Party of any of its obligations hereunder, if such occurs by reason of any act of God, flood, fire, explosion, breakdown of plant, earthquake, strike, lockout, labor dispute, casualty or accident, or war, revolution, civil commotion, acts of public enemies, blockage or embargo, or any injunction, law, order, proclamation, regulation, ordinance, demand or requirement of any government or of any subdivision, authority or representative or any such government, inability to procure or use materials, labor, equipment, transportation, or energy sufficient to meet manufacturing needs without the necessity of allocation, or any other cause whatsoever, whether similar or dissimilar to those above enumerated, beyond the reasonable control of such Party, if and only if the Party affected shall have used reasonable efforts to avoid such occurrence and to remedy it promptly if it shall have occurred.

1.23 "GAAP" shall mean United States generally accepted accounting principles.

1.24 "Infergen" shall mean the product containing Interferon alfacon-1 for which Amgen has obtained Regulatory Approval in each country of the Territory prior to the Effective Date, in either bulk or filled and finished form.

1.25 "IND" shall mean Investigational New Drug application.

1.26 "Interferon alfacon-1" shall mean the polypeptide having the amino acid sequence which is set forth in **Exhibit C**.

1.27 "Licensed Product" shall mean any product comprising Interferon alfacon-1 or **[*]** Licensed Products include but are not limited to Infergen.

1.28 "Losses" shall mean suits, claims, actions, demands, liabilities, expenses and/or losses, including without limitation reasonable legal expenses and attorneys' fees.

1.29 "Net Sales" shall mean all revenues recognized in accordance with GAAP from the sale or other disposition of Licensed Products by InterMune, its Affiliates or Sublicensee to a Third Party, less **[*]**

Amounts received by InterMune, its Affiliates or Sublicensees for the sale of Licensed Products among InterMune, its Affiliates and Sublicensees for resale shall not be included in the computation of Net Sales hereunder. Distributors of InterMune selling Licensed Products shall not be deemed to be Sublicensees of InterMune.

1.30 "Ongoing Clinical Trials" shall mean those clinical trials listed at Exhibit E hereto, which are clinical trials of Infergen that Amgen is conducting in the Territory as of the Effective Date. For avoidance of doubt, Ongoing Clinical Trials shall exclude any Amgen-sponsored investigator-driven clinical trials. Amgen represents that the Ongoing Clinical Trials are the only clinical trials of Infergen being conducted in the Territory by or on Amgen's behalf as of the Effective Date.

1.31 "Other Licensee" shall mean any Third Party to which Amgen has granted or grants a license and/or sublicense to develop or Commercialize a Licensed Product outside the Territory, including without limitation **[*]**

1.32 "Patent" shall mean (i) an issued, unexpired patent (with the term "patent" being deemed to encompass, without limitation, an inventor's certificate) which has not been held invalid or unenforceable by a court of competent jurisdiction from which no appeal can be taken or has been taken within the

required time period, including without limitation any substitution, extension, registration, confirmation, reissue, re-examination, renewal or any like filing thereof or (ii) a pending application for a patent, including without limitation any provisional, converted provisional, continued prosecution application, continuation, divisional or continuation-in-part thereof; any patents issuing therefrom; and any substitution, extension, registration, confirmation, reissue, reexamination, renewal or like filing thereof.

1.33 "PEG Know-How" shall mean any of the following which is conceived, reduced to practice, developed or employed by Amgen (solely or jointly with InterMune) **[*]** the PEG Program: (i) techniques and data specifically relating to (but not necessarily solely to) the **[*]** of PEG-Infergen Product, including, but not limited to, **[*]** and (ii) **[*]** of PEG Infergen Product. For avoidance of doubt, PEG Know-How as it relates to manufacturing, shall only include **[*]** PEG-Infergen Products, and shall not include **[*]**

1.34 "PEG Patent" shall mean **[*]**

1.35 "PEG Program" shall mean a program of collaborative development by the Parties of a PEG-Infergen Product (if any such program is agreed to by the Parties pursuant to Section 3.2).

1.36 "PEG-Infergen Product" shall mean a pharmaceutical composition containing as its active ingredient **[*]**

1.37 "Phase III Clinical Trial" means a clinical trial (or set of clinical trials) of a pharmaceutical product on sufficient numbers of patients which, if the defined end-points are met, are designed or intended to file for Regulatory Approval on the basis thereof.

1.38 "Phase IV Clinical Trial" shall mean a pharmaceutical product support clinical trial of a pharmaceutical product commenced after receipt of Regulatory Approval in the country where such trial is being conducted.

1.39 "Planning Period Date" shall have the meaning assigned such term pursuant to Section 3.2.

1.40 "Regulatory Approval" shall mean any approvals (including supplements, amendments, pre- and post-approvals and price approvals), licenses, registrations or authorizations of any national, supra-national regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity, necessary for the distribution, use or sale of a Licensed Product in a regulatory jurisdiction. Regulatory Approval shall not include any **[*]**

1.41 "Regulatory Authority" shall mean the FDA or any counterpart of the FDA outside the United States.

1.42 "Royalty" or Royalties" shall mean those amounts payable as royalties by InterMune to Amgen pursuant to Sections 6.4 and 6.7(a) of this Agreement.

1.43 "Sublicensee" shall mean a sublicensee of InterMune under InterMune's rights pursuant to Section 2.2, 2.3 and 2.4, the sublicense to whom is permitted pursuant to Section 2.5.

1.44 "Supply Terms" shall mean the terms and conditions set forth in Exhibit F.

1.45 "Term" shall mean the term of this Agreement.

1.46 "Territory" shall mean the United States and Canada, and the possessions and territories of each such country.

1.47 "Third Party" shall mean any entity other than Amgen or InterMune or an Affiliate of either of them.

1.48 "Trademark" shall mean any trade name, service mark, logo or trademark (whether or not registered) together with all goodwill associated therewith, and any renewals, extensions or modifications thereto.

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

ARTICLE 2
LICENSES; EXCLUSIVITY; TRADEMARKS

2.1 Technology Ownership. Except for items (1) and (2) listed in the definition of Amgen Know-How, Amgen shall retain sole right and interest, subject only to the licenses granted in Section 2.2, 2.3 and 2.4 of this Agreement, to the Amgen Technology.

2.2 Patent License to InterMune.

(a) Subject to the terms and conditions of this Agreement, Amgen hereby grants to InterMune an exclusive (even as to Amgen) license, with the right to grant sublicenses (subject to InterMune's compliance with Section 2.5 of this Agreement), under the Amgen Patents to **[*]** Licensed Products in the Territory.

(b) Subject to the terms and conditions of this Agreement, Amgen hereby grants to InterMune an exclusive (even as to Amgen) sublicense, without the right to grant sublicenses, under the Existing License Patents to **[*]** Infergen in the Territory. Except as expressly set forth herein, Amgen does not grant InterMune any other rights with respect to the Existing License or to Existing License Patents.

(c) Subject to the terms and conditions of this Agreement, Amgen hereby grants to InterMune an exclusive license (even as to Amgen), under the PEG Patent, to **[*]** pegylated Licensed Products.

(d) Subject to the terms and conditions of this Agreement, Amgen hereby grants to InterMune an exclusive **[*]** license (even as to Amgen), under PEG Know-How and Patents claiming PEG Know-How, to **[*]** pegylated Licensed Products.

2.3 Trademark and Copyright Licenses to InterMune.

(a) Amgen hereby grants to InterMune an exclusive **[*]** license, with the right to grant sublicenses (subject to InterMune's compliance with Section 2.5 of this Agreement), under the entire right, title and interest in and to the Amgen Trademarks, to use and display the Amgen Trademarks in connection with Licensed Products in the Territory. InterMune shall have the right to select for and use and display with Licensed Products such Trademarks as it desires, consistent with any reasonable quality standards which Amgen may prescribe for use and display of the Amgen Trademarks.

(b) Amgen hereby grants to InterMune an exclusive **[*]** license under Amgen's entire right, title and interest in any copyrights in Infergen-specific promotional materials existing on or before the Effective Date, with the right to grant sublicenses (subject to InterMune's compliance with Section 2.5 of this Agreement), to reproduce, distribute copies of, prepare derivative works of and publicly perform and display such promotional materials in connection with Licensed Products in the Territory.

2.4 Know-How License to InterMune. Subject to the terms and conditions of this Agreement, Amgen grants InterMune a **[*]**, exclusive license under the Amgen Know-How to use the Amgen Know-How for the sole purposes of **[*]** Licensed Products in the Territory.

2.5 Sublicenses. Subject to Amgen's prior written approval in each instance, InterMune may grant sublicenses to Third Parties under Sections 2.2, 2.3 and 2.4. Notwithstanding the sublicensing of all or part of InterMune's rights and obligations hereunder, InterMune shall remain responsible for the full and complete performance of all of InterMune's obligations and duties under this Agreement. There shall be

no presumption that Amgen will provide its approval for InterMune to grant a sublicense to any Third Party, however Amgen shall not unreasonably withhold its consent.

2.6 Sublicensed Technology. Amgen shall timely perform and discharge its obligations under the Existing License during the Term and shall not permit any action to be taken or event to occur, in each case, within Amgen's reasonable control, which would give Existing Licensor

the right to terminate Existing License. InterMune agrees that the rights granted under this Agreement are subject to, and agrees to be bound by, all the terms and conditions required of sublicensees under the Existing License.

2.7 Exclusivity.

(a) Except as explicitly permitted pursuant to this Agreement, Amgen shall not use, develop, import, promote, sell, or offer for sale Licensed Products for use within the Territory.

(b) Amgen shall not **[*]** a Directly Competitive Product in the Territory, and shall not **[*]** take such actions during the Term; *provided, however*, that the foregoing prohibition shall be subject to Amgen's rights pursuant to Section 13.6.

2.8 Retained Rights. Notwithstanding the exclusive license granted InterMune pursuant to Section 2.2, Amgen retains the non-transferable, non-exclusive right under the Amgen Patents and Amgen Know-How to **[*]**; *provided, however*, that, except as authorized under Section 12.2(b) Amgen shall not publish the **[*]**, to the extent **[*]** of the **[*]** in **[*]** nothing shall prohibit Amgen or its Affiliates from fulfilling its obligations or exercising its rights in this Agreement or with regard to Licensed Products outside the Territory.

2.9 Import. The term "import" or "importing" whenever used in this agreement shall not permit InterMune to conduct any activities outside the Territory outside the Territory regarding Licensed Product without the express written consent of the Other Licensees.

2.10 Covenant. Amgen hereby covenants that it and its Affiliates, assignees, and licensees ("Covenantors") shall not sue InterMune, its Affiliates and Sublicensees for infringement of any Patent owned or Controlled by any Covenantor, or under which any Covenantor has the right to sue infringers, in each case during the Term **[*]**

ARTICLE 3
DEVELOPMENT

3.1 Ongoing Clinical Trials. As of the Effective Date, Amgen is conducting the Ongoing Clinical Trials in the Territory. As soon as is reasonably practical after the Effective date, Amgen will assign (to the extent assignable) and transfer its clinical trial contracts covering the Ongoing Clinical Trials to InterMune. Amgen shall make reasonable efforts to complete such assignments within **[*]** days after the Effective Date and transfer to InterMune any data from the Ongoing Clinical Trials that Amgen possesses as of such date. To the extent that Amgen is still conducting the Ongoing Clinical Trials during such **[*]** day transition period, Amgen shall comply with all applicable laws and regulations, and regulations of the Regulatory Authorities having jurisdiction in the Territory in Amgen's conduct of the Ongoing Clinical Trials, shall keep InterMune promptly informed of any inquiries of such Regulatory Authorities regarding the Ongoing Clinical Trials, shall provide InterMune with drafts of all proposed correspondence with any such Regulatory Authority regarding any Ongoing Clinical Trial and permit InterMune to be present at any meeting with such a Regulatory Authority regarding any Ongoing Clinical Trial. InterMune shall reimburse Amgen for all Ongoing Clinical Trial expenses incurred by Amgen after the Effective Date.

3.2 PEG-Infergen Products. InterMune shall have a period of **[*]** days to **[*]** and whether it desires to have Amgen provide **[*]** (as defined in the Code of Federal Regulations, as may be amended from time to time) for the **[*]** The Parties recognize that Amgen's expertise with Infergen may be particularly applicable to the preclinical development of any PEG-Infergen Product. Within **[*]** days after the end of such **[*]** day period, if InterMune notifies Amgen in writing that InterMune wishes to negotiate with Amgen what development activities Amgen would carry out with respect to such PEG-Infergen Product and commercially reasonable terms upon which Amgen would carry out such **[*]** then Amgen and InterMune shall negotiate in good faith such activities and terms for a period of no less than **[*]** The end of such **[*]** day period shall be referred to as the "Planning Period Date". The Parties have agreed that such commercially reasonable terms for the development of PEG-Infergen would include (i) InterMune funding any such development work by Amgen at a rate equal to **[*]** and (ii) all PEG Know How and Patents claiming PEG

Know-How, which shall be included in the Amgen Technology and therefore subject to the licenses of Article 2 of this Agreement.

3.3 Development Efforts. Beginning reasonably promptly after **[*]** InterMune shall commence using Commercially Reasonable Efforts to develop and seek Regulatory Approval for (in due course) a PEG-Infergen Product in the regulatory jurisdictions of the Territory.

3.4 Amgen Interim Activities. As InterMune evaluates the business opportunity for PEG-Infergen Products, Amgen will undertake the following preparatory activities to enable InterMune to better evaluate the possibility of conducting a collaborative PEG Program with Amgen:

(a) Amgen will **[*]** with a **[*]** and provide InterMune with written notice of such accomplishment.

(b) Amgen will prepare and provide to InterMune a written **[*]** work plan detailing activities **[*]** as part of a PEG Program and associated anticipated schedules and costs. Any such plan shall include a description of actions (and associated timings and costs) for Amgen to develop and supply InterMune with quantities of GMP-compliant PEG-Infergen sufficient to commence Phase I Clinical Trials thereof. Such a plan shall be referred to herein as a "**[*]** Work Plan."

Amgen's actions as permitted by this Section 3.4 shall not be deemed to bind InterMune to proceed with a PEG Program in collaboration with Amgen.

3.5 Development Data. [*] InterMune shall provide Amgen with written summaries of all pre-clinical and clinical data generated by InterMune with respect to Infergen (such summaries, the "Development Summaries"). All such Development Summaries shall be considered Confidential Information of InterMune and Amgen may share it with its Other Licensees under appropriate obligations of confidentiality and non-use commensurate with those contained herein. Upon any Other Licensee's request, InterMune will **[*]** in such detail as shall be reasonably necessary to allow **[*]** outside the Territory.

3.6 Development Activities in Territory.

(a) InterMune may collaborate or consult with researchers and investigators and contract for pre-clinical studies without regard to whether such research, investigators and studies are inside or outside of the Territory and without obtaining permission from any Other Licensee, but in no event will InterMune conduct clinical trials with any Licensed Product outside the Territory without advance written consent from the Other Licensee in whose territory outside the Territory InterMune wishes to conduct such clinical trials.

(b) Amgen and any Other Licensee may collaborate or consult with researchers and investigators and contract for pre-clinical studies without regard to whether such research, investigators and studies are inside or outside of the Territory and without obtaining permission from InterMune, but in no event will Amgen or any Other Licensee conduct clinical trials in the Territory with any Licensed Product without advance written consent from InterMune.

ARTICLE 4
REGULATORY

4.1 General. As of the Effective Date, Amgen owns in its own name Regulatory Approvals for Infergen in each country of the Territory. Exhibit D contains a complete list of such Regulatory Approvals existing as of the Effective Date. Subject to Amgen's rights of reference as described below in Section 4.3 and Amgen's other rights pursuant to such Section, Amgen hereby assigns to InterMune Amgen's entire right, title and interest in and to all Regulatory Approvals and Drug Approval Applications for Infergen in the Territory to InterMune. **[*]** after the Effective Date, Amgen shall notify Regulatory Authorities in the Territory of, and as soon as is reasonably practicable thereafter take all actions reasonably necessary to effect or evidence, the transfer of such Regulatory Approvals to InterMune. In light of such assignment

and transfer during the time period when Amgen will be transitioning the Ongoing Clinical Trials to InterMune, the Parties will **[*]** to make appropriate arrangements in accordance with law to allow for Amgen continue to conduct the Ongoing Clinical Trials under Amgen's IND until the transition of the Ongoing Clinical Trials to InterMune is complete. For the avoidance of doubt, the transfer of such Regulatory Approvals shall not be effective to transfer to InterMune ownership of, **[*]** any manufacturing trade secret disclosed therein, including without limitation, **[*]**

4.2 Additional Regulatory Filings. InterMune shall have the exclusive right to file, and will own in its own name, any additional Drug Approval Applications for Licensed Products in the Territory, including without limitation any filings relating to label expansions for Infergen.

4.3 InterMune Access to Amgen Regulatory Data.

(a) Regulatory Data as of the Effective Date. Amgen will, as soon as is reasonably practicable after the Effective Date, provide InterMune originals of the BLA and Canadian equivalent for Infergen in the United States and Canada, respectively, and all supplements to either of the foregoing; *provided, however* that Amgen shall be entitled to redact any trade secret information relating to products other than Licensed Products and any manufacturing trade secrets proprietary to Amgen (other than the **[*]** for Infergen). Amgen has provided InterMune with a list of correspondence between Amgen and the FDA regarding Infergen for the approximately two (2) years prior to the Effective Date and shall provide InterMune with reasonable access to the correspondence referenced in such list, and to other correspondence between Amgen and Regulatory Authorities having jurisdiction in the Territory, upon the request of InterMune.

(b) Regulatory Data Generated After the Effective Date. During the Term, Amgen will provide to InterMune all regulatory data owned or Controlled by Amgen regarding any Licensed Product and necessary for marketing or making regulatory filings for Licensed Products in the Territory as it becomes available. Such data shall be data generated in the Ongoing Clinical Trials (including adverse events encountered in the Ongoing Clinical Trials). Except for the information contained in the CMC section of Amgen's BLA filings for Infergen, Amgen shall have no obligation, for any reason or under any circumstance, to provide InterMune with any information regarding Amgen's manufacturing facility or any information pertaining to the manufacture of Licensed Products (including, without limitation, **[*]**).

(c) Amgen Use of Information. Amgen shall have the right to review, a right of access, a right of reference and the right to use and incorporate all Amgen Know-How outside the Territory or to satisfy Amgen's obligations in the Territory hereunder or to any Other Licensee **[*]** The Parties shall discuss, as soon as practicable after the Effective Date, the form in which the Parties shall exchange information pursuant to this Section 4.3 and Section 4.4.

(d) Legally Required Access. Notwithstanding anything to the contrary in this Agreement, InterMune shall have the right to receive from Amgen, and Amgen shall provide to InterMune, any regulatory data or information (including without limitation manufacturing information) to which InterMune, as the holder of any Regulatory Approval in the Territory, is required by law, rule, regulation or a Regulatory Authority having jurisdiction in the Territory, is required to have access, but shall only be entitled to use such regulatory data or information to the extent required by such law, rule, regulation or Regulatory Authority.

4.4 Adverse Event Reporting; Customer Complaints.

(a) After the Effective Date, InterMune shall be responsible for the adverse experience and safety reporting for the Licensed Product in compliance with the requirements of the U.S. Food, Drug and Cosmetic Act, 21 USC § 321 et seq. and the regulations promulgated thereunder and the equivalent regulations in the Territory; *provided* that Amgen shall provide interim adverse experience and safety reporting services for Infergen on InterMune's behalf for a period of **[*]** after the Effective Date. Amgen shall, as soon as practicable following of the Effective Date, provide InterMune with a

summary of the information relating to the investigation and reporting of adverse experiences regarding Infergen and all information submitted to Regulatory Authorities in Amgen's BLA for Infergen and any BLA supplements relevant to the safe use of Infergen. If Amgen receives any customer complaints regarding the marketing or distribution of Infergen in the Territory more than **[*]** after the Effective Date, it shall promptly refer such complaint to InterMune for handling.

(b) To enable InterMune to satisfy its reporting obligations to the Regulatory Authorities having jurisdiction in the Territory, Amgen shall require each of its Other Licensees to disclose to Amgen and to allow Amgen to disclose to InterMune all information relating to adverse events encountered by or on behalf of such Other Licensee in connection with any Licensed Products.

(c) InterMune shall reasonably promptly disclose to Amgen, and permit Amgen to disclose to Other Licensees all information relating to adverse events encountered by or on behalf of InterMune in connection with the Licensed Products.

4.5 Communications. Except as may be required by law, requested by InterMune or any Regulatory Authority having jurisdiction in the Territory, and except as to issues regarding the manufacture of Licensed Products in the Territory, Amgen shall not communicate regarding any Licensed Product with any Regulatory Authority having jurisdiction in the Territory unless requested to do so by InterMune. Amgen will keep InterMune informed of any such required communications. Amgen will reasonably cooperate with InterMune to make any communications regarding manufacture of any Licensed Product by Amgen for supply to InterMune, with the Regulatory Authorities having jurisdiction in the Territory; *provided* that Amgen shall have no obligation, **[*]** to provide InterMune with any information regarding **[*]** (including, without limitation, **[*]**). For so long as Amgen is supplying InterMune with Infergen hereunder, Amgen shall have the right to be present at all meetings and telephone calls with the Regulatory Authorities having jurisdiction in the Territory at which **[*]** is to be discussed.

4.6 Applications for Regulatory Exclusivity. The Parties recognize that exclusivity rights granted or provided for under regulatory laws of the countries of the Territory may be commercially significant to Licensed Products. To the extent permitted by law, InterMune shall have the exclusive right (even as to Amgen) to file for, request and maintain any regulatory exclusivity rights for Licensed Products in the Territory, including without limitation regulatory exclusivity rights based upon an orphan drug designation of a Licensed Product, and to conduct and prosecute any proceedings or actions to enforce such regulatory exclusivity rights, and Amgen shall reasonably cooperate with InterMune in such actions at InterMune's expense.

4.7 Recalls and Voluntary Withdrawals. The Parties shall exchange their internal standard operating procedures as to product recalls ("SOPs") reasonably promptly after the Effective Date. If either Party becomes aware of information about quantities of Licensed Product supplied by Amgen to InterMune indicating that such quantities of Licensed Product may not conform to the specifications for such product then in effect pursuant to the Supply Terms, or that there are potential adulteration, misbranding and/or other issues regarding safety or effectiveness, it shall promptly so notify the other Party. The Parties will meet to discuss such circumstances and to consider appropriate courses of action, which courses of action with respect to each recall shall be consistent with the internal SOP of the Party having the right to control such recall pursuant to this Section 4.7. InterMune shall have the right to control, and shall bear all costs associated with, a recall of the Licensed Product in the Territory. If **[*]** shall **[*]** not to **[*]** in the **[*]** shall have the **[*]** at **[*]** As between Amgen and InterMune, Amgen shall control, at its sole expense, all recalls of Licensed Product outside the Territory. InterMune and Amgen shall each maintain complete and accurate records of any recall it has the right to control pursuant to this Section 4.7 for such periods as may be required by legal requirements, but in any event for no less than three (3) years.

4.8 Safety and Clinical Database. Within sixty (60) days after the Effective Date, Amgen shall transfer to InterMune Amgen's safety and clinical database relating to Infergen and existing on the Effective Date.

ARTICLE 5
COMMERCIALIZATION

5.1 Pricing. InterMune shall determine in its sole discretion the pricing, discounting policy and other commercial terms relating to Licensed Products in the Territory.

5.2 Diligence.

(a) InterMune shall use its Commercially Reasonable Efforts to Commercialize Infergen in the Territory during the Term.

(b) Beginning promptly after the receipt of Regulatory Approval for a first PEG-Infergen Product in each country of the Territory, InterMune shall use its Commercially Reasonable Efforts to Commercialize a PEG-Infergen Product in such country.

5.3 Reports. InterMune shall provide Amgen with detailed written **[*]** reports concerning its efforts regarding development and Commercialization of the Licensed Products in the Territory. The information contained in such reports shall be deemed to be InterMune's Confidential Information. InterMune shall, at Amgen's request, promptly meet with Amgen no less frequently than **[*]** to discuss the **[*]** reports and InterMune's progress regarding development and Commercialization of the Licensed Products in the Territory.

5.4 Amgen Transition Assistance.

(a) During the period commencing on the Effective Date and ending **[*]** Amgen shall provide (i) reasonable assistance to InterMune in notifying Amgen's distributors and customers as of the Effective Date of InterMune's license to Commercialize and further develop the Licensed Product; and (ii) **[*]** on InterMune's behalf.

(b) Until **[*]** after the Effective Date, Amgen shall provide reasonable assistance to InterMune to enable it to assume its responsibilities pursuant to Section 5.6.

(c) For a period of up to **[*]** after the Effective Date, Amgen shall provide InterMune, at mutually agreed times and locations, with reasonable access to and assistance from those of Amgen's Infergen marketing personnel, as of the Effective Date, selected by Amgen to transition the marketing and sales force training knowledge and materials to InterMune. Such assistance would include, without limitation, meeting with InterMune's marketing and sales personnel to educate them regarding Infergen and the existing marketing arrangements that Amgen had in place for Infergen as of the Effective Date.

5.5 Change of Promotional Material. Promptly after the Effective Date and subject to applicable regulatory requirements and Regulatory Approvals, InterMune, at its own expense, shall prepare all advertising and promotional materials for any Licensed Product to identify InterMune (or its distributors) as the marketer of the Licensed Product, in such form as InterMune shall determine. As soon as practicable after the Effective Date, InterMune, at its own expense, shall make such changes in the package insert, Licensed Product labeling and packaging as may be required to reflect InterMune as the marketer of the Licensed Product, including making all required filings in connection therewith including without limitation filings with the Regulatory Authorities having jurisdiction in the Territory. Promptly after the Effective Date, Amgen shall file with Regulatory Authorities in the Territory a notice that InterMune is the marketer and distributor of the Licensed Product in the United States. To the extent that Regulatory Authorities in the Territory request additional information or meetings regarding InterMune's responsibilities as marketer and distributor of the Licensed Product in the Territory, Amgen and InterMune shall cooperate with each other, and coordinate a response.

5.6 Medical and Other Inquiries. On the Effective Date, InterMune shall assume all responsibility for all correspondence and communication with physicians and other health care professionals and customers in the United States and any other countries in the Territory where Amgen had this responsibility relating

to the Licensed Product. InterMune shall keep such records and make such reports as shall be reasonably necessary to document such communications in compliance with all applicable regulatory requirements. After the Effective Date, Amgen shall refer all questions relating to the Licensed Product raised by health care professionals and customers to InterMune for its response.

5.7 Trade Returns; Reimbursements. Amgen shall bear all costs and expenses related to all returns, charge backs and rebates for units of Licensed Products sold in the Territory prior to or on the Effective Date. InterMune shall bear all costs and expenses related to all returns, charge backs and rebates for units of Licensed Products sold after the Effective Date. **[*]** shall bear all costs and expenses related to Medicaid

reimbursements for the Licensed Product **[*]** **[*]** shall bear all costs and expenses related to Medicaid reimbursements for the Licensed Product **[*]** If Amgen receives any **[*]** it shall promptly refer such **[*]** to InterMune for handling. If InterMune receives any **[*]** InterMune shall promptly refer such **[*]** to Amgen for handling.

5.8 Distribution Agreements. Amgen has **[*]** of all outstanding material contracts, agreements or arrangements between Amgen and any Third Party in the Territory (including government agencies, health maintenance organizations and all other buyers of Licensed Product, other than wholesalers) relating to the sale of the Licensed Product (collectively, "Distribution Agreements"). On the Effective Date, InterMune shall assume Amgen's obligations under the Distribution Agreements, to the extent such Distribution Agreements are assignable by their terms and to the extent (i) pertaining to time periods subsequent to the Effective Date and (ii) not arising on or before the Effective Date. To the extent any Distribution Agreement is not freely assignable, Amgen shall use reasonable efforts to seek the consent of the applicable Distributor(s) to assign such Distribution Agreement to InterMune and, if and when so assigned, InterMune shall assume Amgen's obligations under such Distribution Agreement to the extent (i) pertaining to a time period subsequent to the date such Distribution Agreement is assigned to InterMune, and (ii) not arising on or before such date.

ARTICLE 6
COMPENSATION

6.1 License Fee.

(a) Prior to the Effective Date InterMune paid Amgen one million Dollars ($1,000,000) in consideration of exclusive negotiations that led to the execution of this Agreement.

(b) Within five (5) business days after the Effective Date, InterMune shall pay Amgen a license fee of twenty million Dollars ($20,000,000) in cash by wire transfer of immediately available funds into an account designated by Amgen. This license fee shall be nonrefundable and noncreditable against Royalties due Amgen pursuant to Section 6.3 and any other fees, milestone payments or other payments due Amgen under this Agreement.

6.2 Amgen Performance Milestones.

(a) Within **[*]** days after **[*]** InterMune shall pay Amgen a performance milestone payment equal to **[*]**

(b) Within **[*]** days after the time Amgen provides InterMune with written notice, in accordance with Section **[*]** that Amgen has **[*]** that is **[*]** InterMune shall pay Amgen a performance milestone payment equal to **[*]**

(c) Within **[*]** business days after the time Amgen provides InterMune with a **[*]** to do pursuant to **[*]** InterMune shall pay Amgen a performance milestone payment equal to **[*]**

6.3 Product Milestones.

(a) InterMune shall pay to Amgen milestone payments as set forth in this Section 6.3(a) within **[*]** days after the first achievement of the corresponding milestone for a PEG-Infergen Product that is pegylated **[*]** (an "Amgen PEG-Infergen Product") that is **[*]** to be **[*]**. No milestone payment shall be payable more than once, no matter how many times achieved by a single **[*]** or multiple **[*]** Such milestone payments shall be nonrefundable and noncreditable against royalties payable pursuant to Sections 6.4 and 6.7, and any other fees, milestone payments or other payments due Amgen under this Agreement.

Milestone Event	Milestone Payment Amount
1. [*]	[*]
2. [*]	[*]

3. [*]	[*]
4. [*]	[*]
5. [*]	[*]
Total	[*]

(b) InterMune shall pay to Amgen milestone payments as set forth in this Section 6.3(b) within **[*]** days after the first achievement of the corresponding milestone for an Amgen PEG-Infergen Product **[*]** No milestone payment shall be payable more than once, no matter how many times achieved by a single **[*]** or multiple **[*]** Such milestone payments shall be nonrefundable and

noncreditable against Royalties payable pursuant to Sections 6.4 and 6.7, and any other fees, milestone payments or other payments due Amgen under this Agreement.

Milestone Event	Milestone Payment Amount
1. [*]	[*]
2. [*]	[*]
3. [*]	[*]
4. [*]	[*]
5. [*]	[*]
Total	[*]

(c) [*] Milestone Payments. If any Milestone Event **[*]** to Amgen hereunder of any previously listed Milestone Payment described in Sections 6.3(a) or (b), respectively, with respect to such Licensed Product, then **[*]** all previously listed Milestone Payments described in Sections 6.3(a) or (b) with respect to such Licensed Product **[*]**

6.4 Royalties. Subject to the other terms and conditions of this Agreement, InterMune shall pay Amgen a royalty equal to **[*]** percent **[*]** (the "Royalty") of Net Sales of each Licensed Product sold during each calendar quarter by InterMune and its Affiliates and Sublicensees. For purposes of calculating such royalty, Net Sales of any Combination Product shall be determined as provided pursuant to Section 6.6.

6.5 Term of Royalties. Amgen's right to receive Royalties under Section 6.4 shall expire, on a Licensed Product-by-Licensed Product basis, in each country of the Territory upon the **[*]**

6.6 Combination Products. Net Sales of any Licensed Product sold by or on behalf of InterMune, its Affiliates and/or its Sublicensees as part of a product which consists of the Licensed Product in combination with one or more Active Components ("Combination Product"), for purposes of determining the Royalty payable to Amgen under Section 6.4, shall be calculated as follows:

(a) In the event each of the Active Components and Licensed Product are sold separately, the Net Sales for the purpose of determining Royalties on sales of the Combination Product shall be calculated by multiplying Net Sales of such Combination Product by the fraction A/(A+B) where A is the price to Third Parties of the Licensed Product component of the Combination Product when sold separately, and B is the price to Third Party end users of the Active Component(s) of the Combination Product when sold separately.

(b) If, on a country-by-country basis, the Active Component(s) in the Combination Product are not sold separately in such country, but the Licensed Product is sold separately in such country, Net Sales for the purpose of determining Royalties of the Combination Product shall be calculated by multiplying Net Sales of such Combination Product by the fraction A/C where A is the price to Third Party end users of the Licensed Product when sold separately, and C is the price to Third Parties of the Combination

Product. If, on a country-by-country basis, the Licensed Product is not sold separately in such country, Net Sales for the purposes of determining royalties of the Combination Product shall be D/(D+E), where D is the fair market value of the portion of the Combination Product that contains the Licensed Product and E is the fair market value of the portion of the Combination Product containing the Active Component(s) included in such Combination Product, as such fair market values are determined in good faith by the Parties.

6.7 Existing License Royalties.

(a) Amgen is, as of the Effective Date, a party to the Existing License, and pursuant to the Existing License Amgen owes the Existing Licensor a royalty of **[*]** percent **[*]** on Net Sales of Infergen by Amgen and its sublicensees under its licenses pursuant to the Existing License. In addition

to Royalties payable by InterMune pursuant to Section 6.4, InterMune shall pay to Amgen a royalty equal to **[*]** percent **[*]** of Net Sales of Infergen sold during each calendar quarter by InterMune and its Affiliates. Such obligation to pay Amgen a royalty beyond that due pursuant to Section 6.4 shall expire upon the expiration or termination of Amgen's obligation to pay a royalty for Infergen pursuant to the Existing License in respect of Net Sales of Infergen by InterMune and its Affiliates. Without limiting Amgen's obligations pursuant to Section 2.6, including its obligations thereunder with respect to the Existing License, Amgen shall timely make all payments due to the Existing Licensor under the Existing License in respect of InterMune's and its Affiliates' Net Sales of Infergen. Amgen shall promptly notify InterMune of any notice of default or breach that it receives in relation to the Existing License. If the Existing License terminates or expires in such a way that Amgen does not have a right to sublicense under any intellectual property licensed under the Existing License that relates to Infergen, Amgen shall promptly notify InterMune.

6.8 Royalty Payments and Reports. All Royalties payable to Amgen under this Agreement (including Royalties payable to Amgen under Section 6.6(a) in relation to the Existing License) shall be paid in Dollars within **[*]** days of the end of each calendar quarter except as otherwise specifically provided herein. Each payment of Royalties owing to Amgen shall be accompanied by a statement **[*]** in performing such computations and in accordance with GAAP, on a country-by-country basis, of the amount of gross sales of Licensed Products and Combination Products, an itemized calculation of Net Sales of each Licensed Product and Combination Product during such quarter, showing any deductions provided for in Section 1.30 during such quarter, the amount of aggregate worldwide gross sales of Licensed Product and Combination Product and Net Sales during such quarter and on a cumulative basis for the current year and the amount of Royalty due on Net Sales during such quarter.

6.9 Taxes. Amgen shall be responsible for any and all taxes levied on account of amounts it receives under this Agreement. If InterMune is required by law, rule or regulation to withhold taxes from such types of payments due Amgen hereunder, InterMune will (i) deduct those taxes from the remittable amount, (ii) pay the taxes to the proper taxing authority, and (iii) send original copies of all official receipts evidencing such tax obligation together with written evidence of payment to Amgen within **[*]** following that payment. In the event of such withholding, the Parties agree to confer regarding other reasonable, lawful measures to minimize such withholding.

6.10 Blocked Currency. In any country of the Territory where conversion of the local currency is blocked and such currency cannot be removed from the country, InterMune shall make payments of any Royalties due hereunder in respect of Net Sales of Licensed Products in such country in local currency by depositing such amount to an interest-bearing account in the name of Amgen, in a bank within such country designated by Amgen.

6.11 Foreign Exchange. For the purpose of computing the Net Sales for Licensed Products sold in a currency other than Dollars, such currency shall be converted into Dollars at the average rate of exchange for buying funds as retrieved from the on-line edition of the Wall Street Journal (at http://www.interactive.wsj.com) for the calendar quarter in which such Net Sales were made.

6.12 Patent and Trademark Expenses. InterMune shall reimburse Amgen's costs (as documented by written invoices for legal services and receipts for filing and maintenance fees paid) to **[*]** *provided* that Amgen shall obtain advance written consent from InterMune (such consent not to be unreasonably withheld) in the event any such expenses **[*]** In the event InterMune does not consent to reimburse Amgen for

any aspect related to **[*]** Amgen shall not be obligated to continue any of its activities or to incur any further costs or expenses related to such aspect.

6.13 Late Payments. Any amounts not paid by InterMune when due under this Agreement shall be subject to interest from and including the date payment is due through and including the date upon which InterMune has made a wire transfer of immediately available funds into an account designated by Amgen at a rate equal to the sum of **[*]** plus the annual prime rate or successive annual prime rates of interest

quoted in the Money Rates section of the on-line edition of the Wall Street Journal (at http://www.interactive.wsj.com) calculated daily on the basis of a 365-day year.

ARTICLE 7
Manufacture and Supply

7.1 General. As of the Effective Date, Amgen has established manufacturing arrangements for bulk Infergen and finished Infergen. During the Term, Amgen shall supply to InterMune, and InterMune shall purchase from Amgen, InterMune's requirements of Licensed Products for Commercialization and any further clinical development of Infergen in the Territory during the Term, on the Supply Terms (set forth in Exhibit F). The Parties intend to be bound to a supply relationship pursuant to the Supply Terms. Each Party hereby agrees that the Supply Terms are sufficient to govern such relationship and legally binding upon the Parties.

ARTICLE 8
INTELLECTUAL PROPERTY

8.1 Ownership of Inventions. Each Party shall own any inventions made solely by its employees or agents in their activities hereunder. Inventions hereunder made jointly by employees or agents of each Party ("Joint Inventions") shall be owned jointly by the parties. Except to the extent either Party is restricted by the licenses granted to the other Party and covenants contained herein, and to the extent permitted by law, each Party shall be entitled to practice and sublicense Joint Inventions without restriction or an obligation to account to the other Party. Inventorship shall be determined in accordance with U.S. patent laws.

8.2 Prosecution of Patents.

(a) Amgen Patents. **[*]** at InterMune's expense to the extent provided pursuant to Section 6.12 and, to the extent Amgen elects to incur additional expense for the further prosecution, defend or maintenance of such Amgen Patents, at Amgen's sole expense. **[*]** in the jurisdictions of the Territory. To that end, **[*]** prior to the date such submission is proposed to be made, and will **[*]** shall provide **[*]** with a copy of each submission to a patent authority of a jurisdiction within the Territory regarding any Amgen Patent reasonably promptly after making such filing. **[*]** discretion to abandon or not **[*]** any claim or patent application within the Amgen Patents anywhere in the Territory, then **[*]** and shall provide **[*]** claim or patent application in the Territory **[*]** sole expense.

(b) Joint Patents. With respect to Joint Inventions, the parties shall select and jointly retain mutually acceptable outside counsel to prosecute patent applications claiming such Joint Invention (any such patent application and any patents issuing therefrom a "Joint Patent"). Each party must consent to any action taken with respect to the Joint Patents (which consent will not be withheld if withholding consent will, in the opinion of the retained outside counsel, adversely affect the scope or validity of any patentable claims) on all such patent applications and patents and all correspondence to and from such patent offices, including proposed responses, interferences and oppositions. Each Party shall bear its own internal costs, and the external costs for outside counsel, filing fees, etc. shall be borne equally by the Parties, except as provided in the next sentence of this paragraph. Either Party may disclaim its interest in any particular Patent covering a Joint Invention, in which case (i) the disclaiming Party shall assign its ownership interest in such Patent to the other Party for no additional consideration, (ii) the Party which is then the sole owner shall be solely responsible for all future costs of such Patent, and (iii) the disclaiming Party shall have no further rights under such Patent.

8.3 Infringement of Patents and Trademarks by Third Parties.

(a) [*] the Amgen Trademarks and Amgen Patents against Third Parties and to defend the Amgen Trademarks and Amgen Patents against any challenges in the Territory. In the event **[*]** shall

reasonably assist and cooperate in any such enforcement or defense. **[*]** all costs and expenses (including attorneys' fees) incurred by **[*]** after the Effective Date to carry out the activities described in the foregoing two (2) sentences. Recoveries in any actions under this Section 8.3(a) shall go first to reimburse the Parties' costs and expenses (including attorneys' fees) for such action and any remainder shall **[*]**

(b) [*] does not commence an enforcement and/or defense action pursuant to Section 8.3(a) within **[*]** in writing or infringement of the Amgen Patents or Amgen Trademarks in the Territory (or of the filing of a declaratory judgement action, in the case of defense actions), **[*]** shall be entitled to bring and prosecute such an action **[*]**

(c) Joint Patents. With respect to Third Party Infringement of Joint Patents other than that Infringement described in Sections 8.5(b) and 8.5(c), the Parties shall confer and take such action, and allocate expenses and recoveries, in such manner as they shall agree.

8.4 Infringement of Third Party Rights.

(a) Amgen as Named Party. [*] any action naming Amgen **[*]** and claiming the infringement of (i) any Third Party Trademark through the development or Commercialization of Licensed Product; or (ii) Third Party Patent through the making, using, selling or having sold Licensed Product. The Parties shall confer with each other and cooperate during the defense of any action in which both Amgen and InterMune are named parties. InterMune shall assist and cooperate with Amgen in the defense of any such action and if Amgen finds it necessary or desirable to join InterMune as a party, InterMune shall execute all papers or perform such other acts as may reasonably be required by Amgen. **[*]** be entitled to **[*]** and **[*]** in any **[*] [*]** shall bear all associated costs and expenses (including attorneys' fees) incurred after the Effective Date and pay all damages and settlement amounts with respect to the Territory; *provided, however*, that **[*]** shall have no obligation to bear such costs and expenses and pay such damages and settlement amounts to the extent attributable to **[*]** Licensed Products.

(b) InterMune as Named Party. InterMune **[*]** any action which names InterMune but does not name Amgen and which claims the infringement of (i) any Third Party Trademark through the development or Commercialization of Licensed Product; or (ii) Third Party Patent through the using, selling or having sold Licensed Product. If necessary and at InterMune's expense, Amgen will assist and cooperate with InterMune in any such defense. InterMune shall bear all costs and expenses (including attorneys' fees) and pay all damages and settlement amounts with respect to the Territory, arising out of or in connection with any such action.

(c) Notice. Each Party shall promptly notify the other upon becoming aware of (i) any Third Party claim or action against InterMune and/or Amgen for infringement of any Third Party Trademark through the development or Commercialization of Licensed Product; or Third Party Patent through the using, selling or having sold Licensed Product; or (ii) any Third Party infringement of the Amgen Trademarks or Amgen Patents.

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

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

ARTICLE 9
REPRESENTATIONS AND WARRANTIES

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

(a) Corporate Existence and Power. As of the Effective Date, it is a corporation duly organized, validly existing and in good standing under the laws of the state of Delaware, and has full corporate power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement, including, without limitation, the right to grant the licenses granted hereunder.

(b) Authority and Binding Agreement. As of the Effective Date, (a) it has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (b) it has taken all necessary corporate action on its part required to authorize the execution and delivery of the Agreement and the performance of its obligations hereunder; and (c) the Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid and binding obligation of such Party that is enforceable against it in accordance with its terms.

(c) No Conflict. As of the Effective Date, the execution, delivery and performance of this Agreement by such Party does not conflict with, and would not result in a breach of any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it.

(d) Validity. As of the Effective Date, it is aware of no action, suit, inquiry or investigation instituted by any Third Party which questions or threatens the validity of this Agreement.

9.2 Mutual Covenants. Each Party hereby covenants to the other Party as follows:

(a) No Misappropriation. It shall not knowingly misappropriate the trade secret of a Third Party in its activities to develop or Commercialize Licensed Products.

(b) No Debarment. In the course of the development and manufacture of Licensed Products and during the Term, such Party shall not knowingly use and shall not have knowingly used any employee or consultant who is or has been debarred by the FDA or Regulatory Authorities, or, to the best of such Party's knowledge, is or has been the subject of debarment proceedings by the FDA or Regulatory Authorities.

(c) No Conflict. It will not enter into any agreement with any Third Party that is in conflict with this Agreement, and will not take any action that would in any way prevent it from assuming its obligations or granting the rights granted to the other Party under this Agreement, or that would otherwise materially conflict with or adversely affect its obligations or assuming the rights granted to the other Party under this Agreement.

9.3 Representations, Warranties and Covenants of InterMune.

(a) Expertise. In entering into this Agreement, InterMune has **[*]**

(b) Diligence. InterMune covenants to use **[*]**

(c) Compliance with Trademark Specifications. InterMune covenants to maintain such reasonable quality standards as **[*]** in the use of the Amgen Trademarks to maintain the value of the Amgen Trademarks. During the Term, InterMune shall provide, at the request of Amgen, representative samples of items bearing the Amgen Trademarks (including but not limited to Licensed Product brochures, advertising and other promotional literature).

(d) Compliance by InterMune. InterMune covenants to comply with all applicable statutes, regulations and guidance of Regulatory Authorities relating to the Commercialization and further development of the Licensed Products in each country in the Territory.

9.4 Representations, Warranties and Covenants of Amgen.

(a) Representations and Warranties. Amgen represents and warrants to InterMune as follows:

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[*]

ARTICLE 10
INDEMNIFICATION

10.1 Indemnification by Amgen. Amgen hereby agrees to defend, hold harmless and indemnify (collectively "Indemnify") InterMune and its Affiliates, agents, directors, officers and employees (the "InterMune Indemnitees") from and against any and all Losses arising out of (i) any Third Party claims resulting directly or indirectly out of any of Amgen's representations and warranties set forth in this Agreement being untrue in any material respect when made or any material breach or material default by Amgen of **[*]** To be eligible to be so Indemnified, the InterMune Indemnitees shall provide Amgen with prompt notice of any claim giving rise to the indemnification obligation pursuant to this Section 10.1 and the exclusive ability to defend (with the reasonable cooperation of InterMune Indemnitees) and subject to InterMune's right to participate in and have counsel selected by it participate, at InterMune's expense, in any action for which InterMune seeks to be Indemnified by Amgen). InterMune shall not settle any claim for the Loss associated with which any InterMune Indemnitee seeks to be Indemnified by Amgen, without Amgen's prior written consent, *provided* that the Indemnitor shall be relieved of its obligations only if the failure by the Indemnitee to deliver prompt notice shall have been prejudicial to its ability to defend such action. Amgen's obligation to Indemnify the InterMune Indemnitees pursuant to this Section 10.1 shall not apply to the extent of any Losses (i) that arise from the negligence or intentional misconduct of any InterMune Indemnitee; (ii) that arise from InterMune's breach of this Agreement; or (iii) for which InterMune is obligated to Indemnify the Amgen Indemnitees pursuant to Section 10.2 of this Agreement **[*]**

10.2 Indemnification by InterMune. InterMune hereby agrees to Indemnify Amgen and its Affiliates, agents, directors, officers and employees (the "Amgen Indemnitees") from and against any and all Losses arising from Third Party claims resulting directly or indirectly from (i) any of InterMune's representations and warranties set forth in this Agreement (including without limitation the Supply Terms) being untrue in any material respect when made or any material breach or material default by InterMune of **[*]**; or (ii) the making, having made, using, selling, having sold, offering for sale, or resale and/or otherwise distributing of Licensed Products by, on behalf of, or under the authority of InterMune, its Affiliates or any of its Sublicensees**.** Without limiting the foregoing, InterMune agrees to Indemnify the Amgen Indemnitees from any Losses arising from, relating to, or based upon any claim by a Third Party that a Licensed Product was or is **[*]** or a Licensed Product caused any death or personal injury of any kind, including but not limited to any death or personal injury occurring during the conduct of any clinical trial by, on behalf of, or under the authority of InterMune, its Affiliates or Sublicensees. To be eligible to be Indemnified as described above in this Section 10.2, The Amgen Indemnitees shall provide InterMune with prompt notice of any claim giving rise to the indemnification obligation pursuant to this Section 10.2 and the exclusive ability to defend (with the reasonable cooperation of Amgen Indemnitees and subject to Amgen's right to participate in and have counsel selected by it participate, at Amgen's expense, in any action for which Amgen seeks to be Indemnified by InterMune). Amgen shall not settle any claim for the Loss associated with which any Amgen Indemnitee seeks to be Indemnified by InterMune, without InterMune's prior written consent, provided that InterMune shall be relieved of its obligations only if the failure by the Amgen Indemnitee to deliver prompt notice shall have been prejudicial to its ability to defend such action. InterMune's obligation to Indemnify the Amgen Indemnitees pursuant to this Section 10.2 shall not apply to the extent of any Losses (i) that arise from the negligence or intentional misconduct of any Amgen Indemnitee **[*]**, (ii) for which Amgen is obligated to Indemnify the InterMune Indemnitees pursuant to Section 10.1 of this Agreement or the Supply Terms, or (iii) that arise from any material breach by Amgen of this Agreement **[*]**

10.3 Insurance. Within thirty (30) days of the Effective Date, each Party shall at its own expense procure and maintain during the Term, insurance policy/policies, including product liability insurance,

adequate to cover its obligations hereunder and which are consistent with normal business practices of prudent companies similarly situated. Amgen may self-insure and InterMune may, with the Amgen's prior written consent, self-insure all or part of any such obligation consistent with pharmaceutical industry practices. Each insurance policy required by, and procured under, this Section 10.3 by InterMune shall name Amgen as an additional insured. Such insurance shall not be construed to create a limit of the insuring Party's liability with respect to its indemnification obligations under this Article 10. InterMune shall provide Amgen with written evidence of such insurance upon request. InterMune shall provide Amgen with written notice at least thirty (30) days prior to the cancellation, non-renewal or material change in such insurance or self-insurance which materially adversely affects the rights of Amgen hereunder.

10.4 Pre-Effective Date Losses. In connection with this Agreement, InterMune is not assuming or liable for any Losses resulting from or arising in connection with the use, marketing, sale, manufacture, distribution or promotion of any Licensed Product on or prior to the Effective Date. In addition, InterMune shall not assume or be liable for any Losses whatsoever related to acts or omissions relating to the Licensed Product occurring prior to the Effective Date.

10.5 Limitation of Liability. NEITHER PARTY NOR ITS RESPECTIVE AFFILIATES AND PERMITTED SUBLICENSEES SHALL BE LIABLE FOR SPECIAL, EXEMPLARY, CONSEQUENTIAL OR PUNITIVE DAMAGES, WHETHER IN CONTRACT, WARRANTY, TORT, STRICT LIABILITY OR OTHERWISE INCURRED BY THE OTHER PARTY IN CONNECTION WITH THIS AGREEMENT, INCLUDING BUT NOT LIMITED TO DAMAGES MEASURING LOST PROFITS OR BUSINESS OPPORTUNITIES. NOTWITHSTANDING THE FOREGOING, AMOUNTS PAID BY A PARTY TO A THIRD PARTY AS SPECIAL, EXEMPLARY, CONSEQUENTIAL OR PUNITIVE DAMAGES, WHETHER IN CONTRACT, WARRANTY, TORT, STRICT LIABILITY OR OTHERWISE SHALL BE REIMBURSED SUCH PARTY BY THE OTHER PARTY TO THE EXTENT SUCH OTHER PARTY IS REQUIRED TO INDEMNIFY SUCH FIRST PARTY PURSUANT TO THE INDEMNIFICATIONS OF SECTION 10.2 OR 10.1.

ARTICLE 11
RECORDS; ROYALTY AUDIT; PUBLICATIONS

11.1 Records; Royalty Audit. InterMune shall keep or cause to be kept such records as are required to determine, in a manner consistent with GAAP, the accuracy of calculations of all sums or credits due under this Agreement. Such records shall be retained for no less than a **[*]** period following the year in which any payments were made hereunder. Once per calendar year, Amgen shall have the option to engage, at its own expense, an independent certified public accountant appointed by Amgen and reasonably acceptable to InterMune, to examine, in confidence, the records of InterMune as may be necessary to determine, with respect to any calendar year, the correctness or completeness of any report or payment required to be made under this Agreement. The report of such accountant shall be limited to a certificate verifying any report made or payment submitted by InterMune during such period but may include, in the event the accountant shall be unable to verify the correctness of any such payment, information relating to why such payment is unverifiable. All information contained in any such certificate shall be deemed Confidential Information hereunder. If any audit performed under this Section 11.1 discloses a variance of more than **[*]** from the amount of the original report, Royalty or payment calculation, InterMune shall bear the full cost of the performance of such audit.

11.2 Publications" Prior to oral or written presentation or submission for publication of any data or information relating to Licensed Products, each Party agrees to provide the other Party the opportunity to review any proposed presentations or publication at least **[*]** to their intended submission for publication for its Confidential Information and each Party shall remove the Confidential Information of the other Party from any proposed publication or presentation upon request by such other Party. Amgen will **[*]** permission from each **[*]** relating to Infergen, and shall be **[*]** to review InterMune's publications relating

to Infergen. Any such publications that Amgen discloses to InterMune shall be treated as Amgen Confidential Information hereunder, and Amgen shall only disclose any such publications of InterMune's to Other Licensees that agree to be bound by confidentiality and non-use obligations commensurate with those contained herein.

ARTICLE 12
CONFIDENTIALITY

12.1 Treatment of Confidential Information. The Parties agree that during the Term, and for a period of five (5) years after this Agreement expires or terminates, a Party receiving Confidential Information of the other Party shall (i) maintain in confidence such Confidential Information to the same extent such Party maintains its own proprietary industrial information of similar kind and value (but at a minimum each Party shall use commercially reasonable efforts to maintain Confidential Information in confidence); (ii) not disclose such Confidential Information to any Third Party without prior written consent of the disclosing Party, except for disclosures to its licensees, sublicensees and commercial partners for Licensed Products who agree to be bound by obligations of non-disclosure and non-use at least as stringent as those contained in this Article 12; and (iii) not use such Confidential Information for any purpose except those purposes permitted by this Agreement Amgen shall not knowingly disclose to InterMune any Third Party information or Know-How that Amgen does not have the legal right to disclose to InterMune and/or has a contractual obligation not to disclose to InterMune.

12.2 Authorized Disclosure. Notwithstanding any other provision of this Agreement, each Party may disclose Confidential Information of the other Party:

(a) to the extent and to the persons and entities as required by an applicable law, rule, regulation, legal process, court order or the rules of the National Association of Securities Dealers or of a Regulatory Authority; or

(b) as necessary to file or prosecute those patent applications for which either Party has the right to assume prosecution or maintenance, pursuant to Section 8.2(b) of this Agreement (in the case of Amgen's Confidential Information), prosecute or defend litigation or otherwise establish rights or enforce obligations under this Agreement, but only to the extent that any such disclosure is necessary.

provided, however, that the Party required or intending to disclose the other Party's Confidential Information under Sections 11.2(a) or (b) shall first have given prompt notice to such other Party to enable it to seek any available exemptions from or limitations on such disclosure requirement and shall reasonably cooperate in such efforts by the other Party.

12.3 Publicity; Terms of Agreement. The Parties agree that the existence of and the material terms of this Agreement shall be considered Confidential Information of both Parties, subject to the special authorized disclosure provisions set forth below in this Section 12.3 (in lieu of the authorized disclosure provisions set forth in Section 12.2, to the extent of any conflict) and without limiting the generality of the definition of Confidential Information set forth in Section 1.12. The Parties will mutually agree the text of a press release announcing the execution of this Agreement. Thereafter, if either Party desires to make a public announcement concerning this Agreement or the terms hereof, such Party shall give reasonable prior advance notice of the proposed text of such announcement to the other Party for its prior review and approval, such approval not to be unreasonably withheld. A Party shall not be required to seek the permission of the other Party to repeat any information as to the terms of this Agreement that have already been publicly disclosed by such Party in accordance with the foregoing or by the other Party. Either Party may disclose the terms of this Agreement to potential investors who agree to be bound by obligations of non-disclosure and non-use at least as stringent as those contained in this Article 12. The Parties acknowledge that Amgen and/or InterMune may be obligated to file a copy of this Agreement with the U.S. Securities and Exchange Commission with its next quarterly report on Form 10-Q, annual report on Form 10-K or current report on Form 8-K or with any registration statement filed with the U.S. Securities

and Exchange Commission (the "SEC") pursuant to the Securities Act of 1933, as amended and each such Party shall be entitled to make such filing, *provided* that it requests confidential treatment of the more sensitive terms hereof to the extent such confidential treatment reasonably available to the filing Party under the circumstances then prevailing. In the event of any such filing, the filing Party will provide the non-filing

Party with an advance copy of the Agreement marked to show provisions for which the filing Party intends to seek confidential treatment and shall reasonably consider the non-filings Party's timely comments thereon.

ARTICLE 13
TERM AND TERMINATION

13.1 Term. This Agreement shall become effective on the Effective Date and shall remain in effect, unless earlier terminated pursuant to this Article 13, until the expiration of the later to expire of the last Valid Claim within the Amgen Patents claiming the use or sale of Licensed Product in the Territory.

13.2 Discontinuation of Commercialization or Further Development. In the event InterMune shall at any time elect to discontinue all Commercialization and development activities relating to Licensed Products, InterMune shall notify Amgen in writing of such election and upon Amgen's receipt of such notification, this Agreement shall terminate and all licenses under the Amgen Technology granted to InterMune hereunder shall revert to Amgen.

13.3 Termination for Default.

(a) InterMune. Upon any Default by InterMune under this Agreement Amgen may notify InterMune of such Default and, in the event such Default shall be a payment Default, require that InterMune cure such Default within **[*]** days of Amgen's notice, or in the event such Default shall be a Default other than a payment Default, require that InterMune cure such Default within **[*]** days of Amgen's notice, or, if such Default (other than a payment Default) cannot reasonably be cured within such time period, present a reasonably achievable plan to cure such Default as promptly as is reasonably practicable under the circumstances. In the event InterMune shall not have cured the Default at the end of the applicable grace period, Amgen may terminate this Agreement, and all licenses and assignments granted hereunder to InterMune, its Affiliates and Sublicensees, shall revert to Amgen. Upon termination of this Agreement pursuant to this Section 13.3(a), InterMune shall immediately cease all development and Commercialization of the Licensed Products, return to Amgen all physical manifestations of the Amgen Technology, and promptly take all actions reasonably necessary to effect the transfer to Amgen of all Regulatory Approvals for Infergen in the Territory (including without limitation by making such filings as may be required with Regulatory Authorities and other governmental authorities of the Territory that may be necessary to effect such transfer).

(b) Amgen. Upon any Default by Amgen under this Agreement, InterMune may notify Amgen in writing of such Default and require that Amgen cure such Default within **[*]** days, or, if such Default cannot reasonably be cured within such time period, present a reasonably achievable plan to cure such Default as promptly as is reasonably practicable under the circumstances. In the event Amgen shall not have cured the Default at the end of the **[*]** grace period, InterMune may **[*]** or (ii) terminate this Agreement effective upon a second written notice to Amgen. If Amgen fails to cure a Default as described in clause (i) of the foregoing sentence within **[*]** after such written notice, then any **[*]** and InterMune shall be relieved of its obligations pursuant to **[*]** but the other provisions of this Agreement (including without limitation Section 6.4) shall remain in full force and effect.

13.4 Licenses Upon Expiration. InterMune's licenses pursuant to Sections 2.2, 2.3 and 2.4 shall, upon expiration of this Agreement as provided in Section 13.1 shall automatically convert to being irrevocable and fully paid. Sections 3.1, 3.6, 4.1, 4.2, 4.3, 4.5, 4.6, and 4.8 shall survive expiration of this Agreement.

13.5 Survival. The following provisions shall survive any expiration or termination of this Agreement for the period of time specified**:** Articles 10, 11, 12, 13, 14 and 15 and Sections 2.1, 4.4, 4.7, 8.1, 8.2(b), 8.3 and 8.4 (but only with respect to infringement during the Term), Termination of this Agreement shall not relieve the Parties of any liability which accrued hereunder prior to the effective date of such termination nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement nor prejudice either Party's right to obtain performance of any obligation. The remedies provided in this Article 13 are not exclusive of any other remedies a Party may have in law or equity, subject to the Section 13.6 as it applies to the limited category of Defaults described therein.

13.6 Determination of PEG Diligence. If at any time following the Planning Period Date Amgen believes that InterMune is not meeting its diligence obligations pursuant to Sections 3.3 or 5.2(b), then Amgen may so notify InterMune in writing and the Parties will meet to discuss the situation in good faith. If after such discussions, Amgen continues to believe that InterMune has not met its diligence obligations pursuant to such Sections, then Amgen may **[*]** pursuant to **[*]** solely to the extent pertaining to **[*]** and Amgen shall be entitled to **[*]** in the Territory **[*]** *provided, however*, that if InterMune disagrees as to whether it has met such diligence obligations, then the matter shall be resolved in accordance with Article 14, and **[*]** hereunder shall **[*]** until such dispute is resolved (if it is resolved in favor of Amgen). Notwithstanding anything to the contrary express or implied in this Agreement, the remedy provided pursuant to this Section 13.6 shall be Amgen's exclusive remedy (including without limitation to the exclusion of any remedies provided pursuant to Section 13.2) for InterMune Defaults relating to InterMune's diligence obligations with respect to a PEG-Infergen Product pursuant to Sections 3.3 and 5.2(b).

ARTICLE 14
DISPUTE RESOLUTION

14.1 Disputes. The Parties recognize that disputes as to certain matters may from time to time arise during the term of this Agreement which relate to either Party's rights and/or obligations hereunder. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising from, concerning or in any way relating to this Agreement in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in this Section 14.1 if and when a dispute arises under this Agreement. The Parties shall undertake good faith efforts to resolve any such dispute in good faith. In the event the Parties shall be unable to resolve such dispute, either Party may, by written notice to the other Party, have any dispute between the Parties remaining unresolved after thirty (30) days referred to their respective executive officers designated below or their designees or successors for attempted resolution by good faith negotiations within thirty (30) days after such notice is received. Such designated officers are as follows:

For InterMune: InterMune's General Counsel

For Amgen: Amgen's General Counsel

If the designated officers are not able to resolve such dispute within such thirty (30) day period, either Party may at any time thereafter pursue any legal or equitable remedy available to it. Notwithstanding the above, either Party shall be entitled at all times and without delay to seek equitable relief.

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

Amgen is the initiating Party in a dispute, such suit shall be brought in a state or federal court which has jurisdiction over Burlingame, California; and if InterMune is the initiating Party in a dispute, such suit shall be brought in a state or federal court which has jurisdiction over Thousand Oaks, California.

14.3 Patent and Trademark Dispute Resolution. Any dispute, controversy or claim relating to the scope, validity, enforceability or infringement of any patent rights claiming the use or sale of any Licensed Product or of any Trademark rights relating to Licensed Product shall be submitted to a court of competent jurisdiction in the Territory in which such patent or trademark rights were granted or arose. Notwithstanding the foregoing, any dispute, controversy or claim relating to the scope, validity, enforceability or infringement of any United States patent rights covering the use or sale of any Licensed Product shall be submitted to a court of competent jurisdiction in the State of California. To the extent permitted by law, InterMune agrees that it shall not dispute the scope, validity, enforceability or infringement of any patent right outside the United States which claims the use or sale of any Licensed Product.

ARTICLE 15
MISCELLANEOUS

15.1 Entire Agreement; Amendment. This Agreement (including all Exhibits), the Confidential Disclosure Agreement dated March 9, 2001, and the Exclusive Dealings Binder dated April 12, 2001 set forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto and supersedes and terminates all prior agreements and understandings between the Parties. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

15.2 Force Majeure. Both Parties shall be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented by Force Majeure and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so long as the condition constituting Force Majeure continues and the nonperforming Party uses reasonable efforts to remove the condition.

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

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

For InterMune:	InterMune, Inc. 1710 Gilbreth Road, Suite 301 Burlingame, CA 94010-1317 Facsimile: (650) 259-0774 Attn: General Counsel
With a Copy to:	Cooley Godward LLP Five Palo Alto Square 3000 El Camino Real Palo Alto, CA 94306 Fax: (650) 849-7400 Attention: Robert L. Jones, Esq.
For Amgen:	Amgen, Inc. One Amgen Center Drive Thousand Oaks, CA 91320-1799 Fax: (805) 499-8011 Attention: Vice President, Licensing With a Copy to: Corporate Secretary

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

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

15.6 Assignment. Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other, except that a Party may make such an assignment without the other Party's consent to Affiliates or to an entity that acquires all or substantially all of the business of such Party, whether in a merger, consolidation, reorganization, acquisition, sale or otherwise. This Agreement shall be binding on the successors and assigns of the assigning Party, and the name of a Party appearing herein shall be deemed to include the name(s) of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this Agreement. Any assignment or attempted assignment by either Party in violation of the terms of this Section 15.6 shall be null and void and of no legal effect.

15.7 Performance by Affiliates. Each of Amgen and InterMune acknowledge that obligations under this Agreement may be performed by Affiliates of Amgen and InterMune. Each of Amgen and InterMune guarantee performance of this Agreement by its Affiliates, notwithstanding any assignment to Affiliates in accordance with Section 15.6 of this Agreement. Wherever in this Agreement the Parties delegate responsibility to Affiliates or local operating entities, the Parties agree that such entities may not make decisions inconsistent with this Agreement, amend the terms of this Agreement or act contrary to its terms in any way.

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

15.9 Severability. If any one or more of the provisions of this Agreement is held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good faith effort to replace any invalid or unenforceable

provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

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

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

15.12 Independent Contractors. The relationship between InterMune and Amgen created by this Agreement is one of independent contractors and neither Party shall have the power or authority to bind or obligate the other except as expressly set forth in this Agreement.

15.13 Use of Name. No right, express or implied, is granted to either Party by this Agreement to use in any manner any Trademark (except the Amgen Trademarks as set forth in this Agreement) of the other Party, including the names "Amgen" and "InterMune", without the prior written consent of the owning Party, subject to Section 12.3.

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

In Witness Whereof, the Parties have executed this Agreement in duplicate originals by their duly authorized representatives as of the Effective Date.

Amgen Inc.		**InterMune, Inc.**	
By:	/s/ SCOTT J. FORAKER	By:	/s/ JOHN J. WULF
Print Name:	Scott J. Foraker	Print Name:	John J. Wulf
Title:	Vice President, Licensing	Title:	Senior Vice President of Corporate Development

Exhibit A
Amgen Trademarks

[*]

INFERGEN

3)	Country:	US
	Appln. Date:	8/13/93
	Appln. No.:	74/424795
	Reg. Date:	11/7/95
	Reg. No.:	1933729
	Goods:	Pharmaceutical preparation namely interferon for use in the treatment of viral, neoplastic and autoimmune diseases.
4)	Country:	Canada
	Appln. Date:	9/1/93
	Appln. No.:	736130
	Reg. Date:	7/21/95

Exhibit B
Amgen Patents as of the Effective Date

[*]

[*]

Exhibit C
Protein Sequence of [*]

[*]

Exhibit D
Regulatory Approvals for Infergen as of the Effective Date

United States

BLA for HCV treatment−October 6, 1997
Supplement for SingleJect prefilled syringe−January 6, 1999
Supplement for 48-week retreatment−December 22, 1999
Supplement for geriatric language−August 10, 2000

Canada

BLA for HCV treatment−March 9, 1999

Exhibit E
Ongoing Clinical Trials

[*]	**[*]**
[*]	**[*]**
[*]	**[*]**

Exhibit F
Supply Terms

Supply of Infergen.

Amgen shall supply InterMune with InterMune's requirements of Infergen for development and commercialization in the Licensed Territory in accordance with the terms of this Exhibit F (the "Supply Terms").

Term.

The term of Amgen's supply obligation hereunder shall expire on the earlier of: (1) the date on which InterMune receives Regulatory Approval to market Infergen obtained pursuant to a supply agreement **[*]** Third Party for supply of Infergen in the Licensed Territory; (2) the date on which InterMune receives Regulatory Approval to market Infergen manufactured by InterMune or a Third Party of its choice **[*]** the effective date of termination of the License and Commercialization Agreement **[*]** January 1, 2015.

Effect of Expiration or Termination. [*] in addition to any all other accrued but unpaid payments due Amgen from InterMune, and Amgen will be obligated to deliver to InterMune all such firm orders paid for.

Transfer of Manufacturing Rights.

Amgen's Third Party Contractor. Amgen may assign or sublicense any of its rights or obligations under this Exhibit F to a Third Party contractor, provided that if such assignment or sublicense is made to a Third Party other than **[*]**, Amgen shall first obtain InterMune's prior written consent (not to be unreasonably withheld). Amgen shall continue to supply Infergen to InterMune in accordance with the Supply Terms until such time as InterMune receives all necessary Regulatory Approvals in the Licensed Territory to market Infergen manufactured by such Third Party contractor. **[*]** associated with all work necessary to obtain Regulatory Approval for InterMune to market Infergen manufactured by **[*]** as applicable.

InterMune and its Third Party Contractor. [*] InterMune will be responsible for paying all costs associated with all work necessary for InterMune to obtain Regulatory Approval to market Infergen manufactured by InterMune.

Form of Supply.

Infergen shall be supplied in the following forms only:

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Packaging and Labeling. As of the Effective Date, Amgen has in its inventory certain quantities of **[*]** Infergen, labeled and packaged for commercial sale in the Territory (the "Amgen Infergen Inventory") from which initial orders of Infergen placed by InterMune will be filled. When the Amgen Infergen Inventory is exhausted, InterMune shall thereafter be responsible for and bear all costs associated with the design, development, quality release and Regulatory Approval of all labeling and packaging materials for Infergen supplied hereunder for commercial sale. InterMune shall perform its **[*]** InterMune shall be solely responsible for labeling and packaging Infergen for clinical trial use.

Supply Price; Third Party Royalties; Statements and Payments.

Infergen Supply Price

Amgen shall supply Infergen to InterMune at the following prices:

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[*]

"Standard Cost" shall mean and include the following cost elements incurred by Amgen: **[*]**

Additional Work. If at InterMune's written request and upon Amgen's written consent Amgen performs any work or activities outside the scope of filling purchase orders placed by InterMune pursuant to paragraph 6.3, or if Amgen is required by a Regulatory Authority in the Licensed Territory to perform work not necessitated by or arising from Amgen's negligence in performing its obligations hereunder, then **[*]** Any work performed or to be performed by Amgen which is necessitated by or arises from Amgen's negligence in performing its manufacture and supply obligations hereunder, including but not limited to work required by a Regulatory Authority in the Licensed Territory **[*]**

Third Party Royalties. For purposes of this Section 5.3, "Third Party Payments" shall mean **[*]**

[*]

During the term of Amgen's supply obligation hereunder, **[*]**

Statements and Payments. Amgen shall, on an as delivered basis, provide InterMune with a statement setting forth quantities of Infergen delivered, the supply price, the amount of any Third Party royalties and costs for additional work, if any. Payments shall be due from InterMune within **[*]** following the date of receipt of such shipment at InterMune's designated facility. Delivery costs shall be paid directly by InterMune to its designated carrier.

Forecasts/Orders.

Amgen Infergen Inventory.

Promptly after execution of the License and Commercialization Agreement, Amgen will provide to InterMune a report showing Amgen's then-current inventory levels of Amgen Infergen Inventory. InterMune shall specify by binding written firm purchase order its reasonable requirements of Amgen Infergen Inventory not later than **[*]**

Rolling Forecasts.

InterMune will determine its good faith projected Infergen supply needs, taking into consideration the Amgen Infergen Inventory levels, and will deliver the first rolling forecast for the **[*]** months prior to the requested delivery date for InterMune's first firm order of Infergen to be supplied from Infergen manufactured for InterMune (i.e., not Amgen Infergen Inventory). For each quarter of the rolling forecast, InterMune shall specify the quantity and form per quarter of its future needs of Infergen. Following submission of this first forecast, the forecast shall be amended quarterly (no later than the first day of a calendar quarter) to: (1) add a forecast for the next successive calendar quarter for which no forecast has been submitted and (2) **[*]** Each quarterly forecast shall be **[*]**

Not later than **[*]** days after Amgen's receipt of each rolling forecast, Amgen will confirm in writing that it can manufacture and supply the quantities specified in the forecast in the quarters specified therein (the "Forecast Confirmation"). **[*]** Promptly thereafter the Parties shall discuss in good faith **[*]** If, at any time after Amgen submits to InterMune its Forecast Confirmation, Amgen **[*]** Amgen shall so notify InterMune in writing and the Parties shall discuss in good faith such proposed arrangements and other appropriate means to ensure an uninterrupted supply of Infergen to InterMune consistent with its forecast. **[*]**

Firm Orders. InterMune shall specify by binding written firm purchase order its reasonable requirements of Infergen for each calendar quarter at least **[*]** in advance of each such calendar quarter (collectively "Firm Purchase

Orders"). Each Firm Purchase Order shall specify: the quantity **[*]** and the delivery date. In no event shall a Firm Purchase Order be

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more or less than the amount specified for such applicable quarter in the Rolling Forecast. Amgen will **[*]** Infergen to InterMune in response to Firm Purchase Orders. For as long as Amgen continues to manufacture Infergen **[*]** Amgen's manufacturing capacity for Infergen for such period, *provided however* that InterMune may order and Amgen shall supply Infergen in quantities up to **[*]**

Product Specifications; Noncompliant Goods; Inspections.

cGMP. Infergen supplied by Amgen hereunder will be manufactured in accordance with current Good Manufacturing Practices (as defined in the Code of Federal Regulations) and the manufacturing process approved by the relevant Regulatory Authorities in the Licensed Territory. Infergen shall be manufactured by Amgen in a facility approved by applicable Regulatory Authorities. Amgen shall be responsible for keeping such facility and the manufacturing processes for Infergen in compliance with current Good Manufacturing Practices.

Shelf Life. **[*]**

Product Specifications and Manufacturing Process. Amgen will supply Infergen which complies with the product specifications and the manufacturing process approved by the relevant Regulatory Authorities in the Licensed Territory (collectively, the "Specifications"). For so long as InterMune purchases Infergen from Amgen under the terms and conditions set forth herein, no changes to the Specifications may be made without each Party's prior written consent (which may be withheld in either Party's sole discretion, *provided* that no consent shall be needed from InterMune in order for Amgen to make changes (i) as required by the relevant Regulatory Authorities in the Licensed Territory or (ii) to comply with current Good Manufacturing Practices). **[*]** Amgen shall notify InterMune in writing of any changes in or to the Specifications, Amgen's manufacturing facilities or procedures, vendors, raw materials or capital equipment that will or may require InterMune to amend the BLA for Infergen or otherwise fulfill InterMune's regulatory obligations.

Product Release. Amgen shall be responsible for the manufacturer's release of Infergen. Amgen will provide to InterMune upon release of each lot of Infergen complete and accurate certificates of analysis, certificates of compliance, and deviations and their investigations (the "Disposition Package"). As InterMune may request from time to time, Amgen will make batch records relating to fermentation, bulk Infergen, Infergen for fill and finish manufacturing and packaging available for InterMune's inspection, which records shall be complete and accurate.

Testing and Noncompliant Goods. Amgen and InterMune shall agree on a mutually acceptable Third Party to conduct testing of Infergen for compliance with Specifications, and Amgen and InterMune will each be entitled to a complete copy of all testing data. InterMune shall have **[*]** from receipt of all requested records, in which to (i) review the Disposition Package, and upon InterMune's request, the relevant batch records, provided pursuant to Subsection 7.4 above; (ii) test a shipment of Infergen for compliance with Specifications, and (iii) notify Amgen in writing of any noncompliant Infergen, including but not limited to Infergen manufactured using a manufacturing process not approved

by the relevant Regulatory Authority. Amgen shall cooperate with InterMune in good faith to determine whether such rejection is justified. **[*]**

Final Product Lot Release. **[*]** shall be solely responsible for final lot release of Infergen for all uses (including but not limited to review of the Disposition Package and batch records, and such testing as **[*]** may elect to perform to ensure the final quality assurance and quality control and conformance of such lots to the lot release specifications of all applicable Regulatory Authorities).

Inspections. In addition to its review of the Disposition Package pursuant to subsection 7.4 above, InterMune may visit and inspect and audit, at its own expense, **[*]** in each case in so far as such facilities or records relate solely to the Infergen supplied hereunder. Information obtained by InterMune in the course of such inspections shall be treated as Confidential

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Information, provided however that InterMune may disclose such Confidential Information to the extent necessary to comply with applicable law or regulations or other requirements of the relevant Regulatory Authorities in the Licensed Territory. Inspections conducted hereunder will be limited in scope to what is reasonably necessary to confirm that Amgen has complied with current Good Manufacturing Practices in manufacturing and labeling and packaging Infergen supplied to InterMune hereunder. InterMune may conduct inspections no more frequently than **[*]** InterMune will coordinate all inspections of manufacturing facilities relating to Infergen with Amgen and provide Amgen with **[*]** Amgen shall respond in writing with an action plan for corrective and preventative actions **[*]** Amgen shall reasonably cooperate with applicable Regulatory Authorities with respect to inspections.

Know-How. Except as expressly set forth in the License and Commercialization Agreement, Amgen shall have no obligation to disclose to InterMune, and InterMune shall have no rights with respect to, any Amgen Know-How, including but not limited to that pertaining to the Manufacturing Know-How relating to Infergen; **[*]**

Disclaimer. OTHER THAN THE EXPRESS WARRANTIES SPECIFICALLY SET FORTH IN SUBSECTIONS 7.1, 7.2 AND 7.3 ABOVE, AMGEN MAKES NO REPRESENTATIONS OR WARRANTIES OF ANY KIND AND HEREBY DISCLAIMS ALL OTHER REPRESENTATIONS AND WARRANTIES OF ANY KIND WHATSOEVER, EXPRESS OR IMPLIED, WITH RESPECT TO ITS SUPPLY OF INFERGEN TO INTERMUNE.

Stability. [*]

Shipment and Delivery. All Infergen supplied by Amgen will be delivered to **[*]** InterMune shall be responsible for all delivery logistics, delivery validation, insurance and compliance with laws and regulations (including but not limited to those applicable to the export of each **[*]** delivery from the United States to Canada) and all costs associated with any of the foregoing. **[*]**

Compliance With Laws.

Subject to paragraph 5.2, Amgen shall be responsible for complying with applicable laws and regulations relating to the manufacture of Infergen supplied to InterMune hereunder. Amgen has and shall maintain all necessary government permits, including without limitation, health and safety and environmental permits necessary for the conduct of the actions it undertakes pursuant to its supply obligations hereunder.

Breach of Supply Obligation

If Amgen fails to timely supply material quantities of Infergen in accordance with Firm Purchase Orders (other than by reason of force majeure) or supplies material quantities of Infergen in material breach of paragraphs 7.1, 7.2, or 7.3, then **[*]**

Additional Agreements.

[*]

Supply of Licensed Product. This Exhibit F governs solely the supply of Infergen. The Parties shall negotiate in good faith a separate supply agreement for the supply of Licensed Products other than Infergen.

Definitions. All capitalized terms not otherwise defined herein shall have the meaning assigned to them in the License and Commercialization Agreement.

Formulating Know-How means Amgen's **[*]**

Manufacturing Know-How means any Know-how **[*]**

Manufacturing Patents mean any Patents **[*]**

Amgen Manufacturing Technology means Manufacturing Know-how and Manufacturing Patents.

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

QuickLinks

Exhibit 10.39