

**UNITED STATES
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 December 31, 2001
OR

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

For the transition period from _____ to _____

Commission file number 0-17999

ImmunoGen, Inc.

(Exact name of registrant as specified in its charter)

Massachusetts

(State or other jurisdiction of incorporation or organization)

04-2726691

(I.R.S. Employer Identification No.)

128 Sidney Street, Cambridge, MA 02139

(Address of principal executive offices, including zip code)

(617) 995-2500

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes No

At February 11, 2002 there were 39,826,191 shares of common stock, par value \$.01 per share, of the registrant outstanding.

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IMMUNOGEN, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
AS OF DECEMBER 31, 2001 AND JUNE 30, 2001

	December 31, 2001 (Unaudited)	June 30, 2001
ASSETS		
Cash and cash equivalents	\$ 13,844,875	\$ 14,822,519
Marketable securities	137,223,913	79,673,934
Accounts receivable	846,173	—
Earned and unbilled revenue	378,909	693,835
Inventory	4,542,803	2,160,996
Prepaid and other current assets	1,864,899	2,224,387
Total current assets	158,701,572	99,575,671
Long term marketable securities	—	56,303,267
Property and equipment, net	4,767,950	3,238,082
Other assets	43,700	43,700
Total assets	\$ 163,513,222	\$ 159,160,720
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable	\$ 1,461,188	\$ 842,927
Accrued compensation	1,216,130	703,036
Other current accrued liabilities	4,572,086	2,245,874
Current portion of capital lease obligations	2,820	8,137
Current portion of deferred revenue	1,804,201	1,560,865
Total current liabilities	9,056,425	5,360,839
Deferred revenue, net of current portion	11,444,347	11,353,115
Other long term liabilities	6,000	—
Total liabilities	20,506,772	16,713,954
Stockholders' equity:		
Common stock, \$.01 par value; authorized 75,000,000 shares; issued and outstanding 39,768,876 shares and 38,535,402 shares as of December 31, 2001 and June 30, 2001, respectively	397,689	385,354
Additional paid-in capital	314,472,119	310,971,161
Accumulated deficit	(172,571,382)	(169,246,607)
Accumulated other comprehensive income	708,024	336,858
Total stockholders' equity	143,006,450	142,446,766
Total liabilities and stockholders' equity	\$ 163,513,222	\$ 159,160,720

The accompanying notes are an integral part of the condensed consolidated financial statements.

IMMUNOGEN, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
FOR THE THREE AND SIX MONTHS ENDED DECEMBER 31, 2001 AND 2000
(UNAUDITED)

	Three Months Ended December 31,		Six Months Ended December 31,	
	2001	2000 (Restated, See Note A)	2001	2000 (Restated, See Note A)
Revenues:				
Revenue earned under collaboration agreements	\$ 388,816	\$ 614,750	\$ 785,433	\$ 2,827,912
Clinical materials reimbursement	840,855	—	1,775,416	—
Development fees	314,742	100,069	409,465	100,069
Total revenues	1,544,413	714,819	2,970,314	2,927,981

Expenses:				
Cost of clinical materials reimbursed	840,855	—	1,775,416	—
Research and development	3,015,212	3,619,171	5,518,768	7,188,104
General and administrative	1,242,262	1,047,265	2,440,837	1,901,174
Total expenses	5,098,329	4,666,436	9,735,021	9,089,278
Loss from operations	(3,553,916)	(3,951,617)	(6,764,707)	(6,161,297)
Gain/(loss) on sale of assets	200	—	200	(1,900)
Interest income, net	1,295,868	1,242,923	2,940,805	1,456,524
Realized gains on investments	555,289	—	563,762	—
Other income	3,307	248,706	29,977	268,055
Loss before income tax expense and cumulative effect of change in accounting principle	(1,699,252)	(2,459,988)	(3,229,963)	(4,438,618)
Income tax expense	33,000	55,000	94,812	55,000
Loss before cumulative effect of change in accounting principle	(1,732,252)	(2,514,988)	(3,324,775)	(4,493,618)
Cumulative effect of change in accounting principle	—	—	—	(5,734,478)
Net loss	<u>\$ (1,732,252)</u>	<u>\$ (2,514,988)</u>	<u>\$ (3,324,775)</u>	<u>\$ (10,228,096)</u>
Basic and diluted net loss per common share:				
Loss before cumulative effect of change in accounting principle	\$ (0.04)	\$ (0.07)	\$ (0.08)	\$ (0.13)
Cumulative effect of change in accounting principle	—	—	—	\$ (0.16)
Net loss	<u>\$ (0.04)</u>	<u>\$ (0.07)</u>	<u>\$ (0.08)</u>	<u>\$ (0.29)</u>
Basic and diluted average common shares outstanding	<u>39,730,478</u>	<u>36,408,516</u>	<u>39,270,213</u>	<u>34,854,392</u>

The accompanying notes are an integral part of the consolidated financial statements.

IMMUNOGEN, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE SIX MONTHS ENDED DECEMBER 31, 2001 AND 2000
(UNAUDITED)

	Six Months Ended December 31,	
	2001	2000
Cash flows from operating activities:		
Net loss	\$ (3,324,775)	\$ (10,228,096)
Adjustments to reconcile net loss to net cash used for operating activities:		
Cumulative effect of change in accounting principle	—	5,734,478
Depreciation and amortization	474,776	255,467
Realized gain on sale of marketable securities	(563,762)	—
(Gain)/loss on sale of property and equipment	(200)	1,900
Compensation for stock and stock units	12,000	—
Changes in operating assets and liabilities:		
Due from related parties	—	30,078
Accounts receivable	(846,173)	—
Earned and unbilled revenue	314,926	—
Inventory	(2,381,807)	—
Prepaid and other current assets	359,488	107,372
Accounts payable	(347,697)	(270,496)
Accrued compensation	513,094	(32,916)
Deferred revenue	334,568	4,172,088
Other current accrued liabilities	237,986	255,650
Net cash provided by (used for) operating activities	<u>(5,217,576)</u>	<u>25,525</u>
Cash flows from investing activities:		
Purchases of marketable securities, net	(311,784)	(126,170,835)
Capital expenditures	(1,038,686)	(1,401,005)
Proceeds from sale of property and equipment	200	7,500
Net cash used for investing activities	<u>(1,350,270)</u>	<u>(127,564,340)</u>
Cash flows from financing activities:		
Proceeds from warrants exercised, net	5,096,010	1,710,548

Proceeds from stock options exercised, net	499,509	704,359
Principal payments on capital lease obligations	(5,317)	(31,395)
Proceeds from common stock issuance, net	–	139,784,354
Net cash provided by financing activities	<u>5,590,202</u>	<u>142,167,866</u>
Net change in cash and cash equivalents	(977,644)	14,629,051
Cash and cash equivalents, beginning balance	<u>14,822,519</u>	<u>1,408,908</u>
Cash and cash equivalents, ending balance	<u>\$ 13,844,875</u>	<u>\$ 16,037,959</u>
Supplemental disclosures:		
Cash paid for taxes	<u>\$ 66,912</u>	<u>\$ 55,000</u>
Non cash activities:		
Accrued financing fees	<u>\$ 2,088,226</u>	<u>\$ –</u>
Capital expenditures included in accounts payable	<u>\$ 965,958</u>	<u>\$ –</u>

The accompanying notes are an integral part of the consolidated financial statements.

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IMMUNOGEN, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

A Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements at December 31, 2001 and June 30, 2001 and for the three-month and six-month periods ended December 31, 2001 and 2000 include the accounts of the Company and its subsidiaries, ImmunoGen Securities Corp. and Apoptosis Technology, Inc. (ATI). Although the consolidated financial statements are unaudited, they include all of the adjustments, consisting only of normal recurring adjustments, which management considers necessary for a fair presentation of the Company's financial position in accordance with generally accepted accounting principles for interim financial information. Certain information and footnote disclosures normally included in the Company's annual financial statements have been condensed or omitted. The preparation of interim financial statements requires the use of management's estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the interim financial statements and the reported amounts of revenues and expenditures during the reported period. The results of the interim periods are not necessarily indicative of the results for the entire year. Accordingly, the interim financial statements should be read in conjunction with the audited financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended June 30, 2001.

Revenue Recognition

The Company enters into licensing and development agreements with collaborative partners for the development of monoclonal antibody-based cancer therapeutics. The terms of the agreements typically include non-refundable license fees, payments based upon the achievement of certain milestones and royalties on product sales.

Prior to June 30, 2000, the Company recognized collaboration revenue on up-front, non-refundable license payments upon receipt and milestone payments upon achievement of the milestone and when collection was probable. Revenues recognized were based on the collaboration agreement milestone value and the relationship of costs incurred to the Company's estimates of total cost expected to complete that milestone.

Effective July 1, 2000, the Company changed its method of accounting for revenue recognition in accordance with Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements," (SAB 101). Under the new accounting method, adopted retroactively to July 1, 2000, the Company recognizes revenue from non-refundable, up-front license payments, not specifically tied to a separate earnings process, ratably over the term of the research contract. The cumulative effect of the change in accounting principle on prior years resulted in a non-cash charge to income of \$5.7 million, which is included in the net loss for the six months ended December 31, 2000. Results for the three and six months ended December 31, 2000 have been restated for the retroactive adoption of SAB 101. Included in revenue for each of the three-month and six-month periods ended December 31, 2001 and 2000 is \$219,000 and \$438,000, respectively, of revenue that was recognized in prior years, before the Company's adoption of SAB 101, and included in the cumulative effect of change in accounting principle.

Marketable Securities

In accordance with the Company's investment policy, surplus cash is invested in investment-grade corporate and U.S. Government debt securities typically with maturity dates of less than one year. The Company designates its marketable securities as available-for-sale securities. Effective September 30, 2001, the Company has classified all such securities as current assets since the Company has the ability to use such securities to satisfy current liabilities. Marketable securities continue to be carried at their fair value with unrealized gains and losses included in accumulated other comprehensive income in the accompanying balance sheet.

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Inventory costs primarily relate to clinical trial materials being manufactured for the Company's collaborators. Inventory is stated at the lower of cost or market.

Inventory at December 31, 2001 is summarized below:

Raw materials	\$	1,347,472
Work in process		1,919,551
Finished goods		1,275,780
Total	\$	<u>4,542,803</u>

Computation of Net Loss Per Common Share

Basic and diluted net earnings/loss per share is calculated based upon the weighted average number of common shares outstanding during the period. Diluted net loss per share incorporates the dilutive effect of stock options, warrants and other convertible securities. Common stock equivalents, as calculated in accordance with the treasury-stock accounting method, equaled 3,874,294 and 5,329,604 for the three months ended December 31, 2001 and 2000, respectively, and 3,870,987 and 5,102,868 for the six months ended December 31, 2001 and 2000, respectively. Common stock equivalents have not been included in the net loss per share calculations for the three- and six-month periods ended December 31, 2001 and 2000 because their effect is anti-dilutive.

Comprehensive Loss

The Company presents comprehensive loss in accordance with Statement of Financial Accounting Standards (SFAS) No. 130, "Reporting Comprehensive Income." For the three-month and six-month periods ended December 31, 2001, total comprehensive loss equaled \$2,279,006 and \$2,953,609, respectively. For the three and six months ended December 31, 2000, total comprehensive loss equaled \$2,164,669 and \$9,896,051, respectively. Comprehensive loss was comprised entirely of net loss and net unrealized losses recognized on available-for-sale debt securities.

Recent Accounting Pronouncements

In October 2001, the Financial Accounting Standards Board issued SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." SFAS No. 144 supersedes SFAS No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed of" and provides a single accounting model for long-lived assets to be disposed of. The provisions of SFAS No. 144 are effective for fiscal years beginning after December 15, 2001. Management does not believe the adoption of SFAS No. 144 will have a material effect on the Company's financial position or results of operations.

Reclassifications

Certain prior year balances have been reclassified to conform to current year presentation.

B. Agreements

In November 2001, the Company and Boehringer Ingelheim International GmbH, (BI), of Ingelheim, Germany entered into a collaboration to develop a new product combining the Company's maytansinoid TAP technology with a BI antibody. Under the terms of the agreement, the Company received an up-front payment and is entitled to potential payments upon BI's achievement of certain milestones and royalty payments on future product sales, if and when they commence. The up-front fee was received in December 2001 and will be recognized ratably over the Company's period of involvement during development. BI is responsible for the manufacturing, product development and marketing of any products resulting from the collaboration. The Company will be reimbursed for any preclinical and initial clinical materials that it manufactures under the agreement.

C. Capital Stock

At December 31, 2001, excluding the warrants issued to BioChem Pharma, Inc., discussed below, warrants to acquire 1,828,928 shares of common stock remained outstanding at exercise prices ranging from \$2.31 to \$38.00. These warrants were originally issued in connection with the Company's March 1996 private placement of convertible debt, the private placements of the Company's Series A, Series B and Series C preferred stock and a warrant issued in connection with the Company's November 2000 public offering in satisfaction of anti-dilution provisions of certain warrants then outstanding.

As part of the BioChem agreement, BioChem received warrants to purchase shares of ImmunoGen common stock equal to the amount invested in ATI during the three-year research term. Beginning July 31, 2000, these warrants became exercisable for a number of shares of ImmunoGen common stock determined by dividing \$11.1 million, the amount of BioChem's investment in ATI, by the market price of ImmunoGen common stock on the exercise date, subject to certain limitations imposed by the Nasdaq Stock Market rules, which limit the sale or issuance by an issuer of certain securities at a price less than the greater of book or market value of such securities. Consequently, BioChem's ability to convert all of its ImmunoGen warrants into ImmunoGen common stock is limited to a total of 20% of the number of shares of ImmunoGen's common stock outstanding on the date of the initial transaction if the conversion price is less than the market price of ImmunoGen common stock on that date, unless stockholder approval for such conversion is obtained, if required, or unless the Company has obtained a waiver of that requirement. The exercise price is payable in cash or shares of ATI's preferred stock, at BioChem's option. The warrants are expected to be exercised only in the event that the shares of ATI common stock do not become publicly traded. ImmunoGen expects that BioChem will use its shares of ATI preferred stock, in lieu of cash, to exercise the warrants.

In September 2001, a holder of warrants originally issued in connection with the March 1996 private placement of the Company's convertible debentures and subsequently adjusted, pursuant to the anti-dilution provisions of the warrants, in connection with the Company's November 2000 public offering of common stock, exercised its right to acquire 1,127,374 shares of common stock at prices ranging between \$3.58 and \$5.37 per share. Proceeds from these warrant exercises will be used to fund current operations.

In October 2001, a holder of warrants originally issued in connection with a private placement of the Company's Series B convertible preferred stock exercised its right to acquire 10,931 shares of common stock at \$5.49 per share. Proceeds from this warrant exercise will be used to fund current operations.

In November 2001, the Company's shareholders approved an increase in the amount of the authorized common stock from 50,000,000 to 75,000,000 shares and an amendment to the Company's Restated Stock Option Plan to increase the total number of shares reserved for the grant of options by 2,500,000 to 7,350,000 shares of common stock.

In November 2001, the Company's shareholders approved the establishment of the 2001 Non-Employee Director Stock Plan (the Director Plan) and 50,000 shares of common stock to be reserved for grant thereunder. The Director Plan provides for the granting of awards to Non-Employee Directors and the election of Non-Employee Directors to have all or a portion of their awards in the form of cash, stock or stock units. All stock or stock units issued pursuant to the Director Plan are immediately vested. The Director Plan is administered by the Board of Directors who is authorized to interpret the provisions of the Director Plan, determine which Non-Employee Directors will be granted awards, and determine the number of shares of stock for which a stock right will be granted.

During the six-month period ended December 31, 2001, holders of options issued under the Company's Restated Stock Option Plan exercised their rights to acquire an aggregate of 95,169 shares of common stock at prices ranging from \$0.84 per share to \$15.88 per share. The total proceeds from these option exercises, \$499,509, will be used to fund current operations.

C. Commitments and Contingencies

In December 1995, the Company entered into an agreement with a third party whereby the third party agreed to identify and introduce potential financing sources to the Company in exchange for cash and warrants upon the successful completion of a financing. During the fiscal years ended June 30, 1996 and 1998, the Company issued stock, warrants and cash to the third party relating to certain financings. On November 13, 2001, the Company received a claim asserting that, as a result of certain warrant exercises, the Company owes additional compensation to the third party in the form of \$819,423 in cash and warrants exercisable for the purchase of 250,000 shares of common stock of the Company at \$3.11 per share. The Company is currently negotiating with the third party to settle the claim. The Company believes a settlement of the claim is probable and, accordingly, has accrued \$2.0 million as the estimated amount of the settlement in the accompanying financial statements. Any settlement will be considered an equity financing fee and will be accounted for as a reduction of the gross proceeds of the financings and will not result in a charge to the Company's statement of operations. Accordingly, the estimated settlement is reflected as a reduction in Additional Paid-in Capital in the accompanying balance sheet.

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

OVERVIEW

Since our inception, we have been principally engaged in the development of antibody-based cancer therapeutics. Our Tumor Activated Prodrug (TAP) product candidates consist of an antibody chemically linked, or conjugated, to a highly potent cell-killing, or cytotoxic, agent which is delivered to the tumor cell where it binds to and is internalized by the tumor cell. Once internalized, the cytotoxic agent is released and kills the tumor cell. The cytotoxic agent we currently use in all of our TAPs is the maytansinoid DM1, a chemical derivative of a naturally occurring substance called maytansine.

We have entered into collaborative agreements that allow companies to use our TAP technology to develop commercial products with their antibodies. We also have licensed certain rights to our first two internally developed TAP product candidates to companies that have product development and commercialization capabilities we wish to access in exchange for our receipt of fees, milestone payments and royalties on product sales. Our collaborative partners include GlaxoSmithKline, Genentech, Abgenix, British Biotech, Millennium and Boehringer Ingelheim. We expect that substantially all of our revenue for the foreseeable future will result from payments under our collaborative arrangements. The terms of the collaborative agreements vary, reflecting the value we add to the development of any particular product candidate.

To date, we have not generated revenues from commercial product sales and we expect to incur significant operating losses over the foreseeable future. As of December 31, 2001, we had approximately \$151.1 million in cash and marketable securities. We do not anticipate having a commercially-approved product within the foreseeable future. Research and development expenses are expected to increase significantly in the near term as we continue our development efforts. Moreover, in the next nine to fifteen months we expect to spend approximately \$4.4 million to further expand our development and pilot manufacturing facility in Norwood, Massachusetts. We anticipate that the increase in total cash expenditures will be partially offset by collaboration-derived proceeds. Accordingly, period-to-period operational results may fluctuate dramatically. We believe that our established collaborative agreements, while subject to specified milestone achievements, will provide funding to assist us in meeting obligations under our collaborative agreements while also allowing for the aggressive development of internal product candidates and technologies. However, we can give no assurances that such collaborative agreement funding will, in fact, be realized. Should we not meet some or all of the terms and conditions of our various collaboration agreements, we may be required to pursue additional strategic partners, secure alternative financing arrangements, and/or defer or limit some or all of our research, development and/or clinical projects.

RESULTS OF OPERATIONS

Comparison of Three Months ended December 31, 2001 and 2000

Revenues

Prior to June 30, 2000, we recognized collaboration revenue on up-front, non-refundable license payments upon receipt and milestone payments upon achievement of the milestone and when collection was probable. Revenues recognized were based on the collaboration agreement milestone value and the relationship of costs incurred to our estimates of total cost expected to complete that milestone.

Effective July 1, 2000, we changed our method of accounting for revenue recognition in accordance with Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements" (SAB 101). Under the new accounting method, adopted retroactively to July 1, 2000, we recognize revenue from non-refundable, up-front license payments, not specifically tied to a separate earnings process, ratably over the term of the research contract. The cumulative effect of the change in accounting principle on prior years resulted in a non-cash charge to income of \$5.7 million, which is included in our net loss for the six months ended December 31, 2000. Results for the three months ended December 31, 2000 have been restated for the retroactive adoption of SAB 101.

When milestone payments are specifically tied to a separate earnings process, revenue is recognized when the milestone is achieved. In addition, when appropriate, we recognize revenue from certain research payments based upon the level of research services performed during the period of the research contract. Deferred revenue represents amounts received under collaborative agreements and not yet earned pursuant to these policies. Where we have no continuing involvement, we will record non-refundable license fees as revenue upon receipt and will record milestone revenue upon achievement of the milestone by the collaborative partner.

Our total revenues for the three months ended December 31, 2001 were \$1.5 million, compared with \$715,000 for the three months ended December 31, 2000. The 116% increase in revenues in the quarter ended December 31, 2001 compared to the same period in the prior year is primarily attributable to pre-clinical and clinical materials we manufactured and delivered to our collaborative partners.

During the three months ended December 31, 2001 we recognized collaboration revenue of \$43,000 from GlaxoSmithKline, \$177,000 from Genentech, \$100,000 from Abgenix, and \$69,000 from Millennium. During 2000, we recognized collaboration revenue of \$338,000 from GlaxoSmithKline, \$177,000 from Genentech, and \$100,000 from Abgenix. Deferred revenue of \$13.2 million as of December 31, 2001 represents progress payments received from collaborators pursuant to contract revenues not yet earned.

Clinical materials reimbursement of \$841,000 in the three months ended December 31, 2001, represents our manufacture and delivery of pre-clinical and clinical materials for our collaborators. In 2000, we were not manufacturing any pre-clinical or clinical materials that were reimbursable.

Development fees increased 215% in the three months ended December 31, 2001 to \$315,000 compared to \$100,000 for the same period in 2000. Development fees represent the fully burdened reimbursement of costs incurred in producing research-grade materials and developing antibody-specific conjugation processes on behalf of our collaborators and potential collaborators during the early evaluation and pre-clinical testing stages of drug development.

Expenses

Cost of Clinical Materials Reimbursed. Cost of clinical materials reimbursed of \$841,000 in 2001 represents the fully burdened cost of clinical materials that we produce for our collaborators, and for which we are reimbursed. There were no costs related to clinical materials reimbursed for the same period in 2000.

Research and Development Expenses. Research and development expenses for the three months ended December 31, 2001 decreased 17% to \$3.0 million from \$3.6 million for the three months ended December 31, 2000. The three months ended December 31, 2000 included significant costs associated with supporting our ongoing huC242-DM1/SB-408075 human clinical trials and the pre-clinical development of our second product, huN901-DM1/BB-10901. Although these trials continue, the cost of our on-going financial support is less than it was during the earlier stages of the trials and during pre-clinical development.

Additionally, we entered into a process development agreement with a third party in September 2001. We will share equally with this third party in certain future development costs. These reductions in research and development expenses have been partially offset with increased research and development personnel costs, including estimated fiscal 2002 bonuses that have been accrued. We expect future research and development expenses to increase as we continue development of our product candidates and technologies.

General and Administrative Expenses. General and administrative expenses for the three months ended December 31, 2001 increased 19% to \$1.2 million from \$1.0 million for the three months ended December 31, 2000. This increase was largely due to increased administrative and business development personnel costs and increased expenditures associated with investor relations, partially offset by certain expenses that are reimbursed by our collaborators.

Realized Gains on Investments.

Realized gains on investments were \$555,000 for the three months ended December 31, 2001. There were no realized gains on investments for the same period in 2000.

Other Income.

Other income for the three months ended December 31, 2001 decreased to \$3,000 from \$249,000 for the same period in the prior year. Other income for the three months ended December 31, 2000 included a settlement in a securities litigation case filed on our behalf.

Comparison of the Six Months ended December 31, 2001 and 2000

Revenues

The 72% decrease in collaboration revenues for the six months ended December 31, 2001 compared to the same period in 2000 is primarily attributable to milestone payments we recognized under the GlaxoSmithKline agreement in the six months ended December 31, 2000. During the six months ended December 31, 2001 we recognized collaboration revenue of \$93,000 from GlaxoSmithKline, \$354,000 from Genentech, \$200,000 from Abgenix, and \$138,000 from Millennium. During the six months ended December 31, 2000, we recognized collaboration revenue of \$2.4 million from GlaxoSmithKline, \$354,000 from Genentech, and \$100,000 from Abgenix. Deferred revenue of \$13.2 million at December 31, 2001 represents progress payments received from collaborators pursuant to contract revenues not yet earned.

Clinical materials reimbursement of \$1.8 million in the six months ended December 31, 2001, represents our manufacture and delivery of pre-clinical and clinical materials for our collaborators. In 2000, we were not manufacturing any pre-clinical or clinical materials that were reimbursable.

Development fees increased 309% in the six months ended December 31, 2001 to \$409,000 compared to \$100,000 for the same period in 2000. Development fees represent the fully burdened reimbursement of costs incurred in producing research grade materials and developing antibody-specific conjugation processes on behalf of our collaborators and potential collaborators during the early evaluation and pre-clinical testing stages of drug development.

Expenses

Cost of Clinical Materials Reimbursed. Cost of clinical materials reimbursed of \$1.8 million in the six months ending December 31, 2001 represents the fully burdened cost of clinical materials that we produce for our collaborators, and for which we are reimbursed. There were no costs related to clinical materials reimbursed for the same period in 2000.

Research and Development Expenses. Research and development expenses for the six months ended December 31, 2001 decreased 23% to \$5.5 million from \$7.2 million for the six months ended December 31, 2000. The six months ended December 31, 2000 included significant costs associated with supporting our ongoing huC242-DM1/SB-408075 human clinical trials and the pre-clinical development of our second product, huN901-DM1/BB-10901.

Although these trials continue, the cost of our on-going financial support is less than it was during the earlier stages of the trials and during pre-clinical development. Additionally, we entered into a process development agreement with a third party in September 2001. We will share equally with this third party in certain future development costs. This agreement requires the third party to reimburse us for a portion of certain development costs, expensed by the Company in prior periods, which, due to the nature of the agreement, must be accounted for as a reduction of research and development expenses totaling \$439,000. These reductions in research and development expenses have been partially offset with increased personnel costs, including estimated fiscal 2002 bonuses that have been accrued. We expect future research and development expenses to increase as we continue development of our product candidates and technologies.

General and Administrative Expenses. General and administrative expenses for the six months ended December 31, 2001 increased 28% to \$2.4 million from \$1.9 million for the six months ended December 31, 2000. This increase was largely due to increased administrative and business development personnel costs and increased expenditures associated with investor relations, partially offset by certain expenses that are reimbursed by our collaborators.

Interest Income

Interest income for the six months ended December 31, 2001 increased to \$2.9 million from \$1.5 million for the six months ended December 31, 2000. The increase in interest income from 2000 to 2001 is primarily attributable to higher cash and investment balances resulting from our November 2000 public stock offering, a collaborator investment of \$15.0 million in September 2000, receipt of \$5.0 million in warrant exercise proceeds in September 2001, and receipt of \$9.0 million and \$1.0 million in collaborator payments during the year ended June 30, 2001 and the six months ended December 31, 2001, respectively.

Realized Gains on Investments

Realized gains on investments were \$564,000 for the six months ended December 31, 2001. There were no realized gains on investments for the same period in 2000.

Other Income

Other income for the six months ended December 31, 2001 decreased to \$30,000 from \$268,000 for the same period in the prior year. Other income for the six months ended December 31, 2000 included a cash payment in settlement of a securities litigation case filed on our behalf.

LIQUIDITY AND CAPITAL RESOURCES

As of December 31, 2001, we had approximately \$13.8 million in cash and cash equivalents and \$137.2 million of marketable securities. In November 2000, we completed a public offering of 4.0 million shares of our common stock. Net proceeds of the offering were \$124.8 million. We intend to use the net proceeds from the offering for working capital and general corporate purposes, including research and development. Since July 1, 2000, we have financed the net cash used to support operating activities primarily from various collaborative and financing sources. These sources include up-front and milestone payments received under our collaboration agreements with GlaxoSmithKline, Abgenix, Millennium, and Boehringer Ingelheim, the sale of equity securities to Abgenix, the exercise of stock options and warrants to purchase common stock and income earned on invested assets.

Net cash used in operations during the six months ended December 31, 2001 was \$5.2 million compared to net cash provided by operations of \$26,000 in the six months ended December 31, 2000. This increase in operational cash use is largely due to the increase in operating expenses discussed previously, as well as the increase in accounts receivable and clinical materials inventory produced on behalf of our collaborators during the six months ended December 31, 2001.

Net cash used for investing activities was \$1.4 million for the six months ended December 31, 2001, and consisted of capital expenditures and maturities and sales of marketable securities, net of purchases of marketable securities. Capital purchases were \$1.0 million for the six months ended December 31, 2001 and consisted primarily of costs associated with the purchase of new equipment and the build-out of our existing Norwood, Massachusetts development and pilot manufacturing facility.

Net cash provided by financing activities was \$5.6 million for the six months ended December 31, 2001 compared to \$142.2 million for the six months ended December 31, 2000. For the six months ended December 31, 2000, net cash provided by financing activities is largely due to the September 7, 2000 issuance of 789,473 shares of our common stock to Abgenix for \$15.0 million and the November 2000 public offering of 4.0 million shares of our common stock for net proceeds of \$124.8 million. Our total proceeds from exercises of warrants and stock options during the six months ended December 31, 2001 were \$5.6 million.

We anticipate that our capital resources will enable us to meet our operational expenses and capital expenditures for the foreseeable future. We believe that the proceeds from our November 2000 public stock offering in addition to our established collaborative agreements will provide funding sufficient to allow us to meet our obligations under all collaborative agreements while also allowing us to develop product candidates and technologies not covered by collaborative agreements. However, we cannot assure you that such collaborative agreement funding will, in fact, be realized. Should we not meet some or all of the terms and conditions of our various collaboration agreements, we may be required to pursue additional strategic partners, secure alternative financing arrangements, and/or defer or limit some or all of our research, development and/or clinical projects.

Risk Factors

THE RISKS AND UNCERTAINTIES DESCRIBED BELOW ARE THOSE THAT WE CURRENTLY BELIEVE MAY MATERIALLY AFFECT OUR COMPANY. ADDITIONAL RISKS AND UNCERTAINTIES THAT WE ARE UNAWARE OF OR THAT WE CURRENTLY DEEM IMMATERIAL ALSO MAY BECOME IMPORTANT FACTORS THAT AFFECT OUR COMPANY.

If our TAP technology does not produce safe, effective and commercially viable products, our business will be severely harmed.

Our TAP technology is a novel approach to the treatment of cancer. None of our TAP product candidates has obtained regulatory approval and all of them are in early stages of development. Our TAP product candidates may not prove to be safe, effective or commercially viable treatments for cancer and our TAP technology may not result in any meaningful benefits to our current or potential collaborative partners. Furthermore, we are aware of only one chemotherapeutic product based on technology similar to our TAP technology that has obtained FDA approval. If our TAP technology fails to generate product candidates that are safe, effective and commercially viable treatments for cancer, and fails to obtain FDA approval, our business will be severely harmed.

Clinical trials for our product candidates will be lengthy and expensive and their outcome is uncertain.

Before obtaining regulatory approval for the commercial sale of any product candidates, we and our collaborative partners must demonstrate through pre-clinical testing and clinical trials that our product candidates are safe and effective for use in humans. Conducting clinical trials is a time consuming and expensive process and may take years to complete. Our most advanced product candidates, huC242-DM1/SB-408075 and huN901-DM1/BB-10901, are only in the Phase I and Phase I/II stages of clinical trials, respectively. Historically, the results from pre-clinical testing and early clinical trials have often not been predictive of results obtained in later clinical trials. Frequently, drugs that have shown promising results in pre-clinical or early clinical trials subsequently fail to establish sufficient safety and effectiveness data necessary to obtain regulatory approval. At any time during the clinical trials, we, our collaborative partners or the FDA might delay or halt any clinical trials for our product candidates for various reasons, including:

- ineffectiveness of the product candidate;
- discovery of unacceptable toxicities or side effects;
- development of disease resistance or other physiological factors; or
- delays in patient enrollment.

The results of the clinical trials may fail to demonstrate the safety or effectiveness of our product candidates to the extent necessary to obtain regulatory approval or that commercialization of our product candidates is worthwhile. Any failure or substantial delay in successfully completing clinical trials and obtaining regulatory approval for our product candidates could severely harm our business.

If our collaborative partners fail to perform their obligations under our agreements, our ability to develop and market potential products could be severely limited.

Our strategy for the development and commercialization of our product candidates depends, in large part, upon the formation of collaborative arrangements. Collaborations allow us to:

- fund our internal research and development, pre-clinical testing, clinical trials and manufacturing;
- seek and obtain regulatory approvals;
- successfully commercialize existing and future product candidates; and
- develop antibodies for additional product candidates, and discover additional cell surface markers for antibody development.

If we fail to secure or maintain successful collaborative arrangements, our development and marketing activities may be delayed or scaled back. We may also be unable to negotiate additional collaborative arrangements or, if necessary, modify our existing arrangements on acceptable terms. We have entered into collaboration agreements with GlaxoSmithKline and British Biotech with respect to our two most advanced product candidates, huC242-DM1/SB-408075 and huN901-DM1/BB-10901, respectively. The development, regulatory approval and commercialization of these two product candidates depend primarily on the efforts of these collaborative partners. We have also entered into collaborations with Genentech, Abgenix, Millennium, MorphoSys, Genzyme Transgenics, Raven, Avalon and Boehringer Ingelheim. We cannot control the amount and timing of resources our partners may devote to our products. Our partners may separately pursue competing products, therapeutic approaches or technologies to develop treatments for the diseases targeted by us or our collaborative efforts. Even if our partners continue their contributions to the collaborative arrangements, they may nevertheless determine not to actively pursue the development or commercialization of any resulting products. Also, our partners may fail to perform their obligations under the collaboration agreements or may be slow in performing their obligations. Our partners can terminate our collaborative agreements under certain conditions. If any collaborative partner were to terminate or breach our agreement, or otherwise fail to complete its obligations in a timely manner, our anticipated revenue from the agreement and development and commercialization of our products could be severely limited. If we are not able to establish additional collaborations or any or all of our existing collaborations are terminated and we are not able to enter into alternative collaborations on acceptable terms, we may be required to undertake product development, manufacture and commercialization and we may not have the funds or capability to do this.

We depend on a small number of collaborators for a substantial portion of our revenue. The loss of any one of these collaborators could result in a substantial decline in revenue.

We have and will continue to have collaborations with a limited number of companies. As a result, our financial performance depends on the efforts and overall success of these companies. The failure of any one of our collaboration partners to perform its obligations under its agreement with us, including making

any royalty, milestone or other payments to us, could have a material adverse effect on our financial condition. Also, if consolidation trends in the healthcare industry continue, the number of our potential collaborators could decrease, which could have an adverse impact on our development efforts.

We have a history of operating losses and expect to incur significant additional operating losses.

We have generated operating losses since our inception. As of December 31, 2001, we had an accumulated deficit of \$172.6 million. We may never be profitable. We expect to incur substantial additional operating expenses over the next several years as our research, development, pre-clinical testing and clinical trial activities increase.

We intend to invest significantly in our products and bring more of the product development process in-house prior to entering into collaborative arrangements. We may also incur substantial marketing and other costs in the future if we decide to establish marketing and sales capabilities to commercialize certain of our products. None of our product candidates has generated any commercial revenue and our only revenues to date have been primarily from up-front and milestone payments from our collaboration partners. We do not expect to generate revenues from the commercial sale of our products in the foreseeable future, and we may never generate revenues from the commercial sale of products. Even if we do successfully develop products that can be marketed and sold commercially, we will need to generate significant revenues from those products to achieve and maintain profitability. Even if we do become profitable, we may not be able to sustain or increase profitability on a quarterly or annual basis.

We are subject to extensive government regulations and we may not be able to obtain necessary regulatory approvals.

We or our collaborative partners may not receive the regulatory approvals necessary to commercialize our product candidates, which could cause our business to fail. Our product candidates are subject to extensive and rigorous government regulation. The FDA regulates, among other things, the development, testing, manufacture, safety, record-keeping, labeling, storage, approval, advertising, promotion, sale and distribution of pharmaceutical products. If our potential products are marketed abroad, they will also be subject to extensive regulation by foreign governments. None of our product candidates has been approved for sale in the United States or any foreign market. The regulatory review and approval process, which includes pre-clinical studies and clinical trials of each product candidate, is lengthy, expensive and uncertain. Securing FDA approval requires the submission of extensive pre-clinical and clinical data and supporting information to the FDA for each indication to establish the product candidates' safety and efficacy. Data obtained from pre-clinical and clinical trials are susceptible to varying interpretation, which may delay, limit or prevent regulatory approval. The approval process may take many years to complete and may involve ongoing requirements for post-marketing studies. In light of the limited regulatory history of monoclonal antibody-based therapeutics, we cannot assure you that regulatory approvals for our products will be obtained without lengthy delays, if at all. Any FDA or other regulatory approvals of our product candidates, once obtained, may be withdrawn. The effect of government regulation may be to:

- delay marketing of potential products for a considerable period of time;
- limit the indicated uses for which potential products may be marketed;
- impose costly requirements on our activities; and
- provide a competitive advantage to other pharmaceutical and biotechnology companies.

We may encounter delays or rejections in the regulatory approval process because of additional government regulation from future legislation or administrative action or changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. Failure to comply with applicable FDA or other applicable regulatory requirements may result in criminal prosecution, civil penalties, recall or seizure of products, total or partial suspension of production or injunction, as well as other regulatory action against our product candidates or us. Outside the United States, our ability to market a product is contingent upon receiving clearances from the appropriate regulatory authorities. This foreign regulatory approval process includes all of the risks associated with the FDA approval process. In addition, we are, or may become, subject to various federal, state and local laws, regulations and recommendations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals and the use and disposal of hazardous substances, including radioactive compounds and infectious disease agents, used in connection with our research work. If we fail to comply with the laws and regulations pertaining to our business, we may be subject to sanctions, including the temporary or permanent suspension of operations, product recalls, marketing restrictions and civil and criminal penalties.

We may be unable to establish the manufacturing capabilities necessary to develop and commercialize our potential products.

Currently, we only have one pilot manufacturing facility for the manufacture of products necessary for clinical testing. We do not have sufficient manufacturing capacity to manufacture our product candidates in quantities necessary for commercial sale. In addition, our manufacturing capacity may be inadequate to complete all clinical trials contemplated by us over time. We intend to rely in part on third-party contract manufacturers to produce large quantities of drug materials needed for clinical trials and commercialization of our potential products. Third-party manufacturers may not be able to meet our needs with respect to timing, quantity or quality of materials. If we are unable to contract for a sufficient supply of needed materials on acceptable terms, or if we should encounter delays or difficulties in our relationships with manufacturers, our clinical trials may be delayed, thereby delaying the submission of product candidates for regulatory approval and the market introduction and subsequent commercialization of our potential products. Any such delays may lower our revenues and potential profitability.

We may develop our manufacturing capacity in part by expanding our current facilities or building new facilities. Either of these activities would require substantial additional funds and we would need to hire and train significant numbers of employees to staff these facilities. We may not be able to develop manufacturing facilities that are sufficient to produce drug materials for clinical trials or commercial use. We and any third-party manufacturers that we may use must continually adhere to Current Good Manufacturing Practices regulations enforced by the FDA through its facilities inspection program. If our facilities or the facilities of third-party manufacturers cannot pass a pre-approval plant inspection, the FDA approval of our product candidates will not be granted. In complying with these regulations and foreign regulatory requirements, we and any of our third-party manufacturers will be obligated to expend time, money and effort on production, record-keeping and quality control to assure that our potential products meet applicable specifications and other requirements. If we or any

third-party manufacturer with whom we may contract fail to maintain regulatory compliance, we or the third party may be subject to fines and manufacturing operations may be suspended, which could negatively affect our business.

Our inability to license from third parties their proprietary technologies or processes which we use in connection with the development and manufacture of our TAP product candidates may impair our business.

Other companies, universities and research institutions have or may obtain patents that could limit our ability to use, manufacture, market or sell our product candidates or impair our competitive position. As a result, we may have to obtain licenses from other parties before we could continue using, manufacturing, marketing or selling our potential products. Any such licenses may not be available on commercially acceptable terms, if at all. If we do not obtain required licenses, we may not be able to market our potential products at all or we may encounter significant delays in product development while we redesign potentially infringing products or methods.

We rely on one supplier for the primary component to manufacture our small molecule effector drug, DM1. Any problems experienced by this supplier could negatively affect our operations.

We rely on third-party suppliers for some of the materials used in the manufacturing of our TAP product candidates and small molecule effector drugs. Our most advanced small molecule effector drug is DM1. DM1 is the cytotoxic agent used in all of our current TAP product candidates and the subject of most of our collaborations. One of the primary components required to manufacture DM1 is its precursor, ansamitocin P3. Currently, only one vendor manufactures and is able to supply us with this material. Any problems experienced by this vendor could result in a delay or interruption in the supply of ansamitocin P3 to us until this vendor cures the problem or until we locate an alternative source of supply. Any delay or interruption in our supply of ansamitocin P3 would likely lead to a delay or interruption in our manufacturing operations and pre-clinical and clinical trials of our product candidates, which could negatively affect our business.

We may be unable to establish sales and marketing capabilities necessary to successfully commercialize our potential products.

We currently have no direct sales or marketing capabilities. We anticipate relying on third parties to market and sell most of our primary product candidates. If we decide to market our potential products through a direct sales force, we would need to either hire a sales force with expertise in pharmaceutical sales or contract with a third party to provide a sales force to meet our needs.

We may be unable to establish marketing, sales and distribution capabilities necessary to commercialize and gain market acceptance for our potential products and be competitive. In addition, co-promotion or other marketing arrangements with third parties to commercialize potential products could significantly limit the revenues we derive from these potential products, and these third parties may fail to commercialize our potential products successfully.

If our product candidates do not gain market acceptance, our business will suffer.

Even if clinical trials demonstrate safety and efficacy of our product candidates and the necessary regulatory approvals are obtained, our product candidates may not gain market acceptance among physicians, patients, healthcare payors and the medical community. The degree of market acceptance of any product candidates that we develop will depend on a number of factors, including:

- the degree of clinical efficacy and safety;
- cost-effectiveness of our product candidates;
- their advantage over alternative treatment methods;
- reimbursement policies of government and third-party payors; and
- the quality of our or our collaborative partners' marketing and distribution capabilities for our product candidates.

Physicians will not recommend therapies using any of our future products until such time as clinical data or other factors demonstrate the safety and efficacy of such products as compared to conventional drug and other treatments. Even if the clinical safety and efficacy of therapies using our products is established, physicians may elect not to recommend the therapies for any number of other reasons, including whether the mode of administration of our products is effective for certain indications. Our product candidates, if successfully developed, will compete with a number of drugs and therapies manufactured and marketed by major pharmaceutical and other biotechnology companies. Our products may also compete with new products currently under development by others. Physicians, patients, third-party payors and the medical community may not accept and utilize any product candidates that we, or our collaborative partners, develop. If our products do not achieve significant market acceptance, we will not be able to recover the significant investment we have made in developing such products and our business would be severely harmed.

We may be unable to compete successfully.

The markets in which we compete are well-established and intensely competitive. We may be unable to compete successfully against our current and future competitors. Our failure to compete successfully may result in pricing reductions, reduced gross margins and failure to achieve market acceptance for our potential products. Our competitors include pharmaceutical companies, biotechnology companies, chemical companies, academic and research institutions and government agencies. Many of these organizations have substantially more experience and more capital, research and development, regulatory, manufacturing, sales, marketing, human and other resources than we do. As a result, they may:

- develop products that are safer or more effective than our product candidates;
- obtain FDA and other regulatory approvals or reach the market with their products more rapidly than we can, reducing the potential sales of our product candidates;
- devote greater resources to market or sell their products;

- adapt more quickly to new technologies and scientific advances;
- initiate or withstand substantial price competition more successfully than we can;

- have greater success in recruiting skilled scientific workers from the limited pool of available talent;
- more effectively negotiate third-party licensing and collaboration arrangements; and
- take advantage of acquisition or other opportunities more readily than we can.

A number of pharmaceutical and biotechnology companies are currently developing products targeting the same types of cancer that we target, and some of our competitors' products have entered clinical trials or already are commercially available. In addition, our product candidates, if approved and commercialized, will compete against well-established, existing, therapeutic products that are currently reimbursed by government health administration authorities, private health insurers and health maintenance organizations. We face and will continue to face intense competition from other companies for collaborative arrangements with pharmaceutical and biotechnology companies, for relationships with academic and research institutions, and for licenses to proprietary technology. In addition, we anticipate that we will face increased competition in the future as new companies enter our markets and as scientific developments surrounding prodrug and antibody-based therapeutics for cancer continue to accelerate. While we will seek to expand our technological capabilities to remain competitive, research and development by others may render our technology or product candidates obsolete or noncompetitive or result in treatments or cures superior to any therapy developed by us.

If we are unable to protect our intellectual property rights adequately, the value of our TAP technology and our product candidates could be diminished.

Our success depends in part on obtaining, maintaining and enforcing our patents and other proprietary rights and our ability to avoid infringing the proprietary rights of others. Patent law relating to the scope of claims in the biotechnology field in which we operate is still evolving and surrounded by a great deal of uncertainty and involves complex legal, scientific and factual questions. To date, no consistent policy has emerged regarding the breadth of claims allowed in biotechnology patents. Accordingly, our pending patent applications may not result in issued patents. Although we own several patents, the issuance of a patent is not conclusive as to its validity or enforceability. Through litigation, a third party may challenge the validity or enforceability of a patent after its issuance. Also, patents and applications owned or licensed by us may become the subject of interference proceedings in the United States Patent and Trademark Office to determine priority of invention which could result in substantial cost to us. An adverse decision in an interference proceeding may result in our loss of rights under a patent or patent application subject to such a proceeding.

We cannot assure you how much protection, if any, will be given to our patents if we attempt to enforce them and they are challenged in court or in other proceedings. It is possible that a competitor may successfully challenge our patents or that a challenge will result in limitations of their coverage. In addition, the cost of litigation or interference proceedings to uphold the validity of patents can be substantial. If we are unsuccessful in such proceedings, third parties may be able to use our patented technology without paying us licensing fees or royalties. Moreover, competitors may infringe our patents or successfully avoid them through design innovation. To prevent infringement or unauthorized use, we may need to file infringement claims, which are expensive and time-consuming. In an infringement proceeding a court may decide that a patent of ours is not valid. Even if the validity of our patents were upheld, a court may refuse to stop the other party from using the technology at issue on the ground that its activities are not covered by our patents. Policing unauthorized use of our intellectual property is difficult, and we may not be able to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States.

In addition to our patent rights, we also rely on unpatented technology, trade secrets and confidential information. Others may independently develop substantially equivalent information and techniques or otherwise gain access to or disclose our technology. We may not be able to effectively protect our rights in unpatented technology, trade secrets and confidential information. We require each of our employees, consultants and corporate partners to execute a confidentiality agreement at the commencement of an employment, consulting or collaborative relationship with us. However, these agreements may not provide effective protection of our information or, in the event of unauthorized use or disclosure, they may not provide adequate remedies.

We may be subject to substantial costs and liability or be prohibited from commercializing our potential products as a result of litigation and other proceedings relating to patent rights.

Patent litigation is very common in the biotechnology and pharmaceutical industries. Third parties may assert patent or other intellectual property infringement claims against us with respect to our technologies, products or other matters. Any claims that might be brought against us relating to infringement of patents may cause us to incur significant expenses and, if successfully asserted against us, may cause us to pay substantial damages and limit our ability to use the intellectual property subject to these claims. Even if we were to prevail, any litigation could be costly and time-consuming and could divert the attention of our management and key personnel from our business operations. Furthermore, as a result of a patent infringement suit, we may be forced to stop or delay developing, manufacturing or selling potential products that incorporate the challenged intellectual property unless we enter into royalty or license agreements. Furthermore, because patent applications in the United States are maintained in secrecy until a patent issues, others may have filed patent applications for technology covered by our pending applications. There may be third-party patents, patent applications and other intellectual property relevant to our potential products that may block or compete with our products or processes.

In addition, we sometimes undertake research and development with respect to potential products even when we are aware of third-party patents that may be relevant to our potential products, on the basis that such patents may be challenged or licensed by us. If our subsequent challenge to such patents were not to prevail, we may not be able to commercialize our potential products after having already incurred significant expenditures unless we are able to license the intellectual property on commercially reasonable terms. We may not be able to obtain royalty or license agreements on terms acceptable to us, if at all. Even if we were able to obtain licenses to such technology, some licenses may be non-exclusive, thereby giving our competitors access to the same technologies licensed to

us. Ultimately, we may be unable to commercialize some of our potential products or may have to cease some of our business operations, which could severely harm our business.

We face uncertainties over reimbursement and healthcare reform.

In both domestic and foreign markets, future sales of our potential products, if any, will depend in part on the availability of reimbursement from third-party payors such as government health administration authorities, private health insurers and other organizations. Third-party payors are increasingly challenging the price and cost-effectiveness of medical products and services. Significant uncertainty exists as to the reimbursement status of newly-approved health care products. Even if they were to obtain regulatory approval, our product candidates may not be considered cost-effective and adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investments in product development. Legislation and regulations affecting the pricing of pharmaceuticals may change before any of our product candidates is approved for marketing. Adoption of such legislation and regulations could further limit reimbursement for medical products and services. If the government and third-party payors fail to provide adequate coverage and reimbursement rates for our potential products, the market acceptance of our products may be adversely affected.

ITEM 3. Quantitative and Qualitative Disclosures about Market Risk

In the normal course of business, the financial position of the Company is subject to certain risks, including market risk associated with interest rate movements. The Company regularly assesses these risks and has established policies and business practices designed to mitigate such exposures. The Company invests surplus cash in low-risk debt securities, typically maturing in one year or less, pending use in operations. The Company manages these funds by seeking principal preservation while concurrently enhancing rates of return. The Company's interest income is therefore sensitive to changes in the general level of domestic interest rates. Based on the Company's overall interest rate exposure at December 31, 2001, a near-term change in interest rates would not materially affect the fair value of interest rate sensitive instruments.

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PART II. OTHER INFORMATION

ITEM 2. Changes in Securities and Use of Proceeds.

In September 2001, a holder of warrants originally issued in connection with a March 1996 private placement of the Company's convertible debentures, and adjusted, pursuant to the anti-dilution provisions of the warrants, in connection with the Company's November 2000 public offering of common stock, exercised its right to acquire 1,127,374 shares of common stock at prices ranging between \$3.58 and \$5.37 per share. Proceeds from these warrant exercises will be used to fund current operations.

In October 2001, a holder of warrants originally issued in connection with a private placement of the Company's Series B Convertible Preferred Stock exercised its right to acquire 10,931 shares of Common Stock at \$5.49 per share. Proceeds from this warrant exercise will be used to fund current operations.

During the six-month period ended December 31, 2001, holders of options issued under the Company's Restated Stock Option Plan, as amended, exercised their rights to acquire an aggregate of 95,169 shares of common stock at prices ranging from \$0.84 per share to \$15.88 per share. The total proceeds from these option exercises, \$499,509, will be used to fund current operations.

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

The Company's Annual Meeting of Shareholders was held on November 13, 2001. At the meeting, the following matters were voted upon:

(1) The following persons were elected as Directors of the Company: Mitchel Sayare, Walter A. Blattler, David W. Carter, Michael R. Eisenson, Stuart F. Feiner, and Mark B. Skaletsky. The votes cast were as follows:

Name	For	Withheld
Mitchel Sayare	33,100,846	1,690,319
Walter A. Blattler	33,100,596	1,690,569
David W. Carter	30,920,808	3,870,357
Michael R. Eisenson	34,209,573	581,592
Stuart F. Feiner	34,263,396	527,769
Mark B. Skaletsky	32,527,822	2,263,343

(2) A proposal to increase from 4,850,000 shares to 7,350,000 shares the aggregate number of shares of the Company's common stock for which stock options may be granted under the Company's Restated Stock Option Plan was approved. The votes cast were as follows:

For:	11,328,275
Against:	7,175,828
Abstentions:	178,400
Broker Non-Votes:	16,108,662

(3) A proposal to adopt the Company's 2001 Non-Employee Director Stock Plan and reserve 50,000 shares of common stock for stock or stock units which may be granted under that plan was approved. The votes cast were as follows:

For:	15,183,048
Against:	3,327,738
Abstentions:	171,717
Broker Non-Votes:	16,108,662

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(4) A proposal to amend the Company's Restated Articles of Organization to increase from 50,000,000 shares to 75,000,000 shares the aggregate number of shares of common stock authorized to be issued by the Company was approved. The votes cast were as follows:

For:	33,250,272
Against:	1,407,509
Abstentions:	133,384

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

(a) Exhibits

3.1 Amendment to Restated Articles of Organization

10.1* Agreement between ImmunoGen, Inc. and Boehringer Ingelheim International GmbH, dated November 27, 2001.

* Confidential treatment has been requested for portions of this Exhibit. The portions have been omitted and filed separately with the U.S. Securities and Exchange Commission.

(b) Reports on Form 8-K

Form 8-K dated November 28, 2001- Item 5: Other Events

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SIGNATURES

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

ImmunoGen, Inc.

Date: February 14, 2002

By: /s/ Mitchel Sayare
Mitchel Sayare
President and Chief Executive Officer
(principal executive officer)

Date: February 14, 2002

By: /s/ Gregg D. Beloff
Gregg D. Beloff
Chief Financial Officer and Vice President, Finance
(principal financial and accounting officer)

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INDEX TO EXHIBITS

EXHIBIT NO.	DESCRIPTION
Ex. 3.1	Amendment to Restated Articles of Organization
Ex. 10.1*	Agreement between ImmunoGen, Inc. and Boehringer Ingelheim International GmbH, dated November 27, 2001

*Confidential treatment has been requested for portions of this Exhibit. The portions have been omitted and filed separately with the U.S. Securities and Exchange Commission.

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THE COMMONWEALTH OF MASSACHUSETTS
William Francis Galvin
Secretary of the Commonwealth
One Ashburton Place, Boston, Massachusetts 02108-1512

Examiner

ARTICLES OF AMENDMENT
(General Laws, Chapter 156B, Section 72)

Name

Approved We, Mitchel Sayare, *President
and Jonathan Kravetz, *Clerk
of ImmunoGen, Inc.
(Exact name of corporation)

located at, 128 Sidney Street, Cambridge, MA 02139
(Street address of corporation in Massachusetts)

certify that these Articles of Amendment affecting articles numbered:

3
(Numbered those articles 1, 2, 3, 4, 5 and/or 6 being amended)

of the Articles of Organization were duly adopted at a meeting held on November 13, 2001, by vote of :

33,250,272 shares of Common Stock of 39,680,326 shares outstanding,
(type, class & series, if any)

No Preferred Stock Issued & Outstanding

_____ shares of _____ of _____ shares outstanding, and
(type, class & series, if any)

_____ shares of _____ of _____ shares outstanding,
(type, class & series, if any)

- C]
P] (1)**being at least a majority of each type, class or series outstanding and entitled to vote thereon: / or (2)** being at
M] least two-thirds of each type, class or series outstanding and entitled to vote thereon and of each type, class or
R.A.] series of stock whose rights are adversely affected thereby:

P.C.

*Delete the inapplicable words. **Delete the inapplicable clause.*
(1) For amendments adopted pursuant to Chapter 156B, Section 70.
(2) For amendments adopted pursuant to Chapter 156B, Section 71.
Note: If the space provided under any article or item on this form is insufficient, additions shall be set forth on one side only of separate 8 1/2 x 11 sheets of paper with a left margin of at least 1 inch. Additions to more than one article may be made on a single sheet so long as each article requiring each addition is clearly indicated.

To *change* the number of shares and the part value (if any) of any type, class or series of sock which the corporation is authorized to issue, fill in the following:

The total *presently* authorized is:

WITHOUT PAR VALUE STOCKS		WITH PAR VALUE STOCKS		PAR VALUE
TYPE:	NUMBER OF SHARES	TYPE	NUMBER OF SHARES	
Common:		Common:	50,000,000	\$.01
Preferred		Preferred:	5,000,000*	\$.01

Change the total authorized to:

WITHOUT PAR VALUE STOCKS		WITH PAR VALUE STOCKS		PAR VALUE
TYPE:	NUMBER OF SHARES	TYPE	NUMBER OF SHARES	
Common:		Common:	75,000,000	\$.01

Preferred	Preferred:	5,000,000* \$.01
	*Preferred:	Series A Convertible Preferred Shares \$.01 par value	2,500
		Series B Convertible Preferred Shares \$.01 par value	3,000
		Series C Convertible Preferred Shares \$.01 par value	3,000
		Series D Convertible Preferred Shares \$.01 par value	1,000
		Series E Convertible Preferred Shares \$.01 par value	2,400

The foregoing amendment(s) will become effective when these Articles of Amendment are filed in accordance with General Laws, Chapter 156B, Section 6 unless these articles specify, in accordance with the vote adopting the amendment, a *later* effective date not more than *thirty days* after such filing, in which event the amendment will become effective on such later date.

Late effective date: _____

SIGNED UNDER THE PENALTIES OF PERJURY, this _____ 13th day of _____ November, _____, 20 01 _____,

_____/s/ Mitchel Sayare _____, *President

_____/s/ Jonathan L. Kravetz _____ *Clerk

*Delete the inapplicable words.

THE COMMONWEALTH OF MASSACHUSETTS
ARTICLES OF AMENDMENT
(General Laws, Chapter 156B, Section 72)

I hereby approve the within Articles of Amendment and, the filing fee in the amount of \$_____ having been paid, said articles are deemed to have been filed with me this ____ day of _____, 20 ____.

Effective date: _____

WILLIAM FRANCIS GALVIN
Secretary of the Commonwealth

TO BE FILLED IN BY CORPORATION
Photocopy of document to be sent to:

Jonathan Kravetz, Esquire

Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.

One Financial Center, Boston, MA 02111

Telephone: 617 542-6000

between

ImmunoGen, Inc.
128 Sidney Street
Cambridge, MA 02139
U.S.A.

(hereinafter called "ImmunoGen")

and

Boehringer Ingelheim International GmbH
Binger Strasse 173
55218 Ingelheim am Rhein
GERMANY

(hereinafter called "BI")

having an Effective Date of November 27, 2001 (the "Effective Date").

WITNESSETH:

WHEREAS, BI is a pharmaceutical company engaged in the research, development, manufacture and commercialisation of pharmaceutical products and Controls certain patents and know-how related to the humanised monoclonal antibody BIWA4; and

WHEREAS, ImmunoGen Controls certain patents, and know-how related to ImmunoGen's maytansinoid DM1 technology, and it has the right to grant certain rights and licenses thereunder as set forth herein; and

WHEREAS, BI desires to obtain a license from ImmunoGen to develop, manufacture, market and sell the Licensed Products in the Territory, and ImmunoGen desires to grant such a license to BI, on the terms and conditions contained in this Agreement.

NOW THEREFORE, in consideration of the covenants and promises in this Agreement, ImmunoGen and BI agree as follows:

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1. DEFINITIONS

1.1	"Adverse Event"	shall mean any untoward medical occurrence in a patient or subject who is administered a Licensed Product, whether or not considered related to the Licensed Product, including, without limitation, any undesirable sign (including abnormal laboratory findings of clinical concern), symptom or disease temporally associated with the use of such Licensed Product.
1.2	"Affiliates"	shall mean any company or business entity which controls, is controlled by, or is under common control with, either ImmunoGen or BI. For purposes of this definition, "control" shall mean the possession, directly or indirectly or the power to direct or cause the direction of the management and policies of an entity (other than a natural person), whether through the majority ownership of voting capital stock, by contract or otherwise.
1.3	"BI Materials"	shall mean any tangible chemical, biological or research materials, including without limitation, any assays or antibodies, whether or not patentable, used by BI or furnished by BI to ImmunoGen under this Agreement. BI Materials shall include, without limitation, the BIWA4 antibody.
1.4	"BI Intellectual Property"	shall mean any Technology and Patent Rights Controlled by BI during the Term that are used by BI or

provided by BI for use in the activities contemplated by this Agreement. BI Intellectual Property Patent Rights as of the Effective Date are described on Schedule C.

- 1.5 “BIWI1” shall mean any conjugate of “naked” BIWA4 with DM1.
- 1.6 “Commercially Reasonable Efforts” shall mean the efforts and resources that BI would use for a compound owned by it or to which it has rights, which is of similar market potential at a similar stage in development as the applicable Licensed Product, taking into account the competitiveness of the marketplace, the proprietary position of the Licensed Product, the profitability and the relative potential safety and efficacy of the Licensed Product, and other relevant factors including, without limitation, technical, legal, scientific or medical factors.
- 1.7 “Comparable Product” shall mean any [*] that has the same [*] as a Licensed Product.
- 1.8 “Competent Authorities” shall mean the United States Food and Drug Administration (FDA), the European Commission and any foreign health authority charged with responsibility for regulating the approval to market a Licensed Product for the treatment of humans.

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- 1.9 “Control” shall mean, with respect to tangible or intangible property, including intellectual property or other matters, title to such property and/or possession of the ability to grant a license or sublicense to such property without violating any agreement with a third party.
- 1.10 “[*]” shall mean with respect to any Drug Substance or Drug Product, the [*] of producing (including the [*] of such Drug Substance and Drug Product, including the sum of the following components: (a) the [*], including [*] and [*], of [*] and [*] such BIWI1; (b) all [*] incurred by ImmunoGen attributable to the [*] under the foregoing clause (a), including, without limitation, [*] and [*] which are [*] to [*] or another [*]; (c) any other [*] borne by ImmunoGen for the [*] and/or [*] of such Drug Substance and Drug Product; and (d) [*] and [*] which are [*] to [*] or another [*]. Notwithstanding the foregoing, [*] of Drug Substance shall not include the [*] of [*] any [*] to the [*] by BI pursuant to Section [*] of this Agreement.
- 1.11 “DM1” shall mean that certain maytansine derivative known as “DM1” whose specific chemical name is N²-deacetyl-N²’(3-mercapto-1-oxopropyl)-maytansine.
- 1.12 “Drug Product” shall mean Drug Substance, manufactured under cGMP in the final concentration for clinical use, aseptically filled in unlabeled, primary packaging material.
- 1.13 “Drug Substance” shall mean bulk BIWI1.
- 1.14 “Effective Date” shall mean the date first mentioned above.
- 1.15 “Field” shall mean [*].
- 1.16 “First Commercial Sale” shall mean the date of the first commercial sale (other than for purposes of obtaining regulatory approval) of a Licensed Product by or on behalf of BI or any Sublicensee of BI.
- 1.17 “ImmunoGen Materials” shall mean any tangible chemical, biological or research materials, including without limitation, DM1, or any assays or antibodies other than BI Materials, whether or not patentable, used by ImmunoGen or furnished by ImmunoGen to BI under this Agreement.

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- 1.18 “Improvement(s)” shall mean any enhancement, improvement or modification to the Licensed Technology or covered by the Licensed Patent Rights which is conceived, reduced to practice or discovered during the Term of this Agreement.
- 1.19 “Indication” shall mean [*], e.g. [*] or mean and [*].
- 1.20 “Initiation” shall mean, with respect to any clinical study, the [*] for such clinical study by or on behalf of BI.
- 1.21 “IND” shall mean an investigational new drug application (as defined in Title 21 of the United States Code of Federal Regulations, as amended from time to time) filed or to be filed with the FDA with regard to any Licensed Product.
- 1.22 “Licensed Product(s)” shall mean any product containing a conjugate of DM1 with an antibody or antibody derivative that is specific for the Target Antigen, including, without limitation, BIWI1, and any drug product containing such conjugate. For purposes of clarity, the Parties hereby acknowledge and agree that a given Licensed Product that has one or more Indications shall not be considered to be a Subsequent Licensed Product for purposes of Section 3.3(d) of this Agreement.

1.23	“Licensed Technology”	shall mean (i) the Technology described on <u>Schedule A</u> attached hereto; and (ii) any Improvements thereto (other than Improvements that are Patent Rights) Controlled by ImmunoGen during the Term of the Agreement [*] to the extent [*] in accordance with Section 2.3 hereof, [*] to the extent that any of the foregoing relates to any Licensed Patent Rights or is necessary or useful to develop, have developed, make, have made, sell and have sold Licensed Products.
1.24	“Licensed Patent Rights”	shall mean the Patent Rights in the Field in the Territory Controlled by ImmunoGen during the Term which block, absent a license, the use, making or selling of a Licensed Product. Licensed Patent Rights as of the Effective Date are described on <u>Schedule [*] attached thereto</u> .
1.25	“Major Markets”	shall mean the [*] and the [*] .

1.26	“Net Sales”	<p>shall mean, as to each [*] during the [*], the [*] for all [*] sold by BI and its Sublicensees to third parties throughout the [*] during such [*], less the [*] or [*] by BI or its Sublicensees during such [*] with respect to [*] of [*] regardless of the [*] in which such [*] were made:</p> <p>(a) [*] and [*] or [*] actually taken and allowed, including [*] or [*] to [*] or [*] ;</p> <p>(b) [*] or [*] given or made for [*] or [*] of [*] or for [*] (including [*] and similar types of [*]);</p> <p>(c) any [*] for [*] and other [*] directly related to the [*] of [*] to the extent included in the [*] ;</p> <p>(d) any [*] or [*] levied on the [*] or [*] of a [*] (including any [*] such as a [*] or [*] or [*]) borne by the seller thereof, other than [*] or of any kind whatsoever; and</p> <p>(e) any [*] or [*] or their equivalent borne by the seller.</p>
1.27	“Patent Rights”	shall mean the rights and interests in and to any and all issued patents and pending patent applications (including inventor’s certificates and utility models) in any country or jurisdiction in the Territory, including any and all provisions, non-provisionals, substitutions, continuations, continuations-in-part, divisionals and other continuing applications, supplementary protection certificates, renewals, and all letters patent on any of the foregoing, and any and all reissues, reexaminations, extensions, confirmations, registrations and patents of addition of any of the foregoing.
1.28	“Phase I Trial”	shall mean any clinical study involving the use of the Licensed Product in humans that is designed primarily to obtain preliminary safety data on the use of a Licensed Product in human patients.
1.29	“Phase IIa Trial”	shall mean any controlled clinical study involving the use of the Licensed Product in human patients that is designed primarily to obtain preliminary data on the effectiveness of a specific therapy involving the use of a Licensed Product in human patients. Phase IIa Trials must take place after Phase I Trials.
1.30	“Pivotal Trial”	shall mean any Phase IIb/III clinical study involving a Licensed Product and having adequate statistical power to meet the requirements for regulatory approval by the FDA or the European Commission.
1.31	“Recognised Agents”	shall mean any third party legal entity (other than an Affiliate of BI) engaged by BI in the normal course of its business to market and/or distribute its products in a particular country of the Territory.

1.32	“Sublicensee”	shall mean any person, corporation, unincorporated body, or other entity including Affiliates of BI to whom BI grants a sublicense of the rights granted to BI pursuant to this Agreement. For the avoidance of doubt, Recognised Agents shall not be considered to be Sublicensees for the purposes of this Agreement.
1.33	“Target Antigen”	shall mean either [*] and its [*] or, in case Section [*] applies, [*]
1.34	“Technology”	shall mean and include any and all unpatented proprietary ideas, inventions, discoveries, data, results, formulae, designs, specifications, methods, processes, formulations, techniques, ideas, know-how, technical information (including, without limitation, structural and functional information), process information, and any and all proprietary biological, chemical, pharmacological, toxicological, pharmacokinetic, chemical, analytical, pharmaceutical, and clinical data.
1.35	“Territory”	shall mean the world.
1.36	“Valid Claim”	shall mean a claim in an issued, unexpired patent within the Licensed Patent Rights that (i) has not been

finally cancelled, withdrawn, abandoned or rejected by any administrative agency or other body of competent jurisdiction and (ii) has not been revoked, held invalid, or declared unpatentable or unenforceable in a decision of a court or other body of competent jurisdiction that is unappealable or unappealed within the time allowed for appeal.

2. GRANT OF RIGHTS AND RESTRICTIONS

2.1 Grant of License to BI:

Subject to the terms and conditions of this Agreement, ImmunoGen grants to BI, and BI accepts, an exclusive, royalty-bearing license, including the right to grant sublicenses as described below, within the Field and in the Territory, under the Licensed Technology and the Licensed Patent Rights and ImmunoGen's interest in any Improvements Controlled by ImmunoGen to the extent accepted in accordance with Section 2.3 hereof, to develop, make, use and sell Licensed Products.

2.2 ImmunoGen Retained Rights:

Subject to the other terms of this Agreement, ImmunoGen retains the right to use the Licensed Technology and practice the Licensed Patent Rights and to use ImmunoGen's interest in all Improvements (i) to perform its work under this Agreement (ii) to develop, have developed, make, have made, use, have used, sell have sold, offer for sale, import, have imported, export and have exported any product that is not a Licensed Product and (iii) for any and all uses outside of the Field.

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2.3 Additional Rights:

- (a) ImmunoGen herewith grants to BI [*] during the Term regarding all Improvements (including its interest in any Improvements owned jointly by ImmunoGen and BI) Controlled by ImmunoGen or its Affiliates during the Term to the extent such Improvements relate to any Licensed Patent Rights or are necessary or useful to develop, have developed, make, have made, sell and have sold Licensed Products. If BI [*] ImmunoGen [*] of its [*] in the respective Improvement at any time during the Term, BI shall [*] an [*] so long as such Improvement is Controlled by ImmunoGen at the [*] of such [*], consistent with the terms of [*], which [*] such Improvement to the [*] of the Licensed Patent Rights and/or Licensed Technology, as the case may be, [*] any [*] from BI to ImmunoGen.
- (b) BI hereby grants to ImmunoGen a non-exclusive, royalty-free license under BI Intellectual Property and BI's interest in any Improvements to manufacture the Drug Substance and Drug Product solely for delivery to BI, its Affiliates, Recognised Agents and Sublicensees for the limited duration and purposes as set forth in Section 5 below and subject to the terms of this Agreement and the Clinical Supply Agreement attached as Schedule G.

2.4 Right to Sublicense/Sub-contract and Partner; Right to License BI Improvements:

- (a) BI shall have the right to grant sublicenses of its rights granted under Section 2.1 hereof to its Affiliates and other Sublicensees.
- (b) BI agrees to contractually bind its Sublicensees by terms and obligations substantially similar to those applying to BI hereunder, including without limitation, BI's confidentiality and royalty obligations.
- (c) BI shall have the right to partner with third parties to co-market and/or co-promote the Licensed Products in all countries of the Territory.
- (d) Notwithstanding anything herein to the contrary, BI shall be responsible for all obligations herein to be performed by it and any Sublicensee or partner. BI shall also be responsible for any and all breaches of any obligations hereunder by any Sublicensee, Recognised Agent, partner and other subcontractor of BI.
- (e) BI shall not license its interest in any Improvements to any third party, other than in connection with the grant of a sublicense to a Licensed Product or any license or sublicense to any other product containing DM1 Controlled by BI. Subject to the foregoing, BI shall be free to use its interest in any Improvements for all purposes, including, without limitation, the sale of DM1 and DM1 intermediates to third parties.

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3. PAYMENTS, REPORTS AND RECORDS

3.1 Upfront-fee:

In consideration of the rights granted by ImmunoGen to BI hereunder, BI will pay ImmunoGen the non-refundable, non-creditable sum of [*] to an account designated by ImmunoGen within [*] business days following the Effective Date.

3.2 Milestone Payments:

- (a) In further consideration of the rights granted by ImmunoGen to BI hereunder, including the licenses set forth in Section 2 above, BI will pay ImmunoGen non-refundable, non-creditable milestone payments as follows:

(i) [*]: Payment
Upon [*] of an [*] in the [*] for a [*]. [*]

(ii) [*]: Payment

Upon [*] of the [*] for a [*] [*]

Upon [*] of the [*] for a [*] [*]

Upon [*] of the [*] for a [*] [*]

Upon [*] of the [*] in the [*] for a [*] [*]

Upon [*] of [*] by the [*] for the [*] for a [*] [*]

Upon [*] of [*] by the [*] for the [*] for a [*] [*]

Upon [*] of [*] by the [*] in [*] for the [*] for a [*] [*]

Upon [*] of [*] by the [*] for the [*] for a [*] [*]

Upon [*] of [*] by the [*] for the [*] for a [*] [*]

Upon [*] of [*] by the [*] in [*] for the [*] for a [*] [*]

Upon [*] of the [*] for the [*] for a [*] [*]

(iii) [*]:

A [*] of:

- [*]
- [*]
- [*]
- [*]

(b) BI shall pay ImmunoGen the [*] set forth in Section [*] and [*] within [*] of the occurrence of the respective [*] and the [*] pursuant to Section [*] within [*] of the [*] of the [*]. The [*] pursuant to Section [*] and the [*] pursuant to Section [*] and [*] shall be [*] in [*]. The [*] pursuant to Section [*] shall be [*] in [*].

(c) It is hereby understood that each [*] shall be [*] for the [*] of a [*] by a [*] and that [*] shall be made for any [*] of [*] by a [*].

3.3 Royalty Payments:

(a) In further consideration of the rights granted by ImmunoGen to BI hereunder, including the licenses set forth in Section 2 above, BI will pay ImmunoGen a [*] on [*] of [*] by a [*] under a [*] or [*] as follows:

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

**For purposes of this Section 3.3(a), “[*]” shall refer to the [*] to [*] to [*] such that the “[*]” shall be [*] if ImmunoGen [*] a [*] with such [*].

(b) The above [*] shall be [*] on a [*] basis on the [*] of [*] from its [*] until the [*] of the [*] as provided in Section [*]. The above [*] be [*] by [*] in [*] on a [*] basis with respect to [*] if (i) the [*] or [*] of such [*] in such country is [*] by a [*] in [*] but is [*] by the [*]; or (ii) (A) the [*] in [*] covering the [*] or of a [*], (B) [*] are [*] in such [*] and (C) such [*] have, in the [*] during such [*] or [*] of the [*] in such [*] in connection with the [*] of such [*]

(c) In the event that BI, in order to [*] to it [*] hereunder in any [*], is required to [*] to [*] or [*] (i) to [*] under their [*] in the [*] of which the [*] of a [*] could not [*] be [*] or [*] in such [*] and/or (ii) to [*] under their [*] specific to the [*] used by ImmunoGen to [*], in the [*] of which any of the [*] necessary to [*] as part of a [*] can not [*] be [*] ([*], to the [*], by an [*] of [*]), then [*] due to [*] for a given [*] may be [*] by [*] of the [*] of such [*] Notwithstanding the following, such [*] shall in no event [*] the [*] for such [*] payable under [*] Section [*] to less than [*] of [*] in such [*]

(d) BI shall pay [*] with respect to each [*] on a [*] and [*] basis as follows:

(1) with respect to the [*] by BI or any Sublicensee of BI under this Agreement (the “[*]”) until the [*] of the [*] of the [*] to [*] of the [*] or [*] from [*] of [*] of such [*], and;

(2) with respect to any [*] the [*] of [*] of the [*] (each, a “[*]”);

(A) if BI at the [*] of the [*] is [*] in [*] with [*] of the [*] under Section [*] of this Agreement, then until the [*] of (i) the [*] of the [*] of the [*] covering the [*] or (ii) [*] from the [*] of [*] of such [*]; provided, that, [*] Section [*] of this Agreement, the [*] for any [*] covered by this Section 3.3(d)(2)(A)(ii) shall be [*] and;

(B) if BI at the [*] of the [*] is [*] from [*] of the [*] under Section [*], then until the [*] of (i) the [*] of the [*] of the [*] covering the [*] or (ii) the [*] on which [*] to [*] from [*] of any [*] for an [*] of [*] (whether or not such [*] are [*]).

3.4 Reports:

Each royalty payment shall be accompanied by a written report describing the Net Sales of the Licensed Product sold by or on behalf of BI, its Affiliates and Sublicensees during a "Payment Period" in each country in the Territory in which such Licensed Product occurred in the [*] covered by such statement, specifying: the [*] and [*] in each country's currency; the applicable [*] under this Agreement; the [*] in each country's currency, including an [*] of [*] taken in the [*] of [*]; the [*] to [*] from each [*] to [*], under this Section 3.4; and the [*] in [*]. Payment Period means a [*], commencing upon the [*]

3.5 Method and Manner of Royalty Payment:

- (a) BI shall deliver to ImmunoGen within [*] following the end of each [*] a [*] as set forth in Section [*] along with BI's payment to ImmunoGen of any [*] and [*] to ImmunoGen for such [*].
- (b) All royalty payments shall be [*] and [*] in [*] at [*] as [*] by the [*], and as customarily used by BI in its [*]

3.6 Withholding Tax:

- (a) BI shall [*] any [*] and other [*] from the [*] agreed upon under Sections [*], and [*] of this Agreement and [*] them to the [*] required by law applicable at the date of [*] BI shall maintain [*] of [*] of any [*] and forward these [*] to ImmunoGen.

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- (b) The parties will exercise their best efforts to ensure that any [*] imposed are [*] as far as possible under the provisions of the current or any future [*] between the [*] and the [*].
- (c) The parties hereby acknowledge that according to [*] this [*] requires that the [*] a [*] of [*]
- (d) The parties hereby acknowledge that in order to achieve such [*] ImmunoGen is required to provide [*] with the [*] for a [*] of [*] in respect of [*] performed on the [*] containing the statement of [*] and [*] of the [*] as well as the [*] of [*] a [*], in which it confirms that it does not [*] the [*] through a [*] in [*] BI agrees to provide ImmunoGen with the [*]
- (e) ImmunoGen hereby acknowledges that every [*] ImmunoGen is required to submit a [*], which complies with the above-mentioned prerequisites.

3.8 Records:

BI and/or its Sublicensees shall keep and maintain records of sales of Licensed Product so that the royalties payable and the royalty statements may be verified. Such records shall be open to inspection during business hours for a [*] period after the royalty period to which such records relate, but in any event [*], by a nationally recognised independent certified public accountant selected by ImmunoGen to whom BI has no reasonable objections and retained at ImmunoGen's expense. Said accountant shall sign a confidentiality agreement prepared by ImmunoGen and reasonably acceptable to BI and shall then have the right to examine the records kept pursuant to this Agreement and report to ImmunoGen the findings [*] of said examination of records as are necessary to evidence that the records were or were not maintained and used in accordance with this Agreement. A copy of any report provided to ImmunoGen by the accountant shall be given concurrently to BI. If said examination of records reveals any [*] of the [*], then BI shall promptly pay the balance due to ImmunoGen, and if the [*] is/are more than [*], then BI shall also bear the expenses of said accountant. If said examination of records reveals any overpayment(s) of royalty payable, then ImmunoGen shall credit the amount overpaid against BI's future royalty payment(s).

3.9 Overdue Payments:

Payments not paid within the time period set forth in this Section 3 shall bear interest at a rate of [*] per [*] from the due date until paid in full.

4. **DEVELOPMENT AND COMMERCIALISATION**

4.1 Development Responsibility:

- (a) Except as otherwise set forth in this Agreement, BI shall solely be responsible for the development of the Licensed Product for the Field as provided hereunder, including but not limited to any and all pre-clinical development activities, clinical studies and other testing and work conducted in connection with the Licensed Product for the Field, at BI's own expense and BI shall be solely responsible for making decisions related hereto.

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- (b) If prior to any [*] by BI with respect to a given [*], BI determines, in its reasonable discretion, that the [*] of such [*] using the [*] has [*], then BI shall have the right, upon not less than [*] prior written notice to ImmunoGen, to [*] as the [*] without any [*] from BI to ImmunoGen. Any decision regarding the [*] of [*] of a [*] that is [*] to the [*] is in the [*] of [*]

4.2 Development Obligation:

- (a) After the Effective Date, BI shall use its [*] and shall accept the corresponding responsibility, at its sole cost and expense, for the development, safety of, and all required periodic reporting to Competent Authorities required to obtain all regulatory approvals for, the Licensed Product(s) for the Field in the Major Market countries.
- (b) After the Effective Date, BI shall provide to ImmunoGen regular written reports every[*], setting forth (i) significant developments with respect to Licensed Product, and (ii) the status and progress of the development and/or registration activities related to the Licensed Product.
- (c) BI shall promptly advise ImmunoGen in writing upon the filing for regulatory approval to market a Licensed Product, and upon receipt of regulatory approval to market a Licensed Product, in each case in each country of the Territory.
- (d) ImmunoGen [*] to [*] and [*] the [*] for [*] to meet [*] for [*] of [*], according to the [*] attached as Schedule [*] and thereby agrees to maintain the [*] included in Schedule [*] which may be amended by the Parties during the development. During this [*] and [*], ImmunoGen will keep BI informed on a regular basis and [*] be [*] to [*] and [*] to such [*], as appropriate.
- (e) ImmunoGen shall provide the necessary documentation and assist BI in preparation of the chemical, pharmaceutical, and analytical sections of regulatory submissions for IND or foreign equivalent.

4.3 Marketing Efforts:

- (a) BI will use its Commercially Reasonable Efforts during the Term of this Agreement to commercialise a Licensed Product in each Major Market in which such Licensed Product is approved for marketing. Notwithstanding BI's [*] to [*] in [*], BI shall not discontinue such efforts for any reason other than Force Majeure, mutual agreement of the parties and/or material adverse side effects in rendering such Licensed Product unsuitable as a medicine for human use.
- (b) With respect to each country in the Territory that is not a Major Market, BI shall have the right to determine, in its sole judgement, whether and to what extent it will commercialise the Licensed Product in each such country in which the Licensed Product is approved for marketing.

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- (c) All commercialisation efforts undertaken by BI's Affiliates, Sublicensees and Recognised Agents hereunder shall be attributable to BI.

4.4 Effect of Failure to Use [*]

In the event that BI fails to use [*] as described in Section [*], then ImmunoGen shall have the right to terminate the Agreement in accordance with Section 13.2.

5. **SUPPLY AND MANUFACTURING OBLIGATIONS**

5.1 Non-clinical Material; Clinical Material; Dedicated Equipment

- (a) During the Term of this Agreement, ImmunoGen will [*] BI with its [*] of [*] in [*] and [*] as well as [*] and [*] for the [*] of [*] and [*] and [*] in [*] and in [*] in order for BI to [*] of the [*], as listed on Schedule [*] attached hereto. BI will pay ImmunoGen a transfer price for such [*] equal to [*] of ImmunoGen's [*] of [*]. In addition, ImmunoGen will [*] BI with [*] at least a [*] of the [*] in its [*]. A [*] will be [*] and [*] until the earlier of the [*] of [*] or until [*]. For GLP material, ImmunoGen will provide a Certificate of Analysis for each batch manufactured.
- (b) In the event that, over a given [*], [*] to [*] with [*] of its [*] of [*] for that [*] in the [*] as specified in Schedule [*] and such [*] is not attributable to a [*] set forth in Section [*] or BI's [*] to [*] an [*] of [*] in a timely manner, then, subject to the [*] of [*] Section [*], [*] as follows. If such [*] to [*] to [*], then [*] the [*] and [*] to Section [*]. If [*] to [*] of [*], then [*] the [*] and [*] to Section [*]. The foregoing notwithstanding, [*] the [*] of the [*] to [*] such [*] and [*]
- (c) In addition, [*] with such [*] of [*] in order for BI to [*] until [*] of [*] and [*]. The terms and conditions of the supply of Drug Product shall be governed by the Clinical Supply Agreement between ImmunoGen and Boehringer Ingelheim Pharma KG ("BI Pharma") attached hereto as Schedule G.
- (d) If ImmunoGen determines that it is necessary or advisable to purchase dedicated equipment in order to manufacture non-clinical Drug Substance for BI, BI will reimburse ImmunoGen for the cost of procuring such dedicated equipment [*]. In case of termination, ImmunoGen shall permit BI to remove such dedicated equipment at BI's sole cost and expense.
- (e) The [*] in Section [*] and [*] of the Clinical Supply Agreement shall also apply for non-clinical material.

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5.2 Technology Transfer:

As soon as reasonably practicable following the Effective Date, ImmunoGen will transfer to BI and its agents such Technology within its Control related to the Licensed Technology and [*] as may be reasonably required by BI for the [*] of [*] in accordance with the [*] to be agreed upon by BI and ImmunoGen before [*], the major terms of which are attached hereto as Schedule [*] .

6. PRODUCT INQUIRIES, COMPLAINTS AND ADVERSE EVENTS

6.1 Medical/Scientific Product Inquiries:

- (a) BI shall be solely responsible for responding to all medical questions and inquiries relating to the Licensed Products in each country in the Territory.
- (b) In conjunction with the marketing and sale of Licensed Products in a country in the Territory, BI shall be solely responsible for providing (i) medical, technical and scientific information concerning Licensed Product to healthcare professionals, managed care organisations, sales representatives, medical publishers, consumers, patient assistance programs and others who may request such information, and (ii) after-hours coverage to address emergency requests for medical, technical and such scientific information concerning the Licensed Products.

6.2 Adverse Medical Events and Complaints:

BI agrees to provide ImmunoGen with Adverse Event information and product complaint information relating to Licensed Products as compiled and prepared by BI in the normal course of business in connection with the development, commercialization or sale of any Licensed Product, within time frames consistent with reporting obligations under applicable laws and regulations. [*] agrees to [*] with [*] and [*] to [*] that is [*] and [*] by [*] or [*] in the normal course of business in connection with the [*] or [*] of any such [*], within time frames consistent with reporting obligations under applicable laws and regulations; provided, however, that the foregoing shall not require [*] to [*] any [*] with or [*] owed to [*]. ImmunoGen, in [*] in which it has [*] or [*] a [*] under the [*] and [*], [*] or [*], as the case may be, a [*] to [*] of [*] to the [*] that is the [*] of such [*]. [*] will [*] and [*] these [*] and will [*] to [*] all [*] which is relevant for the [*] of the [*] and its [*] to [*]. [*] hereby affirms to [*] that such [*] is not [*] the [*] owes to [*]. BI shall provide its Adverse Event and product complaint information hereunder to ImmunoGen's designated representative, who shall be its Chief Regulatory Officer unless ImmunoGen otherwise notifies BI. [*] shall [*] its [*] and [*] hereunder to [*] designated representative, who shall be the head of its Drug Safety group in [*] unless [*] otherwise notifies [*] .

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7. RIGHTS AND IMPROVEMENTS

7.1 Ownership of Technology and Proprietary Materials:

All BI Intellectual Property and BI Materials shall be sole and exclusive property of BI and may be used by BI in any manner BI, in its sole discretion, deems appropriate to exercise its rights under this Agreement. All Licensed Technology and ImmunoGen Materials shall be sole and exclusive property of ImmunoGen and may be used by ImmunoGen in any manner ImmunoGen, in its sole discretion, deems appropriate, to exercise its rights under this Agreement, subject to the grant of the licenses to BI described in this Agreement.

7.2 [*]:

- (a) [*] will [*] to [*] any and all [*] or [*] or [*] it or [*] under its [*] during [*] of this Agreement to the extent such [*] are related to [*] or are [*] or [*] to [*] and [*] .
- (b) To the extent any [*] was [*] or [*] or [*] and [*] (a "[*]"), such [*] shall be [*] by [*] and [*] . ImmunoGen and BI each hereby represents that all employees and other persons acting on its behalf in performing its obligations under this Agreement shall be obligated under a binding written agreement or the applicable law to [*] to it or as it [*] all [*] or [*] by such employees or other persons.
- (c) To the extent any [*] was [*] or [*] or [*] one party, the [*] shall be [*] .

8. PATENTS AND TRADEMARKS

8.1 Patent Prosecution:

- (a) ImmunoGen agrees to use commercially reasonable effort to continue, [*] , the prosecution and maintenance of the Licensed Patent Rights; provided, however, that ImmunoGen shall keep BI fully and timely informed in respect of the course and conduct of patent application prosecution matters pertaining to Licensed Products. Prosecution and maintenance of Licensed Patent Rights shall include, but not be limited to, prosecuting pending patent applications therein and maintaining and extending patents therein, including in any defensive proceedings such as oppositions and the like and any reissue or re-examination proceedings, in any country in the Territory should such actions be reasonably deemed necessary or desirable by ImmunoGen. ImmunoGen shall keep BI advised of the status of such prosecution and maintenance by timely providing BI with copies of all patent applications and patents, and all official communications with respect to such patent applications and patents, contained in the Licensed Patent Rights for the purpose of obtaining substantive comment of BI patent counsel.

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- (b) As regards any Patent Rights covering Joint Improvements, ImmunoGen will have the first right, but not the obligation, to undertake filing(s), prosecution and maintenance of inventorship certificate(s), patent application(s) and patent(s) thereon. ImmunoGen shall advise BI within [*] whether it will file any such patent application with respect to any Joint Improvements. If ImmunoGen fails to undertake the

filing(s) of any such patent application within [*] after receipt of written notice from BI that it believes filing(s) of such an application by ImmunoGen is appropriate, BI may undertake such filing(s) at its own expense. In connection with any such filing(s), the filing party will file, prosecute and maintain such patent application in the name of both parties jointly. In any case, the filing party (i) will provide the non-filing party with a copy of any such proposed patent application for review and comment reasonably in advance of filing, and (ii) will keep the non-filing party reasonably informed of the status of such filing, prosecution and maintenance. Costs of any such filing, prosecution and maintenance shall be shared jointly by the parties.

8.2 Patent Abandonment:

If ImmunoGen elects to abandon any patent application or patent included within the Licensed Patent Rights, and/or terminate its future obligations to prosecute and maintain any such patent application or patent, then it shall provide BI with [*] prior written notice of its election. If BI notifies ImmunoGen within such [*] response period, that it wishes to prosecute or maintain such patent application or patent at its own expense, then ImmunoGen shall promptly transfer and assign such patent application or patent to BI and continue to prosecute and maintain such patent application or patent or until such transfer and assignment become effective. Upon such transfer and assignment becoming effective, such patent application or patent shall no longer be considered to be included within the Licensed Patent Rights, and ImmunoGen and its employees shall thereafter reasonably assist BI in the prosecution and maintenance of such patent application or patent; provided, however, that such assistance shall be subject to BI's reimbursement of ImmunoGen's out-of-pocket expenses with respect thereto.

8.3 Trademarks:

BI, in its sole discretion, in its own name and at its own expense, may prepare or develop, adopt and register all trademarks, trade names, brand names and logos for use with the Licensed Products. These trademarks, trade names, brand names and logos shall be and shall remain the sole and exclusive property of BI. All use of such trademarks, trade names, brand names and logos shall inure to the sole benefit of BI. BI shall remain the owner of the trademarks, trade names, brand names and logos and the goodwill associated with the same and ImmunoGen agrees not to assert any ownership interest in such trademarks, trade names, brand names and logos or the goodwill associated therewith.

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9. **INFRINGEMENT**

9.1 Infringement of Third Parties' Rights:

- (a) **Notice.** If the development, registration, manufacture, use, marketing or sale of the Licensed Products results in a claim against a party of infringement or misappropriation of any third party's patent or other intellectual property right ("Third-Party Claim"), the party first having notice of a Third-Party Claim shall promptly notify the other party in writing specifying in reasonable detail the alleged grounds or basis for the Third-Party Claim (to the extent known).
- (b) **Patent Infringement Claims.** If the development, registration, manufacture, use, marketing or sale of Licensed Products in a country in the Territory results in a Third-Party Claim of patent infringement, the parties agree to respond to and/or defend against the Third-Party Claim as follows:
 - (i) Control of Defence. ImmunoGen shall have the initial right to manage solely the defence of the parties against the Third-Party Claim. If ImmunoGen elects to exercise such right as to the Third-Party Claim, BI shall cooperate with ImmunoGen at ImmunoGen's request and shall have the right to be represented by counsel selected and paid for by BI. If ImmunoGen elects not to exercise such right as to the Third-Party Claim, BI shall have the right to manage solely the defence of the parties against the Third-Party Claim and ImmunoGen shall cooperate with BI at BI's request and shall have the right to be represented by counsel selected by ImmunoGen.
 - (ii) Settlements. The party that manages solely the defence of the parties against the Third-Party Claim shall also have the right to settle such Third-Party Claim on terms deemed appropriate by such party provided, however, that (A) neither party shall settle any Third-Party Claim in a manner that is prejudicial to the Licensed Products, (B) such party shall consult with the other party concerning the terms of any settlement agreement before entering into such an agreement, and (C) neither party shall settle any such Third-Party Claim without the prior written consent of the other party, which consent shall not be unreasonably withheld.
 - (iii) Costs of Defence. Each party shall be responsible for its own fees and costs of attorneys and consultants, together with the court costs, incurred in defending against the Third-Party Claim.

9.2 Infringement Claims against Third Parties:

ImmunoGen agrees during the Term of this Agreement to take reasonable actions to protect the Licensed Patent Rights from infringement and the Licensed Technology from unauthorised possession or use.

- (a) A party first having knowledge of any infringement or misappropriation, or knowledge of a reasonable probability of such infringement or misappropriation, by a third party, including that contained in a notice provided under the 1984 Act by a party filing an ANDA or Paper NDA for Licensed Products, or an equivalent action in any other country of the world, shall promptly notify the other party in writing. ImmunoGen shall institute, prosecute, and control, at its own expense and with counsel of its own choosing, any action or proceeding against the third party with respect to such infringement or misappropriation, and keep BI informed of the progress of such enforcement proceeding and shall give due consideration to the suggestions or comments of BI in connection therewith.

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- (b) If ImmunoGen fails to act within a period of [*] after receiving notice of the infringement in a country in the Territory, BI shall have the right to bring and control, at its own expense, any such action by counsel of its own choice. If BI brings any such action or proceeding, ImmunoGen may be joined as a party plaintiff and ImmunoGen agrees to give BI reasonable assistance to file and to prosecute such suit.
- (c) To the extent that ImmunoGen or BI initiates and prosecutes a proceeding under Section 9.2 on its own, without the material assistance of or the participation as a co-plaintiff in the action by the other party, then the party that prosecuted the action shall be entitled to retain for its sole and exclusive benefit any damages or other monetary award recovered therein in its favour.
- (d) To the extent that both ImmunoGen and BI materially assist or participate in, or, pursuant to Section 9.2(b) above, are both parties to, any such proceeding, then:
 - (i) the costs and expenses of each of ImmunoGen and BI under this Section 9.2(d) shall be [*] to [*], based on the [*] by [*], out of any [*] or other [*] therein in favour of ImmunoGen and/or BI; and
 - (ii) the amount of any [*] or other [*] therein in favour of ImmunoGen and/or BI, in excess of the [*] provided for in clause (i) above, shall be [*] as follows: (1) first, to [*], as [*] for [*] associated with [*] and to [*] as [*] for [*] to the extent that the [*] or [*] is [*] to [*] associated with [*]; and (ii) second, any amounts remaining shall be allocated as follows: (a) if [*] is the party prosecuting such action, [*] to [*], (b) if [*] is the party prosecuting such action, [*] to [*] and [*] to [*], and (c) if both parties are prosecuting such action, [*] to [*].

10. REPRESENTATIONS AND WARRANTIES

10.1 ImmunoGen Representations:

ImmunoGen represents and warrants to BI that:

- (a) No Conflict. The execution, delivery and performance of this Agreement by ImmunoGen does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, and does not violate any law or regulation of any court, governmental body or administrative or other agency having authority over it, including, without limitation, 35 U.S.C.A. Sections 203 and 204. ImmunoGen is not currently a party to, and during the Term of this Agreement will not enter into, any agreements, oral or written, that are inconsistent with its obligations under this Agreement.

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- (b) Authority. ImmunoGen is validly existing and in good standing under the laws of the state of its incorporation and has the corporate power and authority to enter into this Agreement. The execution, delivery and performance of this Agreement have been duly authorized by all necessary action on the part of ImmunoGen, its officers and directors.
- (c) Ownership. To ImmunoGen's knowledge, all of the Licensed Patents are subsisting and are valid and enforceable. ImmunoGen (i) has not previously assigned, transferred, conveyed or otherwise encumbered its right, title and interest in Licensed Patents, or any component of the Licensed Technology, and (ii) has no knowledge of the existence of any patent, trademark or other intellectual property right (other than any patent application) owned or controlled by ImmunoGen, other than the Licensed Patent Rights, in case of either (i) or (ii), that would prevent ImmunoGen and BI from manufacturing and supplying Licensed Products, and BI from exploiting its rights granted under Section 2.1. In addition, ImmunoGen has no knowledge of the existence of any patent or intellectual property right (other than any patent application) owned or Controlled by a third party that would materially conflict with the grant of the license set forth in Section 2.1 of this Agreement.
- (d) Litigation. There are no claims, judgements or settlements against, pending with respect to the Licensed Patents or any component of Licensed Technology. In addition, to ImmunoGen's knowledge, no such claims, judgements or settlements are threatened.
- (e) Further Warranties:

ImmunoGen covenants to BI that:

- (i) The development and manufacture of DM1 by ImmunoGen under this Agreement shall be in compliance with the laws, requirements and regulations applicable thereto in the Territory.
- (ii) The documentation to be provided to BI pursuant to Section 5.2 will, at the time of transfer to BI, contain all material know-how and information then in ImmunoGen's Control relating to the production of Licensed Products.
- (iii) All Certificate of Analysis documents which will be provided to BI under this Agreement shall be generated and documented in accordance with generally accepted standards of the pharmaceutical industry.

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- (iv) All [*], submitted to [*] by [*] in [*] to [*], regarding Licensed Technology and Licensed Patent Rights is, to the best of ImmunoGen's knowledge, accurate in all material respects.

10.2 BI Representations and Warranties:

BI represents, warrants and covenants to ImmunoGen that:

- (a) No Conflict. The execution, delivery and performance of this Agreement by BI does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, and does not violate any law or regulation of any court, governmental body or administrative or other agency having authority over it. BI is not currently a party to, and during the term of this Agreement will not enter into, any agreements, oral or written, that are inconsistent with its obligations under this Agreement.
- (b) Authority. BI is validly existing and in good standing under the laws of the state of its incorporation and has the corporate power and authority to enter into this Agreement. The execution, delivery and performance of this Agreement have been duly authorized by all necessary action on the part of BI, its officers and directors.

10.3 Warranty Disclaimer.

Except as otherwise expressly provided in this agreement, neither party makes any warranty with respect to any technology, goods, services, rights or other subject matter of this Agreement and hereby disclaims warranties of merchantability, fitness for a particular purpose and noninfringement with respect to any and all of the foregoing.

11. INDEMNIFICATION

11.1 Indemnification by the Parties:

Each party (the "Indemnitor") will indemnify the other party (the "Indemnitee") against any liability in connection with any claim, suits, liabilities, etc. arising out of the performance by the Indemnitor of its work under the Agreement or the exploitation by the Indemnitor of its rights under the Agreement, including, without limitation, the development, manufacture, promotion, or sale of Licensed Products, unless such liability results from (i) the negligence or wilful misconduct of the Indemnitee or (ii) a breach of the warranties set forth in the Agreement by the Indemnitee.

11.2 Indemnification Procedures:

- (a) The Indemnitee shall: (i) notify the Indemnitor of any liability and full details of the basis therefor with respect to which the Indemnitee intends to claim indemnification as soon as practicable after the Indemnitee becomes aware of any such liability; (ii) permit the Indemnitor to assume the defence thereof; and (iii) cooperate with the Indemnitor, at the Indemnitor's expense, in the defence thereof.

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- (b) With respect to any matter for which the Indemnitor has an obligation to indemnify the Indemnitee under this Agreement, the Indemnitee shall have the right to participate and be represented (at the Indemnitor's expense) by legal counsel of the Indemnitee's choice in all proceedings and negotiations, if representation by counsel retained by Indemnitor would be inappropriate due to actual or potential differing interests between the Indemnitee and any other party represented by such counsel in such proceedings.
 - (c) The indemnity agreement in this Section 11 shall not apply to amounts paid in settlement of any liability if such settlement is effected without the consent of the Indemnitor, which consent shall not be unreasonably withheld.
 - (d) Failure of the Indemnitee to deliver notice to the Indemnitor within thirty (30) days after becoming aware of a liability shall relieve the Indemnitor of any liability to the Indemnitee pursuant to this Section 11 in the event, but only to the extent, such delay is prejudicial to the Indemnitor's ability to defend such action.

12. CONFIDENTIALITY

12.1 Confidential Information:

All data, information, documents and materials transmitted by BI to ImmunoGen or by ImmunoGen to BI in conjunction with this Agreement, including, but not limited to, all scientific, technical and clinical data, information reports, financial or business records, forecasts, orders, summaries and information gathered, generated or transferred by a party during the course of this Agreement is considered confidential and proprietary information of the disclosing party (hereinafter "Confidential Information"). The parties shall use the Confidential Information only for the purpose of executing their rights and fulfilling their obligations under this Agreement.

12.2 Disclosure:

- (a) Upon execution of this Agreement and thereafter on an ongoing basis during the Term of the Agreement, each party shall disclose to the other party, in confidence, subject to the terms of this Section 12, information required by the other party in order to execute its rights and fulfil its obligations pursuant to this Agreement. Notwithstanding the foregoing, a party shall not be obligated to disclose to the other party any information that it is prohibited from disclosing to the other party, either by reason of a contract with a third party or by law. In the event of such a restriction, the parties shall cooperate and take such legally permissible action as may be reasonable to permit such disclosure to be made.
- (b) The receiving party shall not disclose, without prior written consent of the disclosing party, any Confidential Information to any third party other than officers, directors, Affiliates and representatives of the receiving party and to third parties mentioned in Section 2.4. When the receiving party does disclose information, it will only be on a need to know basis, including, without limitation, fulfilment of corporate reporting required by law or regulation, hospital authorities, regulatory authorities and others who have agreed in writing to observe the confidentiality of Confidential Information in the same manner and to the same extent as provided in this Section 12.

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12.3 Publications

- (a) In recognition of BI's assumption of development and marketing responsibilities in connection with the Licensed Product, and in order to assure consistency with BI's marketing plans, except for submissions of manuscripts, abstracts or other publications made prior to the Effective Date, ImmunoGen, its Affiliates, their employees, clinical investigators or consultants shall not have the right to make any public disclosure of information, whether oral or in writing, concerning the pre-clinical and/or clinical trial activities and/or results pertaining specifically to Licensed Products without the express written consent of BI, which consent may be withheld in BI's sole discretion. BI shall be entitled to publish scientific information and data, including the results of clinical trials, as it deems appropriate, to advance the commercialization of the Licensed Product, subject to subsection (b) below.
- (b) Notwithstanding the foregoing, BI shall consult with ImmunoGen prior to the submission of any manuscript for publication if the publication will contain any Confidential Information of ImmunoGen, unless the applicable laws and regulations prohibit such consultation. Such consultation shall include providing a copy of the proposed manuscript to ImmunoGen at least [*] prior to the proposed date of submission to a publisher, incorporating appropriate changes proposed by ImmunoGen regarding its Confidential Information into the manuscript submission and deleting all Confidential Information of ImmunoGen as it may request; provided, however, that ImmunoGen's review hereunder shall be deemed completed at the end of such [*] period.

12.4 Obligation to Obtain Agreements:

The obligations of the receiving party regarding the confidentiality and nondisclosure of Confidential Information shall extend to and be binding upon all employees or agents of the receiving party who have access to Confidential Information pursuant to this Agreement as if such employees or agents were parties hereto.

12.5 Exceptions:

The obligations of the receiving party regarding the confidentiality and nondisclosure of information as provided in this Section 12 shall not apply to certain information if it can be demonstrated by written documentation or other adequate proof that such information:

- (a) Is already known to the receiving party as shown by competent written records;
- (b) Is or becomes publicly available through no fault of the receiving party;

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- (c) Is disclosed to the receiving party by a third party not subject to an obligation of confidentiality to the disclosing party respecting such information;
- (d) Is required to be disclosed by law, regulation, order, decree or subpoena or other legal process; provided that the receiving party has used reasonable efforts to obtain a protective order and has taken reasonable actions to avoid further disclosure of such information to any party not part of such requirement; or
- (e) Is independently developed by the receiving party without reliance on information provided by the disclosing party as shown by competent written records.

12.6 Public Disclosure:

Neither ImmunoGen nor BI shall issue a press release or in any other way announce to the public the existence, terms, conditions of, or performance under this Agreement without the prior written consent of the other party, which consent shall not be unreasonably withheld or delayed, unless the existence, terms, conditions of, or performance under this Agreement is required to be disclosed by law, regulation, order, decree or subpoena or other legal process; provided that the party ordered to so announce has used reasonable efforts to obtain a protective order or other applicable protection against further disclosure or release or announcement of such information. The parties shall mutually agree on the text of a press release announcing the execution of this Agreement and on any confidential treatment request(s) to be filed with the Securities and Exchange Commission with respect to this Agreement. Once any written text is approved for disclosure by both parties as provided herein, either party may make subsequent or repeated public disclosures of the contents thereof without the further approval of the other party. Nothing in the foregoing, however, shall prohibit a party from making such disclosures regarding this Agreement or the terms thereof to the extent deemed necessary under applicable federal or state securities laws or any rule or regulation of any nationally recognized securities exchange, subject to the terms of Section 12.5 above regarding disclosures required to comply with applicable laws, regulations or court order.

13. **TERM AND TERMINATION**

13.1 Term:

Unless earlier terminated pursuant hereto, the term of this Agreement (the "Term") shall continue on a country-by-country basis through the last to expire of any obligation of BI to pay a royalty to ImmunoGen hereunder in such countries in the Territory. However, in the European Union the obligation of ImmunoGen not to license or exploit by itself the Licensed Technology shall expire on a country-by-country basis after expiration of the Licensed Patent Rights in the respective country or after [*] from [*] of the respective Licensed Product, whichever is the longer.

13.2 Early Termination:

Notwithstanding Section 13.1, either party may, in addition to exercising any other available legal or equitable rights or remedies, terminate this Agreement, effective immediately upon the expiration of any applicable cure period, upon the occurrence of an Event of Default (as defined below) with respect to the other party. The term "Event of Default" with respect to a party means the occurrence of any of the following events:

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- (a) The failure of a party to comply with or perform any material provision of this Agreement, and such failure remains uncured for [*] following written notice of such failure (if such default is cured within the cure period, such written notice shall be null and void), provided that, if the defaulting party can establish to the reasonable satisfaction of the other party that it is diligently and actively pursuing a cure at the expiration of the cure period, and that the default is reasonably capable of being cured, then the cure period shall be extended for so long as a cure is being diligently and actively pursued, not to exceed [*] and [*] in the aggregate.
- (b) A party (i) becomes unable to pay its debts as they mature, (ii) is the subject of a voluntary or involuntary petition in bankruptcy or of any other proceeding under bankruptcy, insolvency or similar laws which, if involuntary, is not dismissed within [*] of the date filed, (iii) makes an assignment for the benefit of creditors, (iv) is named in, or its property is subject to, a suit for the appointment of a receiver which is not dismissed within [*] of the date filed, or (v) is dissolved or liquidated.

13.3 Termination by BI:

BI has the right to terminate this Agreement for any reason at any time upon [*] advance written notice given to ImmunoGen.

14. EFFECTS OF TERMINATION

14.1 Further Licenses/Reversion of Rights:

- (a) Upon the expiration of this Agreement pursuant Section 13.1, on a country by country basis, BI shall have a non-exclusive, irrevocable, fully paid-up, royalty free license to use and exploit the Licensed Technology in such country.
- (b) In the event this Agreement is terminated by BI in accordance with Section 13.2(a) of this Agreement as a result of the grant by ImmunoGen to a third party of a license under the Licensed Technology and/or Licensed Patent Rights in violation of the exclusive license granted to BI under Section 2.1, BI's [*] under [*] of this Agreement shall [*] a [*].
- (c) In the event this Agreement is terminated for any other reason other than as described in Section 14.1(a) and (b) above, all rights granted to BI under Section 2.1 shall terminate and revert to ImmunoGen.

14.2 Inventory:

If either party terminates this Agreement, then BI shall have the right, within [*] after such termination, to sell off its remaining inventory of Licensed Product and pay ImmunoGen all royalties on account thereof.

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14.3 Other Penalties:

- (a) Termination of this Agreement by either party shall not prejudice the rights of such party under this Agreement, at law or in equity or otherwise, to seek damages or injunctive relief for any breach of this Agreement by the other party hereto and all payment obligations accruing under this Agreement prior to the effective date of termination.
- (b) Except as otherwise provided in this Agreement, neither ImmunoGen nor BI will be liable with respect to any subject matter of this Agreement under any contract, negligence, strict liability or other legal or equitable theory for any punitive damages or indirect, incidental, consequential damages or lost profits, including, without limitation, cost of procurement of substitute goods or technology, or loss of opportunity, loss of income or compensation for loss of goodwill.

14.4 Accrued Rights:

Termination of this Agreement for whatever reason shall not affect the accrued rights of either ImmunoGen or BI arising under or out of this Agreement. The obligations under any other provision that expressly or by implication are intended to survive expiration or termination shall survive expiration or termination of this Agreement.

14.5 Confidential Information.

Upon the expiration or termination of this Agreement, the receiving party will upon request from the disclosing party promptly return to the disclosing party all of the Confidential Information in the receiving party's possession, as well as all written information and materials that incorporate Confidential Information; provided, however, that the receiving party may keep (i) all information and material that incorporate Confidential Information necessary to exploit the receiving party's rights set forth in Section 14 and/or (ii) one (1) copy of such Confidential Information, or as required by applicable laws, rules or regulations, subject to the confidentiality provisions contained herein.

15. MISCELLANEOUS

- 15.1 Either party shall not be entitled to assign or otherwise transfer its rights and obligations under this Agreement in whole or in part to any third party without the prior written consent of the other party.
- 15.2 This Agreement set forth the entire agreement between the parties and supersedes all previous agreements, written or oral regarding the subject matter hereof. This Agreement may be amended only by an instrument in writing duly executed on behalf of the parties.
- 15.3 Neither party shall be liable for delay or failure to perform hereunder due to any contingency beyond its control, including but not limited to acts of God, fires, floods, wars, civil wars, sabotage, strikes, governmental laws, ordinances, rules or regulations or failure of third party delivery, provided,

such party promptly gives to the other party hereto written notice claiming for force majeure and uses its best efforts to eliminate the effect of such force majeure, insofar as is possible and with all reasonable dispatch. If the period of delay or failure should extend for more than [*] then either party shall have the right to terminate this Agreement forthwith upon written notice at any time after expiration of said [*] period.

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- 15.4 Any waiver shall be made in writing for it to be effective and unless expressly stated shall not be a continuing waiver nor shall it prevent the waiving party from acting upon that or any subsequent breach or from enforcing any term or condition of this Agreement.
- 15.5 The invalidity of any provision of this Agreement or any loophole in this Agreement shall not affect the validity of any other provision hereof. The parties undertake to replace the invalid provision or close the loophole in the Agreement with another provision which reflects legally the originally intended commercial objectives of the parties as closely as possible.
- 15.6 This Agreement shall be governed exclusively by [*]. In the event of any controversy or claim arising out of or relating to any provision of this Agreement, the parties shall first try to settle those conflicts amicably between themselves. Any dispute, controversy or claim initiated by either party arising out of, resulting from or relating to this Agreement, or the performance by either party of its obligations under this Agreement (other than bona fide third party actions or proceedings filed or instituted in an action or proceeding by a third party against a party), whether before or after termination of this Agreement, shall be finally resolved by binding arbitration. Whenever a party shall decide to institute arbitration proceedings, it shall give written notice to that effect to the other party. Any such arbitration shall be conducted under the commercial arbitration rules of the ICC by a panel of three arbitrators appointed in accordance with such rules. Any such arbitration shall be held in [*]. The arbitrators shall have the authority to grant specific performance and to allocate between the parties the costs of arbitration in such equitable manner as they determine. Judgment upon the award so rendered may be entered in any court having jurisdiction or application may be made to such court for judicial acceptance of any award and an order of enforcement, as the case may be. In no event shall a demand for arbitration be made after the date when institution of a legal or equitable proceeding based upon such claim, dispute or other matter in question would be barred by the applicable statute of limitations. Notwithstanding the foregoing, either party shall have the right, without waiving any right or remedy available to such party under this Agreement or otherwise to seek and obtain from any court of jurisdiction any interim or provisional relief that is necessary or desirable to protect the rights or property of such party, pending the selection of the arbitrators hereunder or pending the arbitrators' determination of any dispute, controversy or claim hereunder.
- 15.7 In the performance of this Agreement each party shall be an independent contractor, and therefore, no party shall be entitled to any benefits applicable to any employee of the other party. No party is authorised to act as an agent for the other party for any purpose, and no party shall enter into any contract, warranty or representation as to any matter on behalf of the other party.

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16. SCHEDULES

A reference to the terms of this Agreement shall be meant to include all Schedules. The following Schedules are incorporated and made part of this Agreement:

- Schedule A. Licensed Technology
- Schedule B. Licensed Patent Rights
- Schedule C. BI Intellectual Property
- Schedule D. Provision of Non-clinical BIWI1
- Schedule E. Major Terms of Technical Transfer Plan
- Schedule F: Development Plan
- Schedule G. Clinical Supply Agreement

[Remainder of page intentionally left blank]

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IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed in triplicate by their duly authorised representatives.

Boehringer Ingelheim International GmbH
ppa.

ImmunoGen, Inc.

Dr. K. Wilgenbus

Claudia Jesse

Pauline Jen Ryan

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**Schedule A
Licensed Technology**

[*] (including [*] for [*] of [*], [*] of [*] to [*], [*] of [*], [*] of [*] to [*], [*] of [*], and [*] of [*] and [*] and [*] in biological material and in Drug Substance and Drug Product preparations).

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**Schedule B
Licensed Patent Rights**

[*]

Attorney Reference No.	Country	Appl. No.	Filing Date	Priority Date	Patent No.	Issue Date	Exp. Date
[*]	[*]	[*]	[*]		[*]		
[*]	[*]	[*]	[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]		
[*]	[*]	[*]	[*]	[*]	[*]	[*]	[*]

[*]

Attorney Reference No.	Country	Appl. No.	Filing Date	Priority Date	Patent No.	Issue Date	Exp. Date
[*]	[*]	[*]	[*]		[*]		
[*]	[*]	[*]	[*]	[*]	[*]		

[*] (2)

Attorney Reference No.	Country	Appl. No.	Filing Date	Priority Date	Patent No.	Issue Date	Exp. Date
[*]	[*]	[*]	[*]		[*]		

[*]

Attorney Reference No.	Country	Appl. No.	Filing Date	Priority Date	Patent No.	Issue Date	Exp. Date
[*]	[*]	[*]	[*]	[*]	[*]		
[*]	[*]	[*]	[*]	[*]	[*]		

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**Schedule C
BI Intellectual Property**

[*]	Subject	Expiry and Status Europe	Expiry and Status US	File No. EP and US	Geographic Coverage
[*]	[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]

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Schedule D
Provision of [*]

[*]	[*]	[*]	[*]	[*]
[*]	[*]			
[*]	[*]			
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]			[*]	[*]
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]	[*]		
[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]
TOTAL	[*]	[*]	[*]	[*]

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Schedule E
Major Terms of [*]

It is the intention of the parties that the [*] referenced in Section [*] of this Agreement will be finalized by the parties as soon as practicable and in any event no later than [*]. Both parties agree to negotiate such finalized terms in good faith, which shall be based on the [*] by [*] to [*] of following documentation, to the extent available:

For [*] purposes:

- [*]:
- [*] and [*] for [*] of the [*] covering [*] and [*] ([*] for [*] including [*])
 - [*] and [*] for [*] covering [*] for [*], [*] and [*] ([*] for [*] including [*], and [*])
 - [*] of the [*]
 - [*] of [*] for [*]
 - [*] for [*] ([*])
 - [*] of all [*] of [*]
 - [*] for [*] ([*] and [*] conditions)

- [*]:
- [*] for all [*] of the [*] ([*])
 - [*] of [*] ([*])
 - [*] of all [*] (in [*] and [*])

For [*] Purposes:

- [*] of [*] ([*])
- [*] for [*]
- [*] for [*] (see below)
- [*] ([*]) of each [*] (see below)

[*] of “[*]”:

- [*]
- [*]
- [*]
- [*]
- [*]
- [*]
- [*]

For [*] purposes:

ImmunoGen will [*] BI with [*] that are [*] for [*] (e.g. [*] etc.).
ImmunoGen will [*] BI with all required [*] and [*] on [*] of [*].

-

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For [*] purposes:

- Information about [*] for [*], including [*] for any steps that [*] takes for [*]
- [*] for the [*] with [*] and [*] for [*] and [*]
- [*] of [*] used in the [*]
- [*] for each [*] of the [*] ([*] and [*])

- [*] regarding the [*]
- [*] about different [*], additional information which is necessary [*]
- [*] about necessary [*] for every [*]
- Copies of the [*] and [*] from [*] which were [*] at [*]
- [*] of each [*] (i.e. [*] of [*] of the [*] when [*] in the [*] for example [*])

General:

ImmunoGen will agree to [*] for the collaboration with BI throughout the [*]. To the extent practicable, ImmunoGen will attempt to [*] in the [*] (in the [*] and [*]) who have [*] on the [*] with BI.

ImmunoGen will agree, [*], to [*] an [*] of [*] from BI at [*] during the [*] in order to [*] such [*] in the [*] of the [*] and [*] that are [*] for the [*] of [*]. Such [*] shall take place at [*] at mutually convenient times and shall not exceed an aggregate of in duration. BI shall [*] the [*] and [*] of all such [*]. ImmunoGen will also agree to let BI [*] the [*] of at least [*] of [*].

ImmunoGen will further agree to use [*] to make arrangements for BI [*] to [*] in a [*] to [*].

On not less than [*] prior written notice from BI, ImmunoGen will also agree to [*] to the [*] for a [*] not to exceed [*] in the aggregate, while the [*] is being [*]. BI will have the right to [*] to ImmunoGen as to the [*] and [*] of such [*] desired as well as the [*] of such [*]. To the extent practicable, ImmunoGen will attempt to [*] in such [*] who have [*] on the [*]. ImmunoGen and BI will agree to negotiate in good faith any [*] of such [*]. BI will agree to [*] ImmunoGen for all of its [*] in connection with such [*] at [*] of [*] for [*], and [*] for [*] and [*], such as [*], will also be [*] by BI.

It is the [*] of the [*] that this [*] will [*] as soon as BI Pharma [*] of [*] which comply with [*] and are [*] for [*] for [*].

Schedule F
[*] for [*]

Initial [*]:

Goal: Develop a [*] for [*] of [*] that can be [*] to [*] of [*] in the [*] of [*] to [*] to [*] for [*] and [*]. [*] to be at a [*] of [*] to [*].

Strategy: [*] and [*] will be based on the [*] developed during [*] and [*], with [*] in [*] to take account of increasing [*] as well as [*]. No [*] to the [*] (eg, [*]) are envisaged during this [*].

[*] and
[*] [*] ([*])
[[*]]

[*] of [*] f [*] or [*] based on [*].

[*] [*];
[*] to be [*].
[*] for [*] ([*])

[*] [*]. [*] to [*]. [*] any [*] and [*] for [*].

[*] or [*] [*] at [*] [*] for [*] work

[*] [*]. [*] to [*]. [*] any [*] and [*] for [*].

[*] [*] at [*]
[*]

[*] to
[*] [*] at [*]

[*] [*] to [*]. [*] any [*] and [*] for [*].

[*] to
[*] [*] at [*]

[*] [*] to [*]. [*] any [*] and [*] for [*].

[*] [*] at [*]

ASSUMPTIONS:

- [*] will [*] of [*] for [*] ([*] of [*] may be [*] for [*]), [*] at [*] to [*] are similar to those obtained at [*].
- [*] is [*].

- (c) The [*] are for [*] of [*], and do not include [*].
- (d) [*] that [*] and [*] are [*] and [*] in a [*].

Plan for the [*] of [*] and [*]

[*] of [*] for [*] and [*]

[*] from [*]. [*] to [*] a [*] with [*].

[*] **for** [*]:

[*] under way [*], at [*]. This is an [*] to [*] a [*] for [*]. However, an [*] was [*] for [*] of [*] for [*]

[*] selected for [*] in [*].

[*] using the [*], including [*] was [*] in [*], at [*]. Certain aspects of this [*] are also [*] at [*] with the [*].

[*] of [*]: [*] of [*] to [*].

[*] to [*]: [*] for [*].

[*]: [*] from [*] to [*].

[*]: [*] of [*] from [*] at [*].

[*]: [*] of [*] for [*].

[*] to [*]: [*] in [*].

[*] [*] begins to [*] from [*].

After the [*] is [*], [*] will continue in the area of [*] as well as [*] and [*] of [*].

[*] **for** [*]

[*]: [*] that [*] is [*] to [*] of [*] for [*]. [*] that [*] is [*] of [*]. Some [*] in [*] may [*] the [*]

[*] in the [*] of [*]: [*] from [*] at [*] on a [*] of [*].

[*] from [*] from the [*] of [*] will be [*] to [*] to [*] for [*] of [*]

[*] in [*]: [*] obtained from [*] from the [*] is used in the [*] of [*]. May require [*], as appropriate.

**Schedule G
CLINICAL SUPPLY AGREEMENT**

This CLINICAL SUPPLY AGREEMENT (this "Agreement") is entered into as of November 27, 2001 (the "Effective Date") by and between ImmunoGen, Inc., a Massachusetts corporation having its principal office at 128 Sidney Street, Cambridge, Massachusetts 02139, USA ("ImmunoGen"), and Boehringer Ingelheim Pharma KG, a company organized under the laws of Germany having its principal office at Binger Strasse 173, 55218 Ingelheim am Rhein, Germany ("BI Pharma"). ImmunoGen and BI Pharma are sometimes referred to individually herein as a "Party" and collectively as the "Parties."

WHEREAS, Boehringer Ingelheim International GmbH at Binger Strasse 173, 55218 Ingelheim am Rhein, Germany ("BI") and ImmunoGen have contemporaneously entered into a Development and License Agreement as of the Effective Date (the "License Agreement"), and BI Pharma is an Affiliate of BI; and

WHEREAS, the License Agreement provides the basis for the manufacture and supply of Drug Substance for non-clinical use to BI or as directed by BI under the License Agreement and, moreover, states that ImmunoGen and BI Pharma shall enter or have entered into contemporaneously a supply agreement for the manufacture and supply of Drug Product for clinical use (this "Agreement") attached to that License Agreement as Schedule G; and

WHEREAS, the Parties are in agreement that the definitions used in the License Agreement and this Agreement shall have the same meaning, force and effect, unless expressly otherwise provided for in this Agreement; and

WHEREAS, ImmunoGen has agreed to supply BI Pharma or as directed by BI Pharma with such quantities of Drug Product as BI Pharma may reasonably request subject to the terms and conditions set forth herein;

NOW, THEREFORE, in consideration of the mutual covenants contained herein, and for other good and valuable consideration, the receipt of which is hereby acknowledged, the Parties agree as follows:

1. DEFINITIONS

Whenever used in this Agreement with an initial capital letter, the respective terms shall have the meanings used in the License Agreement and shall be incorporated by reference herein and the terms defined in this Section 1 shall have the meanings specified hereinafter.

1.1 “**BIWA4**” means unconjugated BIWA4 monoclonal antibody.

1.2 “**Drug Substance Batch**” means a specific quantity of the Drug Substance that is intended to be of uniform character and quality and is produced during the same Batch Run.

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1.3 “**Drug Product Batch**” means a specific quantity of the Drug Product that is intended to be of uniform character and quality and is produced during the same aseptic filling campaign.

1.4 “**Batch Run**” shall mean the production and purification process performed by ImmunoGen to generate a Batch of Drug Substance pursuant to this Agreement.

1.5 “**Calendar Quarter**” means each period of three consecutive calendar months ending on March 31, June 30, September 30 or December 31.

1.6 “**Calendar Year**” means each successive period of twelve months commencing on January 1 and ending on December 31.

1.7 “**Certificate of Analysis**” means a document, signed by an authorized representative of ImmunoGen, describing specifications for, and testing methods applied to Drug Product or Drug Substance, and the results thereof. A template of the Certificate of Analysis is attached hereto as Schedule I.

1.8 “[*]” shall mean with respect to any Drug Product or Drug Substance, the [*] of producing (including the [*] and [*] of such Drug Product or Drug Substance, including the [*] of the [*]: (a) the [*], including [*] and [*], of [*] and [*] such Drug Product or Drug Substance; (b) all [*] incurred by ImmunoGen attributable to the [*] under the foregoing clause (a), including [*] and [*] which are [*] to [*] or [*] or another [*]; (c) any other [*] borne by ImmunoGen for the [*] and/or [*] of Drug Product or Drug Substance; and (d) [*] and [*] which are [*] to [*] or [*] or another [*]. [*] shall the [*] to [*]. Notwithstanding the foregoing, [*] of Drug Product or Drug Substance [*] (i) the [*] of [*] any [*] to the extent [*] by BI Pharma pursuant to Section [*] of this Agreement, (ii) the [*] of [*] other than pursuant to Section [*] of this Agreement, (iii) the [*] of [*] at [*] pursuant to Section [*] of this Agreement, or (iv) any [*] to [*] for [*] in the Facility. If [*] as the case may be can [*] to [*] that [*] or [*] used for the [*] of [*] and/or [*] of the [*] and [*] can be [*] at a [*] than [*] and [*] or [*], or that [*] can be [*] on a [*] and [*], then [*] shall [*] such [*] for the [*] of the [*].

1.9 “**Draft Specifications**” means the preliminary written specifications established for the characteristics, and quality as well as quality control testing procedures for Drug Product or Drug Substance as the case may be, as developed and mutually approved by the Parties in accordance with the License Agreement, and attached hereto as Schedule A. Draft Specifications shall dictate the manufacture of Drug Product until such time as the Final Specifications (as hereinafter defined) are agreed to by the Parties in accordance with Section 3.2.

1.10 “**Drug Product**” means Drug Substance, manufactured under cGMP in the final concentration for clinical use, aseptically filled in unlabeled, primary packaging material.

1.11 “**Drug Substance**” means bulk BIWI1 as defined in the License Agreement.

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1.12 “**Dedicated Equipment**” means any equipment or machinery exclusively used by ImmunoGen in the manufacturing of Drug Substance.

1.13 “**Facility**” means ImmunoGen’s manufacturing facility used for manufacture of Drug Substance located at 333 Providence Highway, Norwood, Massachusetts USA 02062 and all equipment contained therein.

1.14 “**Good Manufacturing Practices**” or “**cGMP**” means the current good manufacturing practices applicable to the manufacturing of a Drug Product under Title 21 of the United States Code of Federal Regulations as amended from time to time.

1.15 “**Final Specifications**” means the final written specifications established for the characteristics, quality and quality control testing procedures for Drug Substance or Drug Product, as developed and approved by the Parties in accordance with Section 3.2 of this Agreement.

1.16 “**Manufacturing Process**” means any and all processes (or a singular step in any process) used or planned to be used by ImmunoGen for the manufacturing of Drug Substance and Drug Product as described in Master Batch Records.

1.17 “**Manufacturing Documentation**” shall mean all executed batch records and all deviation reports and investigation reports associated with each individual Batch Run.

1.18 “**Master Batch Record**” means a written description of the Manufacturing Process for Drug Substance or Drug Product, which shall be approved by BI Pharma prior to start of production of the first cGMP Drug Substance or Drug Product Batch. All such batch records shall include all technical requirements and specifications with regard to the manufacturing methods, packaging process, and storage methods and procedures, as applicable.

1.19 “[*]” means any [*] or [*] to [*] on [*] of [*] in order to perform the [*] or any [*] for Drug Substance or Drug Product.

1.20 “**Transfer Price**” shall mean the price of any Drug Product to be invoiced by ImmunoGen and payable by BI Pharma upon delivery of such Drug Product to BI Pharma, which shall be determined in accordance with Section 7.1 hereof.

1.21 “**Other Definitions**” shall have the meaning as defined in the respective Sections enumerated below.

“Shipment Order”, see Section 3.4

“[*]”, see Section [*]

“Drug Product Forecast”, see Section 4.2

“Purchase Order”, see Section 4.3

“Laboratory”, see Section 6.1.3

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“Review”, see Section 6.1.2

“[*]”, see Section [*]

“Term”, see Section 9.1

“Event of Default”, see Section 9.3

“Competent Authority”, see Section 11.3

“Indemnitor”, see Section 12.1.3

“Indemnitee”, see Section 12.1.3

2. SCOPE OF AGREEMENT

2.1 **Scope.** Any reference to a defined term or concept, including but not limited to those relating to the supply of Drug Product, financial terms, intellectual property, indemnification, termination or governance, not specifically contained in or otherwise addressed by this Agreement shall be governed by the terms and conditions as set forth in the License Agreement and, as such, any and all terms and conditions of the License Agreement shall be incorporated by reference herein.

2.2 **Objective.** The overall objective of this Agreement is to govern the terms and conditions pursuant to which ImmunoGen will produce for (or will have produced for as permitted herein) and supply to BI Pharma or as directed by BI Pharma, Drug Product for Phase I and non-pivotal Phase IIa human clinical trials. The production and supply of Drug Substance for non-clinical use is governed by the License Agreement.

3. SUPPLY AND SPECIFICATIONS

3.1 **Supply.** ImmunoGen is obliged to supply BI Pharma with certain quantities of Drug Product in order for BI Pharma to conduct Phase I Trials and non-pivotal Phase IIa Trials. The [*] of [*] to be [*] to [*] by [*] in each respective [*] during the [*] of this [*] is attached hereto as Schedule [*]. It is the understanding of ImmunoGen and BI Pharma that ImmunoGen shall not be obliged to supply BI Pharma with quantities [*] of the [*] of [*] in each [*] as listed in Schedule [*] attached to this Agreement, provided that ImmunoGen [*] to [*]. ImmunoGen shall produce Drug Product in a series of Batch Runs, the exact number and size of which shall be determined by [*]. The Parties acknowledge that the number, size and/or yield of Batch Runs are subject to change due to numerous factors, including but not limited to production and purification processes, recruitment of patients to clinical trials and the number of and dosing schedules chosen for human clinical trials.

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3.2 **Drug Substance and Drug Product Specifications.** Draft Specifications for Drug Substance and Drug Product as provided by BI Pharma are attached hereto as Schedule A. The Parties acknowledge that these Draft Specifications are subject to change with the collection of Batch Run manufacturing data. Final Specifications have to be defined mutually by the Parties prior to manufacture of the first clinical batch. ImmunoGen shall not make any changes to

the Final Specifications and the Master Batch Records, without the prior written permission of BI Pharma; [*] that [*] has [*], [*] be [*] for the [*] of such [*] and for [*] for [*] or [*] arising therefrom. Upon the determination of the Final Specifications, the Draft Specifications will no longer be applicable to the manufacture of Drug Substance and Drug Product and shall be replaced in full by the terms of the Final Specifications.

3.3 **Manufacturing Process and Master Batch Records.** ImmunoGen will provide BI Pharma with Master Batch Records describing the Manufacturing Process for Drug Product as well as for Drug Substance. ImmunoGen shall supply BI Pharma with all required written information, including but not limited to standard operating procedures, describing quality control procedures for testing of Drug Substance and Drug Product. The Master Batch Records will be agreed upon by the Parties prior to manufacturing of the first cGMP batch. Any change to the Master Batch Records requires prior written approval by BI Pharma. ImmunoGen will provide copies of all Manufacturing Documentation to BI Pharma.

3.4 **Provision of BIWA4.** BI Pharma shall deliver the necessary quantities of BIWA4, at BI Pharma's sole cost, for a Batch Run no less than [*] days prior to the scheduled initiation of the Batch Run. The Parties acknowledge that the necessary quantity of BIWA4 is subject to change and is dependent on the number, size and/or yield of Batch Runs. ImmunoGen shall not be responsible for any delay caused by BI Pharma's failure to deliver such BIWA4 as contemplated by this Section 3.4. BI Pharma shall provide or arrange to provide ImmunoGen free of charge with such quantities of BIWA4 as shall be necessary according to the Master Batch Records for the manufacture of Drug Product for BI Pharma. ImmunoGen shall use the BIWA4 exclusively for the manufacturing of Drug Product for BI Pharma. ImmunoGen shall store BIWA4 in controlled areas and in accordance with the conditions specified by BI Pharma. ImmunoGen shall issue a written request for BIWA4 to BI Pharma (a "Shipment Order") including, but not limited to, amount and delivery date not later than [*] prior to the scheduled initiation of the Batch Run.

3.5 **Excipients and Other Components.** ImmunoGen shall purchase at [*] all excipients (pharmacopoeial grade), and other items of any nature whatsoever that ImmunoGen may use or have used in manufacturing the Drug Product, other than BIWA4. [*] the [*] for ensuring that all [*] used in the manufacture of Drug Product, comply with the Draft Specifications and Final Specifications and all applicable laws and regulations. ImmunoGen shall test and release all materials for identity and quality in accordance with the Draft Specifications and Final Specifications prior to using the same. All right, title and interest in and to such items, and in and to all work-in-process incorporating such items, shall remain the sole property of ImmunoGen.

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3.6 [*] has [*] into [*] for the [*] of [*] and [*] (" [*]") and [*], to [*] of its [*], that the [*] of [*] and [*] under the [*], as in effect on the Effective Date, is [*] to [*] for [*] under Section [*] of the Supply Agreement. A list of the [*] is attached hereto as Schedule [*].

4. FORECASTS AND PURCHASE ORDERS

4.1 **Initial Supply Forecast.** The minimum quantities of clinical Drug Product to be supplied to BI Pharma by ImmunoGen during the Term of this Agreement is attached as an initial non-binding forecast for Drug Product in Schedule [*] (provision of clinical Drug Product). In Schedule [*] the [*] of [*] that [*] to [*] from [*] based upon [*] is listed beginning with the first Calendar Year after the Effective Date.

4.2 **Drug Product Forecasts.** BI Pharma shall use its best efforts to submit to ImmunoGen within thirty (30) days of the Effective Date and thereafter at least three (3) calendar months prior to the start of each Calendar Quarter, a rolling written forecast of the quantities of Drug Product estimated to be required for the following four Calendar Quarters ("Drug Product Forecast"). In the Drug Product Forecast, BI Pharma shall include a breakdown of the total quantity of Drug Product by Calendar Quarters. The Parties acknowledge that factors including, but not limited to, number of human clinical studies conducted, clinical study enrollment and stability of Drug Product might affect the accuracy of such Drug Product Forecasts. [*] will [*] from time to time the [*] so as to [*] for such [*].

4.3 **Delivery of Purchase Order; Contents.** Together with each Drug Product Forecast, BI Pharma shall deliver to ImmunoGen, in writing, a binding purchase order ("Purchase Order") for Drug Product for the [*] Subsequent Purchase Orders shall equal the Drug Product Forecast for the [*] of the accompanying forecast. Each Purchase Order shall specify: (i) the total quantity of Drug Product; (ii) a reference to the actual Final Specification and the Master Batch Records; (iii) the requested location for delivery; (iv) time of delivery; and (v) the carrier and/or manner of shipment that ImmunoGen should use in delivering the Drug Product.

4.4 **Governing Terms.** For ordering, the [*] shall use [*] (see Schedule [*] [*]); however all orders shall be subject to the provisions of this Agreement and shall not be subject to any inconsistent terms and conditions contained on any Purchase Order or Shipment Order, except insofar as any such document or request establishes: (a) the quantity of Drug Product to be shipped; (b) the delivery date; (c) the requested location for delivery; or (d) the carrier and/or manner of shipment.

4.5 [*] **for [*] to [*]**. In the event that, over a given [*], [*] to [*] with at [*] of the [*] of [*] specified in the [*] for that [*] or the [*] of [*] specified in Schedule [*] for that [*] and [*] is not [*] to a [*] set forth in Section [*] or to a [*] by [*] or [*] of this Agreement, then, subject to the [*] of [*] Section [*] under the [*] as follows. If [*] to [*] of [*], then [*] the [*] and [*] pursuant to Section [*] of the [*]. If [*] to [*] of [*], then [*] the [*] and [*] pursuant to Section [*] of the [*]. The foregoing notwithstanding, [*] the [*] of the [*] to [*] such [*] and [*].

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4.6 **Notices.** All notices to ImmunoGen under this Section 4 shall be delivered to ImmunoGen to the attention of [*] at 128 Sidney Street, Cambridge, Massachusetts USA 02139 or to such other person and location as ImmunoGen may specify to BI Pharma in writing from time to time.

5. PRODUCTION

5.1 **Batch Runs.** All production and supply by ImmunoGen of Drug Product under this Agreement shall be denominated in terms of Batch Runs. ImmunoGen will review each Drug Product Forecast and determine [*] the exact number and size of the Batch Runs necessary to fulfill each Purchase Order. The Parties acknowledge that the number, size and/or yield of Batch Runs are subject to change due to numerous factors, including but not limited to production and purification processes. [*] to [*] and [*] the [*] for [*] to [*] for [*] of [*] (for details, see [*] Section [*]). The Parties agree that all changes to the Manufacturing Process are subject to a change control procedure and have to be finally agreed upon by BI Pharma. ImmunoGen shall complete in accordance with the requirements of cGMP a Manufacturing Documentation and a Certificate of Analysis for every Drug Substance Batch and Drug Product Batch. ImmunoGen shall provide copies of this documentation and shall maintain all documentation pertaining to the Drug Product for at least [*] of the date of final release by BI Pharma of the Drug Product.

5.2 **Specifications.** All Drug Product supplied to BI Pharma hereunder (i) will comply with all applicable Draft Specifications or Final Specifications at the time of manufacture and (ii) will have been manufactured in accordance with the Master Batch Records and cGMP.

5.3 **Facility.** ImmunoGen shall conduct all manufacturing of the Drug Substance at the Facility and shall maintain at the Facility all equipment, Dedicated Equipment, components and other items used to manufacture Drug Substance. ImmunoGen (i) shall notify BI Pharma in writing, not less than [*] prior to any proposed, foreseeable change in the location or status of the Facility and (ii) shall notify BI Pharma in writing as soon as possible of any unforeseeable change in the location or status of the Facility and (iii) shall be responsible for obtaining, at its own expense, any necessary regulatory approvals in connection with any such change and BI Pharma's agreement thereto. [*] to [*] with the [*] to [*] at the Facility. Any [*] in the [*] of the [*], which shall not be unreasonably withheld.

5.4 [*]. Notwithstanding the following provision, [*] shall not be allowed to [*] any [*] in the [*] and [*] of the [*] the [*] of [*]. The [*] of [*] is attached hereto as Schedule [*]. [*] and [*] of [*] of [*]. [*] (i) shall notify [*] in writing, not less than [*] prior to any [*] in the [*] and (ii) shall notify [*] in writing as soon as possible of any [*] in the [*]. However, in the case of a [*] in [*], [*] of [*] or [*] of [*] shall require the [*] of [*]. [*] hereby [*] that [*] has the [*] to [*] each of [*], to be [*], if feasible, and that the [*] is [*] to [*] into a [*].

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5.5 **Dedicated Equipment.** ImmunoGen shall supply, at its own expense, all equipment required for the purpose of manufacturing the Drug Substance. Notwithstanding the foregoing, if during the Term of this Agreement, [*] determine in [*] that it is necessary or advisable to purchase Dedicated Equipment for ImmunoGen to perform any of its obligations to manufacture Drug Substance under this Agreement, then ImmunoGen shall [*] of [*], along with the [*] for such [*] and [*] for such Dedicated Equipment, in order to achieve BI Pharma's written approval of the same. [*] shall evaluate [*] the [*] of such Dedicated Equipment to [*] to be [*] for such [*] is [*] to [*] and whether such [*] at a [*]. [*] shall provide [*] with a [*] of [*] to [*] of [*], which will be necessary during the production of Drug Product (see Schedule [*]). Subject to the foregoing, promptly after the consummation of such purchase on behalf of BI Pharma, ImmunoGen shall provide BI Pharma with a copy of the invoice or invoices reflecting such purchase(s), and BI Pharma shall reimburse ImmunoGen for the purchase of all such agreed Dedicated Equipment hereunder within [*] of its receipt of such invoices from ImmunoGen. All such Dedicated Equipment shall be owned by BI Pharma, shall be maintained, decontaminated and cleaned by ImmunoGen as long as ImmunoGen has possession thereof, and shall be used by ImmunoGen solely for the benefit of BI Pharma. The Parties hereby agree that any costs that are incurred by ImmunoGen and are reimbursed by BI Pharma under this Section 5.5 shall not be included within the [*] of any [*] under this Agreement. Upon any termination of this Agreement, ImmunoGen shall permit BI Pharma to remove all such Dedicated Equipment from its Facility at BI Pharma's sole cost and expense, provided, that any reimbursement due by BI Pharma for such Dedicated Equipment has been fully paid to ImmunoGen.

5.6 **Maintenance of Facility.** ImmunoGen shall maintain, at its own expense, the Facility, (including, without limitation the equipment and the Dedicated Equipment) in a state of repair, cleanliness and operating efficiency consistent with the requirements of the Draft Specifications and Final Specifications respectively, cGMP and other applicable requirements.

6. DELIVERY, TESTING AND ACCEPTANCE

6.1 Pre-Delivery Testing.

6.1.1. **ImmunoGen Responsibilities.** Prior to delivery to BI Pharma, ImmunoGen shall test, or cause to be tested, a representative sample of each Drug Product Batch (or components as applicable) to demonstrate that such Drug Product Batch complies with the applicable specifications (manufacturer's release). For each Drug Product Batch to be delivered to BI Pharma or to a recipient designated by BI Pharma, ImmunoGen shall prepare and submit a representative sample of such Drug Product Batch, and a Certificate of Analysis that identifies the items tested, the applicable specifications and test results. The present format and required content of the Certificate of Analysis is attached hereto as Schedule I. Any changes thereto shall be agreed upon by the Parties. ImmunoGen will also submit a copy of the Manufacturing Documentation. ImmunoGen shall provide raw data upon reasonable request by BI Pharma.

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6.1.2. **BI Pharma Responsibilities.** Prior to delivery to BI Pharma, BI Pharma shall determine whether the Drug Product conforms to applicable specifications for use in human clinical trials (the "Review"). BI Pharma may conduct a Review by: (i) reviewing the Certificate of Analysis and the Manufacturing Documentation and such other documents, if any, as BI Pharma may request; and (ii) conducting acceptance testing of a representative sample of the Drug Product Batch. BI Pharma shall conduct its Review within [*] of the receipt of a representative sample of the Drug Product Batch including Manufacturing Documentation of Drug Substance, [*] that [*] have a [*] of [*] for [*] after [*] of [*] and [*] after [*] of [*] the [*].

6.1.3. **Specification Dispute Resolution.** In case of any disagreement between the Parties as to whether a Drug Product conformed with applicable Draft Specifications or Final Specifications, a representative sample of the disputed Drug Product shall be submitted for tests and final

determination of whether the Drug Product conformed with such applicable specifications to an independent testing organization mutually agreed upon by the Parties (the "Laboratory"). The Laboratory must meet current Good Laboratory Practices as defined by the FDA from time to time, and the appointment of such Laboratory shall not be unreasonably withheld or delayed by either Party. Such Laboratory shall use the test methods contained in the applicable specifications. The determination of such Laboratory with respect to all or part of the Drug Product shall be final and binding on the Parties. The fees and expenses of the Laboratory incurred in making such determination shall be paid by the Party against whom the determination is made.

6.2 **Notification.** Within [*] of the completion of the Review, BI Pharma shall notify ImmunoGen in writing whether the Drug Product conforms to Final Specifications.

6.3 [*]; **Inspection and Rejection; Shortages.** In the event that any Drug Product Batch after [*] to BI Pharma is [*] to [*] to [*] with the [*], ImmunoGen shall, [*] (a) [*] of such Drug Product to BI Pharma or [*] the [*], as the case may be, [*]; or (b) if [*] is not possible [*], at [*], either [*] or [*] for the [*] for such Drug Product. ImmunoGen may [*] any Drug Product [*] for [*]. The foregoing does not apply if the [*] of the [*] is [*] the [*] of ImmunoGen. [*], the [*] only if [*] is [*] to the [*] of the [*]. [*] shall [*] the [*] and [*] for the [*] of [*] to [*] as the [*] over [*] from [*] with the [*]. Any dispute regarding [*] under [*] Section [*] shall be resolved in the same manner as provided for in Section [*]

6.4 **Failed Batches.** ImmunoGen shall bear the responsibility for a failed Batch Run if such failure is attributable to the [*] or [*] of ImmunoGen. The foregoing notwithstanding, the [*] that there may be [*] not [*] to [*]. [*] of [*] shall take place according to the [*] in [*], in which the [*] to the [*] of [*].

6.5 **Shipment.** Upon receipt of written notice from BI Pharma, ImmunoGen shall deliver to BI Pharma or as directed by BI Pharma the respective Drug Product on the date provided for in the respective Purchase Order. Drug Product delivered pursuant to the terms of this Agreement shall be suitably packed and marked for shipment according to BI Pharma's Purchase Order. Delivery terms shall be DDP location in EU as determined by BI Pharma in the respective Purchase Order or CIP Ridgefield (INCO terms 2000) at BI Pharma's option. [*] to the [*] be [*] to [*] upon [*] of [*]. The Parties shall agree on a preferred carrier, packaging material, and detailed insurance conditions.

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6.6 **Final Release.** BI Pharma shall be responsible for the release of Drug Product for use in clinical trials (final release).

6.7 **Notices.** All notices to ImmunoGen under this Section 6 shall be delivered to ImmunoGen to the attention of [*] at 333 Providence Highway, Norwood, Massachusetts USA 02062 or to such other person and location as ImmunoGen may specify to BI Pharma in writing from time to time.

6.8 [*]. In an effort to [*] the [*] of [*] the [*] of [*] by the [*] of [*], [*] and [*] hereby agree to use [*] during the [*] of this [*] to [*] and [*] an [*] of [*] of the [*] to [*] the [*] listed on Schedule [*] of the [*], as it becomes [*] and to the extent it is [*] or [*] and [*] and [*]. In connection therewith, ImmunoGen shall provide [*] to BI of the [*] of [*] and the [*] as well as the other [*] (if any) of such [*] and [*] to [*] to [*]. Subject to the foregoing, all [*] associated with [*] the [*] of [*] shall be borne by [*]. Upon any termination of this Agreement, [*] shall [*] to [*] all such [*] from its [*] at sole cost and expense, provided, that any [*] due by [*] [*] for such [*] has been fully paid to [*].

7. PRICE AND PAYMENT

7.1 **Transfer Price for Product.** All Drug Product supplied to BI Pharma or a third party designated by BI Pharma under this Agreement shall be supplied to BI Pharma at a Transfer Price equal to [*] of ImmunoGen's [*] of such [*] in accordance with Section [*] hereof.

7.2 **Invoicing and Timing.** The payment will be made [*] upon written notice of [*] of the [*] by [*] and after [*] by [*] of the [*], [*] if any. The [*] or [*] shall [*] the [*] of [*] as described in Schedule [*]. In case of [*] that [*] is [*] to [*] for pursuant to Schedule [*], [*] shall be made within [*] of receipt of such invoice. Any invoices which remain unpaid more than [*] beyond the scheduled payment due date may be subjected to an interest charge at a rate of [*].

7.3 **Notices.** All notices to BI Pharma under this Section 7 shall be delivered to BI Pharma to the attention of Grp.Contr.F+E+M Pharma D, att.: [*] at Birkendorfer Str. 65, 88397 Biberach, Germany, or to such other person and location as BI Pharma may specify to ImmunoGen in writing from time to time.

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8. TITLE AND AUDIT RIGHTS

8.1 **BI Pharma Audit Rights.**

8.1.1. **Audit of Facility.** ImmunoGen agrees that BI Pharma and its agents shall have the right, upon reasonable prior notice to ImmunoGen, to inspect the Facility and audit ImmunoGen's quality control system and [*] during normal business hours in order to ascertain compliance by ImmunoGen with the terms of this Agreement, including, but not limited to, inspection of (a) the materials used in the manufacture of the Drug Product, (b) the holding facilities for such materials, (c) the equipment used to manufacture the Drug Product, (d) the quality control procedures and (e) all records relating to such manufacturing, quality control and Facility. Any information disclosed in writing, orally or by inspection of tangible objects shall be considered ImmunoGen's Confidential Information and protected as such by BI Pharma and its agents pursuant to the terms of the License Agreement. [*] agrees to [*] and [*] of [*] of [*] and [*] a [*] to the [*].

8.1.2. [*] of [*]. [*] shall [*] can be [*] by [*] for [*] in the same manner as described in Section [*].

8.1.3. **Audit of Total Cost.** ImmunoGen shall keep complete and accurate records of its Total Cost of Drug Product supplied under this Agreement in sufficient detail to allow such Total Cost to be determined accurately. BI Pharma shall have the right, during the Term of this Agreement [*], to appoint an independent certified public accountant reasonably acceptable to ImmunoGen to inspect the relevant records of ImmunoGen to verify its statements of Total Cost of Drug Product. ImmunoGen shall make its records available for inspection by such independent certified public accountant during regular business hours at such place or places where such records are customarily kept, upon reasonable notice from BI Pharma, solely to verify the accuracy of its statements of Total Cost of Drug Product. Such inspection right shall not be exercised more than [*] during any [*] period. BI Pharma agrees to hold in strict confidence all information concerning ImmunoGen's costs, and all information learned in the course of any audit or inspection, except to the extent necessary for BI Pharma to reveal such information in order to enforce its rights under this Agreement or if disclosure is required by law, regulation or judicial order. The results of each inspection, if any, shall be binding on both Parties. BI Pharma shall pay for such inspections, except that, in the event an inspection reveals an overcharge to BI Pharma of greater than [*], ImmunoGen shall pay for such inspection.

8.2 **Government Inspections.** ImmunoGen, in accordance with applicable laws and regulations, shall permit representatives of any regulatory agency having jurisdiction over the manufacture and/or marketing of the Drug Substance or the Drug Product, including the FDA and the EMEA, but not limited to the same, to inspect its Facility in conjunction with the manufacture, quality control, registration, storage, handling and shipping of the Drug Product. ImmunoGen shall promptly advise BI Pharma if ImmunoGen receives a notice of an impending inspection or if an authorized agent of the FDA or other governmental agency visits any of ImmunoGen's facilities including the Facility concerning the Drug Product. ImmunoGen shall furnish to BI Pharma non-confidential copies of any report, including any FDA Form 483 notices (or comparable notices of other agencies), regulatory letters or similar documents received from such agency and the application of such report to Drug Product, if any, within [*] of ImmunoGen's receipt of such report.

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9. TERM AND TERMINATION

9.1 **Term.** This Agreement shall become effective on the Effective Date and shall continue in full force and effect until the earlier of the conclusion of Phase I Trials and non-pivotal Phase IIa Trials or the termination of the License Agreement (the "Term").

9.2 **Termination** [*]. This Agreement may be terminated [*] by [*] by giving [*] prior written notice to [*].

9.3 **Early Termination.** Notwithstanding Section 9.1, either Party may, in addition to exercising any other available legal or equitable rights or remedies, terminate this Agreement, effective immediately upon the expiration of any applicable cure period, upon the occurrence of an Event of Default (as defined below) with respect to the other Party. The term "Event of Default" with respect to a Party means the occurrence of any of the following events:

- (a) The failure of a Party to comply with or perform any material provision of this Agreement, and such failure remains uncured for [*] following written notice of such failure (if such default is cured within the cure period, such written notice shall be null and void), provided that, if the defaulting Party can establish to the reasonable satisfaction of the other Party that it is diligently and actively pursuing a cure at the expiration of the cure period, and that the default is reasonably capable of being cured, then the cure period shall be extended for so long as a cure is being diligently and actively pursued, not to exceed [*] in the aggregate.
- (b) A Party (i) becomes unable to pay its debts as they mature, (ii) is the subject of a voluntary or involuntary petition in bankruptcy or of any other proceeding under bankruptcy, insolvency or similar laws which, if involuntary, is not dismissed within [*] of the date filed, (iii) makes an assignment for the benefit of creditors, (iv) is named in, or its property is subject to, a suit for the appointment of a receiver which is not dismissed within [*] of the date filed, or (v) is dissolved or liquidated.

9.4 **Effect of Termination of this Agreement.** The termination of this Agreement shall in no way affect the validity of the License Agreement. Upon termination, ImmunoGen shall invoice BI Pharma for all costs that are incurred but remain unbilled as of the effective date of termination. Payment of such invoice shall be pursuant to the terms of Section 7.2 of this Agreement.

9.5 **Limited Liability.** Except as otherwise provided in this Agreement, neither ImmunoGen nor BI Pharma will be liable with respect to any subject matter of this Agreement under any contract, negligence, strict liability or other legal or equitable theory for any punitive damages or indirect, incidental, consequential damages or lost profits, including, without limitation, cost of procurement of substitute goods or technology, or loss of opportunity, loss of income or compensation for loss of goodwill.

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10. SECRECY OBLIGATIONS

10.1 **General Applicability of the Provisions of the License Agreement.** The Parties are in agreement that the confidentiality and secrecy obligations of the License Agreement shall apply to this Agreement for the Term of this Agreement and for a period of [*] thereafter.

11. ADDITIONAL OBLIGATIONS OF THE PARTIES

11.1 **Laws and Regulations.** The Parties agree to comply with all applicable laws, rules, regulations or requirements in connection with the manufacture of BIWA4, Drug Substance, and Drug Product.

11.2 **Permits and Licenses for Facility / Regulatory Submissions.** ImmunoGen shall be responsible for obtaining, [*], any Facility or other licenses or permits, and any regulatory and government approvals necessary for the manufacture of Drug Substance and the supply of Drug Product to BI Pharma in accordance with the terms and conditions of this Agreement. ImmunoGen shall provide to BI Pharma all information relevant to specific methods of Drug Product manufacture and any other information specific to the Drug Product and relevant to FDA and analogous non-U.S. regulatory submissions, including, without limitation, IND, BLA and other regulatory submissions, in a timely manner to enable punctual submission by BI Pharma of necessary regulatory documentation.

11.3 **Notification of Inspections; Communications.** ImmunoGen shall permit BI Pharma or its agents to be present and participate in any visit to, or inspection of, the Facility as it pertains to Drug Substance or Drug Product or review of the Manufacturing Process by any Competent Authorities. ImmunoGen shall give prompt notice to BI Pharma of any such visit, inspection or review. ImmunoGen shall promptly provide to BI Pharma all information (including copies of any written communication) from and to Competent Authorities concerning the Drug Substance or Drug Product, and shall use reasonable commercial efforts to consult with BI Pharma concerning the response of ImmunoGen to each such communication. It is understood by the Parties that all such communications fall under the confidentiality obligations.

11.4 **Regulatory Assistance.** ImmunoGen agrees to provide to BI Pharma such information and assistance relating to the manufacture and quality control of the Drug Product as BI Pharma may reasonably require for purposes of applying for and maintaining all registrations for the Drug Product including, without limitation, providing BI Pharma with all reports, authorizations, certificates, methodologies, and other documentation in the possession or under the control of ImmunoGen relating to the manufacture and quality control of the Drug Product (or any component thereof).

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11.5 **Debarment.** ImmunoGen represents and warrants that it has not been debarred and is not subject to a pending debarment and that it will not use in any capacity, in connection with the services to be performed under this Agreement, any person who has been debarred pursuant to section 306 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 335a, or who is the subject of a conviction described in such section. ImmunoGen agrees to inform BI Pharma in writing immediately if it or any person who is performing services hereunder is debarred or is the subject of a conviction described in section 306, or if any action, suit, claim, investigation, or legal or administrative proceeding is pending or, to the best of ImmunoGen's knowledge, is threatened, relating to the debarment or conviction of ImmunoGen or any person performing services hereunder.

11.6 **Compliance with U.S. Export Regulations.** BI Pharma understands that Drug Product to be purchased hereunder may require ImmunoGen to obtain a validated export license from the United States Department of Commerce. It shall be ImmunoGen's task and responsibility to obtain such export license and BI Pharma agrees to assist ImmunoGen in obtaining any such required license by supplying appropriate documentation reasonably requested by ImmunoGen. In connection therewith, BI Pharma agrees to comply with U.S. Export Administration Regulations as in effect from time to time and brought to BI Pharma's attention by ImmunoGen. BI Pharma will also maintain all records necessary to comply with United States Export Administration Regulations brought to BI Pharma's attention by ImmunoGen.

12. WARRANTY /LIABILITY

12.1.1. **ImmunoGen Representations:** ImmunoGen represents and warrants to BI Pharma that:

- (a) **No Conflict.** The execution, delivery and performance of this Agreement by ImmunoGen does not conflict with any agreement, instrument or understanding, oral or written, to which it is a Party or by which it may be bound, and does not violate any law or regulation of any court, governmental body or administrative or other agency having authority over it. ImmunoGen is not currently a party to, and during the term of this Agreement will not enter into, any agreements, oral or written, that are inconsistent with its obligations under this Agreement.
- (b) **Authority.** ImmunoGen is validly existing and in good standing under the laws of the state of its incorporation and has the corporate power and authority to enter into this Agreement. The execution, delivery and performance of this Agreement have been duly authorized by all necessary action on the part of ImmunoGen, its officers and directors.

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- (c) **Ownership.** To ImmunoGen's knowledge, all of the Licensed Patents are subsisting and are valid and enforceable. ImmunoGen (i) has not previously assigned, transferred, conveyed or otherwise encumbered its right, title and interest in Licensed Patents, or any component of the Licensed Technology, and (ii) has no knowledge of the existence of any patent, trademark or other intellectual property right (other than any patent application) owned or Controlled by ImmunoGen, other than the Licensed Patent Rights, in case of either (i) or (ii), that would prevent ImmunoGen and BI Pharma from manufacturing and supplying Drug Product, and BI from exploiting its rights granted under Section 2.1 of the License Agreement. In addition, ImmunoGen has no knowledge of the existence of any patent or intellectual property right (other than any patent application) owned or Controlled by a third party that would materially conflict with the grant of the license set forth in Section 2.1 of the License Agreement.
- (d) **Litigation.** There are no claims, judgements or settlements against, pending with respect to the Licensed Patents or any component of Licensed Technology. In addition, to ImmunoGen's knowledge, no such claims, judgements or settlements are threatened.
- (e) **Further Warranties:** ImmunoGen covenants to BI Pharma that:
 - (i) The development and manufacture of Drug Substance and Drug Product by ImmunoGen under this Agreement shall be in compliance with all applicable laws, requirements and regulations.
 - (ii) All Certificates of Analysis which will be provided to BI Pharma under this Agreement shall be generated and documented in accordance with generally accepted standards of the pharmaceutical industry.
 - (iii) ImmunoGen hereby represents and warrants that as of the Effective Date (a) ImmunoGen has [*] the [*] as listed on Schedule [*], and (b) each of the is in [*] and [*] and constitutes a [*] and [*] of [*].

12.1.2. **BI Pharma Representations and Warranties:** BI Pharma represents, warrants and covenants to ImmunoGen that:

- (a) **No Conflict.** The execution, delivery and performance of this Agreement by BI Pharma does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, and does not violate any law or regulation of any court, governmental body or administrative or other agency having authority over it. BI Pharma is not currently a party to, and during the term of this Agreement will not enter into, any agreements, oral or written, that are inconsistent with its obligations under this Agreement.

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- (b) **Authority.** BI Pharma is validly existing and in good standing under the laws of the state of its incorporation and has the corporate power and authority to enter into this Agreement. The execution, delivery and performance of this Agreement have been duly authorized by all necessary action on the part of BI Pharma, its officers and directors.
- (c) **BIWA4.** BI Pharma's manufacture and delivery of BIWA4 under this Agreement shall be in compliance with the laws, requirements and regulations applicable thereto in the Territory.

12.1.3. **Indemnification by the Parties:** Each party (the "Indemnitor") will indemnify the other party (the "Indemnitee") against any liability in connection with any claim, suits, liabilities, etc. arising out of the performance by the Indemnitor of its work under this Agreement or the exploitation by the Indemnitor of its rights under this Agreement, including, without limitation, the development and manufacture of Drug Substance and Drug Product, unless such liability results from (i) the negligence or wilful misconduct of the Indemnitee or (ii) a breach of the warranties set forth in this Agreement by the Indemnitee.

12.1.4. **Indemnification Procedures:**

- (a) The Indemnitee shall: (i) notify the Indemnitor of any liability and full details of the basis therefor with respect to which the Indemnitee intends to claim indemnification as soon as practicable after the Indemnitee becomes aware of any such liability; (ii) permit the Indemnitor to assume the defence thereof; and (iii) cooperate with the Indemnitor, at the Indemnitor's expense, in the defence thereof.
- (b) With respect to any matter for which the Indemnitor has an obligation to indemnify the Indemnitee under this Agreement, the Indemnitee shall have the right to participate and be represented (at the Indemnitor's expense) by legal counsel of the Indemnitee's choice in all proceedings and negotiations, if representation by counsel retained by Indemnitor would be inappropriate due to actual or potential differing interests between the Indemnitee and any other party represented by such counsel in such proceedings.
- (c) The indemnity agreement in this Section 12 shall not apply to amounts paid in settlement of any liability if such settlement is effected without the consent of the Indemnitor, which consent shall not be unreasonably withheld.
- (d) Failure of the Indemnitee to deliver notice to the Indemnitor within [*] after becoming aware of a liability shall relieve the Indemnitor of any liability to the Indemnitee pursuant to this Section 12 in the event, but only to the extent, such delay is prejudicial to the Indemnitor's ability to defend such action.

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13. MISCELLANEOUS

13.1 **Force Majeure.** The Parties shall not be liable in any respect for failure to perform their obligations hereunder or for delay in shipment of BIWA4 or Drug Product pursuant to accepted orders where such failure or delay shall have been due wholly or in part to the elements, acts of God, acts of civil or military authority or terrorism, fires, floods, epidemics, quarantine restrictions, war, riots, strikes, lock outs, break down, differences with workmen, accidents to machinery, delays in transportation or delays in delivery by suppliers or manufacturers beyond the Parties' control. In event of such force majeure, the Party affected thereby shall use reasonable efforts to cure or overcome the same and resume performance of its obligations hereunder.

13.2 **Other Restrictions.** Both Parties will conduct business in a manner that reflects favorably at all times on the products containing DM1, goodwill, and reputation of the other Party. Without limiting the foregoing, neither Party nor its Affiliates shall engage in any deceptive, misleading, illegal, unfair, or unethical practices that are or may be detrimental to the other Party or its Affiliates.

13.3 **Notices.** Unless otherwise and expressly required under this Agreement, all notices shall be in writing and mailed via certified mail, return receipt requested, courier, or facsimile transmission addressed as follows, or to such other address as may be designated by either Party in writing to the other Party from time to time:

If to ImmunoGen:
Attn: Chief Executive Officer
128 Sidney Street
Cambridge, MA 02139
United States of America

If to BI Pharma:
Attn: Clinical Trial Supplies Unit
Department of Pharmaceutical Research and Development
Birkendorfer Strasse 65
88397 Biberach
Germany

13.4 **Governing Law.** This Agreement shall be governed [*]. Where not as otherwise provided for in this Agreement, in the event of any controversy or claim arising out of or relating to any provision of this Agreement, the Parties shall first try to settle those conflicts amicably between themselves. Any dispute, controversy or claim initiated by either Party arising out of, resulting from or relating to this Agreement, or the performance by either Party of its obligations under this Agreement (other than bona fide third Party actions or proceedings filed or instituted in an action or proceeding by a third Party against a Party), whether before or after termination of this Agreement, shall be finally resolved by binding arbitration. Whenever a Party shall decide to institute arbitration proceedings, it shall give written notice to that effect to the other Party. Any such arbitration shall be conducted under the commercial arbitration rules of the ICC by a panel of three arbitrators appointed in accordance with such rules. Any such arbitration shall be held in [*].

The arbitrators shall have the authority to grant specific performance and to allocate between the Parties the costs of arbitration in such equitable manner as they determine. Judgment upon the award so rendered may be entered in any court having jurisdiction or application may be made to such court for judicial acceptance of any award and an order of enforcement, as the case may be. In no event shall a demand for arbitration be made after the date when institution of a legal or equitable proceeding based upon such claim, dispute or other matter in question would be barred by the applicable statute of limitations. Notwithstanding the foregoing, either Party shall have the right, without waiving any right or remedy available to such Party under this Agreement or otherwise to seek and obtain from any court of jurisdiction any interim or provisional relief that is necessary or desirable to protect the rights or property of such Party, pending the selection of the arbitrators hereunder or pending the arbitrators' determination of any dispute, controversy or claim hereunder.

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13.5 **Binding Effect.** This Agreement shall be binding upon and inure to the benefit of the Parties and their respective legal representatives, successors and permitted assigns.

13.6 **Headings.** Section and subsection headings are inserted for convenience of reference only and do not form a part of this Agreement.

13.7 **Amendment; Waiver.** This Agreement may be amended, modified, superseded or canceled, and any of the terms may be waived, only by a written instrument executed by each Party or, in the case of waiver, by the Party or Parties waiving compliance. The delay or failure of any Party at any time or times to require performance of any provisions shall in no manner affect the rights at a later time to enforce the same. No waiver by any Party of any condition or of the breach of any term contained in this Agreement, whether by conduct, or otherwise, in any one or more instances, shall be deemed to be, or considered as, a further or continuing waiver of any such condition or of the breach of such term or any other term of this Agreement.

13.8 **Independent Contractors; No Agency or Partnership.** The relationship between ImmunoGen and BI Pharma is that of independent contractors. Nothing contained in this Agreement shall give either Party the right to bind the other, or be deemed to constitute the Parties as agents for the other or as partners with each other or any third party.

13.9 **Assignment and Successors.** Either Party shall not be entitled to assign or otherwise transfer its rights and obligations under this Agreement in whole or in part to any third party without the prior written consent of the other Party.

13.10 **Integration; Severability.** If any provision of this Agreement is or becomes invalid or is ruled invalid by any court of competent jurisdiction or is deemed unenforceable, it is the intention of the Parties that the remainder of the Agreement shall not be affected.

14. LIST OF SCHEDULES

Schedule A: [*] for Drug Substance and Drug Product as provided by BI Pharma

Schedule B: [*] Dedicated Equipment to [*] of [*], which will be necessary during the production of Drug Product (see Section 5.5)

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Schedule [*]: Table of [*]

Schedule D: Form of Invoice and [*] of [*]

Schedule [*]: [*]

Schedule F: Purchase Order BI Pharma

Schedule G: [*] of [*]

Schedule [*]: [*]

Schedule I: Templates of Certificates of Analysis for Drug Substance and Drug Product

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives.

IMMUNOGEN, INC.

By: _____

Title: _____

BOEHRINGER INGELHEIM PHARMA KG
ppa.

By: _____

1 [*]
1 [*]

[*]
[*]

[*] include [*] and [*].

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SCHEDULE C

[*]

Section [*] of the Agreement [*] by the [*] for certain [*] not [*] to [*]. The [*] of such [*] shall take place in accordance with the table and description below.

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

[*]

[*] represents the [*] of the [*] that result in [*] that [*] and/or [*] The Parties estimate that for the [*], there may be [*] that result in [*] and/or Therefore, [*] may, [*] up to [*] to [*] of [*] five (5) Successful Batch Runs [*] shall [*] In the event that [*] must [*] than to [*] the [*] of [*], [*] shall [*] all [*] associated with [*]

[*]

[*] estimate that for the [*] there may be [*] that result in [*] and/or [*] Therefore, [*] may [*] up to [*] to [*] of [*] shall [*] all [*] associated with [*] In the event that [*] must [*] to [*] the of [*], [*] shall [*] all [*] associated with [*]

[*]

For all [*] of [*] there may be up to [*] Therefore, [*] may, [*] up to [*] of [*] of [*] shall [*] all [*] associated with these [*] In the event that [*] must [*] than [*] to [*] the [*] of [*] shall [*] all [*] associated with [*]

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Schedule D
Form of Invoice and [*] of [*]

Schedule E

List of [*]

(1) For [*]
[*] between [*] and [*]

[*]

(2) For [*]
[*] for the [*] of [*] dated [*] and [*]

[*]

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Schedule F
Purchase Order BI Pharma

Schedule G

[*]

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

This lot of material was manufactured to [*] and to the approved [*].

QU Approval: _____ Date: _____