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# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# FORM 10-Q/A

**AMENDMENT NO. 1 TO 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**

o **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** | **04-2726691** |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (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 o

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

**AMENDMENT TO FORM 10-Q FOR THE QUARTERLY PERIOD ENDED DECEMBER 31, 2001**

The amendment to the Form 10-Q for the quarterly period ended December 31, 2001 for ImmunoGen, Inc. is being filed solely for the purpose of revising Note B to Item 1.d. and Exhibit 10.1.

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

| | December 31, 2001 | June 30, 2001 |
|---|---|---|
| | (Unaudited) | |
| **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 | 2001 | 2000 |

| | | (Restated, See Note A) | | (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 | $ (1,732,252) | $ (2,514,988) | $ (3,324,775) | $ (10,228,096) |
| **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 | $ (0.04) | $ (0.07) | $ (0.08) | $ (0.29) |
| Basic and diluted average common shares outstanding | 39,730,478 | 36,408,516 | 39,270,213 | 34,854,392 |

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 | (5,217,576) | 25,525 |
| 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 | (1,350,270) | (127,564,340) |
| 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 | 5,590,202 | 142,167,866 |
| Net change in cash and cash equivalents | (977,644) | 14,629,051 |
| Cash and cash equivalents, beginning balance | 14,822,519 | 1,408,908 |
| Cash and cash equivalents, ending balance | $ 13,844,875 | $ 16,037,959 |
| Supplemental disclosures: | | |
| Cash paid for taxes | $ 66,912 | $ 55,000 |
| Non cash activities: | | |
| Accrued financing fees | $ 2,088,226 | $ — |
| Capital expenditures included in accounts payable | $ 965,958 | $ — |

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



**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.

*Inventory*

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 | $ | 4,542,803 |

*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 could receive, based upon the exchange rate on November 27, 2001, the effective date of the agreement, approximately $41.5 million, in potential payments upon BI's achievement of certain milestones in addition to 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.

**D. 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.

**PART II. OTHER INFORMATION**

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

(a) Exhibits

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.



**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: January 14, 2003 By: /s/ MITCHEL SAYARE

Mitchel Sayare
*President and Chief Executive Officer*
(principal executive officer)

Date: January 14, 2003 By: /s/ GREGG D. BELOFF

Gregg D. Beloff
*Chief Financial Officer and Vice President, Finance*
(principal financial and accounting officer)



**CERTIFICATIONS**

I, Mitchel Sayare, certify that:

1. I have reviewed this quarterly report on Form 10-Q of ImmunoGen, Inc.;

2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report.

Date: January 14, 2003

/s/ MITCHEL SAYARE

Mitchel Sayare
*Chairman of the Board of Directors,*
*Chief Executive Officer and President*



I, Gregg D. Beloff, certify that:

1. I have reviewed this quarterly report on Form 10-Q of ImmunoGen, Inc.;

2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report.

Date: January 14, 2003

/s/ GREGG D. BELOFF

Gregg D. Beloff
*Vice President and Chief Financial Officer*



**INDEX TO EXHIBITS**

| EXHIBIT NO. | DESCRIPTION |
|---|---|
| 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.



QuickLinks

**Exhibit 10.1**

**Development and License Agreement**

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 is 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 conjugate of DM1 that has the same Target Antigen 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. |
| 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 | "Direct Costs" | shall mean with respect to any Drug Substance or Drug Product, the fully-burdened costs of producing (including the costs associated with product testing and release activities) and packaging of such Drug Substance and Drug Product, including the sum of the following components: (a) the direct costs, including direct labor and materials, of producing and packaging such BIWI1; (b) all manufacturing overhead costs incurred by ImmunoGen attributable to the cost of goods under the foregoing clause (a), including, without limitation, supervisory services, occupancy costs, purchasing, human resources, payroll, information system and accounting which are allocable to company departments based on space occupied or headcount or another activity-based method; (c) any other costs borne by ImmunoGen for the transport, customs clearance, duty, insurance and/or storage of such Drug Substance and Drug Product; and (d) general and administrative costs which are allocable to company departments based on space occupied or headcount or another activity-based method. Notwithstanding the foregoing, Direct Cost |

| | | |
|---|---|---|
| | | of Drug Substance shall not include the cost of purchasing any dedicated equipment to the extent reimbursed by BI pursuant to Section 5.1(d) of this Agreement. |
| 1.11 | "DM1" | shall mean that certain maytansine derivative known as "DM1" whose specific chemical name is $N^{2'}$-deacetyl-$N^{2'}$(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 all human therapeutic uses. |
| 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. |
| 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 shall mean one tumor type, e.g. breast cancer, lung cancer or head and neck cancer. |
| 1.20 | "Initiation" | shall mean, with respect to any clinical study, the start of patient treatment 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 *Schedule A* attached hereto; and (ii) any Improvements thereto (other than Improvements that are Patent Rights) Controlled by ImmunoGen during the Term of the Agreement solely to the extent accepted by BI in accordance with Section 2.3 hereof, solely 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 *Schedule B attached thereto*. |
| 1.25 | "Major Markets" | shall mean the United States of America and the European Union. |
| 1.26 | "Net Sales" | shall mean, as to each calendar quarter during the Term, the gross invoiced sales prices charged for all Licensed Products sold by BI and its Sublicensees to third parties throughout the Territory during such calendar quarter, less the following amounts incurred or allowed by BI or its Sublicensees during such calendar quarter with respect to sales of Licensed Products regardless of the calendar quarter in which such sales were made: |

(a) trade, cash and quantity discounts or rebates actually taken and allowed, including discounts or rebates to governmental or managed care organizations;

(b) credits or allowances given or made for rejection or return of previously sold Licensed Products or for retroactive price reductions (including Medicare and similar types of rebates);

(c) any charges for insurance, freight and other transportation costs directly related to the delivery of Licensed Product to the extent included in the gross invoiced sales price;



(d) any tax, tariff, duty or governmental charge levied on the sales, transfer, transportation or delivery of a Licensed Product (including any tax such as a value added or similar tax or government charge) borne by the seller thereof, other than franchise or income tax of any kind whatsoever; and

(e) any import or export duties or their equivalent borne by the seller.

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.

2.3 *Additional Rights:*

(a) ImmunoGen herewith grants to BI an exclusive option 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 notifies ImmunoGen in writing of its interest in the respective Improvement at any time during the Term, BI shall automatically be granted an appropriate license so long as such Improvement is Controlled by ImmunoGen at the time of such notification, consistent with the terms of Section 2.1, which adds such Improvement to the scope of the Licensed Patent Rights and/or Licensed Technology, as the case may be, without any additional obligations due 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.

**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) Pre-clinical milestones: | Payment |
|---|---|
| Upon [ * ]of an US$ [ * ]in the [ * ]for a [ * ]. | US$[**]million |

| (ii) Clinical milestones: | Payment |
|---|---|
| Upon[ * ] of the US$ [ * ] for a [ * ] | US$[**]million |
| Upon [ * ] of the US$[ * ] for a [ * ] | US$[**]million |
| Upon [ * ] of the US$[ * ] for a [ * ]. | US$[**]million |
| Upon [ * ]of the US$[ * ] in the [ * ] for a [ * ] | US$[**]million |
| Upon [ * ] of US$[ * ] by the [ * ] for the [ * ] for a [ * ] | US$[**]million |
| Upon [ * ] of US$[ * ] by the [ * ] for the[ * ] for a [ * ] | US$[**]million |
| Upon [ * ] of US$[ * ] by the [ * ] in [ * ] for the [ * ] for a [ * ] | US$[**]million |
| Upon [ * ] of US$[ * ] by the [ * ] for the [ * ] for a [ * ] | US$[**]million |
| Upon [ * ] of US$[ * ] by the [ * ] for the [ * ] for a [ * ] | US$[**]million |
| Upon [ * ] of US$[ * ] by the [ * ] in [ * ] for the [ * ] for a [ * ] | US$[**]million |
| Upon [ * ] of the US$[ * ] for the [ * ] for a [ * ] | US$[**]million |

(iii) Performance milestones:

A [**] of:
€ **[ * ]** million if the **[ * ]** € **[ * ]** million
€ **[ * ]** million if the **[ * ]** € **[ * ]** million
€ **[ * ]** million if the **[ * ]** € **[ * ]** million
€ **[ * ]** million if the **[ * ]** € **[ * ]** million

(b) BI shall pay ImmunoGen the milestone payments set forth in Section 3.2(a)(i) and (ii) within **[ * ]** of the occurrence of the respective milestone and the **[ * ]** pursuant to Section 3.2(a)(ii) within **[ * ]** of the end of the respective calendar year. The upfront-fee pursuant to Section 3.1 and the milestone payments pursuant to Section 3.2(a)(i) and (ii) shall be paid in US Dollars. The performance milestone payments pursuant to Section 3.2(a)(iii) shall be paid in EUROS.

(c) It is hereby understood that each milestone payment shall be paid only for the first achievement of a given milestone by a Licensed Product and that no additional milestone payments shall be made for any subsequent achievement of such milestone by a subsequent Licensed Product.



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 **[ * ]** by **[ * ]** as follows:

| **Annual Net Sales*** | **[ * ]**** | **[ * ]**** |
|---|---|---|
| | **(%)** | **(%)** |
| [ * ] up to [ * ] | [ * ] | [ * ] |
| Above [ * ] and up to [ * ] | [ * ] | [ * ] |
| Above [ * ] and up to [ * ] | [ * ] | [ * ] |
| Above [ * ] | [ * ] | [ * ] |

* Staggered royalties on incremental sales.

** For purposes of this Section 3.3(a), "Access" shall refer to the ability of ImmunoGen to have **[ * ]** to BI's **[ * ]** such that the **[ * ]** shall be applicable if ImmunoGen enters into a **[ * ]** providing ImmunoGen with such Access.

(b) The above royalty rates shall be payable on a country-by-country basis on the Net Sales of each Licensed Product from its First Commercial Sale until the expiration of the royalty term as provided in Section 3.3(d). The above royalty **[ * ]** be **[ * ]** by **[ * ]** in any calendar year on a country-by-country basis with respect to any Licensed Product if (i) the manufacture, use or sale of such Licensed Product in such country is not covered by a Licensed Patent Right in such country but is covered by the Licensed Technology; or (ii) (A) the Licensed Patent Right in such country covering the manufacture, use or sale of a Licensed Product **[ * ]**, (B) **[ * ]** are **[ * ]** Comparable Products in such country *and* (C) such third parties have, in the aggregate during such calendar year, **[ * ]** or more of the **[ * ]** in such country in connection with the sale of such Comparable Product.

(c) In the event that BI, in order to exploit the licenses granted to it by ImmunoGen hereunder in any country, is required to make royalty payments to one or more third parties (i) to obtain a license under their patent rights in the absence of which the DM1 portion of a Licensed Product could not legally be developed, manufactured or sold in such country and/or (ii) to obtain a license under their patent rights specific to the Licensed Technology used by ImmunoGen to conjugate DM1 to antibodies, in the absence of which any of the Licensed Patent Rights necessary to conjugate DM1 to an antibody Controlled by BI as part of a Licensed Product can not legally be practised (as evidenced, to the extent reasonably requested by ImmunoGen, by an opinion of patent counsel), then royalties due to ImmunoGen for a given Licensed Product may be **[ * ]** by **[ * ]**

of the amount of such **[ * ]**. Notwithstanding the following, such reductions shall in no event reduce the royalty for such Licensed Product payable under this Section 3.3(c) to less than **[ * ]** of Net Sales in such country.

(d) BI shall pay royalties with respect to each Licensed Product on a country-by-country and Licensed Product-by-Licensed Product basis as follows:

(1) with respect to the first Licensed Product sold by BI or any Sublicensee of BI under this Agreement (the "Initial Licensed Product") until the longer of the expiration of the last to expire of the Licensed Patent Rights or **[ * ]** from date of First Commercial Sale of such Initial Licensed Product, and;

(2) with respect to any Licensed Product launched after the date of First Commercial Sale of the Initial Licensed Product (each, a "Subsequent Licensed Product");



(A) if BI at the First Commercial Sale of the Subsequent Licensed Product is still paying ImmunoGen royalties in connection with sales of the Initial Licensed Product under Section 3.3(a) of this Agreement, then until the longer of (i) the expiration of the last to expire of the Licensed Patent Rights covering the Subsequent Licensed Product or (ii) **[ * ]** from the date of First Commercial Sale of such Subsequent Licensed Product; *provided*, *that*, notwithstanding Section 3.3(a) of this Agreement, the royalty rate for any Subsequent Licensed Product covered by this Section 3.3(d)(2)(A)(ii) shall be **[ * ]** and;

(B) if BI at the First Commercial Sale of the Subsequent Licensed Product is no longer paying royalties from sales of the Initial Licensed Product under Section 3.3(a), then until the longer of (i) the expiration of the last to expire of the Licensed Patent Rights covering the Subsequent Licensed Product or (ii) the date on which BI shall have paid royalties to ImmunoGen from sales of any Licensed Products for an aggregate of **[ * ]** (whether or not such calendar quarters are consecutive).

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 sixty (60) days following the end of each Payment Period a royalty report as set forth in Section 3.4 along with BI's payment to ImmunoGen of any royalty due and payable to ImmunoGen for such Payment Period.

(b) All royalty payments shall be computed and paid in EUROS at exchange rates as published by the European Central Bank, Frankfurt am Main, Germany, and as customarily used by BI in its regular accounting system.

3.6 *Withholding Tax:*

(a) BI shall deduct any withholding taxes and other statutory duties from the payments agreed upon under Sections 3.1, 3.2, and 3.3 of this Agreement and pay them to the proper tax authorities required by law applicable at the date of payment. BI shall maintain official receipts of payment of any withholding taxes and forward these receipts to ImmunoGen.

(b) The parties will exercise their best efforts to ensure that any withholding taxes imposed are reduced as far as possible under the provisions of the current or any future double taxation agreement between the United States of America and the Federal Republic of Germany.

(c) The parties hereby acknowledge that according to German Law this reduction requires that the German Bundesamt für Finanzen issues a certificate of tax exemption.

(d) The parties hereby acknowledge that in order to achieve such reduction ImmunoGen is required to provide BI with the claim for a certificate of tax exemption in respect of royalties performed on the official form (APPLICATION FOR TAX EXEMPTION) containing the statement of residence and Indication of the taxpayer's identification number as well as the Certificate of Filing a Tax Return, in which it confirms that it does not derive the royalties through a permanent establishment maintained in Germany. BI agrees to provide ImmunoGen with the official form.



(e) ImmunoGen hereby acknowledges that every three years ImmunoGen is required to submit a new Application For Tax Exemption unsolicited, 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.

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

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 shall use **[ * ]** to **[ * ]** and **[ * ]** the **[ * ]** for Drug Product to meet BI's requirements for conduct of clinical trials, according to the development plan attached as *Schedule F* and thereby agrees to maintain the basic assumptions included in *Schedule F* which may be amended by the Parties during the development. During this **[ * ]** and **[ * ]**, ImmunoGen will keep BI informed on a regular basis and BI shall be entitled to advise and contribute to such process, 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 right to terminate in 13.3, 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.

(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 Commercially Reasonable Efforts.*

In the event that BI fails to use Commercially Reasonable Efforts as described in Section 4.3(a), 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 supply BI with its requirements of Drug Substance in non-GLP and GLP quality as well as assays and reagents for the determination of DM1 conjugate and free DM1 and DM1 derivatives in biological material and in Drug Substance preparations in order for BI to carry out the non-clinical development of the Licensed Products, as listed on Schedule D attached hereto. BI will pay ImmunoGen a transfer price for such non-clinical Drug Substance equal to **[ * ]** of ImmunoGen's Direct Cost of Drug Substance. In addition, ImmunoGen will provide BI with data showing at least a **[ * ]** of the Drug Product in its **[ * ]**. A stability program will be initiated and continue until the earlier of the Term of the Agreement or until samples are used up. For GLP material, ImmunoGen will provide a Certificate of Analysis for each batch manufactured.

(b) In the event that, over a given calendar year, ImmunoGen fails to supply BI with at least **[ * ]** of its requirements of non-clinical Drug Substance for that calendar year in the amounts as specified in Schedule D and such failure is not attributable to a contingency set forth in Section 15.3 or BI's failure to supply an adequate amount of BIWA4 in a timely manner, then,



subject to the final sentence of this Section 5.1(b), ImmunoGen shall forgo certain milestone payments as follows. If such failure to supply occurs **[ * ]** of **[ * ]** , then ImmunoGen shall forgo the **[ * ]** and **[ * ]** to Section 3.2. If such **[ * ]** to **[ * ]** occurs **[ * ]** of **[ * ]**, then ImmunoGen shall forgo the **[ * ]** and **[ * ]** pursuant to Section 3.2. The foregoing notwithstanding, ImmunoGen shall have **[ * ]** from the **[ * ]** of the calendar year to **[ * ]** such failure and not forgo any milestone payments.

(c) In addition, ImmunoGen shall supply BI with such quantities of Drug Product in order for BI to conduct clinical development activities until conclusion of Phase I Trials and Phase IIa Trials. 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 subject to BI's prior written approval. In case of termination, ImmunoGen shall permit BI to remove such dedicated equipment at BI's sole cost and expense.

(e) The audit rights in Section 8.1.2 and 8.1.3 of the Clinical Supply Agreement shall also apply for non-clinical material.

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 provide such technical assistance as may be reasonably required by BI for the manufacture of Licensed Products in accordance with the Technical Transfer Plan to be agreed upon by BI and ImmunoGen before May 31, 2002, the major terms of which are attached hereto as *Schedule E*.

**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. ImmunoGen agrees to provide BI with Adverse Event and product complaint information relating to any product containing DM1 that is compiled and prepared by ImmunoGen or any third party in the normal course of business in connection with the development, commercialization or sale of any such product, within time frames consistent with reporting obligations under applicable laws and regulations; provided, however, that the foregoing shall not require ImmunoGen to violate any agreements with or confidentiality obligations owed to any third party. ImmunoGen, in each third

party contract in which it has granted or will grant a license under the Licensed Technology and Licensed Patent Rights, has included or will include, as the case may be, a provision requiring each such third party to provide reports of Adverse Events related to the product that is the subject of such license agreement. ImmunoGen will review and assess these reports and will communicate to BI all resulting information which is relevant for the safety of the Licensed Product and its use to BI. ImmunoGen hereby affirms to BI that such communication is not within the confidentiality obligations ImmunoGen owes to any third party. 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. ImmunoGen shall provide its Adverse Event and product complaint information hereunder to BI's designated representative, who shall be the head of its Drug Safety group in BI's Medical Affairs Department unless BI otherwise notifies ImmunoGen.

**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 *Improvements:*

(a) ImmunoGen will disclose promptly to BI any and all Improvements conceived or made by or for it or otherwise coming under its Control during the Term of this Agreement to the extent such Improvements are related to any Licensed Patent Rights or are necessary or useful to develop, have developed, make, have made, sell and have sold Licensed Products.

(b) To the extent any Improvement was conceived or made jointly by or for ImmunoGen and BI (a "Joint Improvement"), such Joint Improvement shall be owned jointly by ImmunoGen and BI. 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 assign to it or as it shall direct all inventions made or developed by such employees or other persons.

(c) To the extent any Improvement was conceived or made by or for one party, the Improvement shall be owned exclusively by such party.

**8. PATENTS AND TRADEMARKS**

8.1 *Patent Prosecution:*

(a) ImmunoGen agrees to use commercially reasonable effort to continue, at its sole cost and expense, 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.

(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 thirty (30) days 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 sixty (60) days 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.



**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.

(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 reimbursed to each party pro rata, based on the actual amounts spent by such party, out of any damages or other monetary awards recovered therein in favour of ImmunoGen and/or BI; and

(ii)

the amount of any damages or other monetary awards recovered therein in favour of ImmunoGen and/or BI, in excess of the reimbursement provided for in clause (i) above, shall be divided as follows: (1) first, to BI, as reimbursement for **[ * ]** associated with Licensed Products and to ImmunoGen as reimbursement for **[ * ]** solely to the extent that the award or compensation is attributable to **[ * ]** associated with Licensed Products; and (ii) second, any amounts remaining shall be allocated as follows: (a) if ImmunoGen is the party prosecuting such action, **[ * ]** to ImmunoGen, (b) if BI is the party prosecuting such action, **[ * ]** to BI and **[ * ]** to ImmunoGen, and (c) if both parties are prosecuting such action, **[ * ]** to each party.

## 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.

(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.

(iv) All written information, submitted to BI by ImmunoGen in response to due diligence investigation, 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.

(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.

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;

(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 ten (10) years from First Commercial Sale 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:

(a) 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 ten (10) years from First Commercial Sale of the respective Licensed Product,

whichever is the longer.

(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 ninety (90) days' 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 license under Section 2.1 of this Agreement shall thereafter become a perpetual, royalty-free, fully-paid license.

(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.

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 damagesor 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.

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 German laws. 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.

**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]



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 |

## Schedule A
## Licensed Technology

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



## Schedule B
## Licensed Patent Rights

**[ * ]**

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

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



## Schedule C
## BI Intellectual Property

| BI Case No. | Subject | Expiry and Status Europe | Expiry and Status US | File No. EP and US | Geographic Coverage |
|---|---|---|---|---|---|
| [ * ] | [ * ] | [ * ] | [ * ] | [ * ] | [ * ] |
| [ * ] | [ * ] | [ * ] | [ * ] | [ * ] | [ * ] |
| [ * ] | [ * ] | [ * ] | [ * ] | [ * ] | [ * ] |
| [ * ] | [ * ] | [ * ] | [ * ] | [ * ] | [ * ] |
| [ * ] | [ * ] | [ * ] | [ * ] | [ * ] | [ * ] |



## Schedule D
## Provision of Non-clinical Drug Substance [g BIWI1]

| Non-clinical Drug Substance (g BIWI 1) | 2001 | 2002 | 2003 | 2004 |
|---|---|---|---|---|

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|---|---|---|---|---|
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| [ * ] | [ * ] | | | |
| [ * ] | [ * ] | [ * ] | [ * ] | [ * ] |
| [ * ] | [ * ] | [ * ] | [ * ] | [ * ] |
| **TOTAL** | [ * ] | [ * ] | [ * ] | [ * ] |



**Schedule E**
**Major Terms of Technical Transfer Plan**

It is the intention of the parties that the Technical Transfer Plan referenced in Section 5.2 of this Agreement will be finalised by the parties as soon as practicable and in any event no later than May 31, 2002. Both parties agree to negotiate such finalized terms in good faith, which shall be based on the transfer by ImmunoGen to BI of following documentation, to the extent available:

***For Analysis purposes:***

Documentation:

- [ * ] and [ * ] for [ * ] of the [ * ] covering [ * ] and [ * ] tests ([ * ] for [ * ] including [ * ]/ [ * ])
- [ * ] and [ * ] for [ * ] covering tests for [ * ], [ * ] and [ * ] (specifications for [ * ] including [ * ]/ [ * ], i.e. [ * ], and [ * ] products)
- Justification of the [ * ]
- Justification of [ * ] / [ * ] for Maytansine DM1
- Preliminary [ * ] data for analytical methods ([ * ]/ [ * ], [ * ], [ * ])
- Analytical results of all batches of [ * ]/ [ * ]
- Preliminary [ * ] data for Maytansine DM1 ([ * ] and [ * ])

Reference substances:

- qualified reference substances for [ * ] of the Maytansine DM1 synthesis (amount: at least [ * ])
- qualified [ * ] of Maytansine DM1 (amount: at least [ * ])
- qualified [ * ] of [ * ] specified [ * ] (in [ * ] and [ * ])

***For Chemical Production Purposes:***

- executed batch records of [ * ] batches ([ * ])
- analytical methods for [ * ]
- testing specifications for [ * ] (see below)
- samples ([ * ]) of each [ * ] (see below)

definition of "[ * ]":

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

- [ * ]
- [ * ]



*For Quality Testing purposes:*

ImmunoGen will supply BI with substances that are necessary for BIWI1 quality testing (e.g. [ * ], [ * ] etc.).

ImmunoGen will supply BI with all required [ * ] and information on [ * ] of BIWI1.

***For Production purposes:***

- Information about safety precautions for all toxic substances, including ImmunoGen's for any steps that ImmunoGen takes for [ * ] safety
- Technical requirements for the work with Maytansine and derivates for lab and scale up
- [ * ] ([ * ]) [ * ] of all equipment used in the BIWI 1 process
- [ * ] for each step of the manufacturing process ([ * ] and [ * ])
- Statistical [ * ]/ [ * ] analysis regarding the executed production batches
- Detailed reports about different process times, reaction times, acceptable/necessary temperatures, additional information which is necessary e.g. working with [ * ] ...
- Detailed report about necessary personal capacity for every production step
- Copies of the DMF and batch protocols from lots which were made at ImmunoGen
- Risk analysis of each production step (i.e. [ * ] [ * ] of each production step, quality of the step when working in the prescribed process limits for example [ * ], [ * ], [ * ], ...)

***General:***

ImmunoGen will agree to [ * ] for the collaboration with BI throughout the [ * ] process. To the extent practicable, ImmunoGen will attempt to include in the process employees (in the [ * ] and [ * ] areas) who [ * ] the project with BI.

ImmunoGen will agree, subject to [ * ], to host an [ * ] number of employees from BI at any time during the Technical Transfer phase in order to [ * ] such employees [ * ] of the ImmunoGen equipment and fixed assets that are necessary for the production of BIWI1. Such [ * ] sessions shall take place at ImmunoGen's facility at mutually convenient times and shall not exceed an aggregate of [ * ] in duration. [ * ] shall [ * ] of [ * ] and [ * ] of all such employees. ImmunoGen will also agree to let BI employees observe the production of at least [ * ] Batch Runs of BIWI1.

ImmunoGen will further agree to use [ * ] to make arrangements for BI employees to partake in a similar visit to ImmunoGen's contractor ChemSyn.

On not less than [ * ] prior written notice from BI, ImmunoGen will also agree to [ * ] to the BI site for a specific time not to exceed [ * ] (inclusive of [ * ]) in the aggregate, while the technology is being transferred. BI will have the right to provide recommendations to ImmunoGen as to the [ * ] and [ * ] of such employees desired as well as the [ * ] of such [ * ] employment. To the extent practicable, ImmunoGen will attempt to include in such [ * ] employment those employees who have [ * ] the BI project. ImmunoGen and BI will agree to negotiate in good faith any required extension of such temporary employment period. BI will agree to [ * ] ImmunoGen for [ * ] of its [ * ] in connection with such temporary employment at an [ * ] of [ * ] for [ * ] with no higher [ * ], and [ * ] for [ * ] with a [ * ]. [ * ] and other [ * ], such as [ * ], will also be [ * ] BI.

It is the expectation of the parties that this Technical Transfer process will terminate as soon as BI Pharma produces at least [ * ] of BIWI1 which comply with [ * ] and are suitable for [ * ] for [ * ].



**Schedule F**
**Development Plan for BIWI1**

*Initial BIWI1 process development:*

*Goal:* Develop a process for production of BIWI1 that can be **[ * ]** to **[ * ]** production of BIWI1 in the range of **[ * ]** per year to meet **[ * ]** for **[ * ]** and **[ * ]** studies. BIWI1 to be at a formulated concentration of **[ * ]**.

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

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

| | |
|---|---|
| | [overall yield at this scale, **[ *** ]] |
| End **[ * ]** /<br>Beginning of **[ * ]** | Recommend process for **[ * ]** based on process data. |
| **[ * ]** | **[ * ]** ;<br>[ ***** ].<br>Drug Substance for **[ * ]** ( **[ * ]** , **[ * ]**) |
| **[ * ]** | Evaluate process data. Compare to previous results. Investigate any anomalies and identify opportunities for process improvements. |
| **[ * ]** or **[ * ]** | **[ * ]** at **[ * ]** Drug Substance for **[ * ]** work |
| **[ * ]** | Evaluate process data. Compare to previous results. Investigate any anomalies and identify opportunities for process improvements. |
| **[ * ]** | **[ * ]** |
| **[ * ]** to<br>**[ * ]** | **[ * ]** at **[ * ]** |
| **[ * ]** | Evaluate process data (**[ * ]**). Compare to previous results. Investigate any anomalies and identify opportunities for process improvements. |
| **[ * ]** to<br>**[ * ]** | **[ * ]** |
| **[ * ]** | Evaluate process data (**[ * ]**). Compare to previous results. Investigate any anomalies and identify opportunities for process improvements. |
| **[ * ]** | **[ * ]** |

*ASSUMPTIONS:*

(a) Development plan will yield **[ * ]** of BIWI1 for **[ * ]** use (though some **[ * ]** of **[ * ]** material may be used for **[ * ]** toxicology work), assuming yields at **[ * ]** are similar to those obtained at **[ * ]**.

(b) [ ***** ] development plan is successfully executed.

(c) The above time-frames are for manufacture of bulk BIWI1, and do not include **[ * ]**.

(d) Assumes that key **[ * ]** and **[ * ]** are available and delivered in a timely manner.



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***Plan for the development of Ansamitocin P3 production and DM1 production***

***Supplies of DM1 for 2001 and 2002***

Purchase **[ * ]**. **[ * ]**.

***Development Plan for Ansamitocin P3 production:***

**[ * ]** under way since **[ * ]** , at **[ * ]**. This is an ongoing development program to develop a **[ * ]** for commercialization. However, an **[ * ]** was selected for manufacture of **[ * ]** for **[ * ]**.

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

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

**[ * ]:** Transfer of **[ * ]** process to **[ * ]**.

**[ * ]** to **[ * ]** : ImmunoGen develops downstream processing for ansamitocin isolation.

**[ * ]:** Transfer **[ * ]** from ImmunoGen to **[ * ]**.

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

**[ * ]**: **[ * ]** of **[ * ]** ready for shipment.

**[ * ]**: **[ * ]** manufactures **[ * ]** in **[ * ]** .

**[ * ]** **[ * ]** begins to produce **[ * ]** .

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

***Development Plan for DM1 production***

**[ * ]:** Ensure that **[ * ]** is ready to **[ * ]** manufacture of DM1 for ImmunoGen. Currently, **[ * ]** estimates that **[ * ]** DM1 is **[ * ]** after **[ * ]** of **[ * ]**. Some development work in **[ * ]** may **[ * ]** the time-frame

Starting in the **[ * ]**: Produce DM1 from **[ * ]** at **[ * ]** on a **[ * ]** basis of **[ * ]**.

**[ * ]** supply from **[ * ]** from the **[ * ]** of **[ * ]** will be sufficient to allow process development work to prepare for **[ * ]** of DM1

**[ * ]:** DM1 obtained from **[ * ]** from the **[ * ]** is used in the **[ * ]** of BIWI1. May require **[ * ]** , as appropriate.



**Schedule G**
**Clinical Supply Agreement**

**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.

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 ***Direct Cost***" shall mean with respect to any Drug Product or Drug Substance, the fully-burdened costs of producing (including the costs associated with product testing and release activities) and packaging of such Drug Product or Drug Substance, including the sum of the following components: (a) the direct costs, including direct labor and materials, of producing and packaging such Drug Product or Drug Substance; (b) all manufacturing overhead costs incurred by ImmunoGen attributable to the cost of goods under the foregoing clause (a), including supervisory services, occupancy costs, purchasing, human resources, payroll, information system and accounting which are allocable to company departments based on space occupied or headcount or another activity-based method; (c) any other costs borne by ImmunoGen for the transport, customs clearance, duty, insurance and/or storage of Drug Product or Drug Substance; and (d) general and administrative costs which are allocable to company departments based on space occupied or headcount or another activity-based method. In no event shall the indirect manufacturing cost allocated to BI Pharma exceed $175,000 per Batch Run. Notwithstanding the foregoing, Direct Cost of Drug Product or Drug Substance shall not include (i) the cost of purchasing any Dedicated Equipment to the extent reimbursed by BI Pharma pursuant to Section 5.5 of this Agreement, (ii) the cost of failed batches other than pursuant to Section 6.4 of this Agreement, (iii) the cost of DM1 Inventory acquired at BI Pharma's expense pursuant to Section 6.8 of this Agreement, or (iv) any indirect costs allocable to batches produced for third parties in the Facility. If BI or BI Pharma as the case may be can reasonably demonstrate to ImmunoGen that any equivalent materials, components or equipment used for the production of Drug Substance and/or Drug Product of the same quality, quantity and timing can be purchased at a lower price than ImmunoGen's Direct Cost and such materials or components, or that equipment can be supplied on a reasonably consistent and reliable basis, then ImmunoGen shall accept such lower price for the calculation of the Direct Cost.

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.

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.



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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 ***"Subcontractor"*** means any independent third party or entity contractually engaged to act on behalf of ImmunoGen in order to perform the Manufacturing Process or any quality control steps 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

"Key Materials Supply Agreements", see Section 3.6

"Drug Product Forecast", see Section 4.2

"Purchase Order", see Section 4.3

"Laboratory", see Section 6.1.3

"Review", see Section 6.1.2

"DM1 Inventory", see Section 6.8

"Term", see Section 9.1

"Event of Default", see Section 0

"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 minimum quantities of clinical Drug Product to be supplied to BI Pharma by ImmunoGen in each respective Calendar Year during the Term of this Agreement is attached hereto as *Schedule G*. It is the understanding of ImmunoGen and BI Pharma that ImmunoGen shall not be obliged to supply BI Pharma with quantities in excess of five percent (5%) of the amounts of Drug Product in each respective Calendar Year as listed in *Schedule G* attached to this Agreement, provided that ImmunoGen shall use all reasonable efforts to fulfill any such request. ImmunoGen shall produce Drug Product in a series of Batch Runs, the exact number and size of which shall be determined by the Parties. 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.

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; in the event that ImmunoGen has made any such unauthorised changes, ImmunoGen shall be held solely liable for the consequences of such changes and for any claim for damages or indemnification 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 **[ * ]** 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.

3.6 ***Key Materials.*** ImmunoGen has entered into agreements for the supply of ansamitocin P3 and DM1 ("the Key Materials Supply Agreements") and believes, to the best of its knowledge, that the supply of ansamitocin P3 and DM1 under the Key Materials Supply Agreements, as in effect on the Effective Date, is sufficient to satisfy BI's requirements for Drug Product under Section 3.1 of the Supply Agreement. A list of the Key Materials Supply Agreements is attached hereto as *Schedule E*.

**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 G* (provision of clinical Drug Product). In *Schedule G* the total quantity of Drug Product that BI Pharma expects to order from ImmunoGen based upon ImmunoGen's current manufacturing capacity 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. BI Pharma therefore will amend from time to time the Drug Product Forecast so as to account for such variables.

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 second Calendar Quarter (as the first Calendar Quarter will already be covered by the initial Purchase Order covering the first and second Calendar Quarters). Subsequent Purchase Orders shall equal the Drug Product Forecast for the second Calendar Quarter 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 Parties shall use their standard forms (see *Schedule F*: Purchase Order BI Pharma), 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 ***Penalty for Failure to Supply.*** In the event that, over a given Calendar Year, ImmunoGen fails to supply BI Pharma with at least **[ * ]** of the lesser amount of **[ * ]** specified in the **[ * ]** for that **[ * ]** or the **[ * ]** of **[ * ]** specified in *Schedule G* for that **[ * ]** and such failure is not attributable to a



contingency set forth in Section 13.1 or to a breach by BI Pharma or BI of this Agreement, then, subject to the final sentence of this Section 4.5, ImmunoGen shall forgo certain milestone payments **[ * ]** under the **[ * ]** as follows. If such **[ * ]** to **[ * ]** occurs **[ * ]** the **[ * ]** of **[ * ]** , then ImmunoGen shall forgo the **[ * ]** milestone payments **[ * ]** and **[ * ]** to Section 3.2 of the **[ * ]**. If such **[ * ]** to **[ * ]** occurs **[ * ]** the **[ * ]** of **[ * ]**, then ImmunoGen shall forgo the **[ * ]** milestone payments **[ * ]** and **[ * ]** pursuant to Section 3.2 of the **[ * ]**. The foregoing notwithstanding, ImmunoGen shall have **[ * ]** from the end of the **[ * ]** to **[ * ]** such **[ * ]** and not forgo any milestone payments.

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 ***Subcontractors.*** Notwithstanding the following provision, ImmunoGen shall not be allowed to engage any Subcontractor in the production and control of the Drug Product without the prior written agreement of BI Pharma. The list of presently agreed-to Subcontractors is attached hereto as *Schedule H*. ImmunoGen bears full responsibility regarding quality, amount, and timing of supplies of Drug Product. ImmunoGen (i) shall notify BI Pharma in writing, not less than six (6) months prior to any proposed, foreseeable change in the Subcontractor and (ii) shall notify BI Pharma in writing as soon as possible of any unforeseeable change in the Subcontractor. However, in the case of a change in Subcontractor, start of manufacturing or control activities of Drug Product shall require the prior written permission of BI Pharma. ImmunoGen hereby assures that BI Pharma has the right to audit each of ImmunoGen?s Subcontractors, to be present during processing, if feasible, and that the Subcontractor is willing to enter into a separate quality agreement with ImmunoGen at BI Pharma?s option.



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, the Parties determine in good faith negotiations 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 provide BI Pharma with written notice within a reasonable time of such determination, along with the estimated price for such purchase and quality parameters for such Dedicated Equipment, in order to achieve BI Pharma's written approval of the same. The Parties shall evaluate jointly the costs of such Dedicated Equipment to determine whether the price to be paid for such Dedicated Equipment is reasonable to the Parties and whether such Dedicated Equipment could be procured at a lower cost. ImmunoGen shall provide BI Pharma with a likely list of Dedicated Equipment to define an upper limit of Dedicated Equipment costs, which will be necessary during the production of Drug Product (see *Schedule B*). 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 thirty (30) days 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 calculation of any Direct Cost 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.

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 **[ * ]** .



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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 ***Defective Product; Inspection and Rejection; Shortages.*** In the event that any Drug Product Batch after delivery to BI Pharma is detected to fail to comply with the Final Specifications, ImmunoGen shall, at its own cost (a) deliver replacement quantities of such Drug Product to BI Pharma or make up the shortage, as the case may be, **[ * ]**; or (b) if replacement is not possible despite ImmunoGen's **[ * ]**, at BI Pharma's discretion, either refund or credit BI Pharma's account for the amount paid for such Drug Product. ImmunoGen may analyze any Drug Product rejected for nonconformity. The foregoing does not apply if the cause of the defect is beyond the reasonable control of ImmunoGen. Moreover, the foregoing applies only if nonconformance is detected prior to the expiry date of the Drug Product Batch. BI Pharma shall bear the cost and responsibility for the replacement of defective product attributable to instability until such time as the Parties determine stability over six months from data generated with the first cGMP Drug Product Batch. Any dispute regarding defective product under this Section 6.3 shall be resolved in the same manner as provided for in Section 6.1.3.

6.4 ***Failed Batches.*** ImmunoGen shall bear the responsibility for a failed Batch Run if such failure is attributable to the negligence or misconduct of ImmunoGen. The foregoing notwithstanding, the Parties acknowledge that there may be Batch Run failures not attributable to either Party. Cost sharing of such failed batches shall take place according to the table in *Schedule C*, in which the success rate improves according to the number of batches produced.

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.

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 ***Inventory***. In an effort to mitigate the risk of having the supply of Drug Product affected by the unavailability of ansamitocin P3, BI Pharma and ImmunoGen hereby agree to use reasonable commercial efforts during the Term of this Agreement to acquire and maintain an inventory of DM1 in excess of the amounts required to manufacture the Drug Product listed on Schedule E of the License



Agreement, as it becomes available and to the extent it is not otherwise committed or allocated to any other party and can be procured under commercially reasonable terms and conditions (the "DM1 Inventory"). In connection therewith, ImmunoGen shall provide reasonable written notice to BI of the availability of such DM1 Inventory and the cost of obtaining such DM1 Inventory as well as the other material terms (if any) of such purchase and BI Pharma shall indicate to ImmunoGen whether it wishes ImmunoGen to obtain such DM1 Inventory on such terms. Subject to the foregoing, all costs associated with obtaining the amount of agreed upon DM1 Inventory shall be borne by BI Pharma. Upon any termination of this Agreement, ImmunoGen shall permit BI Pharma to remove all such DM1 Inventory from its Facility at BI Pharma's sole cost and expense, provided, that any reimbursement due by BI Pharma for such DM1 Inventory has been fully paid to ImmunoGen.

**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 thirty (30) days upon written notice of receipt of the Drug Product by BI Pharma and after receipt by BI Pharma of the respective invoice, detailing VAT separately if any. The invoice or an attachment thereto shall contain the agreed upon breakdown of Direct Costs as described in *Schedule D*. In case of failed batches that BI Pharma is obligated to pay for pursuant to *Schedule C*, payment shall be made within thirty (30) days of receipt of such invoice. Any invoices which remain unpaid more than thirty (30) days beyond the scheduled payment due date may be subjected to an interest charge at a rate of 1% per month (12% per annum), calculated from the scheduled payment due date forward.

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.

**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 be present during Batch Runs 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. ImmunoGen agrees to take adequate and reasonable corrective actions of audit findings of BI Pharma and will issue a formal written response to the audit report.

8.1.2. *Audit of Subcontractors.* ImmunoGen shall insure that Subcontractors' facilities can be inspected by BI Pharma for audit purposes in the same manner as described in Section 8.1.1 above.



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.

**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 by BI Pharma.*** This Agreement may be terminated with or without cause by BI Pharma by giving six (6) months prior written notice to ImmunoGen.

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 ninety (90) days 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 one hundred and eighty (180) days 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 sixty (60) days 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 sixty (60) days 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.

**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, at its expense, 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).

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.

(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 entered into the Key Materials Supply Agreements as listed on *Schedule E*, and (b) each of the Key Materials Supply Agreements is in full force and effect and constitutes a valid and binding obligation of ImmunoGen.

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.

(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.

**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 exclusively by German laws. 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.

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: | Draft Specifications for Drug Substance and Drug Product as provided by BI Pharma |
| Schedule B: | Likely List of Dedicated Equipment to define an upper limit of Dedicated Equipment costs, which will be necessary during the production of Drug Product (see Section 5.5) |
| Schedule C: | Table of Success Rates for Cost Sharing of Failed Batches |
| Schedule D: | Form of Invoice and Breakdown of Direct Cost |
| Schedule E: | List of Key Materials Supply Agreements |
| Schedule F: | Purchase Order BI Pharma |
| Schedule G: | Provision of Clinical Drug Product |
| Schedule H: | List of Subcontractors as of Effective Date |
| 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: _____

Authorized Signatories: A. Dehio Dr. H. Michelberger



**Schedule A**
**Draft Specifications**

**Testing of Drug Substance**

| Test | DRAFT specification |
|---|---|
| [ * ] | [ * ] |
| [ * ] | [ * ] |
| [ * ] | [ * ](1) |
| [ * ] | [ * ](1) |
| [ * ] | [ * ] |
| [ * ] | [ * ] |
| [ * ] | [ * ] |
| [ * ] | [ * ] |
| [ * ] | [ * ] |
| [ * ] | [ * ] |
| [ * ] | [ * ] |
| [ * ] | [ * ] |
| [ * ] | [ * ] |
| [ * ] | [ * ] |

(1) This would depend on the final formulation

**Testing of Drug Product**

| Test | DRAFT specification |
|---|---|
| [ * ] | [ * ] |
| [ * ] | [ * ] |
| [ * ] | [ * ](1) |
| [ * ] | [ * ](1) |
| [ * ] | [ * ] |
| [ * ] | [ * ] |
| [ * ] | [ * ] |
| [ * ] | [ * ] |
| [ * ] | [ * ] |
| [ * ] | [ * ] |
| [ * ] | [ * ] |
| [ * ] | [ * ] |
| [ * ] | [ * ] |
| [ * ] | [ * ] |

(1) This would depend on the final formulation



**Schedule B**

**Likely List of Dedicated Equipment for Clinical BIWI1 Manufacture**

**ULTRAFILTRATION/DIAFILTRATION**

1 **[ * ]** system **[ * ]** for ultra- and diafiltration of **[ * ]** up to **[ * ]** (including **[ * ]**, **[ * ]**, **[ * ]** and **[ * ]**) (**[ * ]**)

**[ * ]**

1 **[ * ]** system **[ * ]** for ultra- and diafiltration of **[ * ]** (including **[ * ]**, **[ * ]**, **[ * ]** and **[ * ]** )

**[ * ]**

**CHROMATOGRAPHY COLUMNS**

1 **[ * ]** column **[ * ]**

1 **[ * ]** column **[ * ]**

total **[ * ]** for **[ * ]**

1 **[ * ]** column **[ * ]**

1 **[ * ]** column **[ * ]**

**[ * ]** include required **[ * ]** (e.g. **[ * ]** and **[ * ]** ) and **[ * ]**.



**SCHEDULE C**

**Cost Sharing for Failed Batches**

Section 6.4 of the Agreement contemplates cost sharing by the Parties for certain Batch Run failures not attributable to either Party. The cost sharing of such failed batches shall take place in accordance with the table and description below.

| Successful Batch Runs | Success Rate |
|---|---|
| **[ * ]** | **[ * ]** |
| **[ * ]** | **[ * ]** |
| **[ * ]** | **[ * ]** |

***Batches [ * ]***

**[ * ]** represents the **[ * ]** of the **[ * ]** that result in **[ * ]** that meets **[ * ]** (a **[ * ]**). The Parties estimate that for the **[ * ]**, there may be up to **[ * ]** that result in **[ * ]** that fails to meet **[ * ]** (a **[ * ]**). Therefore, **[ * ]**, in total, **[ * ]** up to **[ * ]** to achieve the goal of **[ * ]**. **[ * ]** shall **[ * ]** with these **[ * ]**. In the event that **[ * ]** must **[ * ]**

than **[ * ]** to achieve the goal of **[ * ]**, **[ * ]** shall **[ * ]** with all **[ * ]**.

***Batches [ * ]***

The Parties estimate that for the **[ * ]** there may be up to three **[ * ]** that result in **[ * ]** that **[ * ]** to meet **[ * ]**. Therefore, **[ * ]**, in total, conduct up to **[ * ]** to achieve the goal of the **[ * ]**. **[ * ]** shall **[ * ]** with these **[ * ]**. In the event that **[ * ]** must **[ * ]** to achieve the goal of **[ * ]**, **[ * ]** shall **[ * ]** with **[ * ]**.

***Batches [ * ]***

For **[ * ]** of **[ * ]** (e.g. **[ * ]** ) there may be up to **[ * ]**. Therefore, **[ * ]**, in total, conduct up to **[ * ]** to achieve the goal of **[ * ]**. **[ * ]** shall **[ * ]** with these **[ * ]**. In the event that **[ * ]** must **[ * ]** than **[ * ]** to achieve the goal of **[ * ]**, **[ * ]** shall **[ * ]** with **[ * ]**.



## Schedule D

## Form of Invoice and Breakdown of Direct Cost

## Schedule E

## List of Key Materials Supply Agreements

(1) **For DM1, unpurified ansamitocin P3, and research maytansinol**
**[ * ]** Agreement between **[ * ]** (**[ * ]**) and ImmunoGen, Inc. dated **[ * ]**

Entered with:
**[ * ]**

(2) **For ansamitocin P3**
**[ * ]** for the **[ * ]**of **[ * ]** dated **[ * ]** and **[ * ]**

Entered with:
**[ * ]**



## Schedule F

## Purchase Order BI Pharma

## Schedule G

## Provision of Clinical Drug Product

| | Calendar Year | | | |
|---|---|---|---|---|
| | 2002 | 2003 | 2004 | 2005 |
| [ * ] | [ * ] | [ * ] | [ * ] | [ * ] |



## Schedule H

## List of Subcontractors as of Effective Date

**[ * ]**

**[ * ]**

**Schedule I**

**Template of Certificates of Analysis for Drug Substance and Drug Product**

***For Drug Substance:***

**CERTIFICATE OF ANALYSIS**

PRODUCT:

LOT NUMBER:

| TEST | RESULT |
|---|---|
| [ * ] | |
| [ * ] | |
| [ * ] | |
| [ * ] | |
| [ * ] | |
| [ * ] | |
| [ * ] | |
| [ * ] | |
| [ * ] | |
| [ * ] | |
| [ * ] | |
| [ * ] | |
| [ * ] | |
| [ * ] | |

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

QU Approval: _____ Date: _____



**For Drug Product:**

**CERTIFICATE OF ANALYSIS**

PRODUCT:

LOT NUMBER:

| TEST | RESULT |
|---|---|
| [ * ] | |
| [ * ] | |
| [ * ] | |
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| [ * ] | |

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

QU Approval: _____ Date: _____

QuickLinks