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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q**

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

For the quarterly period ended September 30, 2016

OR

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

For the transition period from            to

Commission file number 0-17999

**ImmunoGen, Inc.**

**Massachusetts**

(State or other jurisdiction of incorporation or  
organization)

**04-2726691**

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

**830 Winter Street, Waltham, MA 02451**

(Address of principal executive offices, including zip code)

**(781) 895-0600**

(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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).  Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).  Yes  No

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Shares of common stock, par value \$.01 per share: 87,301,341 shares outstanding as of October 27, 2016.

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**IMMUNOGEN, INC.**  
**FORM 10-Q**  
**FOR THE QUARTER ENDED SEPTEMBER 30, 2016**  
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**ITEM 1. Financial Statements**

**IMMUNOGEN, INC.**  
**CONSOLIDATED BALANCE SHEETS**  
**(UNAUDITED)**  
**In thousands, except per share amounts**

	<u>September 30,</u> <u>2016</u>	<u>June 30,</u> <u>2016</u>
<b>ASSETS</b>		
Cash and cash equivalents	\$ 196,000	\$ 245,026
Accounts receivable	316	883
Unbilled revenue	1,460	1,409
Inventory	2,027	907
Prepaid and other current assets	7,481	4,881
Total current assets	<u>207,284</u>	<u>253,106</u>
Property and equipment, net of accumulated depreciation	20,931	22,704
Other assets	3,133	3,430
Total assets	<u>\$ 231,348</u>	<u>\$ 279,240</u>
<b>LIABILITIES AND SHAREHOLDERS' DEFICIT</b>		
Accounts payable	\$ 8,973	\$ 11,510
Accrued compensation	6,746	10,724
Other accrued liabilities	10,018	9,713
Current portion of deferred lease incentive	784	772
Current portion of liability related to the sale of future royalties, net of deferred financing costs of \$981 and \$1,000, respectively	16,070	14,138
Current portion of deferred revenue	13,634	13,582
Total current liabilities	<u>56,225</u>	<u>60,439</u>
Deferred lease incentive, net of current portion	6,110	6,236
Deferred revenue, net of current portion	19,162	19,288
Convertible 4.5% senior notes, net of deferred financing costs of \$3,206 and \$3,372, respectively	96,794	96,628
Liability related to the sale of future royalties, net of current portion and deferred financing costs of \$3,237 and \$3,473, respectively	171,492	174,761
Other long-term liabilities	4,103	4,192
Total liabilities	<u>353,886</u>	<u>361,544</u>
Commitments and contingencies (Note H)		
Shareholders' deficit:		
Preferred stock, \$.01 par value; authorized 5,000 shares; no shares issued and outstanding	—	—
Common stock, \$.01 par value; authorized 150,000 shares; issued and outstanding 87,314 and 87,209 shares as of September 30, 2016 and June 30, 2016, respectively	873	872
Additional paid-in capital	775,007	770,511
Accumulated deficit	(898,418)	(853,687)
Total shareholders' deficit	<u>(122,538)</u>	<u>(82,304)</u>
Total liabilities and shareholders' deficit	<u>\$ 231,348</u>	<u>\$ 279,240</u>

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

**IMMUNOGEN, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**  
**(UNAUDITED)**

In thousands, except per share amounts

	Three Months Ended September 30,	
	2016	2015
Revenues:		
License and milestone fees	\$ 76	\$ 6,070
Non-cash royalty revenue related to the sale of future royalties	6,184	5,684
Research and development support	1,354	772
Clinical materials revenue	46	2,325
Total revenues	<u>7,660</u>	<u>14,851</u>
Operating Expenses:		
Research and development	32,909	35,132
General and administrative	9,459	8,329
Restructuring charge	4,130	—
Total operating expenses	<u>46,498</u>	<u>43,461</u>
Loss from operations	(38,838)	(28,610)
Investment income, net	146	51
Non-cash interest expense on liability related to the sale of future royalties and convertible senior notes	(5,018)	(5,143)
Interest expense on convertible senior notes	(1,150)	—
Other income (expense), net	129	(38)
Net loss	<u>\$ (44,731)</u>	<u>\$ (33,740)</u>
Basic and diluted net loss per common share	<u>\$ (0.51)</u>	<u>\$ (0.39)</u>
Basic and diluted weighted average common shares outstanding	<u>87,102</u>	<u>86,838</u>
Total comprehensive loss	<u>\$ (44,731)</u>	<u>\$ (33,740)</u>

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

**IMMUNOGEN, INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**(UNAUDITED)**

In thousands, except per share amounts

	Three Months Ended September 30,	
	2016	2015
Cash flows from operating activities:		
Net loss	\$ (44,731)	\$ (33,740)
Adjustments to reconcile net loss to net cash used for operating activities:		
Non-cash royalty revenue related to sale of future royalties	(6,184)	(5,684)
Non-cash interest expense on liability related to sale of future royalties	5,018	5,143
Depreciation and amortization	1,528	1,127
Loss (gain) on sale/disposal of fixed assets	—	(6)
Impairment charge related to restructuring	970	—
Stock and deferred share unit compensation	4,497	5,783
Deferred rent	63	29
Change in operating assets and liabilities:		
Accounts receivable	567	(1,724)
Unbilled revenue	(51)	(185)
Inventory	(1,120)	1,689
Prepaid and other current assets	(2,600)	95
Other assets	292	62
Accounts payable	(2,120)	1,551
Accrued compensation	(3,978)	(5,084)
Other accrued liabilities	38	(871)
Deferred revenue, net of non-cash upfront license payment	(74)	464
Proceeds from landlord for tenant improvements	41	—
Net cash used for operating activities	<u>(47,844)</u>	<u>(31,351)</u>
Cash flows from investing activities:		
Purchases of property and equipment, net	(1,182)	(3,377)
Net cash used for investing activities	<u>(1,182)</u>	<u>(3,377)</u>
Cash flows from financing activities:		
Proceeds from stock options exercised	—	4,462
Net cash provided by financing activities	<u>—</u>	<u>4,462</u>
Net change in cash and cash equivalents	(49,026)	(30,266)
Cash and cash equivalents, beginning of period	245,026	278,109
Cash and cash equivalents, end of period	<u>\$ 196,000</u>	<u>\$ 247,843</u>

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

**IMMUNOGEN, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**September 30, 2016**

**A. Nature of Business and Plan of Operations**

ImmunoGen, Inc. (the Company) was incorporated in Massachusetts in 1981 and is focused on the development of antibody-based anticancer therapeutics. The Company has incurred operating losses and negative cash flows from operations since inception, incurred a net loss of \$44.7 million during the three months ended September 30, 2016, and has an accumulated deficit of \$898.4 million as of September 30, 2016. The Company has primarily funded these losses through payments received from its collaborations and equity and convertible debt financings. To date, the Company has no product revenue and management expects operating losses to continue for the foreseeable future.

At September 30, 2016, the Company had \$196.0 million of cash and cash equivalents on hand. The Company anticipates that its current capital resources and expected future collaborator payments will enable it to meet its operational expenses and capital expenditures into the second quarter of calendar year 2018. Without such collaborator payments, it would last into the first quarter of calendar year 2018. The Company may raise additional funds through equity or debt financings or generate revenues from collaborative partners through a combination of upfront license payments, milestone payments, royalty payments, research funding, and clinical material reimbursement. There can be no assurance that the Company will be able to obtain additional debt or equity financing or generate revenues from collaborative partners on terms acceptable to the Company or at all. The failure of the Company to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on the Company's business, results of operations and financial condition and require the Company to defer or limit some or all of its research, development and/or clinical projects.

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, the development by its competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, manufacturing and marketing limitations, collaboration arrangements, third-party reimbursements and compliance with governmental regulations.

On June 15, 2016, the Company's Board of Directors approved a change in the Company's fiscal year from a fiscal year ending on the last day of June of each year to a calendar fiscal year ending on the last day of December of each year, effective January 1, 2017. Accordingly the Company will be issuing six month transitional financial statements as of December 31, 2016, and calendar year financial statements thereafter.

**B. Summary of Significant Accounting Policies**

*Basis of Presentation*

The accompanying unaudited consolidated financial statements at September 30, 2016 and June 30, 2016 and for the three months ended September 30, 2016 and 2015 include the accounts of ImmunoGen, Inc., or the Company, and its wholly owned subsidiaries, ImmunoGen Securities Corp., ImmunoGen Europe Limited and Hurricane, LLC. The consolidated financial statements 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 accounting principles generally accepted in the U.S. for interim financial information. The June 30, 2016 condensed consolidated balance sheet data presented for comparative purposes was derived from our audited financial statements but certain information and footnote disclosures normally included in the Company's annual financial statements have been condensed or omitted. Certain prior year amounts have been reclassified for consistency with the current period presentation. 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 periods. 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, 2016.

### *Subsequent Events*

The Company has evaluated all events or transactions that occurred after September 30, 2016 up through the date the Company issued these financial statements. The Company did not have any material recognizable or unrecognizable subsequent events during this period.

### *Related Party Transaction*

During fiscal year 2016, the Company entered into a transaction with Sanofi to purchase drug product along with the master and working cell banks for a product that Sanofi previously discontinued and had returned its rights back to the Company. The Company entered into this transaction, at a cost of €1.6 million, in order to continue development of the product, or make it more attractive to re-license the target to another partner. A relationship between an executive from the Company and an executive from Sanofi qualified this transaction as potentially between related parties, and accordingly, the audit committee of the Board of Directors of the Company approved the terms and conditions of the transaction, believing that it was in the best interest of the Company to proceed and that it was done at an arms-length amount. The transaction was substantially completed during fiscal year 2016; however, as of September 30, 2016, \$44,000 is classified as a prepaid expense and approximately \$258,000 more will be payable when a deliverable still pending from Sanofi is received.

### *Revenue Recognition*

The Company enters into licensing and development agreements with collaborative partners for the development of monoclonal antibody-based anticancer therapeutics. The terms of these agreements contain multiple deliverables which may include (i) licenses, or options to obtain licenses, to the Company's antibody-drug conjugate, or ADC, technology, (ii) rights to future technological improvements, (iii) research activities to be performed on behalf of the collaborative partner, (iv) delivery of cytotoxic agents and (v) the manufacture of preclinical or clinical materials for the collaborative partner.

Payments to the Company under these agreements may include upfront fees, option fees, exercise fees, payments for research activities, payments for the manufacture of preclinical or clinical materials, payments based upon the achievement of certain milestones and royalties on product sales. The Company follows the provisions of the Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Topic 605-25, "Revenue Recognition—Multiple-Element Arrangements," and ASC Topic 605-28, "Revenue Recognition-Milestone Method," in accounting for these agreements. In order to account for these agreements, the Company must identify the deliverables included within the agreement and evaluate which deliverables represent separate units of accounting based on if certain criteria are met, including whether the delivered element has stand-alone value to the collaborator. The consideration received is allocated among the separate units of accounting, and the applicable revenue recognition criteria are applied to each of the separate units.

At September 30, 2016, the Company had the following two types of agreements with the parties identified below:

- Development and commercialization licenses, which provide the party with the right to use the Company's ADC technology and/or certain other intellectual property to develop compounds to a specified antigen target:

Amgen (two exclusive single-target licenses <sup>(1)</sup>)

Bayer (one exclusive single-target license)

Biotest (one exclusive single-target license)

CytomX (one exclusive single-target license)

Lilly (three exclusive single-target licenses)

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(1) Amgen has sublicensed one of its exclusive single-target licenses to Oxford BioTherapeutics Ltd.

Novartis (five exclusive single-target licenses and one license to two related targets: one target on an exclusive basis and the second target on a non-exclusive basis)

Roche, through its Genentech unit (five exclusive single-target licenses)

Sanofi (one exclusive single-target license and one exclusive license to multiple individual targets)

Takeda, through its wholly owned subsidiary, Millennium Pharmaceuticals, Inc. (one exclusive single-target license)

- Research license/option agreement for a defined period of time to secure development and commercialization licenses to use the Company's ADC technology to develop anticancer compounds to specified targets on established terms (referred to herein as right-to-test agreements):

CytomX

Takeda

There are no performance, cancellation, termination or refund provisions in any of the arrangements that contain material financial consequences to the Company.

#### Development and Commercialization Licenses

The deliverables under a development and commercialization license agreement generally include the license to the Company's ADC technology with respect to a specified antigen target, and may also include deliverables related to rights to future technological improvements, research activities to be performed on behalf of the collaborative partner and the manufacture of preclinical or clinical materials for the collaborative partner.

Generally, development and commercialization licenses contain non-refundable terms for payments and, depending on the terms of the agreement, provide that the Company will (i) at the collaborator's request, provide research services at negotiated prices which are generally consistent with what other third parties would charge, (ii) at the collaborator's request, manufacture and provide to it preclinical and clinical materials or deliver cytotoxic agents at negotiated prices which are generally consistent with what other third parties would charge, (iii) earn payments upon the achievement of certain milestones and (iv) earn royalty payments, generally until the later of the last applicable patent expiration or 10 to 12 years after product launch. In the case of Kadcyła®, however, the minimum royalty term is 10 years and the maximum royalty term is 12 years on a country by country basis, regardless of patent protection. Royalty rates may vary over the royalty term depending on the Company's intellectual property rights and/or the presence of comparable competing products. The Company may provide technical assistance and share any technology improvements with its collaborators during the term of the collaboration agreements. The Company does not directly control when or whether any collaborator will request research or manufacturing services, achieve milestones or become liable for royalty payments. As a result, the Company cannot predict when or if it will recognize revenues in connection with any of the foregoing.

In determining the units of accounting, management evaluates whether the license has stand-alone value from the undelivered elements to the collaborative partner based on the consideration of the relevant facts and circumstances for each arrangement. Factors considered in this determination include the research capabilities of the partner and the availability of ADC technology research expertise in the general marketplace. If the Company concludes that the license has stand-alone value and therefore will be accounted for as a separate unit of accounting, the Company then determines the estimated selling prices of the license and all other units of accounting based on market conditions, similar arrangements entered into by third parties, and entity-specific factors such as the terms of the Company's previous collaborative agreements, recent preclinical and clinical testing results of therapeutic products that use the Company's ADC technology, the Company's pricing practices and pricing objectives, the likelihood that technological

improvements will be made, and, if made, will be used by the Company's collaborators and the nature of the research services to be performed on behalf of its collaborators and market rates for similar services.

Upfront payments on development and commercialization licenses may be recognized upon delivery of the license if facts and circumstances dictate that the license has stand-alone value from the undelivered elements, which generally include rights to future technological improvements, research services, delivery of cytotoxic agents and the manufacture of preclinical and clinical materials.

The Company recognizes revenue related to research services that represent separate units of accounting as they are performed, as long as there is persuasive evidence of an arrangement, the fee is fixed or determinable, and collection of the related receivable is probable. The Company recognizes revenue related to the rights to future technological improvements over the estimated term of the applicable license.

The Company may also provide cytotoxic agents to its collaborators or produce preclinical and clinical materials at negotiated prices which are generally consistent with what other third parties would charge. The Company recognizes revenue on cytotoxic agents and on preclinical and clinical materials when the materials have passed all quality testing required for collaborator acceptance and title and risk of loss have transferred to the collaborator. Arrangement consideration allocated to the manufacture of preclinical and clinical materials in a multiple-deliverable arrangement is below the Company's full cost, and the Company's full cost is not expected to ever be below its contract selling prices for its existing collaborations. During the three months ended September 30, 2015, the difference between the Company's full cost to manufacture preclinical and clinical materials on behalf of its collaborators as compared to total amounts received from collaborators for the manufacture of preclinical and clinical materials was \$7.0 million. There were no sales of manufactured preclinical or clinical materials during the three months ended September 30, 2016. The majority of the Company's costs to produce these preclinical and clinical materials are fixed and then allocated to each batch based on the number of batches produced during the period. Therefore, the Company's costs to produce these materials are significantly affected by the number of batches produced during the period. The volume of preclinical and clinical materials the Company produces is directly related to the number of clinical trials the Company and its collaborators are preparing for or currently have underway, the speed of enrollment in those trials, the dosage schedule of each clinical trial and the time period such trials last. Accordingly, the volume of preclinical and clinical materials produced, and therefore the Company's per-batch costs to manufacture these preclinical and clinical materials, may vary significantly from period to period.

The Company may also produce research material for potential collaborators under material transfer agreements. Additionally, the Company performs research activities, including developing antibody specific conjugation processes, on behalf of its collaborators and potential collaborators during the early evaluation and preclinical testing stages of drug development. The Company records amounts received for research materials produced or services performed as a component of research and development support revenue. The Company also develops conjugation processes for materials for later-stage testing and commercialization for certain collaborators. The Company is compensated at negotiated rates and may receive milestone payments for developing these processes which are recorded as a component of research and development support revenue.

The Company's development and commercialization license agreements have milestone payments which for reporting purposes are aggregated into three categories: (i) development milestones, (ii) regulatory milestones, and (iii) sales milestones. Development milestones are typically payable when a product candidate initiates or advances into different clinical trial phases. Regulatory milestones are typically payable upon submission for marketing approval with the U.S. Food and Drug Administration, or FDA, or other countries' regulatory authorities or on receipt of actual marketing approvals for the compound or for additional indications. Sales milestones are typically payable when annual sales reach certain levels.

At the inception of each agreement that includes milestone payments, the Company evaluates whether each milestone is substantive and at risk to both parties on the basis of the contingent nature of the milestone. This evaluation includes an assessment of whether (a) the consideration is commensurate with either (1) the entity's performance to achieve the milestone, or (2) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity's performance to achieve the milestone, (b) the consideration relates solely to past performance

and (c) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. The Company evaluates factors such as the scientific, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required to achieve the respective milestone and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this assessment.

Non-refundable development and regulatory milestones that are expected to be achieved partly as a result of the Company's efforts are considered substantive and are recognized as revenue upon the achievement of the milestone, assuming all other revenue recognition criteria are met. Milestones that are not considered substantive because the Company does not contribute effort to the achievement of such milestones are recognized as revenue upon achievement of the milestone, as there are no undelivered elements remaining and no continuing performance obligations, assuming all other revenue recognition criteria are met.

Under the Company's development and commercialization license agreements, the Company receives royalty payments based upon its licensees' net sales of covered products. Generally, under these agreements the Company is to receive royalty reports and payments from its licensees approximately one quarter in arrears, that is, generally in the third month of the quarter after the licensee has sold the royalty-bearing product or products. The Company recognizes royalty revenues when it can reliably estimate such amounts and collectability is reasonably assured. As such, the Company generally recognizes royalty revenues in the quarter reported to the Company by its licensees, or one quarter following the quarter in which sales by the Company's licensees occurred.

#### Right-to-Test Agreements

The Company's right-to-test agreements provide collaborators the right to (a) test the Company's ADC technology for a defined period of time through a research, or right-to-test, license, (b) take options, for a defined period of time, to specified targets and (c) upon exercise of those options, secure or "take" licenses to develop and commercialize products for the specified targets on established terms. Under these agreements, fees may be due to the Company (i) at the inception of the arrangement (referred to as "upfront" fees or payments), (ii) upon taking an option with respect to a specific target (referred to as option fees or payments earned, if any, when the option is "taken"), (iii) upon the exercise of a previously taken option to acquire a development and commercialization license(s) (referred to as exercise fees or payments earned, if any, when the development and commercialization license is "taken"), or (iv) some combination of all of these fees.

The accounting for right-to-test agreements is dependent on the nature of the options granted to the collaborative partner. Options are considered substantive if, at the inception of a right-to-test agreement, the Company is at risk as to whether the collaborative partner will choose to exercise the options to secure development and commercialization licenses. Factors that are considered in evaluating whether options are substantive include the overall objective of the arrangement, the benefit the collaborator might obtain from the agreement without exercising the options, the cost to exercise the options relative to the total upfront consideration, and the additional financial commitments or economic penalties imposed on the collaborator as a result of exercising the options. None of the Company's right-to-test agreements entered into subsequent to the adoption of Accounting Standards Update (ASU) No. 2009-13, "Revenue Arrangements with Multiple Deliverables" on July 1, 2010 has been determined to contain substantive options. For right-to-test agreements where the options to secure development and commercialization licenses to the Company's ADC technology are not considered substantive, the Company considers the development and commercialization licenses to be a deliverable at the inception of the agreement and applies the multiple-element revenue recognition criteria to determine the appropriate revenue recognition. Subsequent to the adoption of ASU No. 2009-13, the Company determined that its research licenses lack stand-alone value and are considered for aggregation with the other elements of the arrangement and accounted for as one unit of accounting.

The Company does not directly control when or if any collaborator will exercise its options for development and commercialization licenses. As a result, the Company cannot predict when or if it will recognize revenues in connection with any of the foregoing.

*Financial Instruments and Concentration of Credit Risk*

Cash and cash equivalents are primarily maintained with three financial institutions in the U.S. Deposits with banks may exceed the amount of insurance provided on such deposits. Generally, these deposits may be redeemed upon demand and, therefore, bear minimal risk. The Company's cash equivalents consist of money market funds with underlying investments primarily being U.S. Government issued securities and high quality, short term commercial paper. Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash, cash equivalents and marketable securities. The Company held no marketable securities as of September 30, 2016 and June 30, 2016. The Company's investment policy, approved by the Board of Directors, limits the amount it may invest in any one type of investment, thereby reducing credit risk concentrations.

*Cash and Cash Equivalents*

All highly liquid financial instruments with maturities of three months or less when purchased are considered cash equivalents. As of September 30, 2016 and June 30, 2016, the Company held \$196.0 million and \$245.0 million, respectively, in cash and money market funds consisting principally of U.S. Government-issued securities and high quality, short-term commercial paper which were classified as cash and cash equivalents.

*Non-cash Investing Activities*

The Company had approximately \$306,000 and \$804,000 of accrued capital expenditures as of September 30, 2016 and June 30, 2016, respectively, which have been treated as a non-cash investing activity and, accordingly, are not reflected in the consolidated statement of cash flows.

*Fair Value of Financial Instruments*

Fair value is defined under ASC Topic 820, "Fair Value Measurements and Disclosures," as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The standard describes a fair value hierarchy to measure fair value which is based on three levels of inputs, of which the first two are considered observable and the last unobservable, as follows:

- Level 1 - Quoted prices in active markets for identical assets or liabilities.
- Level 2 - Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

As of September 30, 2016, the Company held certain assets that are required to be measured at fair value on a recurring basis. The following table represents the fair value hierarchy for the Company's financial assets measured at fair value on a recurring basis as of September 30, 2016 (in thousands):

	<b>Fair Value Measurements at September 30, 2016 Using</b>			
	<b>Total</b>	<b>Quoted Prices in</b>		<b>Significant</b>
		<b>Active Markets for</b>	<b>Significant Other</b>	<b>Unobservable</b>
		<b>Identical Assets</b>	<b>Observable Inputs</b>	<b>Inputs</b>
	<b>(Level 1)</b>	<b>(Level 2)</b>	<b>(Level 3)</b>	
Cash equivalents	\$ 172,058	\$ 172,058	\$ —	\$ —

As of June 30, 2016, the Company held certain assets that are required to be measured at fair value on a recurring basis. The following table represents the fair value hierarchy for the Company's financial assets measured at fair value on a recurring basis as of June 30, 2016 (in thousands):

	Fair Value Measurements at June 30, 2016 Using			
	Total	Quoted Prices in Active Markets for Identical Assets	Significant Other Observable Inputs	Significant Unobservable Inputs
		(Level 1)	(Level 2)	(Level 3)
Cash equivalents	\$ 219,918	\$ 219,918	\$ —	\$ —

The fair value of the Company's cash equivalents is based on quoted prices from active markets.

The carrying amounts reflected in the consolidated balance sheets for accounts receivable, unbilled revenue, prepaid and other current assets, accounts payable, accrued compensation, and other accrued liabilities approximate fair value due to their short-term nature. The gross carrying amount and estimated fair value of the convertible 4.5% senior notes was \$100.0 million and \$85.0 million, respectively, as of September 30, 2016 compared to \$100.0 million and \$91.2 million, respectively, as of June 30, 2016. The fair value of the Convertible Notes is influenced by interest rates, the Company's stock price and stock price volatility and is determined by prices for the Convertible Notes observed in a market which is a Level 2 input for fair value purposes.

#### *Unbilled Revenue*

The majority of the Company's unbilled revenue at September 30, 2016 and June 30, 2016 represents research funding earned prior to those dates based on actual resources utilized under the Company's agreements with various collaborators.

#### *Inventory*

Inventory costs relate to clinical trial materials being manufactured for sale to the Company's collaborators. Inventory is stated at the lower of cost or market as determined on a first-in, first-out (FIFO) basis.

Inventory at September 30, 2016 and June 30, 2016 is summarized below (in thousands):

	September 30, 2016	June 30, 2016
Raw materials	\$ 191	\$ 317
Work in process	1,836	590
Total	\$ 2,027	\$ 907

Raw materials inventory consists entirely of proprietary cell-killing agents the Company developed as part of its ADC technology. All raw materials inventory is currently procured from two suppliers. The Company considers more than a twelve month supply of raw materials that is not supported by firm, fixed orders and/or projections from its collaborators to be excess and establishes a reserve to reduce to zero the value of any such excess raw material inventory with a corresponding charge to research and development expense. In accordance with this policy, the Company recorded no expense related to excess inventory in either the three months ended September 30, 2016 or three months ended September 30, 2015.

Work in process inventory consists of conjugate manufactured for sale to the Company's collaborators to be used in preclinical and clinical studies. All conjugate is made to order at the request of the collaborators and subject to the terms and conditions of respective supply agreements. Based on historical reprocessing or reimbursement required for conjugate that did not meet specification and status of current conjugate on hand, no reserve for work in process inventory was determined to be required at September 30, 2016. As discussed above, the Company's costs to manufacture conjugate on behalf of its partners are greater than the supply prices charged to partners, and therefore costs are capitalized into inventory at the supply prices.

### Computation of Net Loss per Common Share

Basic and diluted net loss per share is calculated based upon the weighted average number of common shares outstanding during the period. During periods of income, participating securities are allocated a proportional share of income determined by dividing total weighted average participating securities by the sum of the total weighted average common shares and participating securities (the “two-class method”). Shares of the Company’s restricted stock participate in any dividends declared by the Company and are therefore considered to be participating securities. Participating securities have the effect of diluting both basic and diluted earnings per share during periods of income. During periods of loss, no loss is allocated to participating securities since they have no contractual obligation to share in the losses of the Company. Diluted (loss) income per share is computed after giving consideration to the dilutive effect of stock options and restricted stock that are outstanding during the period, except where such non-participating securities would be anti-dilutive.

The Company’s common stock equivalents, as calculated in accordance with the treasury-stock method for the options and the if-converted method for the convertible notes, are shown in the following table (in thousands):

	<u>September 30,</u>	
	<u>2016</u>	<u>2015</u>
Options outstanding to purchase common stock and unvested restricted stock	14,929	11,494
Common stock equivalents under treasury stock method for options	3	1,296
Shares issuable upon conversion of convertible notes	23,878	—
Common stock equivalents under if-converted method for convertible notes	23,878	—

The Company’s common stock equivalents have not been included in the net loss per share calculation because their effect is anti-dilutive due to the Company’s net loss position.

### Stock-Based Compensation

As of September 30, 2016 the Company is authorized to grant future awards under one employee share-based compensation plan, which is the ImmunoGen, Inc. 2006 Employee, Director and Consultant Equity Incentive Plan, or the 2006 Plan. At the annual meeting of shareholders on November 11, 2014, an amendment to the 2006 Plan was approved and an additional 5,500,000 shares were authorized for issuance under this plan. As amended, the 2006 Plan provides for the issuance of Stock Grants, the grant of Options and the grant of Stock-Based Awards for up to 17,500,000 shares of the Company’s common stock, as well as 1,676,599 shares of common stock which represent awards granted under the previous stock option plan, the ImmunoGen, Inc. Restated Stock Option Plan, or the Former Plan, that were forfeited, expired or were cancelled without delivery of shares of common stock or which resulted in the forfeiture of shares of common stock back to the Company between November 11, 2006 and June 30, 2014. Option awards are granted with an exercise price equal to the market price of the Company’s stock at the date of grant. Options vest at various periods of up to four years and may be exercised within ten years of the date of grant.

The stock-based awards are accounted for under ASC Topic 718, “Compensation—Stock Compensation.” Pursuant to Topic 718, the estimated grant date fair value of awards is charged to the statement of operations and comprehensive loss over the requisite service period, which is the vesting period. Such amounts have been reduced by an estimate of forfeitures of all unvested awards. The fair value of each stock option is estimated on the date of grant using the Black-Scholes option-pricing model with the assumptions noted in the following table. As the Company has not paid dividends since inception, nor does it expect to pay any dividends for the foreseeable future, the expected dividend yield assumption is zero. Expected volatility is based exclusively on historical volatility data of the Company’s stock. The expected term of stock options granted is based exclusively on historical data and represents the period of time that stock options granted are expected to be outstanding. The expected term is calculated for and applied to one group of stock options as the Company does not expect substantially different exercise or post-vesting termination behavior among its option recipients. The risk-free rate of the stock options is based on the U.S. Treasury rate in effect at the time of grant for the expected term of the stock options.

	<u>Three Months Ended September 30,</u>	
	<u>2016</u>	<u>2015</u>
Dividend	None	None
Volatility	65.65 %	67.07 %
Risk-free interest rate	1.26 %	1.89 %
Expected life (years)	6.3	6.3

Using the Black-Scholes option-pricing model, the weighted average grant date fair values of options granted during the three months ended September 30, 2016 and 2015 were \$1.79 and \$10.31 per share, respectively.

A summary of option activity under the 2006 Plan as of September 30, 2016, and changes during the three month period then ended is presented below (in thousands, except weighted-average data):

	<b>Number of Stock Options</b>	<b>Weighted- Average Exercise Price</b>
Outstanding at June 30, 2016	11,813	\$ 13.03
Granted	3,341	\$ 2.95
Exercised	—	\$ 0.00
Forfeited/Canceled	(436)	\$ 10.41
Outstanding at September 30, 2016	<u>14,718</u>	<u>\$ 10.82</u>

Included in the outstanding options in the table above are approximately 762,000 stock options that will forfeit in the quarter ending December 31, 2016 in connection with the workforce reduction related to the restructuring event in the current period, the details of which are discussed further in Note G. Accordingly, the Company recorded an approximate \$837,000 credit to stock compensation expense in the current period related to these known future forfeitures.

In August 2016, the Company granted 117,800 shares of restricted common stock with a grant date fair value of \$3.15 to certain officers of the Company. These restrictions will lapse in three equal installments upon the achievement of specified performance goals within the next five years. The Company determined it is not currently probable that these performance goals will be achieved, and therefore, no expense has been recorded to date.

Stock compensation expense related to stock options and restricted stock awards granted under the 2006 Plan was \$4.4 million and \$5.7 million during the three months ended September 30, 2016 and 2015, respectively. The decrease in expense is primarily due to greater forfeitures recorded in the current period as discussed above. As of September 30, 2016, the estimated fair value of unvested employee awards was \$24.3 million, net of estimated forfeitures. The weighted-average remaining vesting period for these awards is approximately two years. Included in stock compensation expense for the three months ended September 30, 2016 and 2015 are \$108,000 and \$82,000, respectively, of expense recorded for directors' deferred share units, the details of which are discussed in Note F.

#### *Segment Information*

During the three months ended September 30, 2016, the Company continued to operate in one operating segment which is the business of discovery of monoclonal antibody-based anticancer therapeutics.

The percentages of revenues recognized from significant customers of the Company in the three months ended September 30, 2016 and 2015 are included in the following table:

Collaborative Partner:	Three Months Ended September 30,	
	2016	2015
Biotest	1 %	16 %
Lilly	1 %	35 %
Roche	81 %	38 %

There were no other customers of the Company with significant revenues in the three months ended September 30, 2016 and 2015.

#### *Recent Accounting Pronouncements*

In May 2014, the FASB issued ASU 2014-9, *Revenue from Contracts with Customers (Topic 606)* (“ASU 2014-09”), to clarify the principles for recognizing revenue. This update provides a comprehensive new revenue recognition model that requires revenue to be recognized in a manner to depict the transfer of goods or services to a customer at an amount that reflects the consideration expected to be received in exchange for those goods or services. In August 2015, the FASB issued ASU No. 2015-14, *Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date*, which delayed the effective date of the new standard from January 1, 2017 to January 1, 2018. The FASB also agreed to allow entities to choose to adopt the standard as of the original effective date. In March 2016, the FASB issued ASU No. 2016-08, *Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations*, which clarifies the implementation guidance on principal versus agent considerations. In April 2016, the FASB issued ASU No. 2016-10, *Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing*, which clarifies certain aspects of identifying performance obligations and licensing implementation guidance. In May 2016, the FASB issued ASU No. 2016-12, *Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients* related to disclosures of remaining performance obligations, as well as other amendments to guidance on collectibility, non-cash consideration and the presentation of sales and other similar taxes collected from customers. These standards have the same effective date and transition date of January 1, 2018. The new revenue standard allows for either full retrospective or modified retrospective application. The Company is currently evaluating the timing of its adoption, the transition method to apply and the impact that this guidance will have on its consolidated financial statements and related disclosures.

In August 2014, the FASB issued ASU 2014-15, *Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern*. This new standard gives a company’s management the final responsibilities to decide whether there’s substantial doubt about the company’s ability to continue as a going concern and to provide related footnote disclosures. The standard provides guidance to management, with principles and definitions that are intended to reduce diversity in the timing and content of disclosures that companies commonly provide in their footnotes. Under the new standard, management must decide whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the company’s ability to continue as a going concern within one year after the date that the financial statements are issued, or within one year after the date that the financial statements are available to be issued when applicable. This guidance is effective for annual reporting ending after December 15, 2016, and interim periods thereafter, with early application permitted. Accordingly, the standard is effective for the Company at December 31, 2016. The adoption of this guidance is not expected to have a material impact on the Company’s consolidated financial statements. Refer to Note A, Nature of Business and Plan of Operations for further discussion.

In April 2015, the FASB issued Accounting Standards Update 2015-03, *Interest-Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*. To simplify presentation of debt issuance costs, this new standard requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected by this update. This guidance is effective for annual reporting beginning after December 15, 2015, including interim periods within the year of adoption, and calls for

retrospective application, with early application permitted. The Company implemented the recommendations of this update, resulting in a reduction of prepaid and other current assets and non-current other assets of approximately \$1 million and \$6.8 million, respectively, as of June 30, 2016, with corresponding reductions of the debt liabilities as shown on the face of the accompanying consolidated balance sheet to the financial statements.

In July 2015, the FASB issued Accounting Standards Update 2015-11, *Simplifying the Measurement of Inventory* (Topic 330). To simplify the principles for subsequent measurement of inventory, this new standard requires inventory measured using any method other than LIFO or the retail method shall be measured at the lower of cost and net realizable value, rather than lower of cost or market. This guidance is effective for annual reporting beginning after December 15, 2016, including interim periods within the year of adoption, and calls for prospective application, with early application permitted. Accordingly, the standard is effective for the Company on January 1, 2017. The adoption of this guidance is not expected to have a material impact on the Company's consolidated financial statements.

In January 2016, the FASB issued Accounting Standards Update 2016-1, Recognition and Measurement of Financial Assets and Financial Liabilities (Topic 825). The amendments in this Update supersede the guidance to classify equity securities with readily determinable fair values into different categories (that is, trading or available-for-sale) and require equity securities (including other ownership interests, such as partnerships, unincorporated joint ventures, and limited liability companies) to be measured at fair value with changes in the fair value recognized through net income. The amendments allow equity investments that do not have readily determinable fair values to be remeasured at fair value either upon the occurrence of an observable price change or upon identification of an impairment. The amendments also require enhanced disclosures about those investments. The amendments improve financial reporting by providing relevant information about an entity's equity investments and reducing the number of items that are recognized in other comprehensive income. This guidance is effective for annual reporting beginning after December 15, 2017, including interim periods within the year of adoption, and calls for prospective application, with early application permitted. Accordingly, the standard is effective for the Company on January 1, 2018. The adoption of this guidance is not expected to have a material impact on the Company's consolidated financial statements.

In February 2016, the FASB issued Accounting Standards Update 2016-2, *Leases* (Topic 842) that primarily requires lessees to recognize most leases on their balance sheets but record expenses on their income statements in a manner similar to current accounting. For lessors, the guidance modifies the classification criteria and the accounting for sales-type and direct financing leases. The guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, with early adoption permitted. Accordingly, the standard is effective for the Company on January 1, 2019. The Company is currently evaluating the impact of this guidance on our financial statements and the timing of adoption.

In March 2016, the FASB issued ASU 2016-9, *Improvements to Employee Share-Based Payment Accounting* (Topic 718) that changes the accounting for certain aspects of share-based payments to employees. The guidance requires the recognition of the income tax effects of awards in the income statement when the awards vest or are settled, thus eliminating additional paid in capital pools. The guidance also allows for the employer to repurchase more of an employee's shares for tax withholding purposes without triggering liability accounting. In addition, the guidance allows for a policy election to account for forfeitures as they occur rather than on an estimated basis. The guidance is effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods with early adoption permitted. Accordingly, the standard is effective for the Company on January 1, 2017. The Company is currently evaluating the impact of this guidance on our financial statements and the timing of adoption.

## **C. Agreements**

### *Significant Collaborative Agreements*

#### *Roche*

In 2000, the Company granted Genentech, now a unit of Roche, an exclusive license to use the Company's maytansinoid ADC technology with antibodies, such as trastuzumab, or other proteins that target HER2. Under the terms of this agreement, Roche has exclusive worldwide rights to develop and commercialize maytansinoid ADC compounds targeting HER2. In 2013, the HER2-targeting ADC compound, Kadcyra, was approved for marketing in the U.S., Japan

and the European Union, or EU. Roche has also received marketing approval in various other countries around the world. Roche is responsible for the manufacturing, product development and marketing of any products resulting from the agreement. The Company received a \$2 million non-refundable upfront payment from Roche upon execution of the agreement. The Company is also entitled to receive up to a total of \$44 million in milestone payments, plus royalties on the commercial sales of Kadcyla or any other resulting products. Total milestones are categorized as follows: development milestones—\$13.5 million; and regulatory milestones—\$30.5 million. Through September 30, 2016, the Company has received and recognized \$13.5 million and \$20.5 million in development and regulatory milestone payments, respectively, related to Kadcyla. The next potential milestone the Company will be entitled to receive will be a \$5 million regulatory milestone for marketing approval of Kadcyla for a first extended indication as defined in the agreement. Based on an evaluation of the effort contributed towards the achievement of this future milestone, the Company determined this milestone is not substantive.

The Company receives royalty reports and payments related to sales of Kadcyla from Roche one quarter in arrears. In accordance with the Company's revenue recognition policy, \$6.2 million of non-cash royalties on net sales of Kadcyla for the three-month period ended June 30, 2016 were recorded and included in non-cash royalty revenue for the three-month period ended September 30, 2016 and \$5.7 million of non-cash royalties on net sales of Kadcyla for the three-month period ended June 30, 2015 is included in non-cash royalty revenue for the three-month period ended September 30, 2015. Kadcyla sales occurring after January 1, 2015 are covered by a royalty purchase agreement whereby the associated cash is remitted to Immunity Royalty Holdings, L.P, or IRH, as discussed further in Note E.

#### *Amgen*

Under a now-expired right-to-test agreement established in 2000, Amgen took three exclusive development and commercialization licenses, for which the Company received an exercise fee of \$1 million for each license taken. In May 2013, Amgen took one non-exclusive development and commercialization license, for which the Company received an exercise fee of \$500,000. In October 2013, the non-exclusive license was amended and converted to an exclusive license, for which Amgen paid an additional \$500,000 fee to the Company. Amgen has sublicensed its rights under this license to Oxford BioTherapeutics Ltd. In December 2015, Amgen advised the Company that it had discontinued development of two product candidates, AMG 595 and AMG 172 that had been covered by two of Amgen's four exclusive licenses, and in February 2016, Amgen terminated these two licenses.

For each of the two remaining development and commercialization license taken, the Company is entitled to receive up to a total of \$34 million in milestone payments, plus royalties on the commercial sales of any resulting products. The total milestones per license are categorized as follows: development milestones—\$9 million; regulatory milestones—\$20 million; and sales milestones—\$5 million. Amgen (or its sublicensee(s)) is responsible for the manufacturing, product development and marketing of any products resulting from these development and commercialization licenses. Through September 30, 2016, the Company has received and recognized an aggregate of \$3 million in milestone payments for compounds covered under this agreement now or in the past. In September 2015, Amgen's IND application under the remaining license not sublicensed to Oxford BioTherapeutics became effective, triggering a \$1 million milestone payment to the Company which is included in license and milestone fee revenue for the three month period ended September 30, 2015. The next potential milestone the Company will be entitled to receive under this license will be a development milestone for the first dosing of a patient in a Phase II clinical trial, which will result in a \$3 million payment being due. The next potential milestone the Company will be entitled to receive under the May 2013 license will be a \$1 million development milestone for an IND becoming effective. At the time of execution of each of these development and commercialization licenses, there was significant uncertainty as to whether these milestones would be achieved. In consideration of this, as well as the Company's past involvement in the research and manufacturing of these product candidates, these milestones were deemed substantive.

#### *Lilly*

Eli Lilly and Company (Lilly) took three exclusive development and commercialization licenses under a now-expired right-to-test agreement established in 2011. The Company received a \$20 million upfront payment in connection with the execution of the right-to-test agreement in 2011. Under the terms of this right-to-test agreement, the first license had no associated exercise fee, and the second and third licenses each had a \$2 million exercise fee. The first development and commercialization license was taken in August 2013 and the agreement was amended in December

2013 to provide Lilly with an extension provision and retrospectively include a \$2 million exercise fee for the first license in lieu of the fee due for either the second or third license. The second and third licenses were taken in December 2014, with one including the \$2 million exercise fee and the other not. Under the two licenses with the \$2 million exercise fee, the Company is entitled to receive up to a total of \$199 million in milestone payments, plus royalties on the commercial sales of any resulting products. Under the license taken in December 2014 without the exercise fee, the Company is entitled to receive up to a total of \$200.5 million in milestone payments, plus royalties on the commercial sales of any resulting products. The total milestones are categorized as follows: development milestones—\$29 million for the two development and commercialization licenses with the \$2 million exercise fee, and \$30.5 million for the one development and commercialization license with no exercise fee; regulatory milestones—\$70 million in all cases; and sales milestones—\$100 million in all cases. In September 2015, Lilly began Phase I evaluation of one of its licensed ADC products which triggered a \$5 million milestone payment to the Company which is included in license and milestone fee revenue for the three months ended September 30, 2015. The next payment the Company could receive would be either a \$9 million development milestone for commencement of a Phase II clinical trial under this license or a \$5 million development milestone payment with the initiation of a Phase I clinical trial under either of its other two development and commercialization licenses taken. At the time of execution of this agreement, there was significant uncertainty as to whether these milestones would be achieved. In consideration of this, as well as the Company's expected involvement in the research and manufacturing of these product candidates, these milestones were deemed substantive. The Company also is entitled to receive payments for delivery of cytotoxic agents to Lilly and research and development activities performed on behalf of Lilly. Lilly is responsible for the manufacturing, product development and marketing of any products resulting from this collaboration.

For additional information related to these agreements, as well as the Company's other significant collaborative agreements, please read Note C, *Agreements*, to our consolidated financial statements included within the Company's 2016 Form 10-K

#### **D. Convertible 4.5% Senior Notes**

In June 2016, the Company issued Convertible 4.5% Senior Notes with an aggregate principal amount of \$100 million. The Company received net proceeds of approximately \$96.6 million from the sale of the Convertible Notes, after deducting fees and expenses of approximately \$3.4 million.

The Convertible Notes are governed by the terms of an indenture between the Company, as issuer, and Wilmington Trust, National Association, as the trustee. The Convertible Notes are senior unsecured obligations and bear interest at a rate of 4.5% per year, payable semi-annually in arrears on January 1 and July 1 of each year, commencing on January 1, 2017. The Company recorded approximately \$1.2 million of interest expense in the three months ended September 30, 2016. The Convertible Notes will mature on July 1, 2021, unless earlier repurchased or converted. Holders may convert their notes at their option at any time prior to the close of business on the business day immediately preceding the stated maturity date. Upon conversion, the Company will deliver for each \$1,000 principal amount of converted notes a number of shares equally to the conversion rate, which will initially be 238.7775 shares of common stock, equivalent to an initial conversion price of approximately \$4.19. The conversion rate will be subject to adjustment in some circumstances, but will not be adjusted for any accrued and unpaid interest. In addition, if a "make-whole fundamental change" (as defined in the offering memorandum) occurs prior to the stated maturity date, the Company will increase the conversion rate for a holder who elects to convert its notes in connection with such make-whole fundamental change in certain circumstances. If the Company undergoes a fundamental change, subject to certain conditions, holders may require the Company to repurchase for cash all or part of their notes at a purchase price equal to 100% of the principal amount of the notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change purchase date. In addition, upon an event of default, the holders may require the Company to repurchase for cash all of their notes at a purchase price equal to 100% of the principal amount, plus accrued and unpaid interest. Upon bankruptcy, this becomes an automatic repurchase obligation. Also, if the Company fails to comply with certain reporting requirements as described in the indenture it will constitute an event of default, however the Company may elect to pay additional interest at an annual rate equal to 0.5% of the principal amount for the 90 days following such event as a remedy for the default. Subsequent to the 90 days, if still in default, the principal amount of the notes and accrued interest may become immediately due and payable. If a "restricted event" occurs as described in the indenture that causes the notes not to become freely tradable by holders other than our affiliates after the first anniversary of the original issuance date of the notes, the Company would also become obligated to pay additional interest at an annual rate

equal to 0.5% of the principal amount. The combined additional interest rate under these two circumstances, however, cannot exceed 0.5%.

The Company analyzed the terms of the Convertible Notes and determined that under current accounting guidance the notes would be entirely accounted for as debt and none of the terms of the notes require separate accounting. The accounting treatment will be re-assessed six months from the issuance date when the underlying shares become freely transferable and each subsequent reporting period thereafter. As part of the issuance of the Convertible Notes, the Company incurred \$3.4 million of transaction costs, which are netted against the Convertible Notes in the accompanying consolidated balance sheet and will be amortized to interest expense ratably over the term of the Convertible Notes.

#### **E. Liability Related to Sale of Future Royalties**

In April 2015, Immunity Royalty Holdings, L.P. (IRH) purchased the right to receive 100% of the royalty payments on commercial sales of Kadcyła subsequent to December 31, 2014, arising under the Company's development and commercialization license with Genentech (a unit of Roche), until IRH has received aggregate royalties equal to \$235 million or \$260 million, depending on when the aggregate royalties received by IRH reach a specified milestone. Once the applicable threshold is met, if ever, the Company will thereafter receive 85% and IRH will receive 15% of the Kadcyła royalties for the remaining royalty term. At consummation of the transaction in April 2015, the Company received cash proceeds of \$200 million. As part of this sale, the Company incurred \$5.9 million of transaction costs, which are presented net of the liability in the accompanying consolidated balance sheet and will be amortized to interest expense over the estimated life of the royalty purchase agreement. Although the Company sold its rights to receive royalties from the sales of Kadcyła, as a result of its ongoing involvement in the cash flows related to these royalties, the Company will continue to account for these royalties as revenue and recorded the \$200 million in proceeds from this transaction as a liability related to sale of future royalties (Royalty Obligation) that will be amortized using the interest method over the estimated life of the royalty purchase agreement.

The following table shows the activity within the liability account during the three-month period ended September 30, 2016 (in thousands):

	<b>Period from June 30, 2016 to September 30, 2016</b>
Liability related to sale of future royalties, net — beginning balance	\$ 188,899
Non-cash Kadcyła royalty revenue	(6,184)
Non-cash interest expense recognized	4,847
Liability related to sale of future royalties, net — ending balance	<u>\$ 187,562</u>

As royalties are remitted to IRH, the balance of the Royalty Obligation will be effectively repaid over the life of the agreement. Through September 30, 2016, \$37.0 million in cumulative royalty payments have been received from Roche and paid to IRH. In order to determine the amortization of the Royalty Obligation, the Company is required to estimate the total amount of future royalty payments to be received and remitted to IRH as noted above over the life of the agreement. The sum of these amounts less the \$200 million proceeds the Company received will be recorded as interest expense over the life of the Royalty Obligation. Since inception, the Company's estimate of this total interest expense resulted in an effective annual interest rate of 9.6%. The Company periodically assesses the estimated royalty payments to IRH and to the extent such payments are greater or less than its initial estimates, or the timing of such payments is materially different than its original estimates, the Company will prospectively adjust the amortization of the Royalty Obligation. There are a number of factors that could materially affect the amount and timing of royalty payments from Genentech, most of which are not within the Company's control. Such factors include, but are not limited to, changing standards of care, the introduction of competing products, manufacturing or other delays, biosimilar competition, patent protection, adverse events that result in governmental health authority imposed restrictions on the use of the drug products, significant changes in foreign exchange rates as the royalties remitted to IRH are made in U.S. dollars (USD) while significant portions of the underlying sales of Kadcyła are made in currencies other than USD, and other events or circumstances that could result in reduced royalty payments from Kadcyła, all of which would result in a

reduction of non-cash royalty revenues and the non-cash interest expense over the life of the Royalty Obligation. Conversely, if sales of Kadcyła are more than expected, the non-cash royalty revenues and the non-cash interest expense recorded by the Company would be greater over the term of the Royalty Obligation.

In addition, the royalty purchase agreement grants IRH the right to receive certain reports and other information relating to the royalties and contains other representations and warranties, covenants and indemnification obligations that are customary for a transaction of this nature.

## **F. Capital Stock**

### *2001 Non-Employee Director Stock Plan*

During the three months ended September 30, 2016, the Company recorded approximately (\$3,000) in expense reduction related to stock units outstanding under the Company's 2001 Non-Employee Director Stock Plan, or the 2001 Plan, compared to (\$30,000) in expense reduction recorded during the three months ended September 30, 2015. The value of the stock units are classified as a liability and adjusted to market value at each reporting period as the redemption amount of stock units for this plan will be paid in cash. No stock units have been issued under the 2001 Plan subsequent to June 30, 2004.

### *Compensation Policy for Non-Employee Directors*

On November 12, 2013, the Board amended the Compensation Policy for Non-Employee Directors to make certain changes to the compensation of its non-employee directors, including an increase in the fees paid in cash to the non-employee directors. Under the terms of the amended policy, the redemption amount of deferred share units issued will continue to be paid in shares of common stock of the Company on the date a director ceases to be a member of the Board. Annual retainers vest quarterly over approximately one year from the date of grant, contingent upon the individual remaining a director of ImmunoGen as of each vesting date. The number of deferred share units awarded is now fixed per the plan on the date of the award and is no longer based on the market price of the Company's common stock on the date of the award. All unvested deferred stock awards will automatically vest immediately prior to the occurrence of a change of control.

In addition to the deferred share units, the Non-Employee Directors are also entitled to receive a fixed number of stock options determined using the Black-Scholes option pricing model measured on the date of grant, which would be the date of the annual meeting of shareholders. These options vest quarterly over approximately one year from the date of grant. Any new directors will receive a pro-rated award, depending on their date of election to the Board. The directors received a total of 80,000 stock options in November of 2015 and 2014, respectively, and the related compensation expense for the three months ended September 30, 2016 and 2015 is included in the amounts discussed in the "Stock-Based Compensation" section of footnote B above.

During the three months ended September 30, 2016, the Company recorded approximately \$108,000 in compensation expense, respectively, related to deferred share units issued and outstanding under the Company's Compensation Policy for Non-Employee Directors, compared to \$82,000 in compensation expense recorded during the three months ended September 30, 2015.

## **G. Restructuring Charge**

On September 26, 2016, the Board of Directors approved a plan to reengineer the business, resulting in a reduction of the workforce by approximately 17%, or 65 positions, which included the separation of 60 current employees. Communication of the plan to the impacted employees was substantially completed on September 29, 2016. All of the workforce reduction is expected to be completed during the quarter ending December 31, 2016. As a result of the workforce reduction, in the current period, the Company recorded a restructuring charge totaling \$3.1 million related to termination benefits and other related charges, of which \$2.5 million was recorded as a one-time termination benefit, and \$593,000 recorded as a benefit under an ongoing benefit plan. An additional one-time termination charge of approximately \$257,000 is anticipated to be recorded in the quarter ending December 31, 2016. No cash payments were

made during the current period. The related cash payments will begin to be paid out in October 2016 and will be substantially paid out by June 30, 2017. Additionally, approximately 762,000 stock options will forfeit in the quarter ending December 31, 2016 in connection with the workforce reduction, and as a result, the Company recorded an approximate \$837,000 credit to stock compensation expense related to these known future forfeitures which is included in research and development expense and general and administrative expense for the current period.

In addition to the termination benefits and other related charges, the Company will seek to sub-lease 10,281 square feet of unoccupied office space in Waltham that was leased in February 2016. Based on an estimate of the potential time it will take to find a tenant of approximately nine months, the anticipated sub-lease terms, and consideration of the tenant allowance that was given to the Company to build out the space, the Company determined it did not need to record a loss on the sub-lease. The Company then evaluated the balance of the leasehold improvements for potential impairment as of September 30, 2016. In performing the recoverability test, the Company concluded that a substantial portion of the leasehold improvements were not recoverable. The Company recorded an impairment charge of \$970,000 related to these assets after comparing the fair value (using probability weighted scenarios with discounted cash flows) to the leasehold improvements' carrying value, leaving a remaining cost basis of \$193,000 as of September 30, 2016.

In September 2016, the Compensation Committee of the Board of Directors approved cash and stock option retention incentive awards for certain remaining eligible employees who continue employment with the Company in order to execute the Company's strategic priorities. The cash awards will be payable to these employees in either October 2017 or March 2018 based on continued employment and services performed during these periods. Stock option awards covering 847,000 shares were granted and will vest annually in equal installments over three years from the date of grant and are included in the option summary table within the "Stock-Based Compensation" section of Note B above.

## **H. Commitments and Contingencies**

### *Leases*

The Company currently has a lease agreement with CRP/King 830 Winter L.L.C. for the rental of approximately 110,000 square feet of laboratory and office space at 830 Winter Street, Waltham, MA through March 2026. The Company uses this space for its corporate headquarters and other operations. The Company may extend the lease for two additional terms of five years. Pursuant to lease amendments executed in December 2013, April 2014, and December 2015, the Company received construction allowances of approximately \$746,000, \$1.1 million, and \$186,000, respectively, to build out office and lab space to the Company's specifications. The Company is required to pay certain operating expenses for the leased premises subject to escalation charges for certain expense increases over a base amount.

In February 2016, the Company entered into a lease agreement with PDM 930 Unit, LLC for the rental of 10,281 square feet of additional office space at 930 Winter Street, Waltham, MA through August 31, 2021. The Company received approximately \$617,000 as a construction allowance to build out the office space to the Company's specifications. The Company is required to pay certain operating expenses for the leased premises based on its pro-rata share of such expenses for the entire rentable space of the building. As noted above, the Company will seek to sub-lease this currently unoccupied office space that is no longer required due to the restructuring completed in the current period.

The Company also leases manufacturing and office space at 333 Providence Highway, Norwood, MA under an agreement through 2018 with an option to extend the lease for an additional term of five years. The Company is required to pay certain operating expenses for the leased premises subject to escalation charges for certain expense increases over a base amount.

Effective April 2013, the Company entered into a lease agreement with River Ridge Limited Partnership for the rental of 7,507 square feet of additional office space at 100 River Ridge Drive, Norwood, MA. The initial term of the lease is for five years and two months commencing in July 2013 with an option for the Company to extend the lease for an additional term of five years. The Company is required to pay certain operating expenses for the leased premises subject to escalation charges for certain expense increases over a base amount. The Company entered into a sublease in December 2014 for this space, effective from January 2015 through July 2018.

The minimum rental commitments for the Company's facilities, including real estate taxes and other expenses, for the next five fiscal years and thereafter under the non-cancelable operating lease agreements discussed above are as follows (in thousands):

2017 (nine months remaining)	\$ 5,955
2018	8,056
2019	7,258
2020	7,254
2021	7,302
Thereafter	34,252
Total minimum lease payments	\$ 70,077
Total minimum rental income from subleases	(220)
Total minimum lease payments, net	<u>\$ 69,857</u>

There are no obligations under capital leases as of September 30, 2016, as all of the capital leases were single payment obligations which have all been made.

#### *Collaborations*

The Company is contractually obligated to make potential future success-based development, regulatory or sales milestone payments in conjunction with certain collaborative agreements. These payments are contingent upon the occurrence of certain future events and, given the nature of these events, it is unclear when, if ever, the Company may be required to pay such amounts. Further, the timing of any future payment is not reasonably estimable. As of September 30, 2016, the maximum amount that may be payable in the future under the Company's current collaborative agreements is \$162 million, \$1.4 million of which is reimbursable by a third party under a separate agreement.

In addition, The Company is party to a license agreement covering the manufacture of the antibodies used in certain of product candidates which, under certain circumstances, requires periodic payments once the product reaches a specified stage of clinical development, and royalties on commercial sales of the product. The Company believes that the license agreement, by its terms, does not obligate it to make any further payments thereunder and accordingly, has not accrued a potential payment of £300,000 for one of its product candidates that has reached this stage.

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

### OVERVIEW

ImmunoGen is a clinical-stage biotechnology company that develops targeted cancer therapeutics using our proprietary antibody-drug conjugate, or ADC, technology. An ADC with our technology comprises an antibody that binds to a target found on tumor cells conjugated to one of our potent anti-cancer agents as a "payload" to kill the tumor cell once the ADC has bound to its target. ADCs are an expanding approach to the treatment of cancer, with two approved products and the number of agents in development more than doubling during the last five years.

We have established a leadership position in ADCs. Our technology is deployed in Roche's Kadcyla® (ado-trastuzumab emtansine), the first ADC to demonstrate superiority over standard of care in a randomized pivotal trial, EMILIA, and gain FDA approval. Following Kadcyla are 12 clinical-stage ADCs with our technology: four wholly owned by us and eight through our partnerships with Amgen, Bayer, Biotest, Lilly, Novartis, and Sanofi.

Our proprietary portfolio is led by mirvetuximab soravtansine, a first-in-class ADC targeting folate-receptor alpha, or FR $\alpha$ . Following a meeting with the U.S. Food and Drug Administration, or FDA, in July 2016, we are initiating a Phase 3 registration trial, FORWARD I, with mirvetuximab soravtansine for use as single-agent therapy to treat patients with platinum-resistant ovarian cancer whose tumors express high or medium levels of FR $\alpha$  and who have received up to three prior treatment regimens. Additionally, we are accruing patients in a companion study, FORWARD II, to evaluate mirvetuximab soravtansine in combination regimens to expand the number of patients with ovarian cancer eligible for treatment with the ADC. FORWARD II consists of cohorts assessing mirvetuximab soravtansine in combination with, in separate doublets, Avastin® (bevacizumab), pegylated liposomal doxorubicin, or PLD, and carboplatin. We have also entered into a collaboration with Merck under which Merck will provide Keytruda® (pembrolizumab) for evaluation in combination with mirvetuximab soravtansine as part of the FORWARD II study. We expect to begin reporting clinical findings from FORWARD II in the second quarter of 2017.

We have built a productive platform that continues to generate innovative and proprietary ADCs, including IMG779, our CD33-targeting product candidate for acute myeloid leukemia, or AML. IMG779 integrates one of our new DNA-alkylating IGN payload agents and is progressing through dose escalation in a Phase 1 trial in AML. We also are advancing IMG632, a preclinical CD123-targeting ADC that uses an even more potent IGN payload agent with a new engineered linker and novel antibody, which we are developing for hematological malignancies including AML.

In addition to fueling our organic growth, we also selectively license limited rights to use of our ADC technology to other companies. These licenses can provide us with cash through upfront and milestone payments, research and manufacturing support payments, and royalties on commercial sales, if any, as well as access to complementary technology and capabilities. The most advanced partner program is Roche's marketed product, Kadcyla.

In addition to the discussion below for agreements with activity in the periods presented, details for all of our significant agreements can be found in our 2016 Annual Report on Form 10-K.

*Roche*—In May 2000, we granted Genentech, now a unit of Roche, an exclusive license to use our maytansinoid ADC technology with antibodies, such as trastuzumab, or other proteins that target HER2. Pursuant to this agreement, Roche developed and received marketing approval for its HER2-targeting ADC compound, Kadcyla, in the U.S., Europe, Japan and numerous other countries. We receive royalty reports and payments related to sales of Kadcyla from Roche one quarter in arrears. In accordance with our revenue recognition policy, \$6.2 million of non-cash royalties on net sales of Kadcyla for the three-month period ended June 30, 2016 were recorded and included in non-cash royalty revenue for the three months ended September 30, 2016 and \$5.7 million of non-cash royalties on net sales of Kadcyla for the three-month period ended June 30, 2015 were included in non-cash royalty revenue for the three months ended September 30, 2015. Kadcyla sales occurring after January 1, 2015 are covered by a royalty purchase agreement whereby the associated cash is remitted to Immunity Royalty Holdings, L.P. or IRH, as discussed further in Note E to the consolidated financial statements.

*Amgen*— Under a now-expired right-to-test agreement, in December 2012, Amgen took an exclusive development and commercialization license. The Company is entitled to receive up to a total of \$34 million in milestone payments, plus royalties on the commercial sales of any resulting products from this license. The total milestones are categorized as follows: development milestones—\$9 million; regulatory milestones—\$20 million; and sales milestones—\$5 million. In September 2015, the IND application for its ADC product candidate under this license became effective, triggering a \$1 million milestone payment to us which is included in license and milestone fee revenue for the three months ended September 30, 2015.

*Lilly*— Under a now-expired right-to-test agreement executed in December 2011, Lilly has taken three exclusive development and commercialization licenses. We received a \$20 million upfront payment in connection with the execution of the right-to-test agreement, and for the first development and commercialization license taken in August 2013 and amended in December 2013, we received an exercise fee in the amount of \$2 million and are entitled to receive up to a total of \$199 million in milestone payments, plus royalties on the commercial sales of any resulting products. The second and third exclusive licenses were taken in December 2014, one of which we received an exercise fee in the amount of \$2 million and are entitled to receive up to a total of \$199 million in milestone payments, plus royalties on the commercial sales of any resulting products. For the third license taken in December 2014, for which we did not receive an exercise fee, we are entitled to receive up to a total of \$200.5 million in milestone payments, plus royalties on the commercial sales of any resulting products. The total milestones are categorized as follows: development milestones—\$29 million for the two development and commercialization licenses with the \$2 million exercise fee, and \$30.5 million for the one development and commercialization license with no exercise fee; regulatory milestones—\$70 million in all cases; and sales milestones—\$100 million in all cases. In September 2015, Lilly began Phase I evaluation of one of their potential products which triggered a \$5 million milestone payment to us which is included in license and milestone fee revenue for the three months ended September 30, 2015.

To date, we have not generated revenues from commercial sales of internal products and we expect to incur significant operating losses for the foreseeable future. As of September 30, 2016, we had approximately \$196 million in cash and cash equivalents compared to \$245 million in cash and cash equivalents as of June 30, 2016.

We anticipate that future cash expenditures will be partially offset by collaboration-derived proceeds, including milestone payments and upfront fees. Accordingly, period-to-period operational results may fluctuate dramatically based upon the timing of receipt of the proceeds. We believe that our established collaborative agreements, while subject to specified milestone achievements, will provide funding to assist us in meeting obligations under our collaborative agreements while also assisting in providing funding for the development of internal product candidates and technologies. However, we can give no assurances that such collaborative agreement funding will, in fact, be realized in the time frames we expect, or at all. Should we or our partners not meet some or all of the terms and conditions of our various collaboration agreements, we may be required to secure alternative financing arrangements, find additional partners and/or defer or limit some or all of our research, development and/or clinical projects. However, we cannot provide assurance that any such opportunities presented by additional partners or alternative financing arrangements will be entirely available to us, if at all.

#### *Critical Accounting Policies*

We prepare our consolidated financial statements in accordance with accounting principles generally accepted in the U.S. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates, including those related to our collaborative agreements, clinical trial accruals, inventory and stock-based compensation. We base our estimates on historical experience and various other assumptions that we believe to be reasonable under the circumstances. Actual results may differ from these estimates.

During the current period, the Board of Directors approved a plan to reengineer the business, resulting in a restructuring event, the related accounting of which is discussed further under the Results of Operation. There were no other significant changes to our critical accounting policies from those disclosed in our Annual Report on Form 10-K for the fiscal year ended June 30, 2016.

**RESULTS OF OPERATIONS****Comparison of Three Months ended September 30, 2016 and 2015***Revenues*

Our total revenues for the three months ended September 30, 2016 and 2015 were \$7.7 million and \$14.9 million, respectively. The \$7.2 million decrease in revenues in the three months ended September 30, 2016 from the same period in the prior year is attributable to decreases in license and milestone fees and clinical materials revenue, partially offset by increases in non-cash royalty revenue and research and development support revenue, all of which are discussed below.

Revenues from license and milestone fees for the three months ended September 30, 2016 decreased \$6.0 million to \$76,000 from \$6.1 million in the same period ended September 30, 2015. Included in license and milestone fees for the three months ended September 30, 2015 is a \$5 million development milestone achieved under a license agreement with Lilly and a \$1 million development milestone achieved under a license agreement with Amgen. There were no milestones achieved during the three month period ended September 30, 2016. The amount of license and milestone fees we earn is directly related to the number of our collaborators, the collaborators' advancement of the product candidates, and the overall success in the clinical trials of the product candidates. As such, the amount of license and milestone fees may vary significantly from quarter to quarter and year to year. Total revenue from license and milestone fees recognized from each of our collaborative partners in the three-month periods ended September 30, 2016 and 2015 is included in the following table (in thousands):

License and Milestone Fees	Three Months Ended September 30,	
	2016	2015
Collaborative Partner:		
Amgen	\$ 4	\$ 1,004
Biotest	—	6
Lilly	6	5,006
Novartis	45	45
Sanofi	—	9
Takeda	21	—
Total	<u>\$ 76</u>	<u>\$ 6,070</u>

Deferred revenue of \$32.8 million as of September 30, 2016 primarily represents consideration received from our collaborators pursuant to our license agreements, which we have yet to earn pursuant to our revenue recognition policy. Included within this amount is \$13 million of non-cash consideration recorded in connection with our arrangement with CytomX during fiscal 2014.

Kadcyla is an ADC marketed product resulting from one of our development and commercialization licenses with Roche, through its Genentech unit. We receive royalty reports and payments related to sales of Kadcyla from Roche one quarter in arrears. In accordance with our revenue recognition policy, \$6.2 million of non-cash royalties on net sales of Kadcyla for the three-month period ended June 30, 2016 were recorded and included in revenue for the three months ended September 30, 2016 and \$5.7 million of royalties on net sales of Kadcyla for the three-month period ended June 30, 2015 is included in revenue for the three months ended September 30, 2015. In April 2015, we consummated a royalty purchase transaction — see Liquidity and Capital Resources below for further details.

Research and development support revenue was \$1.4 million for the three months ended September 30, 2016 compared with \$772,000 for the three months ended September 30, 2015. These amounts primarily represent research funding earned based on actual resources utilized under our agreements with our collaborators shown in the table below. Also included in research and development support revenue are fees for developing antibody-specific conjugation

processes on behalf of our collaborators and potential collaborators during the early evaluation and preclinical testing stages of drug development. The amount of research and development support revenue we earn is directly related to the number of our collaborators and potential collaborators, the stage of development of our collaborators' product candidates and the resources our collaborators allocate to the development effort. As such, the amount of research and development support revenue may vary widely from quarter to quarter and year to year. Total revenue recognized from research and development support from each of our collaborative partners in the three-month periods ended September 30, 2016 and 2015 is included in the following table (in thousands):

<b>Research and Development Support</b>	<b>Three Months Ended</b>	
	<b>September 30,</b>	
	<b>2016</b>	<b>2015</b>
<b>Collaborative Partner:</b>		
Amgen	\$ —	\$ 30
Biotest	38	151
CytomX	587	19
Lilly	61	155
Novartis	15	31
Takeda	639	384
Other	14	2
<b>Total</b>	<b>\$ 1,354</b>	<b>\$ 772</b>

Clinical materials revenue was \$46,000 for the three months ended September 30, 2016 compared with \$2.3 million for the three months ended September 30, 2015. We are compensated at negotiated prices which are generally consistent with what other third-parties would charge. The amount of clinical materials revenue we earn, and the related cost of clinical materials charged to research and development expense, is directly related to the number of clinical trials our collaborators who use us to manufacture clinical materials are preparing or have underway, the speed of enrollment in those trials, the dosage schedule of each clinical trial and the time period, if any, during which patients in the trial receive clinical benefit from the clinical materials, and the demand our collaborators have for clinical-grade material for process development and analytical purposes. As such, the amount of clinical materials revenue and the related cost of clinical materials charged to research and development expense may vary significantly from quarter to quarter and year to year.

#### *Research and Development Expenses*

Our research and development expenses relate to (i) research to evaluate new targets and to develop and evaluate new antibodies, linkers and cytotoxic agents, (ii) preclinical testing of our own and, in certain instances, our collaborators' product candidates, and the cost of our own clinical trials, (iii) development related to clinical and commercial manufacturing processes and (iv) manufacturing operations expense which also includes raw materials.

Research and development expense for the three months ended September 30, 2016 decreased \$2.2 million to \$32.9 million from \$35.1 million for the three months ended September 30, 2015. A more detailed discussion of research and development expense in the period follows.

We do not track our research and development costs by project. Since we use our research and development resources across multiple research and development projects, we manage our research and development expenses within each of the categories listed in the following table and described in more detail below (in thousands):

Research and Development Expense	Three Months Ended September 30,	
	2016	2015
Research	\$ 6,273	\$ 5,940
Preclinical and Clinical Testing	14,294	15,498
Process and Product Development	3,757	2,693
Manufacturing Operations	8,585	11,001
Total Research and Development Expense	\$ 32,909	\$ 35,132

*Research:* Research includes expenses primarily associated with activities to identify and evaluate new targets and to develop and evaluate new antibodies, linkers and cytotoxic agents for our products and in support of our collaborators. Such expenses primarily include personnel, contract services, research licensing fees, facilities and lab supplies. Research expenses for the three months ended September 30, 2016 increased \$333,000 compared to the three months ended September 30, 2015. This increase is principally due to an increase in salaries and related expenses driven primarily by increases in personnel from hiring during fiscal year 2016 and an increase in depreciation expense driven by new lab space built out in fiscal 2016.

*Preclinical and Clinical Testing:* Preclinical and clinical testing includes expenses related to preclinical testing of our own and, in certain instances, our collaborators' product candidates, regulatory activities, and the cost of our own clinical trials. Such expenses include personnel, patient enrollment at our clinical testing sites, consultant fees, contract services, and facility expenses. Preclinical and clinical testing expenses for the three months ended September 30, 2016 decreased \$1.2 million to \$14.3 million compared to \$15.5 million for the three months ended September 30, 2015. This decrease is primarily the result of a decrease in contract service expense driven primarily by timing of certain activities related to mirvetuximab ravtansine, partially offset by an increase in clinical trial costs driven by increased activities related to our mirvetuximab soravtansine, IMGN529 combination and IMGN779 studies. Additionally, salaries and related expenses also increased due primarily to increases in personnel from hiring during fiscal year 2016.

*Process and Product Development:* Process and product development expenses include costs for development of clinical and commercial manufacturing processes for our own and collaborator compounds. Such expenses include the costs of personnel, contract services and facility expenses. For the three months ended September 30, 2016, total development expenses increased \$1.1 million compared to the three months ended September 30, 2015. This increase is principally due to an increase in salaries and related expenses driven primarily by increases in personnel from hiring during fiscal year 2016 and an increase in contract services driven by increased development activities related to our IGX cytotoxic agents.

*Manufacturing Operations:* Manufacturing operations expense includes costs to manufacture preclinical and clinical materials for our own and our collaborator's product candidates, and quality control and quality assurance activities and costs to support the operation and maintenance of our conjugate manufacturing facility. Such expenses include personnel, raw materials for our and our collaborators' preclinical studies and clinical trials, development costs with contract manufacturing organizations, manufacturing supplies, and facilities expense. For the three months ended September 30, 2016, manufacturing operations expense decreased \$2.4 million to \$8.6 million compared to \$11.0 million in the same period last year. This decrease is principally the result of a decrease in cost of clinical materials revenue charged to research and development expense due to timing of orders of such clinical materials from our partners and an increase in costs capitalized into inventory due to a greater number of manufactured batches of conjugated materials on behalf of our collaborators in the period. Partially offsetting these decreases, third-party fill/finish costs increased driven primarily by timing of certain scale-up activities related to the mirvetuximab soravtansine program.

### *General and Administrative Expenses*

General and administrative expenses for the three months ended September 30, 2016 increased \$1.1 million compared to the same period last year. This increase is primarily due to an increase in professional fees driven by reengineering consulting services in the current period.

### *Restructuring Charge*

On September 26, 2016, the Board of Directors approved a plan to reengineer the business, resulting in a reduction of the workforce by approximately 17%, or 65 positions, which included the separation of 60 current employees. Communication of the plan to the impacted employees was substantially completed on September 29, 2016. All of the workforce reduction is expected to be completed during the quarter ending December 31, 2016. As a result of the workforce reduction, in the current period, we recorded a restructuring charge totaling \$3.1 million related to termination benefits and other related charges, of which \$2.5 million was recorded as a one-time termination benefit, and \$593,000 recorded as a benefit under an ongoing benefit plan. An additional one-time termination charge of approximately \$257,000 is anticipated to be recorded in the quarter ending December 31, 2016. No cash payments were made during the current period. The related cash payments will begin to be paid out in October 2016 and will be substantially paid out by June 30, 2017. Additionally, approximately 762,000 stock options will forfeit in the quarter ending December 31, 2016 in connection with the workforce reduction, and as a result, we recorded an approximate \$837,000 credit to stock compensation expense related to these known future forfeitures which is included in research and development expense and general and administrative expense for the current period.

In addition to the termination benefits and other related charges, the Company will seek to sub-lease 10,281 square feet of unoccupied office space in Waltham that was leased in February 2016. Based on an estimate of the potential time it will take to find a tenant of approximately six months, the anticipated sub-lease terms, and consideration of the tenant allowance that was given to us to build out the space, we determined it did not need to record a loss on the sub-lease. We then evaluated the balance of the leasehold improvements for potential impairment as of September 30, 2016. In performing the recoverability test, we concluded that a substantial portion of the leasehold improvements were not recoverable. We recorded an impairment charge of \$970,000 related to these assets after comparing the fair value (using probability weighted scenarios with discounted cash flows) to the leasehold improvements' carrying value, leaving a remaining cost basis of \$193,000 as of September 30, 2016.

In September 2016, the Compensation Committee of the Board of Directors approved cash and stock option retention incentive awards for certain remaining eligible employees who continue employment with the Company in order to execute the Company's strategic priorities. The cash awards will be payable to these employees in either October 2017 or March 2018 based on continued employment and services performed during these periods. Stock option awards covering 847,000 shares were granted and will vest annually in equal installments over three years from the date of grant and are included in the option summary table within the "Stock-Based Compensation" section of Note B to our Consolidated Financial Statements.

### *Investment Income, net*

Investment income for the three months ended September 30, 2016 and 2015 was \$146,000 and \$51,000, respectively. The increase in the current period is due to a greater average cash balance driven by the proceeds received in the fourth quarter of fiscal 2016 resulting from the senior convertible notes issuance, which is discussed further in Note D to our Consolidated Financial Statements.

### *Non-Cash Interest Expense on Liability Related to Sale of Future Royalty*

In April 2015, Immunity Royalty Holdings, L.P. (IRH) purchased our right to receive 100% of the royalty payments on commercial sales of Kadcyla subsequent to March 31, 2014, arising under our development and commercialization license with Genentech, until IRH has received aggregate royalties equal to \$235 million or \$260 million, depending on when the aggregate royalties received by IRH reach a specified milestone. As described in Note E to our Consolidated Financial Statements, this royalty sale transaction has been recorded as a liability that amortizes over

the estimated royalty payment period as Kadcyła royalties are remitted directly to the purchaser. During the three months ended September 30, 2016, we recorded \$4.8 million of non-cash interest expense which includes amortization of deferred financing costs. We impute interest on the transaction and record interest expense at the effective interest rate, which we currently estimate to be 9.5%. There are a number of factors that could materially affect the estimated interest rate, in particular, the amount and timing of royalty payments from future net sales of Kadcyła, and we will assess this estimate on a periodic basis. As a result, future interest rates could differ significantly and any such change in interest rate will be adjusted prospectively.

#### *Interest Expense on Convertible Senior Notes*

In June 2016, the Company issued Convertible 4.5% Senior Notes with an aggregate principal amount of \$100 million. The Convertible Notes are senior unsecured obligations and bear interest at a rate of 4.5% per year, payable semi-annually in arrears on January 1 and July 1 of each year, commencing on January 1, 2017. The Company recorded approximately \$1.2 million of interest expense in the three months ended September 30, 2016.

#### *Other Income (Expense), net*

Other income (expense), net for the three months ended September 30, 2016 and 2015 was \$129,000 and \$38,000, respectively. We incurred \$129,000 and \$(44,000) in foreign currency exchange gains (losses) related to obligations with non-U.S. dollar-based suppliers and Euro cash balances maintained to fulfill them during the three months ended September 30, 2016 and 2015, respectively.

## LIQUIDITY AND CAPITAL RESOURCES

	September 30, 2016	June 30, 2016
	(In thousands)	
Cash and cash equivalents	\$ 196,000	\$ 245,026
Working capital	151,059	192,667
Shareholders' (deficit) equity	(122,538)	(82,304)

  

	Three Months Ended September 30,	
	2016	2015
	(In thousand)	
Cash used for operating activities	\$ (47,844)	\$ (31,351)
Cash used for investing activities	(1,182)	(3,377)
Cash provided by financing activities	—	4,462

#### *Cash Flows*

We require cash to fund our operating expenses, including the advancement of our own clinical programs, and to make capital expenditures. Historically, we have funded our cash requirements primarily through equity financings in public markets, payments from our collaborators, including license fees, milestones, research funding, royalties, and more recently, convertible debt. We have also sold our rights to receive royalties on Kadcyła for up-front consideration. As of September 30, 2016, we had approximately \$196.0 million in cash and cash equivalents. Net cash used for operations was \$47.8 million and \$31.4 million for the three months ended September 30, 2016 and 2015, respectively. The principal use of cash for operating activities for both periods presented was to fund our net loss.

Net cash used for investing activities was \$1.2 million and \$3.4 million for the three months ended September 30, 2016 and 2015, respectively, and represents cash outflows for capital expenditures, primarily for the purchase of new equipment and leasehold improvements.

Net cash provided by financing activities was \$4.5 million for the three months ended September 30, 2015, which represents proceeds from the exercise of approximately 402,000 stock options. There were no stock option exercises in the three months ended September 30, 2016 due to a decline in the Company's stock price.

As discussed above, in April 2015, Immunity Royalty Holdings, L.P. purchased our right to receive 100% of the royalty payments on commercial sales of Kadcyła. At consummation of the transaction in April 2015, we received gross cash proceeds of \$200 million. We recorded these cash proceeds as a deferred royalty obligation liability which is being amortized over the expected royalty recovery period. As part of this transaction, the Company incurred approximately \$5.9 million in transaction costs.

The Company anticipates that its current capital resources and expected future collaborator payments will enable it to meet its operational expenses and capital expenditures into the second quarter of calendar year 2018. Without such collaborator payments, it would last into the first quarter of calendar year 2018. However, we cannot provide assurance that such future collaborative agreement funding will, in fact, be received. Should we or our partners not meet some or all of the terms and conditions of our various collaboration agreements, we may be required to pursue additional strategic partners, secure alternative financing arrangements, and/or defer or limit some or all of our research, development and/or clinical projects. Such strategic partner transactions and alternative financing arrangements may not be available when required or may not be available on favorable terms. See Note A of the consolidated financial statements for further discussion.

#### *Contractual Obligations*

There have been no material changes to our contractual obligations during the current period from those disclosed in our Annual Report on Form 10-K for the fiscal year ended June 30, 2016.

#### *Change in Fiscal Year*

On June 15, 2016, the Company's Board of Directors approved a change in our fiscal year from a fiscal year ending on the last day of June of each year to a calendar fiscal year ending on the last day of December of each year, effective January 1, 2017. Accordingly we will be issuing six month transitional financial statements as of December 31, 2016, and calendar year financial statements thereafter.

#### *Recent Accounting Pronouncements*

In May 2014, the FASB issued ASU 2014-9, *Revenue from Contracts with Customers (Topic 606)* ("ASU 2014-09"), to clarify the principles for recognizing revenue. This update provides a comprehensive new revenue recognition model that requires revenue to be recognized in a manner to depict the transfer of goods or services to a customer at an amount that reflects the consideration expected to be received in exchange for those goods or services. In August 2015, the FASB issued ASU No. 2015-14, *Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date*, which delayed the effective date of the new standard from January 1, 2017 to January 1, 2018. The FASB also agreed to allow entities to choose to adopt the standard as of the original effective date. In March 2016, the FASB issued ASU No. 2016-08, *Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations*, which clarifies the implementation guidance on principal versus agent considerations. In April 2016, the FASB issued ASU No. 2016-10, *Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing*, which clarifies certain aspects of identifying performance obligations and licensing implementation guidance. In May 2016, the FASB issued ASU No. 2016-12, *Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients* related to disclosures of remaining performance obligations, as well as other amendments to guidance on collectibility, non-cash consideration and the presentation of sales and other similar taxes collected from customers. These standards have the same effective date and transition date of January 1, 2018. The new revenue standard allows for either full retrospective or modified retrospective application. We are currently evaluating the timing of its adoption, the transition method to apply and the impact that this guidance will have on its consolidated financial statements and related disclosures.

In August 2014, the FASB issued Accounting Standards Update 2014-15, *Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going*

*Concern.* This new standard gives a company's management the final responsibilities to decide whether there's substantial doubt about the company's ability to continue as a going concern and to provide related footnote disclosures. The standard provides guidance to management, with principles and definitions that are intended to reduce diversity in the timing and content of disclosures that companies commonly provide in their footnotes. Under the new standard, management must decide whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the company's ability to continue as a going concern within one year after the date that the financial statements are issued, or within one year after the date that the financial statements are available to be issued when applicable. This guidance is effective for annual reporting ending after December 15, 2016, and interim periods thereafter, with early application permitted. Accordingly, the standard is effective for us at December 31, 2016. The adoption of this guidance is not expected to have a material impact on our consolidated financial statements. Refer to Note A, Nature of Business and Plan of Operations, of our consolidated financial statements for further discussion.

In April 2015, the FASB issued Accounting Standards Update 2015-03, Interest-Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs. To simplify presentation of debt issuance costs, this new standard requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected by this update. This guidance is effective for annual reporting beginning after December 15, 2015, including interim periods within the year of adoption, and calls for retrospective application, with early application permitted. We implemented the recommendations of this update, resulting in a reduction of prepaid and other current assets and non-current other assets of approximately \$1 million and \$6.8 million, respectively, as of June 30, 2016, with corresponding reductions of the debt liabilities as shown on the face of the accompanying consolidated balance sheet to the financial statements.

In January 2016, the FASB issued Accounting Standards Update 2016-1, *Recognition and Measurement of Financial Assets and Financial Liabilities (Topic 825)*. The amendments in this Update supersede the guidance to classify equity securities with readily determinable fair values into different categories (that is, trading or available-for-sale) and require equity securities (including other ownership interests, such as partnerships, unincorporated joint ventures, and limited liability companies) to be measured at fair value with changes in the fair value recognized through net income. The amendments allow equity investments that do not have readily determinable fair values to be remeasured at fair value either upon the occurrence of an observable price change or upon identification of an impairment. The amendments also require enhanced disclosures about those investments. The amendments improve financial reporting by providing relevant information about an entity's equity investments and reducing the number of items that are recognized in other comprehensive income. This guidance is effective for annual reporting beginning after December 15, 2017, including interim periods within the year of adoption, and calls for prospective application, with early application permitted. Accordingly, the standard is effective for us on January 1, 2018. The adoption of this guidance is not expected to have a material impact on our consolidated financial statements.

In February 2016, the FASB issued Accounting Standards Update 2016-2, *Leases (Topic 842)* that primarily requires lessees to recognize most leases on their balance sheets but record expenses on their income statements in a manner similar to current accounting. For lessors, the guidance modifies the classification criteria and the accounting for sales-type and direct financing leases. The guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, with early adoption permitted. Accordingly, the standard is effective for us on January 1, 2019. We are currently evaluating the impact of this guidance on our financial statements and the timing of adoption.

In March 2016, the FASB issued Accounting Standards Update 2016-9, *Improvements to Employee Share-Based Payment Accounting (Topic 718)* that changes the accounting for certain aspects of share-based payments to employees. The guidance requires the recognition of the income tax effects of awards in the income statement when the awards vest or are settled, thus eliminating additional paid in capital pools. The guidance also allows for the employer to repurchase more of an employee's shares for tax withholding purposes without triggering liability accounting. In addition, the guidance allows for a policy election to account for forfeitures as they occur rather than on an estimated basis. The guidance is effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods with early adoption permitted. Accordingly, the standard is effective for us on January 1, 2017. We are currently evaluating the impact of this guidance on our financial statements.

### *Forward-Looking Statements*

This quarterly report includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements relate to analyses and other information which are based on forecasts of future results and estimates of amounts that are not yet determinable. These statements also relate to our future prospects, developments and business strategies.

These forward-looking statements can be identified by their use of terms and phrases, such as “anticipate,” “believe,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “will” and other similar terms and phrases, including references to assumptions. They may also use words such as “will,” “would,” “should,” “could” or “may”. These forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from those contemplated by our forward-looking statements. These known and unknown risks, uncertainties and other factors are described in detail in the “Risk Factors” section and in other sections of this Annual Report on Form 10-K for the year ended June 30, 2016. We disclaim any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

*Avastin®*, *Kadcyla®* and *Keytruda®* are registered trademarks of their respective owners  
*Probody™* is a trademark of CytomX Therapeutics, Inc.

### **OFF-BALANCE SHEET ARRANGEMENTS**

None.

### **ITEM 3. Quantitative and Qualitative Disclosure about Market Risk**

Our market risks, and the ways we manage them, are summarized in Part II, Item 7A, “Quantitative and Qualitative Disclosures About Market Risk” of our Annual Report on Form 10-K for the fiscal year ended June 30, 2016. Since then there have been no material changes to our market risks or to our management of such risks.

### **ITEM 4. Controls and Procedures**

#### *(a) Disclosure Controls and Procedures*

The Company’s management, with the participation of its principal executive officer and principal financial officer, has evaluated the effectiveness of the Company’s disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”)) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on such evaluation, the Company’s principal executive officer and principal financial officer have concluded that, as of the end of such period, the Company’s disclosure controls and procedures were adequate and effective.

#### *(b) Changes in Internal Controls*

There have not been any changes in the Company’s internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended September 30, 2016 that have materially affected, or are reasonably likely to materially affect, the Company’s internal control over financial reporting.

## **PART II. OTHER INFORMATION**

### **ITEM 1A. Risk Factors**

You should carefully review and consider the information regarding certain factors that could materially affect our business, financial condition or future results set forth under Item 1A. (Risk Factors) in our Annual Report on Form 10-K for the fiscal year ended June 30, 2016. There have been no material changes from the factors disclosed in our 2016

Annual Report on Form 10-K, although we may disclose changes to such factors or disclose additional factors from time to time in our future filings with the Securities and Exchange Commission.

**ITEM 6. Exhibits**

<u>Exhibit No.</u>	<u>Description</u>
10.1*	Collaborative Development and License Agreement dated as of July 7, 2006, and Amendment No. 1 thereto dated August 23, 2006, by and between the Registrant and Biotest AG
10.2	Compensation Policy for Non-Employee Directors, as amended through September 14, 2016
31.1	Certification of Principal Executive Officer under Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Principal Financial Officer under Section 302 of the Sarbanes-Oxley Act of 2002
32†	Certifications of Principal Executive Officer and Principal Financial Officer under Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Linkbase
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase

\* Portions of this Exhibit were omitted, as indicated by [\*\*\*], and have been filed separately with the Secretary of the Commission pursuant to the Registrant's application requesting confidential treatment.

† Furnished, not filed.

**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: November 4, 2016

By: /s/Mark J. Enyedy  
Mark J. Enyedy  
President, Chief Executive Officer (Principal Executive Officer)

Date: November 4, 2016

By: /s/ David B. Johnston  
David B. Johnston  
Executive Vice President, Chief Financial Officer  
(Principal Financial and Accounting Officer)

**COLLABORATIVE DEVELOPMENT AND LICENSE AGREEMENT**

**by and between**

**IMMUNOGEN, INC.**

**and**

**BIOTEST AG**

**July 7, 2006**

Portions of this Exhibit were omitted and have been filed separately with the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934.

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#### List of Schedules

Schedule 1	Calculation of Net Income
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## COLLABORATIVE DEVELOPMENT AND LICENSE AGREEMENT

This COLLABORATIVE DEVELOPMENT AND LICENSE AGREEMENT (this "Agreement") is entered into as of July 7, 2006 (the "Effective Date"), by and between ImmunoGen, Inc., a Massachusetts corporation with its principal place of business at 128 Sidney Street, Cambridge, Massachusetts, USA 02139 ("ImmunoGen") and Biotest AG, a corporation organized under the laws of Germany having an address of Landsteinerstraße 5, D-63303 Dreieich, Germany ("Biotest"). Each of Biotest and ImmunoGen is sometimes referred to individually herein as a "Party" and collectively as the "Parties."

WHEREAS, Biotest Controls certain Technology and/or Proprietary Materials related to its proprietary CD138 Antibodies (as defined below); and

WHEREAS, ImmunoGen Controls certain Technology and/or Proprietary Materials related to or otherwise useful in the conjugation of maytansine derivatives to binding proteins; and

WHEREAS, ImmunoGen and Biotest desire to enter into a collaboration for the purpose of Developing and Commercializing Licensed Products derived from the conjugation of Biotest's proprietary CD138 Antibodies with ImmunoGen's maytansine derivatives.

NOW, THEREFORE, in consideration of the mutual covenants contained herein, and for other good and valuable consideration, the Parties hereto, intending to be legally bound, hereby agree as follows:

### 1. DEFINITIONS

Whenever used in this Agreement with an initial capital letter, the terms defined in this Section 1 shall have the meanings specified.

1.1 "**Adverse Event**" means any untoward medical occurrence in a human clinical trial subject or in a patient who is administered a Licensed Product, whether or not having a causal relationship with such Licensed Product, including, without limitation, any unfavorable and unintended sign (including for example, any abnormal laboratory findings of clinical concern), symptom or disease temporarily associated with the use of such Licensed Product.

1.2 "**Affiliate**" means, with respect to any Party, any Person that, directly or through one or more Affiliates, controls, or is controlled by, or is under common control with, such Party. For purposes of this definition, "control" means (a) ownership of more than fifty percent (50%) of the shares of stock entitled to vote for the election of directors, in the case of a corporation, or more than fifty percent (50%) of the equity interests in the case of any other type of legal entity, (b) status as a general partner in any partnership, or (c) any other arrangement whereby a Person controls or has the right to control the Board of Directors or equivalent governing body of a corporation or other entity.

1.3 "**Annual Net Sales**" means the aggregate Net Sales during a particular Calendar Year.

1.4 "**Antibody**" means a composition comprising a whole antibody or fragment thereof (whether polyclonal or monoclonal, human, humanized, chimeric or murine, or derived from

another relevant species, multiple or single chain, recombinant, transgenic animal derived or naturally occurring, and any constructs thereof) or having been derived from nucleotide sequences encoding, or amino acid sequences of, such antibody or fragment.

1.5 “**Anti-CD138 Antibody**” means any Antibody (including without limitation the BT-062 Antibody) that is Controlled by Biotest and that targets the CD138 Antigen.

1.6 “**Anti-CD138 Antibody-MAY Conjugate**” means any conjugate of an Anti- CD138 Antibody with a MAY Compound.

1.7 “**Applicable Laws**” means all Federal, state, local, national and supra-national laws, statutes, rules and regulations, including any rules, regulations, guidelines or requirements of Regulatory Authorities, national securities exchanges or securities listing organizations that may be in effect from time to time during the Term and applicable to a particular activity hereunder.

1.8 “**Audited Party**” means the Party that is the subject of an audit by the other Party under Sections 5.1.4, 5.2.2, 6.2.1 or 6.4.3.

1.9 “**Auditing Party**” means the Party that is conducting an audit of the other Party under Sections 5.1.4, 5.2.2, 6.2.1 or 6.4.3.

1.10 “**Biotest Background Technology**” means any Technology used by Biotest, or provided by Biotest for use, in the Research Program and/or the Development of Licensed Products that is useful in the Field and that is (a) Controlled by Biotest as of the Effective Date or (b) developed or conceived or first reduced to practice by employees of, or consultants to, Biotest after the Effective Date in the conduct of activities outside the Research Program and/or the Development of Licensed Products and without the use in any respect of any ImmunoGen Technology or ImmunoGen Materials or any Program Inventions. For purposes of clarity, Biotest Background Technology shall include, without limitation, any know-how and/or Confidential Information and/or intellectual property relating to Biotest's BT-062 Antibody.

1.11 “**Biotest Co-Promotion Percentage**” means fifty percent (50%) of the Annual Net Income.

1.12 “**Biotest Decision**” means the following decisions which, in the event of deadlock, will be decided by a Biotest member of the JSC: (a) with respect to each Licensed Product that is not a Co-Developed Product, the determination of the indication(s), other than as defined in the initial Development Plan, for which such Licensed Product shall be used, and (b) all decisions with respect to the Development and Commercialization of Co-Developed Products outside the Co-Development Territory.-

1.13 “**Biotest Materials**” means any Proprietary Materials Controlled by Biotest and used by Biotest, or provided by Biotest for use, in the Research Program and/or the Development of Licensed Products. For purposes of clarity, Biotest Material shall include, without limitation, the BT-062 Antibody.

1.14 **“Biotest Patent Rights”** means any Patent Rights containing one or more claims that cover Biotest Technology. For purposes of clarity, Biotest Patent Rights include Biotest’s fifty percent (50%) interest in the CD138 Conjugate Patent Rights.

1.15 **“Biotest Product”** means any Licensed Product that is not a Co-Developed Product.

1.16 **“Biotest Program Technology”** means any Program Invention conceived or first reduced to practice by employees of, or consultants to, Biotest, alone or jointly with Third Parties, without the use in any respect of any ImmunoGen Technology, ImmunoGen Materials or Joint Technology.

1.17 **“Biotest Technology”** means, collectively, Biotest Background Technology and Biotest Program Technology.

1.18 **“Biotest Territory”** means all countries of the world other than the Co-Development Territory.

1.19 **“BT-062 Antibody”** means the chimeric Antibody targeting the CD138 Antigen Controlled by Biotest.

1.20 **“Calendar Quarter”** means the period beginning on the Effective Date and ending on the last day of the calendar quarter in which the Effective Date falls, and thereafter each successive period of three (3) consecutive calendar months ending on March 31, June 30, September 30 or December 31.

1.21 **“Calendar Year”** means each successive period of twelve (12) months commencing on January 1 and ending on December 31.

1.22 **“CD138 Antigen”** means the transmembrane [\*\*\*] [\*\*\*] [\*\*\*] CD138 antigen (aka [\*\*\*]), having the Swiss-Prot primary accession number [\*\*\*].

1.23 **“CD138 Conjugate Patent Rights”** means the Patent Rights that relate to United States Patent Application [\*\*\*] entitled [\*\*\*].

1.24 **“Clinical Materials”** shall mean any MAY Compound or Licensed Product supplied by ImmunoGen to Biotest pursuant to Section 4.5.2(b)(iii) and/or the terms of a Supply Agreement for any use, including for use in any Clinical Trials other than Pivotal Clinical Trials. For the purpose of clarity, Clinical Material shall not comprise unconjugated Antibody.

1.25 **“Clinical Trial Notification” or “CTN”** means the notification submitted to the Japanese Ministry of Health, Labor and Welfare prior to the Initiation of a Clinical Trial in Japan.

1.26 **“Co-Developed Product”** means any Licensed Product with respect to which ImmunoGen has exercised a Co-Development Option as described in Section 5.1.1. For purposes of clarity, Co-Developed Products include Early Stage Co-Developed Products and Late Stage Co-Developed Products.

1.27 **“Co-Development Costs”** means the reasonable Out-of-Pocket Costs and internal costs incurred by a Party (or for its account by an Affiliate or a Third Party) on and after the exercise by ImmunoGen of the applicable Co-Development Option that are generally consistent with the respective activities allocated to such Party in the Co-Development Plan and/or Co-Development Marketing and Sales Plan and, in any case, are specifically attributable to the Development of a Co-Developed Product in the Co-Development Territory. For purposes of this definition (a) Out-of-Pocket Costs relate to the costs attributable to specific external Development activities, and/or Commercialization related to pre-commercial marketing activities, applicable to a Co-Developed Product, including, without limitation (i) all filing fees required for, and other costs associated with, any Regulatory Filings and Drug Approval Applications and (ii) all Third Party Required Payments; (b) internal costs means all direct labor costs to the extent attributable to the Development of a Co-Developed Product in accordance with the Co-Development Plan and/or Co-Development Marketing and Sales Plan, including, without limitation, any employees of a Party that perform project management and other activities attributable to such Development, all as calculated on the basis of an annual rate equal to the Party’s specific FTE Rate; and (c) the reasonable Out-of-Pocket Costs and internal costs of manufacturing or obtaining Co-Developed Products in final dosage form for use in the activities in clause (a) shall be included in the definition of Co-Development Costs. For the avoidance of doubt, Co-Development Costs (a) shall include the costs incurred by either Party in conducting clinical trials with respect to a Co-Developed Product, other than costs incurred with respect to Shared Clinical Trials as defined in 1.128(b), which shall be allocated between the Parties in accordance with Section 5.1.4 and Pivotal MAY Compound Process Development Costs, which shall be paid by Biotest in accordance with Section 5.1.5; and (b) shall not include (i) milestone payments made by Biotest to ImmunoGen pursuant to Section 6.3.1, and (ii) any Co-Development Option Exercise Fee to be paid by ImmunoGen pursuant to Section 5.1.1.

1.28 **“Co-Development Manufacturing Plan”** means, with respect to each Co-Developed Product, the written plan for the manufacture of such Co-Developed Product in the Co-Development Territory prepared by the JDC which shall include, without limitation, expected manufacturing scale-up, formulation and filling activities to be conducted by each Party, as well as a budget and proposed timelines for such activities, as such plan may be amended or updated.

1.29 **“Co-Development Marketing and Sales Plan”** means, with respect to each Co-Developed Product, the written plan for the Commercialization of such Co-Developed Product in the Co-Development Territory prepared by the JMC which shall include, without limitation, (a) a regulatory and Commercialization strategy with proposed timelines and sales forecasts that are, in each case, applicable to such Co-Developed Product and (b) a co-promotion plan which shall describe the Co-Promotion activities to be conducted by each Party in the Co-Development Territory, a budget and proposed timelines, as such plan may be amended or updated.

1.30 **“Co-Development Option Exercise Dates”** means, collectively, the Early Stage Option Commencement Date and the Late Stage Option Commencement Date.

1.31 **“Co-Development Plan”** means, with respect to each Co-Developed Product, the written plan describing the joint Development activities to be carried out by both Parties over each Contract Year commencing with the date of exercise of the Co-Development Option in accordance with Section 5.1.1 for each Co-Developed Product, broken down by Calendar Quarters, and which

shall contain, inter alia, (a) the specific Development objectives, projected milestones, resource allocation requirements and activities to be performed over such period; (b) the Party responsible for such activities; (c) a timeline for such activities; (d) an estimate of the expected Co-Development Costs to be incurred over such period; (e) the expected Regulatory Filings to be required and prepared, and the expected timetable to budget for making such Regulatory Filings; (f) the manufacturing strategy, budget and proposed timelines for manufacturing scale-up, formulation, filling and/or shipping for each such Licensed Product, MAY Compound and Linker; and (g) a Co-Development clinical development plan. The Co-Development Plan shall be set forth in a written document jointly prepared by the Parties and approved by the JDC. Each amendment and/or update to the Co-Development Plan shall be set forth in a written document prepared by the Parties and approved by the JDC, shall specifically state that it is an amendment, modification or update to the Co-Development Plan and shall be attached to the minutes of the meeting of the JDC at which such amendment, modification or update is approved by the JDC. Without limiting the nature or frequency of any other amendments or updates of the Co-Development Plan that may be approved by the JDC, the Co-Development Plan shall be updated at least once prior to the end of each Contract Year to describe the Co-Development activities to be carried out by each Party during the next Contract Year pursuant to this Agreement.

1.32 **“Co-Development Territory”** means, with respect to each Co-Developed Product, the United States of America and its territories and possessions.

1.33 **“Collaboration”** means the association of ImmunoGen and Biotest established pursuant to this Agreement for the purpose of Developing and Commercializing Licensed Products in the Field in the Territory.

1.34 **“Combination Product”** means any Biotest Product that contains both a pharmaceutically active agent or ingredient that constitutes a Biotest Product and one or more other pharmaceutically active agents or ingredients that do not constitute a Biotest Product.

1.35 **“Commercialization”** or **“Commercialize”** means any and all activities directed to the commercialization of a Licensed Product, including but not limited to, pre-launch and post-launch marketing, manufacturing for commercial sale, promoting, Detailing, distributing, offering to sell, having sold, selling, importing, having imported, exporting and having exported a Licensed Product for sale, conducting additional post-approval human clinical studies in the approved indication (but not pre-clinical studies) and interacting with Regulatory Authorities regarding the foregoing. When used as a verb, “Commercializing” means to engage in Commercialization and “Commercialized” has a corresponding meaning.

1.36 **“Commercialization Regulatory Approval”** means, with respect to any Licensed Product, (a) an NDA or (b) the equivalent of an NDA required by Applicable Laws in any country or region in the Territory outside of the United States to sell such Licensed Product for use in the Field in such country or region.

1.37 **“Commercially Reasonable Efforts”** means with respect to the Development and Commercialization of a particular Licensed Product and/or Co-Developed Product by Biotest and/or ImmunoGen, as applicable, the efforts and resources (i) as provided by this Agreement, including, without limitation, the Research Plan, the Development Plan, the Manufacturing Plan,

the Co-Development Marketing and Sales Plan and the Co-Development Manufacturing Plan, and (ii) typically used by the respective Party in the development of its other product candidates or the commercialization of its other products, which are of similar commercial potential and at a similar stage in their development or product life, as applicable, taking into account the competitiveness of the applicable marketplace, the regulatory structure involved, the profitability of the applicable products, the scientific, technical, development and regulatory requirements, obstacles and risks, and other similar factors. For the avoidance of doubt, for the purpose of determining Commercially Reasonable Efforts for a particular Licensed Product and/or Co-Developed Product, the fact that a Party is entitled to a greater share of profits with respect to a product other than a Licensed Product compared to the profit share to which it is entitled according to this Agreement with respect to such Licensed Product and/or Co-Developed Product shall not be taken into account.

1.38 **“Completion”** means, with respect to a clinical trial, the date on which all material data reasonably expected to be derived therefrom has been generated and the study report with respect thereto has been finalized and received by ImmunoGen.

1.39 **“Confidential Information”** means (a) with respect to ImmunoGen, all tangible embodiments of ImmunoGen Technology, (b) with respect to Biotest, all tangible embodiments of Biotest Technology and (c) with respect to each Party, (i) all tangible embodiments of Joint Technology and (ii) all information, Technology and Proprietary Materials disclosed or provided by or on behalf of such Party (the “disclosing Party”) pursuant to this Agreement or the Existing Agreements to the other Party (the “receiving Party”) or to any of the receiving Party’s employees, consultants, Affiliates or sublicensees; provided that none of the foregoing shall be Confidential Information if: (A) as of the date of disclosure, it is known to the receiving Party or its Affiliates, as demonstrated by credible written documentation, other than by virtue of a prior confidential disclosure to such receiving Party or its Affiliates; (B) as of the date of disclosure it is in the public domain, or it subsequently enters the public domain through no fault, in relation to the disclosing Party, of the receiving Party or its Affiliates; (C) it is obtained by the receiving Party from a Third Party having a lawful right to make such disclosure free from any obligation of confidentiality to the disclosing Party; or (D) it is independently developed by or for the receiving Party without reference to or use of any Confidential Information of the disclosing Party as demonstrated by credible written documentation. For purposes of clarity, (i) any scientific, technical or financial information of a disclosing Party disclosed at any meeting of any of the committees or teams established pursuant to the Agreement or disclosed through an audit report prepared pursuant to this Agreement shall constitute Confidential Information of the disclosing Party and (ii) the terms of this Agreement shall constitute Confidential Information of each Party.

1.40 **“Contract Quarter”** means (a) the period beginning on the Effective Date and ending on the last day of the third full calendar month after the Effective Date and (b) each succeeding three (3) month period thereafter.

1.41 **“Contract Year”** means (a) with respect to the first Contract Year, the period beginning on the Effective Date and ending on December 31, 2006 and (b) with respect to the second and each subsequent Contract Year, the Calendar Year.

1.42 **“Control” or “Controlled”** means (a) with respect to Technology (other than Proprietary Materials) or Patent Rights, the possession by a Party of the right to grant a license or

sublicense to such Technology or Patent Rights as provided herein without the payment of additional consideration to, and without violating the terms of any agreement or arrangement with, any Third Party and (b) with respect to Proprietary Materials, the possession by a Party of the right to supply such Proprietary Materials to the other Party as provided herein without the payment of additional consideration to, and without violating the terms of any agreement or arrangement with, any Third Party.

1.43 **“Co-Promotion”** or **“Co-Promote”** means the employment by the Parties of sales representatives to jointly Detail a Co-Developed Product in the Co-Development Territory under the same Licensed Product Trademark and brand using the same Advertising, a coordinated Co-Development Marketing and Sales Plan and an integrated sales force consisting of Representatives of both Biotest and ImmunoGen.

1.44 **“Co-Promotion Percentage”** means, collectively, the Biotest Co-Promotion Percentage and the ImmunoGen Co-Promotion Percentage.

1.45 **“Dedicated Equipment”** shall mean any equipment, instrument or machinery used by ImmunoGen exclusively in the manufacturing of Preclinical Materials or Clinical Materials.

1.46 **“Derived”** means obtained, developed, created, synthesized, designed, derived or resulting from, based upon, containing, incorporating or otherwise generated from (whether directly or indirectly, or in whole or in part).

1.47 **“Designated Senior Officer”** means, with respect to a Party, the senior officer designated by such Party to have final decision-making authority over Disputed Matters which, absent unusual circumstances, shall be the President or Chief Executive Officer of such Party.

1.48 **“Detail”** means, with respect to a Co-Developed Product, an interactive, live, face-to-face contact of a Representative within the Co-Development Territory with a medical professional with prescribing authority or other individuals or entities that have a significant impact or influence on prescribing decisions, in an effort to increase physician prescribing preferences of such Co-Developed Product for its approved uses within the Co-Development Territory, which shall involve (a) a primary product presentation (i.e., a Detail in which the Co-Developed Product is given an important emphasis) or (b) a secondary product presentation (i.e., a non-primary product presentation; provided, however, the emphasis is not less than that placed upon other products presented), in each case as measured by generally accepted industry standards. When used as a verb, “Detailing” means performing Details. When used as an adjective, “Detailing” means of or related to performing Details.

1.49 **“Development”** or **“Develop”** means, with respect to each Licensed Product, all non-clinical and clinical activities required to obtain Regulatory Approval of such Licensed Product in accordance with this Agreement on and after the Effective Date and up to the obtaining of Commercialization Regulatory Approval of such Licensed Product. For purposes of clarity, these activities include, without limitation, the determination of the indication(s) for which each Licensed Product shall be used, test method development and stability testing, regulatory toxicology and pharmacology, formulation, process development, manufacturing, manufacturing scale-up, development-stage manufacturing, statistical analysis and report writing, and clinical

trial design and operations. When used as a verb, “Developing” means to engage in Development and “Developed” has a corresponding meaning.

1.50 **“Development Plan”** means the written plan describing the Development activities to be carried out over each Contract Year to be prepared jointly by the Parties and approved by the JDC in accordance with Section 4.1.1 for each Licensed Product, broken down by Calendar Quarters, and which shall contain, *inter alia*, (a) the specific Development objectives, projected milestones, resource allocation requirements and activities to be performed over such period; (b) the Party responsible for such activities; (c) a timeline for such activities; (d) an estimate of the expected Development costs to be incurred over such period; (e) the expected Regulatory Filings and Drug Approval Applications to be required and prepared, and the expected timetable for making such Regulatory Filing and Drug Approval Applications; and (f) the manufacturing strategy, budget and proposed timelines for manufacturing scale-up, formulation, filling and/or shipping for each such Licensed Product. The initial Development Plan shall contain all activities until December 31, 2007. Each amendment and/or update to the Development Plan shall be set forth in a written document jointly prepared by the Parties and approved by the JDC, shall specifically state that it is an amendment, modification or update to the Development Plan and shall be attached to the minutes of the meeting of the JDC at which such amendment, modification or update is approved by the JDC. Without limiting the nature or frequency of any other amendments or updates of the Development Plan that may be approved by the JDC, the Development Plan shall be updated at least once prior to the end of each Contract Year to describe the Development activities to be carried out by each Party during the next Contract Year pursuant to this Agreement.

1.51 **“Drug Approval Application”** means, with respect to a Licensed Product in a particular country or region, an application for Commercialization Regulatory Approval for such Licensed Product in such country or region, including without limitation: (a) an NDA or sNDA; (b) a counterpart of an NDA or sNDA in any country or region in the Territory; and (c) all supplements and amendments to any of the foregoing.

1.52 **“Early Stage Co-Development Licensed Product”** means any Licensed Product that becomes a Co-Developed Product pursuant to the exercise by ImmunoGen of the Early Stage Co-Development Option.

1.53 **“Early Stage Co-Development Option”** means any Co-Development Option that may be exercised by ImmunoGen during the Early Stage Option Exercise Period.

1.54 **“Early Stage Option Commencement Date”** means, with respect to each Licensed Product, the date of Completion of [\*\*\*] [\*\*\*] [\*\*\*] [\*\*\*] [\*\*\*] [\*\*\*] with respect to that Licensed Product.

1.55 **“ECB”** means the European Central Bank.

1.56 **“EMEA”** means the European Medicines Evaluation Agency, or any successor thereto, which coordinates the scientific review of human pharmaceutical products under the centralized licensing procedures of the European Community.

1.57 **“EU”** means the European Union.

1.58 “**Existing Agreements**” means the Confidentiality Agreement by and between the Parties dated as of [\*\*\*] [\*\*\*] [\*\*\*] and the Material Transfer and Evaluation Agreement by and between the Parties dated as of [\*\*\*] [\*\*\*] [\*\*\*], and the First Amendment thereto, dated as of [\*\*\*] [\*\*\*] [\*\*\*].

1.59 “**FDA**” means the United States Food and Drug Administration or any successor agency or authority thereto.

1.60 “**FDCA**” means the United States Federal Food, Drug, and Cosmetic Act, as amended.

1.61 “**Field**” means all human therapeutic, prophylactic and diagnostic uses.

1.62 “**First Commercial Sale**” means, with respect to a Licensed Product in any country in the Territory, the first sale, transfer or disposition for value, for end use or for consumption of such Licensed Product to a Third Party in such country.

1.63 “**First Interim Analysis**” means, with respect to a clinical trial, the date on which the data from such clinical trial has undergone an interim analysis and such interim analysis has been finalized by Biotest and received by ImmunoGen.

1.64 “**Force Majeure**” means any occurrence beyond the reasonable control of a Party that (a) prevents or substantially interferes with the performance by such Party of any of its obligations hereunder and (b) occurs by reason of any act of God, flood, fire, explosion, earthquake, strike, lockout, labor dispute, casualty or accident, or war, revolution, civil commotion, act of terrorism, blockage or embargo, or any injunction, law, order, proclamation, regulation, ordinance, demand or requirement of any government or of any subdivision, authority or representative of any such government.

1.65 “**FTE**” means a full time person dedicated to the Research Program and/or dedicated to the Development of Licensed Products as described in any Development Plan, or in the case of less than a full-time dedicated person, a full-time, equivalent person year pro rata temporis, based on a total of at least [\*\*\*] hours or [\*\*\*] [\*\*\*] weeks per year of work, on or directly related to the Research Program and/or dedicated to the Development of Licensed Products as described in any Development Plan, measured, with respect to ImmunoGen, in accordance with ImmunoGen’s time allocation practices from time to time or, with respect to Biotest’s FTEs (if applicable), in accordance with Biotest’s time allocation practices from time to time. For purposes of clarity, FTEs shall not include any sales representatives employed by a Party.

1.66 “**FTE Cost**” means, for any Calendar Quarter, the FTE Rate multiplied by the applicable number of FTEs used during such Calendar Quarter.

1.67 “**FTE Rate**” means, in each case pro rata temporis, with respect to any ImmunoGen Activities to be performed by ImmunoGen prior to its exercise of a Co-Development Option (a) during the first Contract Year, the portion of [\*\*\*] [\*\*\*] [\*\*\*] [\*\*\*] Dollars (US \$[\*\*\*]) corresponding to such part of the Calendar Year that is covered by the first Contract Year; and, (b) during each Contract Year thereafter, the result obtained by multiplying \$[\*\*\*] by the sum of (1+CPI) where CPI is a fraction, the numerator of which is the difference between the Consumer

Price Index as of the last month of the immediately preceding Contract Year and the Consumer Price Index as of the month immediately preceding the Effective Date and the denominator of which is the Consumer Price Index as of the month immediately preceding the Effective Date. For purposes of clarity, the FTE rates applicable to ImmunoGen Activities and applicable to activities undertaken by Biotest, both conducted after the exercise by ImmunoGen of the Co-Development Option will be determined by the JFC.

1.68 **“GAAP”** means United States generally accepted accounting principles, consistently applied.

1.69 **“GCP”** means the then current Good Clinical Practice standards promulgated or endorsed by the FDA or in the case of foreign jurisdictions, comparable regulatory standards promulgated or endorsed by the applicable Regulatory Authority, including those procedures expressed or implied in the Regulatory Filings.

1.70 **“GLP”** means the then current Good Laboratory Practice standards promulgated or endorsed by the FDA or in the case of foreign jurisdictions, comparable regulatory standards promulgated or endorsed by the applicable Regulatory Authority, e.g., the EMEA, including those procedures expressed or implied in the Regulatory Filings.

1.71 **“GMP”** means the then current Good Manufacturing Practice standards promulgated or endorsed by the FDA or in the case of foreign jurisdictions, comparable regulatory standards promulgated or endorsed by the applicable Regulatory Authority, e.g., the EMEA, including those procedures expressed or implied in the Regulatory Filings.

1.72 **“Hatch-Waxman Act”** means the Drug Price Competition and Patent Term Restoration Act of 1984, as amended.

1.73 **“ICC”** means the International Chamber of Commerce.

1.74 **“ImmunoGen Activities”** means those activities associated with the Research Program and/or associated with the Development of Licensed Products as described in the Research Plan or any Development Plan that are, in either case, to be undertaken by ImmunoGen.

1.75 **“ImmunoGen Background Technology”** means any Technology used by ImmunoGen, or provided by ImmunoGen for use, in the Research Program and/or the Development of Licensed Products that is useful in the Field and that is (a) Controlled by ImmunoGen as of the Effective Date or (b) developed or conceived or first reduced to practice by employees of, or consultants to, ImmunoGen after the Effective Date other than in the conduct of ImmunoGen Activities and without the use in any respect of any Biotest Technology or Biotest Materials or any Program Inventions.

1.76 **“ImmunoGen Co-Promotion Percentage”** means fifty percent (50%) of the Annual Net Income.

1.77 **“ImmunoGen Decision”** means the following decisions which, in the event of deadlock, will be decided by an ImmunoGen member of the JSC: the selection of Third Party

manufacturers to manufacture Preclinical Materials and Clinical Materials following the request by Biotest pursuant to Section 4.5.2(b).

1.78 **“ImmunoGen Materials”** means any Proprietary Materials Controlled by ImmunoGen and used by ImmunoGen, or provided by ImmunoGen for use, in the Research Program and/or the Development of Licensed Products. For purposes of clarity, ImmunoGen Materials shall include all MAY Compounds and Linkers.

1.79 **“ImmunoGen Patent Rights”** means any Patent Rights that contain one or more claims that cover ImmunoGen Technology. For purposes of clarity, ImmunoGen Patent Rights include Licensed Patent Rights and ImmunoGen’s fifty percent (50%) interest in the CD138 Conjugate Patent Rights.

1.80 **“ImmunoGen Program Technology”** means any Program Invention conceived or first reduced to practice by employees of, or consultants to, ImmunoGen, alone or jointly with any Third Party, without the use in any respect of any Biotest Technology, Biotest Materials or Joint Technology.

1.81 **“ImmunoGen Technology”** means, collectively, ImmunoGen Background Technology and ImmunoGen Program Technology.

1.82 **“Improvement”** means any enhancement, improvement or modification to the Licensed Technology or the Licensed Patent Rights.

1.83 **“IND”** means (a) an Investigational New Drug Application, as defined in the FDCA and the regulations promulgated thereunder, or any successor application or procedure required to initiate clinical testing of a Licensed Product in humans in the United States; (b) a counterpart of an Investigational New Drug Application that is required in any other country or region in the Territory before beginning clinical testing of a Licensed Product in humans in such country or region; and (c) all supplements and amendments to any of the foregoing.

1.84 **“Initiation”** means, with respect to a human clinical trial, the first date that a subject is dosed in such clinical trial.

1.85 **“Joint Development Committee”** or **“JDC”** means the Joint Development Committee of ImmunoGen and Biotest representatives established pursuant to Section 2.2 to oversee the conduct and progress of the Research Program and the Development of Licensed Products.

1.86 **“Joint Finance Committee”** or **“JFC”** means the Joint Finance Committee of ImmunoGen and Biotest representatives established pursuant to Section 2.4 to oversee the allocation between the Parties of Co-Development Costs and Net Income Payments with respect to Co-Developed Products.

1.87 **“Joint Marketing Committee”** or **“JMC”** means the committee of ImmunoGen and Biotest representatives established pursuant to Section 2.5 to coordinate the Commercialization activities of Co-Developed Products within the Co-Development Territory.

1.88 **“Joint Patent Rights”** means Patent Rights that contain one or more claims that cover Joint Technology. For purposes of clarity, Joint Patent Rights shall not include CD138 Conjugate Patent Rights.

1.89 **“Joint Steering Committee”** or **“JSC”** means the Joint Steering Committee of ImmunoGen and Biotest representatives established pursuant to Section 2.1 to oversee the overall conduct and progress of the Development and Commercialization of Licensed Products.

1.90 **“Joint Technology”** means any Program Invention (a) conceived or first reduced to practice jointly by employees of, or consultants to, Biotest and employees of, or consultants to, ImmunoGen or (b) conceived or first reduced to practice by employees of, or consultants to, one Party with the use in any respect of any Technology, Patent Rights or Proprietary Materials of the other Party.

1.91 **“Late Stage Co-Development Licensed Product”** means any Licensed Product that becomes a Co-Developed Product pursuant to the exercise by ImmunoGen of the Late Stage Co-Development Option.

1.92 **“Late Stage Co-Development Option”** means any Co-Development Option that may be exercised by ImmunoGen during the Late Stage Option Exercise Period.

1.93 **“Late Stage Option Commencement Date”** means, with respect to each Licensed Product, the date of Completion of [\*\*\*] [\*\*\*] [\*\*\*] [\*\*\*] [\*\*\*] [\*\*\*] for the first indication in the first country where such clinical trials are performed with respect to that Licensed Product.

1.94 **“Licensed Patent Rights”** means any Patent Rights that are Controlled by ImmunoGen as of the Effective Date (including ImmunoGen Patent Rights and ImmunoGen’s interest in Joint Patent Rights) to the extent necessary to use, Develop, have Developed, make, have made, Commercialize and have Commercialized any Licensed Product. For purposes of clarity, (a) all Licensed Patent Rights existing as of the Effective Date are described on Schedule 2 attached hereto and (b) any Patent Rights that become Controlled by ImmunoGen during the Term of this Agreement that ImmunoGen reasonably believes are necessary and/or useful for the research, Development and Commercialization of Licensed Products in the Field (“New Patent Rights”) shall be presented to Biotest by ImmunoGen and Biotest shall have the right to decide within sixty (60) days following the presentation whether or not to add the New Patent Rights to Licensed Patent Rights on Schedule 2.

1.95 **“Licensed Product”** means any product that contains, is comprised of, or otherwise Derived from, an Anti- CD138 Antibody-MAY Conjugate.

1.96 **“Licensed Product Trademark”** means (a) any trademark or trade name, whether or not registered, or any trademark application, renewal, extension or modification thereto, in the Territory, or any trade dress and packaging, that is applied to or used with Licensed Products by Biotest and (b) all goodwill associated therewith, and any promotional materials relating thereto.

1.97 **“Licensed Technology”** means any ImmunoGen Technology or Joint Technology that (a) relates to the MAY Compound and/or Linker portion of any Licensed Product and (b) is necessary for Biotest to exercise the licenses granted to it pursuant to Sections 8.1.1 and 8.2.1.

1.98 “**Linker**” means any chemical entity utilized to attach a MAY Compound to an Anti- CD138 Antibody, including but not limited to SMCC, SPP, SPDB, CPD, PEG-containing chemical entities.

1.99 “**MAA**” means an application filed with the EMEA, or through the mutual recognition procedures in the European Union, for Regulatory Approval to Commercialize a Licensed Product as a medicinal product in the European Union, or in any country or territory therein.

1.100 “**Manufacturing Cost**” means, with respect to any Preclinical Materials or Clinical Materials manufactured by ImmunoGen, ImmunoGen’s fully-burdened costs (including the costs associated with product testing and release activities) of producing and packaging such Preclinical Materials or Clinical Materials, including the sum of the following components: (a) direct costs, including (1) materials directly used in producing and packaging such Preclinical Materials or Clinical Materials and (2) with respect to any Preclinical Materials or Clinical Materials obtained by ImmunoGen from a Third Party and supplied to Biotest without modification, the amount paid by ImmunoGen to such Third Party for the same; (b) manufacturing overhead costs attributable to the cost of goods under the foregoing clause (a) (1), including manufacturing and quality labor and manufacturing and quality supervisory services, operating and administrative costs of the manufacturing and quality departments and occupancy costs which are allocable to company departments based on space occupied or headcount or another reasonable activity-based method; for the purpose of clarity, any cost allocation shall be (i) in any case applied in accordance with GAAP, and (ii) applied consistently by ImmunoGen in relation to all other Third Parties for which ImmunoGen manufactures comparable materials; (c) any other reasonable and customary Out-of-Pocket Costs borne by ImmunoGen for the testing, transport, customs clearance, duty, insurance and/or storage of such Preclinical Materials or Clinical Materials; and (d) ImmunoGen’s general and administrative costs, including purchasing, human resources, payroll, information system and accounting, which are directly attributable or reasonably allocable to company departments based on space occupied or headcount. Manufacturing overhead costs under the foregoing clause (b) and general and administrative costs under the foregoing clause (d) are allocable to each batch of Preclinical Material and/or Clinical Material produced based upon the [\*\*\*] of [\*\*\*], or any portion of a [\*\*\*], that a Manufacturing [\*\*\*] is [\*\*\*] for the [\*\*\*] (including [\*\*\*] [\*\*\*] and [\*\*\*]) of Preclinical Materials or Clinical Materials, as the use may be, at ImmunoGen’s facilities. Notwithstanding the foregoing, Manufacturing Cost shall not include the cost of purchasing any Dedicated Equipment pursuant to Section 4.5.2(c).

1.101 “**Manufacturing Plan**” means, subject to 4.1.3, with respect to each Licensed Product, the written plan for the manufacture of such Licensed Product in the Territory prepared by the JDC or the JMC which shall include, without limitation, expected manufacturing scale-up, formulation, and filling activities to be conducted for each Licensed Product as well as a budget and proposed timelines for such activities, as such plan may be amended or updated.

1.102 “**Material Use**” means, with respect to Shared Clinical Trial Data, (a) the inclusion of such Shared Clinical Data in a core report of an NDA filed by a Party (as evidenced by (i) the use of a bridging study to utilize such Shared Clinical Data, (ii) the elimination for the need to [\*\*\*] such Shared Clinical Data through a clinical trial within such Party’s respective geographic territory, or (iii) such other reference use of such Shared Clinical Data consistent with clauses (i)-

(ii) above), or (b) the use of such Shared Clinical Data by a Party in a manner substantially similar to that contained in a full Clinical Study Report (CSR), as described in ICH Harmonized Guideline E3 (Structure and Content of Clinical Study Reports), and including the appendices specified in Section 16 of such guideline that are applicable to such Party's NDA. For purposes of clarity, it shall not be deemed to be a Material Use of clinical data if such clinical data is used only to support an NDA filing.

1.103 **"MAY Compound"** means any and all maytansinoid compounds and any and all derivatives of any such maytansinoid compounds, to the extent, in any case, Controlled by ImmunoGen, including without limitation, (a) N<sup>2</sup>-deacetyl-N<sup>2</sup>-(c-mercapto-1 oxopropyl)-maytansine (CAS No. 139504-50-0) commonly referred to as DM1); (b) N<sup>2</sup>-deacetyl-N<sup>2</sup>-(4-mercapto-1-oxopentyl)-maytansine (commonly referred as DM3); and (c) N<sup>2</sup>-deacetyl-N<sup>2</sup>-(4-mercapto-4-methyl-1-oxopentyl)-maytansine (commonly referred as DM4).

1.104 **"NDA"** means a New Drug Application, as defined in the FDCA and applicable regulations promulgated thereunder, or any successor application or procedure required to sell a Licensed Product in the United States.

1.105 **"Net Sales"** means the gross amount billed or invoiced by a Party (a "Selling Party") or any of its Affiliates or Sublicensees to Third Parties throughout the Territory for sales or other dispositions or transfers for value of Licensed Products (including, without limitation, Third Party distributors and wholesalers), less (a) allowances for normal and customary trade, quantity and cash discounts actually allowed and taken, (b) transportation, insurance and postage charges, if prepaid by such Selling Party or any Affiliate of such Selling Party and included on any such party's bill or invoice as a separate item, (c) credits, rebates, returns (including, without limitation, wholesaler and retailer returns) pursuant to agreements (including, without limitation, managed care agreements) or government regulations, to the extent actually allowed, and (d) sales, use and other consumption taxes, including VAT, similarly incurred to the extent stated on the invoice as a separate item. In addition, Net Sales are subject to the following:

(i) If such Selling Party or any of its Affiliates or Sublicensees effects a sale, disposition or other transfer of a Licensed Product to a customer in a particular country other than on customary commercial terms or as part of a package of Licensed Products and services, the Net Sales of such Licensed Product to such customer shall be deemed to be the "fair market value" of such Licensed Product. For purposes of this subsection (i), "fair market value" shall mean the value that would have been derived had such Licensed Product been sold as a separate Licensed Product to another customer in the country concerned on customary commercial terms.

(ii) In the case of pharmacy incentive programs, hospital performance incentive program chargebacks, disease management programs, similar programs or discounts on "bundles" that include Licensed Products, all discounts and the like shall be allocated among the products in such bundles on the basis on which such discounts and the like were actually granted or, if such basis cannot be determined, in proportion to the respective list prices of such products.

(iii) For purposes of clarity, the use of any Licensed Product in clinical trials, pre-clinical studies or other research or development activities, shall not give rise to any Net Sales. In addition, use of any Licensed Product in a compassionate use program shall not give rise to any

deemed sale for purposes of this definition unless such Selling Party or its Affiliates or Sublicensees bills such program for such Licensed Product at a price which exceeds [\*\*\*] [\*\*\*] [\*\*\*] percent ([\*\*\*]%) of such Selling Party's fully-burdened cost to supply such Licensed Product.

1.106 **“Out-of-Pocket Costs”** means the reasonable, direct, documented and specifically identifiable expenses paid by a Party to any Third Party.

1.107 **“Patent Rights”** means the rights and interests in and to issued patents and pending patent applications (which, for purposes of this Agreement, include certificates of invention, applications for certificates of invention and priority rights) in any country or region, including all provisional applications, substitutions, continuations, continuations-in-part, divisions, renewals, all letters patent granted thereon, and all reissues, reexaminations and extensions thereof, and all foreign counterparts of any of the foregoing.

1.108 **“Person”** means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or similar entity or organization, including a government or political subdivision, department or agency of a government.

1.109 **“Phase I Clinical Trial”** means a human clinical trial conducted in a country or countries that generally provides, with respect to that country, for the first introduction into humans of a Licensed Product with the purpose of assessing its safety, tolerability, toxicity, metabolism, absorption, elimination or other pharmacological action as more fully defined in 21 C.F.R. 312.21(a).

1.110 **“Phase II Clinical Trial”** means a human clinical trial conducted in a country or countries in patients with a particular disease or condition with the purpose of further assessing safety and tolerability of a Licensed Product and providing an indication of its efficacy for such disease or condition, as more fully defined in 21 C.F.R. 312.21(b).

1.111 **“Phase IIb Clinical Trial”** means, as to a particular Licensed Product and indication, the portion of a Phase II Clinical Trial designed to generate sufficient data (if successful) to commence a Phase III Clinical Trial of such Licensed Product for such indication.

1.112 **“Phase III Clinical Trial”** means a pivotal human clinical trial conducted in a country or countries in patients with a particular disease or condition with the purpose of establishing the safety and tolerability of a Licensed Product and confirming or establishing its efficacy for such disease or condition as a basis for obtaining Regulatory Approval of such Licensed Product, as more fully defined in 21 C.F.R. 312.21(c).

1.113 **“Pivotal MAY Compound Process Development Costs”** means the reasonable costs incurred by ImmunoGen after the Effective Date (both before and after the exercise of the Co-Development Option) in the conduct of process development activities for pivotal MAY Compounds, provided that such costs (i) are related to activities described in the Pivotal MAY Compound Process Development Plan, and (ii) have been approved by the Biotest members on the JDC, which approval shall not be unreasonably withheld, conditioned or delayed, provided that

withholding, conditioning or delaying of the approval by Biotest for cost reasons would not be deemed to be unreasonable.

1.114 **“Pivotal MAY Compound Process Development Percentage”** means a portion of the Pivotal MAY Compound Process Development Costs calculated by dividing the aggregate amount of Pivotal MAY Compound Process Development Costs incurred by ImmunoGen by the [\*\*\*] [\*\*\*] [\*\*\*], [\*\*\*] [\*\*\*] [\*\*\*] [\*\*\*], at the date the allocation of such Pivotal MAY Compound Process Development Costs is being determined, [\*\*\*] [\*\*\*] [\*\*\*] or [\*\*\*] that [\*\*\*] [\*\*\*] [\*\*\*] that are used in [\*\*\*] [\*\*\*] [\*\*\*] or [\*\*\*] [\*\*\*] and [\*\*\*] and are [\*\*\*] using the [\*\*\*] developed in the conduct of such pivotal process development activities.

1.115 **“Preclinical Materials”** means any MAY Compound, Linker and/or Licensed Product supplied by ImmunoGen to Biotest in accordance with Section 4.5.2(b)(ii) for the purpose of conducting preclinical testing with respect to a Licensed Product. For the purpose of clarity, Preclinical Material shall not include unconjugated Antibody.

1.116 **“Program Invention”** means any Technology (including, without limitation, any new and useful process, method of manufacture or composition of matter) that is conceived or first reduced to practice (actively or constructively) in the conduct of the Research Program and/or the Development of Licensed Products.

1.117 **“Proprietary Materials”** means tangible chemical, biological or physical materials that are furnished by or on behalf of one Party to the other Party in connection with this Agreement, whether or not specifically designated as proprietary by the transferring Party.

1.118 **“Regulatory Approval”** means, with respect to any country or region in the Territory, any approval (including, without limitation, any pricing approval), product and establishment license, registration or authorization of any Regulatory Authority required for the manufacture, use, storage, importation, export, transport, clinical testing or sale of a Licensed Product for use in the Field in such country or region.

1.119 **“Regulatory Authority”** means the FDA or any counterpart of the FDA outside the United States, or other national, supra-national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity with authority over the distribution, importation, exportation, manufacture, production, use, storage, transport, clinical testing or sale of a Licensed Product.

1.120 **“Regulatory Filings”** means, collectively, (a) all INDs, NDAs, establishment license applications, drug master files, applications for designation of a Licensed Product as an “Orphan Product(s)” under the Orphan Drug Act, for “Fast Track” status under Section 506 of the FDCA (21 U.S.C. § 356) or for a Special Protocol Assessment under Section 505(b)(4)(B) and (C) of the FDCA (21 U.S.C. § 355(b)(4)(B)) or all other similar filings (including, without limitation, any counterparts of any of the foregoing in any country region in the Territory, e.g. a CTN) as may be required by any Regulatory Authority for the Development or Commercialization of a Licensed Product; (b) all supplements and amendments to any of the foregoing; and (c) all data contained in, and correspondence relating to, any of the foregoing.

1.121 “**Research Materials**” means any MAY Compound, Linker and/or Licensed Product supplied by ImmunoGen to Biotest in accordance with Section 3.3(b)(ii) for the purpose of conducting research activities under the Research Program with respect to a Licensed Product.

1.122 “**Research Plan**” means the written plan describing the research activities to be carried out by each Party during each Contract Year during the Research Program term in conducting the Research Program pursuant to this Agreement, as such written plan may be amended, modified or updated. Such Research Plan shall also comprise, *inter alia*, (a) the specific objectives, projected milestones, resource allocation requirements and activities to be performed over such period; (b) the Party responsible for such activities; (c) a timeline for such activities; and (d) the estimated FTEs covering ImmunoGen Activities associated with the Research Program. The initial Research Plan shall be prepared jointly by the Parties at the latest fourteen (14) days from the Effective Date and shall describe the research activities (including basic process development) to be carried out by each Party during the first Contract Year and shall, in combination with the initial Development Plan, contain all activities until December 31st, 2007. Each amendment, modification and update to the Research Plan shall be set forth in a written document prepared by, or at the direction of, the JDC and approved by the JDC, shall specifically state that it is an amendment, modification or update to the Research Plan and shall be attached to the minutes of the meeting of the JDC at which such amendment, modification or update was approved by the JDC. Without limiting the nature or frequency of any other amendments, modifications or updates of the Research Plan that may be approved by the JDC, the Research Plan shall be updated at least once prior to the end of each Contract Year to describe the research activities to be carried out by each Party during the next Contract Year during the Research Program term in conducting the Research Program pursuant to this Agreement.

1.123 “**Research Program**” means the collaborative research program commencing on the Effective Date and conducted by the Parties pursuant to Section 3 and the Research Plan.

1.124 “**Royalty-Bearing Product**” means (a) any Biotest Product and (b) any Co-Developed Product to the extent sold outside of the Co-Development Territory.

1.125 “**Royalty-Bearing Territory**” means (a) with respect to Co-Developed Products, all countries within the Biotest Territory and (b) with respect to Biotest Products, all countries within the Territory.

1.126 “**Royalty Term**” means, with respect to each Royalty-Bearing Product in each country in the Royalty-Bearing Territory, the period beginning on the date of First Commercial Sale of such Royalty-Bearing Product in such country and continuing on a country-by-country basis until the later of (a) the expiration of the last to expire Valid Claim in such country that covers such Royalty-Bearing Product or its use, method of delivery or manufacture or (b) twelve (12) years from the date of the First Commercial Sale of such Royalty-Bearing Product in such country.

1.127 “**Serious Adverse Event**” means an Adverse Event occurring at any dose of a drug that (a) results in death or poses a threat to life; (b) requires or prolongs hospitalization; (c) results in a persistent and/or significant disability or incapacity; (d) is medically significant; or (e) results in a congenital anomaly or birth defect.

1.128 **“Shared Clinical Trial”** means (a) any non-U.S. clinical trial conducted by or on behalf of a Party outside the Co-Development Territory, the results of which are included in the Regulatory Filings for a Co-Developed Product in the Co-Development Territory and therefore [\*\*\*] conducting a similar clinical trial for Regulatory Filings for a Co-Developed Product in the Co-Development Territory; and (b) any clinical trial conducted by or on behalf of the Parties for a Co-Developed Product in the Co-Development Territory, the results of which are included in the Regulatory Filings outside the Co-Development Territory and therefore [\*\*\*] conducting a similar clinical trial outside the Co-Development Territory.

1.129 **“Shared Clinical Trial Costs”** means the aggregate amount of Out-of-Pocket Costs and internal costs incurred by either Party (or for its account by an Affiliate or a Third Party) that are specifically attributable to the conduct of a Shared Clinical Trial.

1.130 **“Shared Clinical Trial Cost-Sharing Percentage”** means, with respect to any Shared Clinical Trial, (a) if Biotest uses the results of such Shared Clinical Trial according to 1.128(b), and such Shared Clinical Trial enables Biotest to [\*\*\*] conducting a similar clinical trial outside the Co-Development Territory, [\*\*\*] percent ([\*\*\*]%) for Biotest and [\*\*\*] percent ([\*\*\*]%) for ImmunoGen; and (b) if ImmunoGen and Biotest jointly use the results of such Shared Clinical Trial according to 1.128(a), and such Shared Clinical Trial enables ImmunoGen and Biotest to [\*\*\*] conducting a similar clinical trial in the Co-Development Territory, [\*\*\*] percent ([\*\*\*]%) for ImmunoGen and [\*\*\*] percent ([\*\*\*]%) for Biotest. If data is only supportive then no adjustment of the 50:50 cost sharing will be necessary.

1.131 **“Shared Clinical Trial Data”** means all data, results and information produced in the conduct of a Shared Clinical Trial.

1.132 **“sNDA”** means a Supplemental New Drug Application, as defined in the FDCA and applicable regulations promulgated thereunder.

1.133 **“Sublicensee”** means any Third Party (other than an Affiliate) to which Biotest grants a sublicense in accordance with Section 8.3.

1.134 **“Technology”** means, collectively, all ideas, inventions, discoveries, improvements, trade secrets and proprietary methods, whether or not patentable, including without limitation: (a) methods of production or use of, and structural and functional information pertaining to, chemical and/or biological compounds and (b) data, formulae, designs, specifications, formulations, processes, process information, techniques, know-how and results (including any negative results), pre-clinical information, clinical information, and any and all proprietary biological, chemical, pharmacological, toxicological, pre-clinical, clinical, assay, control and manufacturing data and materials.

1.135 **“Territory”** means all countries of the world.

1.136 **“Third Party”** means any party other than Biotest and ImmunoGen and their respective Affiliates.

1.137 **“Third Party Required Payments”** means all royalty payments paid to any Third Party in any country in the Co-Development Territory in order to obtain a license to an issued patent or patents in the absence of which the portion of the Co-Developed Product consisting of the Licensed Technology or Licensed Patent Rights would not legally be developed, manufactured or sold in such country.

1.138 **“Unanimous Decision”** means any of the following decisions requiring the unanimous approval of all members of the JSC, the JDC and/or the JMC, as the case may be: (a) any determination as to whether a milestone has been achieved under Section 6.3.1 of this Agreement for which a milestone payment is payable; (b) any decision that relates to the Co-Development or Co-Promotion of a Co-Developed Product (including without limitation any decision with respect to the manufacture of such Co-Developed Product within the Co-Development Territory) in the Co-Development Territory; (c) any decision that results, or would reasonably be expected to result, in an increase in the amount of Co-Development Costs payable by a Party pursuant to Section 5.1 of more than [\*\*\*] [\*\*\*] percent ([\*\*\*]%) in any Calendar Year as compared to the amount of Co-Development Costs forecasted in the then current Co-Development Plan for that Calendar Year for any reason (including, without limitation, as a result of a change in the number of patients, number of sites, duration of the study or the number of studies); (d) the initial allocation of Detailing responsibilities between the Parties with respect to a Co-Developed Product; (e) any disputed matter which, in accordance with the terms of this Agreement, is referred to the JSC by the JDC, the JFC or the JMC; and (f) with respect to each Licensed Product that is a Co-Developed Product, the determination of the indication(s) for which such Co-Developed Product shall be used in the Co-Development Territory.

1.139 **“Valid Claim”** means any claim of an issued unexpired patent or a pending patent application within the Licensed Patent Rights that (a) has not been finally cancelled, withdrawn, abandoned or rejected by ImmunoGen and/or any administrative agency or other body of competent jurisdiction, (b) 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, (c) has not been rendered unenforceable through disclaimer or otherwise, and (d) is not lost through an interference proceeding; provided, however, that (i) a claim contained in a pending patent application shall, if and to the extent such claim is not issued on or before [\*\*\*] ([\*\*\*)] years from the date of filing of the subject application, shall cease to constitute a Valid Claim and (ii) if a claim that ceases to be a Valid Claim by reason of subsection (i) above subsequently issues, such claim shall once again be deemed to be a Valid Claim for purposes of this Agreement.

**Additional Definitions.** In addition, each of the following definitions shall have the respective meanings set forth in the section of this Agreement indicated below:

<b>Definition</b>	<b>Section</b>
Additional Co-Promotion Activities	5.5
Adjusted Co-Promotion Percentage	5.5
Advertising	Schedule 1
Alliance Manager	2.3.1
Annual Net Income	Schedule 1

Arbitration Matter	14.1
Biotest Indemnitees	13.1
Briefing Document	4.5.4(a)
Claims	13.1
Commercialization Expense	Schedule 1
Co-Development Option Exercise Fee	5.1.1(c)
Co-Development Option	5.1.1(a)
Co-Promotion Agreement	5.5.2
Cost of Goods	Schedule 1
Disputed Matter	2.1.6
Early Stage Option Exercise Period	5.1.1(a)
FAMC	Schedule 1
General Public Relations	Schedule 1
ImmunoGen Indemnitees	13.2
Indemnified Party	13.3
Indemnifying Party	13.3
Infringement	10.2.1(a)
Infringement Notice	10.2.1(a)
Late Stage Option Exercise Period	5.1.1(a)
Losses	13.1
Sales and Marketing Expense	Schedule 1
Net Income	Schedule 1
Net Income Payments	6.4.2
Patent Coordinator	9.2
Personnel Costs	Schedule 1
Pivotal MAY Compound Process Development Plan	4.1.1
recipient Party	3.8
Representative	Schedule 1
ROFN Notice	5.5.4
ROFN Response	5.5.4
Sales and Marketing Expense	Schedule 1
Second Sublicense Decision Date	5.5.1(a)(ii)
Selling Party	1.105
Supply Agreement	4.5.2(b)(iii)
Term	11.1
Termination Costs	11.3.4
Third Party Payments	6.4.1(c)
transferring Party	3.8

## **2. ADMINISTRATION OF THE COLLABORATION**

### **2.1 Joint Steering Committee.**

2.1.1 **Establishment.** ImmunoGen and Biotest hereby establish the Joint Steering Committee. The JSC shall have and perform the responsibilities set forth in Section 2.1.4.

2.1.2 **Membership.** Each of ImmunoGen and Biotest shall designate an equal (not less than two (2)) number of representatives to the JSC (which may be employees of, or consultants to, such Party). Unless otherwise agreed by the Parties, one of Biotest's representatives

shall be designated as the Chairman of the JSC. Each Party shall have the right at any time to substitute individuals, on a permanent or temporary basis, for any of its previously designated representatives to the JSC by giving written notice to the other Party.

### 2.1.3 Meetings.

(a) Schedule of Meetings; Agenda. The JSC shall establish a schedule of times for regular meetings, taking into account, without limitation, the planning needs of the Research Program and the responsibilities of the JSC. In addition, special meetings may be convened by any member of the JSC upon thirty (30) days (or, if such meeting is proposed to be conducted by teleconference, upon ten (10) days) written notice to the other members; provided that (i) notice of any such special meeting may be waived at any time, either before or after such meeting and (ii) attendance of any member at a special meeting shall constitute a valid waiver of notice from such member. Regular and special meetings of the JSC may be held in person or by teleconference or videoconference; provided that meetings held in person shall alternate between the respective offices of the Parties in Cambridge, Massachusetts and Dreieich, Germany or such other locations mutually agreeable to the JSC members. The Chairman shall have the responsibility for preparing and circulating to each JSC member an agenda for each JSC meeting not later than one (1) week prior to such meeting.

(b) Quorum; Voting; Decisions. At each JSC meeting, (i) the presence in person of at least one (1) member designated by each Party shall constitute a quorum and (ii) each member who is present shall have one vote on all matters before the JSC at such meeting. All decisions of the JSC, other than Unanimous Decisions, Biotest Decisions and ImmunoGen Decisions, shall be made by majority vote; provided, that, any member designated by a Party shall have the right to cast the votes of any of such Party's members on the JSC who are absent from the meeting. Alternatively, the JSC may act by written consent signed by at least one (1) member designated by each Party. All decisions of the JSC that involve Unanimous Decisions shall be made by vote of all members of the JSC. Whenever any action by the JSC is called for hereunder during a time period in which the JSC is not scheduled to meet, the Chairman shall cause the JSC to take the action in the requested time period by calling a special meeting or by circulating a written consent. Representatives of each Party or of its Affiliates who are not members of the JSC (including, without limitation, the Patent Coordinators) may attend JSC meetings as non-voting observers. In the event that the JSC is unable to resolve any matter before it, such matter shall be resolved in accordance with Section 2.1.6.

(c) Minutes. The JSC shall keep minutes of its meetings that record all decisions and all actions recommended or taken in reasonable detail. Drafts of the minutes shall be prepared and circulated to the members of the JSC within a reasonable time after the meeting, not to exceed ten (10) business days, and the Parties shall alternate responsibility for the preparation and circulation of draft minutes. Each member of the JSC shall have the opportunity to provide comments on the draft minutes. Draft minutes shall be approved, disapproved and revised as soon as practicable. Upon approval, final minutes of each meeting shall be circulated to the members of the JSC by the Chairman.

(d) Expenses. ImmunoGen and Biotest shall each bear all expenses of their respective JSC representatives related to their participation on the JSC and attendance at JSC meetings.

2.1.4 **Responsibilities.** Without limiting the generality of the foregoing, the JSC shall have the following responsibilities:

(a) overseeing the JDC's performance of its responsibilities, the JFC's performance of its responsibilities and the JMC's performance of its responsibilities;

(b) reviewing data, reports or other information submitted to it by the JDC, JMC and JFC from time to time;

(c) resolving all JDC, JMC or JFC matters that are referred to the JSC for resolution;

(d) making such other decisions as may be delegated to the JSC pursuant to this Agreement or by mutual written agreement of the Parties after the Effective Date; and

(e) the JSC will meet in accordance with Section 2.1.3 for the purpose of (i) serving as a forum for Biotest and/or ImmunoGen, as applicable, to update each other as to Development and Commercialization progress with respect to Licensed Products, including monitoring the progress of the Development of each Licensed Product in accordance with the Development Plan and the Commercialization of each Co-Developed Product in accordance with the applicable Co-Development Marketing and Sales Plan and reviewing each annual update to each Co-Development Marketing and Sales Plan; and (ii) resolving any matters that require a Unanimous Decision. At each such meeting of the JSC the members of Biotest on the JSC shall provide an update as to Biotest's general strategy for the Development and Commercialization of each Licensed Product in the Field to the extent applicable. In the event ImmunoGen exercises a Co-Development Option, the members of Biotest and ImmunoGen on the JSC shall provide (i) an update as to the Co-Promotion strategy for the Development and Commercialization of each Co-Developed Product in the Field set forth in the Co-Development Plan and/or Co-Development Marketing and Sales Plan (ii) an update concerning the anticipated timelines on a region-by-region basis for the Development of each Co-Developed Product and Regulatory Filings with respect thereto in the Field in the Territory, (iii) an update concerning the anticipated timelines on a region-by-region basis for the commercial launch of each Co-Developed Product and (iv) sales forecast guidance for each Co-Developed Product in the Field in the Territory; provided, that, in providing such update, the members of Biotest on the JSC shall be entitled to omit discussion of Confidential Information of Biotest that Biotest reasonably determines to be materially sensitive. If there is a material change in such timelines or guidance after any such meeting, Biotest will endeavor to notify ImmunoGen thereof through the convenience of a special meeting of the JSC.

2.1.5 **Interests of the Parties.** Notwithstanding any other provisions of this Agreement, all decisions made and all actions taken by the JSC shall be made or taken in the best interest of the Collaboration.

2.1.6 **Dispute Resolution.** The JSC members shall use reasonable efforts to reach agreement on any and all matters. In the event that, despite such reasonable efforts, agreement on a particular matter cannot be reached by the JSC within ten (10) days after the JSC first meets to consider such matter or such later date as may be mutually agreed to by the Parties (each such matter, a "Disputed Matter"), then, if the Disputed Matter does not involve a Unanimous Decision, a Biotest Decision or an ImmunoGen Decision, the Chairman of the JSC shall have the right to make the final decision on such Disputed Matter, but shall only exercise such right in good faith after full consideration of the positions of both Parties. Notwithstanding the foregoing, (a) if the Disputed Matter involves an ImmunoGen Decision, one of the ImmunoGen members of the JSC shall have the right to make the final decision on such Disputed Matter, but shall only exercise

such right in good faith after full consideration of the positions of both Parties, (b) if the Disputed Matter involves a Biotest Decision, one of the Biotest members of the JSC shall have the right to make the final decision on such Disputed Matter, but shall only exercise such right in good faith after full consideration of the positions of both Parties, and (c) if the Disputed Matter involves a Unanimous Decision, the Disputed Matter shall be referred to the Designated Senior Officer of each Party, who shall promptly initiate discussions in good faith to resolve the Disputed Matter. If the Disputed Matter is not resolved by such Designated Senior Officers within the first to occur of (i) ten (10) days after the date the Designated Senior Officers first met to consider such Disputed Matter or such later date as may be mutually agreed to by the Parties or (ii) thirty (30) days after the date the JSC first met to consider such Disputed Matter or such later date as may be mutually acceptable to the Parties, the Disputed Matter shall be resolved in accordance with Section 14.1. In addition, if the Disputed Matter involves determining whether a patent application should be filed with respect to a Program Invention and/or the jurisdictions in which it will be filed, subject to Section 10.1.4, the Party whose Program Invention is involved shall have the right to make the final decision on such Disputed Matter.

## 2.2 **Joint Development Committee.**

2.2.1 **Establishment.** The JDC shall be established as soon as practicable following the execution of the Agreement by ImmunoGen and Biotest but in any case within fourteen (14) days following the Effective Date. The JDC shall have and perform the responsibilities set forth in Section 2.2.4.

2.2.2 **Membership.** Each of ImmunoGen and Biotest shall designate an equal (not less than two (2)) number of representatives to the JDC (which may be employees of, or consultants to, such Party). Unless otherwise agreed by the Parties, one of Biotest's representatives shall be designated by Biotest as the Chairman of the JDC. Each Party shall have the right at any time to substitute individuals, on a permanent or temporary basis, for any of its previously designated representatives to the JDC by giving written notice to the other Party.

### 2.2.3 **Meetings.**

(a) **Schedule of Meetings; Agenda.** The JDC shall establish a schedule of times for regular quarterly meetings, taking into account, without limitation, the planning needs of the Research Program and the responsibilities of the JDC. In addition, special meetings may be convened by any member of the JDC upon thirty (30) days (or, if such meeting is proposed to be conducted by teleconference, upon ten (10) days) written notice to the other members; provided that (i) notice of any such special meeting may be waived at any time, either before or after such meeting and (ii) attendance of any member at a special meeting shall constitute a valid waiver of notice from such member. In no event shall the JDC meet less frequently than four (4) times in each Calendar Year. Regular and special meetings of the JDC may be held in person or by teleconference or videoconference; provided that meetings held in person shall alternate between the respective offices of the Parties in Cambridge, Massachusetts and Dreieich, Germany or such other locations mutually agreeable to the JDC members. The Chairman shall have the

responsibility for preparing and circulating to each JDC member an agenda for each JDC meeting not later than one (1) week prior to such meeting.

(b) Quorum; Voting; Decisions. At each JDC meeting, (i) the presence in person of at least one (1) member designated by each Party shall constitute a quorum and (ii) each member who is present shall have one vote on all matters before the JDC at such meeting. All decisions of the JDC, other than Unanimous Decisions, Biotest Decisions and ImmunoGen Decisions, shall be made by majority vote; provided, that, any member designated by a Party shall have the right to cast the votes of any of such Party's members on the JDC who are absent from the meeting. Alternatively, the JDC may act by written consent signed by at least one (1) member designated by each Party. All decisions of the JDC that involve Unanimous Decisions shall be made by vote of all members of the JDC. Whenever any action by the JDC is called for hereunder during a time period in which the JDC is not scheduled to meet, the Chairman shall cause the JDC to take the action in the requested time period by calling a special meeting or by circulating a written consent. Representatives of each Party or of its Affiliates who are not members of the JDC (including, without limitation, the Patent Coordinators) may attend JDC meetings as non-voting observers. In the event that the JDC is unable to resolve any matter before it, such matter shall be resolved in accordance with Section 2.2.6.

(c) Minutes. The JDC shall keep minutes of its meetings that record all decisions and all actions recommended or taken in reasonable detail. Drafts of the minutes shall be prepared and circulated to the members of the JDC within a reasonable time after the meeting, not to exceed [\*\*\*] ([\*\*\*)] business days, and the Parties shall alternate responsibility for the preparation and circulation of draft minutes. Each member of the JDC shall have the opportunity to provide comments on the draft minutes. Draft minutes shall be approved, disapproved and revised as necessary at the next JDC meeting. Upon approval, final minutes of each meeting shall be circulated to the members of the JDC by the Chairman.

(d) Expenses. ImmunoGen and Biotest shall each bear all expenses of their respective JDC representatives related to their participation on the JDC and attendance at JDC meetings.

2.2.4 **Responsibilities.** The JDC shall be responsible for overseeing the conduct and progress of the Research Program and the Development of Licensed Products. Without limiting the generality of the foregoing, during the Research Program term, the JDC shall have the following responsibilities:

(a) making proposals with respect to and directing the preparation by the Parties of, the Research Plan, the Development Plan and the Co-Development Plan; and discussing and determining whether and which new indications in which territories shall be pursued under each Development Plan and/or Co-Development Plan;

(b) in consultation with the Patent Coordinators, determining the patent applications to be filed with respect to Program Inventions;

(c) monitoring the progress under the Research Plan, the Development Plan, the Pivotal MAY Compound Process Development Plan and the Co-Development Plan and of each Party's activities thereunder;

(d) providing a forum for consensual decision making with respect to the Research Program and the Development Plan and the Co-Development Plan;

(e) reviewing and circulating to the Parties data, reports or other information submitted by either Party with respect to work conducted under the Research Program and the Development Plan and the Co-Development Plan;

(f) providing a forum for the exchange of ImmunoGen Technology necessary for a Third Party to manufacture Preclinical Materials and Clinical Materials under this Agreement;

(g) making such other decisions as may be delegated to the JDC pursuant to this Agreement or by mutual written agreement of the Parties after the Effective Date; and

(h) to the extent reasonably necessary, reviewing invoices issued by ImmunoGen to Biotest for work performed in the conduct of ImmunoGen Activities, such review may result in an approval or a credit note, as applicable.

2.2.5 **Interests of the Parties.** Notwithstanding any other provisions of this Agreement, all decisions made and all actions taken by the JDC shall be made or taken in the best interest of the Collaboration.

2.2.6 **Dispute Resolution.** The JDC members shall use reasonable efforts to reach agreement on any and all matters. The JDC shall be operated by consensus; provided, that, prior to ImmunoGen's exercise of a Co-Development Option in the event that, despite such reasonable efforts, agreement on a particular matter cannot be reached by the JDC, the judgment of the Biotest Chairman shall be determinative. Provided that ImmunoGen has exercised a Co-Development Option, in the event that, despite such reasonable efforts, agreement on a particular matter regarding the Co-Developed Product in the Co-Development Territory cannot be reached by the JDC within ten (10) days after the JDC first meets to consider such matter, then the matter shall be referred to the JSC for resolution pursuant to Section 2.1.6. With respect to the Development of Biotest Products in the Territory and/or Co-Developed Products outside the Co-Development Territory, the judgment of the Biotest Chairman shall be determinative.

### 2.3 **Alliance Managers.**

2.3.1 **Appointment.** Each Party shall appoint a person who shall oversee contact between the Parties for all matters related to the research and Development of Licensed Products between meetings of the JDC and the JSC (each, an "Alliance Manager"). The Alliance Managers shall have the right to attend all meetings of the JSC, JDC, the JFC and the JMC, as the case may be, as non-voting participants and may bring to the attention of the JSC, JDC, the JFC and the JMC, as the case may be, any matters or issues either of them reasonably believes should be

discussed and shall have such other responsibilities as the Parties may mutually agree in writing. Each Party may replace its Alliance Manager at any time by notice in writing to the other Party.

2.3.2 **Responsibilities.** The Alliance Managers shall have the responsibility of creating and maintaining a constructive work environment within the JSC, JDC, the JFC and the JMC, as the case may be, and between the Parties for all matters related to the Collaboration. Without limiting the generality of the foregoing, such Alliance Managers shall:

(a) identify and bring to the attention of the JSC, as applicable, any disputes arising between the Parties related to the Collaboration in a timely manner, including without limitation any asserted occurrence of a material breach by a Party, and function as the point of first referral in the resolution of each dispute;

(b) provide a single point of communication for seeking consensus within the Parties' respective organizations and between the Parties with respect to the Collaboration;

(c) plan and coordinate cooperative efforts and internal and external communications between the Parties with respect to the Collaboration; and

(d) take such steps as may be required to ensure that meetings of the JSC, JDC, the JFC and the JMC, as the case may be, occur as set forth in the Agreement, that procedures are followed with respect to such meetings (including, without limitation, the giving of proper notice and the preparation and approval of minutes) and that relevant action items resulting from such meetings are appropriately carried out or otherwise addressed.

## 2.4 **Joint Finance Committee.**

2.4.1 **Establishment.** As soon as practicable following the exercise by ImmunoGen of a Co-Development Option with respect to a Co-Developed Product in accordance with Section 5.1.1, ImmunoGen and Biotest will establish the Joint Finance Committee. The JFC shall have and perform the responsibilities set forth in Section 2.4.4.

2.4.2 **Membership.** Each Party shall designate, in its sole discretion, up to two (2) members to the JFC (which member may be an employee of, or consultant to, such Party). Each Party shall have the right at any time to substitute any individual, on a permanent or temporary basis, for its previously designated representative to the JFC by giving written notice to the other Party.

### 2.4.3 **Meetings.**

(a) **Schedule of Meetings.** The JFC shall establish a schedule of times for regular meetings, taking into account, without limitation, the need to review Co-Development Costs incurred by the Parties and the Net Income received with respect to Co-Developed Products. Meetings of the JFC may be held in person or by teleconference or videoconference; provided that meetings held in person shall alternate between the respective offices of the Parties.

(b) **Voting; Decisions.** At each JFC meeting, (i) the presence in person of at least one (1) member designated by each Party shall constitute a quorum and (ii) each member who is present shall have one vote on all matters before the JFC at such meeting. All decisions of the JFC related to Co-Developed Products in the Co-Development Territory shall be

made by majority vote; provided, that, any member designated by a Party shall have the right to cast the votes of any of such Party's members on the JFC who are absent from the meeting. Alternatively, the JFC may act by written consent signed by at least one (1) member designated by each Party. In the event that the JFC is unable to resolve any matter before it, such matter shall be referred to the JSC to be resolved in accordance with Section 2.1.6.

(c) **Minutes.** The JFC shall keep minutes of its meetings that record all decisions and all actions recommended or taken in reasonable detail. Drafts of the minutes shall be prepared and circulated to the members of the JFC within a reasonable time after the meeting, not to exceed [\*\*\*] (\*\*\* business days, and the Parties shall alternate responsibility for the preparation and circulation of draft minutes. Each member of the JFC shall have the opportunity to provide comments on the draft minutes. The minutes shall be approved, disapproved and revised as necessary at the next JFC meeting.

(d) **Expenses.** ImmunoGen and Biotest shall each bear all expenses of their respective JFC members related to their participation on the JFC and attendance at JFC meetings.

2.4.4 **Responsibilities.** The JFC shall be responsible for (a) monitoring the activities of, and reconciling issues between, the Parties with respect to the Parties' respective share of Co-Development Costs, Co-Promotion costs and Net Income with respect to Co-Developed Products in the Co-Development Territory and the Co-Promotion Percentage, (b) preparing ongoing rolling forecasts for each Calendar Quarter with respect to all Co-Development Costs and Net Income of Co-Developed Products in the Co-Development Territory, (c) determining the FTE rate applicable to the performance by ImmunoGen of ImmunoGen's activities and by Biotest of Biotest's activities after the exercise of a Co-Development Option and/or with respect to Representatives used by the Parties in Co-Promoting each Co-Developed Product; and (d) making such other decisions as may be delegated to the JFC by mutual agreement of the Parties after the Effective Date.

## 2.5 **Joint Marketing Committee.**

2.5.1 **Establishment.** As soon as practicable following the exercise by ImmunoGen of a Co-Development Option with respect to a Co-Developed Product in accordance with Section 5.1.1, ImmunoGen and Biotest shall establish the Joint Marketing Committee which shall have and perform the responsibilities set forth in Section 2.5.4.

2.5.2 **Membership.** Each Party shall designate, in its sole discretion, not less than two (2) members to the JMC (which members may be employees or consultants of such Party). Unless otherwise agreed by the Parties, one of Biotest's designees shall be designated by Biotest as the Chairman. Each Party shall have the right at any time to substitute individuals, on a permanent or temporary basis, for any of its previously designated representatives to the JMC by giving written notice to the other Party.

### 2.5.3 **Meetings.**

(a) **Schedule of Meetings; Agenda.** The JMC shall establish a schedule of times for regular meetings, taking into account, without limitation, the planning needs for the Co-Developed Products and its responsibilities. If formed, in no event shall the JMC meet less

frequently than four (4) times per Calendar Year. Regular and special meetings of the JMC may be held in person or by teleconference or videoconference; provided, that, meetings held in person shall alternate between the respective offices of the Parties. The Chairman shall prepare and circulate to each JMC member an agenda for each JMC meeting not later than one (1) week prior to each meeting.

(b) Quorum; Voting; Decisions. At each JMC meeting, (i) the presence in person of at least one (1) member designated by each Party shall constitute a quorum and (ii) each member designated by each Party who is present shall have one vote on all matters before the JMC at such meeting. All decisions of the JMC other than Unanimous Decisions, Biotest Decisions and ImmunoGen Decisions shall be made by majority vote; provided, that, any member designated by a Party shall have the right to cast the votes of any of such Party's members on the JMC who are absent from the meeting. Alternatively, the JMC may act by written consent signed by at least one (1) member designated by each Party. All decisions of the JMC that involve Unanimous Decisions shall be made by vote of all members of the JMC. Whenever any action by the JMC is called for hereunder during a time period in which the JMC is not scheduled to meet, the Chairman shall cause the JMC to take the action in the requested time period by calling a special meeting or by circulating a written consent. Representatives of each Party or of its Affiliates who are not members of the JMC may attend JMC meetings as non-voting observers.

(c) Expenses. ImmunoGen and Biotest shall bear all the expenses of their respective JMC members related to their participation on the JMC and attendance at JMC meetings.

2.5.4 Responsibilities. The JMC shall be responsible for overseeing the Co-Promotion of Co-Developed Products in the Co-Development Territory. Without limiting the generality of the foregoing, the JMC shall have the following responsibilities:

(a) preparing or directing the preparation of a Co-Development Marketing and Sales Plan containing a Co-Promotion Plan and a brand plan for each Co-Developed Product in the Co-Development Territory, such Plan to include allocation of responsibilities for Commercialization activities;

(b) reviewing and approving all Additional Co-Promotion Activities to be conducted by either Party pursuant to Section 5.7;

(c) preparing short-term and long-term sales forecasts for Co-Developed Products in the Co-Development Territory;

(d) presenting sales forecasts and the results of all Co-Promotion efforts in the Co-Development Territory to the JSC as needed, but no less often than four (4) times per Calendar Year;

(e) coordinating the Detailing efforts of both Parties in the Co-Development Territory with respect to Co-Developed Products;

(f) overseeing all recalls, market withdrawals and any other corrective actions related to Co-Developed Products in the Co-Development Territory;

(g) receiving and providing to the Parties sales reports pertaining to Co-Developed Products in the Co-Development Territory;

(h) consulting the Parties in the selection of Third Parties to be engaged by either Party to provide Representatives to Co-Promote Co-Developed Products in the Co-Development Territory; and

(i) performing such activities as may be delegated to the JMC pursuant to this Agreement, or by mutual written agreement of the Parties after the Effective Date.

2.5.5 **Dispute Resolution.** The JMC members shall use reasonable efforts to reach agreement on any and all matters. In the event that, despite such reasonable efforts, agreement on a particular matter cannot be reached by the JMC within ten (10) days after the JMC first meets to consider such matter, then the matter shall be referred to the JSC for resolution pursuant to Section 2.1.6.

### **3. RESEARCH PROGRAM**

3.1 **Objectives of the Research Program.** The objective of the Research Program shall be the identification of one or more Licensed Products suitable for further Development and Commercialization.

3.2 **Research Plan.** The JDC shall create a Research Plan to, among other things, enable selection of the best Anti- CD138 Antibody-MAY Conjugate for further Development and to conduct initial research activities with respect to such conjugate, including basic process development, prior to the initiation of formal Development activities. For each Contract Year during the conduct of the Research Program commencing with the second Contract Year, the Research Plan shall be amended and updated by the Parties, which amendments and updates shall be submitted to and approved by the JDC in accordance with Section 2.2.4. Each such amendment shall: (a) set forth (i) the research objectives and activities to be performed for the Contract Year covered by the update with reasonable specificity; (ii) the Party that shall be responsible for performing such activities; (iii) a timeline for such activities; and (iv) with respect to ImmunoGen Activities, the number of FTEs estimated to be required to perform such ImmunoGen Activities; and (b) be consistent with the terms of this Agreement.

3.3 **Conduct of Research Program.** In consultation with the JDC and in accordance with the objectives of the Research Program, each Party shall be primarily responsible for those tasks and obligations in connection with the Research Program that are assigned to it pursuant to this Section 3.3 and in the Research Plan. Without limiting the foregoing, the Parties hereby agree as follows:

(a) **Biotest Activities Under Research Program.** Subject to ImmunoGen's obligations to conduct ImmunoGen Activities and/or to supply Research Materials pursuant to Section 3.3(b)(ii) and Preclinical Materials and Clinical Materials in accordance with Section 4.5.2, Biotest shall have the sole right and responsibility for all aspects related to the research and early stage Development of Licensed Products, including without limitation (i) making all strategic and tactical decisions with respect thereto; (ii) assessing alternative product designs; (iii) the selection of the Antibody, Linker and MAY Compound to be used in each Licensed Product; (iv) the conduct of, at its sole cost and expense, all preclinical and IND-enabling studies (including toxicology testing) with respect to any Licensed Product so selected.

(b) ImmunoGen Activities under the Research Program.

(i) In General. Notwithstanding anything to the contrary in Section 3.3(a), ImmunoGen will undertake (A) any ImmunoGen Activities set forth in the Research Plan, subject to the payment by Biotest of the consideration set forth in Section 6.2 and (B) any other basic research activities that ImmunoGen determines, in its sole discretion and [\*\*\*] [\*\*\*] [\*\*\*] [\*\*\*], are necessary in order to successfully apply ImmunoGen Technology to the research of Licensed Products.

(ii) Supply of Research Materials. Upon Biotest's written request, ImmunoGen will supply Biotest with such quantities of Research Materials as may be reasonably required by Biotest in order to conduct research relating to Licensed Products. To the extent that Biotest requests that ImmunoGen provide such Research Materials, Biotest shall order all amounts of Research Materials, and ImmunoGen shall deliver all such ordered amounts, in accordance with advance ordering timeframes and delivery timeframes and specifications to be agreed upon by the Parties. ImmunoGen shall use commercially reasonable efforts to deliver to Biotest such amounts of Research Materials as are ordered by Biotest in accordance with the foregoing (including such agreed upon timeframes) in a timely manner. ImmunoGen's price to supply Research Materials to Biotest shall equal ImmunoGen's cost of materials plus its manufacturing costs [\*\*\*] [\*\*\*] [\*\*\*] [\*\*\*] [\*\*\*].

3.4 **Diligence.** Each Party shall use commercially reasonable efforts to perform its respective obligations under the Research Program in accordance with the Research Plan and shall commit such resources as are specified in the Research Plan as may be necessary to conduct its activities set forth therein in a timely fashion. Without limiting the foregoing, Biotest and ImmunoGen shall commit such scientific resources, including, but not limited to consultants, facilities, equipment, and Proprietary Materials, as are necessary and commercially reasonable to achieve the objectives of the Research Program.

3.5 **Compliance.** Each Party shall perform its obligations under the Research Plan in good scientific manner and in compliance in all material respects with all Applicable Laws; provided that, for purposes of clarity, (a) with respect to each activity performed under the Research Plan that will or could reasonably be expected to be submitted to a Regulatory Authority in support of a Regulatory Filing in the United States, the Party performing such activity shall comply in all material respects with the regulations and guidance of the FDA that constitute Good Laboratory Practice or Good Manufacturing Practice, in each case as applicable; (b) to the extent Biotest wishes ImmunoGen to comply with the regulations or guidance of any Regulatory Authority outside the United States (including any International Conference on Harmonization (ICH) guidance), Biotest shall provide ImmunoGen with written notice which shall identify such regulations or guidance, and ImmunoGen shall confirm in writing whether it agrees to comply with same within [\*\*\*] ([\*\*\*) business days of its receipt of such notice; and (c) to the extent Biotest wishes ImmunoGen to comply with the regulations or guidance of any Regulatory Authority outside the United States (including any ICH guidance) and ImmunoGen agrees to comply with such regulations or guidance, ImmunoGen agrees to be inspected after prior written notice by Biotest and competent foreign Regulatory Authority to allow for a Regulatory Filing outside the United States. Each Party shall be solely responsible for paying the salaries and benefits of its employees and consultants conducting its activities under the Research Plan.

3.5.1 **Cooperation.** Scientists at ImmunoGen and Biotest shall cooperate in the performance of the Research Program and, subject to the terms of this Agreement and any confidentiality obligations to Third Parties, shall exchange such data, information and materials as is reasonably necessary for the other Party to perform its obligations under the Research Plan.

3.6 **Records.**

3.6.1 **Record Keeping.**

(a) **Records.** Each Party shall maintain records of its activities under the Research Program in sufficient detail, in good scientific manner and otherwise in a manner that reflects all work done and results achieved in the performance of the Research Program.

(b) **Record Keeping Policies.** Without limiting the generality of Section 3.6.1(a), each Party agrees to maintain a policy that requires its employees and consultants to record and maintain all data and information developed during the Research Program in a manner designed to enable the Parties to use such records to establish the earliest date of invention or reduction to practice. At a minimum, the policy shall require such individuals to record such data and information by them in standard laboratory notebooks that are dated and corroborated by non-inventors on a regular, contemporaneous basis.

3.7 **Reports.** At each meeting of the JDC, the Parties shall update the JDC as to such Party's efforts under the Research Program and shall present to the JDC all data and results generated from such efforts. The JDC may decide, from time to time, to cause the Research Plan to be updated to reflect changes in the research activities performed by each Party under the Research Plan.

3.8 **Supply of Proprietary Materials.** From time to time during the Term, either Party (the "transferring Party") may supply the other Party (the "recipient Party") with Proprietary Materials of the transferring Party for use in the Research Program. In connection therewith, each recipient Party hereby agrees that (a) it shall not use such Proprietary Materials for any purpose other than exercising its rights or performing its obligations hereunder; (b) it shall use such Proprietary Materials only in compliance with all Applicable Laws; (c) it shall not transfer any such Proprietary Materials to any Third Party without the prior written consent of the transferring Party, except as expressly permitted hereby or as otherwise permitted under the Existing Agreements; (d) the recipient Party shall not acquire any right, title or interest in or to such Proprietary Materials as a result of such supply by the transferring Party; (e) the recipient Party shall, if and as instructed by the Party, either destroy or return any such Proprietary Materials that are not the subject of the grant of a continuing license hereunder; and (f) to the extent ImmunoGen is the transferring Party, upon Biotest's request, ImmunoGen shall provide Biotest with supply safety data sheets and instructions for use, waste management, transportation, packaging and labeling of ImmunoGen Materials.

## **4. DEVELOPMENT AND COMMERCIALIZATION**

### **4.1 Responsibility; Preparation of Plans.**

4.1.1 **Development Plans.** Until the exercise of a Co-Development Option for a Licensed Product, Biotest will be solely responsible for conducting the Development of Licensed Products. As soon as practicable after the identification in the Research Program of each Licensed Product for further Development, the Parties shall jointly prepare and submit to the JDC for approval a Development Plan covering the activities to be carried out over each Contract Year which shall: (a) set forth (i) the Development objectives and activities to be performed for each Contract Year period covered by the Development Plan with reasonable specificity, broken down by Calendar Quarters, (ii) the Party that shall be responsible for performing such activities, and (iii) a timeline for such activities; and (b) be consistent with the other terms of this Agreement. ImmunoGen will undertake the ImmunoGen Activities set forth in the Development Plan, subject to the payment by Biotest of the consideration set forth in Section 6.2. The Parties shall discuss at meetings of the JDC the scope of, and the expenditures for, any process development activities planned by either Party after the Effective Date for pivotal MAY Compounds, which discussions shall be included in the minutes of the applicable JDC meeting (the portion of such minutes, the "Pivotal MAY Compound Process Development Plan"), taking into account Pivotal MAY Compound Process Development activities of Third Parties, covering the activities to be carried out over each Contract Year including: (a) the process development objectives and activities to be performed for each Contract Year period with reasonable specificity, broken down by Calendar Quarters, (b) the Party that shall be responsible for performing such activities, and (c) a timeline for such activities. The Pivotal MAY Compound Process Development Plan shall include the Pivotal MAY Compound Process Development Costs approved by the JDC as provided in Section 1.113.

4.1.2 **Marketing and Sales Plans.** Until such time as ImmunoGen has exercised a Co-Development Option, (a) Biotest shall be solely responsible for all activities and associated costs related to the worldwide marketing and sales of Licensed Products and (b) decisions regarding marketing and sales will be made solely by Biotest.

4.1.3 **Manufacturing Plan.** Biotest shall be solely responsible for the manufacture of Biotest Products in the Territory and Co-Developed Products in the Biotest Territory. The Parties shall prepare and provide to the JDC for its review and approval a Manufacturing Plan that specifies which manufacturer of MAY Compounds and Anti- CD138 Antibody-MAY Conjugates are to be used for Biotest Products and/or Co-Developed Products and/or Preclinical Materials and/or Clinical Materials, which Manufacturing Plan shall be updated by the Parties and reviewed and approved by the JDC each Contract Year during the Term following the JDC's approval of the initial Manufacturing Plan. Each update to the Manufacturing Plan shall: (a) set forth (i) the manufacturing scale-up, formulation and filling requirements for each Biotest Product and/or Co-Developed Product to be performed for the Contract Year covered by the Manufacturing Plan with reasonable specificity, (ii) a timeline and budget for such activities, (iii) the objectives and activities to be performed for each Contract Year period covered by the Manufacturing Plan with reasonable specificity, (iv) the Party that shall be responsible for performing such activities, (v) the estimated expenses covering the activities associated with the Manufacturing Plan; and (b) be consistent with the other terms of this Agreement. The JDC members shall use reasonable efforts to reach agreement on manufacturing issues. In the event that, despite such reasonable efforts, agreement on a particular matter cannot be reached by the JDC, the judgment of the Biotest Chairman shall be determinative. If the JDC requests that

ImmunoGen manufacture Preclinical Materials and/or Clinical Materials, then the judgment of the ImmunoGen representatives on the JDC shall be determinative.

4.2 **Biotest Products.** Subject to Section 5, Biotest shall have the sole right and responsibility, at its sole cost and expense, for all aspects of the Development and Commercialization of Biotest Products in accordance with the applicable Development Plan in the Field in the Territory, including, without limitation, the conduct of (a) all activities relating to the manufacture and supply of Biotest Products in the Territory, and (b) all marketing, promotion, sales, distribution, import and export activities (including securing reimbursement, sales and marketing and conducting any post-marketing trials or databases and post-marketing safety surveillance) with respect to Biotest Products in the Territory. Without limiting the generality of the foregoing, Biotest shall have the sole right and responsibility, at its sole expense, (a) for the conduct of: (i) all activities related to human clinical trials (including, to the extent conducted, Phase IV clinical trials); (ii) all activities relating to the manufacture and supply of Biotest Products (including all required process development and scale up work with respect thereto) in the Territory; and (iii) all pre-marketing, marketing, promotion, sales, distribution, import and export activities (including securing reimbursement, sales and marketing and conducting any post-marketing trials or databases and post-marketing safety surveillance); (b) making all Regulatory Filings for Biotest Products and filing all Drug Approval Applications and otherwise seeking all Regulatory Approvals for Biotest Products in the Territory, as well as all correspondence and communications with Regulatory Authorities regarding such matters, and (c) reporting of all Adverse Events to Regulatory Authorities for Biotest Products within the Territory if and to the extent required by Applicable Laws.

4.3 **Commercialization Diligence.** Biotest shall use Commercially Reasonable Efforts during the Term to Develop and to Commercialize Biotest Products in the Field and in the Territory. Without limiting the foregoing, Biotest shall, itself or through one or more Sublicensees, seek Regulatory Approvals for, and Commercialize, each Biotest Product in such countries of the Territory that Biotest, in its commercially reasonable judgment, deems appropriate. If ImmunoGen at any time reasonably believes that Biotest is not meeting its diligence obligations pursuant to this Section 4.3, ImmunoGen may give, in the form of detailed reasons, written notice to Biotest requesting written justification, in the form of detailed reasons, that would support the proposition that Biotest is meeting such diligence obligations. In such event, Biotest shall provide such written justification to ImmunoGen within thirty (30) days after such notice is given. In the event that Biotest does not reasonably justify that it is meeting its diligence obligations pursuant to this Section 4.3 within such thirty (30) day period, then, to the extent such failure to meet its diligence obligations constitutes a material breach of this Agreement, ImmunoGen shall have the right, in its sole discretion, to exercise its rights under Section 11.2.1 or any or all other rights or remedies that it may have under this Agreement, at law or in equity.

#### 4.4 **Compliance.**

4.4.1 **In General.** Biotest and/or ImmunoGen, as applicable, shall each perform their respective obligations under each Development Plan and Manufacturing Plan in good scientific and business manner and in compliance in all material respects with all Applicable Laws provided that, for purposes of clarity, with respect to each activity performed under the Development Plan and Manufacturing Plan that will or would reasonably be expected to be

submitted to a Regulatory Authority in support of a Regulatory Filing or Drug Approval Application, Biotest and/or ImmunoGen, as applicable, shall each comply in all material respects, in the Territory, with the regulations and guidance of the relevant authorities in the Territory, e.g., the FDA or the EMEA, that constitute GLP, GMP or GCP (or, if and as appropriate under the circumstances, ICH guidance or other comparable regulation and guidance of any Regulatory Authority in any country or region in the Territory).

4.4.2 **Regulatory Obligations.** Biotest agrees, with respect to each Licensed Product, (a) prior to the Initiation of each clinical trial through and including any Phase IIb Clinical Trial, to carry out a pre-IND meeting with the applicable Regulatory Authority; (b) to file an IND in the United States prior to the Initiation of the first Phase I Clinical Trial in the United States; and (c) on and after such filing of the IND in the United States, to fulfill at least the requirements specified by the FDA for first Phase I Clinical Trial, regardless of where such first Phase I Clinical Trials are ultimately conducted.

#### 4.5 **Information; Updates.**

4.5.1 **Reports.** The Parties shall keep the JDC regularly informed of the progress of its efforts to Develop Biotest Products in the Field. Without limiting the generality of the foregoing, Biotest and ImmunoGen, as applicable, shall, at each JDC meeting, provide the JDC with reports in reasonable detail which shall summarize (a) the status of all Development activities under each Development Plan, together with such additional information that it has in its possession as may be reasonably requested from time to time by the JDC regarding the Development of any Biotest Product in the Territory, (b) the Regulatory Filings and Drug Approval Applications with respect to such Biotest Product that Biotest or any of its Affiliates or Sublicensees have filed, sought or obtained in the prior twelve (12) month period or reasonably expect to make, seek or attempt to obtain in the following twelve (12) month period in the Territory and (c) all clinical and other data generated by Biotest with respect to Biotest Products.

#### 4.5.2 **Supply of Licensed Products for Development and Commercialization.**

(a) **Responsibility of Biotest.** Except as set forth in Section 4.5.2(b), Biotest shall have the sole right and responsibility, at its sole cost, for manufacturing or having manufactured through Third Party contract manufacturers, any materials (including, without limitation, all Anti-CD138 Antibodies, MAY Compounds, Linkers and Licensed Products) as may be required for all preclinical and clinical studies necessary to obtain Regulatory Approval of Licensed Products and any materials and/or quantities of each Licensed Product as may be required for, (i) all preclinical and clinical studies applicable to, and (ii) the Commercialization of, such Licensed Product, but may benefit from economies of scale and established manufacturing services related to the production of MAY Compounds, Linkers and conjugates. ImmunoGen agrees to provide Biotest, within [\*\*\*] ([\*\*\*)] days of the Effective Date and upon Biotest's request in reasonably detailed written format, through the JDC, with information including, but not limited to, procedures, processes, standard operating procedures and Proprietary Materials including, but not limited to, cell lines and Antibodies for MAY Compound detection, relating to any ImmunoGen Technology that may be reasonably necessary to enable any Third Party that is reasonably experienced in the manufacture of pharmaceutical products to manufacture such materials (including without limitation, all MAY Compounds, Linkers and

Licensed Products). If ImmunoGen exercises a Co-Development Option to a Licensed Product (i) both Parties shall be responsible for the manufacture of such Co-Developed Product in the Co-Development Territory and, (ii) the related costs shall be shared equally. Biotest shall remain solely responsible for the manufacture of Licensed Product outside the Co-Development Territory and shall remain free to contract any CMO for such purpose but may benefit from economies of scale and established manufacturing services related to the production of MAY Compounds, Linkers and conjugates.

(b) Supply of Materials by ImmunoGen.

(i) In General. If at any time during the Term, Biotest requests in writing that ImmunoGen supply Biotest with such quantities of Preclinical Materials and/or Clinical Materials as may be reasonably required by Biotest in order to conduct preclinical Development activities (including, without limitation, toxicology testing) relating to Licensed Products and/or conduct any clinical trials up through and including the completion of non-pivotal Phase II Clinical Trials (but not including any pivotal clinical trials) with respect to Licensed Products, ImmunoGen will use commercially reasonable efforts to (1) supply Biotest with such Preclinical Materials and/or Clinical Materials and, (2) with respect to Clinical Materials, to conduct such process development activities that may be necessary to produce such Clinical Materials. Such Preclinical and/or Clinical Material supplied by ImmunoGen to Biotest shall have attached with each shipment the respective safety data sheets and instructions for use, waste management, transportation, packaging and labeling. In connection with such supply, ImmunoGen shall provide a description to Biotest in sufficient detail of the accounting method to be used for ImmunoGen's calculation of Manufacturing Costs for such Preclinical Materials and/or Clinical Materials and the rationale therefor.

(ii) Preclinical Materials. To the extent that Biotest requests that ImmunoGen manufacture Preclinical Materials, (A) Biotest shall order all amounts of Preclinical Materials, and ImmunoGen shall deliver all such ordered amounts, in accordance with advance ordering timeframes and delivery timeframes and specifications to be agreed upon by the Parties; (B) if the Preclinical Materials are Licensed Products, Biotest shall supply ImmunoGen with quantities of Anti-CD138 Antibody sufficient to enable ImmunoGen to produce such Licensed Products; and (C) ImmunoGen shall use commercially reasonable efforts to deliver to Biotest such amounts of Preclinical Materials as are ordered by Biotest in accordance with the foregoing (including such agreed upon timeframes) in a timely manner; provided, that, to the extent such Preclinical Materials are Licensed Products, ImmunoGen's obligations shall be contingent on ImmunoGen's receipt of the required quantities of Anti- CD138 Antibodies from Biotest and any Dedicated Equipment necessary to manufacture such Preclinical Materials. To the extent necessary to fulfill the requirements of a Regulatory Authority or to generate data and results for a Regulatory Filing with respect to a Licensed Product, upon request of Biotest, ImmunoGen shall deliver ordered amounts of Preclinical Material manufactured according to quality guidelines that are reasonably sufficient to support an IND filing for such Licensed Product. ImmunoGen's price to supply Preclinical Materials to Biotest shall equal ImmunoGen's Manufacturing Cost plus [\*\*\*] percent ([\*\*\*]%) for such Preclinical Materials. Biotest shall be entitled to transfer Preclinical Materials to any Third Party under terms obligating such Third Party not to transfer or use such Preclinical Materials except in compliance with the foregoing clause (i) of this Section 4.5.2(b). Biotest shall have the right to audit ImmunoGen's Manufacturing Costs applicable to the

manufacture of Preclinical Materials pursuant to Section 4.5.2(b)(ii) consistent with the audit rights described in Sections 5.1.4, 5.2.2 and 6.2.1.

(iii) Clinical Materials. To the extent that Biotest requests that ImmunoGen manufacture Clinical Materials, (A) the Parties shall share information concerning specifications, forecasting and capacity requirements in order to adequately plan for the manufacture and supply of such Clinical Materials and (B) ImmunoGen and Biotest shall enter into a separate supply and quality agreement detailing the terms of supply for any Clinical Materials that ImmunoGen is so requested to supply to Biotest, which supply agreement shall include, without limitation, the terms set forth on Schedule 3 attached hereto and the remainder of this Section 4.5.2(b)(iii) (the "Supply Agreement"). Subject to the foregoing, Biotest shall order all amounts of Clinical Materials, and ImmunoGen shall deliver all such ordered amounts in accordance with forecasting parameters, advance ordering timeframes and delivery timeframes to be agreed upon by the Parties in the Supply Agreement. The Supply Agreement further shall provide that (A) ImmunoGen shall use commercially reasonable efforts to deliver such amounts of Clinical Materials ordered in accordance with the foregoing (including such agreed upon timeframes) in a timely manner; provided, that, ImmunoGen's obligations shall be contingent on ImmunoGen's receipt of the required quantities of Anti-CD138 Antibodies from Biotest and any Dedicated Equipment necessary to manufacture such Clinical Materials and (B) ImmunoGen's transfer price to supply Clinical Materials to Biotest shall equal ImmunoGen's Manufacturing Cost plus [\*\*\*] ([\*\*\*]%) percent for such Clinical Materials. Biotest hereby agrees that (i) it shall use the Clinical Materials in compliance with all Applicable Laws, and (ii) it (as a matter of contract between itself and ImmunoGen) shall assume all liability for damages that may arise from the use, storage and disposal of such Clinical Materials, except to the extent such liability for damages arises out of a failure on the part of ImmunoGen or any of its Affiliates to use the reasonably required diligence in the use, storage, and disposal of the relevant Clinical Materials. Biotest shall be entitled to transfer Clinical Materials to any Third Party under terms obligating such Third Party not to transfer or use such Clinical Materials except in compliance with the foregoing clause (i) of this Section 4.5.2(b).

(iv) Process Development Activities. To the extent that Biotest requests that ImmunoGen manufacture Preclinical Materials or Clinical Materials as described in this Section 4, ImmunoGen shall conduct such process development activities as the Parties agree are necessary to produce the quantities of Preclinical Materials or Clinical Materials so ordered, which process development activities shall be paid by Biotest pursuant to Sections 4.5.2(b)(ii) and/or (iii) of this Agreement and/or the Supply Agreement.

(c) Purchase of Dedicated Equipment. If, during the Term of this Agreement, the JDC determines in good faith that it is necessary or advisable to purchase Dedicated Equipment in order to perform any of its obligations to manufacture Preclinical Materials or Clinical Materials under Section 4.5.2(b), then ImmunoGen shall provide Biotest with written notice of such determination, along with the estimated price for such purchase and quality parameters for the Dedicated Equipment, for Biotest's approval of such price and features. Promptly after the consummation of such purchase, assuming that Biotest has provided its approval hereunder, ImmunoGen shall provide Biotest with a copy of the invoice or invoices reflecting such purchase, and Biotest shall reimburse ImmunoGen for the purchase of all such approved Dedicated Equipment hereunder within thirty (30) days of its receipt of such invoice

from ImmunoGen; provided, however, that no costs reimbursed by Biotest hereunder (or depreciation of such purchased equipment or instruments) shall be included within the calculation of any Costs under this Agreement. Biotest shall have title and ownership of all such Dedicated Equipment purchased pursuant to this Section 4.5.2(c), and shall have the right to reclaim or retain possession of such Dedicated Equipment at its expense upon reasonable notice at such time as it is no longer required for use by ImmunoGen to carry out this Agreement.

4.5.3 **Adverse Event Reports.** In addition to the updates described in Section 4.5.1, Biotest shall provide ImmunoGen with all Adverse Event information and product complaint information relating to Biotest Products as such information is compiled or prepared by Biotest in the normal course of business in connection with the Development of any Biotest Product and, in any event, within time frames consistent with reporting obligations under Applicable Laws. To the extent that it may apply to a Licensed Product, ImmunoGen agrees to provide Biotest with Serious Adverse Event and product complaint information relating to any product containing a conjugate of an Antibody with a MAY Compound 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, in accordance with procedures that shall be agreed to by the Parties; provided, however, that the foregoing shall not require ImmunoGen to violate any agreements with or confidentiality obligations owed to any Third Party. The Parties shall jointly discuss and agree upon a pharmacovigilance schedule outlining what shall be considered to be an Adverse Event for the purpose of this Section 4.5.3 and outlining Adverse Event reporting procedures after execution of this Agreement taking into account the specific needs of each Party.

4.5.4 **Review of Regulatory Filings and Correspondence.**

(a) **Preparation for Clinical Trials.** Prior to the initiation of the first Phase I Clinical Trial with respect to a Licensed Product, Biotest will prepare a briefing document (the “Briefing Document”) which shall describe in reasonable detail all material aspects of the clinical trial (including quality, safety, non-clinical data and planned clinical trials) with respect to such Licensed Product which shall form the basis for the pre-IND meeting for such Licensed Product. ImmunoGen shall use reasonable efforts to provide to Biotest all information and documents necessary to perform Regulatory Filings. At Biotest’s request, ImmunoGen shall cooperate with and assist Biotest in all reasonable respects, in connection with such preparation, filing and responding to questions and inquiries of any Regulatory Authority. Biotest shall consult with ImmunoGen in good faith in the preparation of such meeting and shall consider all comments made by ImmunoGen in good faith, taking into account the best interests of the Collaboration and of the Development and Commercialization of the applicable Biotest Product on a global basis.

(b) **Regulatory Meetings; Review of Regulatory Filings and Correspondence.** Biotest shall use reasonable efforts to provide ImmunoGen with at least thirty (30) days advance notice of any meeting with the FDA or other Regulatory Authority relating to any Biotest Product and ImmunoGen may elect to send representatives reasonably acceptable to Biotest to participate (at ImmunoGen’s sole cost and expense) in such meeting (including any pre-IND meeting). Subject to any Third Party confidentiality obligations, Biotest shall provide ImmunoGen with drafts of each Regulatory Filing or other document or correspondence pertaining to any Biotest Product and prepared for submission to the FDA or other Regulatory Authority (including without limitation the Briefing Document) sufficiently in advance of

submission so that ImmunoGen may review and comment on the substance of such Regulatory Filing or other document or correspondence. In addition, Biotest shall, without undue delay provide ImmunoGen with copies of any document or other correspondence received from the FDA pertaining to any Biotest Product. If ImmunoGen has not commented on such Regulatory Filing or other document or correspondence within [\*\*\*] ([\*\*\*)] days (or, in the case of an IND, [\*\*\*] ([\*\*\*)] days) after it is provided to ImmunoGen, then ImmunoGen shall be deemed to have no comments on such Regulatory Filing or other documents or correspondence. Biotest shall consider all comments of ImmunoGen in good faith, taking into account the best interests of the Collaboration and of the Development or Commercialization of the applicable Biotest Product on a global basis.

4.6 **Recalls.** In the event that any Regulatory Authority issues or requests a recall or takes similar action in connection with a Biotest Product, a product of ImmunoGen containing a conjugate of an Antibody with a MAY Compound or any other product containing a conjugate of an Antibody with a MAY Compound, and to the extent that a Party becomes aware of such recall or action, or in the event a Party reasonably believes that an event, incident or circumstance has occurred that may result in the need for a recall, market withdrawal or other corrective action regarding a Biotest Product or a product of ImmunoGen containing a conjugate of an Antibody with a MAY Compound or any other product containing a conjugate of an Antibody with a MAY Compound, such Party shall promptly advise the other Party thereof by telephone, e-mail or facsimile. Following such notification, Biotest shall decide and have control of whether to conduct a recall or market withdrawal of any potentially affected Biotest Product (except in the event of a recall or market withdrawal mandated by a Regulatory Authority, in which case it shall be required) or to take other corrective action in any country and the manner in which any such recall, market withdrawal or corrective action related to a Biotest Product shall be conducted; provided that Biotest shall keep ImmunoGen regularly informed regarding any such recall, market withdrawal or corrective action. Biotest shall bear all expenses of any such recall, market withdrawal or corrective action relating to any potentially affected Biotest Product and, to the extent the respective action is taken outside the Co-Development Territory, relating to any Co-Developed Product (including, without limitation, expenses for notification, destruction and return of the affected Biotest Product and any refund to customers).

## 5. CO-DEVELOPMENT OPTION; CO-PROMOTION OPTION

### 5.1 Co-Development Option.

#### 5.1.1 Exercise of Co-Development Option.

(a) Option Grant. Subject to Biotest's rights to sublicense Licensed Products in accordance with Section 8.3, ImmunoGen shall have the option (the "Co-Development Option"), but not the obligation, to co-Develop and Co-Promote any Licensed Product within the Co-Development Territory by providing written notice to Biotest and paying the applicable, noncreditable and nonrefundable Co-Development Option Exercise Fee in immediately available funds within [\*\*\*] ([\*\*\*)] days from the exercise of the applicable Co-Development Option (as defined in Section 5.1.1(c) below) (a) with respect to ImmunoGen's exercise of each Early Stage Co-Development Option, at any time during the period commencing on the Early Stage Option Commencement Date and continuing for a period of [\*\*\*] ([\*\*\*)] days (the "Early Stage Option

Exercise Period”) and (b) with respect to ImmunoGen’s exercise of each Late Stage Co-Development Option, at any time during the period commencing on the Late Stage Option Commencement Date and continuing for a period of [\*\*\*] ([\*\*\*)] days (the “Late Stage Option Exercise Period”). If ImmunoGen does not exercise its Co-Development Option within the applicable Option Exercise Period with respect to a Licensed Product, ImmunoGen shall have no right to co-Develop or Co-Promote such Licensed Product in the Co-Development Territory. For purposes of clarity, Biotest may exercise its right to sublicense Licensed Products in accordance with Section 8.3 at any time during the Term; provided, that, any such sublicense with respect to a Licensed Product shall be subject to ImmunoGen’s Co-Development Option with respect to that Licensed Product as described in this Section 5.1.1.

(b) Co-Developed Products. Until such time as ImmunoGen exercises a Co-Development Option with respect to a Licensed Product, that Licensed Product shall be deemed to be a Biotest Product for purposes of this Agreement. If ImmunoGen exercises a Co-Development Option with respect to a Licensed Product, (i) that Licensed Product shall be deemed to be a Co-Developed Product and shall no longer be deemed to be a Biotest Product in any Territory, (ii) Biotest and ImmunoGen shall equally share all Co-Development Costs incurred by the Parties in accordance with the Co-Development Plan related to such Co-Developed Product related to the Development necessary to get FDA approval including, but not limited to, material costs, FTE costs and filing fees, and (iii) each Party shall receive its respective applicable Co-Promotion Percentage of all Annual Net Income in the Co-Development Territory derived from that Co-Developed Product in accordance with Section 6.4.2. Following such exercise of a Co-Development Option, (i) the Parties shall prepare and submit to the JDC for approval a Co-Development Plan for the Co-Development of such Co-Developed Product which shall be updated by the Parties not less than annually, (ii) the JMC shall prepare a Co-Development Marketing and Sales Plan for the Co-Development Territory for such Co-Developed Product which shall be updated by the JMC not less than annually; (iii) such exercise of a Co-Development Option shall not delay the Development of such Licensed Product as set forth in the Development Plan prepared by Biotest and approved by the JDC; (iv) the Parties shall allocate the responsibilities with respect to the Commercializing of such Co-Developed Product in the Co-Development Territory in accordance with the applicable Co-Development Marketing and Sales Plan, including without limitation, (A) the conduct of: (1) all activities related to Phase IV Clinical Trials; (2) all activities relating to the manufacture and supply of Co-Developed Products (including all required process development and scale up work with respect thereto); and (3) all pre-marketing, marketing, promotion, sales, distribution, import and export activities in the Co-Development Territory (including securing reimbursement, sales and marketing and conducting any post-marketing trials or databases and post-marketing safety surveillance); (B) making all Regulatory Filings for Co-Developed Products and filing all Drug Approval Applications and otherwise seeking all Regulatory Approvals for Co-Developed Products, as well as all correspondence and communications with Regulatory Authorities regarding such matters, and (C) reporting of all Adverse Events to Regulatory Authorities if and to the extent required by Applicable Laws; and (v) [\*\*\*] shall book all sales of Co-Developed Products. Notwithstanding the foregoing, Biotest shall continue to be solely responsible for all Development costs attributable to the Development of any Co-Developed Product outside the Co-Development Territory, subject to the provisions set forth in Section 5.1.4.

(c) Co-Development Option Exercise Fee. As used in this Section 5.1, the term “Co-Development Option Exercise Fee” shall mean (a) with respect to each Early Stage Co-Development Option, Five Million Dollars (US \$5,000,000) and (b) with respect to each Late Stage Co-Development Option, Fifteen Million Dollars (US \$15,000,000).

5.1.2 **Cooperation; Additional Information**. In connection with ImmunoGen’s consideration of the exercise of a Co-Development Option with respect to each Licensed Product, Biotest shall (a) as soon as practicable and in any event on or before [\*\*\*] ([\*\*\*)] days after the Early Stage Option Commencement Date and/or for the Late Stage Option Commencement Date, as the case may be, present in person to ImmunoGen, and/or provide ImmunoGen with, all information Controlled by Biotest reasonably necessary to assist ImmunoGen in determining whether to exercise its Co-Development Option; and (b) upon written request by ImmunoGen and approval by the JDC, provide ImmunoGen with any additional information Controlled by Biotest that ImmunoGen reasonably determines may be necessary or useful to ImmunoGen in exercising such Co-Development Option, including without limitation any additional information concerning the Development Plan applicable to that Licensed Product. Such information will be subject to confidentiality.

5.1.3 **Estimated Co-Development Costs**. If ImmunoGen exercises its Co-Development Option for a Co-Developed Product, (a) Biotest shall provide ImmunoGen with Biotest’s non-binding, good faith estimate of Co-Development Costs it expects to incur with respect to that Co-Developed Product for each Calendar Year for the next five (5) Calendar Years and (b) the Parties will jointly prepare a budget for that Co-Developed Product based on such estimate, which shall allocate expected costs between the Parties and, which shall be reviewed and updated by the Parties not less than once each Calendar Year. The Parties hereby agree that, unless approved by the JDC, any costs or expenses incurred by a Party in excess of the estimated costs allocated in the Co-Development Plan to such Party as set forth in the Co-Development Plan shall be the sole responsibility of such Party.

5.1.4 **Allocation of Shared Clinical Trial Costs**.

(a) Use of Shared Clinical Trial Data. On and after the date of exercise by ImmunoGen of its Co-Development Option for a Co-Developed Product and continuing for the Term of this Agreement, each Party shall provide written notice to the other Party to the extent it intends to make Material Use of any Shared Clinical Trial Data. If such use of Shared Clinical Trial Data enables a Party to [\*\*\*] [\*\*\*] [\*\*\*] [\*\*\*] [\*\*\*] [\*\*\*], such Party shall pay the applicable Shared Clinical Trial Cost Sharing Percentage of such Shared Clinical Trial Costs. As promptly as practicable following such exercise, the Parties shall agree to a mechanism for providing all Shared Clinical Trial Data.

(b) Payment Adjustments. Within [\*\*\*] ([\*\*\*)] days of the end of each Calendar Year following the exercise of the Co-Development Option with respect to a Co-Developed Product, the Party conducting a Shared Clinical Trial with respect to that Co-Developed Product shall provide the other Party with a reasonably detailed written accounting of the actual Shared Clinical Trial Costs with respect to each Shared Clinical Trial. Within [\*\*\*] ([\*\*\*)] days of the end of each Shared Clinical Trial, the non-electing Party shall provide the electing party with a final accounting of the actual Shared Clinical Trial Costs with respect to such Shared Clinical

Trial. Such final accounting shall also include a reasonably detailed calculation of the net amount that one Party may owe the other Party for such costs in the case of Material Use, as applicable. The net amount payable shall be due within thirty (30) days after receipt of an invoice pursuant to Section 5.1.4(d).

(c) Audit. For a period commencing upon the initiation of a Shared Clinical Trial and ending [\*\*\*] ([\*\*\*)] years after the completion of such Shared Clinical Trial, each Party shall keep complete and accurate records of associated Shared Clinical Trial Costs in sufficient detail to allow the accuracy of the payments hereunder to be confirmed. Each Party shall have the right for a period of [\*\*\*] ([\*\*\*)] years after the final accounting of such Shared Clinical Trial Costs for a particular Calendar Quarter to appoint at its expense an independent certified public accountant reasonably acceptable to the other Party to inspect or audit the relevant records of the other Party and its Affiliates to verify that the amount of such Shared Clinical Trial Costs was correctly determined. The Audited Party and its Affiliates shall each make its records available for inspection or audit 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 the Auditing Party, solely to verify that Shared Clinical Trial Costs hereunder were correctly determined. Such inspection or audit right shall not be exercised by the Auditing Party more than once in any Calendar Year. All records made available for inspection or audit shall be deemed to be Confidential Information of the Audited Party. The results of each inspection or audit, if any, shall be binding on both Parties. In the event there was an error in the amount of Shared Clinical Trial Costs reported by the Audited Party hereunder, (a) if the amount of Shared Clinical Trial Costs was over-reported, the Audited Party shall promptly (but in any event no later than thirty (30) days after the Audited Party's receipt of the independent accountant's report so concluding) make payment to the Auditing Party of a percentage of the over-reported amount taking into account the equal sharing of Co-Development Costs and (b) if the amount of Shared Clinical Trial Costs was underreported, the Auditing Party shall promptly (but in any event no later than thirty (30) days after the Auditing Party's receipt of the independent accountant's report so concluding) make payment to the Audited Party of a percentage of the underreported amount taking into account the equal sharing of Co-Development Costs. The Auditing Party shall bear the full cost of such audit unless such audit discloses an over reporting by the Audited Party of more than [\*\*\*] ([\*\*\*)] of the aggregate amount of Shared Clinical Trial Costs reportable in any Calendar Year, in which case the Audited Party shall reimburse the Auditing Party for all costs incurred by the Auditing Party in connection with such inspection or audit.

(d) Data Audit. Promptly following the submission of each Regulatory Filing, and any amendments or supplements thereto, the Party making such submission shall provide a full and complete copy of such filing to the other Party for purposes of determining whether the submitting Party has made Material Use of the other Party's Shared Clinical Trial Data without having paid in full its applicable Shared Clinical Trial Cost Sharing Percentage associated with such Shared Clinical Trial Data. In the event that a Party made Material Use of the other Party's Shared Clinical Trial Data in such submission and therefore was able to [\*\*\*] [\*\*\*] [\*\*\*] [\*\*\*] [\*\*\*] [\*\*\*] [\*\*\*] in the respective territory, the submitting Party shall pay the shortfall of its applicable Shared Clinical Trial Cost Sharing Percentage or the amount needed to match its applicable Shared Clinical Trial Cost Sharing Percentage, as the case may be, to the other Party upon written request and as invoiced by the other Party.

(e) Survival. In the event that a Party enters into an agreement with a Third Party with respect to the conduct by such Third Party of Shared Clinical Trials, such Party shall use commercially reasonable efforts to include in such contracts provisions for cost sharing of Shared Clinical Trial Data consistent with those set forth in this Section 5.1.4.

5.1.5 **Allocation of Pivotal MAY Compound Process Development Costs.**

(a) Payment by Biotest. Notwithstanding anything to the contrary in this Agreement, provided that ImmunoGen has exercised a Co-Development Option, Biotest shall pay ImmunoGen a portion of the Pivotal MAY Compound Process Development Costs equal to the Pivotal MAY Compound Process Development Percentage. Any costs and expenses paid by Biotest to ImmunoGen after the Effective Date for process development activities for pivotal MAY Compounds shall be deducted from the amount payable by Biotest pursuant to this Section 5.1.5. In connection therewith, ImmunoGen estimates as of the Effective Date that the aggregate Pivotal MAY Compound Process Development Costs shall not [\*\*\*] [\*\*\*] [\*\*\*] [\*\*\*] ([\*\*\*]).

(b) Payment of Pivotal MAY Compound Process Development Costs.

(i) Initial Payment. Within [\*\*\*] ([\*\*\*)] days of the exercise by ImmunoGen of a Co-Development Option pursuant to Section 5.1.1(a), ImmunoGen shall provide Biotest with a reasonably detailed written accounting of the Pivotal MAY Compound Process Development Costs incurred through the date of exercise of the Co-Development Option and the applicable Pivotal MAY Compound Process Development Percentage. Biotest shall pay the amount reflected in such accounting with [\*\*\*] ([\*\*\*)] days of receipt of such accounting.

(ii) Subsequent Payments. Subject to Section 5.1.5(b)(i), within [\*\*\*] ([\*\*\*)] days of the end of each Calendar Quarter following the exercise by ImmunoGen of a Co-Development Option pursuant to Section 5.1.1(a), Biotest shall pay the applicable Pivotal MAY Compound Process Development Percentage of the Pivotal MAY Compound Process Development Costs incurred over such Calendar Quarter using a method of allocation to be determined by the JFC in good faith, based on the method of allocation described in Section 5.1.5(b)(i) above.

(c) Records; Audit Rights. For a period of [\*\*\*] ([\*\*\*)] years following receipt by Biotest of any accounting described in this Section 5.1.5, ImmunoGen shall keep complete and accurate records pertaining to the Pivotal MAY Compound Process Development Costs and the Pivotal MAY Compound Process Development Percentage in sufficient detail to allow the accuracy of the payments hereunder to be confirmed. At each meeting of the JDC the Parties shall update the JDC as to such Pivotal MAY Compound Process Development Costs incurred through the date of such JDC meeting. ImmunoGen shall keep complete and accurate records of associated Pivotal MAY Compound Process Development Costs in sufficient detail to allow the accuracy of the payments hereunder to be confirmed. Biotest shall have the right to appoint at its expense an independent certified public accountant reasonably acceptable to ImmunoGen to inspect or audit the relevant records of ImmunoGen and its Affiliates to verify that the amount of such Pivotal MAY Compound Process Development Costs was correctly determined. ImmunoGen and its Affiliates shall each make its records available for inspection or audit 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 Biotest, solely to verify that Pivotal MAY Compound Process Development Costs hereunder were correctly determined. Such inspection or audit right shall not be exercised by Biotest more than once in any Calendar Year. All records made available for inspection or audit shall be deemed to be Confidential Information of ImmunoGen. The results of each inspection or audit, if any, shall be binding on both Parties. In the event there was an error in the amount of Pivotal MAY Compound Process Development Costs reported by ImmunoGen hereunder, (a) if the amount of Pivotal MAY Compound Process Development Costs was over-reported, ImmunoGen shall promptly (but in any event no later than [\*\*\*] ([\*\*\*)] days after the ImmunoGen's receipt of the independent accountant's report so concluding) make payment to Biotest of the amount owed to Biotest, and (b) if the amount of Pivotal MAY Compound Process Development Costs was underreported, Biotest shall promptly (but in any event no later than [\*\*\*] ([\*\*\*)] days after Biotest's receipt of the independent accountant's report so concluding) make payment to ImmunoGen of the amount owed to ImmunoGen. Biotest shall bear the full cost of such audit unless such audit discloses an over reporting by ImmunoGen of more than [\*\*\*] [\*\*\*] ([\*\*\*)] of the aggregate amount of Pivotal MAY Compound Process Development Costs reportable in any Calendar Year, in which case ImmunoGen shall reimburse Biotest for all costs incurred by Biotest in connection with such inspection or audit.

## 5.2 **Reconciliation and Auditing of Co-Development Costs.**

5.2.1 **Reconciliation.** Within [\*\*\*] ([\*\*\*)] days following the end of each Calendar Quarter following the exercise of the Co-Development Option applicable to a given Co-Developed Product, each of ImmunoGen and Biotest shall submit to the JFC a written report setting forth in reasonable detail all Co-Development Costs incurred by each such Party over such Calendar Quarter. Within [\*\*\*] ([\*\*\*)] days following the JFC's receipt of such written reports, the JFC shall prepare and submit to each Party a written report setting forth in reasonable detail (a) the calculation of all Co-Development Costs incurred by both Parties over such Calendar Quarter and (b) the calculation of the net amount owed by ImmunoGen to Biotest or by Biotest to ImmunoGen in order to ensure the equal sharing of the Co-Development Costs. The net amount payable shall be paid by ImmunoGen or Biotest to the other, as applicable, within [\*\*\*] ([\*\*\*)] days after the distribution by the JFC of such written report. If the JFC determines that one Party has overrun the budget for a particular item, the amount by which the actual expense exceeded the budgeted amount shall be borne in its entirety by the Party incurring the overrun.

5.2.2 **Records; Audit Rights.** Each Party shall keep and maintain for [\*\*\*] ([\*\*\*)] years complete and accurate records of Co-Development Costs incurred with respect to Licensed Products in sufficient detail to allow confirmation of same by the JFC. Each Party shall have the right for a period of [\*\*\*] ([\*\*\*)] years after such Development Cost is reconciled in accordance with Section 5.2.1 to appoint at its expense an independent certified public accountant reasonably acceptable to the other Party to inspect or audit the relevant records of the other Party and its Affiliates to verify that the amount of such Co-Development Costs was correctly determined. The Audited Party and its Affiliates shall each make its records available for inspection or audit 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 the Auditing Party, solely to verify that Co-Development Costs hereunder were correctly determined. Such inspection or audit right shall not be exercised by the Auditing Party more than once in any

Calendar Year. All records made available for inspection or audit shall be deemed to be Confidential Information of the Audited Party. The results of each inspection or audit, if any, shall be binding on both Parties. In the event there was an error in the amount of Co-Development Costs reported by the Audited Party hereunder, (a) if the amount of Co-Development Costs was over-reported, the Audited Party shall promptly (but in any event no later than [\*\*\*] ([\*\*\*)] days after the Audited Party's receipt of the independent accountant's report so concluding) make payment to the Auditing Party of a percentage of the over-reported amount consistent with the equal sharing of Development Costs and (b) if the amount of Co-Development Costs was underreported, the Auditing Party shall promptly (but in any event no later than [\*\*\*] ([\*\*\*)] days after the Auditing Party's receipt of the independent accountant's report so concluding) make payment to the Audited Party of a percentage of the underreported amount consistent with the equal sharing of Development Costs. The Auditing Party shall bear the full cost of such audit unless such audit discloses an over reporting by the Audited Party of more than [\*\*\*] [\*\*\*] ([\*\*\*)] of the aggregate amount of Co-Development Costs reportable in any Calendar Year, in which case the Audited Party shall reimburse the Auditing Party for all costs incurred by the Auditing Party in connection with such inspection or audit.

5.3 **Compliance.** Biotest and/or ImmunoGen, as applicable, shall each perform their respective obligations under each Co-Development Plan and Co-Development Manufacturing Plan in good scientific and business manner and in compliance in all material respects with all Applicable Laws; provided, that, for purposes of clarity, with respect to each activity performed under the Co-Development Plan, that will or would reasonably be expected to be submitted to a Regulatory Authority in support of a Regulatory Filing or Drug Approval Application, Biotest and/or ImmunoGen, as applicable, shall each comply in all material respects, in the Co-Development Territory, with the regulations and guidance of the relevant authorities in the Co-Development Territory.

5.4 **Commercialization Diligence.** Biotest and/or ImmunoGen, as applicable, shall each use Commercially Reasonable Efforts during the Term to Develop and to Commercialize Co-Developed Products in the Co-Development Territory. If a Party at any time reasonably believes that the other Party is not meeting its diligence obligations pursuant to this Section 5.4, such Party may give, in the form of detailed reasons, written notice to the other Party requesting written justification, in the form of detailed reasons, that would support the proposition that such other Party is meeting such diligence obligations. In such event, such other Party shall provide such written justification within [\*\*\*] ([\*\*\*)] days after such notice is given. In the event that the other Party does not reasonably justify that it is meeting its diligence obligations pursuant to this Section 5.4 within such [\*\*\*] ([\*\*\*)] day period, then the Party giving notice shall have the right, in its sole discretion, to exercise such rights or remedies that it may have under this Agreement, at law or in equity.

## 5.5 Co-Promotion Rights.

### 5.5.1 Option to Jointly Sublicense.

#### (a) Early Stage Co-Development Option.

(i) Initial Sublicense Decision Date. If ImmunoGen exercises an Early Stage Co-Development Option with respect to a Co-Developed Product, then within [\*\*\*] ([\*\*\*)] days following the First Interim Analysis of the first [\*\*\*] [\*\*\*] [\*\*\*] [\*\*\*] with respect to such Co-Developed Product, the Parties shall discuss in good faith and decide whether to jointly sublicense the right to Develop and Commercialize such Co-Developed Product in the Co-Development Territory to a single Third Party, in which case the Parties shall [\*\*\*] in the consideration received from such Third Party with respect to the grant of such sublicense for the Co-Development Territory.

(ii) Second Sublicense Decision Date. In the event that ImmunoGen exercises the Early Stage Co-Development Option with respect to a Co-Developed Product and the Parties (A) have, pursuant to Section 5.5.1 (a) (i), decided to sublicense the right to Develop and Commercialize such Co-Developed Product to a single Third Party, but the Parties have not entered into an agreement with a Third Party to Develop and Commercialize such Co-Developed Product in accordance with Section 5.5.1(a) (i) and (B) have not obtained accelerated approval from the FDA in accordance with Subpart E of 21 C.F.R. 312 with respect to such Co-Developed Product, then within [\*\*\*] ([\*\*\*)] days following the First Interim Analysis of the first [\*\*\*] [\*\*\*] [\*\*\*] [\*\*\*] with respect to such Co-Developed Product, the Parties shall discuss in good faith and decide whether to jointly sublicense the right to Develop and Commercialize such Co-Developed Product in the Co-Development Territory to a single Third Party, in which case the Parties shall [\*\*\*] in the consideration received from such Third Party with respect to the grant of such sublicense for the Co-Development Territory.

(b) Late Stage Co-Development Option. In the event that ImmunoGen exercises a Late Stage Co-Development Option with respect to a Co-Developed Product, but the Parties have not obtained accelerated approval from the FDA in accordance with Subpart E of 21 C.F.R. 312 with respect to such Co-Developed Product, then within [\*\*\*] ([\*\*\*)] days following the First Interim Analysis of the [\*\*\*] [\*\*\*] [\*\*\*] [\*\*\*] with respect to such Co-Developed Product, the Parties shall discuss in good faith and decide whether to jointly sublicense the right to Develop and Commercialize such Co-Developed Product in the Co-Development Territory to a single Third Party, in which case the Parties shall [\*\*\*] in the consideration received from such Third Party with respect to the grant of such sublicense for the Co-Development Territory.

5.5.2 Failure to Reach Agreement. If the Parties are unable to affirmatively decide to jointly sublicense the right to Develop and Commercialize a Co-Developed Product to a single Third Party pursuant to Section 5.5.1(a) or (b), the Parties shall (a) prepare and execute a mutually acceptable Co-Promotion Agreement between the Parties (the “Co-Promotion Agreement”) in good faith and with sufficient diligence as is required to execute and deliver the Co-Promotion Agreement within [\*\*\*] [\*\*\*] [\*\*\*] ([\*\*\*)] days from the expiration of the applicable [\*\*\*]-day period and (b) jointly Co-Promote the Co-Developed Product. The Co-Promotion Agreement shall contain such provisions as are usual and customary for inclusion in a co-promotion agreement between companies in the pharmaceutical industry of comparable sizes to the respective Parties and shall contain suitable provisions regulating activities equivalent to Section 4.6 that relate to Co-Developed Products in the Co-Development Territory. In the event the Parties fail to execute and deliver the Co-Promotion Agreement within the [\*\*\*] [\*\*\*] [\*\*\*] ([\*\*\*)] day period described in this Section 5.5.2, the Parties shall (A) use reasonable efforts to complete such negotiations and to execute and deliver the Co-Promotion Agreement as soon as

possible after such [\*\*\*] [\*\*\*] [\*\*\*] ([\*\*\*)] day period and (B) without limiting the generality of the foregoing, after the expiration of such [\*\*\*] [\*\*\*] [\*\*\*] ([\*\*\*)] day period, each produce a list of issues on which they have failed to reach agreement and submit its list to the JSC to be resolved in accordance with Section 2.1.6. -

5.5.3 Development Cost-Sharing. For the avoidance of doubt, if the Parties decide to jointly sublicense to a single Third Party the right to Develop and Commercialize a Co-Developed Product as described in Section 5.5.1(a) or (b), the Parties' respective obligations to share in the Co-Development Costs applicable to that Co-Developed Product in accordance with Sections 5.1 and 5.2 shall continue until the effective date of the sublicense agreement.

5.5.4 Option to Unilaterally Sublicense after Commercialization. If at any time during the period commencing on the [\*\*\*] [\*\*\*] of the [\*\*\*] [\*\*\*] [\*\*\*] [\*\*\*] [\*\*\*] [\*\*\*] [\*\*\*] [\*\*\*] and continuing for a period of [\*\*\*] ([\*\*\*)] days, either Party determines that it wishes to engage any Third Party to assume its Co-Promotion rights and fulfill its Co-Promotion obligations with respect to a Co-Developed Product, then notwithstanding anything to the contrary in Section 5.5.2 and subject to Section 8.3.1 and 8.3.2, either Party shall have the right to engage any Third Party to fulfill its Co-Promotion obligations with respect to a Co-Developed Product in accordance with this Section 5.5.4, and such Party shall provide written notice of same to the other Party (the "ROFN Notice", whereby ROFN means Right Of First Negotiation). The Party receiving the ROFN Notice shall have [\*\*\*] ([\*\*\*)] days from the date of the ROFN Notice to provide a written response (the "ROFN Response") as to whether or not it wishes to enter into negotiations with the other Party with respect to such Co-Promotion activities. If the ROFN Response is not received within the [\*\*\*] ([\*\*\*)] day response period, the Party providing the ROFN Notice shall thereafter have the right to engage any Third Party to fulfill its Co-Promotion obligations with respect to a Co-Developed Product. If the ROFN Response is received within the [\*\*\*] ([\*\*\*)] day response period and states that the other Party wishes to enter into negotiations with the Party providing the ROFN Notice, the Parties shall negotiate in good faith for a period of up to [\*\*\*] [\*\*\*] [\*\*\*] ([\*\*\*)] days from the date of the ROFN Response with respect to the terms and conditions of such rights; provided, that the Parties acknowledge and agree that such negotiations shall not be exclusive and the Party providing the ROFN Notice shall also have the right during such period to conduct discussions with one or more Third Parties regarding the grant of such rights. If after the Parties are unable to agree upon terms and conditions of such rights on or before the expiration of such [\*\*\*] [\*\*\*] [\*\*\*] ([\*\*\*)] day period, then the Party providing the ROFN Notice shall thereafter have the right to engage any Third Party to fulfill its Co-Promotion obligations with respect to a Co-Developed Product. For purposes of clarity, the rights of the Parties with respect to a Co-Developed Product under this Section 5.5 shall not affect Biotest's rights to grant sublicenses to any Licensed Product in accordance with Section 8.3. If either Party grants a sublicense according to this Section 5.5.4, such Party shall be deemed to have guaranteed that such Sublicensee will fulfill all of such Party's obligations under this Agreement and the Co-Promotion Agreement applicable to the subject matter of such sublicense; and the respective Party shall not be relieved of any of its obligations pursuant to this Agreement and the Co-Promotion Agreement as a result of such sublicense.

5.6 Co-Development Marketing and Sales Plan. The JMC shall prepare a Co-Development Marketing and Sales Plan for each Co-Developed Product for the Co-Development Territory in accordance with Section 5.1.1(b), which shall include, but not be limited to, (a)

demographics and market dynamics, market strategies, and estimated launch date of such Co-Developed Product in the Co-Development Territory, (b) a sales and expense forecast (including at least five (5) years of estimated sales and expenses) and manufacturing plans for such Co-Developed Product in the Co-Development Territory, (c) a marketing plan (including five (5) year Advertising and Detailing forecasts and pricing strategies) for such Co-Developed Product in the Co-Development Territory, and (d) a five (5) year budget for such Co-Developed Product for the Co-Development Territory. The Co-Development Marketing and Sales Plan and annual written updates thereto shall be submitted to the JMC for review by a date to be established by the JMC taking into account Biotest's and ImmunoGen's annual budget planning calendars, but no later than December 31 of each Calendar Year.

5.7 **Change in Co-Promotion Percentage.** As will be provided in the Co-Development Marketing and Sales Plan, it is the expectation of the Parties that both Parties will typically contribute fifty percent (50%) to the yearly marketing and sales expenses for a Co-Developed Product and therefore share all profits in an equal split. If either Party wishes to increase its Co-Promotion activities with respect to a Co-Developed Product ("Additional Co-Promotion Activities") by increasing the marketing and sales investments above the amount the other party is ready to spend, unequal contributions to the yearly budget shall be possible, unless otherwise provided in the Co-Promotion Agreement, according to the following provisions. The Party wishing to increase its Co-Promotion activities shall submit a written proposal to the JMC which shall describe in reasonable detail the Additional Co-Promotion Activities and the justification for Additional Co-Promotion Activities, an estimated budget and timeline with respect thereto, and the expected adjustment to be made to the Co-Development Marketing and Sales Plan and to the Parties' respective Co-Promotion Percentages to reflect the relative value of Additional Co-Promotion Activities to be conducted by the submitting Party (as so adjusted, the "Adjusted Co-Promotion Percentage"). The JMC shall have to approve this proposal, and each Party shall ensure that its representatives in the JMC do not unreasonably withhold such approval. Upon approval of the proposal and the Adjusted Co-Promotion Percentage by the JMC, (a) the Co-Development Marketing and Sales Plan shall be amended accordingly; (b) the submitting Party shall thereafter conduct the Additional Co-Promotion Activities included in the approved proposal; (c) the Adjusted Co-Promotion Percentage shall thereafter be the Co-Promotion Percentage of the Parties; and (d) the Parties will thereafter continue to share Co-Promotion Costs with respect to that Co-Developed Product, and receive a percentage of the Net Income derived from that Co-Developed Product, according to the Adjusted Co-Promotion Percentage. The Change in Co-Promotion Percentage shall be valid for one Calendar Year and shall be extended or terminated by the JMC in the course of the generation of the new Co-Development Marketing and Sales Plan.

5.8 **Labeling.** All product labels for Co-Developed Products shall include, to the extent allowed by Applicable Laws, in equal prominence, the names of both Biotest and ImmunoGen or their respective Sublicensees. The JMC shall have the responsibility of meeting not less frequently than annually and deciding whether changes in the particular appearance in labeling of packaging and containers of Co-Developed Products or in the product information is required. In addition to the annual review, an emergency review can be implemented at any time by the JMC.

## 6. CONSIDERATION AND FUNDING

6.1 **Upfront Fee.** Biotest shall pay ImmunoGen an upfront fee in the amount of One Million Dollars (US \$1,000,000) in immediately available funds within [\*\*\*] ([\*\*\*)] days from the Effective Date, which shall be non-creditable and non-refundable, it being understood that in the event that ImmunoGen has not applied for, or been given relief from, any obligation it may have to pay taxes in Germany with respect to the upfront fee by the date the upfront fee is due and Biotest reasonably determines that a tax is applicable to such upfront fee, Biotest may, upon notice to ImmunoGen, deduct the amount of any German tax applicable thereto and transfer it to the applicable German tax authorities. ImmunoGen may apply for a refund with the German tax authorities and Biotest shall provide reasonable assistance to ImmunoGen in connection therewith.

6.2 **R&D Funding.** During the period commencing on the Effective Date and continuing on a Licensed Product by Licensed Product basis until the earlier of (a) the exercise by ImmunoGen of a Co-Development Option with respect to such Licensed Product and (b) the expiration of the Research Program term, Biotest shall pay ImmunoGen the aggregate FTE Cost for all FTEs used by ImmunoGen in the conduct of ImmunoGen Activities on a quarterly basis, based on the FTE Rate and the Research Plan and/or Development Plan. Within [\*\*\*] ([\*\*\*)] days following the last day of each Calendar Quarter during the conduct of the Research Program, ImmunoGen shall issue an invoice reflecting the FTE Costs for such Calendar Quarter, as reflected in the then-current Research Plan and Biotest shall pay each such invoice within [\*\*\*] ([\*\*\*)] days from receipt. The amount invoiced for ImmunoGen Activities performed by an FTE shall be calculated based on [\*\*\*] [\*\*\*] [\*\*\*] using an [\*\*\*] [\*\*\*] [\*\*\*] and [\*\*\*] of [\*\*\*] in a [\*\*\*] [\*\*\*] [\*\*\*] the [\*\*\*] of [\*\*\*] [\*\*\*] [\*\*\*] such ImmunoGen Activities, based on a total of [\*\*\*] hours in an FTE year. Such invoice shall have attached to it a copy of the [\*\*\*] [\*\*\*] [\*\*\*] of [\*\*\*] [\*\*\*] [\*\*\*] to the [\*\*\*] [\*\*\*] on such particular invoice. If, at any time during the Term of this Agreement, ImmunoGen determines that the actual number of FTEs for a particular Calendar Quarter agreed to by the Parties is expected to exceed by [\*\*\*] percent ([\*\*\*)] the [\*\*\*] [\*\*\*] set forth in such Research Plan for such Calendar Quarter, ImmunoGen shall give Biotest prompt written notice of same and the Parties shall discuss in good faith whether to [\*\*\*] the [\*\*\*] of such [\*\*\*] [\*\*\*] or to [\*\*\*] the [\*\*\*] to be [\*\*\*], such that such [\*\*\*] [\*\*\*] are [\*\*\*] [\*\*\*]. The JDC shall be the forum for discussions about an extension of ImmunoGen Activities not covered by the budget as laid down in the Research Plan.

6.2.1 **R&D Funding Audit Rights.** ImmunoGen shall keep complete and accurate books and financial records pertaining to its costs and expenses of conducting the ImmunoGen Activities, which books and financial records shall be kept in accordance with GAAP and shall be retained by ImmunoGen until [\*\*\*] ([\*\*\*)] years after the end of the Contract Year to which they pertain. Biotest shall have the right to appoint at its expense an independent certified public accountant reasonably acceptable to ImmunoGen to inspect or audit, the books and financial records of ImmunoGen relating to its costs and expenses of conducting the ImmunoGen Activities during any Contract Year; provided that Biotest shall not have the right to inspect or audit any Contract Year more than once or to conduct more than one such audit in any twelve-month period. Such audit shall be finalized before the end of the third year following the Contract Year to be audited. All books and financial records made available for inspection or audit shall be deemed to be Confidential Information of ImmunoGen. The Auditing Party shall bear the full cost of such audit unless such audit discloses an over reporting by the Audited Party of more than [\*\*\*] [\*\*\*] ([\*\*\*)] of the aggregate amount of costs and expenses reportable in any Calendar Year, in which

case the Audited Party shall reimburse the Auditing Party for all costs incurred by the Auditing Party in connection with such inspection or audit.

### 6.3 **Milestone Payments.**

6.3.1 **Milestones.** Biotest shall, with respect to each Biotest Product, make each of the following nonrefundable, noncreditable (except as set forth in Section 6.3.2) payments to ImmunoGen only after the first occurrence of the corresponding milestone event in accordance with Section 6.3.3:

<b>Milestone Event</b>	<b>Milestone Payment</b>
Initiation of first Phase I Clinical Trial or Phase I/IIa Clinical Trial for a Biotest Product	0.5 million
Initiation of first Phase IIb Clinical Trial for a Biotest Product	2 million
[***] of [***] [***] [***] [***] [***] for a [***] [***]	\$ [***]
[***] of [***] [***] or [***] for a [***] [***]	\$ [***]
[***] [***] [***] [***] in [***] [***] [***] for a [***] [***]	\$ [***]
[***] [***] [***] [***] in [***] [***] for a [***] [***]	\$ [***]
[***] [***] [***] [***] in [***] for a [***] [***]	\$ [***]
[***] [***] of [***] [***] [***] [***] in [***] [***] [***] for a [***] [***]	\$ [***]
[***]	\$

For purposes of clarity, no milestone payments shall be payable under this Section 6.3.1 for any milestone events whether occurring within or outside of the Co-Development Territory for a Co-Developed Product on and after the date of exercise by ImmunoGen of a Co-Development Option with respect to such Co-Developed Product. Biotest shall pay each milestone only once per specific Biotest Product, regardless of how many indications, formulations or methods of treatments will be related to such Biotest Product. A specific Biotest Product shall be defined by the combination of Anti-CD138 Antibody + MAY Compound + Linker. Exchanging either of the three parts shall create a new specific Biotest Product. Combination Products shall not trigger a milestone payment provided that the Biotest Product contained therein has already caused a milestone payment.

6.3.2 **Milestone Notices.** Biotest shall provide ImmunoGen with prompt written notice upon each achievement of a milestone event set forth in Section 6.3.1, which notice shall

include a description of the applicable milestone event. In the event that, notwithstanding the fact that Biotest has not given such a notice, ImmunoGen believes any such milestone event has occurred, it shall so notify Biotest in writing and shall provide to Biotest data, documentation or other information that supports its belief. Any dispute under this Section 6.3.2 that relates to whether or not a milestone event has been achieved shall be referred to the JSC to be resolved in accordance with Section 2.1.6.

6.3.3 **Payment of Milestones.** All milestone payments shall be made by Biotest within [\*\*\*] ([\*\*\*)] days of the occurrence of the corresponding milestone event.

6.4 **Payment of Royalties; Royalty Rates; Payment of Net Income; Accounting and Records.**

6.4.1 **Payment of Royalties.** Biotest shall pay ImmunoGen a royalty based on Annual Net Sales of each Royalty-Bearing Product commencing with the Calendar Year (or partial Calendar Year) in which the First Commercial Sale of such Royalty-Bearing Product occurs and ending upon expiration of the Royalty Term for such Royalty-Bearing Product, at the following rates:

(a) **Biotest Products**

<b>Annual Net Sales of Biotest Products Worldwide</b>	<b>Royalty Rate</b>
Up to \$[***]	[***]%
Equal to or greater than \$[***] [***] [***] [***] [***] [***] [***]	[***]%

(b) **Co-Developed Products**

(i) **Early Stage Co-Developed Products**

<b>Annual Net Sales Outside Co-Development Territory</b>	<b>Royalty Rate</b>
Up to \$[***]	[***]%
Equal to or greater than \$[***]	[***]%

(ii) **Late Stage Co-Developed Products**

<b>Annual Net Sales Outside Co-Development Territory</b>	<b>Royalty Rate</b>
Up to \$[***]	[***]%
Equal to or greater than \$[***]	[***]%

(c) **Royalty Offsets.** In the event that Biotest, in order to practice the license granted to it under Section 8.2.1 of this Agreement in any country in the applicable portion of the Territory in which royalties are payable as provided in Section 6.4.1, is required to and

actually makes royalty payments to any Third Party (“Third Party Payments”) in order to obtain a license to an issued patent or patents in the absence of which the Licensed Technology or Licensed Patent Rights portion of a Licensed Product could not legally be developed, manufactured, used, sold or imported in such country (as evidenced, to the extent reasonably requested by ImmunoGen, by an opinion of patent counsel), then the royalties payable to ImmunoGen for such Licensed Product under this Agreement with respect to such country may be reduced by [\*\*\*] percent ([\*\*\*]%) of the amount of such Third Party Payments. Notwithstanding the foregoing, such reductions shall in no event reduce the royalty rate for such Licensed Product applicable under Section 6.4.1 with respect to such country to less than (i) [\*\*\*] percent ([\*\*\*]%), with respect to the royalty rate set forth in Section 6.4.1(a) above; (ii) [\*\*\*] percent ([\*\*\*]%), with respect to the royalty rates set forth in Section 6.4.1(b)(i); and (iii) [\*\*\*] percent ([\*\*\*]%), with respect to the royalties set forth in Section 6.4.1(b)(ii) above.

(d) Combination Products. In determining Net Sales of any Combination Products under this Agreement in any country, Net Sales shall first be calculated in accordance with the definition of “Net Sales” then multiplied by the percentage value of the Royalty-Bearing Product contained in the Combination Product, such percentage value being the quotient obtained by dividing the current market price of the Royalty-Bearing Product by the sum of the separate current market price of the Royalty-Bearing Product in such country and the other ingredients which are therapeutically or biologically active contained in the Combination Product in such country. The current market price of each therapeutically or biologically active ingredient and of the Royalty-Bearing Product shall be for a comparable quantity sold in such country to that contained in the Combination Product and of the same class, purity and potency. When no current market price is available for any therapeutically active ingredient or for the Royalty-Bearing Product in such country, the Parties shall agree in good faith upon a hypothetical market price with respect to the Combination Product, allocating the same proportions of costs, overhead and profit as are then allocated to all similar substances then being made and marketed by Biotest and having an ascertainable market price in such country; provided, however, that if the Parties are unable to agree upon such hypothetical market price, the Parties shall submit the matter promptly to the Parties respective Designated Senior Officers for resolution.

(e) Payment Dates and Reports. Royalty payments shall be made by Biotest within [\*\*\*] ([\*\*\*]) days after the end of each Calendar Quarter commencing with the Calendar Quarter in which the First Commercial Sale of each Royalty-Bearing Product occurs. All payments shall be made by wire transfer to the credit of such bank account as shall be designated in writing from time to time by ImmunoGen minimum [\*\*\*] ([\*\*\*]) days before the relevant payment is due. Biotest shall also provide, at the same time each such payment is made, a report showing: (i) the Net Sales of each Royalty-Bearing Product by country in the Royalty-Bearing Territory; (ii) the basis for any deductions from gross amounts billed or invoiced to determine Net Sales; (iii) the applicable royalty rates for such Royalty-Bearing Product; (iv) the exchange rates used in calculating any of the foregoing; (v) any reductions in royalties to be paid through payment of Third Party Payments; and (vi) a calculation of the amount of royalty due to ImmunoGen.

6.4.2 Net Income Payments. In lieu of paying any royalty payments with respect to each Co-Developed Product in the Co-Development Territory, each Party shall receive its Co-Promotion Percentage of all Annual Net Income derived from sales of that Co-Developed Product

in the Co-Development Territory as described herein for as long as there are sales of such Co-Developed Product in the Co-Development Territory (such payments, the “Net Income Payments”). Within [\*\*\*] ([\*\*\*)] days following the end of each Calendar Quarter commencing on and after the date of First Commercial Sale of each Co-Developed Product, Biotest and ImmunoGen shall submit to the JFC all Commercialization Expenses incurred by it with respect to such Co-Developed Product in the Co-Development Territory, as well as the Cost of Goods of the applicable Co-Developed Product, as well as Net Sales. Within [\*\*\*] ([\*\*\*)] days following the end of the Calendar Quarter, the JFC shall submit to the Parties a written report setting forth in reasonable detail (a) the calculation of Annual Net Income, determined in accordance with Schedule 1 attached hereto and (b) the calculation of the amount of Annual Net Income payable to each Party in accordance with its respective Co-Promotion Percentage for that Co-Developed Product. In the event that the amount of Net Income Payments is not equally distributed between the Parties, the Party having received the greater portion of Net Income Payments shall pay to the other Party that portion of the excess amount within [\*\*\*] ([\*\*\*)] days following the end of the Calendar Quarter which generates the correct distribution according to the applicable Co-Promotion Percentage.

6.4.3 **Records; Audit Rights.** Biotest and its Affiliates and Sublicensees shall keep and maintain for [\*\*\*] ([\*\*\*)] years from the date of each payment of royalties hereunder complete and accurate records of their respective Commercialization Expenses, as well as all gross sales and Net Sales by Biotest and its Affiliates and Sublicensees of each Licensed Product, in sufficient detail to allow royalties to be determined accurately and ImmunoGen and its Affiliates and Sublicensees shall keep and maintain for [\*\*\*] ([\*\*\*)] years from the date of each payment of Net Income Payments complete and accurate records of its Commercialization Expenses, as well as all gross sales and Net Sales of each Co-Developed Product in sufficient detail to allow Net Income Payments to be determined accurately. Each Party shall have the right for a period of [\*\*\*] ([\*\*\*)] years after receiving any such payment to appoint at its expense an independent certified public accountant reasonably acceptable to the other Party to inspect or audit the relevant records of such Party, its Affiliates and Sublicensees to verify that the amount of such payment was correctly determined. The Audited Party, its Affiliates and Sublicensees shall each make its records available for inspection or audit 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 the Auditing Party, solely to verify that Commercialization Expenses, royalty and Net Income payments hereunder were correctly accounted for or determined. Such inspection or audit right shall not be exercised by the Auditing Party more than once in any Calendar Year or more than once with respect to sales of a particular Licensed Product in a particular period. All records made available for inspection or audit shall be deemed to be Confidential Information of the Audited Party. The results of each inspection or audit, if any, shall be binding on both Parties. In the event there was an underpayment by the Audited Party hereunder, the Audited Party shall promptly (but in any event no later than [\*\*\*] ([\*\*\*)] days after the Audited Party’s receipt of the independent accountant’s report so concluding) make payment to the Auditing Party of any shortfall. In the event that there was an overpayment by the Audited Party hereunder, the Auditing Party shall promptly (but in any event no later than [\*\*\*] ([\*\*\*)] days after the Auditing Party’s receipt of the independent accountant’s report so concluding) refund to the Audited Party the excess amount. The Auditing Party shall bear the full cost of such audit unless such audit discloses an underreporting by the Audited Party of more than [\*\*\*] percent ([\*\*\*)% of the aggregate amount of royalties or Net Income Payments payable, or

Commercialization Expenses allocable, in any Calendar Year, in which case the Audited Party shall reimburse the Auditing Party for all costs incurred by the Auditing Party in connection with such inspection or audit.

6.4.4 **Overdue Royalties, Net Income Payments and Milestones.** All royalty and Net Income Payments not made within the time period set forth in Section 6.4.1 and 6.4.2, and all milestone payments not made within the time period specified in Section 6.3.1, shall bear interest at a rate of [\*\*\*] percent ([\*\*\*]%) per month from the due date until paid in full or, if less, the maximum interest rate permitted by Applicable Laws. Any such overdue royalty, Net Income Payment or milestone payment shall, when made, be accompanied by, and credited first to, all interest so accrued.

6.4.5 **Withholding Taxes.** All payments made by a Party hereunder shall be free and clear of any taxes, duties, levies, fees or charges except for applicable withholding taxes, if any. The paying Party shall make any applicable withholding payments due from the non-paying Party on its behalf and shall promptly thereafter provide the non-paying Party with written documentation of any such payment sufficient to enable non-paying Party to satisfy the requirements of the United States Internal Revenue Service or any tax authority of any other country, as applicable, with regard to an application for a foreign tax credit for such payment.

6.4.6 **Foreign Currency Exchange.** All royalties and Net Income Payments shall be payable in full in United States Dollars, regardless of the countries in which sales are made. For the purpose of computing Net Sales for Licensed Products sold in any currency other than United States Dollars, the quarterly royalty payment will be calculated as follows:

$(A/B) \times C =$  United States Dollars royalty payment on Net Sales sold in any currency other than United States Dollars during a Calendar Quarter, where

A= foreign "Net Sales" (as defined above) in such Calendar Quarter expressed in such foreign currency;

B= foreign exchange conversion rate, expressed in local currency of the foreign country per United States Dollar calculated using a simple four point average, i.e., (the rate at the beginning of the quarter + the rate at the end of month one + the rate at the end of month two + the rate at the end of the quarter)/4 as provided by the ECB for such accounting period; and

C= the royalty rate(s) applicable to such Net Sales under this Agreement.

For purposes of clarity, the ECB publishes reference currency exchange rates under the following internet link: [http://www.bundesbank.de/statistik/statistik\\_aktuell\\_devisenkursstatistik.en.php](http://www.bundesbank.de/statistik/statistik_aktuell_devisenkursstatistik.en.php).

## **7. TREATMENT OF CONFIDENTIAL INFORMATION;**

### **PUBLICITY; NON-SOLICITATION.**

#### **7.1 Confidentiality**

7.1.1 **Confidentiality Obligations.** Each Party recognizes that the other Party's Confidential Information constitutes highly valuable assets of such other Party. ImmunoGen and

Biotest each agrees that, subject to Section 7.1.2, during the Term and for an additional five (5) years thereafter, it will not disclose, and will cause its Affiliates and sublicensees not to disclose, any Confidential Information of the other Party and it will not use, and will cause its Affiliates not to use, any Confidential Information of the other Party except as expressly permitted hereunder. Without limiting the generality of the foregoing, each Party shall take such action, and shall cause its Affiliates and sublicensees to take such action, to preserve the confidentiality of the other Party's Confidential Information as such Party would customarily take to preserve the confidentiality of its own Confidential Information.

7.1.2 **Limited Disclosure.** ImmunoGen and Biotest each agrees that disclosure of its Confidential Information may be made by the other Party to any employee, consultant or Affiliate of such other Party to enable such other Party to exercise its rights or to carry out its responsibilities under this Agreement; provided that any such disclosure or transfer shall only be made to Persons who are bound by written obligations as described in Section 7.1.3. In addition, ImmunoGen and Biotest each agrees that the other Party may disclose its Confidential Information (a) on a need-to-know basis to such other Party's legal and financial advisors, or (b) as reasonably necessary in connection with an actual or potential (i) permitted sublicense of such other Party's rights hereunder, or (ii) merger or sale or other transfer to a Third Party of all or substantially all of such Party's capital stock or the assets which relate to this Agreement; provided the Person receiving such Confidential Information of the other Party agrees in writing to maintain the confidentiality of such Confidential Information of the other Party with terms at least as restrictive as those contained in Section 7.1.1. In addition, each Party agrees that the other Party may disclose such Party's Confidential Information (A) as reasonably necessary to file, prosecute or maintain Patent Rights, or to file, prosecute or defend litigation related to Patent Rights, in accordance with this Agreement; or (B) as required by Applicable Laws; provided that, in the case of any disclosure under this clause (B), the disclosing Party shall (1) if practicable, provide the other Party with reasonable advance notice of and an opportunity to comment on any such required disclosure, (2) if requested by such other Party, seek, or cooperate in all reasonable respects with such other Party's efforts to obtain, confidential treatment or a protective order with respect to any such disclosure to the extent available at such other Party's expense, and (3) use good faith efforts to incorporate the comments of such other Party in any such disclosure or request for confidential treatment or protective order.

7.1.3 **Employees and Consultants.** ImmunoGen and Biotest each hereby represents that all of its employees and consultants, and all of the employees and consultants of its Affiliates, who participate in the activities of the Collaboration or have access to Confidential Information of the other Party are or will, prior to their participation or access, be bound by written obligations to maintain such Confidential Information in confidence and not to use such information except as expressly permitted hereunder. Each Party agrees to use, and to cause its Affiliates to use, reasonable efforts to enforce such obligations.

7.2 **Publicity.** The Parties acknowledge that the terms of this Agreement constitute Confidential Information of each Party and may not be disclosed except as permitted by Section 7.1.2. Notwithstanding anything to the contrary in Section 7.1, the Parties, upon the execution of this Agreement, shall mutually agree to a press release with respect to this Agreement and, once such press release is approved for disclosure by both Parties, either Party may make subsequent public disclosure of the contents of such press release without further approval of the other Party.

Thereafter, neither Party shall publish, present or otherwise disclose publicly any material related to the Research Program or to the Development or Commercialization of a Licensed Product without the prior written consent of the other Party; provided, that notwithstanding the foregoing, (a) neither Party will be prevented from complying with any duty of disclosure it may have pursuant to Applicable Laws; and (b) either Party shall be permitted to publish such material in scientific journals or present such material at scientific conferences in accordance with Section 7.3; and (c) both Parties (i) expressly acknowledge that the respective other Party's ability to attract and raise capital is substantially dependent on its ability to publish, present or otherwise announce publicly developments in its research and development programs or in its product development pipeline and (ii) agree that they shall not unreasonably withhold, condition or delay their respective consent to any request by the respective other Party to publish, present or otherwise announce publicly developments in the Research Program or the Development or Commercialization of Licensed Products.

7.3 **Publications and Presentations.** The Parties acknowledge that scientific publications must be strictly monitored to prevent any adverse effect from premature publication or dissemination of results of the activities hereunder or prepublication of patentable data and content. It is agreed that both Parties may issue press releases only pursuant to Section 7.2. As long as ImmunoGen has not exercised a Co-Development Option to a Licensed Product, Biotest shall be entitled to publish details, data and/or results on the Research Program or the Development Program, e.g., in scientific articles or oral presentations, pursuant to this Section 7.3. Provided that ImmunoGen has exercised a Co-Development Option to a Licensed Product both Parties shall be entitled to publish in full range on the respective Licensed Product only pursuant to this Section 7.3.

Except as required by Applicable Laws, each Party agrees that it shall not publish or present, or permit to be published or presented, the results of the Research Program or the Development or Commercialization of a Licensed Product, including but not limited to, studies or clinical trials carried out by such Party as part of the Collaboration under this Agreement, without the prior review by and the approval of, the JDC, with respect to Development activities or, provided that ImmunoGen has exercised a Co-Development Option and a JMC has been established, the JMC, with respect to Commercialization activities. Each Party shall provide to the JDC the opportunity to review any of the submitting Party's proposed abstracts, manuscripts or presentations (including information to be presented verbally) which relate to the Research Program or the Development or Commercialization of a Licensed Product at least [\*\*\*] ([\*\*\*)] days prior to its intended presentation or submission for publication, and such submitting Party agrees, upon written request from the JDC within such [\*\*\*] ([\*\*\*)] day period, not to submit such abstract or manuscript for publication or to make such presentation until the other Party is given up to [\*\*\*] ([\*\*\*)] days from the date of such written request to seek appropriate patent protection for any material in such publication or presentation which the JDC reasonably believes is patentable. Once such abstracts, manuscripts or presentations have been reviewed by the JDC, the same abstracts, manuscripts or presentations do not have to be provided again to the JDC for review for a later submission for publication. Each Party also shall have the right to require that its Confidential Information that is disclosed in any such proposed publication or presentation be deleted prior to such publication or presentation. In any permitted publication or presentation by a Party, the other Party's contribution shall be duly recognized, and co-authorship shall be determined in accordance with customary industry standards.

## 8. LICENSE GRANTS; EXCLUSIVITY

### 8.1 Research Licenses.

8.1.1 **ImmunoGen Grant.** Subject to the other terms of this Agreement, ImmunoGen hereby grants to Biotest and its Affiliates during the Term an exclusive, royalty-free, worldwide license, without the right to grant sublicenses, under the Licensed Technology and Licensed Patent Rights and ImmunoGen's interest in CD138 Conjugate Patent Rights, Joint Technology and Joint Patent Rights for the sole purpose of researching Licensed Products in the Field, under the Research Program in accordance with the Research Plan and in accordance with the Development Plan; provided, that, ImmunoGen expressly retains such rights as may be necessary to (a) conduct ImmunoGen Activities assigned to ImmunoGen under the Research Program and (b) to conduct research and process development activities with respect to Licensed Products.

8.1.2 **Biotest Grant.** Subject to the other terms of this Agreement, Biotest hereby grants to ImmunoGen and its Affiliates during the Term, a non-exclusive, royalty-free, worldwide license in the Field, without the right to grant sublicenses, under Biotest Technology and Biotest Patent Rights and Biotest's interest in CD138 Conjugate Patent Rights, Joint Technology and Joint Patent Rights for the sole purpose of conducting ImmunoGen Activities under the Research Program in accordance with the Research Plan and/or in connection with the Development of Licensed Products, provided that Biotest expressly retains such rights that may be necessary to (a) conduct the activities assigned to Biotest under the Research Program, and (b) to conduct research and development activities with respect to Licensed Products.

### 8.2 Development and Commercialization Licenses.

8.2.1 **ImmunoGen Grant.** ImmunoGen hereby grants to Biotest during the Term an exclusive, royalty-bearing license, including the right to grant sublicenses as provided in Section 8.3, under the Licensed Technology and Licensed Patent Rights and ImmunoGen's interest in CD138 Conjugate Patent Rights, Joint Technology, Joint Patent Rights and Improvements, for the sole purpose of Developing and Commercializing Licensed Products in the Field in the Territory.

8.2.2 **Biotest Grant.** Biotest hereby grants to ImmunoGen during the Term a co-exclusive, royalty-free, fully paid license, including the right to grant sublicenses solely to the extent as provided in Section 5, under Biotest Technology and Biotest Patent Rights and Biotest's interest in CD138 Conjugate Patent Rights, Joint Technology and Joint Patent Rights for the sole purpose of Co-Developing and Co-Promoting Co-Developed Products in the Field in the Co-Development Territory and to use the Licensed Product Trademark to Co-Promote Co-Developed Products in the Co-Development Territory.

8.2.3 **Improvement License.** Biotest hereby grants to ImmunoGen a non-exclusive, fully paid, irrevocable, royalty-free license, including the right to grant sublicenses as provided below in this Section 8.2.3, under Biotest's interest in Improvements Controlled by Biotest, (a) to manufacture Research Materials, Clinical Materials and/or Preclinical Materials pursuant to the terms of this Agreement, and/or each applicable Supply Agreement and (b) to

develop, make, have made, use, sell, have sold, offer for sale, import, have imported, export and have exported any product that is not a Licensed Product, and otherwise exploit such Improvements for all uses that are not otherwise prohibited by this Agreement and that do not involve a Licensed Product; provided, that, (i) any grant by ImmunoGen of a sublicense is only made in connection with the grant of a license to Technology Controlled by ImmunoGen and used in the conjugation of MAY Compounds to binding proteins; and (ii) the right of ImmunoGen to grant any such sublicense is subject to Biotest obtaining a grant back of a non-exclusive, fully paid, irrevocable, royalty-free license, including the right to grant sublicenses, under that sublicensee's improvements, enhancements or modifications to ImmunoGen Technology and/or ImmunoGen Patent Rights, to Develop and Commercialize Licensed Products in the Field and in the Territory in accordance with Section 8.2.1 of this Agreement.

### 8.3 **Right to Sublicense.**

8.3.1 **Biotest.** Biotest shall, at any time, have the right to grant sublicenses and to sign collaboration agreements under the license granted to it under Section 8.2.1 to any Affiliate of Biotest and to any Third Party with respect to any Licensed Product; provided, that, it shall be a condition of any such sublicense that (a) such Sublicensee agrees to be bound by all terms of this Agreement applicable to the subject matter of such sublicense; (b) to the extent such Sublicensee is a Third Party, Biotest shall provide written notice to ImmunoGen of any such proposed sublicense at least [\*\*\*] ([\*\*\*)] days prior to such execution and provide copies to ImmunoGen of each such sublicense substantially in the form to be executed at least [\*\*\*] ([\*\*\*)] business days prior to such execution (with appropriate redaction of confidential and/or financial terms); (c) if Biotest grants a sublicense, Biotest shall be deemed to have guaranteed that such Sublicensee will fulfill all of Biotest's obligations under this Agreement applicable to the subject matter of such sublicense; (d) Biotest shall not be relieved of any of its obligations pursuant to this Agreement as a result of such sublicense; and (e) if such sublicense agreement is effective prior to ImmunoGen exercising its Co-Development Option under Section 5.1.1 with respect to the applicable Licensed Product, all payments related to such agreement shall be the sole responsibility of Biotest and, subject to Section 6.4.1, all income related to such agreement shall be solely owned by Biotest and shall not be shared between Biotest and ImmunoGen in any way.

8.3.2 **ImmunoGen.** To the extent provided in Section 5.3, ImmunoGen shall have the right to grant sublicenses under the license granted to it under Section 8.2.2 to any Affiliate of ImmunoGen and to any Third Party with respect to any Co-Developed Product in the Co-Development Territory with respect to which ImmunoGen has exercised its Co-Development Option; provided, that: it shall be a condition of any such sublicense that (a) such Third Party agrees to be bound by all terms of this Agreement applicable to the Development and Commercialization of Co-Developed Products in the Co-Development Territory; (b) ImmunoGen shall provide written notice to Biotest of any such proposed sublicense at least [\*\*\*] ([\*\*\*)] days prior to such execution and provide copies to Biotest of each such sublicense substantially in the form to be executed at least [\*\*\*] ([\*\*\*)] business days prior to such execution (with appropriate redaction of confidential and/or financial terms); (c) if ImmunoGen grants a sublicense, ImmunoGen shall be deemed to have guaranteed that such Third Party will fulfill all of ImmunoGen's obligations under this Agreement applicable to the subject matter of such sublicense; and (d) ImmunoGen shall not be relieved of any of its obligations pursuant to this Agreement as a result of such sublicense.

8.4 **No Other Rights.** Biotest shall have no rights to use or otherwise exploit ImmunoGen Technology, ImmunoGen Patent Rights or ImmunoGen Materials, and ImmunoGen shall have no rights to use or otherwise exploit Biotest Technology, Biotest Patent Rights or Biotest Materials, in each case, except as expressly set forth herein.

8.5 **Restricted Activities of ImmunoGen.** During the Term, ImmunoGen shall not, and shall cause each of its Affiliates to not, develop or commercialize, or grant any license or right to any Third Party to utilize any Technology or Patent Rights Controlled by ImmunoGen or any of its Affiliates at any time during the Term for the development or commercialization of any other conjugate comprising a MAY Compound and an Antibody that targets CD138. If, within [\*\*\*] ([\*\*\*)] years of the Effective Date, ImmunoGen decides, in its discretion, to [\*\*\*] to [\*\*\*] to a [\*\*\*] [\*\*\*] a [\*\*\*] to [\*\*\*], [\*\*\*], [\*\*\*] and/or [\*\*\*] a [\*\*\*] [\*\*\*] (i) an Antibody that targets CD138, and (ii) [\*\*\*] or [\*\*\*] [\*\*\*] [\*\*\*] Controlled by ImmunoGen [\*\*\*] than [\*\*\*] [\*\*\*], including without limitation [\*\*\*], [\*\*\*] and [\*\*\*] (an "Additional CD138 Product"), then [\*\*\*] [\*\*\*] so [\*\*\*] [\*\*\*] and, if [\*\*\*] provides [\*\*\*] [\*\*\*] to [\*\*\*] of its [\*\*\*] in [\*\*\*] a [\*\*\*] to such Additional CD138 Product by itself or through any of its Affiliates within [\*\*\*] ([\*\*\*)] [\*\*\*] following [\*\*\*] of such [\*\*\*], then [\*\*\*] [\*\*\*], for a [\*\*\*] of [\*\*\*] ([\*\*\*)] [\*\*\*], [\*\*\*] [\*\*\*] [\*\*\*] [\*\*\*] [\*\*\*] with [\*\*\*] with respect to the [\*\*\*] to [\*\*\*], or to its respective Affiliate, as applicable, of a [\*\*\*] to [\*\*\*] and [\*\*\*] such Additional CD138 Product under [\*\*\*] and [\*\*\*] [\*\*\*] [\*\*\*] to the Parties.

## 9. **INTELLECTUAL PROPERTY RIGHTS**

9.1 **Disclosure of Inventions.** Each of ImmunoGen and Biotest shall promptly provide the other Party through the Patent Coordinators with written notice concerning all Program Inventions that are conceived or reduced to practice by employees or consultants of either of them or their Affiliates, alone or jointly with employees or consultants of the other Party or its Affiliates. The Parties shall, through the Patent Coordinators, amend Schedule 2 from time to time during the Term to list any inventions that are Licensed Patent Rights.

9.1.1 **ImmunoGen Intellectual Property Rights.** As between the Parties, ImmunoGen shall have sole and exclusive ownership of all right, title and interest on a worldwide basis in and to any and all ImmunoGen Technology and ImmunoGen Patent Rights, subject to the rights of, and the licenses granted to, Biotest as set forth herein.

9.1.2 **Biotest Intellectual Property Rights.** As between the Parties, Biotest shall have sole and exclusive ownership of all right, title and interest on a worldwide basis in and to any and all Biotest Technology, Biotest Patent Rights and Patent Rights on Program Inventions that cover the composition of matter and/or a method of use relating specifically to the Anti-CD138 Antibody, and such Patent Rights shall be assigned to Biotest, subject to the rights of, and the licenses granted to, ImmunoGen as set forth herein.

9.1.3 **Joint Technology Rights, CD138 Conjugate Patent Rights.** Biotest and ImmunoGen shall jointly own all Joint Technology, Joint Patent Rights and CD138 Conjugate Patent Rights. Subject to the rights of, and the licenses granted to, each Party hereunder, as joint owners of such rights the Parties hereby agree that in each case in accordance with the provisions of this Agreement (a) each Party may use, exploit or license or sublicense to any Affiliate or Third Party such Joint Technology and/or Joint Patent Rights for any or all purposes without restriction and without any obligation to account to the other Party and (b) each Party may use for internal

research purposes CD138 Conjugate Patent Rights but may only exploit or license or sublicense to any Affiliate or Third Party CD138 Conjugate Patent Rights pursuant to written agreements to be negotiated in good faith and consented to by the other Party, which consent shall not be unreasonably withheld or conditioned.

**Patent Coordinators.** ImmunoGen and Biotest shall each appoint a patent coordinator reasonably acceptable to the other Party (each, a “Patent Coordinator”), who shall serve as such Party’s primary liaison with the other Party on matters relating to patent filing, prosecution, maintenance and enforcement. Each Party may replace its Patent Coordinator at any time by notice in writing to the other Party.

**Inventorship.** In case of a dispute between ImmunoGen and Biotest over inventorship, such dispute shall be resolved by application of United States patent law by patent counsel selected by the JDC who (and whose firm) is not at the time of the dispute, and was not at any time during the five (5) years prior to such dispute, performing services for either of the Parties. Expenses for and of such patent counsel shall be shared equally by the Parties.

## **10. FILING, PROSECUTION AND MAINTENANCE OF PATENT RIGHTS**

10.1 **Patent Filing, Prosecution and Maintenance.** The JDC shall determine the jurisdictions within the Territory in which patent applications will be filed with respect to Joint Patent Rights. Subject to the foregoing, the responsibility for filing, prosecution and maintaining Patent Rights shall be as follows:

10.1.1 **ImmunoGen Patent Rights.** As between the Parties, ImmunoGen, acting through patent counsel of its choice, shall be responsible, at its sole expense, for the preparation, filing, prosecution and maintenance of all ImmunoGen Patent Rights. At ImmunoGen’s request, Biotest shall cooperate with ImmunoGen in all reasonable respects, at ImmunoGen’s expense, in connection with such preparation, filing, prosecution and maintenance of ImmunoGen Patent Rights.

10.1.2 **Biotest Patent Rights.** As between the Parties, Biotest, acting through patent counsel of its choice, shall be responsible, at its own expense, for the preparation, filing, prosecution and maintenance of all Biotest Patent Rights and CD138 Conjugate Patent Rights. At Biotest’s request, ImmunoGen shall cooperate with and assist Biotest in all reasonable respects, at Biotest’s expense, in connection with such preparation, filing, prosecution and maintenance of Biotest Patent Rights and/or CD138 Conjugate Patent Rights.

### **10.1.3 Joint Patent Rights.**

(a) Subject to subsection (b), Biotest, acting through an agent of its choice, shall have primary responsibility for the filing, prosecution and maintenance of Joint Patent Rights that contain one or more claims that solely cover any Licensed Product or its manufacture or a method of its delivery or its use. Biotest agrees to consult with ImmunoGen regarding the filing and contents of any application, amendment, submission or response filed in connection with such Joint Patent Rights, and agrees that the advice and suggestions of ImmunoGen and its patent counsel shall be taken into reasonable consideration.

(b) ImmunoGen, acting through an agent of its choice, shall have primary responsibility for the filing, prosecution and maintenance of Joint Patent Rights that contain one

or more claims that cover MAY Compounds in general and/or that cover both a Licensed Product and one or more other products Controlled by ImmunoGen. ImmunoGen agrees to consult with Biotest regarding the filing and contents of any application, amendment, submission or response filed in connection with such Joint Patent Rights, and agrees that the advice and suggestions of Biotest and its patent counsel shall be taken into reasonable consideration.

(c) Unless the Parties otherwise agree, the Parties, acting through patent counsel or agents of its choice, shall be jointly responsible for the preparation, filing, prosecution and maintenance of all Joint Patent Rights not covered by 10.1.3 (a) or (b) above. Each filing Party shall provide the other Party and its patent counsel with an opportunity to consult with the filing Party and its patent counsel regarding the filing and contents of any application, amendment, submission or response filed in connection with the Joint Patent Rights. The filing Party hereby agrees that the advice and suggestions of the other Party and its patent counsel shall be taken into reasonable consideration by the filing Party and its patent counsel in connection with each filing. Each Party shall, upon request from the filing Party and at the filing Party's sole cost, reasonably cooperate with the filing Party in connection with such patent filing activities.

#### 10.1.4 **Abandonment.**

(a) If ImmunoGen decides or so suggests, as applicable, to abandon or to allow to lapse, or otherwise determines not to prosecute in any country or region (including without limitation by determining not to designate a particular country in a PCT procedure), any of the Licensed Patent Rights, Licensed Product Trademarks or any Joint Patent Rights for which it is the filing party under Sections 10.1.1 or 10.1.3 in any country or region in the Territory, ImmunoGen shall inform Biotest of such decision or suggestion, as applicable, promptly and, in any event, a reasonable amount of time prior to any applicable deadline that may be necessary to establish or preserve such Licensed Patent Rights, Licensed Product Trademarks or Joint Patent Rights in such country or region. Biotest shall have the right to assume sole responsibility for continuing the prosecution of such Licensed Patent Rights, Licensed Product Trademarks or Joint Patent Rights in such country or region and paying any required fees to maintain such Licensed Patent Rights, Licensed Product Trademarks or Joint Patent Rights in such country or region or defending such Licensed Patent Rights, Licensed Product Trademarks or Joint Patent Rights, in each case at Biotest's sole discretion and expense and through patent counsel of its choice. Biotest shall not become an assignee of such Licensed Patent Rights, Licensed Product Trademarks or Joint Patent Rights as a result of its assumption of such responsibility under this Section 10.1.4(a) and such Licensed Patent Rights or Joint Patent Rights shall remain subject to this Agreement. Upon transfer of ImmunoGen's responsibility for prosecuting, maintaining and defending any of the Licensed Patent Rights, Licensed Product Trademarks or Joint Patent Rights to Biotest under this Section 10.1.4(a), (i) ImmunoGen shall promptly deliver to Biotest copies of all necessary files related to the Licensed Patent Rights, Licensed Product Trademarks or Joint Patent Rights with respect to which responsibility has been transferred and shall take all actions and execute all documents reasonably necessary for Biotest to assume such prosecution, maintenance and defense and (ii) Biotest shall have the right to [\*\*\*] its [\*\*\*] [\*\*\*] and [\*\*\*] [\*\*\*] on and after the date of such transfer applicable to the filing, establishing, preserving, maintaining, prosecuting and/or defending of such transferred Licensed Patent Rights, Licensed Product Trademarks and/or Joint Patent Rights against [\*\*\*] [\*\*\*] [\*\*\*] on [\*\*\*] [\*\*\*] [\*\*\*] of [\*\*\*] [\*\*\*] covered by the Licensed Patent Rights, Licensed Product Trademarks or Joint Patent Rights with respect to which

responsibility has been transferred.

(b) If Biotest decides or so suggests, as applicable, to abandon or to allow to lapse, or otherwise determines not to prosecute in any country or region (including without limitation by determining not to designate a particular country in a PCT procedure) any of the CD138 Conjugate Patent Rights or Joint Patent Rights for which it is the filing party under Sections 10.1.2 or 10.1.3 in any country or region in the Territory, Biotest shall inform ImmunoGen of such decision or suggestion, as applicable, promptly and, in any event, a reasonable amount of time prior to any applicable deadline that may be necessary to establish or preserve such CD138 Conjugate Patent Rights or Joint Patent Rights in such country or region. ImmunoGen shall have the right to assume sole responsibility for continuing the prosecution of such CD138 Conjugate Patent Rights or Joint Patent Rights in such country or region and paying any required fees to maintain such CD138 Conjugate Patent Rights or Joint Patent Rights in such country or region or defending such CD138 Conjugate Patent Rights or Joint Patent Rights, in each case at ImmunoGen's sole discretion [\*\*\*] [\*\*\*] and through patent counsel of its choice. ImmunoGen shall not become an assignee of such CD138 Conjugate Patent Rights or Joint Patent Rights as a result of its assumption of such responsibility under this Section 10.1.4(b) and such CD138 Conjugate Patent Rights or Joint Patent Rights shall remain subject to this Agreement. Upon transfer of Biotest's responsibility for prosecuting, maintaining and defending any of the CD138 Conjugate Patent Rights or Joint Patent Rights to ImmunoGen under this Section 10.1.4(b), Biotest shall promptly deliver to ImmunoGen copies of all necessary files related to the CD138 Conjugate Patent Rights or Joint Patent Rights with respect to which responsibility has been transferred and shall take all actions and execute all documents reasonably necessary for ImmunoGen to assume such prosecution, maintenance and defense.

## 10.2 Legal Actions.

10.2.1 **Third Party Infringement.** The Parties, understanding that the value of a Licensed Product is related to the exclusivity provided thereto by the CD138 Conjugate Patent Rights and the Joint Patent Rights, agree that:

(a) In the event either Party becomes aware of any potential infringement in the Field of, or the submission by any Third Party of an abbreviated NDA under the Hatch-Waxman Act for any generic approval of a Licensed Product in the Field that is covered by, any Licensed Patent Rights, ImmunoGen Patent Rights, CD138 Conjugate Patent Rights, Biotest Patent Rights or Joint Patent Rights (an "Infringement"), that Party shall promptly notify the other Party of such potential Infringement and provide it with all details thereof of which it is aware (each, an "Infringement Notice").

(b) [\*\*\*] shall have the first right and option, but not the obligation, to (i) eliminate any such Infringement that is covered by the CD138 Conjugate Patent Rights and any Joint Patent Rights that contain one or more claims that solely cover any Licensed Product or its manufacture or a method of its delivery or its use and/or (ii) institute any patent infringement lawsuit(s) against a Third Party filing an abbreviated NDA for generic approval of a Licensed Product (for example, a Paragraph IV certification against such a patent listed in the Orange Book) by reasonable steps, which may include, in any case, the institution of legal proceedings or other action. [\*\*\*] agrees that, consistent with the Parties' interests hereunder, [\*\*\*] shall be consulted

with respect to decisions related to defense of CD138 Conjugate Patent Rights and such Joint Patent Rights. Subject to Section 10.2.1(f), all costs, including, without limitation, attorneys' fees, relating to such legal proceedings or other action shall be borne by [\*\*\*]. If [\*\*\*] does not take commercially reasonable steps to eliminate the Infringement within [\*\*\*] [\*\*\*] [\*\*\*] ([\*\*\*)] days from an Infringement Notice or within [\*\*\*] ([\*\*\*)] days in the case of a certification against a patent listed in the Orange Book, [\*\*\*] shall have the right to defend the applicable CD138 Conjugate Patent Rights and/or Joint Patent Rights, at its sole cost and expense.

(c) ImmunoGen shall have the first right and option, but not the obligation, to eliminate any such Infringement that is covered by the Licensed Patent Rights and/or any Joint Patent Rights that contain one or more claims that cover MAY Compounds in general and/or that cover both a Licensed Product and one or more other products Controlled by ImmunoGen by taking reasonable steps, which may include the institution of legal proceedings or other action; provided, that, notwithstanding the foregoing, Biotest agrees to cooperate in good faith with ImmunoGen or any Third Party from which ImmunoGen has licensed ImmunoGen Patent Rights to determine the most reasonable method of eliminating the Infringement in view of the Parties' respective interests and ImmunoGen's obligations to such Third Party. ImmunoGen agrees that, consistent with the Parties' interests hereunder, Biotest shall be consulted with respect to decisions related to such defense of the Licensed Patent Rights and/or any Joint Patent Rights. Subject to Section 10.2.1(f), all costs, including, without limitation, attorneys' fees, relating to such legal proceedings or other action shall be borne by ImmunoGen. If ImmunoGen does not take commercially reasonable steps to eliminate the Infringement within [\*\*\*] [\*\*\*] [\*\*\*] ([\*\*\*)] days from any Infringement Notice (or [\*\*\*] ([\*\*\*)] days in the case of an Infringement under the Hatch-Waxman Act, e.g., in the case of a certification against a patent listed in the Orange Book), then Biotest shall have the right and option to do so at its expense.

(d) Biotest shall have the first right and option, but not the obligation, to eliminate any such Infringement that is covered by the Biotest Patent Rights by taking reasonable steps, which may include the institution of legal proceedings or other action. Subject to Section 10.2.1(f), all costs, including, without limitation, attorneys' fees, relating to such legal proceedings or other action shall be borne by Biotest.

(e) ImmunoGen shall have the first right and option, but not the obligation, to eliminate any such Infringement that is covered by the Licensed Patent Rights (to the extent such defense is not covered by Section 10.2.1[d]) and/or the ImmunoGen Patent Rights by taking reasonable steps, which may include the institution of legal proceedings or other action. Subject to Section 10.2.1(f), all costs, including, without limitation, attorneys' fees, relating to such legal proceedings or other action shall be borne by ImmunoGen.

(f) Notwithstanding anything to the contrary in this Section 10.2.1, if ImmunoGen has exercised its Co-Development Option with respect to a Licensed Product under Section 5.1.1 of this Agreement, both Biotest and ImmunoGen (in each case directly or through a Third Party partner, as applicable) will be responsible for jointly eliminating any Infringement of CD138 Conjugate Patent Rights and/or Joint Patent Rights in the Co-Development Territory by reasonable steps, which may include the institution of legal proceedings or other action, at shared cost. Notwithstanding this joint responsibility, the Parties agree that [\*\*\*] shall lead the

defense of such potential infringement, with full cooperation and input from [\*\*\*]. All costs and expenses reasonably incurred by either Party under this subsection (f) shall, to the extent related to the Commercialization of a Co-Developed Product in the Co-Development Territory, be deemed to be Commercialization Expenses.

(g) Each Party shall have the right to participate, and be represented by counsel that it selects, in any legal proceedings or other action instituted under this Section by the other Party. If a Party with the right to initiate legal proceedings under this Section to eliminate an Infringement lacks standing to do so and the other Party has standing to initiate such legal proceedings, then the Party with standing shall initiate such legal proceedings at the request and expense of the other Party. Neither Party shall settle any Infringement claim or proceeding under this Section 10.2.1 without the prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed.

(h) In any action, suit or proceeding instituted under this Section 10.2.1, the Parties shall cooperate with and assist each other in all reasonable respects. Upon the reasonable request of the Party instituting such action, suit or proceeding, the other Party shall join therein and shall be represented using counsel of its own choice, at the requesting Party's expense.

(i) Any amounts recovered by the Parties pursuant to this Section, whether by settlement or judgment, shall be allocated in the following order: (i) first, to reimburse Biotest and ImmunoGen for their reasonable Out-of-Pocket Costs in making such recovery (which amounts shall be allocated pro rata if insufficient to cover the totality of such expenses); and (ii) then, (A) to the extent the Infringement relates to a Royalty-Bearing Product in the Royalty-Bearing Territory, to Biotest in reimbursement for lost sales associated with such Royalty-Bearing Products and to ImmunoGen in reimbursement for lost royalties owing hereunder based on such lost sales and (B) to the extent the Infringement relates to a Co-Developed Product in the Co-Development Territory, to the calculation of Net Income with respect to such Co-Developed Product. Any other damages, awards or amounts recovered (including for punitive damages) shall be allocated as follows: (A) if [\*\*\*] is the Party bringing such suit or proceeding or taking such other legal action, [\*\*\*] percent ([\*\*\*]%) to [\*\*\*] and [\*\*\*] percent ([\*\*\*]%) to [\*\*\*], (B) if [\*\*\*] is the Party bringing such suit or proceeding or taking such other legal action, [\*\*\*] percent ([\*\*\*]%) to [\*\*\*] and (C) if the suit is brought jointly, [\*\*\*] percent ([\*\*\*]%) to [\*\*\*] Party.

(j) For purposes of clarity, the Parties acknowledge that this Section concerns enforcement of the various Patent Rights defined in this Agreement, and does not relate to ownership of the various Patent Rights defined in this Agreement, which are recognized to be separate legal issues.

**10.2.2 Defense of Claims.** In the event that any action, suit or proceeding is brought against either Party or any Affiliate or sublicensee of either Party alleging the infringement of the Technology or Patent Rights of a Third Party by reason of the conduct of the Research Program, the Development or Commercialization of any Licensed Product under the Licensed Patent Rights: (a) ImmunoGen as the owner of the Licensed Patent Rights shall have the right, but not the obligation, to defend such action, suit or proceeding at its sole expense; (b) Biotest shall have the right to participate by separate counsel at its own expense in any such action, suit or

proceeding; and (c) the Parties shall cooperate with each other in all reasonable respects in any such action, suit or proceeding. In the event that any action, suit or proceeding is brought against either Party or any Affiliate or sublicensee of either Party alleging the infringement of the Technology or Patent Rights of a Third Party by reason of the conduct of the Research Program, the Development or Commercialization of any Licensed Product under Biotest Patent Rights: (a) Biotest as the owner of the Biotest Patent Rights shall have the right, but not the obligation, to defend such action, suit or proceeding at its sole expense; (b) the Parties shall cooperate with each other in all reasonable respects in any such action, suit or proceeding. If such action, suit or proceeding relates to Co-Developed Products in the Co-Development Territory or relates to Joint Patent Rights or CD138 Conjugate Patent Rights, both Parties shall equally share the cost and expense of any such action, suit or proceeding and the cost and expense of the above shall be used to calculate Net Income for that Co-Developed Product. Each Party shall provide the other Party with prompt written notice of the commencement of any such suit, action or proceeding, or of any allegation of infringement of which such Party becomes aware, and shall promptly furnish the other Party with a copy of each communication relating to the alleged infringement that is received by such Party. For purposes of clarity, nothing in this Section 10.2.2 shall affect the right of ImmunoGen to defend itself in any such action, suit or proceeding relating to ImmunoGen Patent Rights. Biotest shall not compromise, litigate, settle or otherwise dispose of any such suit, action or proceeding that involves the use of ImmunoGen Patent Rights without ImmunoGen's prior written consent, which shall not be unreasonably withheld, conditioned or delayed.

10.3 **Trademark Prosecution.** Biotest shall be responsible for the filing, prosecution, defense and maintenance before all trademark offices of the Licensed Product Trademarks at Biotest's expense. In the event that ImmunoGen has exercised a Co-Development Option to a Licensed Product both Parties shall be responsible for the filing, prosecution, defense and maintenance before all trademark offices in the Co-Development Territory of the Licensed Product Trademarks of such Co-Developed Product under the direction of the JDC or JMC, as appropriate, and shall equally share all expenses related thereto.

10.4 **Orange Book Listing.** The Parties agree that, upon the filing of an NDA covering a Licensed Product, the Parties will designate which Party shall be responsible for listing the Patent Rights covering the Licensed Product in the Orange Book and, subject to the foregoing, the Party so designated shall promptly list such Patent Rights in the Orange Book.

## 11. **TERM AND TERMINATION**

11.1 **Term.** This Agreement shall commence on the Effective Date and shall continue in full force and effect until such time as all Royalty Terms for all Licensed Products have ended, unless earlier terminated in accordance with the provisions of this Section 11 (the "Term"). Thereafter, if not earlier terminated pursuant to Section 11.2, Biotest shall have a worldwide, fully paid-up and royalty-free license for the use and the Commercialization of all Licensed Products. In the event that either Party discontinues with its activities under this Agreement for good and valid reasons, including, without limitation, toxicological, pharmaceutical and ethical reasons, then the Parties shall, in good faith, discuss the situation and use commercially reasonable efforts in order to agree on an appropriate solution, including, without limitation, an early termination of or an amendment to this Agreement. In the event of a dispute between the Parties as to whether or not any discontinuation by a Party of its activities under this Agreement is justified by good

and valid reasons, such dispute shall first, according to Section 2.1.6, be referred to the JSC, and, to the extent not resolved by the JSC, referred to arbitration according to Section 14.1.

11.2 **Termination.** This Agreement may only be terminated at any time by either Party, or by the Party specified, as follows:

11.2.1 **Termination for Breach.** Either Party may terminate this Agreement, effective immediately upon written notice to the other Party, by giving [\*\*\*] ([\*\*\*)] days' written notice to the other Party committing any material breach with respect to the failure to pay any amounts due hereunder and [\*\*\*] ([\*\*\*)] days' written notice to the Party committing any other material breach; provided that, notwithstanding any indemnity claims of the non-breaching Party against the Party committing the breach according to Section 13, such material breach would render it reasonably unacceptable for the other Party to continue with the collaboration with the breaching Party and the activities under this Agreement. Notwithstanding anything to the contrary set forth herein, (a) if the asserted breach is cured or shown to be non-existent within the applicable cure period, the notice of breach hereunder shall be deemed automatically withdrawn and (b) a material default by a Party shall not give rise to the termination right under this Section 11.2.1 to the extent such material default arises from a Force Majeure event described in Section 14.11; provided, that the Party allegedly breaching the Agreement shall have the burden of demonstrating the occurrence of the Force Majeure event. In the event of a dispute between the Parties as to whether or not any conduct of either Party constitutes a material breach, such dispute shall, first, according to Section 2.1.6, be referred to the JSC, and, to the extent not resolved by the JSC, be referred to arbitration according to Section 14.1.

11.2.2 **Termination for Insolvency.**

(a) In the event of Bankruptcy of a Party, then the other Party may terminate this Agreement effective immediately upon written notice to such Party. For purpose hereof, "Bankruptcy" means, with respect to either Party, (a) such Party shall commence a voluntary case or other proceeding seeking liquidation, reorganization or other relief with respect to itself or its debts under any bankruptcy, insolvency, or other similar law now or hereinafter in effect or seeking the appointment of a trustee, receiver, liquidator, custodian or other similar official of it or any substantial part of its property, or shall consent to any such relief or to the appointment of or taking possession by any such official in an involuntary case or other proceeding commenced against it, or shall make a general assignment for the benefit of creditors, or shall take any corporate action to authorize any of the foregoing; (b) an involuntary case or other proceeding shall be commenced against such Party seeking liquidation, reorganization or other relief with respect to itself or its debts under any bankruptcy, insolvency, or other similar law now or hereinafter in effect or seeking the appointment of a trustee, receiver, liquidator, custodian or other similar official of it or any substantial part of its property, and such involuntary case or other proceeding shall remain undismissed and unstayed for a period of thirty (30) days; (c) a decree or order for relief shall be entered against such Party under any bankruptcy, insolvency, or other similar law as now or hereinafter in effect; (d) such Party's liabilities exceed the fair market value of its assets or such Party otherwise becomes insolvent or (e) the dissolution or liquidation of, or cessation of business in the ordinary course by, such Party or such Party being unable to pay its debts as they come due, or the admission in writing of such Party of the inability to pay its debts as they become due;

(b) all rights and licenses granted under or pursuant to this Agreement are, and will otherwise be deemed to be, for purposes of Section 365(n) of the US Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101 of the US Bankruptcy Code. The Parties agree that Biotest, as licensee of such rights under this Agreement, will retain and may fully exercise all of its rights and elections under the US Bankruptcy Code. The Parties further agree that, in the event of commencement of a bankruptcy proceeding by or against ImmunoGen under the US Bankruptcy Code, Biotest will be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, and the same, if not already in its possession, will be promptly delivered to it (i) upon any such commencement of a bankruptcy proceeding upon its written request therefore, unless ImmunoGen elects to continue to perform all of its obligations under this Agreement, or (ii) if not delivered under (i) above, following the rejection of this Agreement by or on behalf of ImmunoGen upon written request by Biotest;

(c) all rights, powers and remedies of Biotest provided for in this Section 11.2.2 are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in equity (including, without limitation, under the US Bankruptcy Code). In the event of the Bankruptcy of ImmunoGen, Biotest, in addition to the rights, powers and remedies expressly provided herein, shall be entitled to exercise all other such rights and powers and resort to all other such remedies as may now or hereafter exist at law or in equity (including, without limitation, under the US Bankruptcy Code).

11.2.3 **Termination by Biotest.** Biotest may terminate this Agreement at any time upon not less than ninety (90) days written notice at any time prior to the exercise by ImmunoGen of the Co-Development Option pursuant to Section 5.1.1.

11.3 **Consequences of Termination of Agreement.** In the event of the termination of this Agreement pursuant to Section 11.2 the following provisions shall apply, as applicable:

11.3.1 **Termination by ImmunoGen Pursuant to Section 11.2.1 or 11.2.2.** If this Agreement is terminated by ImmunoGen pursuant to Section 11.2.1 or 11.2.2, the following provisions shall apply:

(a) the licenses granted to Biotest pursuant to Sections 8.1.1, 8.2.1 and 8.2.3 shall immediately terminate and Biotest shall be deemed to have granted to ImmunoGen, as of the date of termination, an [\*\*\*] (even as to Biotest), worldwide, royalty-bearing license, with the rights to sublicense, under Biotest Technology and Biotest Patent Rights and Biotest's interest in Joint Technology and Joint Patent Rights, to Develop and have Developed and Commercialize Licensed Products; provided that the royalties payable to Biotest shall be calculated based on the worldwide Annual Net Sales made by ImmunoGen, its Affiliates and/or Sublicensees, based on a royalty rate which shall be consistent with industry standards at such time and reasonably agreed to by the Parties or, if no such agreement is reached by the Parties with respect to such royalty rate within [\*\*\*] ([\*\*\*)] days, determined by an arbitration panel of three (3) persons experienced in the pharmaceutical business who are independent of both Parties, pursuant to Section 14.1 of this Agreement; provided, that any and all Termination Costs incurred by ImmunoGen may, in ImmunoGen's sole discretion, be offset by ImmunoGen against such royalty payments or other amounts payable to Biotest hereunder;

(b) all exclusivity obligations of ImmunoGen under Section 8.5 shall immediately terminate and ImmunoGen shall thereafter have the right to Develop and Commercialize Licensed Products for any and all uses within and outside of the Field;

(c) each Party shall promptly return all Confidential Information of the other Party that are not subject to a continuing license hereunder; provided that each Party may retain one copy of the Confidential Information of the other Party in its archives solely for the purpose of establishing the contents thereof and ensuring compliance with its obligations hereunder;

(d) upon request of ImmunoGen, Biotest shall promptly, and in any event within [\*\*\*] ([\*\*\*)] days after ImmunoGen's request: (i) transfer to ImmunoGen all right, title and interest in and to all Licensed Product Trademarks and registrations thereof, if any (ii) transfer to ImmunoGen all of its right, title and interest in all Regulatory Filings, Drug Approval Applications and Regulatory Approvals then in its name applicable to any Licensed Product, and all material aspects of Confidential Information Controlled by it as of the date of termination relating to Regulatory Filings, Drug Approval Applications and Regulatory Approvals; (iii) notify the applicable Regulatory Authorities and take any other action reasonably necessary to effect such transfer; (iv) provide ImmunoGen with copies of all correspondence between Biotest and such Regulatory Authorities relating to such Regulatory Filings, Drug Approval Applications and Regulatory Approvals; (v) unless expressly prohibited by any Regulatory Authority, transfer control to ImmunoGen of all clinical trials of any Licensed Product being conducted as of the effective date of termination and continue to conduct such trials for up to [\*\*\*] ([\*\*\*)] months to enable such transfer to be completed without interruption of any such trial; (vi) assign (or cause its Affiliates to assign) to ImmunoGen all agreements with any Third Party with respect to the conduct of clinical trials for any Licensed Product including, without limitation, agreements with contract research organizations, clinical sites and investigators, unless expressly prohibited by any such agreement (in which case Biotest shall cooperate with ImmunoGen in all reasonable respects to secure the consent of such Third Party to such assignment); (vii) provide ImmunoGen with all supplies of any Licensed Product in the possession of Biotest or any Affiliate or contractor of Biotest at [\*\*\*] to Biotest's or Affiliate's cost for the supply of such Licensed Product; and (viii) provide ImmunoGen with copies of all reports and data generated or obtained by Biotest or its Affiliates pursuant to this Agreement that relate to any Licensed Product that has not previously been provided to ImmunoGen; and

(e) if Biotest has manufactured, is manufacturing or having manufactured any Licensed Product or any intermediate thereof as of the effective date of termination: (i) Biotest shall, if requested by ImmunoGen, supply ImmunoGen with its requirements for all such Licensed Product and intermediate for up to [\*\*\*] ([\*\*\*)] months following such termination at [\*\*\*] to Biotest's cost for the supply of such Licensed Product or intermediate, and (ii) within [\*\*\*] ([\*\*\*)] days after ImmunoGen's request, Biotest shall provide to ImmunoGen or its designee all information in its possession with respect to the manufacture of each such Licensed Product or intermediate.

11.3.2 **Termination by Biotest Pursuant to Section 11.2.1 or 11.2.2.** If this Agreement is terminated by Biotest pursuant to Section 11.2.1 or 11.2.2:

(a) Biotest shall continue to have the licenses set forth in Sections 8.1.1, 8.2.1 and 8.2.3 to Develop and have Developed Licensed Products and to Commercialize and have Commercialized Licensed Products, subject to a payment of royalties due on and after the effective date of termination with respect thereto, at a rate equal to [\*\*\*] [\*\*\*] [\*\*\*] [\*\*\*] the rates set forth in Section 6.4, calculated on the basis of Annual Net Sales of Royalty-Bearing Products during the Royalty Term, provided, that any and all Termination Costs incurred by Biotest may, in Biotest's sole discretion, be offset by Biotest against such royalty payments or other amounts payable to ImmunoGen hereunder;

(b) all rights (including without limitation the Co-Development Option) and licenses granted to ImmunoGen pursuant to Section 5 and Sections 8.1.2, 8.2.2 and 8.2.3 shall immediately terminate and all Co-Developed Products including Co-Developed Products sold in the Co-Development Territory shall immediately become Royalty-Bearing Products and the applicable territory shall be the Territory; and

(c) each Party shall promptly return all Confidential Information of the other Party that are not subject to a continuing license hereunder; provided that each Party may retain one copy of the Confidential Information of the other Party in its archives solely for the purpose of establishing the contents thereof and ensuring compliance with its obligations hereunder.

(d) upon request of Biotest, ImmunoGen shall promptly, and in any event within [\*\*\*] ([\*\*\*)] days after Biotest's request: (i) transfer to Biotest all right, title and interest in and to all Licensed Product Trademarks and/or Co-Developed Product Trademarks, as applicable, and registrations thereof, if any (ii) transfer to Biotest all of its right, title and interest in all Regulatory Filings, Drug Approval Applications and Regulatory Approvals then in its name applicable to any Licensed Product and/or Co-Developed Product, as applicable, and all material aspects of Confidential Information Controlled by it as of the date of termination relating to Regulatory Filings, Drug Approval Applications and Regulatory Approvals; (iii) notify the applicable Regulatory Authorities and take any other action reasonably necessary to effect such transfer; (iv) provide Biotest with copies of all correspondence between ImmunoGen and such Regulatory Authorities relating to such Regulatory Filings, Drug Approval Applications and Regulatory Approvals; (v) unless expressly prohibited by any Regulatory Authority, transfer control to Biotest of all clinical trials of any Licensed Product and/or Co-Developed Product, as applicable, being conducted as of the effective date of termination and if so requested by Biotest continue to conduct and co-finance such trials in which ImmunoGen is involved for up to [\*\*\*] ([\*\*\*)] months to enable such transfer to be completed without interruption of any such trial; (vi) assign (or cause its Affiliates to assign) to Biotest all agreements with any Third Party with respect to the conduct of clinical trials for any Licensed Product and/or Co-Developed Product, as applicable, including, without limitation, agreements with contract research organizations, clinical sites and investigators, unless expressly prohibited by any such agreement (in which case ImmunoGen shall cooperate with Biotest in all reasonable respects to secure the consent of such Third Party to such assignment); (vii) provide Biotest with all supplies of any Licensed Product and/or Co-Developed Product, as applicable, in the possession of ImmunoGen or any of its Affiliates or contractors at [\*\*\*] to ImmunoGen's or its Affiliate's cost for the supply of such Licensed Product and/or Co-Developed Product; and (viii) provide Biotest with copies of all reports and data generated or obtained by ImmunoGen or its Affiliates pursuant to this Agreement that

relate to any Licensed Product and/or Co-Developed Product that has not previously been provided to Biotest; and

(e) if ImmunoGen has manufactured, is manufacturing or having manufactured any Licensed Product and/or Co-Developed Product or any intermediate thereof as of the effective date of termination: (i) ImmunoGen shall, if requested by Biotest, supply Biotest with its requirements for all such Licensed Product and/or Co-Developed Product and intermediate for up to [\*\*\*] ([\*\*\*)] months following such termination at [\*\*\*] to ImmunoGen's cost for the supply of such Licensed Product and/or Co-Developed Product or intermediate, and (ii) within [\*\*\*] ([\*\*\*)] days after Biotest's request, ImmunoGen shall provide to Biotest or its designee all information in its possession with respect to the manufacture of each such Licensed Product and/or Co-Developed Product or intermediate.

**11.3.3 Termination by Biotest Pursuant to Section 11.2.3.** If this Agreement is terminated by Biotest pursuant to Section 11.2.3:

(a) Biotest shall cease to have the licenses set forth in Sections 8.1.1 and 8.2.1 to Develop and Commercialize Licensed Products and all payment obligations of Biotest to ImmunoGen subsequent to the effective date of termination under this Agreement shall terminate;

(b) all rights (including without limitation the Co-Development Option) and licenses granted to ImmunoGen pursuant to Section 5 and Sections 8.1.2 and 8.2.2 shall immediately terminate; and

(c) each Party shall promptly return all Confidential Information of the other Party that are not subject to a continuing license hereunder; provided that each Party may retain one copy of the Confidential Information of the other Party in its archives solely for the purpose of establishing the contents thereof and ensuring compliance with its obligations hereunder.

**11.3.4 Definition of Termination Costs.** For purposes of Sections 11.3 only, the term Termination Costs means, with respect to any Licensed Product that is subject to termination (a) all Out-of-Pocket Costs paid to a Third Party to transfer Regulatory Filings, Drug Approval Applications and Regulatory Approvals applicable to such Licensed Product, and (b) all internal costs, determined by the applicable FTE Rate for the FTEs used by both Parties in the relevant period on activities directly relating to the transfer of control of such Licensed Product to the non-terminating Party.

**11.4 Surviving Provisions.** Termination or expiration of this Agreement for any reason shall be without prejudice to:

(a) the rights and obligations of the Parties provided in Sections 6.4 (solely to the extent any licenses granted to Biotest survive pursuant to Section 11.3) 7, 8.2, 8.3 (8.2 and 8.3 solely to the extent as provided in Section 11.3), 8.4, 11.3, 13 and 14 (including all other Sections referenced in any such Section and including Section 1), all of which shall survive such termination; and

(b) any other rights or remedies provided at law or equity which either Party may otherwise have.

## 12. REPRESENTATIONS AND WARRANTIES

12.1 **Mutual Representations and Warranties.** ImmunoGen and Biotest each represents and warrants to the other, as of the Effective Date, as follows:

12.1.1 **Organization.** It is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization, and has all requisite power and authority, corporate or otherwise, to execute, deliver and perform this Agreement.

12.1.2 **Authorization.** The execution and delivery of this Agreement and the performance by it of the transactions contemplated hereby have been duly authorized by all necessary corporate action and will not violate (a) such Party's certificate of incorporation or bylaws, (b) any agreement, instrument or contractual obligation to which such Party is bound in any material respect, (c) any requirement of any Applicable Law, or (d) any order, writ, judgment, injunction, decree, determination or award of any court or governmental agency presently in effect applicable to such Party.

12.1.3 **Binding Agreement.** This Agreement is a legal, valid and binding obligation of such Party enforceable against it in accordance with its terms and conditions.

12.1.4 **No Inconsistent Obligation.** It is not under and will not enter into any obligation, contractual or otherwise, to any Person that conflicts with or is inconsistent in any respect with the terms of this Agreement or that would impede the diligent and complete fulfillment of its obligations hereunder.

12.2 **Additional Representations of ImmunoGen.** ImmunoGen further represents and warrants to Biotest, as of the Effective Date, as follows:

12.2.1 **ImmunoGen Licensed Patent Rights.** All Licensed Patent Rights are existing and, to the best of ImmunoGen's knowledge, no Licensed Patent Rights are invalid or unenforceable.

12.2.2 **Claims or Judgments.** There are no claims, judgment or settlements against ImmunoGen pending, or to the best of ImmunoGen's knowledge, threatened, that invalidate or seek to invalidate the Licensed Patent Rights.

12.2.3 **Right to Technology.** ImmunoGen has the right, and will during the Term of this Agreement maintain the right, to (a) use the Licensed Technology and Licensed Patent Rights existing as of the Effective Date as is necessary to fulfill its obligations under this Agreement; and (b) grant the licenses under the Licensed Patent Rights granted pursuant to this Agreement.

12.2.4 **No Infringement.** To the best of ImmunoGen's knowledge, no Third Party is infringing, or threatening to infringe, the Licensed Patent Rights. To the best of ImmunoGen's knowledge, the use of Licensed Patent Rights under this Agreement for the Development,

manufacture, use or Commercialization of Licensed Products does not infringe the Patent Rights of any Third Party, nor has ImmunoGen received any written notice alleging such infringement.

12.2.5 **No Litigation.** To the best of ImmunoGen’s knowledge, there is no pending or threatened litigation that alleges that ImmunoGen’s proposed activities under this Agreement would infringe or misappropriate any intellectual property rights of any Third Party.

### 13. **INDEMNIFICATION**

13.1 **Indemnification of Biotest by ImmunoGen.** ImmunoGen shall indemnify, defend and hold harmless Biotest, its Affiliates, their respective directors, officers, employees and agents, and their respective successors, heirs and assigns (the “Biotest Indemnitees”), against any and all liabilities, damages, losses and expenses (including reasonable attorneys’ fees and expenses of litigation) (collectively, “Losses”) incurred by or imposed upon the Biotest Indemnitees, or any one of them, as a direct result of any claims, suits, actions, demands or judgments of Third Parties, including without limitation personal injury and product liability matters and claims of suppliers and ImmunoGen employees (collectively, “Claims”) arising out of (a) any action by ImmunoGen in the conduct of the activities under this Agreement, including but not limited to, the Research Program, activities under the Research Plan, the Development Plan, the Co-Development Plan, the Manufacturing Plan, the Co-Development Marketing and Sales Plan, the Co-Development Manufacturing Plan or the Co-Promotion of Co-Developed Products; (b) the Co-Development by ImmunoGen of any Co-Developed Product or (c) the Commercialization (including, without limitation, the production, manufacture, promotion, import, sale or use by any Person) of any Co-Developed Product that is manufactured or sold by ImmunoGen or by an Affiliate, Sublicensee, distributor or agent of ImmunoGen; provided that, with respect to any Claim for which ImmunoGen has an obligation to any Biotest Indemnitee pursuant to this Section 13.1 and Biotest has an obligation to any ImmunoGen Indemnitee pursuant to Section 13.2, each Party shall indemnify each of the other Party’s Indemnitees for its Losses to the extent of its responsibility for the facts underlying the Claim relative to the other Party.

13.2 **Indemnification of ImmunoGen by Biotest.** Biotest shall indemnify, defend and hold harmless ImmunoGen, its Affiliates, their respective directors, officers, employees and agents, and their respective successors, heirs and assigns (the “ImmunoGen Indemnitees”), against any and all Losses incurred by or imposed upon the ImmunoGen Indemnitees, or any one of them, as a direct result of any Claims arising out of (a) any action by Biotest in the conduct of the activities under this Agreement, including but not limited to, the Research Program, activities under the Research Plan, the Development Plan, the Co-Development Plan, the Manufacturing Plan, the Co-Development Marketing and Sales Plan or the Co-Promotion of Co-Developed Products; (b) the Development by Biotest of any Biotest Product and the Co-Development by Biotest of any Co-Developed Product or (c) the Commercialization (including, without limitation, the production, manufacture, promotion, import, sale or use by any Person) of any Biotest Product and Co-Developed Product that is manufactured or sold by Biotest or by an Affiliate, Sublicensee, distributor or agent of Biotest; provided that with respect to any Claim for which ImmunoGen has an obligation to any Biotest Indemnitee pursuant to Section 13.1 and Biotest has an obligation to any ImmunoGen Indemnitee pursuant to this Section 13.2, each Party shall indemnify each of the

other Party's Indemnitees for its Losses to the extent of its responsibility for the facts underlying the Claim relative to the other Party.

13.3 **Conditions to Indemnification.** A Person seeking recovery under this Section 13 (the "Indemnified Party") in respect of a Claim shall give prompt notice of such Claim to the Party from which recovery is sought (the "Indemnifying Party") and, provided that the Indemnifying Party is not contesting its obligation under this Section 13, shall permit the Indemnifying Party to control any litigation relating to such Claim and the disposition of such claim; provided that the Indemnifying Party shall (a) act reasonably and in good faith with respect to all matters relating to the settlement or disposition of such Claim as the settlement or disposition relates to Parties being indemnified under Section 13, (b) not settle or otherwise resolve such claim without the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed). The Indemnified Party shall cooperate with the Indemnifying Party in its defense of any such Claim in all reasonable respects and shall have the right to be present in person or through counsel at all legal proceedings with respect to such Claim.

13.4 **Warranty Disclaimer.** EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, (A) NEITHER PARTY MAKES ANY WARRANTY WITH RESPECT TO ANY TECHNOLOGY, GOODS, SERVICES, RIGHTS OR OTHER SUBJECT MATTER OF THIS AGREEMENT AND (B) EACH PARTY HEREBY DISCLAIMS ALL WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT.

13.5 **No Warranty of Success.** Nothing contained in this Agreement shall be construed as a warranty on the part of either Party that (a) the Research Program will yield any Licensed Product or will otherwise be successful, or (b) the outcome of the Research Program will be commercially exploitable in any respect.

13.6 **Limited Liability.** NOTWITHSTANDING ANYTHING TO THE CONTRARY IN THIS AGREEMENT, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY OR ANY OF ITS AFFILIATES FOR ANY SPECIAL, PUNITIVE, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING WITHOUT LIMITATION LOST PROFITS OR LOST REVENUES.

13.7 **Insurance.** Biotest and ImmunoGen shall use commercially reasonable efforts to maintain insurance, including product liability insurance, with respect to its activities hereunder. Such insurance shall be in such amounts and subject to such deductibles as the Parties may agree, based upon standards prevailing in the industry at the time.

## 14. **MISCELLANEOUS**

14.1 **Arbitration.** In the event of any dispute, difference or question arising between the Parties in connection with this Agreement, the construction thereof, or the rights, duties or liabilities of either Party hereunder (including, without limitation, any Disputed Matter that is submitted for arbitration as provided in Section 2.1.6 or any other provision hereof) (each, an

“Arbitration Matter”), the arbitration proceeding shall be conducted in accordance with the Rules of Arbitration of the ICC and otherwise as follows.

(a) The arbitration shall be conducted by a panel of three (3) persons experienced in the pharmaceutical business and/or in questions of law, in each case as applicable, who are independent of both Parties. Within thirty (30) days after initiation of arbitration, each Party shall select one person to act as arbitrator and the two Party-selected arbitrators shall select a third arbitrator within thirty (30) days of their appointment. If the arbitrators selected by the Parties are unable or fail to agree upon the third arbitrator, the third arbitrator shall be appointed by the ICC. The place of arbitration shall be London, United Kingdom of Great Britain and Northern Ireland, and all proceedings and communications shall be in English.

(b) Either Party may apply to the arbitrators for interim injunctive relief until the arbitration decision is rendered or the Arbitration Matter is otherwise resolved. Either Party also may, without waiving any right or remedy under this Agreement, seek from any court having jurisdiction any injunctive or provisional relief necessary to protect the rights or property of that Party pending resolution of the Arbitration Matter pursuant to this Section 14.1. The arbitrators shall have no authority to award punitive or any other type of damages not measured by a Party’s compensatory damages. Each Party shall bear its own costs and expenses and attorneys’ fees, and the Party that does not prevail in the arbitration proceeding shall pay the arbitrators’ fees and any administrative fees of arbitration.

(c) Except to the extent necessary to confirm an award or decision or as may be required by Applicable Laws, neither a Party nor an arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of both Parties. In no event shall an arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the Arbitration Matter would be barred by the applicable New York statute of limitations.

(d) The Parties agree that, in the event of an Arbitration Matter involving the alleged breach of this Agreement (including, without limitation, whether a Party has satisfied its diligence obligations hereunder), neither Party may terminate this Agreement until resolution of the Arbitration Matter pursuant to this Section 14.1.

(e) The Parties hereby agree that any disputed performance or suspended performance pending the resolution of an Arbitration Matter that the arbitrators determine to be required to be performed by a Party must be completed within a reasonable time period following the final decision of the arbitrators.

(f) The Parties hereby agree that any monetary payment to be made by a Party pursuant to a decision of the arbitrators shall be made in United States dollars, free of any tax or other deduction. The Parties further agree that the decision of the arbitrators shall be the sole, exclusive and binding remedy between them regarding determination of Arbitration Matters presented.

14.2 **Notices.** All notices and communications shall be in writing and delivered personally or by courier providing evidence of delivery or by facsimile, addressed as follows, or to such other address as may be designated from time to time:

If to Biotest:

Biotest AG  
Landsteinerstraße 5  
D-63303  
Dreieich, Germany  
Tel: +49(0)6103-801-225  
Fax: +49(0)6103-801-767  
Attention: CEO

If to ImmunoGen:

ImmunoGen, Inc.  
128 Sidney Street  
Cambridge MA 02139  
Tel: 617-995-2500  
Fax: 617-995-2510  
Attention: CEO

With a copy to:

Kaye Scholer (Germany) LLP  
Schillerstrasse 19  
D-60313 Frankfurt, Germany  
Attention: Dr. Gottfried W. Freier  
Tel: +49(0)69-25494-0  
Fax: +49(0)69-25494-444

With a copy to:

Mintz, Levin, Cohn, Ferris, Glovsky  
and Popeo, PC  
One Financial Center  
Boston, Massachusetts 02111  
Attention: John J. Cheney, Esq.  
Tel: +1 (617) 542-6000  
Fax: +1 (617) 542-2241

Except as otherwise expressly provided in this Agreement or mutually agreed in writing, any notice, communication or document (excluding payment) required to be given or made shall be deemed given or made and effective upon actual receipt or, if earlier, (a) one (1) business day after confirmation of receipt of facsimile or electronic mail by the Party; (b) three (3) business days after deposit with an internationally-recognized overnight express courier with charges prepaid, or (c) five (5) business days after mailed by certified, registered or regular mail, postage prepaid, in each case addressed to a Parties at its address stated above or to such other address as such Party may designate by written notice in accordance with this Section 14.2.

14.3 **Governing Law.** This Agreement shall be governed by and construed in accordance with the laws of the State of New York, without regard to the application of principles of conflicts of law.

14.4 **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.

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

14.6 **Counterparts.** This Agreement may be executed simultaneously in two or more counterparts, each of which shall be deemed an original and both of which, together, shall constitute a single agreement.

14.7 **Amendment; Waiver.** This Agreement may be amended, modified, superseded or canceled, and any of the terms of this Agreement 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.

14.8 **No Third Party Beneficiaries.** Except as set forth in Sections 13.1, and 13.2, no Third Party (including, without limitation, employees of either Party) shall have or acquire any rights by reason of this Agreement.

14.9 **Purposes and Scope.** The Parties hereto understand and agree that this Collaboration is limited to the activities, rights and obligations as set forth in this Agreement. Nothing in this Agreement shall be construed (a) to create or imply a general partnership between the Parties, (b) to make either Party the agent of the other for any purpose, (c) to alter, amend, supersede or vitiate any other arrangements between the Parties with respect to any subject matters not covered hereunder, (d) to give either Party the right to bind the other, (e) to create any duties or obligations between the Parties except as expressly set forth herein, or (f) to grant any direct or implied licenses or any other right other than as expressly set forth herein.

14.10 **Assignment and Successors.** Neither this Agreement nor any obligation of a Party hereunder may be assigned by either Party without the consent of the other which shall not be unreasonably withheld, except that each Party may assign this Agreement and the rights, obligations and interests of such Party, in whole or in part, to any of its Affiliates, to any purchaser of all of its assets and/or all of its assets to which this Agreement relates or to any successor corporation resulting from any merger or consolidation of such Party with or into such corporation.

14.11 **Force Majeure.** Neither Biotest nor ImmunoGen shall be liable for failure of or delay in performing obligations set forth in this Agreement, and neither shall be deemed in breach of its obligations, if such failure or delay is due to a Force Majeure. In event of such Force Majeure event, the Party affected thereby shall use reasonable efforts to cure or overcome the same and resume performance of its obligations hereunder.

14.12 **Interpretation.** The Parties hereto acknowledge and agree that: (a) each Party and its counsel reviewed and negotiated the terms and provisions of this Agreement and have contributed to its revision; (b) the rule of construction to the effect that any ambiguities are resolved against the drafting Party shall not be employed in the interpretation of this Agreement; and (c) the terms and provisions of this Agreement shall be construed fairly as to all Parties hereto and not in a favor of or against any Party, regardless of which Party was generally responsible for the preparation of this Agreement.

14.13 **Integration; Severability.** This Agreement and the Existing Agreements are the entire agreements with respect to the subject matter hereof and supersedes all other agreements and understandings between the Parties with respect to such subject matter. 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.

14.14 **Further Assurances.** Each of ImmunoGen and Biotest agrees to duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including, without limitation, the filing of such additional assignments, agreements, documents and instruments, as the other Party may at any time and from time to time reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes of, or to better assure and confirm unto such other Party its rights and remedies under, this Agreement.

**[Remainder of page intentionally left blank.]**

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

IMMUNOGEN, INC.

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

BIOTEST AG

By: \_\_\_\_\_  
Name: Dr. Martin Reinecke  
Title: VP, Strategic Alliances

By: \_\_\_\_\_  
Name: Prof. Dr. Gregor Schulz  
Title: Chief Executive Officer

**CALCULATION OF NET INCOME**

**“Advertising”** means the advertising and promotion of the Co-Developed Products in the Co-Development Territory through any means, including, without limitation, (i) television and radio advertisements; (ii) advertisements appearing in journals, newspapers, magazines or other media; (iii) seminars and conventions; (iv) packaging design; (v) professional education programs; (vi) samples (including related costs for manufacturing, shipping, and use taxes), visual aids and other selling materials; (vii) hospital formulary committee presentations; and (viii) presentations to state and other governmental formulary committees; provided, however, that Advertising shall exclude Detailing and General Public Relations. With regard to advertising and promotion that include Co-Developed Products, the JMC shall determine the percentage of such advertising and promotion that will be deemed Advertising for the purposes of this Agreement.

**“Annual Net Income”** means the Net Income derived in any Calendar Year.

**“Commercialization Expense”** means the sum of (a) promotion expense; (b) marketing expense; (c) any reasonable internal and Out-of-Pocket Costs, expenses and fees incurred in prosecuting, maintaining, enforcing and defending the Licensed Product Trademark, Licensed Patent Rights, Joint Patent Right, CD138 Conjugate Patent Rights and/or Biotest Patent Rights covering a Co-Developed Product; and (d) any other Out-of-Pocket Cost or expense expressly stated to be a Commercialization Expense in this Agreement or under the Co-Development Marketing and Sales Plan.

**“Cost of Goods”** means the fully absorbed manufacturing costs (**“FAMC”**) attributable to the manufacture of a Co-Developed Product calculated in accordance with GAAP or IAS (International Accounting Standards) and consistent with the Co-Development Marketing and Sales Plan and includes, without limitation, the costs of all Third Party manufacturing, direct material, direct labor, direct services costs, and manufacturing overhead consumed (including depreciation), provided or procured by manufacturing facilities in the manufacture of Co-Developed Product. Cost of Goods shall exclude Commercialization Expense.

**“Detail”** has the meaning provided in Section 1.

**“General Public Relations”** means any public relations activity (including a press release or image piece) which (i) promotes generally the business of a company or deals in a general manner with the activities of such company in a general pharmaceutical market; and (ii) mentions in an incidental manner the fact that such company or its Affiliates markets or sells one or more of the Co-Developed Products or provides other incidental information concerning one or more of the Co-Developed Products. Announcements related to this Agreement or that concern primarily the relationship of either Party to each other are not General Public Relations and must be agreed upon by both Parties in writing prior to release.

**“Licensed Product Trademark”** has the meaning provided in Section 1.

**“Net Income”** means, with respect to a Co-Developed Product, Net Sales minus the sum of (a) Cost of Goods of such Co-Developed Product sold and (b) Commercialization Expense

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**CONFIDENTIAL TREATMENT REQUESTED**

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applicable to the Co-Developed Product, in each case, incurred in that Calendar Quarter for that Co-Developed Product.

“**Net Sales**” has the meaning provided in Section 1.

“**Personnel Costs**” means the reasonable costs of employment of personnel employed by or under contract to a Party including, but not limited to, salaries, benefits (including the costs of cars or allowances therefore), travel, lodging, meals and office and computing supplies.

“**Representative**” means an individual (a) employed and trained by Biotest or ImmunoGen or (b) employed by a Third Party or self-employed and trained by or on behalf of Biotest or ImmunoGen, in either case, to Detail a Licensed Product.

“**Sales and Marketing Expense**” means all reasonable Out-of-Pocket Costs and all internal costs on an FTE rate basis (using an appropriate FTE rate determined by the JFC) annually for those individuals fully dedicated to the Co-Developed Product incurred by the Parties that are directly attributable to the following functions for the sale, promotion and marketing of a Co-Developed Product in the Co-Development Territory: (a) market research on such Co-Developed Product, (b) marketing, Advertising and promoting of Co-Developed Products (including, without limitation, educational expenses, advocate development programs and symposia, sales meetings, direct to consumer/patient advertising, samples, agency fees for the development of promotional materials and printing of promotional materials), (c) training and communication materials for the Co-Developed Products (d) corporate accounts (including without limitation administrative costs, expenses related to accounts receivable, expenses related to customer service, fees to banks or authorities, e.g. for legalization of documents), (e) managed care, (f) sales force training, (g) product hotlines, (h) reimbursement support, (i) contracting, (j) pricing, (k) conducting compassionate use programs and for domestic Phase IV studies for Co-Developed Products (including without limitation FAMC for any Co-Developed Product utilized in such compassionate use programs) and (k) telemarketing services. Marketing Expense shall not include any General Public Relations or any other activities that promote the business of a Party as a whole without specifically referencing any Co-Developed Product.

In calculating the Net Income the following principles shall apply:

1. There shall be no double counting of any costs or expenses or of any revenues, and to the extent a cost or expense has been included in one category or sub-category, it shall not be included in another; similarly, to the extent any revenue has been taken into account in one category or sub-category it shall not be taken into account in another.
2. When allocating costs and expenses under this Agreement, each Party shall utilize the same policies and principles as it utilizes consistently within its group and business units when making internal cost allocations.
3. To the extent an item of income or revenue is received by a Party or a cost or expense is incurred by a Party, and is necessary and specifically and directly identifiable, attributable and allocable to the Commercialization of Co-Developed Product and is not otherwise accounted for in the calculation of operating income, such Party shall credit such income or revenue and shall be permitted to charge such cost or expense to the operating income.
4. All costs and expenses shall be determined, and all calculations shall be made, in accordance with GAAP or IAS (International Accounting Standards).
5. Commercialization Expense shall not include any Personnel Costs.

Sched. 1-2

**CONFIDENTIAL TREATMENT REQUESTED**

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Portions of this Exhibit were omitted and have been filed separately with the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934.







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Portions of this Exhibit were omitted and have been filed separately with the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934.

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**MATERIAL TERMS TO BE INCLUDED  
IN SUPPLY AGREEMENT**

All Supply Agreements will include:

- Requirement for Biotest to provide ImmunoGen with a non-binding forecast of the quantity of Clinical Materials it reasonably expects to order over the succeeding twelve (12) month period.
- Requirement for Biotest to supply ImmunoGen with quantities of bulk Anti- CD138 Antibody sufficient and suitable to enable ImmunoGen to produce the quantity of Clinical Materials so requested.
- Systems for forecasting, ordering and delivering Clinical Materials.
- Specifications for Clinical Materials as are mutually agreed to by the Parties in the Supply Agreement.
- Requirement for ImmunoGen to produce Clinical Materials using, or in accordance and/or compliance with, such equipment, processes, procedures and standards, including current Good Manufacturing Practices (“cGMPs”), as are mutually agreed to by the Parties in the Supply Agreement.
- Requirement that all Clinical Materials be [\*\*\*] and [\*\*\*] by ImmunoGen in accordance with such [\*\*\*] [\*\*\*] and [\*\*\*] [\*\*\*] [\*\*\*] and [\*\*\*] as are mutually agreed to by the Parties in the Supply Agreement.
- [\*\*\*] by ImmunoGen that, at the time of delivery of any Clinical Materials, such Clinical Materials shall have been produced, conjugated, manufactured, stored, packaged, labeled, shipped and/or delivered in compliance with all applicable laws, regulations, rules and requirements, including, without limitation, cGMPs.
- Requirement that, ImmunoGen provide Biotest with a [\*\*\*] of [\*\*\*] in a form agreed to by the Parties indicating that the [\*\*\*] [\*\*\*] [\*\*\*] meets the specifications called for by the Supply Agreement.
- Supply prices in accordance with Section 4 of the Agreement.
- Provisions relating to authorized facilities, audit of facilities and records (including records relating to the Policy), and record retention requirements.
- Provisions concerning regulatory matters, including communications with regulatory authorities, compliance with laws and regulations, and assistance with regulatory submissions.
- Provision concerning fees for holding of Clinical Materials inventory at ImmunoGen.
- Other customary provisions, such as indemnification and insurance, force majeure, representations and warranties, and confidentiality.
- Biotest shall have the right to [\*\*\*] ImmunoGen’s [\*\*\*] [\*\*\*] applicable to the manufacture of Clinical Materials consistent with the [\*\*\*] [\*\*\*] described in Sections [\*\*\*], [\*\*\*] and [\*\*\*] of this Agreement.

**Portions of this Exhibit were omitted and have been filed separately with the Secretary of the Commission pursuant to the Company’s application requesting confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934.**

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**AMENDMENT NO. 1 TO COLLABORATIVE DEVELOPMENT  
AND LICENSE AGREEMENT**

This Amendment No. 1 (this "Amendment No. 1") to the Collaborative Development and License Agreement (this "Agreement") entered into as of July 7, 2006 (the "Agreement Effective Date") by and between ImmunoGen, Inc., a Massachusetts corporation with its principal place of business at 128 Sidney Street, Cambridge, Massachusetts, USA 02139 ("ImmunoGen") and Biotest AG, a corporation organized under the laws of Germany having an address of Landsteinerstraße 5, D-63303 Dreieich, Germany ("Biotest") is dated as of August 23, 2006 (the "Amendment Effective Date").

Capitalized terms used but not otherwise defined herein shall have the meanings ascribed to such terms in the Agreement.

WHEREAS, on the Agreement Effective Date, ImmunoGen and Biotest entered into the Agreement for the purpose of Developing and Commercializing Licensed Products derived from the conjugation of Biotest's proprietary CD138 Antibodies with ImmunoGen's maytansine derivatives; and

WHEREAS, the Parties hereto desire to amend the Agreement as set forth herein.

NOW, THEREFORE, in consideration of the mutual covenants contained herein, and for other good and valuable consideration, the Parties hereto, intending to be legally bound, hereby agree as follows:

1. The introduction of Section 6.4.1 of the Agreement and Sections 6.4.1(a) and 6.4.1(b) of the Agreement are hereby deleted in their entirety and replaced with the following:

1. **"6.4.1 Payment of Royalties.** Biotest shall pay ImmunoGen a royalty based on Annual Net Sales of each Royalty-Bearing Product commencing with the Calendar Year (or partial Calendar Year) in which the First Commercial Sale of such Royalty-Bearing Product occurs and ending upon expiration of the Royalty Term for such Royalty-Bearing Product, at the following rates; provided, that, for the purpose of clarity, to the extent a Royalty-Bearing Product is not covered by a Valid Claim in a country in the Territory, the Net Sales of such Royalty-Bearing Product in such country shall not be included in the calculation of Annual Net Sales used to determine the royalty rates in Sections 6.4.1(a) and 6.4.1(b) on and after [\*\*\*] ([\*\*\*)] years from the date of First Commercial Sale of such Royalty-Bearing Product in such country:

Portions of this Exhibit were omitted and have been filed separately with the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934.

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2. (a) Biotest Products

**Annual Net Sales of Biotest Products**

<b>Worldwide</b>	<b>Royalty Rate</b>
Up to \$[***]	[***]%
Equal to or greater than \$[***]	[***]%

3. (b) Co-Developed Products

4. (i) Early Stage Co-Developed Products

<b>Annual Net Sales Outside Co-Development Territory</b>	<b>Royalty Rate</b>
Up to \$[***]	[***]%
Equal to or greater than \$[***]	[***]%

5. (ii) Late Stage Co-Developed Products

<b>Annual Net Sales Outside Co-Development Territory</b>	<b>Royalty Rate</b>
Up to \$[***]	[***]%
Equal to or greater than \$[***]	[***]%"

2. The Parties hereby confirm and agree that, except as amended hereby, the Agreement remains in full force and effect and is a binding obligation of the Parties hereto. This Amendment No. 1 may be executed simultaneously in counterparts, each of which shall be deemed an original.

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

IMMUNOGEN, INC.

Biotest AG

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

By: \_\_\_\_\_  
Name: Dr. Martin Reinecke  
Title: VP, Strategic Alliances

By: \_\_\_\_\_  
Name: Prof. Dr. Gregor Schulz  
Title: Chief Executive Officer

Portions of this Exhibit were omitted and have been filed separately with the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934.

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## ImmunoGen, Inc.

## Compensation Policy for Non-Employee Directors

## Objective

It is the objective of ImmunoGen to compensate non-employee Directors in a manner which will enable recruitment and retention of highly qualified Directors and fairly compensate them for their services as a Director.

Cash Compensation (effective November 13, 2013)

Annual meeting fee for non-employee Directors:	\$40,000 per annum, paid quarterly
Additional annual fees:	
(a) Lead Director / Chairman of the Board: <sup>1</sup>	\$30,000 per annum, paid quarterly
(b) Chairman of the Audit Committee:	\$20,000 per annum, paid quarterly
(c) Chairman of the Compensation Committee:	\$14,000 per annum, paid quarterly
(d) Chairman of the G&N Committee:	\$14,000 per annum, paid quarterly
(e) Other members of the Audit Committee	\$10,000 per annum, paid quarterly
(f) Other members of the Compensation Committee	\$7,000 per annum, paid quarterly
(g) Other members of the G&N Committee	\$7,000 per annum, paid quarterly

Directors are entitled to be reimbursed for their reasonable expenses incurred in connection with attendance at Board and committee meetings during their tenure as a Director. Any reimbursement in one calendar year shall not affect the amount that may be reimbursed in any other calendar year and a reimbursement (or right thereto) may not be exchanged or liquidated for another benefit or payment. Any business expense reimbursements subject to Section 409A of the Internal Revenue Code of 1986 shall be made no later than the end of the calendar year following the calendar year in which such business expense is incurred by the Director.

Quarterly payments shall be paid in arrears within 30 days following the end of each calendar quarter.<sup>2</sup> A non-employee Director may elect to receive any or all of his or her cash compensation in the form of deferred stock units ("DSUs") having an aggregate Fair Market Value equal to the amount deferred, measured on the date of grant which shall be the last day of the calendar quarter for which the retainer is being paid. All elections as to form of payment shall be made annually by December 31<sup>st</sup> of the year prior to service which election shall be effective for all payments to be made in the following calendar year. New non-employee Directors shall make their elections within 30 days of their initial appointment or election to the Board of Directors for all payments to be made in that calendar year. Any such election shall be prospective only for compensation attributable to services performed after the effective date of

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<sup>1</sup> Payable to non-employee Chairman of the Board only.

<sup>2</sup> Quarterly payments will be appropriately pro-rated for Directors who retire, resign or are otherwise removed from the Board prior to the end of a calendar quarter.

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such election and any amounts covered by such election shall be prorated as necessary. Each non-employee Director shall be deemed to have elected to receive payments in cash for payments in periods prior to any such election or if no timely election shall have been made. Notwithstanding the foregoing, a previous election made by a non-employee Director pursuant to the 2004 Non-Employee Director Compensation Deferred Share Unit Plan or under this policy shall remain in effect for subsequent calendar years until it is changed by the completion, signature and delivery to the Company of a new election form, in accordance with the terms of this policy.

Upon making such election, DSUs shall be granted as described above without any further action by the Compensation Committee. These awards are fully vested as to all of the issued DSUs on the date of grant.

Equity Compensation (effective September 14, 2016)

1. Deferred Stock Units.

(a) Initial Grant. New non-employee Directors will automatically be granted, without any further action by the Compensation Committee, 6,500 DSUs (each DSU relating to one (1) share of Common Stock) on the date of their initial election or appointment to the Board. This award will vest pro rata, on a quarterly basis over a three-year period, as to eight and one-third percent (8-1/3%) of the issued DSUs (rounded down to the nearest whole share) per quarter with the first vesting date to be the date that is the first day of the third month following the month in which the date of grant occurs.

(b) First Anniversary Grant. On the first anniversary of a non-employee Director's initial election to the Board, such non-employee Director will automatically be granted, without any further action by the Compensation Committee, 3,000 DSUs on such first anniversary, pro-rated based on the number of whole months (the "Monthly Amount") remaining between the first day of the month in which such first anniversary date occurs and the first May 31 following the date of grant and rounded down to the nearest whole share). This award will vest on the same schedule as the Continuing Director Grants awarded pursuant to paragraph 1(c) below (provided that in all cases the last vesting date of a First Anniversary Grant shall be the first June 1 following the date of grant). The number of issued DSUs that shall vest on any particular date shall be equal to the number of months in each vesting period based on the Monthly Amount calculation.<sup>3</sup>

(c) Continuing Director Grants. After receiving a First Anniversary Grant under paragraph (b), non-employee Directors will automatically be granted, on an annual basis and without further action by the Compensation Committee, 3,000 DSUs on the earlier of the date of ImmunoGen's annual meeting of shareholders or June 20 of the applicable year. These awards will vest pro rata, on a quarterly basis over a one-year period, as to twenty-five percent (25%) of the issued DSUs (rounded down to the nearest whole share) per quarter on each of September 1, December 1, March 1 and June 1 following the date of grant. If a non-employee director receives a First Anniversary Grant under paragraph 1(b) above between June 1 and June 20 of

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<sup>3</sup> For example, if an award is granted on November 15, the amount of the award will be 7/12 of the full-year award (November through May) and such award will vest on December 1 as to 1/12 of the full-year award, March 1 as to 3/12 of the full-year award and June 1 as to 3/12 of the full-year award.

any year, then such non-employee Director will not be eligible to receive a Continuing Director Grant under this paragraph 1(c) for that year.<sup>4</sup>

(d) Terms of Grant. All DSU awards to non-employee Directors under this policy are granted under the 2006 Employee, Director and Consultant Equity Incentive Plan (the “2006 Plan”), and are subject to the terms and conditions set forth in the 2006 Plan and the form of Deferred Stock Unit Agreement approved by the Board of Directors on September 22, 2010; provided, however, that if the 2016 Employee, Director and Consultant Equity Incentive Plan (the “2016 Plan”) is approved by shareholders, all DSU awards to non-Employee Directors granted under this policy after December 9, 2016 will be granted under the 2016 Plan and will be subject to the terms and conditions set forth in the 2016 Plan and the form of Deferred Stock Unit Agreement approved by the Compensation Committee for such awards. All capitalized terms that are not defined herein shall have the meanings set forth in the 2006 Plan (or the 2016 Plan, as applicable).

2. Stock Options.

(a) Annual Stock Option Grants. Non-employee Directors will automatically be granted, on an annual basis and without further action by the Compensation Committee, stock option awards covering 10,000 shares of Common Stock on the earlier of the date of ImmunoGen’s annual meeting of shareholders or June 20 of the applicable year. These awards (i) will be granted with an exercise price equal to the Fair Market Value of the Common Stock on the date of grant, (ii) will vest pro rata, on a quarterly basis over a one-year period, as to twenty-five percent (25%) of the number of shares covered by such awards (rounded to the nearest whole share) per quarter on each of September 1, December 1, March 1 and June 1 following the date of grant, and (iii) will expire on the tenth (10<sup>th</sup>) anniversary of the date of grant. If a non-employee Director receives an Off-Cycle Initial Grant under paragraph (b) below between June 1 and June 20 of any year, then such non-employee Director will not be eligible to receive an Annual Stock Option Grant under this paragraph (a) for that year.<sup>5</sup>

(b) Off-Cycle Initial Grants. If a non-employee Director is first elected to the Board other than at an annual meeting of shareholders, such non-employee Director will automatically be granted, without further action by the Compensation Committee, a stock option award covering 10,000 shares of Common Stock, pro-rated based on the number of whole months (the “Monthly Amount”) remaining between the first day of the month in which such first election occurs and the first May 31 following the date of grant, which shall be the date of their initial election to the Board. This award (i) will be granted with an exercise price equal to the Fair Market Value of the Common Stock on the date of grant, and (ii) will vest on the same schedule as the Annual Stock Option Grants awarded pursuant to paragraph 2(a) above (provided that in all cases the last vesting date of an Off-Cycle Initial Grant shall be the first June 1 following the date of grant). The number of shares as to which an Off-Cycle Initial Grant will vest on any

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<sup>4</sup> Any Director who transitions from an employee director to a non-employee Director without a break in service shall not be eligible to receive an award of DSUs under paragraphs 1(a) or 1(b), but shall be eligible to receive awards under paragraph 1(c), beginning with the first annual meeting of shareholders on or after the date on which such Director ceases to be an employee of the Company.

<sup>5</sup> Any Director who transitions from an employee to a non-employee Director without a break in service shall not be eligible to receive a stock option award under paragraph 2(b), but shall be eligible to receive awards under paragraph 2(a), beginning with the first annual meeting of shareholders on or after the date on which such Director ceases to be an employee of the Company.

particular date shall be equal to the number of months in each vesting period based on the Monthly Amount calculation.<sup>6</sup> This award will expire on the tenth (10th) anniversary of the date of grant.

(c) Terms of Grant. All stock option awards to non-employee Directors under this policy are granted under the 2006 Plan, and are subject to the terms and conditions set forth in the 2006 Plan and the form of Director Option Agreement approved by the Compensation Committee on July 20, 2012. All capitalized terms that are not defined herein shall have the meanings set forth in the 2006 Plan; provided, however, that if the 2016 Plan is approved by shareholders, all stock option awards to non-Employee Directors granted under this policy after December 9, 2016 will be granted under the 2016 Plan and will be subject to the terms and conditions set forth in the 2016 Plan and the form of Director Option Agreement approved by the Compensation Committee for such awards.

3. 2016 Transition Period.

Anything contained in this policy to the contrary notwithstanding, DSU and stock option awards granted under this policy on December 9, 2016 in connection with the 2016 annual meeting of shareholders shall be as follows:

(a) DSUs. Non-employee Directors will automatically be granted, without further action by the Compensation Committee, 1,500 DSUs, which will vest as to fifty percent (50%) of the issued DSUs on each of March 1 and June 1, 2017. Such DSU award shall be granted under the 2006 Plan and will be subject to the terms and conditions set forth in the 2006 Plan and the form of Deferred Stock Unit Agreement approved by the Board of Directors on September 22, 2010.

(b) Stock Options. Non-employee Directors will automatically be granted, without further action by the Compensation Committee, stock option awards covering 5,000 shares of Common Stock. These awards (i) will be granted with an exercise price equal to the Fair Market Value of the Common Stock on the date of grant, (ii) will vest pro rata as to fifty percent (50%) of the number of shares covered by such awards on each of March 1 and June 1, 2017, (iii) will expire on the tenth (10<sup>th</sup>) anniversary of the date of grant, and (iv) will be subject to the terms and conditions set forth in the 2006 Plan and the form of Director Option Agreement approved by the Compensation Committee on July 20, 2012.

Approved by the Board of Directors: September 14, 2016

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<sup>6</sup> For example, if an award is granted on November 15, the amount of the award will be 7/12 of the full-year award (November through May) and such award will vest on December 1 as to 1/12 of the full-year award, March 1 as to 3/12 of the full-year award and June 1 as to 3/12 of the full-year award.

## CERTIFICATIONS

I, Mark Enyedy, certify that:

1. I have reviewed this quarterly report on Form 10-Q of ImmunoGen, Inc.;
2. Based on my knowledge, this 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 report;
3. Based on my knowledge, the financial statements, and other financial information included in this 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 report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted principles;
  - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 4, 2016

/s/ Mark J. Enyedy

Mark J. Enyedy  
President, Chief Executive Officer (Principal Executive  
Officer)

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## CERTIFICATIONS

I, David B. Johnston, certify that:

1. I have reviewed this quarterly report on Form 10-Q of ImmunoGen, Inc.;
2. Based on my knowledge, this 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 report;
3. Based on my knowledge, the financial statements, and other financial information included in this 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 report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted principles;
  - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 4, 2016

/s/ David B. Johnston

David B. Johnston  
Executive Vice President, Chief Financial Officer (Principal  
Financial and Accounting Officer)

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## Certification

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of ImmunoGen, Inc., a Massachusetts corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The Quarterly Report for the period ended September 30, 2016 (the "Form 10-Q") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 4, 2016

/s/MARK J. ENYEDY

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Mark J. Enyedy  
President, Chief Executive Officer  
(Principal Executive Officer)

Dated: November 4, 2016

/s/ DAVID B. JOHNSTON

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David B. Johnston  
Executive Vice President, Chief Financial Officer  
(Principal Financial and Accounting Officer)

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