## UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## **FORM 10-Q**

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

For the quarterly period ended December 31, 2003

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.)

128 Sidney Street, Cambridge, MA 02139

(Address of principal executive offices, including zip code)

(617) 995-2500

(Registrant's telephone number, including area code)

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

Yes 🛛 No o

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 under the Exchange Act).

Yes 🗵 No o

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 – 40,618,655 shares outstanding as of February 9, 2004

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## IMMUNOGEN, INC. CONSOLIDATED BALANCE SHEETS AS OF DECEMBER 31, 2003 AND JUNE 30, 2003

	 December 31, 2003 (Unaudited)		June 30, 2003
	(,		
ASSETS			
Cash and cash equivalents	\$ 9,533,422	\$	10,132,389
Marketable securities	91,141,269		91,140,757
Accounts receivable	706,360		674,458
Unbilled revenue	5,206,970		105,351
Inventory, net	6,910,264		5,620,713
Prepaid and other current assets, net	526,045		978,723
Total current assets	114,024,330		108,652,391
Property and equipment, net	9,698,865		9,045,847
Other assets	333,700		333,700
Total assets	\$ 124,056,895	\$	118,031,938
LIABILITIES AND STOCKHOLDERS' EQUITY			
Accounts payable	\$ 1,231,337	\$	148,888
Accrued compensation	1,155,953		392,201
Other current accrued liabilities	1,919,149		2,514,824
Current portion of deferred revenue	6,447,384		2,754,799
Total current liabilities	10,753,823		5,810,712
Deferred revenue	15,969,543		9,495,545
Other long term liabilities	74,268		46,551
Total liabilities	26,797,634		15,352,808
Stockholders' equity:			
Common stock, \$.01 par value; authorized 75,000,000 shares; issued and outstanding 44,291,326 shares and			
44,261,334 shares as of December 31, 2003 and June 30, 2003	442,913		442,613
Additional paid-in capital	317,149,342		317,035,931
Treasury stock	(11,071,417)		(11,071,417)
Accumulated deficit	(209,317,777)		(203,858,754)
Accumulated other comprehensive income	56,200		130,757
Total stockholders' equity	97,259,261		102,679,130
Total liabilities and stockholders' equity	\$ 124,056,895	\$	118,031,938

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

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### IMMUNOGEN, INC. CONSOLIDATED STATEMENTS OF OPERATIONS FOR THE THREE AND SIX MONTHS ENDED DECEMBER 31, 2003 AND 2002 (UNAUDITED)

	Three Months Ended December 31,			Six Mont Decem		
	 2003	2002		2003		2002
Revenues:						
Research and development support	\$ 3,886,386	\$ —	\$	5,094,067	\$	_
License fees and milestone payments	1,050,507	1,479,685		1,696,833		2,959,356
Clinical materials reimbursement	226,827	947,896		2,175,527		1,774,165
Development fees	_	48,578		87,476		88,948
Total revenues	5,163,720	2,476,159		9,053,903		4,822,469

Expenses:				
Cost of clinical materials reimbursed	226,826	843,168	1,985,635	1,595,564
Research and development	5,194,770	6,566,748	9,966,137	10,676,099
General and administrative	1,412,206	1,296,974	3,246,429	 3,039,348
Total expenses	6,833,802	8,706,890	15,198,201	 15,311,011
Loss from operations	(1,670,082)	(6,230,731)	(6,144,298)	(10,488,542)
Interest income, net	353,305	740,814	732,677	1,633,221
Net realized (losses) gains on investments	(35,542)	217,569	(57,415)	371,019
Other income	 30,000		 30,593	 12,692
Loss before income tax expense	(1,322,319)	(5,272,348)	(5,438,443)	(8,471,610)
Income tax expense	 10,290	12,850	 20,580	 35,125
Net loss	\$ (1,332,609)	\$ (5,285,198)	\$ (5,459,023)	\$ (8,506,735)
Basic and diluted net loss per common share	\$ (0.03)	\$ (0.12)	\$ (0.13)	\$ (0.20)
Basic and diluted weighted average common shares outstanding	40,597,674	42,773,645	 40,593,343	 42,413,951

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

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## IMMUNOGEN, INC. CONSOLIDATED STATEMENTS OF CASH FLOWS FOR THE SIX MONTHS ENDED DECEMBER 31, 2003 AND 2002 (UNAUDITED)

		Six Months Ended December		
		2003		2002
Cash flows from operating activities:				
Net loss	\$	(5,459,023)	\$	(8,506,735
Adjustments to reconcile net loss to net cash provided by (used for) operating activities:	Ψ	(3,433,023)	Ψ	(0,500,755
Depreciation and amortization		551,537		587,433
Loss (gain) on sale of marketable securities		57,415		(371,019
Compensation for stock options, stock and stock units		42,711		23,989
Changes in operating assets and liabilities:		42,711		20,000
Accounts receivable		(31,902)		801,342
Unbilled revenue		(5,101,619)		(39,917
Inventory		(1,289,551)		(1,487,647
Prepaid and other current assets		452,678		793,347
Other assets		452,070		(290,000
Accounts payable		1,082,449		455,958
Accrued compensation		763,752		(1,252,177
Other current accrued liabilities		(595,675)		2,399,820
Deferred revenue		10,166,583		(1,116,324
Net cash provided by (used for) operating activities		639,355		(8,001,930
iver cash provided by (used for) operating activities		055,555		(0,001,950
Cash flows from investing activities:				
Proceeds from maturities or sales of marketable securities		163,446,911		163,155,248
Purchases of marketable securities		(163,579,395)		(153,188,009
Capital expenditures		(1,204,555)		(2,100,351
Deposit on construction in progress				(813,444
Net cash (used for) provided by investing activities		(1,337,039)		7,053,444
Cash flows from financing activities:				
Repurchases of common stock				(6,301,681
Proceeds from stock options exercised		98,717		1,970
Net cash provided by (used for) financing activities		98,717		(6,299,711
The cash provided by (abed for) manening deavides		50,717		(0,200,711
Net change in cash and cash equivalents		(598,967)		(7,248,197
Cash and cash equivalents, beginning balance		10,132,389		16,233,408
Cash and cash equivalents, ending balance	\$	9,533,422	\$	8,985,211
Supplemental disclosure:				
Cash paid for income taxes	\$		\$	38,100
Cash part for meane taxes	Ψ		¥	50,100

Non cash activities:		
Capital expenditures included in accounts payable	\$ \$	128,594
Repurchases of common stock included in other accrued liabilities	\$ — \$	357,386

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

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### IMMUNOGEN, INC. NOTES TO CONSOLIDATED FINANCIAL STATEMENTS DECEMBER 31, 2003

### A. Summary of Significant Accounting Policies

#### Basis of Presentation

The accompanying consolidated financial statements at December 31, 2003 and June 30, 2003 and for the three and six months ended December 31, 2003 and 2002 include the accounts of the Company and its subsidiaries, ImmunoGen Securities Corp. and Apoptosis Technology, Inc. (ATI). Although the consolidated financial statements are unaudited, they include all of the adjustments, consisting only of normal recurring adjustments, which management considers necessary for a fair presentation of the Company's financial position in accordance with accounting principles generally accepted in the United States for interim financial information. Certain information and footnote disclosures normally included in the Company's annual financial statements have been condensed or omitted. The preparation of interim financial statements requires the use of management's estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the interim financial statements and the reported amounts of revenues and expenditures during the reported period. The results of the interim periods are not necessarily indicative of the results for the entire year. Accordingly, the interim financial statements should be read in conjunction with the audited financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended June 30, 2003.

### Revenue Recognition

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

At December 31, 2003, the Company has the following four types of collaborative contracts with the counterparties identified below:

Shared product license - the Company retains commercial rights worldwide excluding the European Union and Japan:

Vernalis plc (formerly British Biotech plc)

As discussed further in Note D, in January 2004, the Company announced that it had regained the rights to develop and commercialize huN901-DM1. Pursuant to the terms and conditions of the agreement between Vernalis and the Company, Vernalis has given written notice to the Company that it will relinquish its rights to develop and commercialize this product under the shared product license.

License to a single target antigen (single target license):

Genentech, Inc.

Boehringer Ingelheim International GmbH

Millennium Pharmaceuticals, Inc.

• Broad option agreements to acquire a specific number of licenses over a specified time period (broad license):

Genentech, Inc.

Abgenix, Inc.

Millennium Pharmaceuticals, Inc.

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Broad agreement to discover, develop and commercialize antibody-based anticancer products:

### Aventis Pharmaceuticals, Inc.

Excluding the shared product license agreement and the agreement with Aventis, all of these collaboration agreements provide that the Company will (i) manufacture preclinical and clinical materials for its collaborators, at the collaborator's request and cost, (ii) receive payments upon the collaborators' achievements of certain milestones and (iii) receive royalty payments, generally until the later of the last applicable patent expiration or 12 years after product launch. The Company is required to provide technical training and any process improvements and know-how to its collaborators during the term of the collaborator agreements. Practically, once a collaborator receives U. S. Food and Drug Administration (FDA) approval for any drug and the manufacturing process used to produce the drug, the collaborator will not be able to incorporate any process improvements or know-how into its manufacturing process

without additional testing and review by the FDA. Accordingly, the Company believes that it is very unlikely that its collaborators will require the Company's services subsequent to FDA approval.

Generally, upfront payments on single target licenses are deferred over the period of the Company's substantial involvement during development. ImmunoGen employees are available to assist the Company's collaborators during the development of their products. The Company estimates this development phase to begin at the inception of the contract and conclude when the product receives FDA approval. The Company believes this period of involvement is, on average, six years. At each reporting period, the Company analyzes individual product facts and circumstances and reviews the estimated period of its substantial involvement to determine whether a significant change in its estimates has occurred and adjusts the deferral period accordingly to reflect any such change. In the event that a single target license were terminated, the Company would recognize as revenue any portion of the upfront fee that had not previously been recorded as revenue, but was classified as deferred revenue at the date of such termination.

The Company defers upfront payments received from its broad option agreements over the period during which the collaborator may elect to receive a license. These periods are specific to each collaboration agreement, but are between seven and 12 years. If a collaborator selects an option to acquire a license under these agreements, any option fee is deferred and recorded over the life of the option, generally 12 to 18 months. If a collaborator exercises an option and the Company grants a single target license to the collaborator, the Company defers the license fee and accounts for the fee as it would an upfront payment on a single target collaboration agreement, as discussed above. In the event that a broad option agreement were terminated, the Company would recognize as revenue any portion of the upfront fee that had not previously been recorded as revenue, but was classified as deferred revenue at the date of such termination.

The Company's shared product license collaboration with Vernalis, the entity created by the merger of British Biotech and Vernalis, provides for an upfront payment to ImmunoGen that was paid upon signing of the agreement. The agreement also stipulates that upon FDA approval, ImmunoGen will pay Vernalis, as successor in interest to British Biotech, a milestone payment. The Company deferred the upfront payment and anticipated recognizing such revenue concurrent with the milestone payment that the Company would have been required to pay to Vernalis if and when the product received such FDA approval. As discussed further in Note D, pursuant to the terms and conditions of the agreement between Vernalis and the Company, in January 2004, Vernalis gave written notice to the Company that it will relinquish its rights to develop and commercialize huN901-DM1, the product subject to the shared product license. As a result, in the quarter ending March 31, 2004, the Company will recognize as revenue the \$1.5 million upfront fee that was paid to the Company upon signing of the agreement.

The Company's discovery, development and commercialization agreement with Aventis provides for an upfront payment of \$12.0 million that Aventis paid to ImmunoGen in August 2003. The Company deferred the upfront payment and will record it ratably over the period of the Company's substantial involvement. The Company estimates this period to be five years, which includes the term of the collaborative research program in addition to two 12-month extensions that Aventis may exercise. The discovery, development and commercialization agreement also provides that ImmunoGen will (i) receive committed research funding over a three-year period; (ii) manufacture preclinical and clinical materials for Aventis, at Aventis' request and cost; (iii) receive payments upon the collaboration's and/or Aventis' achievements of certain milestones; and (iv) receive royalty payments until the last applicable patent expiration or 12 years after product launch. The committed funding is based upon resources that ImmunoGen is required to contribute to the collaboration. The Company records the research funding as it is earned based upon its actual resources utilized in the collaboration.

When milestone payments are specifically tied to a separate earnings process, revenue is recognized when the milestone is achieved. In addition, when appropriate, the Company recognizes revenue from certain research payments based upon the level of research services performed during the period of the research contract. Deferred revenue represents amounts received under

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collaborative agreements and not yet earned pursuant to these policies. Where the Company has no continuing involvement, the Company will record non-refundable license fees as revenue upon receipt and will record milestone revenue upon achievement of the milestone by the collaborative partner.

The Company may produce preclinical and clinical materials for its collaborators and, at the collaborators' request, may perform process development work. The Company also produces preclinical material for potential collaborators under material transfer agreements. Generally, the Company is reimbursed for its fully burdened cost of producing these materials or providing these services. The Company recognizes revenue on preclinical and clinical materials when it has shipped the materials, the materials have passed all quality testing required for collaborator acceptance and title has transferred to the collaborator. The Company recognizes revenue on process development services as those services are performed.

## Marketable Securities

In accordance with the Company's investment policy, surplus cash is invested in investment-grade corporate and U.S. Government debt securities, assetbacked and United States government agency securities, banknotes and commercial paper, typically with maturity dates of less than two years. The Company designates its marketable securities as available-for-sale securities. The Company classifies all such securities as current assets since the Company has the ability to use such securities to satisfy current liabilities. Marketable securities are carried at their fair value with unrealized gains and losses included in Accumulated Other Comprehensive Income. Realized gains and losses and declines in value judged to be other than temporary, if any, on available-for-sale securities are reported as realized gains or losses on investments. In determining realized gains or losses on the sale of marketable securities, the cost of securities sold is based on the specific identification method.

#### Unbilled Revenue

The Company's Unbilled Revenue at December 31, 2003, primarily represents committed research funding earned based on actual resources utilized under the Company's discovery, development and commercialization agreement with Aventis. As of June 30, 2003, the majority of the Company's Unbilled Revenue represents clinical materials that have passed quality testing, that the Company has shipped and title has transferred to the collaborator, but the Company has not yet invoiced. Also included in Unbilled Revenue are costs the Company has incurred in completing development work on behalf of its collaborators but has not yet invoiced.

#### Inventory

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

Inventory at December 31, 2003 and June 30, 2003 is summarized below:

	D	ecember 31, 2003	June 30, 2003		
Raw materials, net	\$	3,472,059	\$	3,299,536	
Work in process		3,214,453		1,870,598	
Finished goods, net		223,752		450,579	
Total	\$	6,910,264	\$	5,620,713	

Included in inventory is a valuation allowance of \$1.7 million and \$1.2 million as of December 31, 2003 and June 30, 2003, respectively. The valuation allowance represents the cost of DM1 that the Company considers to be excess based on current collaborator firm fixed orders and projections and the cost of huN901-DM1 conjugate produced for Vernalis that the Company is required to pay pursuant to the terms of the amended license agreement.

DM1, the Company's most advanced small molecule effector drug, is the cytotoxic agent used in all of its current TAP product candidates and the subject of most of its collaborations. One of the primary components required to manufacture DM1 is its precursor, ansamitocin P3. Once manufactured, the ansamitocin P3 is then converted to DM1.

In fiscal 2002, the Company entered into several agreements with two outside vendors to perform large-scale manufacture of DM1 and ansamitocin P3. Under the terms of these agreements, the manufacturers, together with the Company, will

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improve the fermentation and conversion processes used to generate ansamitocin P3 and DM1, respectively. Pursuant to these agreements, the two outside vendors will also manufacture, under current Good Manufacturing Processes, large-scale batches of ansamitocin P3 and DM1 to be used in the manufacture of both the Company's and its collaborators' products. Once manufactured, the ansamitocin P3 is delivered from one vendor to the other vendor for conversion to DM1.

The actual amount of ansamitocin P3 and DM1 that will be produced is highly uncertain. The Company currently anticipates that a significant amount of ansamitocin P3 and DM1 will be manufactured for the Company over the next two to four years at these manufacturers. If the Company's and the manufacturers' process development efforts are successful, the amount of ansamitocin P3 and/or DM1 produced could be higher than expected. The Company anticipates that its investment in ansamitocin P3 and DM1 will be significant.

The Company produces preclinical and clinical materials for its collaborators either in anticipation of or in support of clinical trials or for process development and analytical purposes. Under the terms of supply agreements with two of its collaborators, the Company generally receives rolling six-month firm fixed orders for conjugate that the Company is required to manufacture and rolling 12-month manufacturing projections for the quantity of conjugate the collaborator expects to need in any given 12-month period. The Company's other collaborative agreements do not require that the collaborators provide firm fixed manufacturing orders, although the collaborators provide the Company with their projected conjugate requirements. The amount of clinical material produced is directly related to the number of on-going clinical trials for which the Company is producing clinical material for its collaborators, the speed of enrollment in those trials and the dosage schedule of each clinical trial. As a result, the actual amount of conjugate that the Company manufactures can differ significantly from the collaborators' projections. To the extent that a collaborator has provided the Company with a firm fixed order, the collaborator is contractually required to reimburse the Company the full cost of the conjugate, and any margin thereon, even if the collaborator subsequently cancels the manufacturing run.

The Company accounts for the DM1 and ansamitocin P3 inventory as follows:

- a) That portion of the DM1 and/or ansamitocin P3 that the Company intends to use in the production of its own products is expensed as incurred;
- b) To the extent that the Company has firm fixed orders or collaborator projections for no more than 12 months, the Company capitalizes the value of DM1 and ansamitocin P3 that will be used in the production of conjugate subject to these firm fixed orders and/or projections;
- c) The Company considers more than a 12-month supply of ansamitocin P3 and/or DM1 that is not supported by collaborators' firm fixed orders to be excess. The Company establishes a reserve to record any such excess ansamitocin P3 or DM1 inventory at its net realizable value or expenses as received any such excess ansamitocin P3 or DM1 product received in any period; and
- d) The Company considers any other external factors and information of which it becomes aware and assesses the impact of such factors or information on the net realizable value of the DM1 and ansamitocin P3 inventory at each reporting period.

At December 31, 2003, the Company's on-hand supply of DM1 and ansamitocin P3, including \$3.5 million of DM1 received from the DM1 manufacturer and \$1.5 million of ansamitocin P3 held at its third party manufacturers, represented more than a 12-month supply based upon current collaborator firm fixed orders and projections. In the six month period ended December 31, 2003, the Company recorded as research and development expense \$20,000 of amounts paid or payable to the manufacturers of ansamitocin P3 and DM1 to produce material that the Company has identified as excess based upon the Company's inventory policy as described above. Any changes to the Company's collaborators' projections could result in significant changes in the Company's estimate of the net realizable value of DM1 and ansamitocin P3 inventory. Reductions in collaborators' projections could indicate that the Company has additional excess DM1 and/or ansamitocin P3 inventory and the Company would then evaluate the need to record further valuation allowances, included as charges to research and development, to record the DM1 and/or ansamitocin P3 inventory at its estimated net realizable value.

In April 2003, one of the Company's collaborators informed ImmunoGen that the collaborator may explore alternative sources of ansamitocin P3 and/or DM1. In applying its inventory policy, the Company has included this collaborator's firm fixed orders and 12-month order projections in the determination of the Company's 12-month supply of ansamitocin P3 and DM1. At December 31, 2003, the Company believes that approximately \$424,000 of its ansamitocin P3 and/or DM1 inventory will be used to produce conjugate for this collaborator. If the collaborator finds and elects to use an alternative source of ansamitocin P3 and/or DM1, the Company will evaluate its inventory and, if necessary, will record an inventory valuation allowance to reduce to its net realizable value any ansamitocin P3 or DM1 inventory identified as excess. The Company is unable to determine when, if ever, the collaborator would be able to secure an alternative source of ansamitocin P3 and/or DM1.

#### Computation of Net Loss Per Common Share

Basic and diluted net loss per common share is calculated based upon the weighted average number of common shares outstanding during the period. Diluted net loss per common share incorporates the dilutive effect of stock options, warrants and other convertible securities. The total number of options, warrants and other securities convertible into ImmunoGen Common Stock and ImmunoGen Common Stock equivalents, as calculated in accordance with the treasury-stock accounting method, are included in the following table:

	Three Mont Decemb		Six Month Decemb	
	2003	2002	2003	2002
Options, warrants and other securities convertible into Common Stock	5,185,211	5,073,914	5,185,211	5,073,914
Common Stock equivalents	1,520,802	969,504	1,460,556	896,211

ImmunoGen Common Stock equivalents have not been included in the net loss per common share calculations for the three and six months ended December 31, 2003 and 2002 because their effect is anti-dilutive.

#### Comprehensive Loss

The Company presents comprehensive loss in accordance with Statement of Financial Accounting Standards (SFAS) No. 130, "Reporting Comprehensive Income." For the three and six months ended December 31, 2003, total comprehensive loss equaled \$1.3 million and \$5.5 million, respectively. For the three and six months ended December 31, 2002, total comprehensive loss equaled \$5.6 million and \$8.6 million, respectively. Comprehensive loss was comprised entirely of the change in unrealized gains and losses recognized on available-for-sale marketable securities.

#### Stock-Based Compensation

In accounting for its stock-based compensation plans, the Company applies Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" (APB 25), and related interpretations for all awards granted to employees. Had compensation costs for the Company's stock based employee compensation been determined based on the fair value at the grant dates as calculated in accordance with SFAS No. 123, "Accounting for Stock Based Compensation" (SFAS 123), the Company's basic and diluted net loss per common share for the three and six months ended December 31, 2003 and 2002 would have been adjusted to the pro forma amounts indicated below:

	Three Months Ended December 31,			Six Months Ended De				
		2003		2002		2003		2002
Net loss, as reported	\$	(1,332,609)	\$	(5,285,198)	\$	(5,459,023)	\$	(8,506,735)
Add: Total stock-based compensation expense determined under the intrinsic value method for all employee awards		3,250				6,714		_
Deduct: Total stock-based compensation expense determined under the fair value method for all employee awards		(1,617,623)		(1,684,582)		(3,233,140)		(3,365,356)
Pro forma net loss	\$	(2,946,982)	\$	(6,969,780)	\$	(8,685,449)	\$	(11,872,091)
Basic and diluted net loss per common share, as reported	\$	(0.03)	\$	(0.12)	\$	(0.13)	\$	(0.20)
Basic and diluted net loss per common share, pro forma	\$	(0.07)	\$	(0.16)	\$	(0.21)	\$	(0.28)
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The fair value of each stock option is estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions:

	Three Months Ended	December 31,	Six Months Ended December 31,			
	2003	2002	2003	2002		
Dividend	None	None	None	None		
Volatility	94.72%	98.15%	94.72%	98.15%		
Risk-free interest rate	3.35%	2.92%	3.30%	3.11%		
Expected life (years)	5.5	5.5	5.5	5.5		

Using the Black-Scholes option-pricing model, the weighted average fair value of options granted during the three months ended December 31, 2003 and 2002 were \$3.62 and \$2.30, respectively, and \$3.58 and \$2.26 during the six months ended December 31, 2003 and 2002, respectively.

The Black-Scholes option-pricing model was developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable. In addition, option-pricing models, including the Black-Scholes model, require the use of highly subjective assumptions, such as the expected stock price volatility. Because the Company's employee stock options have characteristics significantly different from those of traded options, and because changes in the subjective assumptions can materially affect the fair value estimates, in management's opinion, the Black-Scholes and other existing models do not necessarily provide a reliable single measure of the fair value of its employee stock-based compensation.

#### **Recent Accounting Pronouncements**

In November 2002, the FASB issued Emerging Issues Task Force (EITF) Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables." EITF Issue No. 00-21 addresses certain aspects of the accounting by a company for arrangements under which it will perform multiple revenue-generating

activities. EITF Issue No. 00-21 addresses when and how an arrangement involving multiple deliverables should be divided into separate units of accounting. The provisions of EITF Issue No. 00-21 will apply to revenue arrangements entered into after June 30, 2003. The provisions of the EITF Issue No. 00-21 do not impact the accounting treatment of the Company's existing revenue arrangements. The Company's adoption of EITF Issue No. 00-21 did not result in a material change to its existing revenue recognition policy for revenue arrangements entered into on or after July 1, 2003. The Company's adoption of EITF Issue No. 00-21 did not have a material impact on its consolidated financial statements.

In May 2003, the FASB issued Statement of Financial Accounting Standards No. 150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity" ("SFAS 150"). SFAS 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity and it requires that an issuer classify a financial instrument that is within its scope as a liability. The Company adopted SFAS 150 in the quarter ended September 30, 2003. The Company's adoption of SFAS 150 did not have a material impact on its financial position or results of operations.

#### Reclassifications

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

#### B. Agreements

In July 2003, the Company and Aventis Pharmaceuticals, Inc. entered into a broad collaboration agreement to discover, develop and commercialize anticancer therapeutics. The agreement provides Aventis with worldwide commercialization rights to new product candidates created through the collaboration as well as worldwide commercialization rights to three product candidates in ImmunoGen's pipeline: a TAP compound for acute myeloid leukemia, anti-IGF-IR antibody and a product candidate for certain B-cell malignancies. The overall term of the agreement extends to the later of the latest patent to expire or 12 years after the latest launch of any product discovered, developed and/or commercialized under the agreement. The agreement provides that ImmunoGen will receive a minimum of \$50.7 million of committed research funding during a three-year

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research program. Aventis has the option, with 12 months' advance notice, to request that ImmunoGen extend the research program for two additional 12month periods. If Aventis requests an extension of the research program for one or both periods, the Company and Aventis will negotiate the research funding level for each such extension period at the time such extension is requested. If Aventis and ImmunoGen were to agree to extend the agreement for each of the two 12-month periods and the research funding continued at the same level as in the final year of the original term of the agreement, ImmunoGen would receive an additional \$36.4 million of research funding. Aventis paid to ImmunoGen an upfront fee of \$12.0 million in August 2003. The Company has deferred the upfront fee and is recognizing it as revenue over the period of ImmunoGen's substantial involvement. The Company estimates this period to be five years, which includes the term of the collaborative research program in addition to two 12-month extensions that Aventis may exercise. The collaboration agreement also provides for certain other payments based on the achievement of product candidate milestones and royalties on sales of any resulting products, if and when such sales commence. Assuming all benchmarks are met, the Company will receive milestone payments of between \$21.5 million and \$30.0 million per antigen target.

The agreement provides ImmunoGen an option for certain co-promotion rights in the United States on a product-by-product basis. Aventis will be responsible for product development, manufacturing, and commercialization, and will cover all associated costs for any products created through the collaboration. ImmunoGen will be reimbursed for any preclinical and clinical materials that it makes under the agreement.

The terms of the Company's collaboration agreement with Aventis place certain restrictions upon ImmunoGen. Subject to the Company's obligations under its other collaboration agreements that were in effect at the time the Company signed the collaboration agreement with Aventis, (i) ImmunoGen may only enter into a specified number of additional single target TAP collaboration agreements and (ii) during the term of the collaborative research program and for a specified period thereafter, ImmunoGen is prohibited from entering into any single target license, other than with Aventis, utilizing the Company's TAP technology to bind any taxane effector molecule to any antibody. Additionally, the terms of the collaboration agreement allow Aventis to elect to terminate ImmunoGen's participation in the research program and/or the Company's co-promotion rights upon a change of control of ImmunoGen.

## C. Capital Stock

On August 27, 2002, the Company announced that, effective immediately, its Board of Directors had authorized the repurchase of up to 4.1 million shares of the Company's common stock. The repurchases are to be made at the discretion of management and as market conditions warrant. No time limit was set for the completion of the repurchase program. As of December 31, 2003, the Company had repurchased 3,675,062 shares of its common stock at a total cost of \$11.1 million.

Under the Company's 2001 Non-Employee Director Stock Plan, approved in November 2001, the Company recorded \$36,000 in compensation expense related to the issuance of 3,805 stock units and 3,804 shares of stock for directors' services rendered during the six months ended December 31, 2003.

During the six months ended December 31, 2003, holders of options issued under the Company's Restated Stock Option Plan exercised their rights to acquire an aggregate of 25,279 shares of common stock at prices ranging from \$2.53 to \$3.95 per share. The total proceeds from these option exercises, \$98,717, will be used to fund current operations.

### D. Subsequent Event

In July 2003, British Biotech announced its proposed acquisition of Vernalis. In late August 2003, the acquisition was declared unconditional in all respects after a significant majority of Vernalis' shareholders accepted British Biotech's tender offer. In connection with the acquisition, the merged company announced that it intended to review its merged product candidate portfolio. On October 1, 2003, the entity created by the merger of British Biotech and Vernalis, which is now called Vernalis plc, held its Annual General Meeting. At its Annual General Meeting, and in the press release issued in connection therewith, Vernalis announced that it had completed its product candidate portfolio review, and that, as a result of the review, it intended to discuss certain of its collaborations with its partners, including its collaboration with ImmunoGen on huN901-DM1. After discussion with Vernalis, in January 2004, the Company announced that ImmunoGen will take over future development of the product, which will include advancement of huN901-DM1 into a clinical trial managed by ImmunoGen. Pursuant to the terms of the termination agreement dated January 7, 2004, Vernalis, which has agreed to relinquish its right to the product, will, at its own expense, complete the UK Phase I clinical study currently underway and will continue the US Phase I/II clinical study until June 30,

2004. In connection with the termination of Vernalis' shared product license, ImmunoGen will record as revenue in the quarter ending March 31, 2004 the \$1.5 million upfront fee it received and deferred for accounting purposes when the original agreement was signed.

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

### **OVERVIEW**

Since the Company's inception, we have been principally engaged in the development of antibody-based cancer therapeutics and novel treatments in the field of oncology. The combination of our expertise in antibodies and cancer has resulted in the generation of proprietary products and technologies. Our proprietary, tumor-activated prodrug, or TAP, technology combines extremely potent, small-molecule drugs with monoclonal antibodies that recognize and bind specifically to tumor cells. Our targeted delivery technology increases the potency of these cancer-specific antibodies, which allows our drugs to kill cancer cells with minimal harm to healthy tissue. The cytotoxic agent we currently use in all of our TAP products is the maytansinoid DM1, a chemical derivative of a naturally occurring substance called maytansine. We also use our expertise in antibodies and cancer to develop other types of therapeutics, such as naked antibody anticancer products.

We have entered into collaborative agreements that allow companies to use our TAP technology to develop commercial products containing their antibodies. We have also used our proprietary TAP technology in conjunction with our in-house antibody expertise to develop our own anticancer products. In July 2003, we announced a discovery, development and commercialization collaboration with Aventis Pharmaceuticals, Inc. Under the terms of the agreement, Aventis gains commercialization rights to three of the most advanced products in our preclinical pipeline and commercialization rights to certain new products developed during the research program portion of the collaboration. This collaboration allows us to access Aventis' cancer targets and their clinical development and commercialization capabilities. The terms of our other collaborative agreements vary, reflecting the value we add to the development of any particular product candidate; however, the agreements generally provide that we receive upfront and milestone payments, royalties on sales of any resulting products and reimbursement of our fully burdened cost to manufacture preclinical and clinical materials. Under certain agreements, we receive our fully burdened cost to manufacture preclinical and clinical materials plus a profit margin. Under the terms of the Aventis agreement, we also are entitled to receive committed research funding of approximately \$50.7 million during the three-year term of the research program. Should Aventis elect to exercise its contractual right to extend the term of the research program, we will receive additional research funding. Currently, our collaborative partners include Abgenix, Inc., Aventis, Boehringer Ingelheim International GmbH, Genentech, Inc., and Millennium Pharmaceuticals, Inc. We expect that substantially all of our revenue for the foreseeable future will result from payments under our collaborative arrangements.

In January 2004, we announced that pursuant to the terms and conditions of the agreement between Vernalis and ourselves, Vernalis relinquished its rights to develop and commercialize huN901-DM1 under the shared product license. As a result, we have regained the rights to develop and commercialize huN901-DM1, thereby terminating the shared product license, and will take over future development of the product. Vernalis will complete the Phase I clinical study currently underway in the United Kingdom and will continue the Phase I/II clinical study being conducted in the United States until June 30, 2004, at its own expense. We plan to initiate an additional clinical trial of huN901-DM1 in the United States in hematologic malignancies.

To date, we have not generated revenues from commercial product sales and we expect to incur significant operating losses over the foreseeable future. As of December 31, 2003, we had approximately \$100.7 million in cash and marketable securities. In August 2003, we received \$12.0 million from Aventis, representing the non-refundable, upfront payment owed us upon the execution of our collaboration agreement. We anticipate that our current capital resources and future collaboration payments, including the \$50.7 million of committed research funding due us under the Aventis agreement, will enable us to meet our current and projected operational expenses and capital expenditures for at least the next five to seven fiscal years.

We do not anticipate that we will have a commercially approved product within the foreseeable future. Research and development expenses are expected to increase significantly in the near term as we continue our development efforts. On July 23, 2002, we signed a sublease on approximately 15,000 square feet of laboratory and office space in a building located at 148 Sidney Street, Cambridge, Massachusetts.

On August 27, 2002, we announced that our Board of Directors had authorized the open market repurchase of up to 4.1 million shares of ImmunoGen common stock. The repurchases are to be made at the discretion of management and as market conditions warrant. No time limit was set for the completion of the repurchase program. As of December 31, 2003, the Company had repurchased 3,675,062 shares of its common stock at a total cost of \$11.1 million. Because repurchases are at management's discretion and subject to market conditions, we are unable to estimate the total cost of the repurchase program or the period during which such repurchases may take place.

On January 8, 2004, we announced that we intend to advance our lead product candidates, cantuzumab mertansine and huN901-DM1, into clinical trials ourselves. We plan to conduct a proof of concept trial of huN901-DM1 in hematologic

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malignancies. We are in the process of establishing the clinical plan and potential indications to study cantuzumab mertansine in further clinical testing. We expect to incur expenses of \$4-6 million over the next 2-3 years related to these clinical trials. Based upon the results of such clinical trials, if and when they are completed, we will evaluate whether to continue clinical development of cantuzumab mertansine and huN901-DM1 and, if so, whether we will seek a collaborative partner or partners to continue the clinical development and commercialization of either or both of these product candidates. Given the uncertainties related to new drug development, we are currently unable to estimate when, if ever, these product candidates will generate revenues and cash flows.

We anticipate that the increase in our total cash expenditures will be partially offset by collaboration-derived proceeds including milestone payments and the committed research funding we will receive pursuant to the Aventis collaboration. Accordingly, period-to-period operational results may fluctuate dramatically. We believe that our established collaborative agreements, while subject to specified milestone achievements, will provide funding to assist us in meeting obligations under our collaborative agreements while also allowing for the development of our own product candidates and technologies. However, we can give no assurances that such collaborative agreement funding will, in fact, be realized. 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.

#### Critical Accounting Policies

We prepare our consolidated financial statements in accordance with accounting principles generally accepted in the United States. 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 and inventory. 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.

We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our consolidated financial statements.

#### Revenue Recognition

We estimate the period of our significant involvement during development for each of our collaborative agreements. We recognize any upfront fees received from our collaborators ratably over this estimated period of significant involvement. We generally believe our period of significant involvement occurs between the date we sign a collaboration agreement and projected FDA approval of our collaborator's product that is the subject of the collaboration agreement. We estimate that this time period is generally six years. The actual period of our involvement could differ significantly based upon the results of our collaborators' preclinical and clinical trials, competitive products that are introduced into the market and the general uncertainties surrounding drug development. Any difference between our estimated period of involvement during development and our actual period of involvement could have a material effect upon our results of operations.

#### Inventory

We review our estimates of the net realizable value of our inventory at each reporting period. Our estimate of the net realizable value of our inventory is subject to judgment and estimation. The actual net realizable value of our inventory could vary significantly from our estimates and could have a material effect on our financial condition and results of operations in any reporting period. We consider any DM1 or ansamitocin P3 raw material inventory in excess of 12 months' projected usage that is not supported by collaborators' firm fixed orders to be excess. We record any such raw material identified as excess at its net realizable value. Our estimate of 12 months' usage of DM1 and ansamitocin P3 raw material inventory is based upon our collaborators' estimates of their future clinical material requirements. Our collaborator's estimates of their clinical material requirements are based upon expectations regarding their clinical trials, including the timing, size, dosing schedule and maximum tolerated dose of each product. Our collaborators' actual requirements for clinical materials may vary significantly from their projections. Significant differences between our collaborators' actual manufacturing orders and their projections could result in our actual 12-months-usage of DM1 and ansamitocin P3 varying significantly from our estimated usage at an earlier reporting period. During the six months ended December 31, 2003, we recorded as research and development expense \$20,000 of amounts paid or payable to the manufacturers of ansamitocin P3 and DM1 to produce material that we have identified as excess based upon our inventory policy.

In April 2003, one of our collaborators informed us that it may explore alternative sources of ansamitocin P3 and/or DM1. In applying our inventory policy, we included this collaborator's 12-months' projected usage in the determination of our 12-month

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supply of ansamitocin P3 and DM1. At December 31, 2003, we believe that approximately \$424,000 of our ansamitocin P3 and/or DM1 inventory will be used to produce conjugate for this collaborator. If the collaborator finds and elects to use an alternative source of ansamitocin P3 and/or DM1, we will evaluate our inventory and, if necessary, will record an inventory valuation allowance to reduce to its net realizable value any ansamitocin P3 or DM1 inventory identified as excess. We are unable to determine when, if ever, the collaborator would be able to secure an alternative source of ansamitocin P3 and/or DM1.

#### **RESULTS OF OPERATIONS**

### Comparison of Three Months ended December 31, 2003 and 2002

#### Revenues

Our total revenues for the three months ended December 31, 2003 were \$5.2 million compared with \$2.5 million for the three months ended December 31, 2002. The 109% increase in revenues in the quarter ended December 31, 2003 compared to the same period in the prior year is primarily attributable to committed research funding earned under our discovery, development and commercialization agreement with Aventis, offset by lower revenues from license fees and milestone payments and lower clinical materials reimbursement.

Research and development support of \$3.9 million in the three months ended December 31, 2003 represents committed research funding earned based on actual resources utilized under our discovery, development and commercialization agreement with Aventis. The agreement provides that we will receive a minimum of \$50.7 million of committed research funding during a three-year research program. We entered into the agreement with Aventis in July 2003.

Revenues from license fees and milestone payments for the three months ended December 31, 2003 decreased 29% to \$1.1 million compared to \$1.5 million in the same period in the prior year. Included in license fees and milestone payments for the quarter ended December 31, 2002, is a \$1.0 million milestone payment from Millennium related to the initiation of clinical trials of MLN2704. We did not earn any similar milestone payment during the quarter ended December 31, 2003 is \$600,000 related to that portion of the upfront fee of \$12.0 million we received from Aventis attributable to our performance during the quarter then ended. Total revenue from license fees and milestone payments in the quarters ended December 31, 2003 and 2002 is included in the following table:

	Three months ended December 31,				
	 2003	2002			
Collaborative Partner:					
Aventis	\$ 600,000 \$	—			
Genentech	160,704	160,704			
Abgenix	137,500	125,000			

Millennium	110,636	1,110,648
Boehringer Ingelheim	41,667	41,667
GlaxoSmithKline		41,666
Total	\$ 1,050,507	\$ 1,479,685

Clinical materials reimbursement of \$227,000 in the three months ended December 31, 2003 represents reimbursement for our manufacture of preclinical and clinical materials for our collaborators. In the same period in 2002, clinical materials reimbursement was \$948,000. The cost of clinical materials reimbursed for the quarters ended December 31, 2003 and 2002 was \$227,000 and \$843,000, respectively. Under certain collaborative agreements, we are reimbursed for our fully burdened cost to produce clinical materials plus a profit margin. The amount of clinical materials reimbursement we earn, and the related cost of clinical materials, is directly related to (i) the number of on-going clinical trials for which we are producing clinical material for our collaborators, the speed of enrollment in those trials, the dosage schedule of each clinical grade material on behalf of our collaborators, either in anticipation of clinical trials, or for process development and analytical purposes. As such, the amount of clinical materials reimbursement and the related cost of clinical materials reimbursement and annually.

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Deferred revenue of \$22.4 million as of December 31, 2003 represents upfront fees, option fees and accumulated progress payments received from collaborators pursuant to contract revenues not yet earned.

We had no development fees in the three months ended December 31, 2003 compared to \$49,000 during the same period in 2002. Development fees represent the fully burdened reimbursement of costs incurred in producing research-grade materials in accordance with Good Laboratory Practices and developing antibody-specific conjugation processes on behalf of our collaborators and potential collaborators during the early evaluation and preclinical testing stages of product development. The amount of development fees we earn is directly related to the number of our collaborators or potential collaborators, the stage of development of our collaborators' products and the resources our collaborators allocate to the development effort. As such, the amount of development fees may vary from quarter to quarter and annually.

### Research and Development Expenses

We report research and development expense net of reimbursements we receive from our collaborators. Our net research and development expenses consist of (i) research to identify and evaluate new targets and to develop and evaluate new antibodies and cytotoxic drugs, (ii) preclinical testing and clinical trials of our own and, in certain instances, our collaborators' product candidates, and (iii) development related to improving clinical and commercial manufacturing processes. Our research efforts are primarily focused in the following areas:

- Our contributions to the clinical development of huN901-DM1;
- Process improvements related to clinical and commercial production of the huN901 antibody;
- Process improvements to our TAP technology;
- Preclinical development of our own and Aventis' potential products;
- Process improvement related to the production of DM1 and strain development of its precursor, ansamitocin P3;
- Process development related to the commercial manufacture of huN901-DM1 conjugate;
- Operation, maintenance and expansion of our pilot scale manufacturing plant;
- Identification and evaluation of potential antigen targets;
- Evaluation of internally developed and in-licensed antibodies; and
- Development and evaluation of additional cytotoxic agents.

### Vernalis plc

Vernalis is currently conducting Phase I and Phase I/II clinical trials of huN901-DM1. The Phase I/II study is being conducted in the United States. Vernalis is also conducting a Phase I clinical trial of huN901-DM1 in the United Kingdom. Vernalis is the sponsor of these trials and, as such, has control over the clinical trial schedule and progress.

In July 2003, British Biotech announced its proposed acquisition of Vernalis. In late August 2003, the acquisition was declared unconditional in all respects after a significant majority of Vernalis' shareholders accepted British Biotech's tender offer. In connection with the acquisition, the merged company announced that it intended to review its merged product candidate portfolio. On October 1, 2003, the entity created by the merger of British Biotech and Vernalis, which is now called Vernalis plc, held its Annual General Meeting. At its Annual General Meeting, and in the press release issued in connection therewith, Vernalis announced that it had completed its product candidate portfolio review, and that, as a result of the review, it intended to discuss certain of its collaborations with its partners, including its collaboration with ImmunoGen on huN901-DM1. After discussion with Vernalis, in January 2004, we announced that we will take over future development of the product, which will include advancement of huN901-DM1 into a clinical trial managed by ImmunoGen. Pursuant to the terms of the termination agreement dated January 7, 2004, Vernalis, which has agreed to relinquish its right to the product, will complete, at their cost, the Phase I clinical study currently underway in the United Kingdom and will continue the Phase I/II clinical study being conducted in the United States until June 30, 2004.

We are developing various processes related to the commercial manufacture of the huN901-DM1 conjugate. Worldwide antibody manufacturing capacity is currently constrained, and generally, manufacturing capacity must be reserved months in

advance of production. We anticipate that we may incur substantial costs to complete clinical and commercial conjugation process development efforts, reserve manufacturing space and manufacture humanized antibody. We also expect that we may continue to devote significant human resources to the manufacturing process development efforts over the next five years.

#### GlaxoSmithKline plc

In January 2003, we announced that we would regain the development and commercialization rights to cantuzumab mertansine from GlaxoSmithKline, thereby terminating our collaborative agreement. In June 2002, GlaxoSmithKline informed us that it would not advance cantuzumab mertansine into Phase II clinical development without renegotiation of the terms of our license agreement. We conducted negotiations with GlaxoSmithKline. However, we determined that it was not in the best interests of ImmunoGen to enter into a revised agreement with GlaxoSmithKline. In January 2004, we announced that we will advance cantuzumab mertansine into proof of concept Phase II testing and that we will manage this trial.

#### Aventis Pharmaceuticals, Inc.

As discussed above, we have licensed three of our most advanced preclinical product candidates to Aventis under the terms of our discovery, development, and commercialization collaboration. Those three internally-developed product candidates are a TAP compound for acute myeloid leukemia (AML), an anti-IGF-IR antibody and a compound for certain B-cell malignancies. The TAP compound for AML is a humanized monoclonal antibody conjugated to a maytansinoid derivative and is in preclinical development. At December 31, 2003, we continued to conduct preclinical safety and efficacy studies on the TAP compound for AML. Pending the successful preclinical development of this TAP compound and favorable outcomes of preclinical safety and efficacy studies and any other studies, we expect Aventis to be prepared to file an Investigational New Drug application (IND) for the TAP compound for AML. The continued development of the TAP compound and the actual filing of this IND is now controlled by and dependent upon Aventis, as well as the results of any and all preclinical studies.

Anti-IGF-IR antibody is a naked antibody directed against a target found on various solid tumors including certain breast, lung and prostate cancers. At December 31, 2003, we have identified a lead antibody product candidate. A third potential product is directed at certain B-cell malignancies, including non-Hodgkin's lymphoma, and is in the early stages of preclinical development.

Under the terms of our discovery, development and research collaboration with Aventis, they have licensed three of our most advanced preclinical product candidates. With the exception of those antibodies or antibody targets that are the subject of our preexisting or future collaboration and license agreements, during the term of our collaborative research program, we are required to propose for inclusion in the collaborative research program certain antibody or antibody targets that we believe will have utility in oncology. Aventis then has the right to either include or exclude these proposed antibodies and antibody targets in the collaborative research program. If Aventis elects to exclude any antibodies or antibody targets, we may elect to develop the products ourselves. Furthermore, Aventis may only include a certain number of antibody targets in the research program at any one time. Aventis must therefore exclude any proposed antibody or antibody target in excess of this number. The cost to develop new products and advance those products to the IND stage can be significant. Over the original, three-year term of the research program, we will receive a minimum of \$50.7 million of committed research funding and will devote a significant amount of our internal research and development resources to advancing the research program. Under the terms of the agreement, we may advance any TAP or antibody products ourselves that Aventis has elected either not to include initially or to advance in the research program.

At present, the potential product candidates in our pipeline that are not part of the Aventis collaboration are at an early stage of discovery research and we are unable to accurately estimate which potential products, if any, will eventually move into our internal preclinical research program. We are unable to reliably estimate the costs to develop our potential products as a result of the uncertainties related to discovery research efforts as well as preclinical and clinical testing. Our decision to move a product into the clinical development phase is predicated upon the results of preclinical tests. We cannot accurately predict which, if any, of the discovery research stage product candidates will advance from preclinical testing and move into our internal clinical development program. The costs to take a product through clinical trials is dependent upon, among other things, the medical indications, the timing, size and dosing schedule of each clinical trial, the number of patients enrolled in each trial, and the speed at which patients are enrolled and treated. In many cases, we are unable to determine what, if any, indication a particular product candidate will treat until we have completed extensive preclinical studies. Given the uncertainties related to new drug development, we are currently unable to estimate when, if ever, our research stage product candidates will generate revenues and cash flows.

DM1 is the cytotoxic agent that we currently use in the manufacture of all of our collaborators' and our own conjugates. In order to make commercial manufacture of DM1 conjugates viable, we have devoted substantial resources to improve the strain of

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the microorganism that produces ansamitocin P3, the precursor to DM1, to enhance manufacturing yields. We also continue to devote considerable resources to improve other DM1 manufacturing processes.

We believe that our research and development costs by project are confidential and the disclosure of such costs could have a material negative effect on our ability to negotiate with our suppliers, collaborators and potential collaborators and, accordingly, do not disclose our individual project research and development expenses.

Research and development expenses for the three months ended December 31, 2003 decreased 21% to \$5.2 million from \$6.6 million for the three months ended December 31, 2002. Included in research and development expense for the three months ended December 31, 2002 is \$1.9 million of antibody that we purchased in anticipation of potential future clinical trials. We made antibody payments of \$380,000 during the quarter ended December 31, 2003. We expect future research and development expenses to increase as we continue development of our own and our collaborators' product candidates and technologies.

General and administrative expenses for the three months ended December 31, 2003 increased 9% to \$1.4 million from \$1.3 million for the three months ended December 31, 2002. Included in general and administrative salaries and wages for the three months ended December 31, 2003 was approximately \$54,000 related to estimated and accrued bonuses for the fiscal year ending June 30, 2004. There is no similar expense or accrual in the three months ended December 31, 2002.

#### Interest Income

Interest income for the three months ended December 31, 2003 decreased 52% to \$353,000 from \$741,000 for the three months ended December 31, 2002. The difference is primarily a result of lower rates of return on investments and lower average cash and investment balances.

#### Net Realized (Losses) Gains on Investments

Net realized (losses) gains on investments were (\$36,000) and \$218,000 for the three months ended December 31, 2003 and 2002, respectively. The difference is attributable to market conditions and the timing of investment sales.

#### Comparison of Six Months ended December 31, 2003 and 2002

#### Revenues

Our total revenues for the six months ended December 31, 2003 were \$9.1 million compared with \$4.8 million for the six months ended December 31, 2002. The 88% increase in revenues in the six months ended December 31, 2003 compared to the same period in the prior year is primarily attributable to committed research funding earned under our discovery, development and commercialization agreement with Aventis and higher clinical materials reimbursement offset by lower revenues from license fees and milestone payments.

Research and development support of \$5.1 million in the six months ended December 31, 2003 represents committed research funding earned based on actual resources utilized under our discovery, development and commercialization agreement with Aventis. The agreement provides that we will receive a minimum of \$50.7 million of committed research funding during a three-year research program. We entered into the agreement with Aventis in July 2003.

Revenues from license fees and milestone payments for the six months ended December 31, 2003 decreased 43% to \$1.7 million compared to \$3.0 million in the same period in the prior year. Included in license fees and milestone payments for the six months ended December 31, 2002, is a \$1.0 million milestone payment from Boehringer Ingelheim related to the initiation of clinical trials of bivatuzumab mertansine and a \$1.0 million milestone payment from Millennium related to the initiation of clinical trials of bivatuzumab mertansine and a \$1.0 million milestone payment from Millennium related to the initiation of clinical trials of MLN2704. We did not earn any similar milestone payment during the six months ended December 31, 2003. Included in license fees and milestone payments for the six months ended December 31, 2003 is \$800,000 related to that portion of the upfront fee of \$12.0 million we received from Aventis attributable to our performance during the six months then ended. Total revenue from license fees and milestone payments in the six months ended December 31, 2003 and 2002 is included in the following table:

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	 Six Months End 2003	ed Dec	<u>cember 31,</u> 2002
Collaborative Partner:		-	
Aventis	\$ 800,000	\$	_
Genentech	321,408		321,408
Abgenix	270,834		250,000
Millennium	221,257		1,221,281
Boehringer Ingelheim	83,334		1,083,334
GlaxoSmithKline			83,333
Total	\$ 1,696,833	\$	2,959,356

Clinical materials reimbursement of \$2.2 million in the six months ended December 31, 2003 represents reimbursement for our manufacture of preclinical and clinical materials for our collaborators. In the same period in 2002, clinical materials reimbursement was \$1.8 million. The cost of clinical materials reimbursed for the six months ended December 31, 2003 and 2002 was \$2.0 million and \$1.6 million, respectively. Under certain collaborative agreements, we are reimbursed for our fully burdened cost to produce clinical materials plus a profit margin. The amount of clinical materials reimbursement we earn, and the related cost of clinical materials reimbursed, is directly related to (i) the number of on-going clinical trials for which we are producing clinical material for our collaborators, 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 (ii) our production of clinical grade material on behalf of our collaborators, either in anticipation of clinical trials, or for process development and analytical purposes. As such, the amount of clinical materials reimbursement and the related cost of clinical materials reimbursed may vary from quarter to quarter and annually.

#### Research and Development Expenses

Research and development expenses for the six months ended December 31, 2003 decreased 7% to \$10.0 million from \$10.7 million for the six months ended December 31, 2002. Included in research and development expense for the six months ended December 31, 2002 is \$2.2 million of antibody that we purchased in anticipation of potential future clinical trials. Payments related to P3 fermentation and DM1 conversion were \$927,000 and \$1.7 million during the six months ended December 31, 2003 and 2002, respectively. Offsetting these decreases were increases in compensation and benefits and facility costs allocated to research and development. Research and development compensation and benefits increased by \$984,000 in the six months ended December 31, 2003 was approximately \$654,000 related to estimated and accrued bonuses for the fiscal year ending June 30, 2004 as well as granted and paid bonuses awarded by the Board of Directors in August 2003. There is no similar expense or accrual in the six months ended December 31, 2003 compared to 89 at December 31, 2002. The remaining increase is attributable to personnel increases. The number of research and development personnel increased to 99 at December 31, 2003 compared to 89 at December 31, 2002. There was an increase in facility costs allocated to the research and development departments of \$831,000 resulting from an increase in rent at 128 Sidney Street and the costs of the new facility at 148 Sidney Street. We expect future research and development expenses to increase as we continue development of our own and our collaborators' product candidates and technologies.

#### General and Administrative Expenses

General and administrative expenses for the six months ended December 31, 2003 increased 7% to \$3.2 million from \$3.0 million for the six months ended December 31, 2002. Included in general and administrative salaries and wages for the six months ended December 31, 2003 was approximately \$416,000 related to estimated and accrued bonuses for the fiscal year ending June 30, 2004 as well as granted and paid bonuses awarded by the Board of Directors in August 2003. There is no similar expense or accrual in the three months ended December 31, 2002. Insurance costs increased by \$134,000 in the six months ended December 31, 2003 compared to the same period in 2002. Included in general and administrative expenses for the six months ended December 31, 2003, is a reserve of \$400,000 we established for the estimated settlement of a claim asserted against the Company in July 2002.

#### Interest Income

Interest income for the six months ended December 31, 2003 decreased 55% to \$733,000 from \$1.6 million for the six months ended December 31, 2002. The difference is primarily a result of lower rates of return on investments and lower average cash and investment balances.

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#### Net Realized (Losses) Gains on Investments

Net realized (losses) gains on investments were (\$57,000) and \$371,000 for the six months ended December 31, 2003 and 2002, respectively. The difference is attributable to market conditions and the timing of investment sales.

### LIQUIDITY AND CAPITAL RESOURCES

As of December 31, 2003, we had approximately \$9.5 million in cash and cash equivalents and \$91.1 million of marketable securities. In November 2000, we completed a public offering of 4.0 million shares of our common stock. Net proceeds of the offering were \$124.8 million. We have used a portion of the net proceeds from the offering for working capital and general corporate purposes, including research and development. Since July 1, 2000, we have financed the net cash used to support operating activities primarily from various collaborative and financing sources. These sources include upfront and milestone payments received under our collaboration agreements with GlaxoSmithKline, Genentech, Abgenix, Millennium, Boehringer Ingelheim, and Aventis, the sale of equity securities to Abgenix, as well as the exercise of stock options and warrants to purchase common stock.

Net cash provided by operations during the six months ended December 31, 2003 was \$639,000 compared to net cash used for operations of \$8.0 million during the six months ended December 31, 2002. This increase in operational cash is a result of the upfront fee of \$12.0 million received in August 2003 pursuant to the terms of the Aventis collaboration offset by higher working capital requirements in the six months ended December 31, 2003 compared to the same period in the prior year.

Net cash used for investing activities was \$1.3 million for the six months ended December 31, 2003 compared to net cash provided by investing activities of \$7.1 million for the six months ended December 31, 2002. Cash flows from investing activities in the six months ended December 31, 2003 and 2002 reflects the proceeds of sales and maturities of marketable securities, purchases of marketable securities and capital expenditures. Capital expenditures were \$1.2 million and \$2.1 million for the six months ended December 31, 2003 and 2002, respectively, and consisted primarily of costs associated with the renovation of the laboratory and office space we have leased at 148 Sidney Street, the purchase of new equipment and the build-out of our existing Norwood, Massachusetts development and pilot manufacturing facility.

Net cash provided by financing activities was \$99,000 for the six months ended December 31, 2003 compared to net cash used for financing activities of \$6.3 million for the six months ended December 31, 2002. For the six months ended December 31, 2002, net cash used for financing activities reflects the repurchase of 1,945,176 shares of common stock of the Company. For the six months ended December 31, 2003, net cash provided by financing activities reflects the proceeds to the Company from the exercise of 25,279 stock options at prices ranging from \$2.53 to \$3.95 per share.

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

On August 27, 2002, we announced that our Board of Directors had authorized the open market repurchase of up to 4,100,000 shares of ImmunoGen common stock. The repurchases are to be made at the discretion of management and as market conditions warrant. No time limit was set for the completion of the repurchase program. As of February 9, 2004, the Company had repurchased 3,675,062 shares of its common stock at a total cost of \$11.1 million. As our repurchases are at management's discretion and subject to market conditions, we are unable to estimate the total cost of the repurchase program or the period during which such repurchases may take place.

#### Contractual Obligations

There have been no significant changes in our contractual obligations since June 30, 2003.

## **Risk Factors**

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

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

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

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

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

- ineffectiveness of the product candidate;
- discovery of unacceptable toxicities or side effects;
- development of disease resistance or other physiological factors;
- delays in patient enrollment; or
- other reasons that are internal to the businesses of our collaborative partners, which reasons they may not share with us.

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

## If our collaborative partners fail to perform their obligations under our agreements, or determine not to continue with clinical trials for particular product candidates, our ability to develop and market potential products could be severely limited.

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

- generate cash flow and revenue;
- offset some of the costs associated with our internal research and development, preclinical testing, clinical trials and manufacturing;
- seek and obtain regulatory approvals;
- successfully commercialize existing and future product candidates; and
- develop antibodies for additional product candidates and discover additional cell surface markers for antibody development.

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If we fail to secure or maintain successful collaborative arrangements, our development and marketing activities may be delayed or scaled back. In addition, we may be unable to negotiate other collaborative arrangements or, if necessary, modify our existing arrangements on acceptable terms. The development, regulatory approval and commercialization of our product candidates depend primarily on the efforts of collaborative partners.

We have also entered into collaborations with Genentech, Abgenix, Millennium, Boehringer Ingelheim and Aventis. We cannot control the amount and timing of resources our partners may devote to our products. Our partners may separately pursue competing products, therapeutic approaches or technologies to develop treatments for the diseases targeted by us or our collaborative efforts. Even if our partners continue their contributions to the collaborative arrangements, they may nevertheless decide not to pursue the development or commercialization of any resulting products. Also, our partners may fail to perform their obligations under the collaborative agreements or may be slow in performing their obligations. Our partners can terminate our collaborative agreements under certain conditions. The decision to advance a product that is covered by a collaborative agreement through clinical trials and ultimately to commercialization is in the sole discretion of our collaborative partners. If any collaborative partner were to terminate or breach our agreement with it, or fail to complete its obligations to us in a timely manner, our anticipated revenue from the agreement and development and commercialization of our products could be severely limited. If we are not able to establish additional collaborations or any or all of our existing collaborations are terminated and we are not able to enter into alternative collaborations on acceptable terms, we may be required to undertake product development, manufacture and commercialization of our products, our business will be severely harmed.

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

We have and will continue to have collaborations with a limited number of companies. As a result, our financial performance depends on the efforts and overall success of these companies. The failure of any one of our collaborative partners to perform its obligations under its agreement with us, including making any royalty, milestone or other payments to us, could have a material adverse effect on our financial condition. Further, any material reduction by any one of our collaborative partners in its level of commitment of resources, funding, personnel, and interest in continued development under its agreement with us could have a material adverse effect on our financial condition. Also, if consolidation trends in the healthcare industry continue, the number of our potential collaborators could decrease, which could have an adverse impact on our development efforts.

# If our collaborators' requirements for clinical product that we manufacture for them are significantly lower than we have estimated, our financial results and condition could be significantly harmed.

We procure certain components of finished conjugate including ansamitocin P3, DM1, and linker on behalf of our collaborators. In order to meet our commitments to our collaborators, we are required to enter into agreements with third parties to produce these components well in advance of our production of clinical materials on behalf of our collaborators. If our collaborators do not require as much clinical material as we have contracted to produce, we may not be able to recover our investment in these components and we may suffer significant losses.

In April 2003, one of our collaborators informed us that it may explore alternative sources of ansamitocin P3 and/or DM1. If the collaborator finds and elects to use an alternative source, we may be required to write down excess inventory relating to this collaborator's product.

In addition, we run a pilot manufacturing facility. A significant portion of the cost for salaries of the personnel operating this facility, including the cost of manufacturing personnel, is charged to the cost of producing clinical materials on behalf of our collaborators. If we produce fewer batches of clinical materials for our collaborators, less of the cost of operating the pilot manufacturing facility will be charged to our collaborators and our financial condition could be significantly harmed.

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

We have generated operating losses since our inception. As of December 31, 2003, we had an accumulated deficit of \$209.3 million. For the six months ended December 31, 2003 and the fiscal years ended June 30, 2003, 2002 and 2001, we generated losses of \$5.5 million, \$20.0 million, \$14.6 million and \$15.3 million, respectively. We may never be profitable. We expect to incur substantial additional operating expenses over the next several years as our research, development, preclinical testing and collaborator support activities increase. We intend to continue to invest significantly in our products and bring more of the product development process in-house, which will be a time-consuming and expensive process. Further, we expect to invest significant resources supporting our existing collaborators as they work to develop, test and commercialize TAP and other antibody products, and we or our collaborators may encounter technological or regulatory difficulties as part of this development

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and commercialization process that we cannot overcome or remedy. We may also incur substantial marketing and other costs in the future if we decide to establish marketing and sales capabilities to commercialize our products. None of our product candidates has generated any commercial revenue and our only revenues to date have been primarily from upfront and milestone payments and clinical materials reimbursement from our collaborative partners. We do not expect to generate revenues from the commercial sale of our products in the foreseeable future, and we may never generate revenues from the commercial sale of products. Even if we do successfully develop products that can be marketed and sold commercially, we will need to generate significant revenues from those products to achieve and maintain profitability. Even if we do become profitable, we may not be able to sustain or increase profitability on a quarterly or annual basis.

## We and our collaborative partners are subject to extensive government regulations and we and our collaborative partners may not be able to obtain regulatory approvals.

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

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

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

the laws and regulations pertaining to our business, we may be subject to sanctions, including the temporary or permanent suspension of operations, product recalls, marketing restrictions and civil and criminal penalties.

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

Currently, we only have one in-house pilot scale manufacturing facility for the manufacture of products necessary for clinical testing. We do not have sufficient manufacturing capacity to manufacture all of our product candidates in quantities necessary for commercial sale. In addition, our manufacturing capacity may be insufficient to complete all clinical trials contemplated by us or our collaborators over time. We intend to rely in part on third-party contract manufacturers to produce sufficiently large quantities of drug materials that are and will be needed for clinical trials and commercialization of our potential products. Third-party manufacturers may not be able to meet our needs with respect to timing, quantity or quality of materials. If we are unable to contract for a sufficient supply of needed materials on acceptable terms, or if we should encounter delays or

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difficulties in our relationships with manufacturers, our clinical trials may be delayed, thereby delaying the submission of product candidates for regulatory approval and the market introduction and subsequent commercialization of our potential products. Any such delays may lower our revenues and potential profitability.

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

# We have only one in-house pilot manufacturing facility, and any prolonged and significant disruption at that facility could impair our ability to manufacture products for clinical testing.

Currently, we are contractually obligated to manufacture Phase I and non-pivotal Phase II clinical products for certain of our collaborators. We manufacture this material in a pilot scale manufacturing facility. We only have one such manufacturing facility in which we can manufacture clinical products. Our current manufacturing facility contains highly specialized equipment and utilizes complicated production processes developed over a number of years that would be difficult, time-consuming and costly to duplicate. Any prolonged disruption in the operations of our manufacturing facility would have a significant negative impact on our ability to manufacture products for clinical testing on our own and would cause us to seek additional third-party manufacturing contracts, thereby increasing our development costs. Even though we carry manufacturing interruption insurance policies, we may suffer losses as a result of business interruptions that exceed the coverage available under our insurance policies. Certain events, such as natural disasters, fire, sabotage or business accidents, which could impact our current or future facilities, could have a significant negative impact on our operations by disrupting our product development efforts until such time as we are able to repair our facility or put in place third-party contract manufacturers to assume this manufacturing role.

# We rely on single source suppliers to manufacture the primary component for our small molecule effector drug and DM1 itself. Any problems experienced by either supplier could negatively affect our operations.

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

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

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

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

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

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

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

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

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

Physicians will not recommend therapies using any of our future products until such time as clinical data or other factors demonstrate the safety and efficacy of those products as compared to conventional drug and other treatments. Even if the clinical safety and efficacy of therapies using our products is established, physicians may elect not to recommend the therapies for any number of other reasons, including whether the mode of administration of our products is effective for certain conditions, and whether the physicians are already using competing products that satisfy their treatment objectives. Physicians, patients, third-party payors and the medical community may not accept and use any product candidates that we, or our collaborative partners, develop. If our products do not achieve significant market acceptance, we will not be able to recover the significant investment we have made in developing such products and our business would be severely harmed.

### We may be unable to compete successfully.

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

- develop products that are safer or more effective than our product candidates;
- obtain FDA and other regulatory approvals or reach the market with their products more rapidly than we can, reducing the potential sales of our product candidates;
- devote greater resources to market or sell their products;
- adapt more quickly to new technologies and scientific advances;
- initiate or withstand substantial price competition more successfully than we can;

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

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

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

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

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

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

# If we are forced to litigate or undertake other proceedings in order to enforce our intellectual property rights, we may be subject to substantial costs and liability or be prohibited from commercializing our potential products.

Patent litigation is very common in the biotechnology and pharmaceutical industries. Third parties may assert patent or other intellectual property infringement claims against us with respect to our technologies, products or other matters. Any claims that might be brought against us relating to infringement of patents may cause us to incur significant expenses and, if successfully asserted against us, may cause us to pay substantial damages and limit our ability to use the intellectual property subject to these claims. Even if we were to prevail, any litigation would be costly and time-consuming and could divert the attention of our

management and key personnel from our business operations. Furthermore, as a result of a patent infringement suit, we may be forced to stop or delay developing, manufacturing or selling potential products that incorporate the challenged intellectual property unless we enter into royalty or license agreements. There may be third-party patents, patent applications and other intellectual property relevant to our potential products that may block or compete with our products or processes. In addition, we sometimes undertake research and development with respect to potential products even when we are aware of third-party patents that may be relevant to our potential products, on the basis that such patents may be challenged or licensed by us. If our subsequent challenge to such patents were not to prevail, we may not be able to commercialize our potential products after having already incurred significant expenditures unless we are able to license the intellectual property on commercially reasonable terms. We may not be able to obtain royalty or license agreements on terms acceptable to us, if at all. Even if we were able to obtain licenses to such technology, some licenses may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. Ultimately, we may be unable to commercialize some of our potential products or may have to cease some of our business operations, which could severely harm our business.

# We use hazardous materials in our business, and any claims relating to improper handling, storage or disposal of these materials could harm our business.

Our research and development activities involve the controlled use of hazardous materials, chemicals, biological materials and radioactive compounds. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials and certain waste products. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards prescribed by applicable laws and regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials. In the event of such an accident, we could be held liable for any resulting damages, and any liability could exceed our resources. We may be required to incur significant costs to comply with these laws in the future. Failure to comply with these laws could result in fines and the revocation of permits, which could prevent us from conducting our business.

### We face product liability risks and may not be able to obtain adequate insurance.

The use of our product candidates during testing or after approval entails an inherent risk of adverse effects, which could expose us to product liability claims. Regardless of their merit or eventual outcome, product liability claims may result in:

- decreased demand for our product;
- injury to our reputation and significant media attention;
- withdrawal of clinical trial volunteers;
- costs of litigation;
- distraction of management; and
- substantial monetary awards to plaintiffs.

We may not have sufficient resources to satisfy any liability resulting from these claims. We currently have \$5.0 million of product liability insurance for products which are in clinical testing. This coverage may not be adequate in scope to protect us in the event of a successful product liability claim. Further, we may not be able to maintain our current insurance or obtain general product liability insurance on reasonable terms and at an acceptable cost if we or our collaborative partners begin commercial production of our proposed product candidates. This insurance, even if we can obtain and maintain it, may not be sufficient to provide us with adequate coverage against potential liabilities.

#### We depend on our key personnel and we must continue to attract and retain key employees and consultants.

We depend on our key scientific and management personnel. Our ability to pursue the development of our current and future product candidates depends largely on retaining the services of our existing personnel and hiring additional qualified scientific personnel to perform research and development. We will also need to hire personnel with expertise in clinical testing, government regulation, manufacturing, business development, marketing and finance. Attracting and retaining qualified personnel is and will continue to be critical to our success. We may not be able to attract and retain personnel on acceptable terms given the competition for such personnel among biotechnology, pharmaceutical and healthcare companies, universities and non-profit research

institutions. Failure to retain our existing key management and scientific personnel or to attract additional highly qualified personnel could delay the development of our product candidates and harm our business.

## If we are unable to obtain additional funding when needed, we may have to delay or scale back some of our programs or grant rights to third parties to develop and market our products.

We will continue to expend substantial resources developing new and existing product candidates, including costs associated with research and development, acquiring new technologies, conducting preclinical and clinical trials, obtaining regulatory approvals and manufacturing products as well as providing certain support to our collaborators in the development of their products. We believe that our current working capital and future payments, if any, from our collaboration arrangements, including committed research funding that we expect to receive from Aventis pursuant to the terms of our collaboration agreement, will be sufficient to meet our current and projected operating and capital requirements for at least the next five to seven years. However, we may need additional financing sooner due to a number of factors including:

- if either we or any of our collaborators incur higher than expected costs or experience slower than expected progress in developing product candidates and obtaining regulatory approvals;
- lower revenues than expected under our collaboration agreements; or
- acquisition of technologies and other business opportunities that require financial commitments.

Additional funding may not be available to us on favorable terms, or at all. We may raise additional funds through public or private financings, collaborative arrangements or other arrangements. Debt financing, if available, may involve covenants that could restrict our business activities. If we are unable to raise additional funds through equity or debt financing when needed, we may be required to delay, scale back or eliminate expenditures for some of our development programs or grant rights to develop and market product candidates that we would otherwise prefer to internally develop and market. If we are required to grant such rights, the ultimate value of these product candidates to us may be reduced.

#### Fluctuations in our quarterly revenue and operating results may cause our stock price to decline.

Our operating results have fluctuated in the past and are likely to continue to do so in the future. Our revenue is unpredictable and may fluctuate due to the timing of non-recurring licensing fees, decisions of our collaborative partners with respect to our agreements with them, reimbursement for manufacturing services, the achievement of milestones and our receipt of the related milestone payments under new and existing licensing and collaboration agreements. Revenue historically recognized under our prior collaboration agreements may not be an indicator of revenue from any future collaborations. In addition, our expenses are unpredictable and may fluctuate from quarter-to-quarter due to the timing of expenses, which may include obligations to manufacture or supply product or payments owed by us under licensing or collaboration agreements. It is possible that our quarterly operating results will not meet the expectations of securities analysts or investors, causing the market price of our common stock to decline. We believe that quarter to quarter comparisons of our operating results are not a good indicator of our future performance and should not be relied upon to predict the future performance of our stock price.

#### We do not intend to pay cash dividends on our common stock.

We have not paid cash dividends since our inception and do not intend to pay cash dividends in the foreseeable future. Therefore, shareholders will have to rely on appreciation in our stock price, if any, in order to achieve a gain on an investment.

#### ITEM 3. Quantitative and Qualitative Disclosures about Market Risk

We maintain an investment portfolio in accordance with our Investment Policy. The primary objectives of our Investment Policy are to preserve principal, maintain proper liquidity to meet operating needs and maximize yields. Although our investments are subject to credit risk, our Investment Policy specifies credit quality standards for our investments and limits the amount of credit exposure from any single issue, issuer or type of investment. Our investments are also subject to interest rate risk and will decrease in value if market interest rates increase. However, due to the conservative nature of our investments and relatively short duration, interest rate risk is mitigated. We do not own derivative financial instruments in our investment portfolio.

Accordingly, we do not believe that there is any material market risk exposure with respect to derivative or other financial instruments that would require disclosure under this item.

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

### (a) Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this report, the Company's principal executive officer and principal financial officer evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(c) and 15d-15(c)) and have concluded, based on such

evaluation, that the design and operation of the Company's disclosure controls and procedures were adequate and effective to ensure that material information relating to the Company, including its consolidated subsidiaries, was made known to them by others within those entities, particularly during the period in which this Quarterly Report on Form 10-Q was being prepared.

#### (b) Changes in Internal Controls

There were no changes, identified in connection with the evaluation described above, in the Company's internal controls over financial reporting or in other factors that could significantly affect those controls that have materially affected or are reasonably likely to materially affect, the Company's internal control over financial reporting.

#### PART II. OTHER INFORMATION

#### ITEM 2. Changes in Securities and Use of Proceeds.

During the six months ended December 31, 2003, holders of options issued under the Company's Restated Stock Option Plan exercised their rights to acquire an aggregate of 25,279 shares of common stock at prices ranging from \$2.53 to \$3.95 per share. The total proceeds from these option exercises, \$98,717, will be used to fund current operations.

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

(a) Exhibits	
31.1 31.2	Certification of Chief Executive Officer under Section 302 of the Sarbanes-Oxley Act of 2002. Certification of Principal Financial Officer under Section 302 of the Sarbanes-Oxley Act of 2002.
32.	Certifications of Chief Executive Officer and Principal Financial Officer under Section 906 of the Sarbanes-Oxley Act of 2002

(b) Reports on Form 8-K

Form 8-K dated October 1, 2003 - Item 5 - Other Events

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## SIGNATURES

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

Date: February 13, 2004

Date: February 13, 2004

#### ImmunoGen, Inc.

By:	/s/ Mitchel Sayare
	Mitchel Sayare
	President and Chief Executive Officer
	(principal executive officer)
By:	/s/ Virginia A. Lavery
	Virginia A. Lavery
	Vice President, Finance and Treasurer
	(principal financial and accounting officer)

I, Mitchel Sayare, certify that:

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

2. Based on my knowledge, this 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)) 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) 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

c) 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: February 13, 2004

/s/ Mitchel Sayare Mitchel Sayare

Chairman of the Board of Directors, Chief Executive Officer and President

#### CERTIFICATIONS

I, Virginia A. Lavery, 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)) 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) 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

c) 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: February 13, 2004

/s/ Virginia A. Lavery Virginia A. Lavery Vice President, Finance and Treasurer

#### 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 December 31, 2003 (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: February 13, 2004

/s/ Mitchel Sayare

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

Dated: February 13, 2004

/s/ Virginia A. Lavery Virginia A. Lavery Vice President, Finance and Treasurer