

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q**

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

For the quarterly period ended September 30, 2002

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

At November 4, 2002 there were 42,871,168 shares of common stock, par value \$.01 per share, of the registrant outstanding.

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**IMMUNOGEN, INC.**  
**CONSOLIDATED BALANCE SHEETS**  
**AS OF SEPTEMBER 30, 2002 AND JUNE 30, 2002**

	<u>September 30, 2002</u>	<u>June 30, 2002</u>
<b>(Unaudited)</b>		
<b>ASSETS</b>		
Cash and cash equivalents	\$ 15,239,778	\$ 16,233,408
Marketable securities	111,942,398	121,606,576
Accounts receivable	2,504,698	1,957,292
Unbilled revenue	470,958	588,455
Inventory, net	4,116,594	2,888,448
Prepaid and other current assets, net	2,724,833	2,134,814
	<hr/>	<hr/>
Total current assets	136,999,259	145,408,993
Property and equipment, net	7,030,110	6,703,149
Deposit on construction in progress	1,850,000	—
Other assets	333,700	43,700
	<hr/>	<hr/>
Total assets	\$ 146,213,069	\$ 152,155,842
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Accounts payable	\$ 573,442	\$ 580,789
Accrued compensation	457,249	1,600,982
Other current accrued liabilities	4,223,741	2,095,073
Current portion of deferred revenue	1,905,585	2,226,868
	<hr/>	<hr/>
Total current liabilities	7,160,017	6,503,712
Deferred revenue	10,965,580	11,428,586
Other long term liabilities	16,155	8,431
	<hr/>	<hr/>
Total liabilities	18,141,752	17,940,729
Stockholders' equity:		
Common stock, \$.01 par value; authorized 75,000,000 shares; issued and outstanding 44,253,888 shares and 40,155,560 shares as of September 30, 2002 and June 30, 2002, respectively	442,539	401,556
Additional paid-in capital	317,025,491	317,062,204
Treasury stock	(3,122,714)	—
Accumulated deficit	(187,097,983)	(183,876,446)
Accumulated other comprehensive income	823,984	627,799
	<hr/>	<hr/>
Total stockholders' equity	128,071,317	134,215,113
	<hr/>	<hr/>
Total liabilities and stockholders' equity	\$ 146,213,069	\$ 152,155,842
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The accompanying notes are an integral part of the consolidated financial statements.

**IMMUNOGEN, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
**FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2002 AND 2001**  
**(UNAUDITED)**

	<b>Three Months Ended September 30,</b>	
	<u>2002</u>	<u>2001</u>
Revenues:		

Revenue earned under collaboration agreements	\$	1,479,671	\$	396,617
Clinical materials reimbursement		826,269		934,561
Development fees		40,370		94,723
<b>Total revenues</b>		<b>2,346,310</b>		<b>1,425,901</b>
Expenses:				
Cost of clinical materials reimbursed		752,396		934,561
Research and development		4,109,351		2,503,556
General and administrative		1,742,374		1,198,575
<b>Total expenses</b>		<b>6,604,121</b>		<b>4,636,692</b>
<b>Loss from operations</b>		<b>(4,257,811)</b>		<b>(3,210,791)</b>
Interest income, net		892,407		1,644,937
Realized gains on investments		153,450		8,473
Other income		12,692		26,670
<b>Net loss before income tax expense</b>		<b>(3,199,262)</b>		<b>(1,530,711)</b>
Income tax expense		22,275		61,812
<b>Net loss</b>	<b>\$</b>	<b>(3,221,537)</b>	<b>\$</b>	<b>(1,592,523)</b>
<b>Basic and diluted net loss per common share</b>	<b>\$</b>	<b>(0.08)</b>	<b>\$</b>	<b>(0.04)</b>
<b>Basic and diluted weighted average common shares outstanding</b>		<b>42,825,811</b>		<b>38,809,948</b>

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

**IMMUNOGEN, INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2002 AND 2001**  
**(UNAUDITED)**

	Three Months Ended September 30,	
	2002	2001
Cash flows from operating activities:		
Net loss	\$ (3,221,537)	\$ (1,592,523)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation and amortization	285,072	228,225
Realized gains on sale of marketable securities	(153,450)	(8,473)
Compensation for stock and stock units	11,994	–
Changes in operating assets and liabilities:		
Accounts receivable	(547,406)	(1,237,480)
Unbilled revenue	117,497	(368,745)
Inventory	(1,228,146)	(730,796)
Prepaid and other current assets	(590,019)	83,310
Other assets	(290,000)	–
Accounts payable	178,423	17,363
Accrued compensation	(1,143,733)	377,212
Deferred revenue	(784,289)	(346,617)
Other current accrued liabilities	1,552,066	(419,408)
<b>Net cash used for operating activities</b>	<b>(5,813,528)</b>	<b>(3,997,932)</b>
Cash flows from investing activities:		
Proceeds from sales and maturities of marketable securities	92,059,231	116,939,266
Purchases of marketable securities	(82,045,418)	(115,767,977)
Capital expenditures	(797,803)	(552,052)
Payment of deposit on construction in progress	(1,850,000)	–
<b>Net cash provided by investing activities</b>	<b>7,366,010</b>	<b>619,237</b>
Cash flows from financing activities:		

Repurchases of common stock	(2,546,112)	–
Proceeds from warrants exercised, net	–	5,035,999
Proceeds from stock options exercised, net	–	222,267
Principal payments on capital lease obligations	–	(2,607)
	<hr/>	<hr/>
Net cash provided by (used for) financing activities	(2,546,112)	5,255,659
	<hr/>	<hr/>
Net change in cash and cash equivalents	(993,630)	1,876,964
Cash and cash equivalents, beginning balance	16,233,408	14,822,519
	<hr/>	<hr/>
Cash and cash equivalents, ending balance	\$ 15,239,778	\$ 16,699,483
	<hr/>	<hr/>
Supplemental disclosures:		
Cash paid for taxes	\$ 29,000	\$ 66,912
	<hr/>	<hr/>
Non-cash activities:		
Repurchases of common stock included in other accrued liabilities	\$ 576,602	\$ –
	<hr/>	<hr/>

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

IMMUNOGEN, INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**A. Summary of Significant Accounting Policies**

***Basis of Presentation***

The accompanying consolidated financial statements at September 30, 2002 and June 30, 2002 and for the three-month periods ended September 30, 2002 and 2001 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, except as discussed in *Prepaid and Other Current Assets*, 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, 2002.

***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.

The Company currently has the following four types of out-license and development contracts.

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

British Biotech plc

- Full product license (product license):

GlaxoSmithKline plc

- 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.

Excluding the shared product license agreement, all of these collaboration agreements provide that the Company will (i) manufacture preclinical and clinical materials for its collaborators, at the collaborators' 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 collaboration 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 product and 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 the collaborators' 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 looks at 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 appropriately to reflect any such change.

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.

The Company's shared product license collaboration with British Biotech provides for an upfront payment from British Biotech to the Company that was paid upon signing of the agreement. The agreement also stipulates that upon FDA approval of the product, the Company will pay British Biotech a milestone payment, which the Company expects will exceed the upfront payment the Company received. The Company has deferred the upfront payment and anticipates recognizing such revenue concurrent with the milestone payment that the Company is required to pay to British Biotech if and when the product receives such FDA approval. In the event that the product does not receive such FDA approval, the Company will record as revenue the non-refundable upfront payment previously received upon the termination of the license agreement.

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 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 produces 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, asset-backed and United States government agency securities, banknotes and commercial paper, typically with maturity dates of less than one year. The Company designates its marketable securities as available-for-sale securities. 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 majority of the Company's Unbilled Revenue at September 30, 2002 and June 30, 2002 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.

#### *Prepaid and Other Current Assets*

Included in Prepaid and Other Current Assets at September 30, 2002 and June 30, 2002 is \$1.5 million and \$1.3 million, respectively, related to prepayments made to an antibody manufacturer to reserve manufacturing space and partial payment for antibody that had not been delivered to the Company at September 30, 2002 and June 30, 2002. Under the terms of the Company's shared product license collaboration with British Biotech, the Company is responsible for certain manufacturing and process development costs. The Company's actual cost to manufacture huN901 antibody exceeded its original estimates. In June 2002, the Company and British Biotech agreed that ImmunoGen and British Biotech would share the costs to manufacture antibody in excess of the original estimates and subsequently executed a letter agreement to this effect. Based upon this agreement with British Biotech, the Company determined that a valuation allowance of \$648,000 and \$492,000 was required to reduce the value of the prepaid material to its estimated net realizable value as of September 30, 2002 and June 30, 2002, respectively. During the three months ended September 30, 2002, the Company received a portion of the antibody to be delivered under this contract, thereby reducing the prepaid asset and related reserve by approximately \$696,000 and \$209,000, respectively. Subsequent to June 30, 2002, the Company expenses as incurred (or paid, in the case of prepayments) that portion of the cost of antibody that it expects to pay for under the terms of the letter agreement with British Biotech. During the quarter ended September 30, 2002, the Company recorded \$365,000 as research and development expense and a

related prepaid asset valuation allowance related to prepayments made to the antibody manufacturer. The cost of the huN901 antibody that was received by the Company during the quarter and the related reserve are included in raw materials inventory at September 30, 2002.

### Inventory

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

Inventory at September 30, 2002 is summarized below:

	<u>September 30,</u> <u>2002</u>	
Raw materials, net	\$	2,961,690
Work in process, net		980,042
Finished goods		174,862
<b>Total</b>	<b>\$</b>	<b>4,116,594</b>

Included in inventory is a valuation allowance of \$349,000 as of September 30, 2002. This valuation allowance represents the cost of on-hand conjugate produced for British Biotech that the Company may not realize and, as discussed in *Prepaid and Other Current Assets*, that portion of the cost of huN901 antibody that exceeds the original estimates that the Company is required to pay under its agreement with British Biotech. The Company does not believe that it will be reimbursed for the full amount of the cost of the conjugate and has established a reserve of \$140,000 to reduce the value of huN901-DM1/BB-10901 inventory to \$881,000, the Company's estimate of the net realizable value at September 30, 2002. The entire huN901-DM1/BB-10901 conjugate valuation allowance relates to work in process inventory. The huN901-DM1/BB-10901 conjugate valuation allowance was charged to research and development expense for the year ended June 30, 2002.

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 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. At September 30, 2002, the Company had not yet received any final DM1 product from the DM1 manufacturer, although ansamitocin P3 had been delivered from one of the third party manufacturers to the other manufacturer who was in the process of converting the ansamitocin P3 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 three to five 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. As a result, the Company anticipates that its working capital investment in ansamitocin P3 and DM1 inventory will be significant.

The Company produces preclinical and clinical materials for its collaborators either in anticipation or support of clinical trials, or for process development and analytical purposes. Under the terms of supply agreements with two of its collaborators, the Company receives rolling six month firm fixed orders for conjugate that the Company is required to manufacture and rolling twelve month manufacturing projections for how much conjugate the collaborator expects to need in any given twelve-month period. The Company's other collaboration agreements do not require that the collaborators provide firm fixed manufacturing orders, although the collaborators provide the Company with the collaborators' projected conjugate requirements. The amount of clinical materials 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 collaborator projections. To the extent that a collaborator has provided the Company with a firm fixed order, the collaborator will be 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 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 twelve 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 twelve-month supply of ansamitocin P3 and/or DM1 that is not supported by collaborators' firm fixed orders to be excess and will establish a reserve to write down any such excess ansamitocin P3 or DM1. Any reserve so established will be charged to research and development expense.

At September 30, 2002, the Company's on-hand supply of DM1, including \$1.7 million of DM1 inventory the Company acquired from GlaxoSmithKline and the ansamitocin P3 held at its third party manufacturers, represented less than a twelve-month supply based upon current collaborator firm fixed orders and projections. 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 excess DM1 and/or ansamitocin P3 inventory

and the Company would then evaluate the need to record additional valuation allowances, included as charges to research and development, to record the DM1 and/or ansamitocin P3 inventory at its estimated net realizable value. Increases in collaborators' projections and/or firm fixed orders could result in a reversal of previously established valuation allowances and an associated reduction in research and development expense.

#### *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. Common stock equivalents, as calculated in accordance with the treasury-stock accounting method, equaled 813,556 and 4,403,677 for the three months ended September 30, 2002 and 2001, respectively. Common stock equivalents have not been included in the net loss per common share calculations for the three months ended September 30, 2002 and 2001 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 months ended September 30, 2002 and 2001, total comprehensive loss equaled \$3.0 million and \$675,000, respectively. Comprehensive loss was comprised entirely of net loss and the change in net unrealized gains recognized on available-for-sale securities.

#### *Reclassifications*

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

### **B. Agreements**

On October 8, 2002, Boehringer Ingelheim GmbH confirmed with the Company that clinical trials of the novel anti-cancer agent composed of ImmunoGen's DM1 Tumor-Activated Prodrug (TAP) technology and Boehringer Ingelheim's anti-CD44v6 antibody had been initiated on or about September 24, 2002. The achievement of this milestone triggered a milestone payment of \$1.0 million from Boehringer Ingelheim to ImmunoGen. This milestone payment is included in collaboration revenue in the accompanying statement of operations for the three months ended September 30, 2002. The Company received cash payment of this milestone from Boehringer Ingelheim on October 4, 2002.

In June 2002, GlaxoSmithKline informed the Company that it has elected not to advance cantuzumab mertansine into Phase II clinical development under the present terms of the companies' license agreement. The Company has conducted, and continues to conduct, negotiations with GlaxoSmithKline. However, should the Company determine that it is not in the best interests of ImmunoGen to enter into a revised agreement with GlaxoSmithKline, or if the Company cannot reach satisfactory terms on a revised agreement, rights to cantuzumab mertansine will be returned to ImmunoGen and the Company will be free to develop and/or relicense the product as it considers most appropriate.

The Company continues to recognize a portion of the deferred upfront payment received from GlaxoSmithKline over the Company's estimated period of involvement during development, assuming that the collaboration with GlaxoSmithKline will continue. At September 30, 2002, approximately \$389,000 of the previously received upfront payment remained as deferred revenue. In the event that the collaboration agreement with GlaxoSmithKline is terminated, the Company will recognize as revenue that portion of the upfront payment that remains in deferred revenue at the date of any such termination.

### **C. Capital Stock**

In July 1997, the Company's majority-owned subsidiary, Apoptosis Technology, Inc. (ATI), entered into a collaboration agreement with BioChem Pharma. As previously disclosed in the Company's annual reports on Form 10-K, as part of the agreement, BioChem Pharma received warrants to purchase shares of common stock of the Company equal to \$11.1 million, the amount BioChem Pharma invested in ATI during the three-year research term. On July 29, 2002, Shire Biochem, Inc. (Shire), as successor in interest to BioChem Pharma, delivered to the Company a notice of exercise of warrants to acquire the number of shares of common stock of the Company equal to \$11.1 million divided by the average of the closing price per share, as reported by Nasdaq, for the five days preceding the exercise of such warrants. As provided by the terms of the warrants, Shire delivered 11,125 shares of ATI in lieu of cash to exercise the warrants. The Company issued to Shire 4,096,098 shares of restricted common stock of the Company. Upon the request of Shire and pursuant to the Registration Rights Agreement dated July 31, 1997 between the two parties, on September 26, 2002, the Company filed a registration statement on Form S-3 with the Securities and Exchange Commission to register the resale by Shire of the shares of common stock issued upon the exercise of the warrants.

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 September 30, 2002, the Company had repurchased 952,800 shares of its common stock at a total cost of \$3.1 million.

Under the Company's 2001 Non-Employee Director Stock Plan, approved in November 2001, the Company issued 2,230 shares of common stock and 1,852 stock units to Non-Employee Directors of the Company during the three months ended September 30, 2002.

### **D. Commitments and Contingencies**

In March 2002, the Company settled a claim with a third party and its principals (together, the "Settling Parties") relating to compensation for the provision of services. The settlement of the claim included the issuance of restricted shares of the Company's common stock (the "Settlement Proceeds") in favor of the Settling Parties. The Settling Parties have recently alleged that the Company failed to disclose material information during the course of the settlement negotiations that had an effect on the value of the Settlement Proceeds. Attorneys for the Settling Parties have notified the Company that they intend to file a complaint with respect to this matter in the United States District Court for the District of Massachusetts if the issue is not settled. The Company expressly denies these allegations and believes that a settlement of the claim is probable and, accordingly, has accrued \$400,000 as the currently estimated amount of settlement. The reserve was charged to general and administrative expense during the three months ended September 30, 2002.

## **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. 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 allow 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 have entered into collaborative agreements that allow companies to use our TAP technology to develop commercial products containing their antibodies. We also use our proprietary TAP technology in conjunction with our in-house antibody expertise to develop our own anti-cancer products. We licensed certain rights to our two most advanced, internally developed TAP product candidates to companies that have product development and commercialization capabilities that we wished to access. The terms of the 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. Currently, our collaborative partners include GlaxoSmithKline plc, Genentech, Inc., Abgenix, Inc., British Biotech plc, Millennium Pharmaceuticals, Inc. and Boehringer Ingelheim International GmbH. We expect that substantially all of our revenue for the foreseeable future will result from payments under our collaborative arrangements.

In June 2002, GlaxoSmithKline informed us that they have elected not to advance cantuzumab mertansine into Phase II clinical development under the present terms of our license agreement. We have conducted, and continue to conduct, negotiations with GlaxoSmithKline. However, should we determine that it is not in the best interests of the Company to enter into a revised agreement with GlaxoSmithKline, or we cannot reach satisfactory terms on a revised agreement, rights to cantuzumab mertansine will be returned to ImmunoGen and we will be free to develop and/or re-license the product as we consider most appropriate.

To date, we have not generated revenues from commercial product sales and we expect to incur significant operating losses for the foreseeable future. As of September 30, 2002, we had approximately \$127.2 million in cash and marketable securities. We anticipate that our current capital resources and future collaboration payments, if any, will enable the Company to meet its operational expenses and capital expenditures for at least the next three 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 in the near term as we continue our development efforts. In the next nine months we expect to pay out approximately \$0.2 million to further expand our development and pilot manufacturing facility in Norwood, Massachusetts. 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. We expect that we will spend in the range of \$1.8 million to \$2.0 million over the next six to nine months to renovate this additional space.

On August 27, 2002, we announced that, effective immediately, 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 September 30, 2002, the Company had repurchased 952,800 shares of its common stock at a total cost of \$3.1 million. We anticipate that we will purchase additional shares of our common stock and that the total cost of the shares repurchased will be significant. 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.

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

In December 2001, the U.S. Securities and Exchange Commission (SEC) requested that all registrants discuss their "critical accounting policies" in management's discussion and analysis of financial condition and results of operations. In addition, under the Sarbanes-Oxley Act of 2002, the Company's independent auditors will be required to disclose in their reports to, and discuss with, the Audit Committee the critical accounting policies used by ImmunoGen. The SEC indicated that a "critical accounting policy" is one that is both important to the portrayal of the company's financial condition and results and that requires management's most difficult, subjective or complex judgments. Such judgments are often the result of a need to make estimates about the effect of matters that are inherently uncertain. While our significant accounting policies are more fully described in Note A to our consolidated financial statements included in this report, we currently believe the following accounting policies to be critical:

##### *Revenue Recognition*

We currently have four types of out-license and development contracts.

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

British Biotech plc

- Full product license (product license):

GlaxoSmithKline plc

- 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.



Excluding the shared product license agreement, all of these collaboration agreements provide that we will (i) manufacture preclinical and clinical materials for our collaborators, at their request and cost, (ii) receive payments upon our 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. We are required to provide technical training and any process improvements and know-how to our collaborators during the term of the collaboration 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, our collaborator will not be able to incorporate any process improvements or know-how into their manufacturing process without additional testing and review by the FDA. Accordingly, we believe that it is very unlikely that our collaborators will require our services subsequent to FDA approval.

Generally, upfront payments on product and single target licenses are deferred over the period of our substantial involvement. We are available to assist our collaborators during the development of their products. We estimate this development phase to begin at the inception of the contract and conclude when the product receives FDA approval. We believe this time period is, on average, six years. At each reporting period we look at individual product facts and circumstances and review the estimated period of our substantial involvement. Significant changes in our estimates could result in changes to the deferral period. In the event that the product or a single target license were terminated, we 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.

We defer upfront payments we receive from our 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 our collaborator exercises an option and we grant a single target license to the collaborator, we defer the license fee and account for it as we would an upfront payment on a single target collaboration agreement, as discussed above.

Our shared product license collaboration provides for an upfront payment from our collaborator to us that was paid at the start of the agreement and, upon FDA approval of the product, we will pay the collaborator a milestone payment, which we expect will exceed the upfront payment we have received. We have deferred the upfront payment and anticipate recognizing such revenue concurrent with the milestone payment that is required from us when and if the product receives such FDA approval. In the event that the product does not receive such FDA approval, we will record as revenue the non-refundable upfront payment we previously received upon the termination of the license agreement.

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

The Company produces 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.

#### *Inventory*

Inventory costs primarily relate to clinical trial materials being manufactured for our collaborators. Inventory is stated at the lower of cost or market. We evaluate the estimated net realizable value of inventory at each reporting period. If necessary, we establish a valuation allowance to record inventory at its estimated net realizable value. At September 30, 2002, inventory valuation allowances of \$349,000 represent the cost of on-hand conjugate and huN901 antibody produced for British Biotech that we may not realize.

Under the terms of our shared product license collaboration with British Biotech, we are responsible for certain manufacturing and process development costs. Our actual cost to manufacture the huN901 antibody and conjugate exceeded our original estimates. In June 2002, we agreed that ImmunoGen and British Biotech would share the costs to manufacture huN901 antibody in excess of our estimates and determined the amount we would be reimbursed for huN901-DM1/BB-10901 conjugate and huN901 antibody. As of September 30, 2002 the reserve related to huN901-DM1/BB-10901 and huN901 antibody inventory was \$349,000, which represents that portion of the cost of the on-hand conjugate and huN901 antibody that British Biotech may not reimburse. During the three months ended September 30, 2002, we wrote down \$121,000 of huN901-DM1/BB-10901-conjugate cost against the \$261,000 valuation allowance previously established. The write down did not result in any additional charge or reversal of any portion of the previously established valuation allowance. At September 30, 2002, approximately \$140,000 and \$209,000 of the inventory valuation allowance represents the remaining cost of on hand conjugate produced for British Biotech and huN901 antibody that we may not realize, respectively.

DM1, our most advanced small molecule effector drug, 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. Once manufactured, the ansamitocin P3 is then converted to DM1.

In fiscal 2002, we entered into several agreements with two outside vendors to perform large scale manufacture of DM1 and ansamitocin P3. Under the terms of these agreements, we, together with the manufacturers, will 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 our own and our collaborators' products. Once manufactured, the ansamitocin P3 is delivered from one vendor to the other vendor for conversion to DM1. At September 30, 2002, we had not yet received any final DM1 product from the DM1 manufacturer, although ansamitocin P3 had been delivered from one of the third party manufacturers to the other manufacturer who was in the process of converting the ansamitocin P3 to DM1.

The actual amount of ansamitocin P3 and DM1 that will be produced is highly uncertain. We anticipate that a significant amount of ansamitocin P3 and DM1 will be manufactured for us over the next three to five years at these manufacturers. If our and our manufacturers' process development efforts are successful, the amount of ansamitocin P3 and/or DM1 produced could be higher than expected. As a result, we anticipate that our working capital investment in ansamitocin P3 and DM1 inventory will be significant.

We produce preclinical and clinical materials for our collaborators either in anticipation or support of clinical trials, or for process development and analytical purposes. Under the terms of supply agreements with two of our collaborators, we receive rolling six month firm fixed orders for conjugate that we are

required to manufacture and rolling twelve month manufacturing projections for how much conjugate the collaborator expects to need in any given twelve month period. Our other collaboration agreements do not require that the collaborators provide firm fixed manufacturing orders, although the collaborators provide us with their projected conjugate requirements. The amount of clinical materials produced is directly related to the number of on-going clinical trials for which we are producing clinical material for our 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 we manufacture can differ significantly from the collaborator projections. To the extent that a collaborator has provided us a firm fixed order, the collaborator will be required to reimburse us the full cost of the conjugate, and any margin thereon, even if the collaborator subsequently cancels the manufacturing run.

We account for the DM1 and ansamitocin P3 inventory as follows:

- a) That portion of the DM1 or ansamitocin P3 that we intend to use in the production of our own products is expensed as incurred;
- b) To the extent that we have firm fixed orders or collaborator projections for no more than twelve months, we capitalize 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) We consider more than a twelve-month supply of ansamitocin P3 and/or DM1 that is not supported by collaborators' firm fixed orders to be excess and will establish a reserve to write down any such excess ansamitocin P3 or DM1. Any reserve so established will be charged to research and development expense.

At September 30, 2002, our on-hand supply of DM1, including \$1.7 million of DM1 inventory we acquired from GlaxoSmithKline and the ansamitocin P3 held at its third party manufacturers, represented less than a twelve-month supply, based upon current collaborator firm fixed orders and projections. Any changes to our collaborators' projections could result in significant changes in our estimate of the net realizable value of our DM1 and ansamitocin P3 inventory. Reductions in collaborators' projections could indicate that we have excess DM1 and/or ansamitocin P3 inventory and we would then evaluate the need to record additional valuation allowances, included as charges to research and development, to record the DM1 and/or ansamitocin P3 inventory at its estimated net realizable value. Increases in collaborators' projections and/or firm fixed orders could result in a reversal of previously established valuation allowances and an associated reduction in research and development expense.

## RESULTS OF OPERATIONS

### *Comparison of Three Months ended September 30, 2002 and 2001*

#### *Revenues*

Our total revenues for the three months ended September 30, 2002 were \$2.3 million compared with \$1.4 million for the three months ended September 30, 2001. The 65% increase in revenues in the quarter ended September 30, 2002 compared to the same period in the prior year is primarily attributable to a milestone achieved under our single target license agreement with Boehringer Ingelheim. On October 8, 2002, Boehringer Ingelheim confirmed to us that clinical trials of the novel anti-cancer agent composed of ImmunoGen's DM1 Tumor-Activated Prodrug (TAP) technology and Boehringer Ingelheim's anti-CD44v6 antibody had been initiated on or about September 24, 2002. The achievement of this milestone triggered a milestone payment of \$1.0 million from Boehringer Ingelheim to us. This milestone payment was recognized as revenue during the three months ended September 30, 2002. We received cash payment of the milestone from Boehringer Ingelheim on October 4, 2002.

During the three months ended September 30, 2002 we recognized collaboration revenue of \$42,000 from GlaxoSmithKline, \$161,000 from Genentech, \$125,000 from Abgenix, \$111,000 from Millennium and the \$1.0 million from Boehringer Ingelheim referred to above. During the same period in 2001, we recognized collaboration revenue of \$51,000 from GlaxoSmithKline, \$177,000 from Genentech, \$100,000 from Abgenix and \$69,000 from Millennium. Deferred revenue of \$12.9 million as of September 30, 2002 represents accumulated progress payments received from collaborators pursuant to contract revenues not yet earned.

We continue to recognize a portion of the deferred upfront payment received from GlaxoSmithKline over our estimated period of involvement during the development of cantuzumab mertansine, assuming that the collaboration with GlaxoSmithKline will continue. At September 30, 2002, approximately \$389,000 of the previously received upfront payment remained as deferred revenue. In the event that the collaboration agreement with GlaxoSmithKline is terminated, we will recognize as revenue that portion of the upfront payment that remains in deferred revenue at the date of any such termination.

Clinical materials reimbursement of \$826,000 in the three months ended September 30, 2002 represents reimbursement for our manufacture of preclinical and clinical materials for our collaborators. In the same period in 2001, clinical materials reimbursement was \$935,000. The cost of clinical materials reimbursed for the quarters ending September 30, 2002 and 2001 were \$752,000 and \$935,000, respectively. Under certain collaboration agreements, we are reimbursed our fully burdened cost to produce clinical materials plus a profit margin. During the quarter ended September 30, 2002, we earned clinical materials reimbursement on which we were entitled to a profit margin of \$74,000. 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.

Development fees decreased 57% in the three months ended September 30, 2002 to \$40,000 compared to \$95,000 for the same period in 2001. Development fees represent the fully burdened reimbursement of costs incurred in producing research-grade materials and developing antibody-specific conjugation processes on behalf of our collaborators and potential collaborators during the early evaluation and preclinical testing stages of drug 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, 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 cantuzumab mertansine and huN901-DM1/BB-10901;
- Process improvements related to clinical and commercial production of the huN901 antibody;
- Process improvements to our TAP technology;
- Preclinical development of our own 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/BB-10901;
- Operation, maintenance and expansion of our pilot 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.

GlaxoSmithKline is currently completing one phase I clinical trial of cantuzumab mertansine. The length of this trial is dependent upon how well the remaining patient tolerates the cantuzumab mertansine and the period, if any, during which the patient derives clinical benefit from the administration of the TAP. The actual length of this trial may vary from our estimates. Additionally, GlaxoSmithKline is the sponsor of this trial and, as such, has control over the clinical trial schedule and progress. We are funding a portion of the cost of this on-going phase I clinical trial. In June 2002, GlaxoSmithKline informed us that they have elected not to advance cantuzumab mertansine into Phase II clinical development under the present terms of our license agreement. We have conducted and continue to conduct negotiations with GlaxoSmithKline. However, should we determine that it is not in the best interests of the Company to enter into a revised agreement with GlaxoSmithKline, or we cannot reach satisfactory terms on a revised agreement, the rights to cantuzumab mertansine will be returned to ImmunoGen and we will either develop and/or re-license the product as we consider most appropriate.

British Biotech is currently conducting two phase I clinical trials of huN901-DM1/BB-10901. The first Phase I study is being conducted in the United States. British Biotech is also conducting a second Phase I clinical trial of huN901-DM1/BB-10901 in the United Kingdom. We anticipate that both trials of huN901-DM1/BB-10901 will be completed in calendar year 2003. However, the actual length of these trials may vary from our estimates. Additionally, British Biotech is the sponsor of this trial and, as such, has control over the clinical trial schedule and progress.

In addition to retaining commercial rights to huN901-DM1/BB-10901 worldwide excluding the European Union and Japan, we retain worldwide manufacturing rights. Under the terms of the contract, we are responsible for all clinical and commercial manufacturing process development. We continue process development efforts to improve clinical huN901 antibody production. Under an arrangement with Genzyme Transgenics Corporation, we are investigating the viability of commercial production of huN901 antibody using transgenic goats. We also continue to develop various other processes related to the commercial manufacture of the huN901-DM1/BB-10901 conjugate. We anticipate that we will continue to devote significant financial and human resources to these efforts over the next five years.

Our three internally developed product candidates that are most advanced at September 30, 2002 are huMy9-6-DM1, an anti-IGF1-R antibody and a third product. huMy9-6-DM1 is a humanized monoclonal antibody conjugated to DM1 and is directed against acute myeloid leukemia. huMy9-6-DM1 is in early preclinical development. We intend to continue to conduct preclinical safety and efficacy studies on huMy9-6-DM1. Pending the successful preclinical development of huMy9-6-DM1 and favorable outcome of preclinical safety and efficacy studies and any other studies, we expect to be prepared to file an Investigational New Drug application (IND) for huMy9-6-DM1 in the next 15 to 21 months. The actual filing of this IND is dependent upon the development of huMy9-6-DM1 and the results of any and all preclinical studies and the financial and human resources that we are able to direct to the development of the product and completion of the IND application. As a result, the timing of the filing of this IND, if it occurs at all, may vary from our estimates.

Anti-IGF1-R antibody is a naked antibody directed against breast, lung and prostate cancers. We are performing preclinical experiments to evaluate candidate antibodies and, pending the results of these studies, expect to move one antibody into preclinical development in calendar year 2003. Our third, undisclosed, potential product is directed at a specific cancer and is in the early stages of preclinical development.

The cost to develop new products and advance those products to the IND stage can be significant. Worldwide antibody manufacturing capacity is currently constrained, and, generally, manufacturing capacity must be reserved months in advance of production. We anticipate that we will incur substantial costs to reserve manufacturing space and manufacture humanized antibody. We expect to devote substantial financial and human resources to the development of our three most advanced products for the foreseeable future. We review the results of all preclinical studies and tests to evaluate the viability of products under development. We evaluate the value of each potential product at each stage of development to determine when, if ever, we should consider out-licensing the product. We are unable to reliably estimate the costs to develop our potential products as a result of the uncertainties related to 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 our product candidates will move into clinical development. 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 potential 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 enhance manufacturing yields, we have devoted substantial resources to improve the strain of the microorganism that produces ansamitocin P3, the precursor to DM1. We also continue to devote considerable resources to improve the DM1 manufacturing processes. In connection with these efforts, we anticipate that we will incur research and development expense of \$1.7 million to \$2.0 million over the next twelve months.

We generally do not track our historical research and development costs by project; rather, we track such costs by department and expense category. For this reason, we cannot accurately estimate with any degree of certainty what our historical costs have been for any particular research and development project. We believe that our research and development costs by project would be 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, would not disclose our individual project research and development expense.

Research and development expenses for the three months ended September 30, 2002 increased 64% to \$4.1 million from \$2.5 million for the three months ended September 30, 2001. Under the terms of our shared product license collaboration with British Biotech, we are responsible for certain manufacturing and process development costs. To date, the actual cost to manufacture huN901 antibody has exceeded our original estimates. In June 2002, we agreed with British Biotech that we would share in the costs of huN901 antibody in excess of our estimates. We recorded an additional reserve of \$365,000 as a charge to research and development expense for the three months ended September 30, 2002 related to prepayments we made to produce huN901 antibody. The reserve is equal to our estimate of that portion of the cost in excess of our original estimates that we will pay under the terms of our June 2002 agreement with British Biotech. The actual realized value of the prepaid asset may differ from our estimate based upon actual manufacturing yields.

During the three months ended September 30, 2002 and 2001, we produced three and eight batches of conjugates, respectively, on behalf of certain collaborators. Due to lower utilization of the Norwood pilot manufacturing plant during the three months ended September 30, 2002, manufacturing and quality control costs included in research and development expense increased approximately \$650,000. This increase represents costs of operating the Norwood plant that we were unable to allocate to cost of batches manufactured on behalf of our collaborators during the quarter. The number of research and development personnel increased to 84 at September 30, 2002 compared to 61 at September 30, 2001. Research and development base salaries and wages increased by \$359,000 in the three months ended September 30, 2002 compared to the three months ended September 30, 2001 as a result of the personnel increases. Included in salaries and wages for the three months ended September 30, 2001 was approximately \$211,000 related to estimated and accrued bonuses. There is no similar expense or accrual in the three-month period ended September 30, 2002. Patent costs increased \$101,000 in the quarter ended September 30, 2002 compared to the same period in the prior year. We expect future research and development expenses to increase as we continue development of our product candidates and technologies.

In September 2001 we entered into a process development agreement with a third party. Under the original terms of the agreement, the third party and ImmunoGen shared equally certain development costs. This agreement required the third party to reimburse us for a portion of certain development costs that we had expensed in prior periods, which, due to the nature of the agreement, was accounted for as a reduction of research and development expenses totaling \$439,000 in the quarter ended September 30, 2001.

#### *General and Administrative Expenses*

General and administrative expenses for the three months ended September 30, 2002 increased 45% to \$1.7 million from \$1.2 million for the three months ended September 30, 2001. Legal and accounting services increased by approximately \$270,000. A legal settlement reserve of \$400,000 was recorded during the three months ended September 30, 2002, for the probable settlement related to a claim asserted against the Company in July 2002. General and administrative expenses for the three months ended September 30, 2002 and 2001 are reported net of \$26,000 and \$226,000, respectively, of expenses for which we are entitled to reimbursement from our collaborators. Included in general and administrative salaries and wages for the three months ended September 30, 2001 was approximately \$81,000 related to estimated and accrued bonuses. There is no similar expense or accrual in the three-month period ended September 30, 2002.

#### *Interest Income*

Interest income for the three months ended September 30, 2002 decreased 46% to \$892,000 from \$1.6 million for the three months ended September 30, 2001. The decrease is primarily a result of lower rates of return on investments and lower average cash and investment balances.

#### *Realized Gains on Investments*

Realized gains on investments were \$153,000 and \$8,000 for the three months ended September 30, 2002 and 2001, respectively. The increase is attributable to the timing of investment sales.

## **LIQUIDITY AND CAPITAL RESOURCES**

As of September 30, 2002, we had approximately \$15.2 million in cash and cash equivalents and \$111.9 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, and Boehringer Ingelheim, the sale of equity securities to Abgenix, the exercise of a put option by GlaxoSmithKline, the exercise of stock options and warrants to purchase common stock and income earned on invested assets.

Net cash used in operations during the three-month period ended September 30, 2002 was \$5.8 million compared to \$4.0 million during the three-month period ended September 30, 2001. This increase in operational cash use is largely due to the increase in operating expenses discussed previously, as well as the cash payout of the 2002 bonus in July 2002.

Net cash provided by investing activities was \$7.3 million for the three months ended September 30, 2002 compared to \$619,000 for the three months ended September 30, 2001. Cash provided by investing activities in the three months ended September 30, 2002 and 2001 reflects the net proceeds of sales and maturities of marketable securities net of capital purchases. In addition, during the quarter ended September 30, 2002, we paid a deposit of \$1.9 million relating to the renovation of the laboratory and office space we have leased at 148 Sidney Street. Capital purchases were \$798,000 and \$552,000 for the three months ended September 30, 2002 and 2001, respectively, and consisted primarily of costs associated with the purchase of new equipment and the build-out of our existing Norwood, Massachusetts development and pilot manufacturing facility.

Net cash used for financing activities was \$2.5 million for the three months ended September 30, 2002 compared to net cash provided by financing activities of \$5.3 million for the three months ended September 30, 2001. For the three months ended September 30, 2002 net cash used for financing activities reflects the repurchase of 756,600 shares of common stock of the Company. At September 30, 2002, the Company had commitments to purchase an additional 196,200 shares for \$576,602. For the three months ended September 30, 2001, net cash provided by financing activities reflects the proceeds from exercises of warrants and stock options.

We anticipate that our capital resources and future collaborator payments, if any, will enable us to meet our operational expenses and capital expenditures for at least the next three fiscal 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 all collaborative agreements while also allowing us to develop product

candidates and technologies not covered by collaborative agreements. However, we cannot assure you that such collaborative agreement funding will, in fact, be realized. Should we not meet some or all of the terms and conditions of our various collaboration agreements, we may be required to pursue additional strategic partners, secure alternative financing arrangements, and/or defer or limit some or all of our research, development and/or clinical projects.

## **Risk Factors**

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

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

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

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

Before obtaining regulatory approval for the commercial sale of any product candidates, we and our collaborative partners must demonstrate through 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, cantuzumab mertansine and huN901-DM1/BB-10901, are only in the Phase I stage of clinical trials. Historically, the results from preclinical testing and early clinical trials have often not been predictive of results obtained in later clinical trials. Frequently, drugs that have shown promising results in preclinical or early clinical trials subsequently fail to establish sufficient safety and effectiveness data necessary to obtain regulatory approval. At any time during the clinical trials, we, our collaborative partners or the FDA might delay or halt any clinical trials for our product candidates for various reasons, including:

- ineffectiveness of the product candidate;
- discovery of unacceptable toxicities or side effects;
- development of disease resistance or other physiological factors;
- 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 the clinical trials may fail to demonstrate the safety or effectiveness of our product candidates to the extent necessary to obtain regulatory approval or that commercialization of our product candidates is worthwhile. Any failure or substantial delay in successfully completing clinical trials and obtaining regulatory approval for our product candidates could severely harm our business.

### **If our collaborative partners fail to perform their obligations under our agreements, 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.

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. We have entered into collaboration agreements with GlaxoSmithKline and British Biotech with respect to our two most advanced product candidates, cantuzumab mertansine and huN901-DM1/BB-10901, respectively. The development, regulatory approval and commercialization of our two clinical-stage product candidates depend primarily on the efforts of these collaborative partners. We have also entered into collaborations with Genentech, Abgenix, Millennium, and Boehringer Ingelheim. We cannot control the amount and timing of resources our partners may devote to our products. Our partners may separately pursue competing products, therapeutic approaches or technologies to develop treatments for the diseases targeted by us or our collaborative efforts. Even if our partners continue their contributions to the collaborative arrangements, they may nevertheless determine not to actively pursue the development or commercialization of any resulting products. Also, our partners may fail to perform their obligations under the collaboration agreements or may be slow in performing their obligations. Our partners can terminate our collaborative agreements under certain conditions. 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, 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 ourselves, and we may not have the funds or capability to do this. If our collaborators fail to successfully develop and commercialize TAP products our business will be severely harmed.

**The outcome of our ongoing negotiations with GlaxoSmithKline relating to cantuzumab mertansine is uncertain and may ultimately be unfavorable to us.**

In June 2002, GlaxoSmithKline informed us that they have elected not to advance cantuzumab mertansine into Phase II clinical development under the present terms of our license agreement with them. We have conducted and continue to conduct negotiations with GlaxoSmithKline. However, renegotiation of the agreement will be time-consuming, and we may not be able to renegotiate the agreement on terms that are favorable to us. If we ultimately decide that entering into a renegotiated agreement with GlaxoSmithKline is not in our best interests, or we cannot reach satisfactory terms on a revised agreement, the rights to cantuzumab mertansine will be returned to us. This will mean that we will either proceed with clinical trials of cantuzumab mertansine on our own, which will be time-consuming and expensive, or find another collaborative partner that will undertake the clinical trials, which will require us to negotiate another collaborative agreement, possibly on terms that are less favorable to us than the existing GlaxoSmithKline agreement.

**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 their 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.

**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 September 30, 2002, we had an accumulated deficit of \$187.1 million. We may never be profitable. We expect to incur substantial additional operating expenses over the next several years as our research, development, preclinical testing, clinical trial 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 products, and we or our collaborators may encounter technological or regulatory difficulties as part of this development 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 are subject to extensive government regulations and we 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 all of the risks associated with the FDA approval process. In addition, we are, or may become, subject to various federal, state and local laws, regulations and recommendations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals and the use and disposal of hazardous substances, including radioactive compounds and infectious disease agents, used in connection with our research work. If we fail to comply with the laws and regulations pertaining to our business, we may be subject to sanctions, including the temporary or permanent suspension of operations, product recalls, marketing restrictions and civil and criminal penalties.

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

Currently, we only have one pilot 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 inadequate to complete all clinical trials contemplated by us 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 difficulties in our relationships with manufacturers, our clinical trials may be delayed, thereby delaying the submission of product candidates for regulatory approval and the market introduction and subsequent commercialization of our potential products. Any such delays may lower our revenues and potential profitability.

We may develop our manufacturing capacity in part by expanding our current facilities or building new facilities. Either of these activities would require substantial additional funds and we would need to hire and train significant numbers of employees to staff these facilities. We may not be able to develop

manufacturing facilities that are sufficient to produce drug materials for clinical trials or commercial use. We and any third-party manufacturers that we may use must continually adhere to Current Good Manufacturing Practices regulations enforced by the FDA through its facilities inspection program. If our facilities or the facilities of third-party manufacturers cannot pass a pre-approval plant inspection, the FDA approval of our product candidates will not be granted. In complying with these regulations and foreign regulatory requirements, we and any of our third-party manufacturers will be obligated to expend time, money and effort on production, record-keeping and quality control to assure that our potential products meet applicable specifications and other requirements. If we or any third-party manufacturer with whom we may contract fail to maintain regulatory compliance, we or the third party may be subject to fines and/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 hurt 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.

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

Other companies, universities and research institutions have or may obtain patents that could limit our ability to use, manufacture, market or sell our product candidates or impair our competitive position. As a result, we 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 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 would likely lead to a delay or interruption in our manufacturing operations and preclinical and clinical trials of our product candidates or our collaborators' product candidates, which could negatively affect our business.

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

We currently have no direct sales or marketing capabilities. We anticipate relying on third parties to market and sell most of our primary product candidates. If we decide to market our potential products through a direct sales force, we would need to either hire a sales force with expertise in pharmaceutical sales or contract with a third party to provide a sales force to meet our needs. We may be unable to establish marketing, sales and distribution capabilities necessary to commercialize and gain market acceptance for our potential products and be competitive. In addition, co-promotion or other marketing arrangements with third parties to commercialize potential products could significantly limit the revenues we derive from these potential products, and these third parties may fail to commercialize our potential products successfully.

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

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

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

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

Our success depends in part on obtaining, maintaining and enforcing our patents and other proprietary rights and our ability to avoid infringing the proprietary rights of others. Patent law relating to the scope of claims in the biotechnology field in which we operate is still evolving, 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 and confidential information. Others may independently develop substantially equivalent information and techniques or otherwise gain access to or disclose our technology. We may not be able to effectively protect our rights in unpatented technology, trade secrets and confidential information. We require each of our employees, consultants and corporate partners to execute a confidentiality agreement at the commencement of an employment, consulting or collaborative relationship with us. However, these agreements may not provide effective protection of our information or, in the event of unauthorized use or disclosure, they may not provide adequate remedies.

**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. Furthermore, because patent applications in the United States are maintained in secrecy until a patent issues, others may have filed patent applications for technology covered by our pending applications. There may be third-party patents, patent applications and other intellectual property relevant to our potential products that may block or compete with our products or processes. In addition, we sometimes undertake research and development with respect to potential products even when we are aware of third-party patents that may be relevant to our potential products, on the basis that such patents may be challenged or licensed by us. If our subsequent challenge to such patents were not to prevail, we may not be able to commercialize our potential products after having already incurred significant expenditures unless we are able to license the intellectual property on commercially reasonable terms. We may not be able to obtain royalty or license agreements on terms acceptable to us, if at all. Even if we were able to obtain licenses to such technology, some licenses may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. Ultimately, we may be unable to commercialize some of our potential products or may have to cease some of our business operations, which could severely harm our business.

**We 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 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 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 supporting our collaborators in the development of their TAP products. We believe that our current working capital and future payments, if any, from our collaboration arrangements will be sufficient to meet our operating and capital requirements for at least the next three 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 in the future, 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 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

Within the 90-day period prior to the filing of 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-14(c) and 15d-14(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 significant changes in the Company's internal controls or in other factors that could significantly affect those controls subsequent to the date of their evaluation, nor were there any significant deficiencies or material weaknesses in the Company's internal controls. Accordingly, no corrective actions were required or undertaken.

## PART II. OTHER INFORMATION

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

On July 29, 2002, Shire BioChem, Inc. (Shire) exercised warrants to acquire 4,096,098 restricted shares of common stock of the Company. Shire delivered 11,125 shares of ATI in lieu of cash to exercise the warrants.

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 September 30, 2002, the Company had repurchased 952,800 shares of its common stock at a total cost of \$3.1 million. Through November 4, 2002, the Company had repurchased 1,384,220 shares of its common stock at a total cost of \$4.4 million.

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

#### (a) Exhibits

None.

#### (b) Reports on Form 8-K

None.

## SIGNATURES

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

#### ImmunoGen, Inc.

Date: November 12, 2002

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

Date: November 12, 2002

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



5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, 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 in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
- b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this quarterly report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: November 12, 2002

\_\_\_\_\_  
/s/ Gregg D. Beloff  
Gregg D. Beloff  
Vice President and Chief Financial Officer