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, 2001
OR

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

For the transition period from _____ to _____

Commission file number 0-17999

ImmunoGen, Inc.

(Exact name of registrant as specified in its charter)

Massachusetts	**04–2726691**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

128 Sidney Street
Cambridge, MA 02139
(Address of principal executive offices, including zip code)

(617) 995-2500
(Registrant's telephone number, including area code)

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

Yes ☒ No o

At November 6, 2001 there were 39,699,641 shares of common stock, par value $.01 per share, of the registrant outstanding.

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

	September 30, 2001 (Unaudited)	June 30, 2001
ASSETS		
Cash and cash equivalents	$ 16,699,483	$ 14,822,519
Marketable securities	135,732,305	79,673,934
Accounts receivable	1,237,480	–
Earned and unbilled revenue	1,062,580	693,835
Inventory	2,891,792	2,160,996
Prepaid and other current assets	2,141,077	2,224,387
Total current assets	159,764,717	99,575,671
Long term marketable securities	–	56,303,267
Property and equipment, net	3,561,909	3,238,082
Other assets	43,700	43,700
Total Assets	$ 163,370,326	$ 159,160,720
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable	$ 860,290	$ 842,927
Accrued compensation	1,080,248	703,036
Other current accrued liabilities	1,826,466	2,245,874
Current portion of capital lease obligations	5,530	8,137
Current portion of deferred revenue	1,601,965	1,560,865
Total current liabilities	5,374,499	5,360,839
Deferred revenue	10,965,398	11,353,115
Total liabilities	16,339,897	16,713,954
Stockholders' equity:		
Common stock, $.01 par value; authorized 50,000,000 shares; issued and outstanding 39,685,326 shares and 38,535,402 shares as of September 30, 2001 and June 30, 2001, respectively	396,854	385,354
Additional paid–in capital	316,217,927	310,971,161
Accumulated deficit	(170,839,130)	(169,246,607)
Accumulated other comprehensive income	1,254,778	336,858
Total stockholders' equity	147,030,429	142,446,766
Total liabilities and stockholders' equity	$ 163,370,326	$ 159,160,720

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

IMMUNOGEN, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2001 AND 2000
(UNAUDITED)

	Three Months Ended September 30,	
	2001	2000 (Restated, See Note A)
Revenues:		
Revenue earned under collaboration agreements	$ 396,617	$ 2,213,162
Clinical materials reimbursement	934,561	–
Development fees	94,723	–

Total revenues	1,425,901	2,213,162
Expenses:		
Cost of clinical materials reimbursed	934,561	–
Research and development	2,503,556	3,568,933
General and administrative	1,198,575	853,909
Total expenses	4,636,692	4,422,842
Loss from operations	(3,210,791)	(2,209,680)
Interest income, net	1,644,937	213,601
Realized gains on investments	8,473	–
Loss on the sale of assets	–	(1,900)
Other income	26,670	19,349
Loss before income tax expense and cumulative effect of change in accounting principle	(1,530,711)	(1,978,630)
Income tax expense	61,812	–
Loss before cumulative effect of change in accounting principle	(1,592,523)	(1,978,630)
Cumulative effect of change in accounting principle	–	(5,734,478)
Net loss	$ (1,592,523)	$ (7,713,108)
Basic and diluted net loss per common share:		
Loss before cumulative effect of change in accounting principle	$ (0.04)	$ (0.06)
Cumulative effect of change in accounting principle	–	(0.17)
Net loss	$ (0.04)	$ (0.23)
Basic and diluted average common shares outstanding	38,809,948	33,307,465

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

IMMUNOGEN, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2001 AND 2000
(UNAUDITED)

	Three Months Ended September 30,	
	2001	**2000**
Cash flows from operating activities:		
Net loss	$ (1,592,523)	$ (7,713,108)
Adjustments to reconcile net loss to net cash used for operating activities:		
Cumulative effect of change in accounting principle	–	5,734,478
Depreciation and amortization	228,225	126,441
Loss on sale of property and equipment	–	1,900
Changes in operating assets and liabilities:		
Due from Collaborative Partners	–	(5,000,000)
Due from related parties	–	6,741
Accounts receivable	(1,237,480)	–
Earned and unbilled revenue	(368,745)	–
Inventory	(730,796)	–
Prepaid and other current assets	83,310	291,138
Accounts payable	17,363	70,493
Accrued compensation	377,212	45,094
Deferred revenue	(346,617)	2,786,838
Other current accrued liabilities	(419,408)	780,775
Net cash used for operating activities	(3,989,459)	(2,869,210)
Cash flows from investing activities:		
Sales or maturities (purchases) of marketable securities, net	1,162,816	(10,211,353)

Capital expenditures	(552,052)	(723,074)
Proceeds from sale of property and equipment	–	7,500
Net cash provided by (used for) investing activities	610,764	(10,926,927)
Cash flows from financing activities:		
Proceeds from warrants exercised, net	5,035,999	1,332,773
Proceeds from stock options exercised, net	222,267	527,605
Principal payments on capital lease obligations	(2,607)	(15,431)
Proceeds from common stock issuance, net	–	15,000,000
Net cash provided by financing activities	5,255,659	16,844,947
Net change in cash and cash equivalents	1,876,964	3,048,810
Cash and cash equivalents, beginning balance	14,822,519	1,408,908
Cash and cash equivalents, ending balance	$ 16,699,483	$ 4,457,718
		–
Supplemental disclosures:		
Cash paid for taxes	$ 66,912	$ –

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

IMMUNOGEN, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

A. Summary of Significant Accounting Policies

Basis of Presentation

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

Revenue Recognition

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

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

Effective July 1, 2000, ImmunoGen changed its method of accounting for revenue recognition in accordance with Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements," (SAB 101). Under the new accounting method, adopted retroactively to July 1, 2000, the Company recognizes revenue from non-refundable, up-front license payments, not specifically tied to a separate earnings process, ratably over the term of the research contract. The cumulative effect of the change in accounting on prior years resulted in a non-cash charge to income of $5.7 million, which is included in the net loss for the three months ended September 30, 2000. Results for the three months ended September 30, 2000 have been restated for the retroactive adoption of SAB 101. Included in revenue for each of the three month periods ended September 30, 2001 and 2000 is $219,000 of revenue that was recognized in prior years, before the Company’s adoption of SAB 101, and included in the cumulative effect of change in accounting principle.

Marketable Securities

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

Inventory

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

Inventory at September 30, 2001 is summarized below:

Raw materials	$ 654,385
Work in process	1,949,988

Finished goods	287,419
Total	$ 2,891,792

Computation of Earnings/(Loss) Per Common Share

Basic and diluted earnings/(loss) per share is calculated based upon the weighted average number of common shares outstanding during the period. Diluted earnings per share incorporate 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 4,403,677 and 4,677,120 for the three months ended September 30, 2001 and 2000, respectively. Common stock equivalents have not been included in the loss per share calculations for the three-month periods ended September 30, 2001 and 2000 because their effect is anti-dilutive.

Comprehensive Income/(Loss)

The Company presents comprehensive income in accordance with Statement of Financial Accounting Standards No. 130, "Reporting Comprehensive Income." For the three-month period ended September 30, 2001, total comprehensive loss equaled $675,000. For the three months ended September 30, 2000, total comprehensive loss equaled $7,731,382. Comprehensive loss was comprised entirely of net loss and net unrealized losses recognized on available-for-sale debt securities.

Recent Accounting Pronouncements

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

Reclassifications

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

B. Capital Stock

At September 30, 2001, excluding the warrants issued to BioChem Pharma, Inc. discussed below, warrants to acquire 1,828,928 shares of Common Stock remained outstanding at exercise prices ranging from $2.31 to $4.00. These warrants were originally issued in connection with the Company’s March 1996 private placement of convertible debt and the private placements of the Company’s Series A, Series B and Series C preferred stock.

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

During the quarter ended September 30, 2001, a holder of warrants originally issued in connection with a March 1996 private placement of the Company’s convertible debentures and adjusted, pursuant to the anti-dilution provisions of the warrants, in connection with the Company’s November 2000 public offering of common stock, exercised its right to acquire 1,127,374 shares of common stock at prices ranging between $3.58 and $5.37. Proceeds from these warrant exercises will be used to fund current operations.

During the three-month period ended September 30, 2001, holders of options issued under the Company's Restated Stock Option Plan, as amended, exercised their rights to acquire an aggregate of 22,500 shares of common stock at prices ranging from $0.84 per share to $14.75 per share. The total proceeds from these option exercises, $222,267, will be used to fund current operations.

C. Commitments and Contingencies

In December 1995, the Company entered into an agreement with a third party (the "Finder") whereby the Finder agreed to identify and introduce potential financing sources to the Company in exchange for cash and warrants upon the successful completion of a financing. During the fiscal years ended June 30, 1996 and 1998, the Company issued stock, warrants and cash to the Finder relating to certain financings. On November 13, 2001, the Company received a claim asserting that, as a result of certain warrant exercises, the Company owes additional compensation to the Finder in the amount of $819,423 cash and warrants exercisable for the purchase of 250,000 shares of common stock of the Company at $3.11 per share (the "Claim"). The Company is currently assessing the validity of the Claim and the method of computing its value, and based on a preliminary review, has identified certain aspects of the Claim that it believes to be inaccurate and which the Company intends to dispute. Accordingly, no adjustment has been made to the financial statements for the quarter ending September 30, 2001. If any portion of the Claim were determined to be valid, such consideration would be accounted for as a reduction of the gross proceeds of the financings and would not be considered a charge to the Company's statement of operations.

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

Overview

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

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

To date, we have not generated revenues from commercial product sales and we expect to incur significant operating losses over the foreseeable future. As of September 30, 2001, we had approximately $152.4 million in cash and marketable securities. We do not anticipate having a commercially-approved product within the foreseeable future. Research and development expenses are expected to increase significantly in the near term as we continue our development efforts. Moreover, in the next twelve to eighteen months we expect to spend approximately $4.4 million to further expand our development and pilot manufacturing facility in Norwood, Massachusetts. We anticipate that the increase in total cash expenditures will be partially offset by collaboration-derived proceeds. Accordingly, period-to-period operational results may fluctuate dramatically. We believe that our established collaborative agreements, while subject to specified milestone achievements, will provide funding sufficient to allow us to meet our obligations under all collaborative agreements while also allowing the aggressive development of internal product candidates and technologies. However, we can give no assurances that such collaborative agreement funding will, in fact, be realized. Should we not meet some or all of the terms and conditions of our various collaboration agreements, we may be required to pursue additional strategic partners, secure alternative financing arrangements, and/or defer or limit some or all of our research, development and/or clinical projects.

Results of Operations

Comparison of Three Months ended September 30, 2001 and 2000

Revenues

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

Effective July 1, 2000, we changed our method of accounting for revenue recognition in accordance with Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements" (SAB 101). Under the new accounting method, adopted retroactively to July 1, 2000, we recognize revenue from non-refundable, up-front license payments, not specifically tied to a separate earnings process, ratably over the term of the research contract. The cumulative effect of the change in accounting on prior years resulted in a non-cash charge to income of $5.7 million, which is included in our net loss for the three months ended September 30, 2000. Results for the three months ended September 30, 2000 have been restated for the retroactive adoption of SAB 101.

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

Our total revenues for the three months ended September 30, 2001 were $1.4 million, compared with $2.2 million for the three months ended September 30, 2000. The 36% decrease in revenues from 2000 to 2001 is primarily attributable to milestone payments we recognized under the GlaxoSmithKline agreement in 2000. During 2001 we recognized collaboration revenue of $51,000 from GlaxoSmithKline, $177,000 from Genentech, $100,000 from Abgenix, and $69,000 from Millennium. During 2000, we recognized collaboration revenue of $2.0 million from GlaxoSmithKline and $177,000 from Genentech. Deferred revenue of $12.6 million as of September 30, 2001 represents progress payments received from collaborators pursuant to contract revenues not yet earned.

During the three months ended September 30, 2001, we shipped $935,000 of reimbursable clinical materials to our collaborators. There were no shipments of reimbursable clinical materials during the same period of 2000.

Expenses

Cost of Clinical Materials Reimbursed. Cost of clinical materials reimbursed, of $935,000 in three months ended September 30, 2001, represents the fully burdened cost of clinical materials that we produce for our collaborators, and for which we are reimbursed. There were no costs related to clinical materials reimbursed for the same period in 2000.

Research and Development Expenses. Research and development expenses for the three months ended September 30, 2001 decreased 30% to $2.5 million from $3.6 million for the three months ended September 30, 2000. The three months ended September 30, 2000 included significant costs associated with supporting our ongoing huC242-DMI/SB-408075 human clinical trials and the pre-clinical development of our second product, huN901-DMI/BB-10901. Although these trials continue, the cost of our ongoing financial support is less than it was during the earlier stages of the trials and during pre-clinical development. Additionally, during the three months ended September 30, 2001, we entered into a process development agreement with a third party. We will share equally with this third party in certain future developments costs. This agreement requires the third party to reimburse us for a portion of certain development costs, expensed by the Company in prior periods, which, due to the nature of the agreement, must be accounted for as a reduction of research and development expenses totaling $439,000. These reductions in research and development expenses have been partially offset with increased personnel costs, including estimated fiscal 2002 bonuses that have been accrued. We expect future research and development expenses to increase as we continue development of our product candidates and technologies.

General and Administrative Expenses. General and administrative expenses for the three months ended September 30, 2001 increased 40% to $1.2 million from $854,000 for the three months ended September 30, 2000. This increase was largely due to increased administrative and business development personnel costs and increased expenditures associated with investor relations.

Interest Income. Interest income for the three months ended September 30, 2001 increased to $1.6 million from $0.2 million for the three months ended September 30, 2000. The increase in interest income from the first fiscal quarter 2000 to 2001 is primarily attributable to higher cash and investment balances resulting from our November 2000 public stock offering, a collaborator investment of $15.0 million in September 2000 and receipt of $9.0 million in collaborator payments during the year ended June 30, 2001.

Liquidity and Capital Resources

As of September 30, 2001, we had approximately $16.7 million in cash and cash equivalents. In November 2000, we completed a public offering of 4.0 million shares of our common stock. Net proceeds of the offering were $124.8 million. We intend to use the net proceeds from the offering for working capital and general corporate purposes, including research and development. Since July 1, 2000, we have financed the net cash used to support operating activities primarily from various collaborative and financing sources. These sources include milestone revenues earned under our collaboration agreement with GlaxoSmithKline, the sale of equity securities to Abgenix, the exercise of stock options and warrants to purchase common stock and income earned on invested assets.

Net cash used in operations during the three months ended September 30, 2001 was $4.0 million compared to net cash used in operations of $2.9 million in the three months ended September 30, 2000. This increase in operational cash use is largely due to the increase in operating expenses discussed previously, as well as the increase in accounts receivable and clinical materials inventory produced on behalf of our collaborators during the three months ended September 30, 2001.

Net cash provided by investing activities was $611,000 for the three months ended September 30, 2001, and primarily represents maturities and sales of marketable securities, net of purchases of marketable securities. Capital purchases were $552,000 for the three months ended September 30, 2001, and consisted primarily of costs associated with the purchase of new equipment and the buildout of our existing Norwood, Massachusetts development and pilot manufacturing facility.

Net cash provided by financing activities decreased to $5.3 million for the three months ended September 30, 2001 versus $16.8 million provided by financing activities for the three months ended September 30, 2000. The decrease is largely due to the September 7, 2000 issuance of 789,473 shares of our common stock to Abgenix for $15.0 million. Our total proceeds from exercises of warrants and stock options during the three months ended September 30, 2001 were $5.3 million.

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

Recent Accounting Pronouncements

In October 2001, the FASB issued SFAS No. 144, “Accounting for the Impairment or Disposal of Long-Lived Assets.” SFAS No. 144 supersedes SFAS No. 121, “Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed of” and provides a single accounting model for long-lived assets to be disposed of. The provisions of SFAS No. 144 are effective for fiscal years beginning after December 15, 2001. We do not believe the adoption of SFAS No. 144 will have a material effect on our financial position or results of operations.

Risk Factors

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We have generated operating losses since our inception. As of September 30, 2001, we had an accumulated deficit of $170.8 million. We may never be profitable. We expect to incur substantial additional operating expenses over the next several years as our research, development, pre-clinical testing and clinical trial activities increase. We intend to invest significantly in our products and bring more of the product development process in-house prior to entering into collaborative arrangements. We may also incur substantial marketing and other costs in the future if we decide to establish marketing and sales capabilities to commercialize certain of our products. None of our product candidates has generated any commercial revenue and our only revenues to date have been primarily from up-front and milestone payments from our collaboration partners. We do not expect to generate revenues from the commercial sale of our products in the foreseeable future, and we may never generate revenues from the commercial sale of products. Even if we do successfully develop products that can be marketed and sold commercially, we will need to generate significant revenues from those products to achieve and maintain profitability. Even if we do become profitable, we may not be able to sustain or increase profitability on a quarterly or annual basis.

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

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

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

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

compounds and infectious disease agents, used in connection with our research work. If we fail to comply with the laws and regulations pertaining to our business, we may be subject to sanctions, including the temporary or permanent suspension of operations, product recalls, marketing restrictions and civil and criminal penalties.

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

Currently, we only have one pilot manufacturing facility for the manufacture of products necessary for clinical testing. We do not have sufficient manufacturing capacity to manufacture our product candidates in quantities necessary for commercial sale. In addition, our manufacturing capacity may be inadequate to complete all clinical trials contemplated by us over time. We intend to rely in part on third–party contract manufacturers to produce large quantities of drug materials needed for clinical trials and commercialization of our potential products. Third–party manufacturers may not be able to meet our needs with respect to timing, quantity or quality of materials. If we are unable to contract for a sufficient supply of needed materials on acceptable terms, or if we should encounter delays or difficulties in our relationships with manufacturers, our clinical trials may be delayed, thereby delaying the submission of product candidates for regulatory approval and the market introduction and subsequent commercialization of our potential products. Any such delays may lower our revenues and potential profitability. We may develop our manufacturing capacity in part by expanding our current facilities or building new facilities. Either of these activities would require substantial additional funds and we would need to hire and train significant numbers of employees to staff these facilities. We may not be able to develop manufacturing facilities that are sufficient to produce drug materials for clinical trials or commercial use. We and any third–party manufacturers that we may use must continually adhere to Current Good Manufacturing Practices regulations enforced by the FDA through its facilities inspection program. If our facilities or the facilities of third–party manufacturers cannot pass a pre-approval plant inspection, the FDA approval of our product candidates will not be granted. In complying with these regulations and foreign regulatory requirements, we and any of our third–party manufacturers will be obligated to expend time, money and effort on production, record–keeping and quality control to assure that our potential products meet applicable specifications and other requirements. If we or any third–party manufacturer with whom we may contract fail to maintain regulatory compliance, we or the third party may be subject to fines and manufacturing operations may be suspended, which could negatively affect our business.

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

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

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

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

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

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

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

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

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

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

We may be unable to compete successfully.

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

- develop products that are safer or more effective than our product candidates;
- obtain FDA and other regulatory approvals or reach the market with their products more rapidly than we can, reducing the potential sales of our product candidates;
- devote greater resources to market or sell their products;
- adapt more quickly to new technologies and scientific advances;
- initiate or withstand substantial price competition more successfully than we can;
- have greater success in recruiting skilled scientific workers from the limited pool of available talent;
- more effectively negotiate third–party licensing and collaboration arrangements; and
- take advantage of acquisition or other opportunities more readily than we can.

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

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

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

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

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

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

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

In addition, we sometimes undertake research and development with respect to potential products even when we are aware of third–party patents that may be relevant to our potential products, on the basis that such patents may be challenged or licensed by us. If our subsequent challenge to such patents were not to prevail,

we may not be able to commercialize our potential products after having already incurred significant expenditures unless we are able to license the intellectual property on commercially reasonable terms. We may not be able to obtain royalty or license agreements on terms acceptable to us, if at all. Even if we were able to obtain licenses to such technology, some licenses may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. Ultimately, we may be unable to commercialize some of our potential products or may have to cease some of our business operations, which could severely harm our business.

We face uncertainties over reimbursement and healthcare reform.

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

ITEM 3. Quantitative and Qualitative Disclosures about Market Risk

In the normal course of business, the financial position of the Company is subject to certain risks, including market risk associated with interest rate movements. The Company regularly assesses these risks and has established policies and business practices designed to mitigate such exposures. The Company invests surplus cash in low-risk debt securities, typically maturing in one year or less, pending use in operations. The Company manages these funds by seeking principal preservation while concurrently enhancing rates of return. The Company's interest income is therefore sensitive to changes in the general level of domestic interest rates. Based on the Company's overall interest rate exposure at September 30, 2001, a near-term change in interest rates would not materially affect the fair value of interest rate sensitive instruments.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

The Company is not a party to any material legal proceedings.

Item 2. Changes in Securities and Use of Proceeds.

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

During the three-month period ended September 30, 2001, holders of options issued under the Company's Restated Stock Option Plan, as amended, exercised their rights to acquire an aggregate of 22,500 shares of common stock at prices ranging from $0.84 per share to $14.75 per share. The total proceeds from these option exercises, $222,267, will be used to fund current operations.

Item 3. Defaults Upon Senior Securities.

Not applicable

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

Not applicable

Item 5. Other Information.

Not applicable

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

(a) Exhibits

None.

(b) Reports on Form 8-K

Form 8-K dated August 31, 2001 – Item 4: Changes in Registrant’s Certifying Accountants

Form 8-K/A dated August 31, 2001 - Item 4: Changes in Registrant’s Certifying Accountants

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 14, 2001

By: /s/ Mitchel Sayare

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

Date: November 14, 2001

By: /s/ Gregg D. Beloff

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