

IMMUNOGEN INC  
Form 10-K/A  
July 28, 2005

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 10-K/A**

**Amendment No. 1**

**ý Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934  
for the Fiscal Year Ended June 30, 2004**

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

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**ImmunoGen, Inc.**

(Exact name of registrant as specified in its charter)

**Massachusetts**  
(State or other jurisdiction  
of incorporation or organization)

**04-2726691**  
(I.R.S. Employer Identification No.)

**128 Sidney Street, Cambridge, MA 02139**

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(Address of principal executive offices, including zip code)

**(617) 995-2500**

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

**None**

Securities registered pursuant to Section 12(g) of the Act:

**Common Stock, \$.01 par value**

(Title of class)

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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

Aggregate market value, based upon the closing sale price of the shares as reported by the Nasdaq National Market, of voting stock held by non-affiliates at December 31, 2003: \$182,533,563 (excludes shares held by executive officers, directors, and beneficial owners of more than 10% of the Company's Common Stock). Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, direct or indirect, to direct or cause the direction of management or policies of the registrant, or that such person is controlled by or under common control with the registrant. Common Stock outstanding at August 18, 2004: 40,789,369 shares.

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the Registrant's Definitive Proxy Statement for its 2004 Annual Meeting of Shareholders are incorporated by reference into Part III of this Report.

**EXPLANATORY NOTE**

This Amendment No. 1 to the Form 10-K for the year ended June 30, 2004 for ImmunoGen, Inc. is being filed solely for the purpose of revising certain information set forth in Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations.

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**Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations**

**Overview**

Since the Company's inception, we have been principally engaged in the development of antibody-based cancer therapeutics and novel treatments in the field of oncology. The combination of our expertise in antibodies and cancer has resulted in the generation of both proprietary product candidates and technologies. Our lead, proprietary, tumor-activated prodrug, or TAP, technology combines extremely potent, small molecule cytotoxic agents 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 the potential to cause only modest damage to healthy tissue. The cytotoxic agent we currently use in our TAP compounds involved in clinical testing is the maytansinoid DM1, a chemical derivative of a naturally occurring substance called maytansine. We also use our expertise in antibodies and cancer to develop other types of therapeutics, such as naked antibody anticancer products.

We have entered into collaborative agreements that allow companies to use our TAP technology to develop commercial product candidates containing their antibodies. We have also used our proprietary TAP technology in conjunction with our in-house antibody expertise to develop our own anticancer product candidates. Under the terms of our collaborative agreements, we are entitled to upfront fees, milestone payments and royalties on any commercial product sales. In July 2003, we announced a discovery, development and commercialization collaboration with Aventis Pharmaceuticals, Inc. Under the terms of the agreement, Aventis gains commercialization rights to three of the most advanced product candidates in our preclinical pipeline and the commercialization rights to certain new product candidates developed during the research program portion of the collaboration. This collaboration allows us to access Aventis' cancer targets and their clinical development and commercialization capabilities. Under the terms of the Aventis agreement, we also are entitled to receive committed research funding of approximately \$50.7 million during the three-year research program. Should Aventis elect to exercise its contractual right to extend the term of the research program, we will receive additional research funding.

Under certain collaborative agreements, we receive our fully burdened cost to manufacture preclinical and clinical materials plus a profit margin. Currently, our collaborative partners include Abgenix, Inc., Aventis, Boehringer Ingelheim International GmbH, Genentech, Inc. and Millennium Pharmaceuticals, Inc. We expect that substantially all of our revenue for the foreseeable future will result from payments under our collaborative arrangements.

In August 2003, British Biotech completed its acquisition of Vernalis. In connection with the acquisition, the merged company, called Vernalis plc, announced that it intended to review its merged product candidate portfolio, including its collaboration with ImmunoGen on huN901-DM1. After discussion with Vernalis, in January 2004, the Company announced that ImmunoGen would take over future development of the product, which will include advancement of huN901-DM1 into a Phase I trial designed to assess its clinical utility in a hematological malignancy, in a study managed by ImmunoGen. Pursuant to the terms of the termination agreement dated January 7, 2004, Vernalis, which relinquished its right to the product candidate, will, at its own expense, complete the Phase I clinical study currently underway. ImmunoGen will be responsible for completion of the U.S. Phase I/II study in the United States and further development of huN901-DM1.

On January 8, 2004, we announced that we intend to advance our lead product candidates, cantuzumab mertansine and huN901-DM1, into clinical trials to assess the clinical utility of the compounds in certain indications. In addition to continuation of the Phase I/II study of huN901-DM1 for SCLC underway in the United States, we plan to initiate a clinical trial of huN901-DM1 in a CD56-positive hematological malignancy in the United States in 2005. We also plan to advance cantuzumab mertansine, or an improved version of the compound, in clinical trials that we expect to begin in 2005. We expect to incur expenses of \$4-6 million over the next 2-3 years related to these clinical trials. Based upon the results of such clinical trials, if and when they are completed, we will evaluate whether to continue clinical development of these compounds, and, if so, whether we will seek a collaborative partner or partners to continue the clinical development and commercialization of

either or both of these compounds.

To date, we have not generated revenues from commercial product sales and we expect to incur significant operating losses over the foreseeable future. We do not anticipate that we will have a commercially approved product within the foreseeable future. Research and development expenses are expected to increase significantly in the near term as we continue our development efforts. As of June 30, 2004, we had approximately \$94.6 million in cash and marketable securities. We anticipate that our current capital resources and future collaboration payments, including the committed research funding due us under the Aventis agreement over the three-year research program, will enable us to meet our operational expenses and capital expenditures for at least the next three to five fiscal years.

We anticipate that the increase in total cash expenditures will be partially offset by collaboration-derived proceeds, including milestone payments and the committed research funding we will receive pursuant to the Aventis collaboration. Accordingly, period-to-period operational results may fluctuate dramatically. We believe that our established collaborative agreements, while subject to specified milestone achievements, will provide funding to assist us in meeting obligations under our collaborative agreements while also allowing for the development of 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.

On May 12, 2004 our Board of Directors terminated, effective immediately, the share repurchase agreement that it originally authorized in August 2002. Between August 2002 and May 2004 our Board of Directors had authorized the open market repurchase of up to 4.1 million shares of ImmunoGen common stock. The repurchases were made at the discretion of management and as market conditions warranted. Through May 12, 2004, the Company had repurchased 3,675,062 shares of its common stock at a total cost of \$11.1 million.

#### *Critical Accounting Policies*

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

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

#### *Revenue Recognition*

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

We recognize the \$12.0 million upfront fee we received from Aventis ratably over our estimated period of significant involvement of five years. This estimated period includes the term of the collaborative

research program and two 12-month extensions that Aventis may exercise. In the event our period of involvement is less than we estimated, the remaining deferred balance of the upfront fee will be recognized over this shorter period.

In January 2004, our shared product license with Vernalis plc terminated. As a result we recognized \$1.5 million of revenue during the year ended June 30, 2004, related to the upfront fee that we received upon signing the original collaboration agreement with Vernalis, which was deferred for accounting purposes.

In February 2003, our full product license with GlaxoSmithKline terminated. During the year ended June 30, 2003, we recognized \$348,000 of revenue related to the GlaxoSmithKline upfront fee that remained in deferred revenue as of the termination date.

### *Inventory*

We review our estimates of the net realizable value of our inventory at each reporting period. Our estimate of the net realizable value of our inventory is subject to judgment and estimation. The actual net realizable value of our inventory could vary significantly from our estimates and could have a material effect on our financial condition and results of operations in any reporting period. We consider any raw material inventory of DM1, or related maytansinoid effector molecules, collectively referred to as DMx, or ansamitocin P3 in excess of 12 months' projected usage that is not supported by collaborators' firm fixed orders to be excess. We record any such raw material identified as excess at its net realizable value. Our estimate of 12 months' usage of DMx and ansamitocin P3 raw material inventory is based upon our collaborators' estimates of their future clinical material requirements. Our collaborators' estimates of their clinical material requirements are based upon expectations of their clinical trials, including the timing, size, dosing schedule and maximum tolerated dose of each clinical trial. Our collaborators' actual requirements for clinical materials may vary significantly from their projections. Significant differences between our collaborators' actual manufacturing orders and their projections could result in our actual 12 months' usage of DMx and ansamitocin P3 varying significantly from our estimated usage at an earlier reporting period. During the year ended June 30, 2004, we recorded as research and development expense \$307,000 of ansamitocin P3 and DMx material that we have identified as excess based upon our inventory policy.

## **Results of Operations**

### *Revenues*

Our total revenues for the year ended June 30, 2004 were \$26.0 million compared with \$7.6 million and \$5.9 million for the years ended June 30, 2003 and 2002, respectively. The \$18.3 million increase in revenues from 2003 to 2004 is primarily attributable to committed research funding earned under our discovery, development and commercialization agreement with Aventis, in addition to higher revenues from license fees and higher clinical materials reimbursement, as discussed below. The \$1.7 million increase in revenues from 2002 to 2003 is primarily attributable to higher license fee and milestone payments received in 2003 as compared to 2002.

Research and development support of \$13.6 million for the year ended June 30, 2004 represents committed research funding earned based on actual resources utilized under our discovery, development and commercialization agreement with Aventis. The agreement provides that we will receive a minimum of \$50.7 million of committed research funding during a three-year research program.



Revenue from license fees and milestone payments for the year ended June 30, 2004 increased \$1.4 million to \$5.5 million from \$4.2 million in the year ended June 30, 2003. Revenue from license fees and milestone payments for the year ended June 30, 2002 was \$1.7 million. The increase in license fees and milestone payments from 2003 to 2004 is primarily attributable to the recognition of \$2.0 million related to the amortization of the \$12.0 million upfront fee received from Aventis. We recognize this upfront payment over our estimated period of significant involvement of 5 years. Also included in license fees and milestone payments for the year ended June 30, 2004, was \$1.75 million of revenue related to our termination agreement with Vernalis which was executed in January 2004. Revenue of \$1.5 million is related to the upfront fee that

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we received upon signing the original collaboration agreement with Vernalis, which was deferred for accounting purposes. The remaining \$250,000 was recognized in June 2004 pursuant to our termination agreement with Vernalis.

Included in license fees and milestone payments for the year ended June 30, 2003 is a \$1.0 million milestone payment from Boehringer Ingelheim related to the initiation of clinical testing of the novel anticancer agent bivatuzumab mertansine and a \$1.0 million milestone from Millennium related to the initiation of clinical testing of MLN2704. In addition, during the year ended June 30, 2003, we recognized collaboration revenue of \$348,000 from GlaxoSmithKline that represents the portion of the upfront payment GlaxoSmithKline had previously paid to ImmunoGen that had not been recognized as revenue at the date of termination of the license agreement. We did not earn any similar milestone payments during the year ended June 30, 2002. Total revenue recognized from license fees and milestone payments from each of our collaborative partners in the years ended June 30, 2004, 2003 and 2002 is included in the following table:

| Collaborative Partner: | Year ended June 30, |                     |                     |
|------------------------|---------------------|---------------------|---------------------|
|                        | 2004                | 2003                | 2002                |
| Abgenix                | \$ 545,829          | \$ 500,000          | \$ 433,318          |
| Aventis                | 2,000,000           |                     |                     |
| Boehringer Ingelheim   | 166,667             | 1,166,667           | 83,334              |
| Genentech              | 642,816             | 642,816             | 691,954             |
| GlaxoSmithKline        |                     | 431,026             | 176,684             |
| Millennium             | 442,529             | 1,442,529           | 331,420             |
| Vernalis               | 1,750,000           |                     |                     |
| <b>Total</b>           | <b>\$ 5,547,841</b> | <b>\$ 4,183,038</b> | <b>\$ 1,716,710</b> |

Deferred revenue of \$21.1 million at June 30, 2004 represents payments received from our collaborators pursuant to our license and supply agreements which we have yet to earn pursuant to our revenue recognition policy.

Clinical materials reimbursement increased \$3.4 million to \$6.6 million in the year ended June 30, 2004 compared to \$3.2 million in the year ended June 30, 2003. We earned clinical materials reimbursement of \$3.5 million during the year ended June 30, 2002. During the years ended June 30, 2004 and 2003, we shipped clinical materials in support of the huN901-DM1, bivatuzumab mertansine, and MLN2704 clinical trials, as well as preclinical materials in support of the development efforts of certain other collaborators. The increase in clinical materials reimbursement in 2004 as compared to 2003 and 2002 is primarily related to the advancement of the clinical trials of bivatuzumab mertansine and MLN2704. Millennium initiated a second clinical trial, a multi-dose Phase I/II study, with its compound MLN2704 during the year ended June 30, 2004. Under certain collaborative agreements, we are reimbursed for our fully burdened cost to produce clinical materials plus a profit margin. The amount of clinical materials reimbursement we earn, and the related cost of clinical materials reimbursed, is directly related to (i) the number of on-going clinical trials for which we are producing clinical material for our collaborators, the speed of enrollment in those trials, the dosage schedule of each clinical trial and the time period, if any, during which patients in the trial receive clinical benefit from the clinical materials, and (ii) our production of clinical grade material on behalf of our collaborators, either in anticipation of clinical trials, or for process development and analytical purposes, respectively. As such, the amount of clinical materials reimbursement and the related cost of clinical materials reimbursed may vary significantly from quarter to quarter and annually.

Development fees decreased approximately \$2,000 from \$275,000 for the year ended June 30, 2003 to \$274,000 for the year ended June 30, 2004. Development fees were \$654,000 in the year ended June 30, 2002. To date, our development fees represent the fully burdened reimbursement of costs incurred in producing research-grade materials in accordance with Good Laboratory Practices and developing antibody-specific conjugation processes on behalf of our collaborators and potential collaborators during the early evaluation and preclinical testing stages of drug development. Development fees decreased in 2004 and 2003 compared to 2002, primarily as a result of the advancement into clinical trials of bivatuzumab mertansine and MLN2704, the products that are the subject of our collaborations with Boehringer Ingelheim



and Millennium, respectively. The amount of development fees we earn is directly related to the number of our collaborators and 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 widely from quarter to quarter and year to year.

*Research and Development Expenses*

We report research and development expense net of certain reimbursements we receive from our collaborators. Our net research and development expenses consist of (i) research to identify and evaluate new targets and to develop and evaluate new antibodies and cytotoxic agents, (ii) preclinical testing and clinical trials of our own, and in certain instances, our collaborators' product candidates, (iii) development to improve clinical and commercial manufacturing processes and (iv) manufacturing operations. During the three fiscal years ended June 30, 2004, our research efforts have been primarily focused in the following areas:

Our activities pursuant to our discovery, development and commercialization agreement with Aventis;

Our contributions to the preclinical and clinical development of huN901-DM1 and cantuzumab mertansine;

Process development improvements related to clinical and commercial production of the huN901 antibody and huN901-DM1 conjugate;

Process improvements related to clinical and commercial production of the huC242 antibody and cantuzumab mertansine;

Process improvements to our TAP technology;

Preclinical development of our own potential products;

Process improvement related to the production of DM1 and related maytansinoid effector molecules and strain development of their precursor, ansamitocin P3;

Operations and , maintenance and expansion of our pilot scale manufacturing plant;

Identification and evaluation of potential antigen targets;

Evaluation of internally developed and in-licensed antibodies; and

Development and evaluation of additional cytotoxic agents.

DM1 is the cytotoxic agent that we currently use in the manufacture of all of our TAP product candidates in clinical testing. We have also investigated the viability of other maytansinoid effector molecules, which, collectively with DM1, we refer to as DMx. In order to make commercial manufacture of DMx conjugates viable, we have devoted substantial resources to improve the strain of the microorganism that produces ansamitocin P3, the precursor to DMx, to enhance manufacturing yields. We also continue to devote considerable resources to improve other DMx manufacturing processes.

On January 8, 2004, we announced that pursuant to the terms and conditions of the termination agreement between Vernalis and ourselves, Vernalis relinquished its rights to develop and commercialize huN901-DM1. As a result, we have regained the rights to develop and commercialize huN901-DM1. Vernalis will complete the Phase I study currently underway, Study 002. Effective July 1, 2004, we assumed responsibility for the weekly-dosing Phase I/II clinical study, Study 001. We expect to take steps to expedite the completion of Study 001. Additionally, we plan to initiate a clinical trial of huN901-DM1 in the United

States for a CD56-positive hematological malignancy. We expect to incur expenses of approximately \$800,000 related to clinical development of this product candidate during fiscal year 2005. We intend to evaluate whether to out license all or part of the development and commercial rights to this compound after the clinical trial process.

In January 2003, we announced that we would regain the development and commercialization rights to cantuzumab mertansine from GlaxoSmithKline, thereby terminating our collaborative agreement. In January 2004, we announced that we plan to advance cantuzumab mertansine, or an improved version of the compound, into a clinical trial that we will manage. We expect that the clinical trial will be initiated in 2005. We estimate that we will incur expenses of approximately \$2.1 million during fiscal year 2005 related to clinical development of this product candidate. We intend to evaluate whether to out license all or part of the development and commercial rights to this compound after the clinical trial process.

As discussed above, we have licensed three of the most advanced product candidates in our preclinical pipeline to Aventis under the terms of our discovery, development and commercialization collaboration. Those three product candidates are a TAP compound for acute myeloid leukemia, an anti-IGF-1R antibody and a TAP compound for certain B-cell malignancies. The TAP compound for acute myeloid leukemia is in preclinical development. We believe that Aventis is on track to file an Investigational New Drug Application (IND) for this TAP compound in the first half of our fiscal year 2005. However, the continued development of the TAP compound for acute myeloid leukemia and the actual filing of this IND are subject to the development and clinical strategy established by Aventis, as well as the results of any and all preclinical studies. As a result, the timing of the filing of this IND, if it occurs at all, may vary from our estimate.

The anti-IGF-1R antibody is a naked antibody directed against a target found on various solid tumors including certain breast, lung and prostate cancers. At June 30, 2004, pursuant to our collaboration research program with Aventis, we continued to perform preclinical experiments to evaluate candidate antibodies and identified a lead antibody product candidate and several alternate product candidates. The third, potential product candidate is directed at certain B-cell malignancies, including non-Hodgkin's lymphoma, 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. Under the terms of our discovery, development and research collaboration with Aventis, they have licensed three of our most advanced preclinical product candidates. With the exception of those antibodies or antibody targets that are the subject of our preexisting or future collaboration and license agreements, during the term of our collaborative research program, we are required to propose for inclusion in the collaborative research program certain antibodies or antibody targets that we believe will have utility in oncology. Aventis then has the right to either include in or exclude from the collaborative research program these proposed antibodies and antibody targets. Furthermore, Aventis may only include a certain number of antibody targets in the research program at any one time. Aventis must therefore exclude any proposed antibody or antibody target in excess of this number. Over the original, three-year term of the research program, we will receive a minimum of \$50.7 million of committed research funding and will devote a significant amount of our internal research and development resources to advancing the research program. Under the terms of the agreement, we may develop any TAP compound, antibody or antibody target that Aventis has elected not to either initially include or later advance in the research program.

The potential product candidates that may eventually be excluded from the Aventis collaboration are in an early stage of discovery research and we are unable to accurately estimate which potential products, if any, will eventually move into our internal preclinical research program. We are unable to reliably estimate the costs to develop these potential products as a result of the uncertainties related to discovery research efforts as well as preclinical and clinical testing. Our decision to move such a product candidate into the clinical development phase is predicated upon the results of preclinical tests. We cannot accurately predict which, if any, potential discovery research stage product candidates will advance from preclinical testing and move into our internal clinical development program. The clinical trial and regulatory approval processes for our product candidates which have advanced or we intend to advance to clinical testing are lengthy.



expensive and uncertain in both timing and outcome. As a result, the pace and timing of the clinical development of our product candidates is highly uncertain and may not ever result in approved products. Completion dates and development costs will vary significantly for each product candidate and are difficult to predict. A variety of factors, many of which are outside our control, could cause or contribute to preventing or delaying successful completion of our clinical trials, or delays in or failure to obtain necessary regulatory approvals. The costs to take a product through clinical trials are 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. Product candidates may be found ineffective or cause harmful side effects during clinical trials, may take longer to progress through clinical trials than anticipated, may fail to receive necessary regulatory approvals or may prove impracticable to manufacture in commercial quantities at reasonable cost or with acceptable quality.

The lengthy process of securing FDA approvals for new drugs requires the expenditure of substantial resources. Any failure by us to obtain, or any delay in obtaining, regulatory approvals would materially adversely affect our product development efforts and our business overall. Accordingly, we cannot currently estimate, with any degree of certainty, the amount of time or money that we will be required to expend in the future on our product candidates prior to their regulatory approval, if such approval is ever granted. As a result of these uncertainties surrounding the timing and outcome of our clinical trials, we are currently unable to estimate when, if ever, our product candidates which have advanced or we intend to advance into clinical testing will generate revenues and cash flows.

Research and development expense for the year ended June 30, 2004 decreased \$1.2 million to \$22.2 million from \$23.4 million for the year ended June 30, 2003. Research and development expense for the year ended June 30, 2002 was \$17.7 million. The number of research and development personnel increased to 116 at June 30, 2004 compared to 94 at June 30, 2003. We had 78 research and development personnel at June 30, 2002. Research and development salaries and related expenses increased by \$1.8 million in the year ended June 30, 2004 compared to the year ended June 30, 2003 and increased by \$2.0 million in the year ended June 30, 2003 compared to the year ended June 30, 2002. Facilities expense also increased by \$1.4 million during the year ended June 30, 2004 as compared to the same period in 2003 and increased \$827,000 in the year ended June 30, 2003 compared to the year ended June 30, 2002 due to an increase in rent for the 128 Sidney Street lease and expenses related to our 2003 expansion at 148 Sidney Street, Cambridge, Massachusetts. We expect future research and development expenses to increase as we continue development of our and our collaborators' product candidates and technologies.

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

| Research and Development         | 2004          | 2003          | 2002          |
|----------------------------------|---------------|---------------|---------------|
| Research                         | \$ 10,546,000 | \$ 8,662,000  | \$ 7,922,000  |
| Preclinical and Clinical Testing | 3,198,000     | 2,505,000     | 1,953,000     |
| Process and Product Development  | 4,907,000     | 4,464,000     | 3,643,000     |
| Manufacturing Operations         | 3,573,000     | 7,798,000     | 4,176,000     |
|                                  | \$ 22,224,000 | \$ 23,429,000 | \$ 17,694,000 |



**Research:** Research includes expenses associated with activities to identify and evaluate new targets and to develop and evaluate new antibodies and cytotoxic agents for our products and in support of our collaborators. Such expenses primarily include personnel, fees to in-license certain technology, facilities and lab supplies. Research expenses increased \$1.9 million to \$10.5 million in 2004 and increased \$740,000 to \$8.7 million in 2003. The increase in research expenses in both 2004 and 2003 was primarily the result of an increase in salaries and related expenses, and an increase in facilities expense. The increase in salaries and related expenses was the result of an increase in personnel to support our own internal as well as our collaborators research projects. Facilities expenses also increased in 2004 and in 2003 due to an increase in rent as well as the renovation of certain laboratory and office space. The increases in 2003 were partially offset by a \$1.1 million decrease in fees to in-license certain technology.

**Preclinical and Clinical Testing:** Preclinical and clinical testing includes expenses related to preclinical testing of our own and, in certain instances, our collaborators product candidates, and the cost our own clinical trials. Such expenses include personnel, patient enrollment at our clinical testing sites, consultant fees, contract services, and facility expenses. Preclinical and clinical testing expenses increased \$693,000 to \$3.2 million in 2004 and \$552,000 to \$2.5 million in 2003. The increase in both periods is substantially due to an increase in salaries and related expense, the result of an increase in personnel to support both our own as well as our collaborators preclinical and clinical activities.

**Process and Product Development:** Process and product development expenses include costs for development of clinical and commercial manufacturing processes. Such expenses include the costs of personnel, contract services and facility expenses. Total development expenses increased \$443,000 to \$4.9 million in 2004 and increased \$821,000 to \$4.5 million in 2003. The increase in 2004 as compared to 2003 is primarily the result of higher salaries and related expenses due to an increase in personnel and higher facilities expense resulting primarily from increased rent and renovation of certain laboratory and office space. These increases were partially offset by a decrease of \$700,000 in contract services substantially related to reduced ansamitocin P3 and DMx process development activity. The increase in 2003 as compared to 2002 was primarily the result of an increase in salaries and related expenses due to an increase in personnel.

**Manufacturing Operations:** Manufacturing operations expense includes costs to manufacture preclinical and clinical materials for our own product candidates and cost to support the operations and maintenance of our pilot scale manufacturing plant. Such expenses include personnel, raw materials for our own preclinical and clinical trials, manufacturing supplies, and facilities expense. A portion of these costs are recorded as Costs of Clinical Materials Reimbursed in our Statement of Operations. Manufacturing operations expense decreased \$4.2 million to \$3.6 million in 2004 and increased \$3.6 million to \$7.8 million in 2003. The decrease in 2004 as compared to 2003 was primarily the result of (i) lower contract service expenses for antibody production, (ii) higher reimbursement amounts for the manufacture of clinical materials on behalf of our collaborators, (iii) a decrease in expenses to reserve for excess quantities of ansamitocin P3 and DMx in accordance with our inventory reserve policy and (iv) partially offset by an increase in salaries and related expenses. The increase in 2003 as compared to 2002 was primarily the result of (i) higher contract service expenses for antibody production, (ii) lower reimbursement amounts for the manufacture of clinical materials on behalf of our collaborators, (iii) an increase in salaries and related expenses and (iv) partially offset by a decrease of inventory amounts written off.

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Antibody purchased in anticipation of potential future clinical trials was \$1.2 million in 2004 compared to \$3.4 million in 2003 resulting in lower contract services in 2004, as noted above. There were no

similar amounts in the year ended June 30, 2002 resulting in higher contract services in 2003, as noted above. Approximately \$818,000 of the antibody expense during 2004 and \$531,000 of the antibody expense during both 2003 and 2002, related to the purchase of antibody in support of one of the preclinical product candidates that was licensed by Aventis. We expect to receive reimbursement of the total \$1.3 million amount from Aventis, as discussed below in Other Income. The process of antibody production is lengthy as is the lead time to establish a satisfactory production process at a vendor. Accordingly, amounts incurred related to antibody production have fluctuated from period to period and we expect that these period fluctuations will continue in the future.

During 2004 and 2003 we recorded research and development expenses of \$307,000 and \$1.7 million, respectively, related to ansamitocin P3 and DMx inventory that we have identified as excess based upon the Company's inventory policy. The lower write off of inventory in 2004 as compared to 2003 contributed to the decrease in manufacturing operations expense, as noted above. In 2002, we recorded charges of \$1.5 million and \$753,000 to reduce the value of cantuzumab mertansine inventory and huN901 prepaid assets and inventory, respectively, to their net realizable value. The higher write off in 2002 as compared to 2003 partially offset the increase in manufacturing operations in 2003, as noted above.

#### *General and Administrative Expenses*

General and administrative expense for the year ended June 30, 2004 increased \$674,000 to \$6.6 million from \$6.0 million for the year ended June 30, 2003. General and administrative expenses for the year ended June 30, 2002 were \$5.4 million. There was an increase of approximately \$412,000 in salary and related expenses in 2004 compared to 2003. This increase in salaries and related expenses was substantially related to \$477,000 of bonuses awarded by the Board of Directors as compared to \$64,000 in bonuses awarded by the Board of Directors in the same period in the prior year. Insurance costs increased by \$163,000 in 2004 as a result of increased premiums. Recruiting fees of approximately \$260,000 were incurred during the year ended June 30, 2004 related to our efforts to appoint a new director to our Board and to fill various open positions within the general and administrative functions as compared to \$1,000 of similar fees in the year ended June 30, 2003. Offsetting these increases was a payment of \$400,000 for the settlement of a legal claim asserted against the Company that was included in the general and administrative expense for the year ended June 30, 2003. The 10% increase in general and administrative expense from 2002 to 2003 was primarily due to this legal settlement payment made during 2003. In addition, facilities expense increased by \$302,000 due to an increase in rent for the 128 Sidney Street lease and expenses related to our new location at 148 Sidney Street, Cambridge, Massachusetts. Included in general and administrative expense during the year ended June 30, 2002 is \$209,000 related to a valuation allowance established to record cantuzumab mertansine inventory at its net realizable value.

#### *Interest Income*

Interest income for the year ended June 30, 2004 decreased \$1.3 million to \$1.4 million from \$2.7 million for the year ended June 30, 2003. Interest income for the year ended June 30, 2002 was \$5.1 million. The decline in interest income from 2003 to 2004 and from 2002 to 2003 is, in each case, attributable to a lower average cash and investments balance combined with lower rates of return.

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

Net realized (losses) gains on investments were \$(58,000), \$540,000, and \$945,000 for the years ended June 30, 2004, 2003, and 2002, respectively. The decrease in net realized gains is attributable to the timing of investment sales.

*Other Income*

Other income for the year ended June 30, 2004 decreased \$42,000, as compared to the year ended June 30, 2003. During the year ended June 30, 2004, we recorded as other income reimbursement of

approximately \$1.3 million from Aventis for the GMP production of antibody manufactured by BioInvent pursuant to its agreement with ImmunoGen and delivered during May 2004. Included in other income during the year ended June 30, 2003 is \$1.4 million, which represents the net gain on the final financial settlement of the GlaxoSmithKline collaboration. Other income for the year ended June 30, 2002 was \$53,000.

## Liquidity and Capital Resources

|                                 | June 30, |         |            |
|---------------------------------|----------|---------|------------|
|                                 | 2004     |         | 2003       |
| Cash and short-term investments | \$       | 94,610  | \$ 101,273 |
| Working capital                 |          | 101,302 | 102,956    |
| Stockholders' equity            |          | 97,137  | 102,679    |

### Cash Flows

We require cash to fund our operating expenses, including advancement of our clinical programs, and to make capital expenditures. Historically, we have funded our cash requirements primarily through equity financings in public markets and payments from our collaborators, including equity investments, license fees, milestone payments and research funding. As of June 30, 2004, we had approximately \$94.6 million in cash and short-term investments. Net cash used in operations during the year ended June 30, 2004 was \$5.0 million compared to net cash used in operations of \$21.9 million in the year ended June 30, 2003. The principal use of cash in operating activities for all periods presented was to fund our net loss. The decrease in operational cash use from 2003 to 2004 is substantially due to amounts received from Aventis, including the \$12.0 million upfront fee received in August 2003 and \$9.4 million of the \$13.6 million of committed research funding we earned during the year ended June 30, 2004. We received \$2.0 million in license fees and milestone payments during the year ended June 30, 2003. Net cash used in operations during the year ended June 30, 2002 was \$16.0 million. The increase in operational cash use in 2003 compared to 2002 was largely due to the increase in operating expenses as well as the increase in clinical materials inventory produced on behalf of our collaborators.

Net cash provided by investing activities was \$1.1 million and \$26.8 million for the years ended June 30, 2004 and 2003, respectively, and primarily represents the sales and maturities of marketable securities. Net cash used in investing activities was \$11.3 million for the year ended June 30, 2002. Capital purchases were \$2.0 million and \$3.7 million for the fiscal years ended June 30, 2004 and 2003, respectively, and consisted primarily of costs associated with the build-out of our existing development and pilot scale manufacturing facility located in Norwood, Massachusetts, and the renovation of our new laboratory and office facility at 148 Sidney Street, Cambridge, Massachusetts.

Net cash provided by financing activities was \$599,000 for the year ended June 30, 2004. Net cash used for financing activities was \$11.1 million for the year ended June 30, 2003 versus \$6.1 million provided by financing activities for the year ended June 30, 2002. For the year ended June 30, 2004, net cash provided by financing activities includes proceeds from the exercise of 194,392 stock options. For the year ended June 30, 2003, net cash used for financing activities includes the repurchase of 3,675,062 shares of common stock for \$11.1 million offset by proceeds from the exercise of 2,375 stock options. For the year ended June 30, 2002, net cash provided by financing activities includes proceeds from the exercise of 1,279,422 warrants and 150,336 stock options.

We anticipate that our current capital resources and future collaborator payments, including committed research funding that we expect to receive from Aventis pursuant to the terms of our collaboration agreement, will enable us to meet our operational expenses and capital expenditures for at least the next three to five fiscal years. We believe that our existing capital resources 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 provide assurance

that such collaborative agreement funding will, in fact, be realized. Should we not meet some or all of the terms and conditions of our various

collaboration agreements, we may be required to pursue additional strategic partners, secure alternative financing arrangements, and/or defer or limit some or all of our research, development and/or clinical projects.

*Contractual Obligations*

Below is a table that presents our contractual obligations and commercial commitments as of June 30, 2004:

|                                    | Total         | Payments Due by Period |              |              |                   |
|------------------------------------|---------------|------------------------|--------------|--------------|-------------------|
|                                    |               | Less than One Year     | 1-3 Years    | 4-5 Years    | More than 5 Years |
| Operating lease obligations        | \$ 13,690,367 | \$ 3,116,044           | \$ 8,944,023 | \$ 1,397,400 | \$ 232,900        |
| Unconditional Purchase Obligations | \$ 2,440,000  | 2,440,000              |              |              |                   |
| Total                              | \$ 16,130,367 | \$ 5,556,044           | \$ 8,944,023 | \$ 1,397,400 | \$ 232,900        |

In addition to the above, we have committed to make potential future milestone payments to a third party as part of an in-licensing arrangement. Payments under this arrangement generally become due and payable only upon achievement of certain developmental, regulatory and/or commercial milestones. Because the achievement of these milestones is neither probable nor reasonably estimable, such contingencies have not been included in the table above.

**Certain Factors That May Affect Future Results of Operations**

This report contains certain forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. Such statements are based on our current expectations and are subject to a number of factors and uncertainties which could cause actual results to differ materially from those described in the forward-looking statements. We caution investors that there can be no assurance that actual results or business conditions will not differ materially from those projected or suggested in such forward-looking statements as a result of various factors, including, but not limited to, the following: the success of our and our collaborators' research and clinical development processes; the difficulties inherent in the development of pharmaceuticals, including uncertainties as to the timing, expense and results of preclinical studies and clinical trials; our dependence upon existing and potential collaborative partners; uncertainty as to whether our TAP compounds or those of our collaborators will succeed in entering human clinical trials and uncertainty as to the results of such trials; the risk that our and/or our collaborators may not be able to obtain regulatory approvals necessary to commercialize product candidates; the potential development by competitors of competing products and technologies; uncertainty whether our TAP technology will produce safe, effective and commercially viable products; the lack of assurance regarding patent and other protection for our proprietary technology; governmental regulation of our activities, facilities, products and personnel; the dependence on key personnel; uncertainties as to the extent of reimbursement for the costs of our potential products and related treatments by government and private health insurers and other organizations; the potential adverse impact of government-directed health care reform; the risk of product liability claims; and economic conditions, both generally and those specifically related to the biotechnology industry. As a result, our future development efforts involve a high degree of risk. For further information, refer to the more specific risks and uncertainties discussed throughout this Annual Report on Form 10-K.

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Amendment No. 1 to Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

**IMMUNOGEN, INC.**

/s/ Mitchel Sayare

**Mitchel Sayare**  
***Chairman of the Board and***  
***Chief Executive Officer***

By:

Dated: July 27, 2005