

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

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

Washington, D.C. 20549

**FORM 10-Q/A**

Amendment No. 1

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

For the quarterly period ended December 31, 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

**ImmunoGen, Inc.**

Massachusetts  
(State or other jurisdiction of incorporation or  
organization)

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

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**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

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

Yes  No

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

Shares of common stock, par value \$.01 per share 40,853,385 shares outstanding as of February 7, 2005

**EXPLANATORY NOTE**

This Amendment No. 1 to the Form 10-Q for the quarterly period ended December 31, 2004 is being filed solely for the purpose of revising certain information set forth in Item 2, Management's Discussion and Analysis of Financial Condition and Results of Operations.

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

**OVERVIEW**

Since the Company's inception, we have been principally engaged in the development of antibody-based anticancer 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 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 technology uses the antibody to deliver the cytotoxic agent specifically to cancer cells, and the cytotoxic agent is used to kill the cancer cell. Currently, the cytotoxic agent used in each TAP in preclinical or clinical testing is either DM1 or DM4 (collectively DMx), derivatives of a naturally occurring substance called maytansine. We also use our expertise in antibodies and cancer to develop other types of therapeutics, such as naked antibody anticancer products.

We have entered into collaborative agreements that allow companies to use our TAP technology to develop commercial products containing their antibodies and our cytotoxic agents. We have also used our 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 the commercial sales of any resultant product. In July 2003, we announced a discovery, development and commercialization collaboration with Aventis Pharmaceuticals, Inc. Under the terms of the agreement, Aventis gained commercialization rights to three compounds that were in our preclinical pipeline and commercialization rights to certain new products developed during the research program portion of the collaboration. This collaboration allows us to access Aventis' cancer targets and their clinical development and commercialization capabilities. 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. In August 2004, Aventis completed its merger with Sanofi-Synthelabo; it is now sanofi-aventis. We do not know yet what effect, if any, the merger will have on our relationship with sanofi-aventis.

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., Biogen Idec, Boehringer Ingelheim International GmbH, Centocor, Inc., Genentech, Inc., Millennium Pharmaceuticals, Inc., and sanofi-aventis. We expect that substantially all of our revenue for the foreseeable future will result from payments under our collaborative arrangements.

To date, we have not generated revenues from commercial product sales and we expect to incur significant operating losses over the foreseeable future. As of December 31, 2004, we had approximately \$93.3 million in cash and marketable securities. We anticipate that our current capital resources and future collaboration payments, including the committed research funding due to us under the sanofi-aventis agreement over the remainder of the three-year research program, will enable us to meet our operational and capital expenditures for at least the next three to five fiscal years.

We anticipate that the increase in our total cash expenditures will be partially offset by collaboration-derived proceeds including milestone payments and the committed research funding we will receive pursuant to the sanofi-aventis collaboration. Accordingly, period-to-period operational results may fluctuate dramatically. We believe that our established collaborative agreements, while subject to specified milestone achievements, will provide funding to assist us in meeting obligations under our collaborative agreements while also allowing for the development of our own product candidates and technologies. However, we can give no assurances that such collaborative agreement funding will, in fact, be realized. Should we or our partners not meet some or all of the terms and conditions of our various collaboration agreements, we may be required to pursue additional strategic partners, secure alternative financing arrangements, and/or defer or limit some or all of our research, development and/or clinical projects.



*Critical Accounting Policies*

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

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

*Revenue Recognition*

We estimate the period of our significant involvement during development for each of our collaborative agreements. We recognize any upfront fees received from our collaborators ratably over this estimated period of significant involvement. We generally believe our period of significant involvement occurs between the date we sign a collaboration agreement and projected FDA approval of our collaborators' 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 million upfront fee we received from sanofi -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 sanofi-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.

*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 quantities of DM1 and DM4, 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 fully reserve any such material identified as excess with a corresponding charge to research and development expense. Our estimate of 12 months' usage of DMx and ansamitocin P3 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 six months ended December 31, 2004, we recorded as research and development expense \$980,000 of ansamitocin P3 and DMx that we have identified as excess based upon our inventory policy, and \$185,000 to write down certain ansamitocin P3 and DMx batches to their net realizable value.



**RESULTS OF OPERATIONS***Comparison of Three Months ended December 31, 2004 and 2003**Revenues*

Our total revenues for the three months ended December 31, 2004 were \$9.0 million compared with \$5.2 million for the three months ended December 31, 2003. The \$3.9 million increase in revenues in the quarter ended December 31, 2004 compared to the same period in the prior year is primarily attributable to higher clinical materials reimbursement, as well as an increase in research and development support revenue and development fees.

Research and development support revenue was \$4.1 million and \$3.9 million in the three months ended December 31, 2004 and 2003, respectively. These amounts represent committed research funding earned based on actual resources utilized under our discovery, development and commercialization agreement with sanofi-aventis. The agreement provides that we will receive a minimum of \$50.7 million of committed research funding during a three-year research program. We entered into the agreement with sanofi-aventis in July 2003; initiation of the committed research funding began September 1, 2003.

Revenues from license and milestone fees for the three months ended December 31, 2004 decreased \$17,000 from \$1.1 million in the three month period ended December 31, 2003 to \$1.0 million in the same period ended December 31, 2004. Total revenue from license and milestone fees recognized from each of our collaborative partners in the three month periods ended December 31, 2004 and 2003 is included in the following table:

	<b>Three months ended December</b>	
	<b>31,</b>	
	<b>2004</b>	<b>2003</b>
<b>Collaborative Partner:</b>		
Sanofi-aventis	\$ 600,000	\$ 600,000
Genentech	160,704	160,704
Abgenix	120,833	137,500
Millennium	110,635	110,636
Boehringer Ingelheim	41,667	41,667
<b>Total</b>	<b>\$ 1,033,839</b>	<b>\$ 1,050,507</b>

Deferred revenue of \$18.1 million as of December 31, 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 \$3.6 million in the three months ended December 31, 2004, compared to \$227,000 in the three months ended December 31, 2003. During the three months ended December 31, 2004, we shipped clinical materials in support of bivatuzumab mertansine and MLN2704 clinical trials as well as preclinical materials in support of the development efforts of other collaborators. The increase in clinical materials reimbursement in the three months ended December 31, 2004 as compared to the three months ended December 31, 2003 is primarily related to the advancement of the clinical trials of bivatuzumab mertansine and MLN2704. In addition,

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during the three months ended December 31, 2004, we shipped and released one clinical batch of an anti-CD33 TAP compound to sanofi-aventis. The cost of clinical materials reimbursed for the three months ended December 31, 2004 and 2003 was \$3.0 million and \$227,000, respectively. Under certain collaborative agreements, we are reimbursed for our fully burdened cost to produce clinical materials plus a profit margin. The amount of clinical materials reimbursement we earn, and the related cost of clinical materials reimbursed, are directly related to the number of on-going clinical trials for which we are producing clinical material for our collaborators, the speed of enrollment in those trials, 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 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 from quarter to quarter and year to year.

We had development fees of \$310,000 in the three months ended December 31, 2004 compared to none during the same period in 2003. Development fees represent the fully burdened reimbursement of costs incurred in producing research-grade materials and developing antibody-specific conjugation processes on behalf of our collaborators during the early evaluation and preclinical testing stages of product development. The amount of development fees we earn is directly related to the number of our collaborators or potential collaborators, the stage of development of our collaborators' products and the resources our collaborators allocate to the development effort. As such, the amount of development fees may vary from quarter to quarter and year to year.

*Research and Development Expenses*

We report research and development expense net of certain reimbursements we receive from our collaborators that do not qualify as revenue under the guidelines of EITF 99-19, Reporting Revenue Gross as Principal versus Net as an Agent. 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 of our own and, in certain instances, preclinical testing of our collaborators' product candidates and the cost of our own clinical trials, (iii) development related to clinical and commercial manufacturing processes and (iv) manufacturing operations. Our research efforts are primarily focused in the following areas:

Our activities pursuant to our discovery, development and commercialization agreement with sanofi-aventis;

Our contributions to the preclinical and clinical development of huN901-DM1 and huC242-DM4;

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

Process development related to clinical and commercial production of the huC242 antibody and huC242-DM4 conjugate;

Process improvement related to the production of DM1, DM4 and related maytansinoid cytotoxic agents and strain development of their precursor, ansamitocin P3;

Operations and maintenance of our pilot scale manufacturing plant;

Process improvements to our TAP technology;

Identification and evaluation of potential antigen targets;

Evaluation of internally-developed and in-licensed antibodies; and

Development and evaluation of additional cytotoxic agents.

Our TAP technology involves the attachment of a highly potent cell-killing agent to antibodies that target cancer cells to achieve targeted killing of cancer cells. The cytotoxic agents we currently use in the manufacture of our collaborators' and our own conjugates are made from a precursor compound, ansamitocin P3, which is produced by fermentation. We have devoted substantial resources to improve the strain of the microorganism that produces ansamitocin P3 to enhance manufacturing yields and expect to continue to devote considerable resources to improve further the manufacturing processes for our effector molecules.

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 regained the rights to develop and commercialize huN901-DM1. Vernalis agreed to complete the Study 002 Phase I study that was initiated in the United Kingdom by its predecessor, British Biotech. Effective July 1, 2004, we assumed responsibility for the weekly dosing Phase I/II clinical study, Study 001. We are currently taking steps to expedite the patient enrollment in Study 001. Additionally, we currently plan to initiate a clinical trial of huN901-DM1 in the United States for a CD56-positive hematological malignancy, specifically multiple myeloma. We expect to incur external expenses of approximately \$400,000 related to clinical development of this product during the remainder of the current fiscal year. During the six months ended December 31, 2004, we have incurred approximately \$100,000 of external costs related to 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 is completed.

On January 2004, we announced our intention to advance cantuzumab mertansine, or a modified version of the compound, into a clinical trial that we plan to manage. In October 2004 we decided to move forward with a modified version of cantuzumab mertansine called huC242-DM4. We currently expect that a Phase I clinical trial will be initiated with huC242-DM4 in the calendar year 2005. We estimate that we will incur external expenses of approximately \$1.5 million during the remainder of the current fiscal year related to clinical development of this product candidate. During the six months ended December 31, 2004, we have incurred approximately \$500,000 in external costs related to 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 is completed.

We licensed our three most advanced preclinical product candidates to sanofi-aventis in 2003 under the terms of our discovery, development, and commercialization collaboration. These three product candidates are an anti-CD33 TAP compound for acute myeloid leukemia, an anti-IGF-1R antibody and a TAP compound for certain B-cell malignancies. During the quarter, sanofi-aventis filed an Investigational New Drug Application (IND) for the anti-CD33 TAP compound. We currently expect sanofi-aventis to initiate clinical testing of the anti-CD33 TAP compound in the near future.

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, as well as some hematological malignancies. At December 31, 2004, pursuant to our collaboration research program with sanofi-aventis, we continued to perform preclinical experiments to evaluate candidate antibodies, 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.

The cost to develop new products to the IND stage can be significant. Under the terms of our discovery, development and commercialization collaboration with sanofi-aventis, they licensed three of our most advanced preclinical product candidates. With the exception of those antibodies or antibody targets that are the subject of our preexisting or future collaboration and license agreements, during the term of our collaborative research program, we are required to propose for inclusion in the collaborative research program certain antibody or antibody targets that we believe will have utility in oncology. Sanofi-aventis then has the right to either include in or exclude from the collaborative research program these proposed antibodies and antibody targets. Sanofi-aventis may only include a certain number of antibody targets in the research program at any one time. Sanofi-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 collaborative research program. Under the terms of the agreement, we may advance any TAP compound, antibody or antibody target that sanofi-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 sanofi-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 a product candidate into the clinical development phase is predicated upon the results of preclinical tests. We cannot accurately predict which, if any, of the discovery research stage product candidates will advance from preclinical testing and move into our internal clinical development program. The 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 the prevention or delay of the successful completion of our clinical trials, or delay 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 or delay by us to obtain 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 expenses for the three months ended December 31, 2004 increased \$1.4 million to \$6.6 million from \$5.2 million for the three months ended December 31, 2003. The number of research and development personnel increased to 133 at December 31, 2004 compared to 99 at December 31, 2003. As a result, research and development compensation and benefits increased by \$1.1 million in the three months ended December 31, 2004 compared to the three months ended December 31, 2003. In addition, during the three months ended December 31, 2004, facilities expense increased \$236,000 as compared to the same period in the prior year. The increase in facilities expense is of the result of placing into service two manufacturing suites in September and October 2004.

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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.

	<b>Three Months Ended December 31,</b>	
	<b>2004</b>	<b>2003</b>
Research	\$ 3,582,000	\$ 2,520,000
Preclinical and Clinical Testing	1,321,000	697,000
Process and Product Development	1,036,000	882,000
Manufacturing Operations	678,000	1,096,000
<b>Total Research and Development Expense</b>	<b>\$ 6,617,000</b>	<b>\$ 5,195,000</b>

**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. For the three months ended December 31, 2004, research expenses increased \$1.1 million to \$3.6 million, compared to \$2.5 million in the three months ended December 31, 2003. The increase in research expenses for the period was primarily the result of an increase in salaries and related expense and an increase in contract services for the production of research materials. The increase in salaries and related expenses was the result of an increase in personnel to support the sanofi-aventis collaboration.

**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 of our own clinical trials. Such expenses include personnel, patient enrollment at our clinical testing sites, consultant fees, contract services, and facility expenses. For the three months ended December 31, 2004, preclinical and clinical testing expenses increased \$623,000 to \$1.3 million, compared to \$697,000 in the three months ended December 31, 2003. This increase in preclinical and clinical testing expense is substantially due to an increase in salaries and related expense and contract services expense. These increase in salaries and related expenses is the result of an increase in personnel to support both our own as well as our collaborators' preclinical and clinical activities. Contract services increased \$200,000 as a result of an increase in certain preclinical studies related to our own product candidates.

**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. For the three months ended December 31, 2004, total development expenses increased \$155,000 to \$1.0 million, compared to \$ 882,000 for the three months ended December 21, 2003. This increase is primarily attributable to an increase in salaries and related expenses.

**Manufacturing Operations:** Manufacturing operations expense includes costs to manufacture preclinical and clinical materials for our own product candidates and costs 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. For the three months ended December 31, 2004, manufacturing operations expense decreased \$418,000 to \$678,000 compared to \$1.1 million for the three months ended December 31, 2003. The decrease for the current three-month period compared to the same period in the prior year was primarily the result of higher reimbursement amounts for the manufacture of clinical materials on behalf of our collaborators and lower contract service expenses for antibody production. This decrease was partially offset by higher salaries and related expenses and higher facility expenses.

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Antibody purchased in anticipation of potential future clinical trials was \$240,000 during the quarter ended December 31, 2004, compared to \$380,000 during the quarter ended December 31, 2003, resulting in lower contract services, as noted above. 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.

### General and Administrative Expenses

General and administrative expenses for the three months ended December 31, 2004 increased \$622,000 to \$2.0 million from \$1.4 million for the three months ended December 31, 2003. The increase was substantially the result of hiring additional staff. The number of general and administrative personnel increased to 22 at December 31, 2004 compared to 15 at December 31, 2003. As a result, general and administrative compensation and benefits expense increased by \$399,000 in the three months ended December 31, 2004 compared to the three months ended December 31, 2003. Related to the increase in personnel, recruiting fees increased \$61,000 during the three month period ended December 31, 2004 compared to the same period in the prior year. In addition, professional fees increased \$100,000 during the three months ended December 31, 2004 due to consulting work performed related to Sarbanes Oxley Section 404 compliance.

### *Interest Income*

Interest income for the three months ended December 31, 2004 increased \$104,000 to \$457,000 from \$353,000 for the three months ended December 31, 2003. The difference is due to higher rates of return resulting from improved market conditions.

### *Net Realized Losses on Investments*

Net realized losses on investments were \$1,000 and \$36,000 for the three months ended December 31, 2004 and 2003, respectively. The difference is attributable to market conditions and the timing of investment sales.

### ***Comparison of Six Months ended December 31, 2004 and 2003***

#### *Revenues*

Our total revenues for the six months ended December 31, 2004 were \$18.1 million compared with \$9.1 million for the six months ended December 31, 2003. The \$9.0 million increase in revenues in the six months ended December 31, 2004 compared to the same period in the prior year is primarily attributable to an increase in committed research funding earned under our discovery, development and commercialization agreement with sanofi-aventis, and increased clinical materials reimbursement revenue.



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Research and development support revenue was \$8.2 million and \$5.1 million in the six months ended December 31, 2004 and 2003, respectively. These amounts represent committed research funding earned based on actual resources utilized under our discovery, development and commercialization agreement with sanofi-aventis. The agreement provides that we will receive a minimum of \$50.7 million of committed research funding during a three-year research program. We entered into the agreement with sanofi-aventis in July 2003. However, no resources were utilized under the agreement until September 2003.

Revenues from license and milestone fees for the six months ended December 31, 2004 increased \$879,000 to \$2.6 million in the six month period ended December 31, 2004 compared to \$1.7 million in the six month period ended December 31, 2003. Total revenue from license and milestone fees recognized from each of our collaborative partners in the six month periods ended December 31, 2004 and 2003 is included in the following table:

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	Six months ended December 31,	
	2004	2003
<b>Collaborative Partner:</b>		
Sanofi-aventis	\$ 1,700,000	\$ 800,000
Genentech	321,408	321,408
Abgenix	250,000	270,834
Millennium	221,269	221,257
Boehringer Ingelheim	83,334	83,334
<b>Total</b>	<b>\$ 2,576,011</b>	<b>\$ 1,696,833</b>

Clinical materials reimbursement increased \$4.3 million to \$6.5 million in the six months ended December 31, 2004, compared to \$2.2 million in the six months ended December 31, 2003. During the six months ended December 31, 2004, we shipped clinical materials in support of bivatuzumab mertansine and MLN2704 clinical trials as well as preclinical materials in support of the development efforts of other collaborators. The increase in clinical materials reimbursement in the six months ended December 31, 2004 as compared to the six months ended December 31, 2003 is primarily related to the advancement of the clinical trials of bivatuzumab mertansine and MLN2704. In addition, during the six months ended December 31, 2004, we shipped and released one clinical batch of AVE9633 to sanofi-aventis in addition to material produced for sanofi -aventis for preclinical purposes. The cost of clinical materials reimbursed for the three months ended December 31, 2004 and 2003 was \$5.5 million and \$2.0 million, respectively. Under certain collaborative agreements, we are reimbursed for our fully burdened cost to produce clinical materials plus a profit margin. The amount of clinical materials reimbursement we earn, and the related cost of clinical materials reimbursed, is directly related to (i) the number of on-going clinical trials for which we are producing clinical material for our collaborators, the speed of enrollment in those trials, the dosage schedule of each clinical trial and the time period, if any, during which patients in the trial receive clinical benefit from the clinical materials, and (ii) our production of clinical grade material on behalf of our collaborators, either in anticipation of clinical trials, or for process development and analytical purposes. As such, the amount of clinical materials reimbursement and the related cost of clinical materials reimbursed may vary from quarter to quarter and annually.

We had development fees of \$820,000 in the six months ended December 31, 2004 compared to \$87,000 during the same period in 2003. Development fees represent the fully burdened reimbursement of costs incurred in producing research-grade materials and developing antibody-specific conjugation processes on behalf of our collaborators and potential collaborators during the early evaluation and preclinical testing stages of product development. The amount of development fees we earn is directly related to the number of our collaborators or potential collaborators, the stage of development of our collaborators' products and the resources our collaborators allocate to the development effort. As such, the amount of development fees may vary from quarter to quarter and annually.

*Research and Development Expenses*

Research and development expenses for the six months ended December 31, 2004 increased \$4.5 million to \$14.5 million from \$10.0 million for the six months ended December 31, 2003. The number of research and development personnel increased to 133 at December 31, 2004 compared to 99 at December 31, 2003. As a result, research and development compensation and benefits increased by \$1.6 million in the six months ended December 31, 2004 compared to the six months ended December 31, 2003. Facility expenses increased \$579,000 due to the addition of two manufacturing suites that were placed into service in September and October 2004 as well as expense associated with the expansion of certain laboratory space that was completed in the first half of fiscal 2004.

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.



	Six Months Ended December 31,	
	2004	2003
Research	\$ 6,382,000	\$ 5,057,000
Preclinical and Clinical Testing	2,460,000	1,400,000
Process and Product Development	2,373,000	1,734,000
Manufacturing Operations	3,257,000	1,775,000
Total Research and Development Expense	\$ 14,472,000	\$ 9,966,000

**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. For the six months ended December 31, 2004, research expenses increased \$1.3 million to \$6.4 million, compared to \$5.1 million in the six months ended December 31, 2003. The increase in research expenses for the period was primarily the result of increases in salaries and related expenses, facilities expense and an increase in contract services for the production of research materials. The increase in salaries and related expenses is the result of an increase in personnel to support our collaboration with sanofi aventis.

**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. For the six months ended December 31, 2004, preclinical and clinical testing expenses increased \$437,000 to \$2.5 million, compared to \$1.4 million in the six months ended December 31, 2003. This increase in preclinical and clinical testing expense is substantially due to increases in salaries and related expense and an increase in contract services. The increase in salaries and related expense is the result of an increase in personnel to support our own clinical activities. The increase in contract services is a result of an increase in certain preclinical studies related to our own product candidates.

**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. For the six months ended December 31, 2004, total development expenses increased \$639,000 to \$2.4 million, compared to \$1.7 million for the six months ended December 21, 2003. This increase is primarily attributable to an increase in salaries and related expenses as well as an increase in facilities expense.

**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. For the six months ended December 31, 2004, manufacturing operations expense increased \$1.5 million to \$3.3 million, compared to \$1.8 million for the six months ended December 31, 2003. The increase in expense for the current six month period compared to the same period in the prior year was primarily the result of increases in (i) salaries and related expenses,(ii) facilities expense and manufacturing supplies

and (iii) an increase in expenses to reserve for excess quantities of ansamitocin P3 and DMx in accordance with our inventory reserve policy . These increases were partially offset by an increase in reimbursement amounts for the manufacture of clinical materials on behalf of our collaborators.

During the six months ended December 31, 2004, we recorded as expense \$980,000 of ansamitocin P3 and DMx that we have identified as excess based upon our inventory policy. During the same period in the prior year, we recorded only \$20,000 in similar expenses. The higher write-off in 2004 as compared to 2003 contributed to the increase in other manufacturing operations expense in 2004, as noted above.

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Reserve requirements for excess quantities of P3 and DMx are principally determined based on our collaborators' forecasted demand compared to our inventory position. Due to the lead times required to secure material and the changing requirements of our collaborators, expenses to provide for excess quantities have fluctuated from period to period and we expect that these period fluctuations will continue in the future. (See Inventory within our Critical Accounting Policies for future discussion of our inventory reserve policy).

### *General and Administrative Expenses*

General and administrative expenses for the six months ended December 31, 2004 increased \$281,000 to \$3.5 million from \$3.2 million for the six months ended December 31, 2003. General and administrative compensation and benefits expense increased by \$321,000 in the six months ended December 31, 2004 compared to the six months ended December 31, 2003 as a result of hiring additional staff. The number of general and administrative personnel increased to 22 at December 31, 2004 compared to 15 at December 31, 2003.

### *Interest Income*

Interest income for the six months ended December 31, 2004 increased \$88,000 to \$821,000 from \$733,000 for the six months ended December 31, 2003. The difference is due to higher rates of return resulting from improved market conditions.

### *Net Realized Losses on Investments*

Net realized losses on investments were \$4,000 and \$57,000 for the six months ended December 31, 2004 and 2003, respectively. The difference is attributable to market conditions and the timing of investment sales.

## **LIQUIDITY AND CAPITAL RESOURCES**

We require cash to fund our operating expenses, including the conduct 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 December 31, 2004, we had approximately \$93.3 million in cash and marketable securities. Net cash used for operations during the six months ended December 31, 2004 was \$62,000 compared to net cash provided by operations of \$639,000 during the six months ended December 31, 2003. This decrease in operational cash in fiscal 2005 is a result of the upfront fee of \$12.0 million received in August 2003 pursuant to the terms of the sanofi-aventis collaboration, offset by higher working capital requirements in the six months ended December 31, 2003 compared to the same period in the current year.

Net cash provided by investing activities during the six months ended December 31, 2004 was \$129,000 compared to net cash used for investing activities of \$1.3 million during the six months ended December 31, 2003. Cash flows from investing activities in the six months ended December 31, 2004 and 2003 primarily reflects the proceeds of sales and maturities of marketable securities, purchases of marketable securities and capital expenditures. In the six months ended December 31, 2003, purchases of marketable securities include the investment of the sanofi-aventis upfront payment in marketable securities. Capital expenditures were \$1.2 million for both six month periods ended December 31,

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2004 and 2003. Capital expenditures for the six months ended December 31, 2004 consisted primarily of machinery and equipment for the build-out of our existing Norwood, Massachusetts development and pilot manufacturing facility, while capital expenditures for the six months ended December 31, 2003 consisted primarily of costs associated with the renovation of the laboratory and office space we have leased at 148 Sidney Street as well as the purchase of new equipment.

Net cash provided by financing activities was \$90,000 for the six months ended December 31, 2004

compared to net cash provided by financing activities of \$99,000 for the six months ended December 31, 2003. For the six months ended December 31, 2004, net cash provided by financing activities reflects the proceeds to the Company from the exercise of 38,505 stock options at prices ranging from \$0.84 to \$3.95 per share. For the six months ended December 31, 2003, net cash provided by financing activities reflects the proceeds to the Company from the exercise of 25,279 stock options at prices ranging from \$2.53 to \$3.95 per share.

We currently anticipate that our existing capital resources and future payments from our collaborators, including committed research funding that we expect to receive from sanofi-aventis pursuant to the terms of our collaboration agreement, will enable us to meet our current and projected operational expenses and capital expenditures for at least the next three to five fiscal years. We currently 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*

On September 15, 2004, the Company entered into an agreement to sublease 6,864 square feet of space at 64 Sidney Street, Cambridge, Massachusetts for general and administrative purposes. Under the terms of the agreement, the annual rent is \$152,000 and the Company is required to pay its allocable share of operating and tax expenses related to the premises. The sublease expires on March 31, 2008. There have been no other significant changes in our contractual obligations since June 30, 2004.

Minimum rental commitments, including real estate taxes and other expenses, under all non-cancelable operating lease agreements are the following for the next five fiscal years ended June 30,

2005 (remaining six months)	\$	1,682,114
2006		3,364,228
2007		3,394,228
2008		2,868,073
2009		698,700
Thereafter		931,600
Total minimum lease payments	\$	12,938,943

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.



**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this Amendment No. 1 to Form 10-Q to be signed on its behalf by the undersigned thereunto duly authorized.

**ImmunoGen, Inc.**

Date: July 27, 2005

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

Date: July 27, 2005

By: /s/ Daniel M. Junius  
Daniel M. Junius  
Senior Vice President and Chief Financial Officer  
(principal financial officer)