

IMMUNOGEN INC  
Form 10-Q  
May 05, 2006

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**FORM 10-Q**

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

**For the quarterly period ended March 31, 2006**

**OR**

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

**For the transition period from            to**

**Commission file number 0-17999**

**ImmunoGen, Inc.**

**Massachusetts**

(State or other jurisdiction of incorporation  
or organization)

**04-2726691**

(I.R.S. Employer Identification No.)

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

(Address of principal executive offices, including zip code)

**(617) 995-2500**

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.  Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

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Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of 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: 41,399,755 shares outstanding as of May 5, 2006.

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**IMMUNOGEN, INC.**  
**CONSOLIDATED BALANCE SHEETS**  
**AS OF MARCH 31, 2006 AND JUNE 30, 2005**  
**(UNAUDITED)**

In thousands, except per share amounts

	March 31, 2006	June 30, 2005
<b>ASSETS</b>		
Cash and cash equivalents	\$ 4,050	\$ 3,423
Marketable securities	78,715	87,142
Accounts receivable	1,500	1,418
Unbilled revenue	5,429	5,035
Inventory, net	1,813	1,520
Prepaid and other current assets	1,467	1,398
Total current assets	92,974	99,936
Property and equipment, net	9,503	9,883
Other assets	265	313
Total assets	\$ 102,742	\$ 110,132
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Accounts payable	\$ 1,477	\$ 2,099
Accrued compensation	1,946	728
Other current accrued liabilities	2,495	1,327
Current portion of deferred revenue	6,661	5,072
Total current liabilities	12,579	9,226
Deferred revenue, net of current portion	11,368	13,739
Other long-term liabilities	374	325
Total liabilities	24,321	23,290
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$.01 par value; authorized 75,000 shares; issued and outstanding 45,074 shares and 44,695 shares as of March 31, 2006 and June 30, 2005, respectively	451	447
Additional paid-in capital	321,187	318,300
Deferred compensation	-	(13)
Treasury stock	(11,071)	(11,071)
Accumulated deficit	(231,916)	(220,727)
Accumulated other comprehensive loss	(230)	(94)
Total stockholders' equity	78,421	86,842
Total liabilities and stockholders' equity	\$ 102,742	\$ 110,132

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



**IMMUNOGEN, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
**FOR THE THREE AND NINE MONTHS ENDED MARCH 31, 2006 AND 2005**  
**(UNAUDITED)**

In thousands, except per share amounts

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2006	2005	2006	2005
<b>Revenues:</b>				
Research and development support	\$ 5,258	\$ 4,776	\$ 16,175	\$ 13,751
License and milestone fees	3,275	3,040	5,811	5,615
Clinical materials reimbursement	822	2,415	1,734	8,918
<b>Total revenues</b>	<b>9,355</b>	<b>10,231</b>	<b>23,720</b>	<b>28,284</b>
<b>Expenses:</b>				
Cost of clinical materials reimbursed	779	2,286	1,778	7,822
Research and development (1)	10,216	9,669	28,467	23,659
General and administrative (1)	2,193	2,277	7,319	6,213
<b>Total expenses</b>	<b>13,188</b>	<b>14,232</b>	<b>37,564</b>	<b>37,694</b>
<b>Loss from operations</b>	<b>(3,833)</b>	<b>(4,001)</b>	<b>(13,844)</b>	<b>(9,410)</b>
Interest income	875	509	2,351	1,257
Net realized losses on investments	(7)	(55)	(33)	(59)
Gain on sale of assets	-	-	3	-
Other income (expense)	(15)	1	351	8
<b>Loss before income tax expense</b>	<b>(2,980)</b>	<b>(3,546)</b>	<b>(11,172)</b>	<b>(8,204)</b>
Income tax expense	1	5	17	27
<b>Net loss</b>	<b>\$ (2,981)</b>	<b>\$ (3,551)</b>	<b>\$ (11,189)</b>	<b>\$ (8,231)</b>
<b>Basic and diluted net loss per common share</b>	<b>\$ (0.07)</b>	<b>\$ (0.09)</b>	<b>\$ (0.27)</b>	<b>\$ (0.20)</b>
<b>Basic and diluted weighted average common shares</b>	<b>41,188,183</b>	<b>40,870,768</b>	<b>41,108,821</b>	<b>40,819,687</b>

outstanding

(1) Includes the following stock compensation expense for the three and nine months ended March 31,

	2006	2005	2006	2005
Research and development	\$ 378	\$ -	\$ 1,080	\$ -
General and administrative	215	(50)	759	130
Total	\$ 593	\$ (50)	\$ 1,839	\$ 130

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



**IMMUNOGEN, INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**FOR THE NINE MONTHS ENDED MARCH 31, 2006 AND 2005**  
**(UNAUDITED)**  
**In thousands**

	<b>Nine Months Ended March 31,</b>	
	<b>2006</b>	<b>2005</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (11,189)	\$ (8,231)
<b>Adjustments to reconcile net loss to net cash used for operating activities:</b>		
Depreciation and amortization	2,024	1,625
Gain on sale of fixed assets	(3)	-
Loss on sale of marketable securities	33	59
Inventory reserve	(226)	1,321
Stock and deferred share unit compensation	1,839	130
Deferred rent	30	4
<b>Change in operating assets and liabilities:</b>		
Accounts receivable	(81)	1,496
Unbilled revenue	(394)	(522)
Inventory	(66)	3,494
Prepaid and other current assets	(70)	259
Other assets	48	19
Accounts payable	(622)	1,133
Accrued compensation	1,218	2,012
Other current accrued liabilities	1,167	(172)
Deferred revenue	(781)	(4,144)
Net cash used in operating activities	(7,074)	(1,517)
<b>Cash flows from investing activities:</b>		
Proceeds from maturities or sales of marketable securities	459,593	783,402
Purchases of marketable securities	(451,335)	(779,570)
Capital expenditures	(1,644)	(1,866)
Proceeds from sale of fixed assets	3	-
Net cash provided by investing activities	6,617	1,966
<b>Cash flows from financing activities:</b>		
Proceeds from stock options exercised	1,084	480
Net cash provided by financing activities	1,084	480
Net change in cash and cash equivalents	627	929
Cash and cash equivalents, beginning balance	3,423	6,768
Cash and cash equivalents, ending balance	\$ 4,050	\$ 7,697

Supplemental disclosure:

Cash paid for income taxes	\$	17	\$	16
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The accompanying notes are an integral part of the consolidated financial statements.

**IMMUNOGEN, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**MARCH 31, 2006**

**A. Summary of Significant Accounting Policies**

*Basis of Presentation*

The accompanying consolidated financial statements at March 31, 2006 and June 30, 2005 and for the three and nine months ended March 31, 2006 and 2005 include the accounts of ImmunoGen, Inc. (the "Company") and its wholly-owned subsidiaries, ImmunoGen Securities Corp. and ImmunoGen Europe Limited. Although the consolidated financial statements are unaudited, they include all of the adjustments, consisting only of normal recurring adjustments, which management considers necessary for a fair presentation of the Company's financial position in accordance with accounting principles generally accepted in the United States for interim financial information. Certain information and footnote disclosures normally included in the Company's annual financial statements have been condensed or omitted. The preparation of interim financial statements requires the use of management's estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the interim financial statements and the reported amounts of revenues and expenditures during the reported period. The results of the interim periods are not necessarily indicative of the results for the entire year. Accordingly, the interim financial statements should be read in conjunction with the audited financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended June 30, 2005.

*Revenue Recognition*

The Company enters into out-licensing and development agreements with collaborative partners for the development of monoclonal antibody-based cancer therapeutics. The Company follows the provisions of the Securities and Exchange Commission's Staff Accounting Bulletin No. 104 (SAB No. 104), *Revenue Recognition*, and EITF 00-21, *Accounting for Revenue Arrangements with Multiple Elements* (EITF 00-21). In accordance with SAB No. 104 and EITF 00-21, the Company recognizes revenue related to research activities as they are performed, as long as there is persuasive evidence of an arrangement, the fee is fixed or determinable, and collection of the related receivable is probable. The terms of the Company's agreements contain multiple elements which typically include non-refundable license fees, payments based upon the achievement of certain milestones and royalties on product sales. The Company evaluates such arrangements to determine if the deliverables are separable into units of accounting and then applies applicable revenue recognition criteria to each unit of accounting.

At March 31, 2006, the Company had the following three types of collaborative contracts with the parties identified below:

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

Biogen Idec, Inc.

Boehringer Ingelheim International GmbH

Centocor, Inc., a wholly-owned subsidiary of Johnson & Johnson

Genentech, Inc. (multiple licenses)

Millennium Pharmaceuticals, Inc.

• Broad option agreements to acquire rights to a limited number of targets over a specified time period (broad license):

Amgen, Inc. (formerly Abgenix, Inc.)

Genentech, Inc.

Millennium Pharmaceuticals, Inc.

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

Sanofi-aventis Group (sanofi-aventis)

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Generally, all of these collaboration agreements provide that the Company will (i) manufacture preclinical and clinical materials for its collaborators, at the collaborator's request and cost, or in some cases, cost plus a profit margin, (ii) receive payments upon the collaborators' achievements of certain milestones and (iii) receive royalty payments, generally until the later of the last applicable patent expiration or 12 years after product launch. The Company is required to provide technical training and any process improvements and know-how to its collaborators during the term of the collaboration agreements. Practically, once a collaborator receives U. S. Food and Drug Administration (FDA) approval for any drug and the manufacturing process used to produce the drug, the collaborator will not be able to incorporate any process improvements or know-how into its manufacturing process without additional testing and review by the FDA. Accordingly, the Company believes that it is very unlikely that its collaborators will require the Company's services subsequent to FDA approval.

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

The Company defers upfront payments received from its broad licenses over the period during which the collaborator may elect to receive a license. These periods are specific to each collaboration agreement, but are between seven and 12 years. If a collaborator selects an option to acquire a license under these agreements, any option fee is deferred and recorded over the life of the option, generally 12 to 18 months. If a collaborator exercises an option and the Company grants a single target license to the collaborator, the Company defers the license fee and accounts for the fee as it would an upfront payment on a single target license, as discussed above. In the event that a broad license agreement were to be terminated, the Company would recognize as revenue any portion of the upfront fee that had not previously been recorded as revenue, but was classified as deferred revenue at the date of such termination. In the event that a collaborator elects to discontinue development of a specific product candidate under a single target license, but retains its right to use the Company's technology to develop an alternative product candidate to the same target or a target substitute, the Company would cease amortization of any remaining portion of the upfront fee until there is substantial pre-clinical activity on another product candidate.

The Company's discovery, development and commercialization agreement with sanofi-aventis included an upfront payment of \$12.0 million that sanofi-aventis paid to ImmunoGen in August 2003. The Company deferred the upfront payment and recognizes it ratably over the period of the Company's substantial involvement. The Company estimates this period to be five years, which includes the term of the collaborative research program of three years and two 12-month extensions that sanofi-aventis may exercise. The discovery, development and commercialization agreement also provides that ImmunoGen will receive committed funding of \$50.7 million over the initial three-year period, as determined in each of the three research program years. The committed research funding is based upon resources that ImmunoGen is required to contribute to the collaboration. The Company records the research funding as it is earned based upon its actual resources utilized in the collaboration. In August 2005, sanofi-aventis exercised the first of the two 12-month extensions. This extension will provide the Company with \$18.2 million in additional committed funding over the twelve months beginning September 1, 2006.

At the conclusion of the second sanofi-aventis research program year on August 31, 2005, a review of research activities during this period was conducted. This review identified \$1.1 million in billable research activities performed under the program during the fiscal year ended June 30, 2005, which had not been billed or recorded as

revenue. Accordingly, the Company has included this additional \$1.1 million of research and support revenue in the accompanying consolidated statement of operations for the nine months ended March 31, 2006. The Company does not believe such previously unrecorded revenue was material to the results of operations or the financial position of the Company for any interim period of 2005 or for the year ended June 30, 2005.

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

The Company may produce preclinical and clinical materials for its collaborators. The Company is reimbursed for its fully burdened cost to produce clinical materials and, in some cases, fully burdened cost plus a profit margin. The Company recognizes revenue on preclinical and clinical materials when it has shipped the materials, the materials have passed all quality testing required for collaborator acceptance and title has transferred to the collaborator.

The Company also produces research material for potential collaborators under material transfer agreements. Additionally, research activities are performed, including developing antibody-specific conjugation processes, on behalf of the Company's collaborators and potential collaborators during the early evaluation and preclinical testing stages of drug development. Generally, the Company is reimbursed for its fully burdened cost of producing these materials or providing these services. The Company records the amounts received for the materials produced or services performed as a component of research and development support.

#### *Marketable Securities*

The Company invests its cash balances in marketable securities of highly rated financial institutions and investment-grade debt instruments and limits the amount of credit exposure with any one entity. The Company has classified its marketable securities as "available-for-sale" and, accordingly, carries such securities at aggregate fair value. Unrealized gains and losses, if any, are reported as other comprehensive income (loss) in stockholders' equity. The amortized cost of debt securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is included in interest income. Realized gains and losses on available-for-sale securities are included in net realized losses on investments. The cost of securities sold is based on the specific identification method. Interest and dividends are included in interest income.

#### *Unbilled Revenue*

The majority of the Company's unbilled revenue at March 31, 2006 represents (i) committed research funding earned based on actual resources utilized under the Company's discovery, development and commercialization agreement with sanofi-aventis; (ii) reimbursable expenses incurred under the Company's discovery, development and commercialization agreement with sanofi-aventis that the Company has not yet invoiced; and (iii) research funding earned based on actual resources utilized under the Company's development and license agreements with Biogen Idec and Centocor.

#### *Inventory*

Inventory costs primarily relate to clinical trial materials being manufactured for sale to the Company's collaborators. Inventory is stated at the lower of cost or market as determined on a first-in, first-out (FIFO) basis.

Inventory at March 31, 2006 and June 30, 2005 is summarized below (in thousands):

	<b>March 31, 2006</b>	<b>June 30, 2005</b>
Raw materials	\$ -	\$ 797
Work in process	1,813	723
Total	\$ 1,813	\$ 1,520

Inventory cost is stated net of a valuation allowance of \$3.5 million and \$3.7 million as of March 31, 2006 and June 30, 2005, respectively. The valuation allowance represents the cost of DM1, DM4 and ansamitocin P3 that the Company considers to be in excess of a 12-month supply based on current collaborator firm fixed orders and projections.

DM1 and DM4 are cell-killing agents used in all Tumor-Activated Prodrug (TAP) product candidates currently in preclinical and clinical testing, and are the subject of the Company's collaborations. DM1 and DM4 (collectively referred to as DMx) are both

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manufactured from a precursor, ansamitocin P3.

The actual amount of ansamitocin P3 and DMx that will be produced in future periods under certain current and future potential agreements is highly uncertain. As such, the amount of ansamitocin P3 and/or DMx produced could be more than is required

to support the development of the Company's and its collaborators' products. Such excess product, as determined under the Company's inventory reserve policy, has been charged to research and development expense to date.

The Company produces preclinical and clinical materials for its collaborators either in anticipation of or in support of clinical trials, or for process development and analytical purposes. Under the terms of supply agreements with its collaborators, the Company generally receives rolling six month firm-fixed orders for conjugate that the Company is required to manufacture, and rolling 12-month manufacturing projections for the quantity of conjugate the collaborator expects to need in any given 12-month period. The amount of clinical material produced is directly related to the number of on-going clinical trials for which the Company is producing clinical material for itself and its collaborators, the speed of enrollment in those trials and the dosage schedule of each clinical trial. Because these elements can vary significantly over the course of a trial, significant differences between our collaborators' actual manufacturing orders and their projections could result in our actual 12-month usage of DMx and ansamitocin P3 varying significantly from our estimated usage at an earlier reporting period. To the extent that a collaborator has provided the Company with a firm fixed order, the collaborator is contractually required to reimburse the Company the full cost of the conjugate and any agreed margin thereon, even if the collaborator subsequently cancels the manufacturing run.

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

- a) That portion of the DMx and/or ansamitocin P3 that the Company intends to use in the production of its own products is expensed as incurred;
- b) To the extent that the Company has collaborator projections for up to 12 months of firm fixed orders, the Company capitalizes the value of DMx and ansamitocin P3 that will be used in the production of conjugate subject to these firm fixed orders and/or projections;
- c) The Company considers more than a 12-month supply of ansamitocin P3 and/or DMx that is not supported by collaborators' firm fixed orders or projections to be excess. The Company establishes a reserve to reduce to zero the value of any such excess ansamitocin P3 or DMx inventory with a corresponding charge to research and development expense; and
- d) The Company also considers any other external factors and information of which it becomes aware and assesses the impact of such factors or information on the net realizable value of the DMx and ansamitocin P3 inventory at each reporting period.

At March 31, 2006, the Company's on-hand supply of DMx and ansamitocin P3 (including \$2.1 million of DMx and \$1.8 million of ansamitocin P3) represented more than a 12-month supply based upon current collaborator firm fixed orders and projections. In the year ended June 30, 2005, the Company recorded as research and development expense \$2.3 million of ansamitocin P3 and DMx that the Company identified as excess based upon the Company's inventory policy as described above. No additional amounts were recorded during the nine months ended March 31, 2006 related to excess inventory, as the total amount of the Company's on-hand supply of DMx and ansamitocin P3 was fully reserved. However, in the nine months ended March 31, 2006, the Company recorded \$153,000 to write down certain batches of ansamitocin P3 and DMx and certain work in process amounts to their net realizable value. If the Company experiences an increase in on-hand supply of DMx or ansamitocin P3, a corresponding change to the

Company's collaborators' projections could result in significant changes in the Company's estimate of the net realizable value of DMx and ansamitocin P3 inventory. Reductions in collaborators' projections could indicate that the Company has additional excess DMx and/or ansamitocin P3 inventory and the Company would then evaluate the need to record further valuation allowances, included as charges to research and development expense.

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*Computation of Net Loss Per Common Share*

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

	<b>Three Months Ended March 31,</b>		<b>Nine Months Ended March 31,</b>	
	<b>2006</b>	<b>2005</b>	<b>2006</b>	<b>2005</b>
Options and warrants convertible into Common Stock	5,409	5,443	5,409	5,443
Common Stock Equivalents	1,086	1,723	1,382	1,622

ImmunoGen common stock equivalents have not been included in the calculations of dilutive net loss per common share calculations for the three and nine months ended March 31, 2006 and 2005 because their effect is anti-dilutive due to the Company's net loss position.

*Comprehensive Loss*

The Company presents comprehensive income (loss) in accordance with Statement of Financial Accounting Standards (SFAS) No. 130, "Reporting Comprehensive Income." For the three and nine months ended March 31, 2006, total comprehensive loss equaled \$3.1 million and \$11.3 million, respectively. For the three and nine months ended March 31, 2005, total comprehensive loss equaled \$3.6 million and \$8.3 million, respectively. Comprehensive loss comprises the Company's net loss and the change in its unrealized gains and losses on its available-for-sale marketable securities for all periods presented.

*Stock-Based Compensation*

As of March 31, 2006, the Company has one share-based compensation plan, which is the ImmunoGen, Inc. Restated Stock Option Plan. The compensation cost that has been incurred during the three and nine months ended March 31, 2006 under this plan is \$593,000 and \$1.8 million, respectively.

The Company's Restated Stock Option Plan as amended, or the Plan, which is shareholder-approved, permits the grant of share options to its employees, consultants and directors for up to 8.55 million shares of common stock. Option awards generally are granted with an exercise price equal to the market price of the Company's stock at the date of grant. Options vest at various periods of up to four years and may be exercised within ten years of the date of grant.

Effective July 1, 2005, the Company adopted the fair value recognition provisions of Financial Accounting Standards Board (FASB) Statement 123(R), *Share-Based Payment* (Statement 123(R)), using the modified-prospective-transition method. Under that transition method, compensation cost recognized for the first nine months of 2006 includes: (a) compensation cost for all share-based payments granted, but not yet vested as of July 1, 2005, based on the grant-date fair value estimated in accordance with the original provisions of Statement 123 (as defined below), and (b) compensation cost for all share-based payments granted subsequent to July 1, 2005, based on

the grant-date fair value estimated in accordance with the provisions of Statement 123(R). Such amounts have been reduced by the Company's estimate of forfeitures of all unvested awards. Prior to July 1, 2005, the Company accounted for its stock-based compensation plans under the recognition and measurement provisions of Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" (APB 25), and related interpretations for all awards granted to employees. Under APB 25, when the exercise price of options granted to employees under these plans equals the market price of the common stock on the date of grant, no compensation expense is recorded. When the exercise price of options granted to employees under these plans is less than the market price of the common stock on the date of grant, compensation expense is recognized over the vesting period. Results for prior periods have not been restated. For stock options granted to non-employees, the Company recognizes compensation expense in accordance with the requirements of Statement of Financial Accounting Standards (SFAS) No. 123, "Accounting for Stock Based Compensation" (Statement 123). Statement 123 requires that companies recognize compensation expense based on the estimated fair value of options granted to non-employees over their vesting period, which is generally the period during which services are rendered

by such non-employees.

As a result of adopting Statement 123(R) on July 1, 2005, the Company's net loss for the three and nine months ended March 31, 2006 is \$574,000 and \$1.8 million greater, respectively, than if it had continued to account for share-based compensation under APB 25. Basic and diluted net loss per share for the three and nine months ended March 31, 2006 would have been \$(0.06) and \$(0.23), respectively, had the Company not been required to adopt Statement 123(R), compared to basic and diluted net loss per share of \$(0.07) and \$(0.27), as reported.

The following table illustrates the effect on net loss and net loss per share if the Company had applied the fair value recognition provisions of Statement 123 (2005) and 123(R) (2006) to options granted under the Company's stock option plans in all periods presented. For purposes of this pro-forma disclosure, the value of the options is estimated using a Black-Scholes option-pricing model and amortized to expense over the options' vesting periods (in thousands, except per share data).

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2006	2005	2006	2005
Net loss, as reported	\$ (2,981)	\$ (3,551)	\$ (11,189)	\$ (8,231)
Add: Total stock-based compensation expense determined under the intrinsic value method for all employee awards	-	22	-	84
Deduct: Total stock-based compensation expense determined under the fair value method for all employee awards	-	(694)	-	(2,150)
Net loss (pro forma 2005)	\$ (2,981)	\$ (4,223)	\$ (11,189)	\$ (10,297)
Basic and diluted net loss per common share, as reported	\$ (0.07)	\$ (0.09)	\$ (0.27)	\$ (0.20)
Basic and diluted net loss per common share (pro forma 2005)	\$ (0.07)	\$ (0.10)	\$ (0.27)	\$ (0.25)

The fair value of each stock option is estimated on the date of grant using the Black-Scholes option-pricing model that uses the assumptions noted in the following table. Expected volatility is based exclusively on historical volatility data of the Company's stock. The expected term of stock options granted is based exclusively on historical data and represents the period of time that stock options granted are expected to be outstanding. The expected term is calculated for and applied to one group of stock options as the Company does not expect substantially different exercise or post-vesting termination behavior amongst its employee population. The risk-free rate of the stock options is based on the U.S. Treasury yield curve in effect at the time of grant for the expected term period.

	<b>Three Months Ended March 31,</b>		<b>Nine Months Ended March 31,</b>	
	<b>2006</b>	<b>2005</b>	<b>2006</b>	<b>2005</b>
Dividend	None	None	None	None
Volatility	81.60%	87.30%	81.60%	87.30%
Risk-free interest rate	4.51%	3.74%	4.26%	3.33%
Expected life (years)	6.0	5.5	6.0	5.5

Using the Black-Scholes option-pricing model, the weighted average grant date fair values of options granted during the three months ended March 31, 2006 and 2005 were \$3.24 and \$4.97, respectively, and \$4.15 and \$4.09 for options granted during the nine months ended March 31, 2006 and 2005, respectively.

A summary of option activity under the Plan as of March 31, 2006, and changes during the nine month period then ended is presented below (in thousands, except weighted-average data):

	Number of Stock Options	Weighted-average Exercise Price	Weighted-average Remaining Life in Yrs	Aggregate Intrinsic Value
Outstanding at June 30, 2005	5,862	\$ 6.73		
Granted	148	5.61		
Exercised	(379)	2.86		
Forfeited/Canceled	222	11.42		
Outstanding at March 31, 2006	5,409	6.84	5.64	\$ 4,356
Exercisable at March 31, 2006	3,883	\$ 7.32	3.99	\$ 4,263

A summary of the status of the Company's nonvested shares as of March 31, 2006 is presented below (in thousands, except weighted-average data):

	Shares	Weighted-average grant date fair value
Nonvested at June 30, 2005	1,612	\$ 4.43
Granted during the year	148	4.15
Vested during the year	(90)	5.09
Forfeited during the year	(144)	4.94
Nonvested at March 31, 2006	1,526	\$ 4.23

As of March 31, 2006, the estimated fair value of unvested employee awards was \$4.4 million net of estimated forfeitures. The weighted-average remaining vesting period for these awards is approximately 2.0 years.

A summary of option activity for shares vested during the nine month periods ended March 31, 2006 and 2005 is presented below (in thousands):

	Nine Months ended March 31,	
	2006	2005
Total fair value of shares vested	\$ 497	\$ 538
Total intrinsic value of options exercised	707	817
Cash received for exercise of stock options	1,084	480

On February 1, 2006, the Company's Board of Directors approved certain changes to the ImmunoGen, Inc. Restated Stock Option Plan (the Plan). The amendments provide that in the event of a Change of Control of the Company all options outstanding under the Plan shall become fully vested and immediately exercisable as of the date of the Change of Control. This provision shall apply to all options currently outstanding under the Plan and all new options granted

on or after the date of the amendment. Currently, the Company is not involved in any transactions or discussions thereof that would constitute a Change in Control. The amendments did not have an impact on the Company's statement of operations.



During the nine months ended March 31, 2006, holders of options issued under the Plan exercised their rights to acquire an aggregate of 379,219 shares of common stock at prices ranging from \$1.31 to \$6.27 per share. The total proceeds to the Company from these option exercises were approximately \$1.1 million.

During the three and nine months ended March 31, 2006, the Company recorded approximately \$31,000 of compensation expense related to the modification of certain outstanding common stock options.

### *Reclassifications*

Certain prior period amounts have been adjusted to conform to the current year presentation.

### *Segment Information*

During the three and nine months ended March 31, 2006, the Company continued to operate in one reportable business segment under the management approach of SFAS No. 131, "Disclosures about Segments of an Enterprise and Related Information," which is the business of discovery of monoclonal antibody-based cancer therapeutics.

Revenues from sanofi-aventis accounted for approximately 65% and 70% of revenues for the three months ended March 31, 2006 and 2005, respectively, and 73% and 62% for the nine months ended March 31, 2006 and 2005, respectively. Revenues from Genentech accounted for approximately 27% and 5% of revenues for the three months ended March 31, 2006 and 2005, respectively, and 16% and 6% for the nine months ended March 31, 2006 and 2005, respectively. Revenues from Boehringer Ingelheim accounted for approximately 0% and 8% of revenues for the three months ended March 31, 2006 and 2005, respectively, and 0% and 16% for the nine months ended March 31, 2006 and 2005, respectively. Revenues from Millennium Pharmaceuticals accounted for 1% and 10% of revenues for the three months ended March 31, 2006 and 2005, respectively, and 2% and 13% for the nine months ended March 31, 2006 and 2005, respectively. There were no other significant customers of the Company in the three and nine months ended March 31, 2006 and 2005.

### *Recent Accounting Pronouncements*

In June 2005, the FASB issued SFAS No. 154, *Accounting Changes and Error Corrections*, which will require entities that voluntarily make a change in accounting principle to apply that change retrospectively to prior periods' financial statements, unless this would be impracticable. SFAS No. 154 supercedes APB Opinion No. 20, *Accounting Changes*, which previously required that most voluntary changes in accounting principle be recognized by including in the current period's net income the cumulative effect of changing to the new accounting principle. SFAS No. 154 also makes a distinction between "retrospective application" of an accounting principle and the "restatement" of financial statements to reflect the correction of an error. Another significant change in practice under SFAS No. 154 will be that if an entity changes its method of depreciation, amortization, or depletion for long-lived, non-financial assets, the change must be accounted for as a change in accounting estimate. Under APB No. 20, such a change would have been reported as a change in accounting principle. SFAS No. 154 applies to accounting changes and error corrections that are made in fiscal years beginning after December 15, 2005. We do not expect the adoption of this pronouncement to have a material effect on the Company's financial position or results of operations.

## **B. Agreements**

### *Sanofi-Aventis*

In August 2005, sanofi-aventis exercised the first of its two options to extend the term of the research collaboration with the Company for another year, and committed to pay the Company a minimum of \$18.2 million in research support over the twelve months beginning September 1, 2006. This funding is in addition to the \$50.7 million in research support already committed for the three-year period ending August 31, 2006.

### *Genentech, Inc.*

In May 2000, the Company executed two separate licensing agreements with Genentech. The first agreement grants an exclusive license to Genentech for ImmunoGen's maytansinoid technology for use with antibodies, such as

trastuzumab (Herceptin®), that target the HER2 cell surface receptor. The second agreement executed in May 2000 provides Genentech with broad access to ImmunoGen's TAP technology, "Technology Access Agreement", for use with Genentech's other proprietary antibodies. This multi-year agreement provides Genentech with a license to utilize ImmunoGen's TAP platform in its antibody product research efforts and an option to obtain product licenses for a limited number of antigen targets over the agreement's five-year term. The multi-year agreement included a provision that allowed Genentech to renew the agreement for one additional three-year term by payment of a \$2.0 million access fee. On April 27, 2005, Genentech renewed the agreement and paid the related \$2.0 million technology access fee to ImmunoGen.

On April 27, 2005, July 22, 2005 and December 12, 2005, Genentech licensed exclusive rights to use ImmunoGen's maytansinoid TAP technology with its therapeutic antibodies to undisclosed targets. Under the terms defined in the May 2000 Technology Access

Agreement, for each of these three licenses ImmunoGen received a \$1.0 million license fee, and is entitled to receive milestone payments that total \$38 million, assuming all benchmarks are met; ImmunoGen also is entitled to receive royalties on the sales of any resulting products. Genentech is responsible for the development, manufacturing, and marketing of any products resulting from the licenses.

On January 27, 2006, Genentech notified the Company that the trastuzumab-DM1 Investigational New Drug (IND) application submitted by Genentech to the FDA had become effective. Under the terms of the May 2000 exclusive license agreement for the HER2 target, this event triggered a \$2.0 million milestone payment to the Company.

*Millennium Pharmaceuticals, Inc.*

On January 25, 2006, Millennium Pharmaceuticals, Inc. notified the Company that, as part of its ongoing portfolio management process and based on the evaluation of recent clinical data in the context of other opportunities in its pipeline, Millennium had decided not to continue the development of its MLN2704 compound. MLN2704 consists of a Millennium antibody to the Prostate-Specific Membrane Antigen (PSMA) and ImmunoGen's DM1 and was in development by Millennium under a 2002 license that gave Millennium exclusive rights to use ImmunoGen's maytansinoid TAP technology with antibodies targeting PSMA. Millennium retains its right to use ImmunoGen's maytansinoid TAP technology with antibodies targeting PSMA. As a result, the Company anticipates that Millennium Pharmaceuticals, Inc. will have no demand for conjugate material in the near future. However, this anticipated reduction in demand did not result in any further write-down of DM1 or P3 inventory. We have ceased amortization of the remaining portion of the upfront fee paid by Millennium as they retain rights to develop an alternative product candidate with an antibody targeting PSMA.

On March 27, 2006, Millennium extended the agreement that provides Millennium with certain rights to test ImmunoGen's (TAP) technology with antibodies to specific targets and to license the right to use the technology to develop products on the terms defined in the agreement. This agreement was scheduled to expire March 30, 2006 unless extended by Millennium. It is now scheduled to expire March 30, 2007. In consideration for this extension, Millennium paid to the Company an extension fee equal to \$250,000.

The Company has agreements with other companies with respect to its compounds, as described elsewhere in this Quarterly Report and in its Annual Report on Form 10-K.

**C. Capital Stock**

During the three and nine months ended March 31, 2006, the Company recaptured approximately \$19,000 and \$35,000 of previously recorded compensation expense, respectively, related to stock units outstanding under the Company's 2001 Non-Employee Director Stock Plan (a stock appreciation right plan). No stock units have been issued under the 2001 Plan subsequent to June 30, 2004.

Under the Company's 2004 Non-Employee Director Compensation and Deferred Share Unit Plan (a stock appreciation right plan), approved in June 2004, the Company issued 13,817 deferred share units during the nine months ended March 31, 2006. The Company recorded approximately \$6,000 and \$54,000 in compensation expense related to deferred share units outstanding under the 2004 Plan during the three and nine months ended March 31, 2006, respectively. The Company recorded approximately \$(5,100) and \$39,900 in compensation (expense reduction) and expense related to the issuance of 10,169 stock units for director services rendered during the three and nine months ended March 31, 2005.

The value of stock units and deferred share units, discussed above, will fluctuate from period to period as the market value of the Company's common stock increases or decreases at each reporting period.



## 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. The combination of our expertise in antibodies and cancer biology has resulted in the development of both proprietary product candidates and technologies. Our proprietary Tumor-Activated Prodrug, or TAP, technology combines extremely potent small molecule cytotoxic agents with monoclonal antibodies that bind specifically to cancer cells. Our TAP technology is designed to increase the potency of tumor-targeting antibodies and kill cancer cells with only modest damage to healthy tissue. The cytotoxic agents we use in our TAP compounds currently involved in clinical testing are the maytansinoid DM1 and DM4 molecules, chemical 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 product candidates.

We have entered into collaborative agreements that enable 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. (now the sanofi-aventis Group). Under the terms of this agreement, sanofi-aventis gained 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 sanofi-aventis' clinical development and commercialization capabilities. Under the terms of the sanofi-aventis agreement, we also are entitled to receive committed research funding of approximately \$50.7 million during the three-year research program. In August 2005, sanofi-aventis exercised its contractual right to extend the term of its research program with the Company and committed to fund \$18.2 million in research support over the twelve months beginning September 1, 2006. This funding is in addition to the research support already committed for the three years ending August 31, 2006. Should sanofi-aventis elect to exercise its contractual right to extend the term of the research program for the second additional 12-month period, we will receive additional research funding.

We are reimbursed our fully burdened cost to manufacture preclinical and clinical materials and, under certain collaborative agreements, the reimbursement includes a profit margin. Currently, our collaborative partners include Amgen, Inc. (formerly Abgenix, Inc.), Biogen Idec, Boehringer Ingelheim International GmbH, Centocor, Inc., Genentech, Inc., Millennium Pharmaceuticals, Inc., and the sanofi-aventis Group. We expect that substantially all of our revenue for the foreseeable future will result from payments under our collaborative arrangements.

On January 27, 2006, Genentech notified us that the trastuzumab-DM1 Investigational New Drug (IND) application submitted by Genentech to the FDA had become effective. Under the terms of the May 2000 exclusive license agreement for antibodies to HER2, this event triggered a \$2.0 million milestone payment.

On January 25, 2006, Millennium Pharmaceuticals, Inc. notified us that, as part of its ongoing portfolio management process and based on the evaluation of recent clinical data in the context of other opportunities in its pipeline, Millennium had decided not to continue the development of its MLN2704 compound. MLN2704 consists of a Millennium antibody to the Prostate-Specific Membrane Antigen (PSMA) and ImmunoGen's DM1 and was in development by Millennium under a 2002 license that gave Millennium exclusive rights to use ImmunoGen's maytansinoid TAP technology with antibodies targeting PSMA. Millennium retains its right to use ImmunoGen's maytansinoid TAP technology with antibodies targeting PSMA. As a result, we anticipate that Millennium

Pharmaceuticals, Inc. will have no demand for conjugate material in the near future. However, this reduction in demand did not result in any further write-down of DM1 or P3 inventory.

In August 2003, Vernalis completed its acquisition of British Biotech. In connection with this 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, we announced that we would take over further development of the product candidate. Pursuant to the terms of the termination agreement executed on January 7, 2004, Vernalis retained responsibility for the conduct and expense of the study it initiated in the United States (Study 001) until June 30, 2004, and the study it had started in the United Kingdom (Study 002) through completion. We took over responsibility for Study 001 on July 1, 2004 and, in September 2005, we announced the initiation of our own clinical trial with huN901-DM1 in multiple myeloma (Study 003). On December 15, 2005, we executed an amendment to the January 7, 2004 Termination Agreement with Vernalis. Under the terms of the amendment, ImmunoGen assumed responsibility for Study 002 as of December 15, 2005, including the cost of its completion. Under the amendment, Vernalis paid ImmunoGen \$365,000 in consideration of the expected cost of the obligations assumed by ImmunoGen with the amendment. This \$365,000 has been recognized as other income in the accompanying Consolidated Statements of Operations for the nine months ended March 31, 2006.

On January 8, 2004, we announced that we intended to advance cantuzumab mertansine into human testing to assess the clinical utility of the compound in certain indications. In October 2004, we decided to move forward huC242-DM4 into clinical trials instead of cantuzumab mertansine (huC242-DM1). We initiated a Phase I clinical trial with huC242-DM4 in June 2005.

Based upon the results of our clinical trials, if and when they are completed, we will evaluate whether to continue clinical development of huN901-DM1 and huC242-DM4, 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 for 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, including expanded clinical trials. As of March 31, 2006, we had approximately \$82.8 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 sanofi-aventis collaboration over the remainder of the research program, will enable us to meet our operational expenses and capital expenditures for at least the next two to three 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 to which we are entitled pursuant to the sanofi-aventis collaboration. Accordingly, period-to-period operational results may fluctuate dramatically based upon the timing of receipt of the proceeds. 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 assisting in providing funding 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 on the time frames we expect, or at all. 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 \$12.0 million upfront fee we received from sanofi-aventis ratably over our estimated period of significant involvement of five years. This estimated period includes the initial three-year term of the collaborative research program, the one 12-month extension sanofi-aventis exercised on August 2005, and one remaining 12-month extension 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, collectively referred to as DMx, and ansamitocin P3 in excess of 12 months' projected usage that is not supported by collaborators' firm fixed orders and projections to be excess. To date, we have fully reserved 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 nine months ended March 31, 2006, we recorded \$153,000 to write down certain P3 and DMx batches and certain work in process amounts to their net realizable value.

### *Stock Based Compensation*

Effective July 1, 2005, we adopted the fair value recognition provisions of Financial Accounting Standards Board (FASB) Statement 123(R), *Share-Based Payment*, using the modified-prospective-transition method. Under that transition method, compensation cost recognized for the first nine months of 2006 includes: (a) compensation cost for all share-based payments granted, but not yet vested as of, July 1, 2005, based on the grant-date fair value estimated in accordance with the original provisions of Statement 123 (as defined below), and (b) compensation cost for all share-based payments granted subsequent to July 1, 2005, based on the grant-date fair value estimated in accordance with the provisions of Statement 123(R). Such amounts are reduced by our estimate of forfeitures of all unvested awards.

Prior to July 1, 2005, we accounted for our stock-based compensation plans under the recognition and measurement provisions of Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" (APB 25), and related interpretations for all awards granted to employees. Under APB 25, when the exercise price of options granted to employees under these plans equals the market price of the common stock on the date of grant, no compensation expense is recorded. When the exercise price of options granted to employees under these plans is less than the market price of the common stock on the date of grant, compensation expense is recognized over the vesting period. For stock options granted to non-employees, we recognize compensation expense in accordance with the requirements of Statement of Financial Accounting Standards (SFAS) No. 123, "Accounting for Stock Based Compensation" (Statement 123). Statement 123 requires that companies recognize compensation expense based on the estimated fair value of options granted to non-employees over their vesting period, which is generally the period during which services are rendered by such non-employees.

As a result of adopting Statement 123(R) on July 1, 2005, our net loss for the nine months ended March 31, 2006 is \$1.8 million greater than if we had continued to account for share-based compensation under APB 25. Basic and diluted net loss per share for the nine months ended March 31, 2006 would have been \$(0.23) had we not adopted Statement 123(R), compared to basic and diluted net loss per share of \$(0.27), as reported. We estimated the fair value of share-based payments to employees using the Black-Scholes model and related assumptions, consistent with our fair value estimates made under Statement 123.

As of March 31, 2006, the estimated fair value of unvested employee awards was \$4.4 million net of estimated forfeitures. The weighted average remaining vesting period for these awards is approximately 2.0 years. The amount

of stock compensation expensed recognized in any future period cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. The adoption of SFAS 123(R) did not require any cumulative adjustments to our financial statements.

## **RESULTS OF OPERATIONS**

### *Comparison of Three Months ended March 31, 2006 and 2005*

#### *Revenues*

Our total revenues for the three months ended March 31, 2006 were \$9.4 million compared with \$10.2 million for the three months ended March 31, 2005. The \$875,000 decrease in revenues in the quarter ended March 31, 2006 compared to the same period in the prior year is primarily attributable to lower clinical materials reimbursement, partially offset by higher research and

development support, and to a lesser extent, license and milestone fees.

Research and development support revenue was \$5.3 million and \$4.8 million in the three months ended March 31, 2006 and 2005, respectively. These amounts primarily represent committed research funding earned based on actual resources utilized under our discovery, development and commercialization agreement with sanofi-aventis. During the three months ended March 31, 2006 and 2005, this revenue also includes amounts earned for actual resources utilized under our development and license agreements with certain of our other collaborative partners. These amounts are the result of certain process development and research work performed by the Company on behalf of collaborators, as well as samples of research-grade material shipped to collaborators. Fees for this material and service represent the fully burdened reimbursement of costs incurred in producing research-grade materials and developing antibody-specific conjugation processes on behalf of our collaborators and potential collaborators during the early evaluation and preclinical testing stages of drug development. The fees that we earn associated with this material and service are 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 these fees may vary widely from quarter to quarter and year to year.

Revenues from license and milestone fees increased \$236,000 to \$3.3 million in the three months ended March 31, 2006 compared to \$3.0 million in the three months ended March 31, 2005. Included in license and milestone fees for the quarter ended March 31, 2006 is \$2.0 million of milestone revenue earned under the Genentech collaboration. Included in license and milestone fees for the quarter ended March 31, 2005 is \$2.0 million of milestone revenue earned under the sanofi-aventis collaboration. Total revenue from license and milestone fees recognized from each of our collaborative partners in the three-month periods ended March 31, 2006 and 2005 is included in the following table:

	<b>Three Months Ended March</b>	
	<b>31,</b>	
	<b>2006</b>	<b>2005</b>
	<b>(in thousands)</b>	
Collaborative Partner:		
Amgen (formerly Abgenix)	\$ 100	\$ 112
Biogen Idec	12	-
Boehringer Ingelheim	-	14
Centocor	42	42
Genentech	2,452	161
Millennium	69	111
sanofi-aventis	600	2,600
<b>Total</b>	<b>\$ 3,275</b>	<b>\$ 3,040</b>

Deferred revenue of \$18.0 million as of March 31, 2006 primarily 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 decreased \$1.6 million to \$822,000 in the three months ended March 31, 2006, compared to \$2.4 million in the three months ended March 31, 2005. This decrease is primarily the result of a reduction in demand for clinical material to support our collaborator programs, particularly the Boehringer Ingelheim and Millennium programs. During the three months ended March 31, 2006, we shipped clinical materials in support of AVE9633 clinical trials as well as preclinical materials in support of the development efforts of our collaborators. During the same period in 2005, we shipped clinical materials in support of bivatuzumab mertansine, MLN2704, and AVE9633 clinical trials as well as preclinical materials in support of the development efforts of other collaborators.

The cost of clinical materials reimbursed for the three months ended March 31, 2006 and 2005 was \$779,000 and \$2.3 million, respectively. We are reimbursed for our fully burdened cost to produce clinical materials plus, under certain collaborative agreements, 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 our collaborators have underway, 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 research, development and analytical purposes. As such, the amount of clinical materials reimbursement and the related cost of clinical materials reimbursed may continue to vary significantly 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 relate to (i) research to identify and evaluate new targets and to develop and evaluate new antibodies and cytotoxic drugs, (ii) preclinical testing of our own and, in certain instances, 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 and development efforts have been primarily focused in the following areas:

- Our activities pursuant to our discovery, development and commercialization agreement with sanofi-aventis;
- Our activities related to the preclinical and clinical development of huN901-DM1 and huC242-DM4;
- Process development related to production of the huN901 antibody and huN901-DM1 conjugate for clinical materials;
- Process development related to production of the huC242 antibody and huC242-DM4 conjugate for clinical materials;
- Process improvements related to the production of DM1, DM4 and strain development of their precursor, ansamitocin P3;
- Operation and maintenance of our conjugate manufacturing plant;
- Process improvements to our TAP technology;
- Identification and evaluation of potential antigen targets;
- Evaluation of internally-developed and in-licensed antibody candidates; and
- Development and evaluation of additional cytotoxic agents.

DM1 and DM4 are the cytotoxic agents that we currently use in the manufacture of our two TAP product candidates in clinical testing. We have also investigated the viability of other maytansinoid effector molecules, which, collectively with DM1 and DM4, we refer to as DMx. In order to make commercial manufacture of DMx conjugates viable, we have devoted substantial resources to improving 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 a termination agreement between us and Vernalis, Vernalis relinquished its rights to develop and commercialize huN901-DM1. As a result, we regained the rights to develop and commercialize huN901-DM1. Under the terms of our January 7, 2004 Termination Agreement with Vernalis, we assumed responsibility of one of the studies underway with the compound, Study 001, on July 1, 2004. Since then, we have expanded this study due to the occurrence of objective activity among the initial patients enrolled and have expanded the number of clinical centers participating in this study to expedite patient enrollment. Additionally, we initiated a Phase I clinical trial with huN901-DM1 in CD56-positive multiple myeloma (Study 003) in September, 2005. On December 15, 2005, we and Vernalis executed an amendment to the January 7, 2004 Termination Agreement. Under the terms of the amendment, we assumed responsibility as of December 15, 2005, at our own expense, to complete the huN901-DM1 clinical study (Study 002) that had been initiated in the United Kingdom. Vernalis paid us approximately \$365,000 in consideration of the expected cost of the obligations assumed by us under the amendment. Such consideration is included in other income/expense in the accompanying

consolidated statements of operations for the nine months ended March 31, 2006. We intend to evaluate whether to out-license all or part of the development and commercial rights to this compound as we move through the clinical trial process.

In January 2004, we announced that we planned to advance cantuzumab mertansine, or an improved version of the compound, into a clinical trial that we would manage. In October 2004, we decided to move forward in developing a modified version of cantuzumab mertansine which we call huC242-DM4. Patient dosing was initiated for the Phase I study of huC242-DM4 in June 2005. We intend to evaluate whether to out-license all or part of the development and commercial rights to this compound as we move through the clinical trial process for this compound.

In 2003, we licensed our then three most advanced product candidates in our preclinical portfolio to sanofi-aventis under the terms of our discovery, development and commercialization collaboration. These three product candidates are an anti-CD33 TAP compound for acute myeloid leukemia (AVE9633), an anti-IGF-1R antibody (AVE1642), and an anti-CD19 TAP compound for certain B-cell malignancies (SAR3419). In December 2004, sanofi-aventis filed an Investigational New Drug Application (IND) for AVE9633. Clinical testing of this compound was initiated in March 2005.

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 March 31, 2006, pursuant to our collaboration research program with sanofi-aventis, we were continuing to perform preclinical experiments to evaluate candidate antibodies and have identified a lead antibody product candidate and several alternate product candidates. The third potential product candidate is directed at certain anti-CD19 B-cell malignancies, including non-Hodgkin's lymphoma, and is in preclinical development. Additional compounds also are being developed as part of this collaboration.

During the term of our research collaboration with sanofi-aventis, 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, with the exception of those antibodies or antibody targets that are the subject of our preexisting or future collaboration and license agreements. Sanofi-aventis then has the right to either include in or exclude from the collaborative research program these proposed antibodies and antibody targets. If sanofi-aventis elects to exclude any antibodies or antibody targets, we may elect to develop the products for our own pipeline. Furthermore, 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 the agreed-upon number. Over the original, three-year term of the research program and agreed-upon one-year extension, we will receive a minimum of \$68.9 million of committed research funding and will devote a significant amount of our internal research and development resources to advancing the research program. Under the terms of the agreement, we may advance any TAP or antibody products that sanofi-aventis has elected not to either initially include or later advance in the research program.

The potential product candidates that have been or 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 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 that 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 clinical 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 that have advanced into clinical testing will generate revenues and cash flows.

Research and development expense for the three months ended March 31, 2006 increased \$547,000 to \$10.2 million, from \$9.7 million for the three months ended March 31, 2005, due to the reasons set forth below. The number of our research and development personnel increased to 150 at March 31, 2006 compared to 134 at March 31, 2005.

Research and development salaries and related expenses increased by \$364,000 to \$4.2 million in the three months ended March 31, 2006 compared to \$3.8 million in the three months ended March 31, 2005. Included in salaries and related expenses for the three months ended March 31, 2006 is \$346,000 of stock compensation costs incurred with the adoption of SFAS 123(R) on July 1, 2005. Contract service expense increased \$967,000 substantially due to the manufacture of and process development efforts related to materials for use in our clinical trials during the three months ended March 31, 2006 as compared to the same period ended March 31, 2005. Clinical trial costs increased by \$279,000 in the three months ended March 31, 2006 as compared to the same period in the prior year due to the advancement of our clinical trials. Facilities expense, including depreciation, also increased \$291,000 from \$1.4 million to \$1.7 million for the three months ended

March 31, 2006 compared to the same period for the prior year. This increase was due to capital additions and an increase in administrative expenses primarily resulting from increased rent for the Norwood facility and higher utility costs. During the three months ended March 31, 2005, we recorded \$1.3 million of expense to reserve for excess quantities of ansamitocin P3 and DMx in accordance with our inventory policy. No similar expense was incurred during the three months ended March 31, 2006. 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.

	<b>Three Months Ended March</b>	
	<b>31,</b>	
	<b>2006</b>	<b>2005</b>
	<b>(in thousands)</b>	
Research	\$ 3,373	\$ 3,097
Preclinical and Clinical Testing	1,942	1,200
Process and Product Development	1,657	1,189
Manufacturing Operations	3,244	4,183
Total Research and Development Expense	\$ 10,216	\$ 9,669

**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 for the three months ended March 31, 2006 increased \$276,000 to \$3.4 million from \$3.1 million for the three months ended March 31, 2005. The increase in research expenses was primarily the result of an increase in consulting fees, fees to in-license certain technology and an increase in facilities expense.

**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. Preclinical and clinical testing expenses for the three months ended March 31, 2006 increased \$743,000 to \$1.9 million compared to \$1.2 million for the three months ended March 31, 2005. This increase is primarily due to an increase in salaries and related expense, facilities expense, and clinical trial costs. The increase in salaries and related expense is the result of an increase in personnel to support our own as well as our collaborators' preclinical and clinical activities, along with compensation costs incurred with the adoption of SFAS 123(R) as of July 1, 2005. Clinical trial costs increased due to expanding trial activity.

**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 March 31, 2006, total development expenses increased \$467,000 to \$1.7 million compared to \$1.2 million for the three months ended March 31, 2005. The increase was substantially due to increased contract services and to a lesser extent an increase in salaries and related expenses. Contract service expenses increased due to higher ansamitocin P3 and DMx development expenses incurred during the three months ended March 31, 2006, as compared to the same period in the prior year.

**Manufacturing Operations:** Manufacturing operations expense includes costs to manufacture preclinical and clinical materials for our own product candidates and cost to support the operation and maintenance of our conjugate manufacturing plant. Such expenses include personnel, raw materials for our preclinical and clinical trials, manufacturing supplies, and facilities expense. Manufacturing costs related to the production of material for our collaborators are recorded as cost of clinical material reimbursed in our statement of operations. For the three months ended March 31, 2006, manufacturing operations expense decreased \$939,000 to \$3.2 million compared to \$4.2 million in the same period last year. During the three months ended March 31, 2006, we did not record any expense related to ansamitocin P3 and DMx that we had identified as excess based upon our inventory policy, as compared to \$1.3 million of similar expense recognized during the three months ended March 31, 2005. Overhead utilization from the manufacture of clinical materials on behalf of our collaborators increased during the three months ended March 31, 2006 as compared to the same period prior year. These decreases in expense were partially offset by an increase in contract service expense resulting from increased

antibody purchases made during the three month period ended March 31, 2006, as compared to the same period in the prior year.

Reserve requirements for excess quantities of ansamitocin P3 and DMx are principally 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 further discussion of our inventory reserve policy).

#### *General and Administrative Expenses*

General and administrative expenses for the three months ended March 31, 2006 decreased \$83,000 to \$2.2 million, as compared to the three months ended March 31, 2005. This decrease is primarily due to a decrease in contract service expense, partially offset by an increase in salaries and related expense. Contract service expense decreased primarily due to lower consulting fees related to corporate strategic planning incurred during the three months ended March 31, 2006 as compared to the three months ended March 31, 2005. Salaries and related expenses increased due to an increase in personnel, along with compensation costs incurred with the adoption of SFAS 123(R) as of July 1, 2005.

#### *Interest Income*

Interest income for the three months ended March 31, 2006 increased \$365,000 to \$875,000 from \$510,000 for the three months ended March 31, 2005. The difference is due to higher prevailing interest rates.

#### *Net Realized Losses on Investments*

Net realized losses on investments were \$7,000 and \$55,000 for the three months ended March 31, 2006 and 2005, respectively. The difference is attributable to market conditions and the timing of investment sales.

### ***Comparison of Nine Months ended March 31, 2006 and 2005***

#### *Revenues*

Our total revenues for the nine months ended March 31, 2006 were \$23.7 million compared with \$28.3 million for the nine months ended March 31, 2005. The \$4.6 million decrease in revenues in the nine months ended March 31, 2006 compared to the same period in the prior year is primarily attributable to a decrease in clinical materials reimbursement revenue, partially offset by higher research and development support, and to a lesser extent, license and milestone fees.

Research and development support revenue was \$16.2 million and \$13.8 million in the nine months ended March 31, 2006 and 2005, respectively. These amounts primarily represent committed research funding earned based on actual resources utilized under our discovery, development and commercialization agreement with sanofi-aventis, as well as amounts earned for actual resources utilized under our development and license agreements with Biogen Idec and Centocor. The sanofi-aventis agreement provides that we will receive a minimum of \$50.7 million of committed research funding during a three-year research program, as determined in each of the three research program years. At the conclusion of the second sanofi-aventis research program year on August 31, 2005, a review of research activities during this period was conducted. This review identified \$1.1 million in billable activities performed under the program during the fiscal year ended June 30, 2005 which had not been billed or recorded as revenue. Accordingly, we have included this additional \$1.1 million of research and support revenue in the accompanying consolidated

statement of operations for the nine months ended March 31, 2006. Also included in research and development support revenue are fees related to process development and research work performed by the Company on behalf of collaborators, as well as samples of research-grade material shipped to collaborators. To date, our development fees represent the fully burdened reimbursement of costs incurred in producing research-grade materials and developing antibody-specific conjugation processes on behalf of our collaborators and potential collaborators during the early evaluation and preclinical testing stages of drug development. The amount of development fees we earn is directly related to the number of our collaborators 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.

Revenues from license and milestone fees increased \$196,000 to \$5.8 million in the nine month period ended March 31, 2006 compared to \$5.6 million in the nine month period ended March 31, 2005. Included in license and milestone fees for the nine months

ended March 31, 2006 is \$2.0 million of milestone revenue earned under the Genentech collaboration. Included in license and milestone fees for the nine months ended March 31, 2005 is \$2.5 million of milestone revenue earned under the sanofi-aventis collaboration. Total revenue from license and milestone fees recognized from each of our collaborative partners in the nine month periods ended March 31, 2006 and 2005 is included in the following table:

	<b>Nine Months ended March</b>	
	<b>31,</b>	
	<b>2006</b>	<b>2005</b>
	(in thousands)	
<b>Collaborative Partner:</b>		
Amgen (formerly Abgenix)	\$ 300	\$ 362
Biogen Idec	36	-
Boehringer Ingelheim	-	97
Centocor	125	42
Genentech	3,260	482
Millennium	290	332
sanofi-aventis	1,800	4,300
<b>Total</b>	<b>\$ 5,811</b>	<b>\$ 5,615</b>

Clinical materials reimbursement decreased \$7.2 million to \$1.7 million in the nine months ended March 31, 2006, compared to \$8.9 million in the nine months ended March 31, 2005. This decrease is primarily the result of a reduction in demand for clinical material to support our collaborator programs, particularly the Boehringer Ingelheim and Millennium programs. During the nine months ended March 31, 2006, we shipped clinical materials in support of the AVE9633 trial and in the anticipation of the clinical trials to be conducted by our partners, as well as preclinical materials in support of the development efforts of our collaborators. During the same period in 2005, we shipped clinical materials in support of the bivatuzumab mertansine, MLN2704 and AVE9633 clinical trials being conducted by partners, as well as preclinical materials in support of the development efforts of our collaborators. The cost of clinical materials reimbursed for the nine months ended March 31, 2006 and 2005 was \$1.8 million and \$7.8 million, respectively. Included in the cost of clinical materials reimbursed for the nine months ended March 31, 2006 and March 31, 2005 is \$153,000 and \$186,000, respectively, of expense to write down certain batches of ansamitocin P3 and DMx and certain work in process amounts to their net realizable value. We are reimbursed for our fully burdened cost to produce clinical materials plus, under certain collaborative agreements, 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 our collaborators have underway, 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 research, development and analytical purposes. As such, the amount of clinical materials reimbursement and the related cost of clinical materials reimbursed may continue to vary significantly from quarter to quarter and year to year.

#### *Research and Development Expenses*

Research and development expenses for the nine months ended March 31, 2006 increased \$4.8 million to \$28.5 million from \$23.7 million for the nine months ended March 31, 2005. The number of research and development personnel increased to 150 at March 31, 2006 compared to 134 at March 31, 2005. Research and development salaries and related expenses increased by \$2.3 million to \$13.0 million in the nine months ended March 31, 2006 compared to \$10.7 million in the nine months ended March 31, 2005. Included in salaries and related expenses for the nine months ended March 31, 2006 is \$1.1 million of stock compensation costs incurred with the adoption of SFAS 123(R) on July

1, 2005. Overhead utilization from the manufacture of clinical materials on behalf of our collaborators decreased \$439,000 in the nine months ended March 31, 2006 as compared to the same period ended March 31, 2005. Contract service expense increased \$1.9 million due primarily to the manufacture of and process development efforts related to materials for use in our clinical trials. Clinical trial costs increased \$691,000 due to our increasing clinical trials activity. Facility expense for the nine months ended March 31, 2006, including depreciation, increased \$947,000 to \$5.0 million from \$4.1 million in the nine months ended March 31, 2005, due to the addition of capital equipment, an increase in salaries and related expense due to an increase in headcount, and an increase in administrative expenses. In the nine months ended March 31, 2006 we did not incur any expense related to ansamitocin P3 and DMx that we had identified as excess based upon our inventory policy, as compared to \$2.3 million of similar expense recognized during the nine months ended March 31, 2005.

We expect our research and development expenses to continue to increase as we expand our clinical trial activity. 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>Nine Months Ended March</b>	
	<b>31,</b>	
	<b>2006</b>	<b>2005</b>
	(in thousands)	
Research	\$ 10,362	\$ 8,998
Preclinical and Clinical Testing	5,534	3,659
Process and Product Development	4,249	3,563
Manufacturing Operations	8,322	7,439
Total Research and Development Expense	\$ 28,467	\$ 23,659

**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 nine months ended March 31, 2006, research expenses increased \$1.4 million to \$10.4 million, compared to \$9.0 million in the nine months ended March 31, 2005. The increase in research expenses for the period was primarily the result of increases in salaries and related expenses, contract service expense, and facilities expense. The increase in salaries and related expense was the result of an increase in personnel to support the sanofi-aventis collaboration and our own internal projects, along with compensation costs incurred with the adoption of SFAS 123(R) as of July 1, 2005.

**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 nine months ended March 31, 2006, preclinical and clinical testing expenses increased \$1.9 million to \$5.5 million, compared to \$3.7 million in the nine months ended March 31, 2005. This increase in preclinical and clinical testing expense is substantially due to increases in salaries and related expense, clinical trial costs and facilities expense, partially offset by a decrease in contract service expense. The increase in salaries and related expense is the result of an increase in personnel to support our own as well as our collaborators' preclinical and clinical activities, along with compensation costs incurred with the adoption of SFAS 123(R) as of July 1, 2005. The decrease in contract service expense in the nine months ended March 31, 2006 is primarily a result of lower costs associated with huC242-DM4 preclinical studies.

**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 nine months ended March 31, 2006, total development expenses increased \$686,000 to \$4.2 million, compared to \$3.6 million for the nine months ended March 31, 2005. This increase was primarily the result of an increase in salaries and related expenses. Salaries and related expenses increased due to an increase in personnel, along with compensation costs incurred related to option grants accounted for under SFAS 123(R).



**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 conjugate 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 nine months ended March 31, 2006, manufacturing operations expense increased \$882,000 to \$8.3 million, compared to \$7.4 million for the nine months ended March 31, 2005. The increase in expense for the current nine month period compared to the same period in the prior year was primarily the result of lower overhead utilization from the manufacture of clinical materials on behalf of our collaborators, and increases in salaries and related expenses, administrative expenses, contract services, and facilities expense. These increases were partially offset by a decrease in expenses to reserve for excess quantities of ansamitocin P3 and DMx in accordance with our inventory reserve policy.

During the nine months ended March 31, 2005, we recorded research and development expenses of \$2.3 million of ansamitocin

P3 and DMx that we had identified as excess based upon our inventory policy, and \$186,000 to write down certain batches of ansamitocin P3 and DMx and certain work in process amounts to their net realizable value. During the same period in the current year, we recorded only \$153,000 in similar expenses. 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 further discussion of our inventory reserve policy).

#### *General and Administrative Expenses*

General and administrative expenses for the nine months ended March 31, 2006 increased \$1.1 million to \$7.3 million from \$6.2 million for the nine months ended March 31, 2005. This increase is primarily due to an increase in salaries and related expense, and expanded patent filings. Salaries and related expenses increased due to an increase in personnel, along with compensation costs incurred with the adoption of SFAS 123(R) as of July 1, 2005.

#### *Interest Income*

Interest income for the nine months ended March 31, 2006 increased \$1.1 million to \$2.4 million from \$1.3 million for the nine months ended March 31, 2005. The difference is due to higher prevailing interest rates.

#### *Net Realized Losses on Investments*

Net realized losses on investments were \$33,000 and \$59,000 for the nine months ended March 31, 2006 and 2005, respectively. The difference is attributable to market conditions and the timing of investment sales.

#### *Other Income*

During the nine months ended March 31, 2006, we recorded as other income \$365,000 for consideration of the expected cost of the obligations assumed by us resulting from the Amendment to the January 7, 2004 Termination Agreement executed by us and Vernalis. Under the terms of the Amendment, we assumed responsibility as of December 15, 2005, at our own expense, to complete Study 002 for huN901-DM1.

## **LIQUIDITY AND CAPITAL RESOURCES**

We require cash to fund our operating expenses, including the conduct of our clinical programs, manufacture of material to support 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 March 31, 2006, we had approximately \$82.8 million in cash and marketable securities. Net cash used for operations during the nine months ended March 31, 2006 was \$7.1 million, compared to net cash used for operations of \$1.5 million during the nine months ended March 31, 2005. Cash used in operations is primarily to fund our net loss. The increased use of funds during the nine months ended March 31, 2006 is principally due to the increased net loss, as a result of increased research and development costs and general and administrative expenses, for the period compared to the same period last year, without the benefit of the reduction in working capital that occurred in the same period last year.

Net cash provided by investing activities during the nine months ended March 31, 2006 was \$6.6 million compared to net cash provided by investing activities of \$2.0 million during the nine months ended March 31, 2005. Cash flows

from investing activities in the nine months ended March 31, 2006 and 2005 primarily reflects the proceeds of sales and maturities of marketable securities and capital expenditures. The variance primarily relates to an increase in the sale and maturities of marketable securities to fund our operations. Capital expenditures were \$1.6 million and \$1.9 million for the nine month periods ended March 31, 2006 and 2005, respectively.

Net cash provided by financing activities was \$1.1 million for the nine month period ended March 31, 2006 compared to net cash provided by financing activities of \$480,000 for the nine months ended March 31, 2005. For the nine months ended March 31, 2006, net cash provided by financing activities reflects the proceeds to us from the exercise of 379,219 stock options under our Restated Stock Option Plan, at prices ranging from \$1.31 to \$6.27 per share. For the nine months ended March 31, 2005, net cash provided by financing activities reflects the proceeds to us from the exercise of 217,315 stock options at prices ranging from \$0.84 to \$6.78 per share.

We anticipate that our current capital resources and future collaborator payments, 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 operational expenses and capital expenditures for at least the next two to three 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 received. Should we not meet some or all of the terms and conditions of our various collaboration agreements, we may be required to pursue additional strategic partners, secure alternative financing arrangements, and/or defer or limit some or all of our research, development and/or clinical projects.

#### *Recent Accounting Pronouncements*

In June 2005, the FASB issued SFAS No. 154, *Accounting Changes and Error Corrections*, which will require entities that voluntarily make a change in accounting principle to apply that change retrospectively to prior periods' financial statements, unless this would be impracticable. SFAS No. 154 supercedes APB Opinion No. 20, *Accounting Changes*, which previously required that most voluntary changes in accounting principle be recognized by including in the current period's net income the cumulative effect of changing to the new accounting principle. SFAS No. 154 also makes a distinction between "retrospective application" of an accounting principle and the "restatement" of financial statements to reflect the correction of an error. Another significant change in practice under SFAS No. 154 will be that if an entity changes its method of depreciation, amortization, or depletion for long-lived, non-financial assets, the change must be accounted for as a change in accounting estimate. Under APB No. 20, such a change would have been reported as a change in accounting principle. SFAS No. 154 applies to accounting changes and error corrections that are made in fiscal years beginning after December 15, 2005.

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

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

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

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

As of the end of the period covered by this report, the Company's principal executive officer and principal financial officer evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and have concluded, based on such evaluation, that the design and operation of the Company's disclosure controls and procedures were adequate and effective to ensure that material information relating to the Company, including its consolidated subsidiaries, was made known to them by others within those entities, particularly during the period in which this Quarterly Report on Form 10-Q was being prepared.

#### *(b) Changes in Internal Controls*

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

## PART II. OTHER INFORMATION

### ITEM 1. Legal Proceedings.

None.

### ITEM 1A. Risk Factors.

#### Risk Factors

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

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

Our TAP technology yields novel anticancer product candidates for the treatment of cancer. No TAP product candidate has obtained regulatory approval and all of them are in early stages of development. The most advanced TAP product candidates are only in the Phase I or Phase I/II stage of clinical trials. Our/our collaborators' TAP product candidates may not prove to be safe, effective or commercially viable treatments for cancer and our TAP technology may not result in any meaningful benefits to our current or potential collaborative partners. Furthermore, we are aware of only one antibody-drug conjugate that has obtained FDA approval and is based on technology similar to our TAP technology. If our TAP technology fails to generate product candidates that are safe, effective and commercially viable treatments for cancer, and fails to obtain FDA approval, our business is likely to be severely harmed.

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

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

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

Other reasons that are internal to the businesses of our collaborative partners, which reasons they may not share with us.

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

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

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

- generate cash flow and revenue;
  - offset some of the costs associated with our internal research and development, preclinical testing, clinical trials and manufacturing;
  - seek and obtain regulatory approvals faster than we could on our own;
  - successfully commercialize existing and future product candidates;
- develop antibodies for additional product candidates, and discover additional cell surface markers for antibody development; and
- secure access to targets which, due to intellectual property restrictions, would otherwise be unavailable to our technology.

If we fail to secure or maintain successful collaborative arrangements, our development and marketing activities may be delayed or scaled back. In addition, we may be unable to negotiate other collaborative arrangements or, if necessary, modify our existing arrangements on acceptable terms. We have entered into collaborations with Amgen (formerly Abgenix), Biogen Idec, Boehringer Ingelheim, Centocor, Genentech, Millennium and sanofi-aventis. We cannot control the amount and timing of resources our partners may devote to our products. Our partners may separately pursue competing products, therapeutic approaches or technologies to develop treatments for the diseases targeted by us or our collaborative efforts, or may decide for reasons not known to us to discontinue development of products under our agreements with them. For example, in February 2005, Boehringer Ingelheim discontinued development of bivatuzumab mertansine. Under our 2001 agreement with them, Boehringer Ingelheim retained its right to use ImmunoGen's DM1 TAP technology and has exercised its right to create an anticancer compound to a different antigen target. In addition, in January 2006, Millennium announced that it had decided not to continue development of its MLN2704 compound. Even if our partners continue their contributions to the collaborative arrangements, they may nevertheless determine not to actively pursue the development or commercialization of any resulting products. Also, our partners may fail to perform their obligations under the collaborative agreements or may be slow in performing their obligations. Our partners can terminate our collaborative agreements under certain conditions. The decision to advance a product that is covered by a collaborative agreement through clinical trials and ultimately to commercialization is in the sole discretion of our collaborative partners. If any collaborative partner were to terminate or breach our agreements, or fail to complete its obligations to us in a timely manner, our anticipated revenue from the agreement and from the development and commercialization of our products could be severely limited. If we are not able to establish additional collaborations or any or all of our existing collaborations are terminated and we are not able to enter into alternative collaborations on acceptable terms, our continued development, manufacture and commercialization of our product candidates could be delayed or scaled back as we may not have the funds or capability to continue these activities. If our collaborators fail to successfully develop and commercialize TAP compounds, our business will be severely harmed.

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



We have and will continue to have collaborations with a limited number of companies. As a result, our financial performance depends on the efforts and overall success of these companies. Also, the failure of any one of our collaborative partners to perform its obligations under its agreement with us, including making any royalty, milestone or other payments to us, could have a material adverse effect on our financial condition. Further, any material reduction by any one of our collaborative partners in its level of commitment of resources, funding, personnel, and interest in continued development under its agreement with us could have a material adverse effect on our financial condition. If consolidation trends in the healthcare industry continue, the number of our potential collaborators could decrease, which could have an adverse impact on our development efforts. If a present or future collaborator of ours were to be involved in a business combination, their continued pursuit and emphasis on our product development program could be delayed, diminished or terminated. For example, in February 2005, Boehringer Ingelheim discontinued development of bivatuzumab mertansine. Under our 2001 agreement with them, Boehringer Ingelheim retained its right to use ImmunoGen's DM1 TAP technology and has exercised its right to create an anticancer compound to a different antigen target. In addition, in January 2006, Millennium announced that it had decided not to continue development of its MLN2704 compound.

**If our collaborators' requirements for clinical materials to be manufactured by us are significantly lower than we have estimated, our financial results and condition could be significantly harmed.**

We procure certain components of finished conjugate including ansamitocin P3, DM1, DM4, and linker on behalf of our collaborators. In order to meet our commitments to our collaborators, we are required to enter into agreements with third parties to produce these components well in advance of our production of clinical materials on behalf of our collaborators. If our collaborators do not require as much clinical material as we have contracted to produce, we may not be able to recover our investment in these components and we may suffer significant losses. For example, in February 2005, Boehringer Ingelheim discontinued development of bivatuzumab mertansine and in January 2006, Millennium discontinued development of MLN2704. As a result, in the periods subsequent to discontinuation of development, we have or expect to have reduced demand for conjugated material. Specifically, the discontinuation of bivatuzumab mertansine has contributed to the decrease in clinical materials reimbursement in the current fiscal period.

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

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

We have generated operating losses since our inception. As of March 31, 2006, we had an accumulated deficit of \$231.9 million. For the nine months ended March 31, 2006, and the fiscal years ended June 30, 2005, 2004 and 2003, we generated losses of \$11.2 million, \$11.0 million, \$5.9 million and \$20.0 million, respectively. We may never be profitable. We expect to incur substantial additional operating expenses over the next several years as our research, development, preclinical testing, clinical studies and collaborator support activities increase. We intend to continue to invest significantly in our product candidates. Further, we expect to invest significant resources supporting our existing collaborators as they work to develop, test and commercialize TAP and other antibody compounds, and we or our collaborators may encounter technological or regulatory difficulties as part of this development and commercialization process that we cannot overcome or remedy. We may also incur substantial marketing and other costs in the future if we decide to establish marketing and sales capabilities to commercialize our product candidates. None of our product candidates has generated any commercial revenue and our only revenues to date have been primarily from upfront and milestone payments, research and development support and clinical materials reimbursement from our collaborative partners. We do not expect to generate revenues from the commercial sale of our product candidates in the foreseeable future, and we may never generate revenues from the commercial sale of products. Even if we do successfully develop products that can be marketed and sold commercially, we will need to generate significant revenues from those products to achieve and maintain profitability. Even if we do become profitable, we may not be able to sustain or increase profitability on a quarterly or annual basis.

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

We or our collaborative partners may not receive the regulatory approvals necessary to commercialize our product candidates, which could cause our business to be severely harmed. Pharmaceutical product candidates, including those in development by us and our collaborative partners, are subject to extensive and rigorous government regulation. The FDA regulates, among other things, the development, testing, manufacture, safety, record-keeping, labeling, storage, approval, advertising, promotion, sale and distribution of pharmaceutical products. If our/our collaborators' potential products are marketed abroad, they will also be subject to extensive regulation by foreign governments. None of our

product candidates has been approved for sale in the United States or any foreign market. The regulatory review and approval process, which includes preclinical studies and clinical trials of each product candidate, is lengthy, complex, expensive and uncertain. Securing FDA approval requires the submission of extensive preclinical and clinical data and supporting information to the FDA for each indication to establish the product candidate's safety and efficacy. Data obtained from preclinical and clinical trials are susceptible to varying interpretation, which may delay, limit or prevent regulatory approval. The approval process may take many years to complete and may involve ongoing requirements for post-marketing studies. In light of the limited regulatory history of monoclonal antibody-based therapeutics, regulatory approvals for our products may not be obtained without lengthy delays, if at all. Any FDA or other regulatory approvals of our product candidates, once obtained, may be withdrawn. The effect of government regulation may be to:

- delay marketing of potential products for a considerable period of time;
- limit the indicated uses for which potential products may be marketed;

- impose costly requirements on our activities; and
- provide competitive advantage to other pharmaceutical and biotechnology companies.

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

**Our/our collaborators' product candidates will remain subject to ongoing regulatory review even if they receive marketing approval. If we fail to comply with continuing regulations, we could lose these approvals and the sale of our products could be suspended.**

Even if we receive regulatory approval to market a particular product candidate, the approval could be conditioned on us conducting additional costly post-approval studies or could limit the indicated uses included in our labeling. Moreover, the product may later cause adverse effects that limit or prevent its widespread use, force us to withdraw it from the market or impede or delay our ability to obtain regulatory approvals in additional countries. In addition, the manufacturer of the product and its facilities will continue to be subject to FDA review and periodic inspections to ensure adherence to applicable regulations. After receiving marketing approval, the manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion and record-keeping related to the product will remain subject to extensive regulatory requirements. We may be slow to adapt, or we may never adapt, to changes in existing regulatory requirements or adoption of new regulatory requirements.

If we fail to comply with the regulatory requirements of the FDA and other applicable U.S. and foreign regulatory authorities or previously unknown problems with our products, manufacturers or manufacturing processes are discovered, we could be subject to administrative or judicially imposed sanctions, including:

- restrictions on the products, manufacturers or manufacturing processes;
    - warning letters;
    - civil or criminal penalties;
      - fines;
      - injunctions;
    - product seizures or detentions;
      - import bans;
  - voluntary or mandatory product recalls and publicity requirements;
    - suspension or withdrawal of regulatory approvals;
    - total or partial suspension of production; and
- refusal to approve pending applications for marketing approval of new drugs or supplements to approved applications.

**We rely on single source suppliers to manufacture the primary component for our cell-killing agents, DM1 and DM4. Any problems experienced by either supplier could negatively affect our operations.**

We rely on third-party suppliers for some of the materials used in the manufacturing of TAP product candidates and cytotoxic agents. Our cell-killing agents include DM1 and DM4 (collectively DMx). DM1 and DM4 are used in our TAP product candidates in preclinical and clinical testing and are the subject of most of our collaborations. One of the primary components required to manufacture DM1 and DM4 is their precursor, ansamitocin P3. Currently, only one vendor manufactures and is able to supply us with this material. Any problems experienced by this vendor could result in a delay or interruption in the supply of ansamitocin P3 to us until this vendor cures the problem or until we locate an alternative source of supply. Any delay or interruption in our supply of ansamitocin P3 would likely lead to a delay or interruption in our manufacturing operations and preclinical and clinical trials of our product candidates, which could negatively affect our business. We also have an agreement with only one vendor to convert

ansamitocin P3 to DMx. Any problems experienced by this vendor could result in a delay or interruption in the supply of DMx to us

until this vendor cures the problem or until we locate an alternative source of supply. Any delay or interruption in our supply of DMx could lead to a delay or interruption in our manufacturing operations and preclinical and clinical trials of our product candidates or our collaborators' product candidates, which could negatively affect our business. We are currently in negotiations with a potential additional supplier of these materials. We cannot assume that we would be able to reach agreement with this supplier on acceptable terms, or at all.

**Unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives applicable to our product candidates could limit our potential product revenue.**

The regulations governing drug pricing and reimbursement vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed and, in many of these countries, the pricing review period begins only after approval is granted. In some countries, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. Although we monitor these regulations, our product candidates are currently in the development stage and we will not be able to assess the impact of price regulations for at least several years. As a result, we may obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay the commercial launch of the product and may negatively impact the revenues we are able to derive from sales in that country.

Successful commercialization of our products will also depend in part on the extent to which coverage and adequate payment for our products will be available from government health administration authorities, private health insurers and other third-party payors. If we succeed in bringing a product candidate to the market, it may not be considered cost-effective and reimbursement to the patient may not be available or sufficient to allow us to sell it at a satisfactory price. Because our product candidates are in the development stage, we are unable at this time to determine their cost-effectiveness. We may need to conduct expensive studies in order to demonstrate cost-effectiveness. Moreover, third-party payors frequently require that drug companies provide them with predetermined discounts from list prices and are increasingly challenging the prices charged for medical products. Because our product candidates are in the development stage, we do not know the level of reimbursement, if any, we will receive for any products that we are able to successfully develop. If the reimbursement for any of our product candidates is inadequate in light of our development and other costs, our ability to achieve profitability could be affected.

We believe that the efforts of governments and third-party payors to contain or reduce the cost of healthcare will continue to affect the business and financial condition of pharmaceutical and biopharmaceutical companies. A number of legislative and regulatory proposals to change the healthcare system in the United States and other major healthcare markets have been proposed and adopted in recent years. For example, the U.S. Congress enacted a limited prescription drug benefit for Medicare recipients as part of the Medicare Prescription Drug, Improvement and Modernization Act of 2003. While the program established by this statute may increase demand for any products that we are able to successfully develop, if we participate in this program, our prices will be negotiated with drug procurement organizations for Medicare beneficiaries and are likely to be lower than prices we might otherwise obtain. Non-Medicare third-party drug procurement organizations may also base the price they are willing to pay on the rate paid by drug procurement organizations for Medicare beneficiaries. In addition, ongoing initiatives in the United States have and will continue to increase pressure on drug pricing. The announcement or adoption of any such initiative could have an adverse effect on potential revenues from any product candidate that we may successfully develop.

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

Currently, we only have one in-house conjugate manufacturing facility for the manufacture of conjugated compounds necessary for preclinical and clinical testing. We do not have sufficient manufacturing capacity to manufacture all of our product candidates in quantities necessary for commercial sale. In addition, our manufacturing capacity may be insufficient to complete all clinical trials contemplated by us or our collaborators over time. We intend to rely in part on third-party contract manufacturers to produce sufficiently large quantities of drug materials that are and will be needed for clinical trials and commercialization of our potential products. Third-party manufacturers may not be able to meet our needs with respect to timing, quantity or quality of materials. If we are unable to contract for a sufficient supply of needed materials on acceptable terms, or if we should encounter delays or difficulties in our relationships with manufacturers, our clinical trials may be delayed, thereby delaying the submission of product candidates for regulatory approval and the market introduction and subsequent commercialization of our potential products. Any such delays may lower our revenues and potential profitability.

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

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

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

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

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

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

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

**If our product candidates or those of our collaborators do not gain market acceptance, our business will suffer.**

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

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

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

**We may be unable to compete successfully.**

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

- develop products that are safer or more effective than our product candidates;



• obtain FDA and other regulatory approvals or reach the market with their products more rapidly than we can, reducing the potential sales of our product candidates;

- devote greater resources to market or sell their products;
- adapt more quickly to new technologies and scientific advances;
- initiate or withstand substantial price competition more successfully than we can;
- have greater success in recruiting skilled scientific workers from the limited pool of available talent;
- more effectively negotiate third-party licensing and collaboration arrangements; and
- take advantage of acquisition or other opportunities more readily than we can.

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

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

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

Also, patents and applications owned or licensed by us may become the subject of interference proceedings in the United States Patent and Trademark Office to determine priority of invention that could result in substantial cost to us. An adverse decision in an interference proceeding may result in our loss of rights under a patent or patent application. It is unclear how much protection, if any, will be given to our patents if we attempt to enforce them and they are challenged in court or in other proceedings. A competitor may successfully challenge our patents or a challenge could result in limitations of the patents' coverage. In addition, the cost of litigation or interference proceedings to uphold the validity of patents can be substantial. If we are unsuccessful in these proceedings, third parties may be able to use our patented technology without paying us licensing fees or royalties. Moreover, competitors may infringe our patents or successfully avoid them through design innovation. To prevent infringement or unauthorized use, we may need to file infringement claims, which are expensive and time-consuming. In an infringement proceeding a court may decide that a patent of ours is not valid. Even if the validity of our patents

were upheld, a court may refuse to stop the other party from using the technology at issue on the ground that its activities are not covered by our patents. Policing unauthorized use of our intellectual property is difficult, and we may not be able to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States.

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

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

Patent litigation is very common in the biotechnology and pharmaceutical industries. Third parties may assert patent or other intellectual property infringement claims against us with respect to our technologies, products or other matters. Any claims that might be brought against us relating to infringement of patents may cause us to incur significant expenses and, if successfully asserted against us, may cause us to pay substantial damages and limit our ability to use the intellectual property subject to these claims. Even if we were to prevail, any litigation would be costly and time-consuming and could divert the attention of our management and key personnel from our business operations. Furthermore, as a result of a patent infringement suit, we may be forced to stop or delay developing, manufacturing or selling potential products that incorporate the challenged intellectual property unless we enter into royalty or license agreements. There may be third-party patents, patent applications and other intellectual property relevant to our potential products that may block or compete with our products or processes. In addition, we sometimes undertake research and development with respect to potential products even when we are aware of third-party patents that may be relevant to our potential products, on the basis that such patents may be challenged or licensed by us. If our subsequent challenge to such patents were not to prevail, we may not be able to commercialize our potential products after having already incurred significant expenditures unless we are able to license the intellectual property on commercially reasonable terms. We may not be able to obtain royalty or license agreements on terms acceptable to us, if at all. Even if we were able to obtain licenses to such technology, some licenses may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. Ultimately, we may be unable to commercialize some of our potential products or may have to cease some of our business operations, which could severely harm our business.

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

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

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

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

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

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

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

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

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

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

• if either we or any of our collaborators incur higher than expected costs or experience slower than expected progress in developing product candidates and obtaining regulatory approvals;

- lower revenues than expected under our collaboration agreements; or
- acquisition of technologies and other business opportunities that require financial commitments.

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

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

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

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

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

**ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds.**

None.

**ITEM 3. Defaults Upon Senior Securities.**

None.

**ITEM 4. Submission of Matters to a Vote of Security Holders.**

None.

**ITEM 5. Other Information.**

(a) Not applicable.

(b) Not applicable.

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**ITEM 6. Exhibits.**

(a) Exhibits

3.3 By-Laws, as amended (2)

31.1 Certification of Chief Executive Officer under Section 302 of the Sarbanes-Oxley Act of 2002.

31.2 Certification of Principal Financial Officer under Section 302 of the Sarbanes-Oxley Act of 2002.

32. Certifications of Chief Executive Officer and Principal Financial Officer under Section 906 of the Sarbanes-Oxley Act of 2002.

(2) Previously filed with the Commission as an exhibit to, and incorporated herein by reference from, the Registrant's report on Form 8-K dated November 2, 2005.

**SIGNATURES**

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

**ImmunoGen, Inc.**

Date: May 5, 2006

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

Date: May 5, 2006

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