

Edgar Filing: CYTOGEN CORP - Form 10-Q

CYTOGEN CORP
Form 10-Q
August 09, 2005

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2005

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 000-14879

Cytogen Corporation

(Exact Name of Registrant as Specified in Its Charter)

Delaware

22-2322400

(State or Other Jurisdiction of
Incorporation or Organization)

(I.R.S. Employer
Identification Number)

650 College Road East, Suite 3100, Princeton, NJ 08540-5308

(Address of Principal Executive Offices and Zip Code)

Registrant's Telephone Number, Including Area Code: (609) 750-8200

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 X No .
--- ---

Indicate by check mark whether the registrant is an accelerated filer (as
defined in Rule 12b-2 of the Exchange Act). Yes X No .
--- ---

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

Class

Outstanding at August 5, 2005

Edgar Filing: CYTOGEN CORP - Form 10-Q

Common Stock, \$.01 par value

17,155,933

CYTOGEN CORPORATION

TABLE OF CONTENTS

| | Page |
|--|------|
| | ---- |
| PART I. FINANCIAL INFORMATION..... | 1 |
| Item 1. Consolidated Financial Statements (unaudited)..... | 1 |
| Consolidated Balance Sheets as of June 30, 2005 and December 31, 2004..... | 2 |
| Consolidated Statements of Operations for the Three Months and Six Months Ended June 30, 2005 and 2004..... | 3 |
| Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2005 and 2004 | 4 |
| Notes to Consolidated Financial Statements..... | 5 |
| Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations..... | 15 |
| Item 3. Quantitative and Qualitative Disclosures About Market Risk.. | 31 |
| Item 4. Controls and Procedures..... | 31 |
| PART II. OTHER INFORMATION..... | 33 |
| Item 4. Submission of Matters to a Vote of Security Holders..... | 33 |
| Item 6. Exhibits..... | 34 |
| SIGNATURES..... | 35 |

ProstaScint(R), Quadramet(R) and OncoScint(R) are registered United States trademarks of Cytogen Corporation. All other trade names, trademarks or servicemarks appearing in this Quarterly Report on Form 10-Q are the property of their respective owners, and not the property of Cytogen Corporation or any of its subsidiaries.

Edgar Filing: CYTOGEN CORP - Form 10-Q

PART I - FINANCIAL INFORMATION

ITEM 1 - CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

-1-

CYTOGEN CORPORATION AND SUBSIDIARIES
 CONSOLIDATED BALANCE SHEETS
 (All amounts in thousands, except share and per share data)
 (Unaudited)

| | JUNE 30, 2005 |
|---|------------------|
| | ----- |
| ASSETS: | |
| Current assets: | |
| Cash and cash equivalents..... | \$ 20,532 |
| Short-term investments..... | -- |
| Accounts receivable, net..... | 1,821 |
| Inventories..... | 5,103 |
| Prepaid expenses..... | 563 |
| Other current assets..... | 145 |
| | ----- |
| Total current assets..... | 28,164 |
| Property and equipment, net..... | 801 |
| Quadramet license fee, net..... | 6,675 |
| Other assets..... | 400 |
| | ----- |
| | \$ 36,040 |
| | ===== |
| LIABILITIES AND STOCKHOLDERS' EQUITY: | |
| Current liabilities: | |
| Current portion of long-term liabilities..... | \$ 2,298 |

Edgar Filing: CYTOGEN CORP - Form 10-Q

| | | |
|--|-----------|-------|
| Liability related to joint venture..... | 1,100 | |
| Accounts payable and accrued liabilities..... | 6,130 | |
| | | ----- |
| Total current liabilities..... | 9,528 | ----- |
| Long-term liabilities..... | 38 | ----- |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Preferred stock, \$.01 par value, 5,400,000 shares authorized-Series C Junior Participating Preferred Stock, \$.01 par value, 200,000 shares authorized, none issued and outstanding..... | -- | |
| Common stock, \$.01 par value, 50,000,000 shares authorized, 15,527,920 and 15,489,116 shares issued and outstanding at June 30, 2005 and December 31, 2004, respectively..... | 155 | |
| Additional paid-in capital..... | 427,228 | |
| Unearned compensation..... | (847) | |
| Common stock to be issued (92,799 shares)..... | 500 | |
| Accumulated other comprehensive income..... | 50 | |
| Accumulated deficit..... | (400,612) | |
| | | ----- |
| Total stockholders' equity..... | 26,474 | ----- |
| | \$ 36,040 | ===== |

The accompany notes are an integral part of these statements.

-2-

CYTOGEN CORPORATION AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(All amounts in thousands, except per share data)
(Unaudited)

| | THREE MONTHS ENDED JUNE 30, | |
|-----------------------------------|--------------------------------|----------|
| | 2005 | 2004 |
| | ----- | ----- |
| REVENUES: | | |
| Product revenue: | | |
| Quadramet..... | \$ 2,153 | \$ 1,616 |
| ProstaScint..... | 1,924 | 2,312 |
| Other..... | -- | -- |
| | ----- | ----- |
| Total product revenue..... | 4,077 | 3,928 |
| License and contract revenue..... | 79 | 24 |

Edgar Filing: CYTOGEN CORP - Form 10-Q

| | | |
|---|------------|------------|
| | ----- | ----- |
| Total revenues..... | 4,156 | 3,952 |
| | ----- | ----- |
| OPERATING EXPENSES: | | |
| Cost of product revenue..... | 2,251 | 2,396 |
| Selling, general and administrative..... | 6,692 | 4,914 |
| Research and development..... | 1,362 | 541 |
| Equity in loss of joint venture..... | 1,704 | 542 |
| | ----- | ----- |
| Total operating expenses..... | 12,009 | 8,393 |
| | ----- | ----- |
| Operating loss..... | (7,853) | (4,441) |
| INTEREST INCOME..... | 154 | 106 |
| INTEREST EXPENSE..... | (42) | (49) |
| | ----- | ----- |
| NET LOSS | \$ (7,741) | \$ (4,384) |
| | ===== | ===== |
| BASIC AND DILUTED NET LOSS PER SHARE..... | \$ (0.50) | \$ (0.30) |
| | ===== | ===== |
| WEIGHTED AVERAGE COMMON SHARES OUTSTANDING..... | 15,525 | 14,848 |
| | ===== | ===== |

The accompany notes are an integral part of these statements.

-3-

CYTOGEN CORPORATION AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(All amounts in thousands)
(Unaudited)

| | SIX MONTHS ENDED JU | |
|---|---------------------|----|
| | ----- | |
| | 2005 | |
| | ----- | |
| CASH FLOWS FROM OPERATING ACTIVITIES: | | |
| Net loss | \$ (14,334) | \$ |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization..... | 492 | |
| Stock-based compensation expenses..... | 13 | |
| Stock-based milestone obligation..... | 500 | |
| Decrease in provision for doubtful accounts..... | (39) | |
| Amortization of premiums/discounts on investments, net..... | 52 | |
| Deferred rent..... | 21 | |
| Loss on disposition of assets..... | -- | |

Edgar Filing: CYTOGEN CORP - Form 10-Q

| | | |
|--|-----------|-------|
| Write down of property and equipment..... | -- | |
| Changes in assets and liabilities: | | |
| Receivables..... | (376) | |
| Inventories..... | (1,474) | |
| Other assets..... | 690 | |
| Liability related to joint venture..... | 704 | |
| Accounts payable and accrued liabilities..... | (1,535) | |
| | ----- | |
| Net cash used in operating activities..... | (15,286) | |
| | ----- | |
| CASH FLOWS FROM INVESTING ACTIVITIES: | | |
| Maturities of short-term investments..... | 22,727 | |
| Purchases of short-term investments..... | -- | |
| Purchases of property and equipment..... | (163) | |
| | ----- | |
| Net cash provided by (used in) investing activities..... | 22,564 | |
| | ----- | |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | |
| Proceeds from issuance of common stock..... | 215 | |
| Payment of long-term liabilities..... | (7) | |
| | ----- | |
| Net cash provided by financing activities..... | 208 | |
| | ----- | |
| Net increase in cash and cash equivalents..... | 7,486 | |
| Cash and cash equivalents, beginning of period..... | 13,046 | |
| | ----- | |
| Cash and cash equivalents, end of period..... | \$ 20,532 | \$ |
| | ===== | ===== |
| Supplemental disclosure of non-cash information: | | |
| Capital lease of equipment..... | \$ 1 | \$ |
| | ===== | ===== |
| Unrealized holding gain on marketable securities..... | \$ 50 | \$ |
| | ===== | ===== |
| Supplemental disclosure of cash information: | | |
| Cash paid for interest..... | \$ 84 | \$ |
| | ===== | ===== |

The accompany notes are an integral part of these statements.

-4-

CYTOGEN CORPORATION AND SUBSIDIARIES
 NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
 (Unaudited)

1. THE COMPANY

BACKGROUND

Founded in 1980, Cytogen Corporation (the "Company" or "Cytogen") of

Edgar Filing: CYTOGEN CORP - Form 10-Q

Princeton, NJ is a product-driven biopharmaceutical company that develops and commercializes innovative molecules that can be used to build leading franchises. The Company's marketed products include QUADRAMET(R) (samarium Sm-153 lexitronam injection) and PROSTASCINT(R) (capromab pendetide) kit for the preparation of Indium In-111 capromab pendetide in the United States. The Company also has exclusive United States marketing rights to COMBIDEX(R) (ferumoxtran-10) for all applications, and the exclusive right to market and sell ferumoxtol (formerly Code 7228) for oncology applications in the United States. On March 3, 2005, the U.S. Food and Drug Administration's (the "FDA") Oncologic Drugs Advisory Committee (ODAC) voted to not recommend approval of the proposed broad indication for COMBIDEX. On March 24, 2005, Advanced Magnetics, Inc. informed Cytogen that Advanced Magnetics received an approvable letter from the FDA for Combidex, subject to certain conditions.

The Company is also developing therapeutics targeting prostate-specific membrane antigen (PSMA), a protein highly expressed on the surface of prostate cancer cells and the neovasculature of solid tumors.

The Company has had a history of operating losses since its inception. The Company currently relies on two products, PROSTASCINT and QUADRAMET, for substantially all of its revenues. In addition, the Company has, from time to time, stopped selling certain products, such as NMP22 BLADDERCHEK, BRACHYSEED and ONCOSCINT, that the Company previously believed would generate significant revenues. The Company's products are subject to significant regulatory review by the FDA and other federal and state agencies, which requires significant time and expenditures in seeking, maintaining and expanding product approvals. In addition, the Company relies on collaborative partners to a significant degree, among other things, to manufacture its products, to secure raw materials, and to provide licensing rights to their proprietary technologies for the Company to sell and market to others. The Company is also subject to credit concentration risks as a limited number of its customers provide a high percentage of total revenues and corresponding receivables.

The Company has also incurred negative cash flows from operations since its inception, and has expended, and expects to continue to expend, substantial funds to implement its planned product development efforts, including acquisition of products and complementary technologies, research and development, clinical studies and regulatory activities, and to further the Company's marketing and sales programs. The Company expects that it will have additional requirements for debt or equity capital, irrespective of whether or when it reaches profitability,

-5-

for further product development costs, product and technology acquisition costs and working capital.

BASIS OF CONSOLIDATION

The consolidated financial statements include the financial statements of Cytogen and its subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

BASIS OF PRESENTATION

The consolidated financial statements and notes thereto of Cytogen are unaudited and include all adjustments which, in the opinion of management, are necessary to present fairly the financial condition and results of operations as of and for the periods set forth in the Consolidated Balance Sheets,

Edgar Filing: CYTOGEN CORP - Form 10-Q

Consolidated Statements of Operations and Consolidated Statements of Cash Flows. All such accounting adjustments are of a normal, recurring nature. The consolidated financial statements do not include all of the information and footnote disclosures normally included in financial statements prepared in accordance with U.S. generally accepted accounting principles and should be read in conjunction with the consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K, as amended, filed with the Securities and Exchange Commission, which includes financial statements as of and for the year ended December 31, 2004. The results of the Company's operations for any interim period are not necessarily indicative of the results of the Company's operations for any other interim period or for a full year.

USE OF ESTIMATES

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

CASH AND CASH EQUIVALENTS

Cash and cash equivalents include cash on hand, cash in banks and all highly-liquid investments with a maturity of three months or less at the time of purchase.

SHORT-TERM INVESTMENTS

The Company had no short-term investments at June 30, 2005 compared to \$22.8 million at December 31, 2004, which consisted of investments in U.S. government agency notes. The Company had the ability and intent to hold these investments until maturity and therefore had classified the investments as held-to-maturity. Held-to-maturity investments were recorded at amortized cost, adjusted for the accretion of discounts or premiums. Discounts or premiums were accreted into interest income over the life of the related investment using the straight-line method, which approximated the effective yield method. Dividend and interest income were recognized when earned.

-6-

INVENTORIES

The Company's inventories are primarily related to ProstaScint. Inventories are stated at the lower of cost or market using the first-in, first-out method and consisted of the following (all amounts in thousands):

| | JUNE 30, 2005 | DECEMBER 31, 2004 |
|----------------------|---------------|-------------------|
| Raw materials..... | \$ 283 | \$ 427 |
| Work-in-process..... | 4,616 | 2,345 |
| Finished goods..... | 204 | 851 |
| | ----- | ----- |
| | \$ 5,103 | \$ 3,623 |
| | ===== | ===== |

NET LOSS PER SHARE

Basic net loss per common share is calculated by dividing the Company's net

Edgar Filing: CYTOGEN CORP - Form 10-Q

loss by the weighted-average common shares outstanding during each period. Diluted net loss per common share is the same as basic net loss per share for each of the three and six month periods ended June 30, 2005 and 2004 because the inclusion of common stock equivalents, which consist of warrants and options to purchase shares of the Company's common stock, would be antidilutive due to the Company's losses.

VARIABLE INTEREST ENTITIES

The Company follows the revised Financial Accounting Standards Board ("FASB") Interpretation No. 46 ("FIN 46R"), "Consolidation of Variable Interest Entities", which addresses how a business enterprise should evaluate whether it has a controlling financial interest in an entity through means other than voting rights and accordingly should consolidate the entity.

In June 1999, Cytogen entered into a joint venture with Progenics Pharmaceuticals, Inc. ("Progenics," and collectively with Cytogen, the "Members") to form the PSMA Development Company LLC (the "Joint Venture"). The Joint Venture is currently developing antibody-based and vaccine immunotherapeutic products utilizing Cytogen's exclusively licensed prostate-specific membrane antigen ("PSMA") technology. The Joint Venture is owned equally by the Members (see Note 2). Cytogen accounts for the Joint Venture using the equity method of accounting. The Company is not required to consolidate the Joint Venture under the requirements of FIN 46R.

STOCK-BASED COMPENSATION

The Company follows the intrinsic value method of accounting for stock-based employee compensation in accordance with APB Opinion No. 25, "Accounting for Stock Issued to Employees," and related interpretations. The Company records deferred compensation for option grants to employees for the amount, if any, by which the market price per share exceeds the exercise price per share at the measurement date, which is generally the grant date.

-7-

The Company follows the disclosure provisions of SFAS No. 123, "Accounting for Stock-Based Compensation," as amended by SFAS No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure." Had compensation cost for options been recognized in the consolidated statements of operations using the fair value method of accounting, the Company's net loss and net loss per share would have been as follows (all amounts in thousands, except per share data):

| | THREE MONTHS ENDED JUNE 30, | |
|--|--------------------------------|------------|
| | 2005 | 2004 |
| Net loss, as reported..... | \$ (7,741) | \$ (4,384) |
| Add: Stock-based employee compensation expense included in reported net loss | 13 | - |
| Deduct: Total stock-based employee compensation expense determined under fair value-based method for all awards..... | (565) | (341) |

Edgar Filing: CYTOGEN CORP - Form 10-Q

| | | |
|---|------------------------------|------------------------------|
| Pro forma net loss..... | ----- \$ (8,293) ===== | ----- \$ (4,725) ===== |
| Basic and diluted net loss per share, as reported..... | \$ (0.50) ===== | \$ (0.30) ===== |
| Pro forma basic and diluted net loss per share..... | \$ (0.53) ===== | \$ (0.32) ===== |

On June 14, 2005, the Company awarded an aggregate of 168,600 shares of restricted common stock, \$0.01 par value per share, to employees of the Company pursuant to the terms of the Company's 2004 Stock Incentive Plan, as a long term incentive. Such restricted shares are subject to future vesting over a period of six years, and will be issued upon the satisfaction of such vesting provisions and other terms and conditions related thereto. The Company recorded \$868,000 of unearned compensation upon the granting of the restricted stock, which represented the fair market value of Cytogen's common stock on the date of grant. The unearned compensation is amortized on a straight-line basis over the six year vesting period. For the three months ended June 30, 2005, the Company recorded a charge of \$9,000 in the accompanying statements of operations for the amortization of unearned compensation. The Company reversed \$12,000 of unearned compensation related to unvested restricted stock upon the termination of certain employees in the second quarter of 2005.

OTHER COMPREHENSIVE INCOME OR LOSS

Other comprehensive income consisted of an unrealized holding gain or loss on marketable securities. For the three months ended June 30, 2005, the unrealized holding loss of those securities was \$19,000, and as a result, the comprehensive loss for the three months ended June 30, 2005 was \$7,760,000. For the six months ended June 30, 2005, the unrealized holding gain of the securities was \$50,000 and as a result the comprehensive loss for the six months ended June 30, 2005 was \$14,284,000. There was no other comprehensive income or loss in the three and six months ended June 30, 2004.

-8-

RECENT ACCOUNTING PRONOUNCEMENTS

ABNORMAL INVENTORY COSTS

In November 2004, the FASB issued SFAS No. 151, "Inventory Costs, an amendment of ARB No. 43, Chapter 4" ("SFAS No. 151"), to clarify that abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage) should be recognized as current period charges, and that fixed production overheads should be allocated to inventory based on the normal capacity of production facilities. This statement is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. Accordingly, the Company will adopt SFAS No. 151 in its fiscal year beginning January 1, 2006. The Company is currently evaluating the impact of adopting this statement.

SHARE-BASED PAYMENT

In December 2004, the FASB issued SFAS No. 123(R), "Share-Based Payment", which revised SFAS No. 123 and superseded APB Opinion No. 25, "Accounting for Stock Issued to Employees." SFAS No. 123(R) requires that companies recognize

Edgar Filing: CYTOGEN CORP - Form 10-Q

compensation expense associated with grants of stock options and other equity instruments to employees in the financial statements effective as of the first interim or annual reporting period that begins after June 15, 2005. In April 2005, the SEC announced the adoption of a new rule allowing companies to implement SFAS No. 123(R) at the beginning of their next fiscal year that begins after June 15, 2005. Compensation cost will be measured based on the fair value of the instrument on the grant date and will be recognized over the vesting period. This pronouncement applies to all grants after the effective date and to the unvested portion of stock options outstanding as of the effective date. SFAS No. 123(R) eliminates the ability to account for such transactions using the intrinsic method currently used by the Company. SFAS No. 123(R) also requires that companies recognize compensation expense associated with purchases of shares of common stock by employees at a discount to market value under employee stock purchase plans that meet certain criteria. Accordingly, the Company will adopt SFAS No. 123(R) in the fiscal year beginning January 1, 2006. Although management has not yet determined the impact of the adoption of this standard, it is expected to have a material effect on the Company's consolidated financial statements.

RECLASSIFICATION

Certain amounts in prior years' consolidated financial statements have been reclassified to conform to the current year presentation.

2. EQUITY LOSS IN THE PSMA DEVELOPMENT COMPANY LLC

In June 1999, Cytogen entered into a joint venture with Progenics to form the PSMA Development Company LLC (the "Joint Venture"), a development stage enterprise. The Joint Venture is currently developing antibody-based and vaccine immunotherapeutic products utilizing Cytogen's proprietary PSMA technology. The Joint Venture is owned equally by Cytogen and Progenics.

-9-

Cytogen accounts for the Joint Venture using the equity method of accounting. Cytogen has recognized 50% of the Joint Venture's operating results in its consolidated statements of operations for the three and six months ended June 30, 2005 and 2004. On June 6, 2005, Cytogen and Progenics agreed on a work plan and annual budget for the Joint Venture for 2005. In 2005, the Members each expect to provide up to \$5.7 million in funding for the development of the PSMA technologies through the Joint Venture. Each Member has funded \$1.6 million to the Joint Venture as of June 30, 2005. The report of the independent auditors on the financial statements of the Joint Venture included in the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2004 filed with the Securities and Exchange Commission, contained an explanatory paragraph which states that the Joint Venture has suffered recurring losses from operations and has a net capital deficiency that raises substantial doubt about its ability to continue as a going concern, and that its financial statements do not include any adjustments that might result from the outcome of that uncertainty. The Members have not committed to fund the Joint Venture beyond December 31, 2005 at this time, except for obligations under existing contractual commitments as of that date. The Joint Venture may incur losses in future years provided an agreement between the Members is reached on research program goals and budgets for periods after 2005 and the Joint Venture's operations are funded.

For the three and six months ended June 30, 2005, Cytogen recognized \$1.7 million and \$2.2 million, respectively, of the Joint Venture's losses, compared to \$542,000 and \$1.4 million of the Joint Venture's losses in the same periods of 2004. As of June 30, 2005, the carrying value of the Company's investment in

Edgar Filing: CYTOGEN CORP - Form 10-Q

the Joint Venture was \$102,000, which represents the Company's investment in the Joint Venture, less its cumulative share of losses, which net investment is recorded in other assets. At June 30, 2005 and December 31, 2004, Cytogen's liability to the Joint Venture was \$1.1 million and \$396,000, respectively. The respective liability, as reported in the Liability related to Joint Venture in the accompanying consolidated balance sheets, represents Cytogen's obligation related to the capital contribution to the Joint Venture at June 30, 2005 and Cytogen's cumulative share of losses in excess of its investment in the Joint Venture at December 31, 2004. Selected financial statement information of the Joint Venture is as follows (all amounts in thousands):

-10-

BALANCE SHEET DATA:

| | JUNE 30, 2005 |
|--|------------------|
| | ----- |
| ASSETS: | |
| Cash..... | \$ 161 |
| Prepaid expenses..... | 28 |
| | ----- |
| | \$ 189 |
| | ===== |
| LIABILITIES AND MEMBERS' DEFICIT: | |
| Accounts payable to Cytogen Corporation, a related party..... | \$ 131 |
| Accounts payable to Progenics Pharmaceuticals, Inc., a related party..... | 1,257 |
| Accounts payable and accrued expenses..... | 814 |
| | ----- |
| Total liabilities..... | 2,202 |
| | ----- |
| Capital contributions..... | 28,698 |
| Contributions receivable..... | (2,200) |
| Deficit accumulated during the development stage..... | (28,511) |
| | ----- |
| Total members' deficit..... | (2,013) |
| | ----- |
| Total liabilities and members' deficit..... | \$ 189 |
| | ===== |

INCOME STATEMENT DATA:

| THREE MONTHS ENDED JUNE 30, | SIX MONTHS ENDED JUNE 30, |
|-----------------------------------|---------------------------------|
| ----- | ----- |

Edgar Filing: CYTOGEN CORP - Form 10-Q

| | 2005 ---- | 2004 ---- | 2005 ---- | 2004 ---- |
|----------------------|--------------|--------------|--------------|--------------|
| Interest income..... | \$ 2 | \$ 2 | \$ 3 | \$ 5 |
| Total expenses..... | 3,409 | 1,086 | 4,406 | 2,707 |
| | ----- | ----- | ----- | ----- |
| Net loss..... | \$ (3,407) | \$ (1,084) | \$ (4,403) | \$ (2,702) |
| | ===== | ===== | ===== | ===== |

In June 2005, the Joint Venture entered into a collaboration agreement (the "SGI Agreement") with Seattle Genetics, Inc. ("SGI"). Under the SGI Agreement, SGI provided an exclusive worldwide license to its proprietary antibody-drug conjugate technology (the "ADC Technology") to the Joint Venture. Under the license, the Joint Venture has the right to use the ADC Technology to link cell-killing drugs to the Joint Venture's monoclonal antibodies that target prostate-specific membrane antigen. During the initial research term of the SGI Agreement, SGI will also provide technical information to the Joint Venture related to implementation of the licensed technology, which period may be extended for an additional period upon payment of an additional fee. The Joint Venture may replace PSMA with another antigen, subject to certain restrictions, upon payment of an antigen replacement fee. The ADC Technology is based, in part, on technology licensed by SGI from third parties (the "Licensors"). The Joint Venture is responsible for research, product development, manufacturing and commercialization of all products under the SGI Agreement. The Joint Venture may sub-license the ADC Technology to a third-party to

-11-

manufacture the ADC's for both research and commercial use. The Joint Venture made a \$2.0 million technology access payment to SGI upon execution of the SGI Agreement and will make additional maintenance payments during the term of the SGI Agreement. In addition, the Joint Venture will make payments aggregating \$15.0 million, upon the achievement of certain defined milestones and will pay royalties to SGI and its Licensors, as applicable, on a percentage of net sales, as defined. In the event that SGI provides materials or services to the Joint Venture under the SGI Agreement, SGI will receive supply and/or labor cost payments from the Joint Venture at agreed-upon rates. The Joint Venture's monoclonal antibody project is currently in the pre-clinical phase of research and development. All costs incurred by the Joint Venture under the SGI Agreement during the research and development phase of the project will be expensed in the period incurred. The SGI Agreement terminates at the later of (a) the tenth anniversary of the first commercial sale of each licensed product in each country or (b) the latest date of expiration of patents underlying the licensed products. The Joint Venture may terminate the SGI Agreement upon advance written notice to SGI. SGI may terminate the SGI Agreement if the Joint Venture breaches an SGI in-license that is not cured within a specified time period after written notice. In addition, either party may terminate the SGI Agreement, upon breach by the other party that is not cured within a specified time period after written notice or in the event of bankruptcy of the other party. The ability of the Joint Venture to comply with the terms of the SGI Agreement will depend on agreement by the Members regarding work plans and budgets of the Joint Venture in future years.

3. BRISTOL-MYERS SQUIBB MEDICAL IMAGING, INC.

Effective January 1, 2004, the Company entered into a new manufacturing and

Edgar Filing: CYTOGEN CORP - Form 10-Q

supply agreement with Bristol-Myers Squibb Medical Imaging, Inc. ("BMSMI"), whereby BMSMI will manufacture, distribute and provide order processing and customer service for Cytogen relating to Quadramet. Under the terms of the agreement, Cytogen is obligated to pay at least \$4.2 million annually, subject to future annual price adjustment, through 2008, unless terminated by BMSMI or Cytogen on two years prior written notice. This agreement will automatically renew for five successive one-year periods unless terminated by BMSMI or Cytogen on two years prior written notice. During each of the three month periods ended June 30, 2005 and 2004 Cytogen incurred \$1.0 million of manufacturing costs for Quadramet, all of which is included in cost of product revenue. During each of the six month periods ended June 30, 2005 and 2004, Cytogen incurred \$2.1 million of manufacturing costs for Quadramet. The Company also pays BMSMI a variable amount per month for each Quadramet order placed to cover the costs of customer service which is included in selling, general and administrative expenses.

The two primary components of Quadramet, particularly Samarium-153 and EDTMP, are provided to BMSMI by outside suppliers. BMSMI obtains its supply of Samarium-153 from a sole supplier, and EDTMP from another sole supplier. Alternative sources for these components may not be readily available, and any alternate suppliers would have to be identified and qualified, subject to all applicable regulatory guidelines. If BMSMI cannot obtain sufficient quantities of these components on commercially reasonable terms, or in a timely manner, it would be unable to manufacture Quadramet on a timely and cost-effective basis.

-12-

4. LAUREATE PHARMA, L.P.

In September 2004, the Company entered into a non-exclusive manufacturing agreement with Laureate Pharma, L.P. pursuant to which Laureate shall manufacture ProstaScint and its primary raw materials for Cytogen in Laureate's Princeton, New Jersey facility. Laureate is the sole manufacturer of ProstaScint and its antibodies. The agreement will terminate, unless terminated earlier pursuant to its terms, upon Laureate's completion of the specified production campaign for ProstaScint and shipment of the resulting products from Laureate's facility. Under the terms of the agreement, the Company is obligated to pay at least an aggregate of \$5.1 million through 2006. Approximately \$4.1 million has been incurred under this agreement through June 30, 2005, and is recorded as inventory in the accompanying balance sheet as of June 30, 2005. Of this amount, approximately \$1.1 million and \$1.8 million were recorded during the three and six month periods ended June 30, 2005.

5. THE DOW CHEMICAL COMPANY

On May 6, 2005, the Company entered into a license agreement with The Dow Chemical Company to create a targeted oncology product designed to treat prostate and other cancers. The agreement applies proprietary MeO-DOTA bifunctional chelant technology from Dowpharma to radiolabel Cytogen's PSMA antibody with a therapeutic radionuclide. Under the agreement, proprietary chelation technology and other capabilities, provided through ChelaMedSM radiopharmaceutical services from Dowpharma, will be used to attach a therapeutic radioisotope to the same murine monoclonal antibody utilized in Cytogen's ProstaScint molecular imaging agent which is called 7E11-C5.3 (or 7E11). The 7E11 antibody was excluded from the PSMA technology licensed to the Joint Venture. As a result of the agreement, Cytogen is obligated to pay a minimal license fee and aggregate future milestone payments of \$1.9 million for each licensed product and royalties based on sales of related products, if any. Unless terminated earlier, the Dow agreement terminates at the later of (a) the

Edgar Filing: CYTOGEN CORP - Form 10-Q

tenth anniversary of the date of first commercial sale for each licensed product or (b) the expiration of the last to expire valid claim that would be infringed by the sale of the licensed product. The Company may terminate the license agreement with Dow on 90 days written notice.

6. INCREASE IN AUTHORIZED COMMON STOCK

On June 14, 2005, the Company's stockholders approved an amendment to the Company's Certificate of Incorporation to increase the total authorized shares of common stock of the Company from 25,000,000 to 50,000,000 shares.

7. SALE OF COMMON STOCK AND WARRANTS

On July 19, 2005, the Company announced that it entered into a Securities Purchase Agreement (the "Securities Purchase Agreement") with certain institutional investors for the sale of 3,104,380 shares of its common stock and 776,096 warrants (the "Warrants") to purchase shares of its common stock having an exercise price of \$6.00 per share, through a registered direct offering. In exchange for \$4.50, the purchasers received one share of common stock and .25 warrants to purchase common stock. These warrants are exercisable for ten years, beginning six months after their issuance. The transaction provided gross proceeds of approximately \$14.0

-13-

million to Cytogen before deducting costs associated with the offering. The transaction closed on July 20, 2005 and August 2, 2005. There was no placement agent in this transaction.

The shares of common stock and the shares of common stock underlying the Warrants offered by the Company in this transaction will be registered upon issuance under the Company's existing shelf Registration Statement (referred to below). The Company is not listing the Warrants on an exchange or any trading system and does not expect that a trading market for the Warrants will develop.

8. PROSTAGEN MILESTONE PAYMENT

Pursuant to a Stock Exchange Agreement (the "Prostagen Agreement") related to the Company's acquisition of Prostagen Inc. ("Prostagen") in 1999, as amended in May 2002, August 2002, and November 2004, the Company agreed to issue up an additional \$1.5 million worth of Cytogen common stock to the shareholders and debtholders of Prostagen (the "Prostagen Partners"), if certain milestones are achieved in the PSMA development programs. During the second quarter of 2005, the Company recorded a \$500,000 charge to research and development expense upon the achievement of certain milestone related to PSMA program as specified in the Prostagen Agreement with the corresponding amount recorded in Common Stock To Be Issued in the accompanying consolidated balance sheets. 92,799 shares of Cytogen common stock will be issued in the third quarter of 2005 related to this milestone. The remaining \$1.0 million of future milestone payment, if any, will be paid in Cytogen common stock upon the achievement of a certain milestone in the PSMA development programs.

-14-

ITEM 2 - MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Edgar Filing: CYTOGEN CORP - Form 10-Q

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements regarding future events and our future results are based on current expectations, estimates, forecasts, and projections and the beliefs and assumptions of our management including, without limitation, our expectations regarding results of operations, selling, general and administrative expenses, research and development expenses and the sufficiency of our cash for future operations. Forward-looking statements may be identified by the use of forward-looking terminology such as "may," "will," "expect," "estimate," "anticipate," "continue," or similar terms, variations of such terms or the negative of those terms. These forward-looking statements include the impact of SFAS No. 123(R), additional funding and development of the PSMA technologies, growth and market penetration for Quadramet and ProstaScint, revenues, if any, from our joint venture with Progenics Pharmaceuticals, Inc., increased expenses resulting from our sales force and marketing expansion, including sales and marketing expenses for ProstaScint and Quadramet, the sufficiency of our capital resources and supply of products for sale, the continued cooperation of our contractual and collaborative partners, our need for additional capital and other statements included in this Quarterly Report on Form 10-Q that are not historical facts. Such forward-looking statements involve a number of risks and uncertainties and investors are cautioned not to put any undue reliance on any forward-looking statement. We cannot guarantee that we will actually achieve the plans, intentions or expectations disclosed in any such forward-looking statements. Factors that could cause actual results to differ materially, include, market acceptance of our products, the results of our clinical trials, our ability to hire and retain employees, economic and market conditions generally, our receipt of requisite regulatory approvals for our products and product candidates, the continued cooperation of our marketing and other collaborative and strategic partners, our ability to protect our intellectual property, and the other risks identified under the caption "Additional Factors That May Affect Future Results" in our Annual Report on Form 10-K for the year ended December 31, 2004, as amended, and those under the caption "Risk Factors," as included in certain of our other filings, from time to time, with the Securities and Exchange Commission.

Any forward-looking statements made by us do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make. We do not assume, and specifically disclaim, any obligation to update any forward-looking statements, and these statements represent our current outlook only as of the date given.

The following discussion and analysis should be read in conjunction with the consolidated financial statements and related notes thereto contained elsewhere herein, as well as in our Annual Report on Form 10-K for the year ended December 31, 2004, as amended, and from time to time in our other filings with the Securities and Exchange Commission.

-15-

OVERVIEW

Founded in 1980, Cytogen Corporation of Princeton, NJ is a product-driven biopharmaceutical company that develops and commercializes innovative molecules that can be used to build leading franchises. Our marketed products include Quadramet (R) (samarium Sm-153 leixidronam injection) and ProstaScint (R) (capromab pendetide) kit for the preparation of Indium In-111 capromab pendetide in the United States. We also have exclusive United States marketing rights to Combindex (R) (ferumoxtran-10) for all applications, and the exclusive right to

Edgar Filing: CYTOGEN CORP - Form 10-Q

market and sell ferumoxytol (formerly Code 7228) for oncology applications in the United States. We are also developing therapeutics targeting prostate-specific membrane antigen (PSMA), a protein highly expressed on the surface of prostate cancer cells and the neovasculature of solid tumors. Full prescribing information for our products is available at www.cytogen.com or by calling 1-800-833-3533.

SIGNIFICANT EVENTS IN 2005

FDA COMMITTEE VOTES NOT TO RECOMMEND APPROVAL OF PROPOSED BROAD INDICATION FOR COMBIDEX

On March 3, 2005, the FDA's Oncologic Drugs Advisory Committee voted to not recommend approval of the proposed broad indication for Combixex.

ADVANCED MAGNETICS RECEIVES APPROVABLE LETTER FOR COMBIDEX

On March 24, 2005, we announced that Advanced Magnetics, Inc., the developer of Combixex(R) which is exclusively licensed to Cytogen for marketing in the United States, had informed Cytogen that Advanced Magnetics received an approvable letter from the FDA for Combixex, subject to certain conditions.

COLLABORATION WITH THE DOW CHEMICAL COMPANY TO DEVELOP PSMA ANTIBODY FOR TREATMENT OF CANCER

On May 6, 2005, we announced that we had entered into a collaboration with The Dow Chemical Company to create a targeted oncology product designed to treat prostate and other cancers. The agreement applies proprietary MeO-DOTA bifunctional chelant technology from Dowpharma to radiolabel Cytogen's prostate-specific membrane antigen (PSMA) antibody with a therapeutic radionuclide. PSMA is a protein highly expressed on the surface of prostate cancer cells and the neovasculature of many solid tumors. Under the agreement, proprietary chelation technology and other capabilities, provided through ChelaMedSM radiopharmaceutical services from Dowpharma, will be used to attach a therapeutic radioisotope to the same murine monoclonal antibody utilized in Cytogen's ProstaScint(R) (capromab pendetide) molecular imaging agent. This antibody, called 7E11-C5.3 (or 7E11), is directed against an intracellular epitope of PSMA. Dowpharma's MeO-DOTA bifunctional chelant will be utilized to attach the beta emitting radionuclide lutetium-177 as a payload to the 7E11 antibody, enabling targeted delivery of this cytotoxic agent. The 7E11 antibody was excluded from the PSMA technology licensed to our PSMA joint venture. We intend to develop the resulting innovative molecule for the treatment of various cancers, initially in prostate, that express the PSMA marker.

-16-

CYTOGEN AND PROGENICS APPROVE 2005 WORK PLAN AND BUDGET FOR JOINT VENTURE

On June 6, 2005, we and Progenics Pharmaceuticals, Inc. agreed on a work plan and annual budget for 2005 for our PSMA joint venture.

SALE OF COMMON STOCK AND WARRANTS

On July 19, 2005, we announced that we entered into a Securities Purchase Agreement with certain institutional investors for the sale of 3,104,380 shares of our common stock and 776,096 warrants to purchase shares of our common stock having an exercise price of \$6.00 per share, through a registered direct offering. In exchange for \$4.50, the purchasers received one share of common stock and .25 warrants to purchase common stock. These warrants are exercisable

Edgar Filing: CYTOGEN CORP - Form 10-Q

for ten years, beginning six months after their issuance. The transaction provided gross proceeds of approximately \$14.0 million to us before deducting costs associated with the offering. The transaction closed on July 20, 2005 and August 2, 2005. There was no placement agent in this transaction.

RESULTS OF OPERATIONS

THREE MONTHS ENDED JUNE 30, 2005 AND 2004

REVENUES

| | 2005 | | 2004 | | INCREASE/ (DECREASE) | |
|---------------------------|--|---|----------|---|----------------------|-------|
| | \$ | % | \$ | % | \$ | % |
| | ----- | | ----- | | ----- | |
| | (ALL AMOUNTS IN THOUSANDS, EXCEPT PERCENTAGE DATA) | | | | | |
| Quadramet..... | \$ 2,153 | | \$ 1,616 | | \$ 537 | 33% |
| ProstaScint..... | 1,924 | | 2,312 | | (388) | (17)% |
| License and Contract..... | 79 | | 24 | | 55 | 229% |
| | ----- | | ----- | | ----- | |
| | \$ 4,156 | | \$ 3,952 | | \$ 204 | 5% |
| | ===== | | ===== | | ===== | |

Total revenues for the second quarter of 2005 were \$4.2 million compared to \$4.0 million for the same period in 2004. Product revenues accounted for 98% and 99% of total revenues for the second quarters of each of 2005 and 2004, respectively. License and contract revenues accounted for the remainder of revenues.

QUADRAMET. Quadramet sales were \$2.2 million for the second quarter of 2005, compared to \$1.6 million in the second quarter of 2004. Quadramet sales accounted for 53% and 41% of product revenues for the second quarters of each of 2005 and 2004, respectively. We believe such increase was due, in part, to increased demand associated with our focused marketing programs. We have the right to market Quadramet in North America and Latin America. Currently, we market Quadramet only in the United States. We believe that the future growth and market penetration of Quadramet is dependent upon, among other things: (i) distinguishing the physical properties of Quadramet from first-generation agents within its class, (ii) empowering and marketing to key prescribing audiences, (iii) broadening palliative use within label beyond prostate cancer to include breast, lung, multiple myeloma, (iv) evaluating the role of Quadramet in combination with other commonly used oncology agents, and (v)

-17-

expanding clinical development to demonstrate the potential tumoricidal versus palliative attributes of Quadramet. We cannot provide any assurance that we will be able to successfully market Quadramet or that Quadramet will achieve greater market penetration on a timely basis or result in significant revenues for us.

PROSTASCINT. ProstaScint sales were \$1.9 million for the second quarter of 2005, compared to \$2.3 million in the second quarter of 2004. ProstaScint sales accounted for 47% and 59% of product revenues for the second quarters of each of 2005 and 2004, respectively. We believe that ProstaScint sales have been consistent, except for the increased purchases by distributors in the second quarter of 2004 associated with the implementation of a price increase for ProstaScint in late June 2004. We believe that future growth and market penetration of ProstaScint is dependent upon, among other things, (i) improving image quality through fusion technology, (ii) validating the antigen targeted by ProstaScint as an independent prognostic factor, (iii) the publication and presentation of outcomes data, (iv) development of image-guided applications

Edgar Filing: CYTOGEN CORP - Form 10-Q

including brachytherapy, intensity modulated radiation therapy, surgery, and cryotherapy, and (v) expanding clinical development to demonstrate the potential for ProstaScint to monitor response to cytotoxic therapies and image other cancers. We cannot provide any assurance that we will be able to successfully market ProstaScint, or that ProstaScint will achieve greater market penetration on a timely basis or result in significant revenues for us.

LICENSE AND CONTRACT REVENUES. License and contract revenues were \$79,000 and \$24,000 for the second quarters of 2005 and 2004, respectively. During the second quarter of 2005, we recognized \$78,000 of contract revenues compared to \$15,000 in the second quarter of 2004 for limited research and development services provided by us to the PSMA Development Company LLC, our joint venture with Progenics. The level of future revenues for the remainder of 2005, if any, for contract services provided to the joint venture may vary and will depend upon the extent of research and development services required by the joint venture.

OPERATING EXPENSES

| | 2005 ---- | 2004 ---- | INCREASE/ (DECREASE) | |
|--|--------------|--------------|----------------------|------|
| | | | \$ | % |
| (ALL AMOUNTS IN THOUSANDS, EXCEPT PERCENTAGE DATA) | | | | |
| Cost of product revenue..... | \$ 2,251 | \$ 2,396 | \$ (145) | (6)% |
| Selling, general and administrative.... | 6,692 | 4,914 | 1,778 | 36% |
| Research and development..... | 1,362 | 541 | 821 | 152% |
| Equity in loss of joint venture..... | 1,704 | 542 | 1,162 | 214% |
| | \$ 12,009 | \$ 8,393 | \$ 3,616 | 43% |
| | ===== | ===== | ===== | |

Total operating expenses for the second quarter of 2005 were \$12.0 million compared to \$8.4 million in the same quarter of 2004.

COST OF PRODUCT REVENUE. Cost of product revenue for the second quarters of 2005 and 2004 were \$2.3 million and \$2.4 million, respectively, and primarily reflects manufacturing costs for ProstaScint and Quadramet, royalties on our sales of products and amortization of the up-front payment to Berlex Laboratories to reacquire the marketing rights to Quadramet in 2003.

-18-

SELLING, GENERAL AND ADMINISTRATIVE. Selling, general and administrative expenses for the second quarter of 2005 were \$6.7 million compared to \$4.9 million in the same period of 2004. The increase from the prior year period is primarily driven by the expanded investment for the commercial support of both Quadramet and ProstaScint, including the implementation of new marketing initiatives and expansion of our sales force which was substantially completed in January 2005.

RESEARCH AND DEVELOPMENT. Research and development expenses for the second quarter of 2005 were \$1.4 million compared to \$541,000 in the same period of 2004. The increase from the prior year period is primarily driven by new clinical development initiatives for both Quadramet and ProstaScint and a \$500,000 charge in the second quarter of 2005 for a non-cash milestone

Edgar Filing: CYTOGEN CORP - Form 10-Q

obligation incurred related to the progress of PSMA development programs and the preclinical development costs associated with our radiolabeled therapeutic program to attach the therapeutic radionuclide lutetium-177 as a payload to the 7E11 monoclonal antibody utilized in ProstaScint. The increase is partially offset by savings from the closure of our AxCell Biosciences facility in the fourth quarter of 2004. During the second quarter of 2005, we incurred \$6,000 in expenses relating to AxCell's operations compared to \$167,000 in the same period of 2004. Research projects through academic, governmental and corporate collaborators to be supported and additional applications for the intellectual property and technology at AxCell are being pursued.

EQUITY IN LOSS OF JOINT VENTURE. Our share of the loss of the PSMA Development Company LLC, our joint venture with Progenics, was \$1.7 million and \$542,000 during the second quarters of 2005 and 2004, respectively. Such amounts represented 50% of the joint venture's operating losses. We equally share ownership and costs of the joint venture with Progenics and account for the joint venture using the equity method of accounting. The increase over the prior year period is primarily due to our share of the \$2.0 million upfront fee incurred by the joint venture to license proprietary antibody-drug conjugate technology from Seattle Genetics, Inc. for use with the joint venture's antibodies targeting PSMA. On June 6, 2005, we and Progenics agreed on a work plan and annual budget for the joint venture for 2005. In 2005, we and Progenics each expect to provide up to \$5.7 million in funding for the development of the PSMA technologies through the joint venture. Each member of the joint venture has funded \$1.6 million as of June 30, 2005. We and Progenics have not committed to fund the joint venture beyond December 31, 2005 at this time, except for obligations under existing contractual commitments as of that date. We may incur significant and increasing costs in the future to fund our share of the development costs of the joint venture, although we cannot provide any assurance that any further agreements between us and Progenics will be reached regarding the joint venture.

The joint venture's work plan and budget for 2005 includes funding to be made by the joint venture in accordance with a collaboration agreement (the "SGI Agreement") with Seattle Genetics, Inc. ("SGI"), commencing in June 2005. Under the SGI Agreement, SGI provided an exclusive worldwide license to its proprietary antibody-drug conjugate technology (the "ADC Technology") to the joint venture. Under the license, the joint venture has the right to use the ADC Technology to link cell-killing drugs to the joint venture's monoclonal antibodies that targets prostate-specific membrane antigen. During the initial research term of the Agreement, SGI will also provide technical information to the joint venture related to implementation of the licensed technology, which period may be extended for an additional period upon payment of an

-19-

additional fee. The joint venture may replace PSMA with another antigen, subject to certain restrictions, upon payment of an antigen replacement fee. The ADC Technology is based, in part, on technology licensed by SGI from third parties. The joint venture is responsible for research, product development, manufacturing and commercialization of all products under the SGI Agreement. The joint venture may sub-license the ADC Technology to a third-party to manufacture the ADC's for both research and commercial use. The joint venture made a \$2.0 million technology access payment to SGI, upon execution of the SGI Agreement during June 2005, following a capital contribution by the members. The SGI Agreement requires the joint venture to make maintenance payments during the term of the SGI Agreement, aggregate payments of \$15.0 million upon the achievement of certain defined milestones, and royalties, on a percentage of net sales, as defined, to SGI and its third party licensors. In the event that SGI provides materials or services to the joint venture under the SGI Agreement, SGI

Edgar Filing: CYTOGEN CORP - Form 10-Q

will receive supply and/or labor cost payments from the joint venture at agreed upon rates. Unless terminated earlier, the SGI Agreement terminates at the later of (a) the tenth anniversary of the first commercial sale of each licensed product in each country or (b) the latest date of expiration of patents underlying the licensed products. The ability of the joint venture to comply with the terms of the SGI Agreement will depend on agreement by the members regarding work plans and budgets of the joint venture in future years.

INTEREST INCOME/EXPENSE. Interest income for the second quarter of 2005 was \$154,000 compared to \$106,000 in the same period of 2004. The increase in 2005 from the prior year period was due to higher average yield on cash balances in 2005. Interest expense for the second quarter of 2005 was \$42,000 compared to \$49,000 in the same period in 2004. Interest expense includes interest on outstanding debt and finance charges related to various equipment leases that are accounted for as capital leases.

NET LOSS. Net loss for the second quarter of 2005 was \$7.7 million compared to \$4.4 million reported in the second quarter of 2004. The basic and diluted net loss per share for the second quarter of 2005 was \$0.50 based on 15.5 million weighted average common shares outstanding, compared to a basic and diluted net loss per share of \$0.30 based on 14.8 million weighted average common shares outstanding for the same period in 2004.

SIX MONTHS ENDED JUNE 30, 2005 AND 2004

REVENUES

| | 2005 | 2004 | INCREASE/ (DECREASE) | |
|---------------------------|--|----------|----------------------|--------|
| | ---- | ---- | \$ | % |
| | ----- | ----- | ----- | ----- |
| | (ALL AMOUNTS IN THOUSANDS, EXCEPT PERCENTAGE DATA) | | | |
| Quadramet..... | \$ 4,207 | \$ 3,470 | \$ 737 | 21% |
| ProstaScint..... | 3,823 | 4,039 | (216) | (5)% |
| NMP22 BladderChek..... | -- | 1 | (1) | (100)% |
| License and Contract..... | 120 | 43 | 77 | 179% |
| | ----- | ----- | ----- | |
| | \$ 8,150 | \$ 7,553 | \$ 597 | 8% |
| | ===== | ===== | ===== | |

-20-

Total revenues for the first half of 2005 were \$8.2 million compared to \$7.6 million for the same period in 2004. Product revenues accounted for 99% of total revenues for the first half of each of 2005 and 2004. License and contract revenues accounted for the remainder of revenues.

QUADRAMET. Cytogen recorded Quadramet sales of \$4.2 million for the first half of 2005 compared to \$3.5 million of Quadramet sales during the first half of 2004. Quadramet sales accounted for 52% and 46% of product revenues for such periods, respectively. We have the right to market Quadramet in North America and Latin America. Currently, we market Quadramet only in the United States. We believe that the future growth and market penetration of Quadramet is dependent upon, among other things: (i) distinguishing the physical properties of Quadramet from earlier generation agents within its class, (ii) empowering and marketing to key prescribing audiences, (iii) broadening palliative use within

Edgar Filing: CYTOGEN CORP - Form 10-Q

label beyond prostate cancer to include breast, lung, multiple myeloma, (iv) evaluating the role of Quadramet in combination with other commonly used oncology agents, and (v) expanding clinical development to demonstrate the potential tumoricidal versus palliative attributes of Quadramet. We cannot provide any assurance that we will be able to successfully market Quadramet or that Quadramet will achieve greater market penetration on a timely basis or result in significant revenues for us.

PROSTASCINT. ProstaScint sales were \$3.8 million for the first half of 2005, a decrease of \$216,000 from \$4.0 million in the first half of 2004. Sales of ProstaScint accounted for 48% and 54% of product revenues for such periods, respectively. We believe that ProstaScint sales have been consistent, except for the increased purchases by distributors in the second quarter of 2004 associated with the implementation of a price increase for ProstaScint in late June 2004. We believe that future growth and market penetration of ProstaScint is dependent upon, among other things, (i) improving image quality through fusion technology, (ii) validating the antigen targeted by ProstaScint as an independent prognostic factor, (iii) the publication and presentation of outcomes data, (iv) development of image-guided applications including brachytherapy, intensity modulated radiation therapy, surgery, and cryotherapy, and (v) expanding clinical development to demonstrate the potential for ProstaScint to monitor response to cytotoxic therapies and image other cancers. We cannot provide any assurance that we will be able to successfully market ProstaScint, or that ProstaScint will achieve greater market penetration on a timely basis or result in significant revenues for us.

NMP22 BLADDERCHEK. There were no sales of NMP22 BladderChek during the first half of 2005 compared to \$1,000 in the same period in 2004. Effective December 31, 2004, we stopped selling NMP22 BladderChek.

LICENSE AND CONTRACT REVENUES. License and contract revenues were \$120,000 and \$43,000 for the first half of 2005 and 2004, respectively. During the first half of 2005, we recognized \$119,000 of contract revenues compared to \$28,000 in the first half of 2004 for limited research and development services provided by us to the PSMA Development Company LLC, our joint venture with Progenics. We expect that the level of future revenues for the remainder of 2005, if any, for contract services provided to the joint venture may vary and will depend upon the extent of research and development services required by the joint venture.

-21-

OPERATING EXPENSES

| | 2005 | 2004 | INCREASE/ (D) |
|--|---|-----------|---------------|
| | ----- | ----- | \$ |
| | (ALL AMOUNTS IN THOUSANDS, EXCEPT PERCENTAGE) | | |
| Cost of product revenues..... | \$ 4,678 | \$ 4,795 | \$ (117) |
| Selling, general and administrative..... | 13,716 | 8,805 | 4,911 |
| Research and development..... | 2,101 | 1,345 | 756 |
| Equity in loss of joint venture..... | 2,202 | 1,351 | 851 |
| | ----- | ----- | ----- |
| | \$ 22,697 | \$ 16,296 | \$ 6,401 |

Edgar Filing: CYTOGEN CORP - Form 10-Q

=====

=====

=====

Total operating expenses for the first half of 2005 were \$22.7 million compared to \$16.3 million in the same period of 2004.

COST OF PRODUCT REVENUES. Cost of product revenues for the first half of 2005 were \$4.7 million compared to \$4.8 million in the same period of 2004 and primarily reflects manufacturing costs for ProstaScint and Quadramet, royalties on our sales of products and amortization of the up-front payment to Berlex Laboratories to reacquire the marketing rights to Quadramet in 2003.

SELLING, GENERAL AND ADMINISTRATIVE. Selling, general and administrative expenses for the first half of 2005 were \$13.7 million compared to \$8.8 million in the same period of 2004. The increase from the prior year period is primarily driven by the expanded investment for the commercial support of both Quadramet and ProstaScint, including the implementation of new marketing initiatives and expansion of our sales force which was substantially completed in January 2005.

RESEARCH AND DEVELOPMENT. Research and development expenses for the first half of 2005 were \$2.1 million compared to \$1.3 million in the same period of 2004. The increase from the prior year period is primarily driven by new clinical development initiatives for both Quadramet and ProstaScint and a \$500,000 charge in the second quarter of 2005 for a non-cash milestone obligation incurred related to the progress of PSMA development programs and the preclinical development costs associated with our radiolabeled therapeutic program to attach the therapeutic radionuclide lutetium-177 as a payload to the 7E11 monoclonal antibody utilized in ProstaScint. The increase is partially offset by savings from the closure of our AxCell Biosciences facility in the fourth quarter of 2004. During the first half of 2005 and 2004, we incurred \$12,000 and \$418,000, respectively, in expenses relating to AxCell's operations.

EQUITY IN LOSS OF JOINT VENTURE. Our share of the loss of the PSMA Development Company LLC, our joint venture with Progenics, was \$2.2 million during the first half of 2005 compared to \$1.4 million in the same period of 2004 and represented 50% of the joint venture's operating losses. We equally share ownership and costs of the joint venture with Progenics and account for the joint venture using the equity method of accounting. The increase over the prior year period is primarily due to our share of the \$2.0 million upfront fee incurred by the joint venture to license proprietary antibody-drug conjugate technology from Seattle Genetics, Inc. for use with the joint venture's antibodies targeting PSMA. On June 6, 2005, we and Progenics

-22-

agreed on a work plan and annual budget for the joint venture for 2005. In 2005, we and Progenics each expect to provide up to \$5.7 million in funding for the development of the PSMA technologies through the joint venture. Each member of the joint venture has funded \$1.6 million as of June 30, 2005. We and Progenics have not committed to fund the joint venture beyond December 31, 2005 at this time, except for obligations under existing contractual commitments as of that date. We may incur significant and increasing costs in the future to fund our share of the development costs of the joint venture, although we cannot provide any assurance that any further agreements between us and Progenics will be reached regarding the joint venture.

The joint venture's work plan and budget for 2005 includes funding to be made by the joint venture in accordance with a collaboration agreement (the "SGI Agreement") with Seattle Genetics, Inc. ("SGI"), commencing in June 2005. Under

Edgar Filing: CYTOGEN CORP - Form 10-Q

the SGI Agreement, SGI provided an exclusive worldwide license to its proprietary antibody-drug conjugate technology (the "ADC Technology") to the joint venture. Under the license, the joint venture has the right to use the ADC Technology to link cell-killing drugs to the joint venture's monoclonal antibodies that targets prostate-specific membrane antigen. During the initial research term of the Agreement, SGI will also provide technical information to the joint venture related to implementation of the licensed technology, which period may be extended for an additional period upon payment of an additional fee. The joint venture may replace PSMA with another antigen, subject to certain restrictions, upon payment of an antigen replacement fee. The ADC Technology is based, in part, on technology licensed by SGI from third parties. The joint venture is responsible for research, product development, manufacturing and commercialization of all products under the SGI Agreement. The joint venture may sub-license the ADC Technology to a third-party to manufacture the ADC's for both research and commercial use. The joint venture made a \$2.0 million technology access payment to SGI, upon execution of the SGI Agreement during June 2005, following a capital contribution by the members. The SGI Agreement requires the joint venture to make maintenance payments during the term of the SGI Agreement, aggregate payments of \$15.0 million upon the achievement of certain defined milestones, and royalties, on a percentage of net sales, as defined, to SGI and its third party licensors. In the event that SGI provides materials or services to the joint venture under the SGI Agreement, SGI will receive supply and/or labor cost payments from the joint venture at agreed upon rates. Unless terminated earlier, the SGI Agreement terminates at the later of (a) the tenth anniversary of the first commercial sale of each licensed product in each country or (b) the latest date of expiration of patents underlying the licensed products. The ability of the joint venture to comply with the terms of the SGI Agreement will depend on agreement by the members regarding work plans and budgets of the joint venture in future years.

INTEREST INCOME/EXPENSE. Interest income for the first half of 2005 was \$297,000 compared to \$170,000 in the same period of 2004. The increase in 2005 from the prior year period was due to a higher average yield on cash balances in 2005. Interest expense was \$84,000 and \$93,000 for the first half of 2005 and 2004, respectively. Interest expense includes interest on outstanding debt and finance charges related to various equipment leases that are accounted for as capital leases.

NET LOSS. Net loss for the first half of 2005 was \$14.3 million compared to \$8.7 million reported in the first half of 2004. The basic and diluted net loss per share for the first half of 2005 was \$0.92 based on 15.5 million weighted average common shares outstanding, compared

-23-

to a basic and diluted net loss per share of \$0.63 based on 13.9 million weighted average common shares outstanding for the same period in 2004.

COMMITMENTS

We have entered into various contractual and commercial commitments. The following table summarizes our obligations with respect to these commitments as of June 30, 2005:

| LESS THAN 1 YEAR | 1 TO 3 YEARS | 4 TO 5 YEARS | MORE 5 YE |
|------------------------|-----------------|-----------------|--------------|
| ----- | ----- | ----- | ----- |

Edgar Filing: CYTOGEN CORP - Form 10-Q

(ALL AMOUNTS IN THOUSANDS)

| | | | | |
|--|----------|----------|----------|--------|
| Long-term debt(1)..... | \$ 2,300 | \$ -- | \$ -- | \$ -- |
| Capital lease obligations..... | 18 | 38 | -- | -- |
| Facility leases..... | 338 | 451 | -- | -- |
| Research and development and other obligations..... | 159 | 162 | 151 | 5 |
| Manufacturing contracts(2)..... | 5,410 | 4,401 | -- | -- |
| Capital contribution to joint venture(3)..... | 4,100 | -- | -- | -- |
| Minimum royalty payments(4)..... | 1,077 | 2,000 | 2,000 | 3,3 |
| | ----- | ----- | ----- | ----- |
| Total..... | \$13,402 | \$ 7,052 | \$ 2,151 | \$ 3,9 |
| | ===== | ===== | ===== | ===== |

(1) In August 1998, we received \$2.0 million from Elan Corporation, plc in exchange for a convertible promissory note. The note is convertible into shares of our common stock at \$28 per share, subject to adjustments, and matures in August 2005. The note bears annual interest of 7%, compounded semiannually, however, such interest was not payable in cash but was added to the principal of the note through August 2000. For subsequent periods, interest is payable in cash. The note contains certain non-financial covenants, with which we were in compliance as of June 30, 2005.

(2) Effective January 1, 2004, we entered into a new manufacturing and supply agreement with BMSMI for QUADRAMET whereby BMSMI manufactures, distributes and provides order processing and customer services for us relating to QUADRAMET. Under the terms of our agreement, we are obligated to pay at least \$4.2 million annually, subject to future annual price adjustment, through 2008, unless terminated by BMSMI or us on a two year prior written notice. This agreement will automatically renew for five successive one-year periods unless terminated by BMSMI or us on a two-year prior written notice. Accordingly, we have not included commitments beyond June 30, 2007.

Additionally, in September 2004, we entered into a non-exclusive manufacturing agreement with Laureate Pharma, L.P. pursuant to which Laureate shall manufacture ProstaScint for us in its Princeton, New Jersey facility. The agreement will terminate, unless earlier terminated pursuant to its terms, upon Laureate's completion of the production campaign for PROSTASCINT and shipment of the resulting products from Laureate's facility. Under the terms of the agreement, we are obligated to pay at least an aggregate of \$5.1 million through 2006, of which approximately \$4.1 million was incurred through June 30, 2005. We expect that the agreement will provide us with a sufficient supply of ProstaScint to satisfy our commercial requirements for approximately the next four years, based upon current sales levels. In addition, we believe the agreement will provide sufficient supply of 7E11 required for initial clinical development of our therapeutic program.

(3) On June 6, 2005, we and Progenics agreed on a work plan and annual budget for the joint venture for 2005. In 2005, we have each funded \$1.6 million as of June 30, 2005. We may incur significant and increasing costs in the future to fund our share of the development costs from the joint venture, although we cannot be

Edgar Filing: CYTOGEN CORP - Form 10-Q

sure that any further agreements between us and Progenics will be reached regarding the joint venture. The joint venture's work plan and budget for 2005 includes funding to be made by the joint venture in accordance with the SGI Agreement with SGI, commencing in June 2005. The joint venture made a \$2.0 million technology access payment to SGI, upon execution of the SGI Agreement during June 2005, following a capital contribution by the members. The SGI Agreement requires the joint venture to make maintenance payments during the term of the SGI Agreement, aggregate payments of \$15.0 million upon the achievement of certain defined milestones, and royalties, on a percentage of net sales, as defined, to SGI and its licensors. In the event that SGI provides materials or services to the joint venture under the SGI Agreement, SGI will receive supply and/or labor cost payments from the joint venture at agreed upon rates. The ability of the joint venture to comply with the terms of the SGI Agreement will depend on agreement by the members regarding work plans and budgets of the joint venture in future years.

- (4) We acquired an exclusive license from The Dow Chemical Company for QUADRAMET for the treatment of osteoblastic bone metastases in certain territories. The agreement requires us to pay Dow royalties based on a percentage of net sales of QUADRAMET, or a guaranteed contractual minimum payment, whichever is greater, and future payments upon achievement of certain milestones. Future annual minimum royalties due to Dow are \$1.0 million per year in 2005 through 2012 and \$833,000 in 2013.

In addition to the above, we are obligated to make certain royalty payments based on sales of the related product and certain milestone payments if our collaborative partners achieve specific development milestones or commercial milestones.

LIQUIDITY AND CAPITAL RESOURCES

CONDENSED STATEMENT OF CASH FLOWS:

| | JUNE 30, 2005 |
|--|----------------------------|
| | (ALL AMOUNTS IN THOUSANDS) |
| Net loss..... | \$ (14,334) |
| Adjustments to reconcile net loss to net cash used in operating activities..... | (952) |
| | ----- |
| Net cash used in operating activities..... | (15,286) |
| Net cash provided by investing activities..... | 22,564 |
| Net cash provided by financing activities..... | 208 |
| | ----- |
| Net increase in cash and cash equivalents..... | \$ 7,486 |
| | ===== |

OVERVIEW

Our cash and cash equivalents were \$20.5 million as of June 30, 2005, compared to \$13.0 million as of December 31, 2004. As of June 30, 2005, our total cash, cash equivalents and short-term investments was \$20.5 million compared to \$35.8 million as of December 31, 2004. The decrease in cash, cash equivalents and short term investments from the December 31, 2004 balance was primarily due to the build-up of ProstaScint inventory and to increased operating expenditures in 2005, including costs to promote and support our oncology products and to expand our internal sales force, new clinical

Edgar Filing: CYTOGEN CORP - Form 10-Q

development initiatives for both Quadramet and ProstaScint and funding for the PSMA Development Company joint venture. During the first half of 2005 and 2004, net cash used for operating activities was \$15.3 million and \$8.9 million, respectively. In 2005, we expect operating expenditures to increase over 2004 levels.

Historically, our primary sources of cash have been proceeds from the issuance and sale of our stock through public offerings and private placements, product related revenues, revenues

-25-

from contract research services, fees paid under license agreements and interest earned on cash and short-term investments.

On July 19, 2005, we announced that we entered into a Securities Purchase Agreement with certain institutional investors for the sale of 3,104,380 shares of its common stock and 776,096 warrants (the "Warrants") to purchase shares of its common stock having an exercise price of \$6.00 per share, through a registered direct offering. In exchange for \$4.50, the purchasers received one share of common stock and .25 warrants to purchase common stock. These warrants are exercisable for ten years, beginning six months after their issuance. The transaction provided gross proceeds of approximately \$14.0 million to us before deducting costs associated with the offering. The transaction closed on July 20, 2005 and August 2, 2005. There was no placement agent in this transaction. The shares of common stock and the shares of common stock underlying the Warrants offered by us in this transaction will be registered upon issuance under the Company's existing shelf Registration Statement (referred to below). We are not listing the Warrants on an exchange or any trading system and do not expect that a trading market for the Warrants will develop. On November 5, 2004, we filed a registration statement (File No. 333-120262) (the "Registration Statement") on Form S-3 with the Securities and Exchange Commission (the "Commission") relating to the public offering pursuant to Rule 415 under the Securities Act of 1933, as amended, of up to an aggregate of \$70,000,000 of debt securities, common stock, preferred stock, warrants and units of the Company. The Commission declared the Registration Statement effective on November 14, 2004.

Our financial objectives are to meet our capital and operating requirements through revenues from existing products and licensing arrangements. To achieve these objectives, we may enter into research and development partnerships and acquire, in-license and develop other technologies, products or services. Certain of these strategies may require payments by us in either cash or stock in addition to the costs associated with developing and marketing a product or technology. However, we believe that, if successful, such strategies may increase long-term revenues. There can be no assurance as to the success of such strategies or that resulting funds will be sufficient to meet cash requirements until product revenues are sufficient to cover operating expenses, if ever. To fund these strategic and operating activities, we may sell equity, debt or other securities as market conditions permit or enter into credit facilities.

OTHER LIQUIDITY EVENTS

In September 2004, we entered into a non-exclusive manufacturing agreement with Laureate Pharma, L.P. pursuant to which Laureate is manufacturing ProstaScint for us in its Princeton, New Jersey facility. Our agreement will terminate, unless terminated earlier pursuant to its terms, upon Laureate's completion of the production campaign and shipment of the resulting products from Laureate's facility. Under the terms of the agreement, we are obligated to pay at least an aggregate of \$5.1 million through 2006. Approximately \$4.1

Edgar Filing: CYTOGEN CORP - Form 10-Q

million has been incurred under this agreement through June 30, 2005, and is recorded as inventory in the accompanying balance sheet as of June 30, 2005. Of this amount, approximately \$1.8 million was recorded during the first half of 2005. We expect that the agreement will provide us with a sufficient supply of ProstaScint to satisfy our commercial requirements for approximately the next four years, based upon current sales levels. In addition, we believe the agreement will provide sufficient supply of 7E11 required for initial clinical development of our therapeutic

-26-

program. In October 2004, Laureate was acquired by Safeguard Scientifics, Inc. Laureate has continued to operate as a full service contract manufacturing organization and we have not experienced any disruption in Laureate's performance of its obligations to produce ProstaScint.

Effective January 1, 2004, we entered into a new manufacturing and supply agreement with BMSMI whereby BMSMI manufactures, distributes and provides order processing and customer services for us relating to Quadramet. Under the terms of the new agreement, we are obligated to pay at least \$4.2 million annually, subject to future annual price adjustment, through 2008, unless terminated by BMSMI or us on two years prior written notice. During the first half of 2005, we incurred \$2.1 million of manufacturing costs for Quadramet. This agreement will automatically renew for five successive one-year periods unless terminated by BMSMI or us on a two year prior written notice. We also pay BMSMI a variable amount per month for each Quadramet order placed to cover the costs of customer service. In addition, we expect our Quadramet sales and marketing expenses to increase in 2005.

Beginning in December 2001, we began to equally share the costs of the joint venture with Progenics. On June 6, 2005, we and Progenics agreed on a work plan and annual budget for the Joint Venture for 2005. In 2005, we and Progenics each expect to provide up to \$5.7 million in funding for the development of the PSMA technologies through the Joint Venture. Each member of the joint venture has funded \$1.6 million as of June 30, 2005. The joint venture's work plan and budget for 2005 includes funding to be made by the joint venture in accordance with the SGI Agreement with SGI, commencing in June 2005. The joint venture made a \$2.0 million technology access payment to SGI, upon execution of the SGI Agreement during June 2005, following a capital contribution by the members. The SGI Agreement requires the joint venture to make maintenance payments during the term of the SGI Agreement, aggregate payments of \$15.0 million upon the achievement of certain defined milestones, and royalties, on a percentage of net sales, as defined, to SGI and its licensors. In the event that SGI provides materials or services to the joint venture under the SGI Agreement, SGI will receive supply and/or labor cost payments from the joint venture at agreed upon rates. The ability of the joint venture to comply with the terms of the SGI Agreement will depend on agreement by the members regarding work plans and budgets of the joint venture in future years. We and Progenics have not committed to fund the Joint Venture beyond December 31, 2005 at this time, except for obligations under existing contractual commitments as of that date. We may incur significant and increasing costs in the future to fund our share of the development costs from the joint venture although we cannot provide any assurance that any further agreements between us and Progenics will be reached regarding the joint venture. Any funding amount in subsequent periods may vary dependent upon, among other things, the results of the clinical trials and research and development activities, competitive and technological developments, and market opportunities. If no agreement is reached with Progenics, we also may have commitments for certain wind down costs under third party agreements with the joint venture.

Edgar Filing: CYTOGEN CORP - Form 10-Q

We acquired an exclusive license from The Dow Chemical Company for Quadramet for the treatment of osteoblastic bone metastases in certain territories. The agreement requires us to pay Dow royalties based on a percentage of net sales of Quadramet, or a guaranteed contractual minimum payment, whichever is greater, and future payments upon achievement of certain milestones. Future annual minimum royalties due to Dow are \$1.0 million per year in 2005 through 2012 and \$833,000 in 2013.

-27-

On May 6, 2005, we entered into a license agreement with The Dow Chemical Company to create a targeted oncology product designed to treat prostate and other cancers. The agreement applies proprietary MeO-DOTA bifunctional chelant technology from Dowpharma to radiolabel our PSMA antibody with a therapeutic radionuclide. Under the agreement, proprietary chelation technology and other capabilities, provided through ChelaMedSM radiopharmaceutical services from Dowpharma, will be used to attach a therapeutic radioisotope to the 7E11 monoclonal antibody utilized in our ProstaScint molecular imaging agent. As a result of the agreement, we are obligated to pay a minimal license fee and aggregate future milestone payments of \$1.9 million for each licensed product and royalties based on sales of related products, if any. Unless terminated earlier, the Dow Agreement terminates at the later of (a) the tenth anniversary of the date of first commercial sale for each licensed product or (b) the expiration of the last to expire valid claim that would be infringed by the sale of the licensed product. We may terminate the license agreement with Dow on 90 days written notice.

We have incurred negative cash flows from operations since our inception, and have expended, and expect to continue to expend in the future, substantial funds to implement our planned product development efforts, including acquisition of products and complementary technologies, research and development, clinical studies and regulatory activities, and to further our marketing and sales programs. We expect that our existing capital resources, along with the \$14 million gross proceeds from the July 2005 financing, should be adequate to fund our operations and commitments at least into mid-2006. We cannot assure you that our business or operations will not change in a manner that would consume available resources more rapidly than anticipated. We expect that we will have additional requirements for debt or equity capital, irrespective of whether and when we reach profitability, for further product development costs, product and technology acquisition costs, and working capital.

Our future capital requirements and the adequacy of available funds will depend on numerous factors, including: (i) the successful commercialization of our products; (ii) the costs associated with the acquisition of complementary products and technologies; (iii) progress in our product development efforts and the magnitude and scope of such efforts; (iv) progress with clinical trials; (v) progress with regulatory affairs activities; (vi) the cost of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights; (vii) competing technological and market developments; and (viii) the expansion of strategic alliances for the sales, marketing, manufacturing and distribution of our products. To the extent that the currently available funds and revenues are insufficient to meet current or planned operating requirements, we will be required to obtain additional funds through equity or debt financing, strategic alliances with corporate partners and others, or through other sources. There can be no assurance that the financial sources described above will be available when needed or at terms commercially acceptable to us. If adequate funds are not available, we may be required to delay, further scale back or eliminate certain aspects of our operations or attempt to obtain funds through arrangements with collaborative partners or

Edgar Filing: CYTOGEN CORP - Form 10-Q

others that may require us to relinquish rights to certain of our technologies, product candidates, products or potential markets. If adequate funds are not available, our business, financial condition and results of operations will be materially and adversely affected.

-28-

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Financial Reporting Release No. 60 requires all companies to include a discussion of critical accounting policies or methods used in the preparation of financial statements. Note 1 to our Consolidated Financial Statements in our Annual Report on Form 10-K for the year ended December 31, 2004, as amended, includes a summary of our significant accounting policies and methods used in the preparation of our Consolidated Financial Statements. The following is a brief discussion of the more significant accounting policies and methods used by us. The preparation of our Consolidated Financial Statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Our actual results could differ materially from those estimates.

REVENUE RECOGNITION

Product revenues include product sales by us to our customers. Product sales are recognized when the customer takes ownership of the products and assumes risk of loss, collection of the relevant receivable is probable, persuasive evidence of an agreement exists and the sales price is fixed and determinable. Product returns are accepted under limited circumstances and are estimated based upon historical experience. We may provide rebates and volume discounts to our customers from time to time. Such rebates and discounts are recorded as a reduction of product sales when earned by the customer.

License and contract revenues include milestone payments and fees under collaborative agreements with third parties, revenues from research services, and revenues from other miscellaneous sources.

In 2003, Staff Accounting Bulletin No. 104, "Revenue Recognition" ("SAB 104") replaced Staff Accounting Bulletin No. 101, "Revenue Recognition In Financial Statements" ("SAB 101"), which the Company adopted in 2000. The provisions related to non-refundable, up-front license fees were unchanged in SAB 104 compared to SAB 101. Accordingly, we defer up-front license fees and recognize them over the estimated performance period of the related agreement, when we have continuing involvement. Since the term of the performance periods is subject to management's estimates, future revenues to be recognized could be affected by changes in such estimates.

ACCOUNTS RECEIVABLE

Our accounts receivable balances are net of an estimated allowance for uncollectible accounts. We continuously monitor collections and payments from our customers and maintain an allowance for uncollectible accounts based upon our historical experience and any specific customer collection issues that we have identified. While we believe our reserve estimate to be appropriate, we may find it necessary to adjust our allowance for uncollectible accounts if the future bad debt expense exceeds our estimated reserve. We are subject to concentration risks as a limited number of our customers provide a high percent of total revenues, and corresponding receivables.

INVENTORIES

Inventories are stated at the lower of cost or market, as determined using the first-in, first-out method, which most closely reflects the physical flow of our inventories. Our products and raw materials are subject to expiration dating. We regularly review quantities on hand to determine the need for reserves for excess and obsolete inventories based primarily on our estimated forecast of product sales. Our estimate of future product demand may prove to be inaccurate, in which case we may have understated or overstated our reserve for excess and obsolete inventories.

CARRYING VALUE OF FIXED AND INTANGIBLE ASSETS

Our fixed assets and certain of our acquired rights to market our products have been recorded at cost and are being amortized on a straight-line basis over the estimated useful life of those assets. If indicators of impairment exist, we assess the recoverability of the affected long-lived assets by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows. If impairment is indicated, we measure the amount of such impairment by comparing the carrying value of the assets to the present value of the expected future cash flows associated with the use of the asset. Adverse changes regarding future cash flows to be received from long-lived assets could indicate that an impairment exists, and would require the write down of the carrying value of the impaired asset at that time.

RECENT ACCOUNTING PRONOUNCEMENTS

ABNORMAL INVENTORY COSTS

In November 2004, the FASB issued SFAS No. 151, "Inventory Costs, an amendment of ARB No. 43, Chapter 4" ("SFAS No. 151"), to clarify that abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage) should be recognized as current period charges, and that fixed production overheads should be allocated to inventory based on the normal capacity of production facilities. This statement is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. Accordingly, we will adopt SFAS No. 151 in our fiscal year beginning January 1, 2006. We are currently evaluating the impact of adopting this statement.

SHARE-BASED PAYMENT

In December 2004, the FASB issued SFAS No. 123(R), "Share-Based Payment", which revised SFAS No. 123 and superseded APB Opinion No. 25, "Accounting for Stock Issued to Employees." SFAS No. 123(R) requires that companies recognize compensation expense associated with grants of stock options and other equity instruments to employees in the financial statements effective as of the first interim or annual reporting period that begins after June 15, 2005. In April 2005, the SEC announced the adoption of a new rule allowing companies to implement SFAS No. 123(R) at the beginning of their next fiscal year that begins after June 15, 2005. Compensation cost will be measured based on the fair value of the instrument on the grant date and will be recognized over the vesting period. This pronouncement applies to all grants

Edgar Filing: CYTOGEN CORP - Form 10-Q

after the effective date and to the unvested portion of stock options outstanding as of the effective date. SFAS No. 123(R) eliminates the ability to account for such transactions using the intrinsic method currently used by us. SFAS No. 123(R) also requires that companies recognize compensation expense associated with purchases of shares of common stock by employees at a discount to market value under employee stock purchase plans that meet certain criteria. Accordingly, we will adopt SFAS No. 123(R) in the fiscal year beginning January 1, 2006. Although management has not yet determined the impact of the adoption of this standard, it is expected to have a material effect on our consolidated financial statements.

ITEM 3 - QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We do not have operations subject to risks of foreign currency fluctuations, nor do we use derivative financial instruments in our operations. Our exposure to market risk is principally confined to interest rate sensitivity. Our cash equivalents and short-term investments are conservative in nature, with a focus on preservation of capital. Due to the short-term nature of our investments and our investment policies and procedures, we have determined that the risks associated with interest rate fluctuations related to these financial instruments are not material to our business. As of June 30, 2005, we had \$2.3 million of debt outstanding with a fixed interest rate of 7%. We do not have exposure to market risks associated with changes in interest rates, as we have no variable interest rate debt outstanding. However, downward changes in interest rates could expose us to market risk associated with any fixed interest rate debt.

ITEM 4 - CONTROLS AND PROCEDURES

(a) Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2005. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Securities Exchange Act of 1934 is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applied its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our chief executive officer and chief financial officer concluded that, as of June 30, 2005, our disclosure controls and procedures were effective.

-31-

(2) Changes in Internal Control Over Financial Reporting

Edgar Filing: CYTOGEN CORP - Form 10-Q

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended as of June 30, 2005 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

-32-

PART II - OTHER INFORMATION

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

On June 14, 2005, we held our annual meeting of stockholders to: (i) elect nine directors; (ii) consider and vote upon a proposal to approve an amendment to the Company's Certificate of Incorporation to increase the total authorized shares of common stock, \$0.01 par value per share, of the Company from 25,000,000 to 50,000,000; and (iii) transact such other business as may come before the meeting.

There were represented at the our annual meeting, either in person or by proxy, 14,500,670 shares of our common stock out of a total number of 15,571,688 shares of common stock issued and outstanding and entitled to vote at the meeting.

The following tables set forth information regarding the number of votes cast for, withheld, abstentions and broker non-votes, with respect to each matter presented at the meeting.

(i) Election of Directors:

| Nominees | For | Withheld | Abstentions |
|-----------------------|------------|-----------|-------------|
| John E. Bagalay, Jr. | 12,283,163 | 2,217,507 | N/A |
| Michael D. Becker | 12,814,980 | 1,685,690 | N/A |
| Allen Bloom | 12,818,453 | 1,682,217 | N/A |
| Stephen K. Carter | 12,780,677 | 1,719,993 | N/A |
| James A. Grigsby | 12,749,748 | 1,750,922 | N/A |
| Dennis H. Langer | 12,817,960 | 1,682,710 | N/A |
| Robert F. Hendrickson | 12,799,781 | 1,720,879 | N/A |
| Kevin G. Lokay | 12,818,490 | 1,682,180 | N/A |
| Joseph A. Mollica | 12,815,962 | 1,684,708 | N/A |

(ii) Proposal to approve an amendment to the Company's Certificate of Incorporation:

| For | Against | Abstentions | Broker Non-Votes |
|------------|---------|-------------|------------------|
| 11,951,000 | 916,347 | 1,633,323 | 0 |

-33-

Edgar Filing: CYTOGEN CORP - Form 10-Q

ITEM 6. EXHIBITS.

| Exhibit No. ----- | Description ----- |
|----------------------|--|
| 3.1 | Certificate of Amendment to the Restated Certificate of Incorporation dated June 15, 2005. Filed herewith. |
| 31.1 | Certification of President and Chief Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. Filed herewith. |
| 31.2 | Certification of Senior Vice President and Chief Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. Filed herewith. |
| 32.1 | Certification of President and Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. Filed herewith. |
| 32.2 | Certification of Senior Vice President and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. Filed herewith. |

-34-

SIGNATURES

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

CYTOGEN CORPORATION

Date: August 9, 2005

By:/s/ Michael D. Becker

Michael D. Becker
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 9, 2005

By:/s/ Christopher P. Schnittker

Christopher P. Schnittker
Senior Vice President and

Edgar Filing: CYTOGEN CORP - Form 10-Q

Chief Financial Officer
(Principal Financial and Accounting Officer)

-35-