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CYTOGEN CORP
Form 10-Q
November 09, 2004

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 September 30, 2004

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:

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| Class | Outstanding at November 1, 2004 |
|-------------------------------|---------------------------------|
| ----- | ----- |
| Common Stock, \$.01 par value | 15,436,501 |

CYTOGEN CORPORATION

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ProstaScint(R) and OncoScint(R) are registered United States trademarks of Cytogen Corporation. Cytogen Corporation is the owner of a pending United States trademark application, Serial No. 78374967, relating to Quadramet. 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.

PART I - FINANCIAL INFORMATION

ITEM 1 - CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

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

| | SEPTEMBER 30, 2014 | SEPTEMBER 30, 2013 |
|--------------------------------|--------------------|--------------------|
| ASSETS: | | |
| Current assets: | | |
| Cash and cash equivalents..... | \$ 13 | 27 |
| Short-term investments..... | 1 | 2 |
| Accounts receivable, net | 1 | 1 |
| Inventories | 45 | |
| Other current assets | | |
| Total current assets | | |

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| | |
|---|-------|
| Property and equipment, net | 7 |
| Quadramet license fee, net..... | |
| Other assets..... | |
| | ----- |
| | \$ 53 |
| | ===== |
| LIABILITIES AND STOCKHOLDERS' EQUITY: | |
| Current liabilities: | |
| Current portion of long-term liabilities..... | \$ 2 |
| Accounts payable and accrued liabilities..... | 5 |
| | ----- |
| Total current liabilities..... | 7 |
| | ----- |
| Long-term liabilities..... | |
| | ----- |
| 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, 25,000,000 shares authorized, | |
| 15,436,501 and 12,857,488 shares issued and outstanding | |
| at September 30, 2004 and December 31, 2003, respectively | |
| Additional paid-in capital | 425 |
| Accumulated deficit | (380) |
| | ----- |
| Total stockholders' equity..... | 45 |
| | ----- |
| | \$ 53 |
| | ===== |

The accompanying notes are an integral part of these statements.

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

| THREE MONTHS ENDED SEPTEMBER 30, | |
|-------------------------------------|-------|
| 2004 | 2003 |
| ----- | ----- |

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REVENUES:

Product related:

| | | |
|--|------------|-----------|
| Quadramet..... | \$ 1,924 | \$ 1,159 |
| ProstaScint..... | 1,308 | 1,519 |
| Others..... | -- | 116 |
| | ----- | ----- |
| Total product revenues..... | 3,232 | 2,794 |
| | | |
| Quadramet royalties..... | -- | 191 |
| | ----- | ----- |
| Total product related revenues..... | 3,232 | 2,985 |
| | | |
| License and contract..... | 29 | 2,520 |
| | ----- | ----- |
| Total revenues..... | 3,261 | 5,505 |
| | ----- | ----- |
| OPERATING EXPENSES: | | |
| Cost of product related revenues..... | 2,188 | 2,154 |
| Selling, general and administrative..... | 5,343 | 2,780 |
| Research and development..... | 608 | 753 |
| Equity in loss of joint venture..... | 805 | 714 |
| | ----- | ----- |
| Total operating expenses..... | 8,944 | 6,401 |
| | ----- | ----- |
| Operating loss..... | (5,683) | (896) |
| | | |
| INTEREST INCOME..... | 133 | 32 |
| INTEREST EXPENSE..... | (46) | (46) |
| | ----- | ----- |
| Loss before income taxes..... | (5,596) | (910) |
| | | |
| INCOME TAX BENEFIT..... | -- | -- |
| | ----- | ----- |
| NET LOSS..... | \$ (5,596) | \$ (910) |
| | ===== | ===== |
| | | |
| BASIC AND DILUTED NET LOSS PER SHARE..... | \$ (0.36) | \$ (0.08) |
| | ===== | ===== |
| | | |
| WEIGHTED AVERAGE COMMON SHARES OUTSTANDING | 15,435 | 10,866 |
| | ===== | ===== |

The accompanying notes are an integral part of these statements.

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

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| | NINE MONTHS END |
|---|-----------------|
| | 2004 |
| CASH FLOWS FROM OPERATING ACTIVITIES: | |
| Net loss..... | \$ (14,262) |
| Adjustments to reconcile net loss to net cash used in operating activities: | |
| Depreciation and amortization..... | 804 |
| Stock-based compensation expenses..... | 15 |
| Amortization of deferred revenue..... | -- |
| Asset impairment..... | 100 |
| Loss on disposition of assets..... | 3 |
| Changes in assets and liabilities: | |
| Receivables, net..... | 61 |
| Inventories..... | (142) |
| Other assets..... | (100) |
| Accounts payable, accrued liabilities and other liabilities..... | 456 |
| Net cash used in operating activities..... | (13,065) |
| CASH FLOWS FROM INVESTING ACTIVITIES: | |
| Purchase of product rights..... | -- |
| Purchases of property and equipment..... | (463) |
| Maturities of short-term investments..... | 12,500 |
| Purchases of short-term investments..... | (23,017) |
| Net cash used in investing activities..... | (10,980) |
| CASH FLOWS FROM FINANCING ACTIVITIES: | |
| Proceeds from issuance of common stock..... | 23,999 |
| Payment of long-term liabilities..... | (124) |
| Net cash provided by financing activities..... | 23,875 |
| Net decrease in cash and cash equivalents..... | (170) |
| Cash and cash equivalents, beginning of period..... | 13,630 |
| Cash and cash equivalents, end of period..... | \$ 13,460 |
| Supplemental disclosure of non-cash information: | |
| Capital leases of equipment..... | \$ 70 |
| Supplemental disclosure of cash information: | |
| Cash paid for interest..... | \$ 99 |

The accompanying notes are an integral part of these statements.

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

1. THE COMPANY

BACKGROUND

Founded in 1980, Cytogen Corporation (the "Company" or "Cytogen") of Princeton, NJ is a product-driven biopharmaceutical company that develops and commercializes innovative molecules that can be used to build leading franchises across multiple markets. The Company's marketed products include Quadramet™ (samarium Sm-153 lexidronam injection) and ProstaScint(R) (capromab pendetide) kit for the preparation of Indium In-111 capromab pendetide in the United States. The Company has exclusive United States marketing rights to Combidex(R) (ferumoxtran-10) for all indications. Combidex, an investigational molecular imaging agent consisting of iron oxide nanoparticles, is currently being developed for use in conjunction with magnetic resonance imaging to aid in the differentiation of cancerous and non-cancerous lymph nodes, and is under review by the U.S. Food and Drug Administration. 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.

Cytogen 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 OncoScint CR/OV and the BrachySeed products, that the Company previously expected would generate significant revenues for its business. 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 to, among other things, manufacture its products, secure raw materials, and provide licensing rights to their proprietary products for the Company to sell and market to others.

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, 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

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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, filed with the Securities and Exchange Commission, which includes financial statements as of and for the year ended December 31, 2003. 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

Short-term investments at September 30, 2004 and December 31, 2003 were \$27.1 million and \$16.6 million, respectively, and consisted of investments in U.S. government agency notes. The Company has the ability and intent to hold these investments until maturity. Held-to-maturity investments are recorded at amortized cost, adjusted for the accretion of discounts or premiums. Discounts or premiums are accreted into interest income over the life of the related investment on a straight-line basis. Dividend and interest income are recognized when earned. These investments mature at various times through June 15, 2005.

IMPAIRMENT OF LONG-LIVED ASSETS

In accordance with Statement of Financial Accounting Standards ("SFAS") No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets," if indicators of impairment exist, management assesses 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 and eventual disposition of the asset. If impairment is indicated, management measures 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.

During the second quarter of 2004, the Company recorded a non-cash charge of \$100,000 for equipment impairment associated with the initiation of the closure of the facilities at the Company's AxCell BioSciences subsidiary in July 2004 (see Note 6, "Closure of AxCell BioSciences Facilities"). This charge is included in selling, general and administrative expenses for the nine months ended September 30, 2004 in the accompanying consolidated statement of operations.

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COSTS ASSOCIATED WITH EXIT OR DISPOSAL ACTIVITIES

In accordance with the SFAS No. 146, "Accounting for Costs Associated with

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Exit or Disposal Activities," the Company is required to record a liability for costs associated with an exit or disposal activity, measured at fair value, in the period in which the liability is incurred. A liability related to one-time termination benefits provided to severed employees as a result of the exit or disposal activity will be recorded when certain criteria have been met and the employees are notified of the details of the plan. A liability for costs to terminate a lease or other contract before the end of its term shall be recognized and measured at its fair value when the Company terminates the contract in accordance with the contract terms. If the contract is an operating lease, the fair value of the liability at the cease-use date shall be determined based on the remaining lease rentals, reduced by estimated sublease rentals that could be reasonably obtained for the property, even if the Company does not intend to enter into a sublease.

In July 2004, as part of our continuing effort to reduce non-strategic expenses, the Company initiated the closure of its AxCell BioSciences facilities, which will be accounted for pursuant to SFAS No. 146 (see Note 6, "Closure of AxCell BioSciences Facilities").

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):

| | SEPTEMBER 30, 2004 | DECEMBER 31, 2003 |
|----------------------|--------------------|-------------------|
| | ----- | ----- |
| Raw materials..... | \$ -- | \$ 11 |
| Work-in-process..... | 870 | 1,089 |
| Finished goods..... | 1,159 | 787 |
| | ----- | ----- |
| | \$ 2,029 | \$ 1,887 |
| | ===== | ===== |

NET LOSS PER SHARE

Basic net loss per common share is calculated by dividing the Company's net 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 nine month periods ended September 30, 2004 and 2003 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

In December 2003, the Financial Accounting Standards Board ("FASB") issued FASB Interpretation No. 46 (revised December 2003) ("FIN 46R"), "Consolidation of Variable Interest Entities" ("VIEs"), 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. FIN 46R replaced FASB Interpretation No. 46 ("FIN 46") which

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was issued in January 2003. The Company was required to apply FIN 46R to variable interests in VIEs created after December 31, 2003. For variable interests in VIEs created before January 1, 2004, FIN 46R applied beginning on March 31, 2004. For any VIEs that must be consolidated under FIN 46R that were

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created before January 1, 2004, the assets, liabilities and noncontrolling interests of the VIE initially are measured at their carrying amounts with any difference between the net amount added to the balance sheet and any previously recognized interest being recognized as the cumulative effect of an accounting change. If determining the carrying amounts is not practicable, fair value at the date FIN 46R first applies may be used to measure the assets, liabilities and noncontrolling interest of the VIE.

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, "Equity Loss in the PSMA Development Company LLC"). Cytogen accounts for the Joint Venture using the equity method of accounting.

The Company believes it 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.

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 SEPTEMBER 30, | | |
|--|-------------------------------------|------------|----|
| | 2004 | 2003 | |
| | ---- | ---- | |
| Net loss, as reported..... | \$ (5,596) | \$ (910) | \$ |
| Add: Stock-based employee compensation expense included in reported net loss..... | 4 | 2 | |
| Deduct: Total stock-based employee compensation expense determined under fair value-based method for all awards..... | (1,088) | (382) | |
| | ----- | ----- | |
| Pro forma net loss..... | \$ (6,680) | \$ (1,290) | \$ |
| | ===== | ===== | == |
| Basic and diluted net loss per share, as reported..... | \$ (0.36) | \$ (0.08) | \$ |

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| | | | |
|---------------------------------|-----------|-----------|-------|
| | ===== | ===== | ===== |
| Pro forma basic and diluted net | | | |
| loss per share..... | \$ (0.43) | \$ (0.12) | \$ |
| | ===== | ===== | ===== |

On September 3, 2004, H. Joseph Reiser tendered his resignation from the Company's Board of Directors. In connection with Dr. Reiser's resignation, the Company accelerated the vesting of options to purchase 20,000 shares of the Company's common stock held by Dr. Reiser such that these options became immediately exercisable as of September 3, 2004. In addition, the expiration dates of an aggregate of 21,000 options to purchase shares of the Company's common stock held by Dr. Reiser were amended to September 3, 2005. As a result of the foregoing, the Company recorded a charge for the change in the intrinsic value of these modified options in the amount of \$5,000 in its consolidated statement of operations for the third quarter of 2004.

NEW ACCOUNTING PRONOUNCEMENTS

In March 2004, the FASB issued a Proposed SFAS, "Share-Based Payment - An Amendment of SFAS Nos. 123 and 95" ("Exposure Draft"). The Exposure Draft would eliminate the ability to account for share-based compensation transactions using APB Opinion No. 25, and generally would require such transactions be accounted for using a fair-value-based method and the resulting cost recognized in the financial statements. Based on the provisions of the Exposure Draft and subsequent FASB deliberations and tentative conclusions, the final standard would be effective for publicly-traded companies for awards granted, modified or settled in interim periods beginning after June 15, 2005. The Company is closely monitoring developments related to the Exposure Draft and will adopt the final standards, if any, in the appropriate period following issuance. The eventual adoption of the Exposure Draft, if issued in final form by the FASB, 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.

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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 is owned equally by Cytogen and Progenics. 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. The Joint Venture is expected to continue to incur losses in future years provided an agreement between the Members is reached on research program goals and budgets for periods after 2004 and the Joint Venture's operations are funded. In 2004, the Members each expect to provide \$4.2 million in funding for the development of the PSMA technologies through the Joint Venture. Cytogen has funded \$2.0 million of its \$4.2 million annual commitment, as of September 30, 2004. The Members have not committed to fund the Joint Venture beyond December 31, 2004 at this time, except for obligations under existing contractual commitments as of that date.

For the three months ended September 30, 2004 and 2003, Cytogen recognized \$805,000 and \$714,000, respectively, of the Joint Venture's losses. For the nine months ended September 30, 2004 and 2003, Cytogen recognized \$2.2 million and \$2.7 million, respectively, of the Joint Venture's losses. As of September 30,

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2004 and December 31, 2003, the carrying value of Cytogen's investment in the Joint Venture was \$343,000 and \$550,000, respectively, which represents Cytogen's investment to date in the Joint Venture less its cumulative share of losses and is recorded in other assets. Selected financial statement information of the Joint Venture is as follows (all amounts in thousands):

BALANCE SHEET DATA:

| | SEPTEMBER 30, 2004 |
|--|-----------------------|
| Cash | \$ 1,171 |
| Prepaid expenses..... | 22 |
| Accounts receivable from Progenics, a related party..... | -- |
| Total assets..... | \$ 1,193 |
| Accounts payable to Progenics, a related party..... | \$ 3 |
| Other accounts payable and accrued expenses..... | 520 |
| Total liabilities..... | 523 |
| Capital contributions..... | 23,298 |
| Accumulated deficit..... | (22,628) |
| Total stockholders' equity..... | 670 |
| Total liabilities and stockholders' equity..... | \$ 1,193 |

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INCOME STATEMENT DATA:

| | THREE MONTHS ENDED SEPTEMBER 30, | | NINE MONTHS ENDED SEPTEMBER 30, | | FOR THE PER FROM JUNE 15, (INCEPTION) |
|----------------------|--|------------|---------------------------------------|------------|---|
| | 2004 | 2003 | 2004 | 2003 | SEPTEMBER 30, |
| Interest income..... | \$ 1 | \$ 1 | \$ 6 | \$ 2 | \$ 2 |
| Total expenses..... | 1,611 | 1,430 | 4,318 | 5,362 | 22,8 |
| Net loss..... | \$ (1,610) | \$ (1,429) | \$ (4,312) | \$ (5,360) | \$ (22,6 |

3. BRISTOL-MYERS SQUIBB MEDICAL IMAGING, INC.

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As a result of the Company's reacquisition of marketing rights to Quadramet from Berlex Laboratories Inc. ("Berlex") in August 2003, the Company assumed all of Berlex's obligations under a manufacturing and supply agreement with Bristol-Myers Squibb Medical Imaging, Inc. ("BMSMI"). Effective January 1, 2004, the Company entered into a new manufacturing and supply agreement with BMSMI whereby BMSMI manufactures, distributes and provides order processing and customer services for Cytogen relating to Quadramet. Under the terms of the new agreement, Cytogen is obligated to pay at least \$4.2 million annually 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 the three and nine month periods ended September 30, 2004, Cytogen incurred \$1.1 million and \$3.2 million, respectively, of manufacturing costs for Quadramet, all of which is included in cost of product related revenues. The Company also pays BMSMI a variable amount per month for each order of Quadramet placed to cover the costs of customer service, which is included in selling, general and administrative expenses.

4. LITIGATION AND OTHER RELATED MATTERS

In September 2004, the Company announced the settlement of a patent infringement suit against Cytogen and C.R. Bard Inc. for an agreed-upon payment, without any admission of fault or liability. The charge related to this settlement is recorded in the accompanying statements of operations for the three and nine months ended September 30, 2004. Immunomedics, Inc. filed suit on February 17, 2000 against Cytogen and Bard, alleging that use of Cytogen's ProstaScint product infringed U.S. Patent No. 4,460,559, which claims a method for detecting and localizing tumors. The settlement with Immunomedics is on behalf of Cytogen and Bard.

In connection with a recent review of certain of the Company's intellectual property, it was determined that the Company was the recipient, beginning in 1998, of correspondence from legal counsel representing the former employer of Dr. Julius Horoszewicz, the sole inventor on the principal United States patent covering ProstaScint. Such correspondence alleged that the patent rights to Dr. Horoszewicz's discoveries were the property of such former employer and that Dr. Horoszewicz had no right to assign them to the Company. The Company vigorously disputed those allegations, and the Company has no record of the matter having been pursued by such former employer subsequent to August 2000. The Company believes that in view of the

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marketing of the technology covered by the patent through the sale of ProstaScint by the Company, the Company's right to use the underlying technology in its continuing production and sale of ProstaScint should not be at risk. However, if such claims were reasserted, and if it were to be concluded that Dr. Horoszewicz in fact had no right to assign the patent to the Company, a court could determine that the Company has no right to use the technology covered by the patent or that any royalties paid by or payable by the Company in respect of the use of the patent should have been paid in the past, and should in the future be payable, to Dr. Horoszewicz's former employer in lieu of Dr. Horoszewicz. The amount of any such payments, and the Company's liability for them, if any, is not presently determinable, and the Company cannot give any assurance that an adverse determination could not result in a material expenditure to the Company or have a material adverse effect on the Company's financial condition, results of operations or liquidity.

The Company has certain rights to indemnification against litigation and

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litigation expenses from the inventor of technology used in ProstaScint, which may be offset against royalty payments on sales of ProstaScint. The Company cannot give any assurance that litigation expenses will not exceed any offsetting royalty payments.

In addition, the Company is, from time to time, subject to claims and suits arising in the ordinary course of business. In the opinion of management, the ultimate resolution of any such matters would not have a material effect on the Company's financial condition, results of operations or liquidity.

5. 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 for the Company in its Princeton, New Jersey facility. The agreement was effective immediately and shall terminate, unless earlier terminated pursuant to the terms thereof, upon Laureate's completion of the production campaign and shipment of the resulting products from Laureate's facility. Under the terms of the agreement, Cytogen is obligated to pay at least an aggregate of \$5.1 million through 2006.

6. CLOSURE OF AXCELL BIOSCIENCES FACILITIES

In July 2004, the Company initiated the closure of the facilities at its AxCell BioSciences subsidiary as part of the Company's continuing efforts to reduce non-strategic expenses. In connection with such closure, in August 2004, the Company sold certain of the assets remaining at the AxCell facility for net proceeds of approximately \$181,000, which amount approximated the net value of such assets. The Company may record impairment charges related to future rental payments on the leased premises in the fourth quarter of 2004, when such leased premises will no longer be used for AxCell's operations. Research projects through academic, governmental and corporate collaborators will continue to be supported and additional applications for the intellectual property and technology at AxCell are being pursued.

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7. SALE OF COMMON STOCK

In April 2004, the Company sold and issued through a registered direct offering 2,570,000 shares of its common stock at \$10.10 per share, resulting in net proceeds to the Company of approximately \$24.0 million after the payment of placement agency fees and expenses related to the offering.

8. STOCK INCENTIVE PLANS

At the Company's 2004 Annual Meeting of Stockholders held on June 15, 2004, the stockholders of the Company approved the adoption of the Company's 2004 Stock Incentive Plan (the "2004 Plan") and the Company's 2004 Non-Employee Director Stock Incentive Plan (the "2004 Director Plan" and together with the 2004 Plan, collectively, the "2004 Incentive Plans"). An aggregate of 1,200,000 and 375,000 shares of the Company's common stock have been reserved for issuance upon the exercise of option grants or restricted stock awards (as applicable) under the 2004 Plan and 2004 Director Plan, respectively. The 2004 Plan provides for the grant of incentive stock options, non-qualified stock options or restricted stock to the Company's employees, officers, consultants and advisors. The 2004 Director Plan provides for the grant of non-qualified stock options and shares of the Company's common stock, in certain circumstances, to members of the Company's Board of Directors who are not employees of the Company. The Company intends to file a registration statement on Form S-8 with the Securities

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and Exchange Commission to register the shares of the Company's common stock underlying option grants or other awards under the 2004 Incentive Plans. Furthermore, upon approval of the 2004 Incentive Plans by our stockholders, no further option grants or awards were, or will be, made under the Company's existing 1995 Stock Option Plan or 1999 Non-Employee Director Stock Option Plan. Any unissued and unallocated options previously reserved under these plans were released from reserves.

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

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 statements regarding our intent to hold our investments until maturity, additional funding of the PSMA technologies, potential charges resulting from the closure of AxCell BioSciences, growth and market penetration for Quadramet and ProstaScint, revenues, if any, from NMP22 BladderChek and 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 and expenses in preparation for the launch of Combindex upon final regulatory approval, 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 in our Annual Report on Form 10-K for the year ended December 31, 2003 under the caption "Additional Factors That May Affect Future Results" 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

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elsewhere herein, as well as in our Annual Report on Form 10-K for the year ended December 31, 2003 and from time to time in our other filings with the Securities and Exchange Commission.

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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 across multiple markets. Our marketed products include Quadramet™ (samarium Sm-153 lexitronam injection) and ProstaScint(R) (capromab pendetide) kit for the preparation of Indium In-111 capromab pendetide in the United States. We have exclusive United States marketing rights to Combidx(R) (ferumoxtran-10) for all indications. Combidx, an investigational molecular imaging agent consisting of iron oxide nanoparticles, is currently being developed for use in conjunction with magnetic resonance imaging to aid in the differentiation of cancerous and non-cancerous lymph nodes, and is under review by the U.S. Food and Drug Administration. 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 THE THIRD QUARTER OF 2004

MANUFACTURING AGREEMENT WITH LAUREATE PHARMA, L.P.

On September 10, 2004, we entered into a non-exclusive Manufacturing Agreement with Laureate Pharma, L.P. for our ProstaScint product. The agreement was effective immediately and shall terminate, unless earlier terminated pursuant to the terms thereof, upon Laureate's completion of the production campaign and shipment of the resulting products from Laureate's facility in Princeton, NJ. It is intended 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.

ADVANCED MAGNETICS SUBMITS COMPLETE RESPONSE TO APPROVABLE LETTER FOR COMBIDEX

On October 19, 2004, we jointly announced with Advanced Magnetix, Inc. that Advanced Magnetix has submitted a complete response to the approvable letter received from the FDA for Combidx, Advanced Magnetix' investigational molecular imaging agent, to which we have exclusive United States marketing rights. The September 30, 2004 submission was accepted and assigned a user fee goal date of March 30, 2005.

PATENT INFRINGEMENT LITIGATION SETTLED

On September 29, 2004, we announced the settlement of a patent infringement suit against us and C.R. Bard Inc. for an agreed-upon payment, without any admission of fault or liability. The charge related to this settlement is recorded in the accompanying statements of operations for the three and nine months ended September 30, 2004. Immunomedics filed suit on February 17, 2000 against us and Bard, alleging that use of our ProstaScint product infringed U.S. Patent No. 4,460,559, which claims a method for detecting and localizing tumors. The settlement with Immunomedics is on behalf of Cytogen and Bard.

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CLOSURE OF AXCELL BIOSCIENCES FACILITIES

In July 2004, as part of our continuing efforts to reduce non-strategic expenses, we initiated the closure of facilities at our AxCell BioSciences subsidiary. Research projects through academic, governmental and corporate collaborators will continue to be supported and additional applications for the intellectual property and technology at AxCell are being pursued.

ADDITION TO SENIOR MANAGEMENT

On August 23, 2004, we announced that William J. Thomas, Esq. joined us as Senior Vice President and General Counsel. Mr. Thomas was formerly a senior partner with the law firm of Wilmer Cutler Pickering Hale and Dorr, and has almost 19 years of experience in representing emerging growth and high technology businesses in the areas of, among others, general corporate issues, securities law compliance, venture capital, underwriting, strategic alliances and mergers and acquisitions. Mr. Thomas has represented numerous public and private companies in the software, pharmaceutical, telecommunications and e-commerce industries. Mr. Thomas is responsible for all legal matters at Cytogen.

RESIGNATION OF DIRECTOR

On September 3, 2004, we announced that H. Joseph Reiser, Ph.D. tendered his resignation from our Board of Directors, effective immediately. Dr. Reiser's resignation letter contained no disagreement with management concerning any matter relating to our operations, policies or practices.

RESULTS OF OPERATIONS

THREE MONTHS ENDED SEPTEMBER 30, 2004 AND 2003

REVENUES

| | | | INCREASE/ (DECREASE) | |
|---|--------------|---------------|----------------------|-----------------|
| | 2004 | 2003 | \$ | % |
| | ---- | ---- | ----- | ----- |
| | (ALL AMOUNTS | IN THOUSANDS, | EXCEPT | PERCENTAGE DATA |
| Quadramet | | | | |
| Product Sales (commenced August 2003).... | \$ 1,924 | \$ 1,159 | \$ 765 | 66% |
| Royalties (ceased July 2003)..... | -- | 191 | (191) | (100)% |
| ProstaScint..... | 1,308 | 1,519 | (211) | (14)% |
| NMP22 BladderChek..... | -- | 116 | (116) | (100)% |
| License and Contract..... | 29 | 2,520 | (2,491) | (99)% |
| | ----- | ----- | ----- | |
| | \$ 3,261 | \$ 5,505 | \$ (2,244) | (41)% |
| | ===== | ===== | ===== | |

Total revenues for the third quarter of 2004 were \$3.3 million compared to \$5.5 million for the same period in 2003. Product related revenues, which include product sales and royalties (in 2003), accounted for 99% and 54% of total revenues for the third quarters of 2004 and 2003, respectively. License and contract revenues accounted for the remainder of revenues. In the

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third quarter of 2003, we recognized \$2.0 million of previously deferred license revenue including the remaining unamortized deferred revenue in the amount of \$1.9 million related to an up-front license payment net of associated costs, which we received from Berlex Laboratories in 1998 for granting them the marketing rights to Quadramet.

QUADRAMET. Cytogen recorded Quadramet sales of \$1.9 million for the third quarter of 2004 compared to \$1.2 million in Quadramet sales and \$191,000 of Quadramet royalty revenue during the third quarter of 2003. Quadramet sales and royalties accounted for 60% and 45% of product related revenues for the third quarters of 2004 and 2003, respectively. Berlex Laboratories marketed Quadramet in the United States through July 31, 2003. On August 1, 2003, we reacquired marketing rights to Quadramet from Berlex and began marketing Quadramet through our internal specialty sales force. Effective upon the reacquisition of such marketing rights, we no longer receive royalty revenue from Berlex for Quadramet and we pay royalties to Berlex on our sales of Quadramet. On August 1, 2003, we began recognizing product revenue from our sales of Quadramet. Currently, we market Quadramet only in the United States and have no rights to market Quadramet in Europe. We believe that the future growth and market penetration of Quadramet is dependent upon, among other things: (i) new clinical data supporting the expanded and earlier use of Quadramet in various cancers; (ii) novel research supporting combination uses with other therapies, such as chemotherapeutics and bisphosphonates; and (iii) establishing the use of Quadramet at higher doses to target and treat primary bone cancers. 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 \$1.3 million for the third quarter of 2004, compared to \$1.5 million in the third quarter of 2003. Sales of ProstaScint accounted for 40% and 51% of product related revenues for the third quarters of 2004 and 2003, respectively. We believe that such decrease in ProstaScint sales is due to the effects of buying patterns relating to our implementation of a price increase for ProstaScint in late June 2004, in which we limited the quantities of ProstaScint that could be purchased by distributors at the pre-increase price. This decrease was partially offset by increased demand due to a higher ProstaScint reimbursement value established for 2004 compared to 2003 and our identification of new distribution channels to better accommodate customer needs. We believe that demand for ProstaScint has been consistently higher during 2004 than 2003 as evidenced by the higher year-to-date sales in 2004, and that the quarterly fluctuations in quantities of ProstaScint sold in 2004 have been due to the change in buying patterns described above. ProstaScint has historically been a challenging product for physicians and technologists to use, in part due to inherent limitations in nuclear medicine imaging. We believe that future growth and market penetration of ProstaScint is dependent upon, among other things, the implementation and continued research relating to advances in imaging technology, new product applications and the validation of PSMA as an independent prognostic indicator. 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 third quarter of 2004 compared to \$116,000 in the third quarter of 2003. We began promoting NMP22 BladderChek to both urologists and oncologists in the United States in November 2002.

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using our internal sales force. On October 30, 2003, we entered into an amended and restated distribution agreement with Matritech whereby, effective November 8, 2003, we had the right to non-exclusively market NMP22 BladderChek to urologists through December 31, 2003 and have the right to exclusively market NMP22 BladderChek to oncologists through December 31, 2004. We do not expect significant revenues from sales of NMP22 BladderChek.

LICENSE AND CONTRACT REVENUES. License and contract revenues were \$29,000 and \$2.5 million for the third quarters of 2004 and 2003, respectively. Under SAB 101, which we adopted in 2000, license revenues from certain up-front, non-refundable license fees previously recognized were deferred and were being amortized over the estimated performance period. The deferred revenue was fully recognized as of December 31, 2003. In the third quarter of 2003, we recognized \$2.0 million of previously deferred license revenue including the remaining unamortized deferred revenue in the amount of \$1.9 million related to an up-front license payment net of associated costs, which we received from Berlex Laboratories in 1998 for granting them the marketing rights to Quadramet. In August 2003, the 1998 license agreement was terminated and we reacquired those rights from Berlex Laboratories. In addition, during the third quarter of 2003, we recognized as revenue a \$500,000 payment from Antisoma in connection with Antisoma's acquisition of certain royalty rights to its lead product, R1549 (formerly Pentumomab), because we have no continuing involvement in this arrangement. We also recognized \$20,000 and \$59,000 of contract revenues for limited research and development services provided by us to the PSMA Development Company LLC, our joint venture with Progenics Pharmaceuticals Inc. in the third quarters of 2004 and 2003, respectively. The level of future revenues for the remainder of 2004, 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

| | 2004 | 2003 | INCREASE/ (DECREASE) |
|--|-----------------|-------------------|----------------------|
| | ---- | ---- | ----- |
| | (ALL AMOUNTS IN | THOUSANDS, EXCEPT | PERCENTAGE DATA) |
| Cost of product related revenues..... | \$ 2,188 | \$ 2,154 | \$ 34 |
| Selling, general and administrative..... | 5,343 | 2,780 | 2,563 |
| Research and development..... | 608 | 753 | (145) |
| Equity in loss of joint venture..... | 805 | 714 | 91 |
| | ----- | ----- | ----- |
| | \$ 8,944 | \$ 6,401 | \$ 2,543 |
| | ===== | ===== | ===== |

Total operating expenses for the third quarter of 2004 were \$8.9 million compared to \$6.4 million in the same quarter of 2003.

COST OF PRODUCT RELATED REVENUES. Cost of product related revenues for the third quarters of both 2004 and 2003 were \$2.2 million and includes our assumption, in August 2003, of the responsibility for manufacturing costs for Quadramet including contractual increases in 2004 related to our new agreement with Bristol-Myers Squibb Medical Imaging, royalties to Berlex on our sales of Quadramet and the amortization of the up-front payment to Berlex to reacquire Quadramet.

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SELLING, GENERAL AND ADMINISTRATIVE. Selling, general and administrative expenses for the third quarter of 2004 were \$5.3 million compared to \$2.8 million in the same period of 2003. The increase from the prior year period is due primarily to the expansion of our sales force and the implementation of other marketing initiatives for our existing products, including Quadramet, which we reacquired from Berlex in August 2003. The selling, general and administrative expenses in 2004 also include a payment related to the settlement, in September 2004, of a patent infringement suit filed by Immunomedics, Inc. against us and C.R. Bard Inc. in February 2000. As of November 1, 2004, we employed 40 people in sales and marketing. The employees in sales and marketing included 9 Clinical Oncology Specialists and 22 Professional Oncology Representatives. By comparison, we had 31 employees in sales and marketing as of December 31, 2003. We anticipate that expenditure levels will continue to increase as we continue this expansion and as we continue our efforts to prepare for the launch of Combidex pending final regulatory approval.

RESEARCH AND DEVELOPMENT. Research and development expenses for the third quarter of 2004 were \$608,000 compared to \$753,000 in the same period of 2003. The current year expenses reflect costs associated with our product development efforts in support of new and expanded uses for Quadramet and ProstaScint and savings from the recent closure of our AxCell BioSciences facility. During the third quarter of 2004 and 2003, we incurred \$113,000 and \$382,000, 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 \$805,000 and \$714,000 during the third quarters of 2004 and 2003, respectively. Such amounts represented 50% of the joint venture's operating losses. 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.

INTEREST INCOME/EXPENSE. Interest income for the third quarter of 2004 was \$133,000 compared to \$32,000 in the same period of 2003. The increase in 2004 from the prior year period was due to higher average cash balances in 2004. Interest expense for each of the third quarters of 2004 and 2003 was \$46,000. 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 third quarter of 2004 was \$5.6 million compared to \$910,000 reported in the third quarter of 2003. The basic and diluted net loss per share for the third quarter of 2004 was \$0.36 based on 15.4 million weighted average common shares outstanding, compared to a basic and diluted net loss per share of \$0.08 based on 10.9 million weighted average common shares outstanding for the same period in 2003.

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NINE MONTHS ENDED SEPTEMBER 30, 2004 AND 2003

REVENUES

IN

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| | 2004 | 2003 | |
|--|-----------------------------------|-----------|-------|
| | ---- | ---- | ----- |
| | (ALL AMOUNTS IN THOUSANDS, EXCEPT | | |
| Quadramet | | | |
| Product Sales (commenced August 2003)..... | \$ 5,394 | \$ 1,159 | \$ 4, |
| Royalties (ceased July 2003)..... | -- | 1,105 | (1, |
| ProstaScint..... | 5,347 | 4,738 | |
| NMP22 BladderChek..... | 1 | 239 | (|
| BrachySeed (ceased January 2003)..... | -- | 240 | (|
| License and Contract..... | 72 | 2,827 | (2, |
| | ----- | ----- | ----- |
| | \$ 10,814 | \$ 10,308 | \$ |
| | ===== | ===== | ===== |

Total revenues for the first nine months of 2004 were \$10.8 million compared to \$10.3 million for the same period in 2003. Product related revenues, which include product sales and royalties, accounted for 99% and 73% of total revenues for the first nine months of 2004 and 2003, respectively. License and contract revenues accounted for the remainder of revenues. In the first nine months of 2003, we recognized \$2.2 million of previously deferred license revenue including the remaining unamortized deferred revenue in the amount of \$1.9 million related to an up-front license payment net of associated costs, which we received from Berlex Laboratories in 1998 for granting them the marketing rights to Quadramet.

QUADRAMET. Cytogen recorded Quadramet sales of \$5.4 million for the first nine months of 2004 compared to \$1.2 million in Quadramet sales and \$1.1 million of Quadramet royalty revenue during the first nine months of 2003. Quadramet sales and royalties accounted for 50% and 30% of product related revenues for such periods, respectively. Berlex Laboratories marketed Quadramet in the United States through July 31, 2003. On August 1, 2003, we reacquired marketing rights to Quadramet from Berlex and began marketing Quadramet through our internal specialty sales force. Effective upon the reacquisition of such marketing rights, we no longer receive royalty revenue from Berlex for Quadramet and we pay royalties to Berlex on our sales of Quadramet. On August 1, 2003, we began recognizing product revenue from our sales of Quadramet. Currently, we market Quadramet only in the United States and have no rights to market Quadramet in Europe. We believe that the future growth and market penetration of Quadramet is dependent upon, among other things: (i) new clinical data supporting the expanded and earlier use of Quadramet in various cancers; (ii) novel research supporting combination uses with other therapies, such as chemotherapeutics and bisphosphonates; and (iii) establishing the use of Quadramet at higher doses to target and treat primary bone cancers. 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 \$5.3 million for the first nine months of 2004, an increase of \$609,000 from \$4.7 million in the first nine months of 2003. Sales of ProstaScint

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accounted for 50% and 63% of product related revenues for such periods, respectively. We believe that such increase in ProstaScint sales is due to increased demand associated with our focused marketing programs, a higher

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ProstaScint reimbursement value established for 2004 compared to 2003 and our identification of new distribution channels to better accommodate customer needs. We believe that demand for ProstaScint has been consistently higher during 2004 than 2003 as evidenced by the higher year-to-date sales in 2004. ProstaScint has historically been a challenging product for physicians and technologists to use, in part due to inherent limitations in nuclear medicine imaging. We believe that future growth and market penetration of ProstaScint is dependent upon, among other things, the implementation and continued research relating to advances in imaging technology, new product applications and the validation of PSMA as an independent prognostic indicator. 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. NMP22 BladderChek sales during the first nine months of 2004 were \$1,000 compared to \$239,000 in the same period in 2003. We began promoting NMP22 BladderChek to both urologists and oncologists in the United States in November 2002 using our internal sales force. On October 30, 2003, we entered into an amended and restated distribution agreement with Matritech whereby, effective November 8, 2003, we had the right to non-exclusively market NMP22 BladderChek to urologists through December 31, 2003 and have the right to exclusively market NMP22 BladderChek to oncologists through December 31, 2004. We do not expect significant revenues from sales of NMP22 BladderChek.

BRACHYSEED. There were no BrachySeed sales during the first nine months of 2004 compared to \$240,000 during the first nine months of 2003, which represented 3% of product related revenues. Effective January 24, 2003, we stopped accepting and filling new orders for the BrachySeed products.

LICENSE AND CONTRACT REVENUES. License and contract revenues were \$72,000 and \$2.8 million for the first nine months of 2004 and 2003, respectively. Under SAB 101, which we adopted in 2000, license revenues from certain up-front, non-refundable license fees previously recognized were deferred and were being amortized over the estimated performance period. The deferred revenue was fully recognized as of December 31, 2003. In the first nine months of 2003, we recognized \$2.2 million of previously deferred license revenue including the remaining unamortized deferred revenue in the amount of \$1.9 million related to an up-front license payment net of associated costs, which we received from Berlex Laboratories in 1998 for granting them the marketing rights to Quadramet. In August 2003, the 1998 license agreement was terminated and we reacquired those rights from Berlex Laboratories. In addition, during the first nine months of 2003, we recognized as revenue a \$500,000 payment from Antisoma in connection with Antisoma's acquisition of certain royalty rights to its lead product, R1549 (formerly Pemtumomab), because we have no continuing involvement in this arrangement. We also recognized \$47,000 and \$158,000 of contract revenues for limited research and development services provided by us to the PSMA Development Company LLC, our joint venture with Progenics Pharmaceuticals Inc. in the first nine months of 2004 and 2003, respectively. The level of future revenues for the remainder of 2004, 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.

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OPERATING EXPENSES

INCREAS

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| | 2004 | 2003 | \$ |
|--|--------------|---------------|-------------|
| | ---- | ---- | ----- |
| | (ALL AMOUNTS | IN THOUSANDS, | EXCEPT PERC |
| Cost of product related revenues..... | \$ 6,983 | \$ 3,964 | \$ 3,019 |
| Selling, general and administrative..... | 14,148 | 8,146 | 6,002 |
| Research and development..... | 1,953 | 2,283 | (330) |
| Equity in loss of joint venture..... | 2,156 | 2,680 | (524) |
| | ----- | ----- | ----- |
| | \$ 25,240 | \$ 17,073 | \$ 8,167 |
| | ===== | ===== | ===== |

Total operating expenses for the first nine months of 2004 were \$25.2 million compared to \$17.1 million in the same period of 2003.

COST OF PRODUCT RELATED REVENUES. Cost of product related revenues for the first nine months of 2004 were \$7.0 million compared to \$4.0 million in the same period of 2003. The increase from the prior year period is due primarily to our assumption, in August 2003, of the responsibility for manufacturing costs for Quadramet including contractual increases in 2004 related to our new agreement with Bristol-Myers Squibb Medical Imaging, royalties to Berlex on our sales of Quadramet and the amortization of the up-front payment to Berlex to reacquire Quadramet.

SELLING, GENERAL AND ADMINISTRATIVE. Selling, general and administrative expenses for the first nine months of 2004 were \$14.1 million compared to \$8.1 million in the same period of 2003. The increase from the prior year period is due primarily to the expansion of our sales force and the implementation of other marketing initiatives for our existing products, including Quadramet, which we reacquired from Berlex in August 2003. The selling, general and administrative expenses in 2004 also include a payment related to the settlement, in September 2004, of a patent infringement suit filed by Immunomedics, Inc. against us and C.R. Bard Inc. in February 2000. As of November 1, 2004, we employed 40 people in sales and marketing. The employees in sales and marketing included 9 Clinical Oncology Specialists and 22 Professional Oncology Representatives. By comparison, we had 31 employees in sales and marketing as of December 31, 2003. We anticipate that expenditure levels will continue to increase as we continue this expansion and as we continue our efforts to prepare for the launch of Combidex pending final regulatory approval.

RESEARCH AND DEVELOPMENT. Research and development expenses for the first nine months of 2004 were \$2.0 million compared to \$2.3 million in the same period of 2003. The current year expenses reflect costs associated with our product development efforts in support of new and expanded uses for Quadramet and ProstaScint and savings from the recent closure of our AxCell BioSciences facility. During the first nine months of 2004 and 2003, we incurred \$631,000 and \$1.2 million, 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 nine months of 2004 compared to \$2.7 million in the same period of 2003 and represented 50% of the joint venture's operating losses. We may incur significant and increasing costs in the future to fund

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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.

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INTEREST INCOME/EXPENSE. Interest income for the first nine months of 2004 was \$303,000 compared to \$91,000 in the same period of 2003. The increase in 2004 from the prior year period was due to higher average cash balances in 2004. Interest expense for each of the first nine months of 2004 and 2003 was \$139,000. Interest expense includes interest on outstanding debt and finance charges related to various equipment leases that are accounted for as capital leases.

INCOME TAX BENEFIT. During the first nine months of 2003, we sold a portion of our New Jersey state net operating losses and research and development credit carryforwards, which resulted in the recognition of \$584,000 in income tax benefit. No such sales occurred in the first nine months of 2004. Assuming the State of New Jersey continues to fund this program, which is uncertain, the future amount of net operating losses and research and development credit carryforwards which we may sell will also depend upon the allocation among qualifying companies of an annual pool established by the State of New Jersey.

NET LOSS. Net loss for the first nine months of 2004 was \$14.3 million compared to \$6.2 million reported in the first nine months of 2003. The basic and diluted net loss per share for the first nine months of 2004 was \$0.99 based on 14.4 million weighted average common shares outstanding, compared to a basic and diluted net loss per share of \$0.65 based on 9.6 million weighted average common shares outstanding for the same period in 2003.

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COMMITMENTS

We have entered into various contractual obligations and commercial commitments. The following table summarizes our contractual obligations as of September 30, 2004 and does not include approximately \$1.9 million related to these contractual obligations which are currently recorded in accounts payable and accrued liabilities in the accompanying balance sheets (all amounts in thousands):

| | LESS THAN 1 YEAR | 1 TO 3 YEARS | 4 TO 5 YEARS | MORE 5 YEARS |
|--|------------------------|-----------------|-----------------|-----------------|
| Long-term debt(1) | \$ 2,280 | \$ - | \$ - | \$ - |
| Capital lease obligations..... | 40 | 40 | 11 | |
| Facility leases..... | 529 | 820 | 28 | |
| Research and development and other obligations..... | 1,013 | 327 | 201 | |
| Manufacturing contracts(2) | 7,453 | 5,233 | 44 | |
| Capital contribution to joint venture(3) | 2,250 | - | - | |
| Minimum royalty payments(4)..... | 1,000 | 2,000 | 2,000 | 4,000 |
| | ----- | ----- | ----- | ----- |
| Total..... | \$14,565 | \$ 8,420 | \$ 2,284 | \$ 4,044 |
| | ===== | ===== | ===== | ===== |

(1) In August 1998, we received \$2.0 million from Elan Corporation, plc in exchange for a convertible promissory note. The note is convertible

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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 semi-annually, however, such interest was not payable in cash but was added to the principal through August 2000; thereafter, interest is payable in cash. The note contains certain non-financial covenants, with which we were in compliance as of September 30, 2004.

- (2) As a result of the August 2003 reacquisition of marketing rights to Quadramet, we assumed all of Berlex's obligations under a manufacturing and supply agreement with BMSMI, including an obligation to pay manufacturing costs. 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 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 September 30, 2006. 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 was effective immediately and shall terminate, unless earlier terminated pursuant to the terms thereof, 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. We intend 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.
- (3) In 2004, each of Cytogen and Progenics expects to provide \$4.2 million in funding for the development of the PSMA technologies through our joint venture with Progenics. Cytogen has funded \$2.0 million of its \$4.2 million annual commitment, as of September 30, 2004. Cytogen and Progenics have not yet committed to fund the joint venture beyond December 31, 2004 at this time, except for obligations under existing contractual commitments as of that date. We may incur significant and increasing costs in the

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future to fund our share of the development costs from the joint venture, although we cannot be sure that any further agreements between us and Progenics will be reached regarding the joint venture.

- (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 2004 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

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milestones.

LIQUIDITY AND CAPITAL RESOURCES

CONDENSED STATEMENT OF CASH FLOWS:

| | 2004 |
|--|----------------------------|
| | ----- |
| | (ALL AMOUNTS IN THOUSANDS) |
| Net loss..... | \$ (14,262) |
| Adjustments to reconcile net loss to net cash used in operating activities..... | 1,197 |
| | ----- |
| Net cash used in operating activities..... | (13,065) |
| Net cash used in investing activities..... | (10,980) |
| Net cash provided by financing activities..... | 23,875 |
| | ----- |
| Net decrease in cash and cash equivalents..... | \$ (170) |
| | ===== |

OVERVIEW

Our cash and cash equivalents were \$13.5 million as of September 30, 2004, compared to \$13.6 million as of December 31, 2003. As of September 30, 2004, our total cash, cash equivalents and short-term investments were \$40.5 million compared to \$30.2 million as of December 31, 2003. The increase in cash, cash equivalents and short term investments from the December 31, 2003 balance was primarily due to our receipt of net proceeds of approximately \$24.0 million from a registered direct offering of our common stock in April 2004, offset by operating expenditures in 2004, including costs to manufacture, promote and support our existing oncology products and to expand our internal sales force. During the first nine months of 2004 and 2003, net cash used for operating activities was \$13.1 million and \$7.8 million, respectively. In 2004, we expect operating expenditures to increase over 2003 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 from contract research services, fees paid under license agreements and interest earned on cash and short-term investments.

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

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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 or debt securities as market conditions permit or enter into credit facilities.

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

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development, clinical studies and regulatory activities, and to further our marketing and sales programs. We expect that our existing capital resources should be adequate to fund our operations and commitments into 2007. 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 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.

2004 CAPITAL RAISING

In April 2004, we sold 2,570,000 shares of our common stock to certain institutional investors for \$10.10 per share through a registered direct offering, resulting in net proceeds of approximately \$24.0 million after the payment of placement agency fees and expenses related to the offering.

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OTHER LIQUIDITY EVENTS

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 was effective immediately and shall terminate, unless earlier terminated pursuant to the terms thereof, 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. We intend 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 October 2004, Laureate entered into a definitive agreement with Safeguard Scientifics, Inc. pursuant to which it is intended that Safeguard will acquire Laureate's business and assets. Following the transaction, which is expected to be consummated in the fourth quarter of 2004, Laureate is expected to continue to operate as a full service contract manufacturing organization. We do not anticipate that we will experience any disruption in Laureate's performance of its obligations to produce ProstaScint.

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In 2003, we reacquired the marketing rights to Quadramet from Berlex. Accordingly, effective August 1, 2003, we began recording all revenue from sales of Quadramet. Effective upon the reacquisition of such marketing rights, we no longer receive royalty revenue from Berlex and pay Berlex royalties on our sales of Quadramet. As a result of the reacquisition, we assumed all of Berlex's obligations under a manufacturing and supply agreement with BMSMI. 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 through 2008, unless terminated by BMSMI or us on two years prior written notice. For the first nine months of 2004, we incurred \$3.2 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 2004.

Beginning in December 2001, we began to equally share the costs of the joint venture with Progenics. Cytogen and Progenics each expect to provide funding of \$4.2 million in 2004. Cytogen has funded \$2.0 million of its \$4.2 million annual commitment, as of September 30, 2004. Cytogen and Progenics have not committed to fund the joint venture beyond December 31, 2004 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.

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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 2004 through 2012 and \$833,000 in 2013.

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, 2003 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

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Product related revenues include product sales by Cytogen to its customers and Quadramet royalties. Product sales are recognized when the customer takes ownership and assumes risk of loss, and when the collection of the relevant receivable is probable, persuasive evidence of an arrangement exists and the sales price is fixed and determinable. Product sales are recorded net of discounts, rebates and estimated allowances for product returns based on our historical experience and any specific product return issues that we may have identified.

Prior to the reacquisition of marketing rights to Quadramet from our marketing partner, Berlex Laboratories, in August 2003, we recognized royalty revenue on Quadramet sales made by Berlex during each period as Berlex sold the product. As a result of our reacquisition, effective August 1, 2003, we began recognizing revenue from the sales of Quadramet and no longer receive Quadramet royalty revenue.

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" replaced Staff Accounting Bulletin No. 101, "Revenue Recognition In Financial Statements," 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 non-refundable, 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 performance periods is subject to management's estimates, future revenues to be recognized could be affected by changes in such estimates.

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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

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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.

NEW ACCOUNTING PRONOUNCEMENTS

In March 2004, the FASB issued a Proposed SFAS, "Share-Based Payment - An Amendment of SFAS Nos. 123 and 95" ("Exposure Draft"). The Exposure Draft would eliminate the ability to account for share-based compensation transactions using APB Opinion No. 25, and generally would require such transactions be accounted for using a fair-value-based method and the resulting cost recognized in the financial statements. Based on the provisions of the Exposure Draft and subsequent FASB deliberations and tentative conclusions, the final standard would be effective for publicly-traded companies for awards granted, modified or settled in interim periods beginning after June 15, 2005. We are closely monitoring developments related to the Exposure Draft and will adopt the final standards, if any, in the appropriate period following issuance. The eventual adoption of the Exposure Draft, if issued in final form by the FASB, is expected to have a material effect on our consolidated financial statements.

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COMPLIANCE WITH SARBANES-OXLEY REQUIREMENTS

Section 404 of the Sarbanes-Oxley Act of 2002 requires management to perform an evaluation of its internal control over financial reporting and have our independent auditors attest to such evaluation. Along with many other companies whose fiscal year ends on December 31, we must implement these requirements for the first time in connection with the preparation of the annual report for the year ending December 31, 2004. We have been actively preparing for the implementation of this requirement by, among other things, establishing an ongoing program to document, evaluate and test the systems and processes necessary for compliance. While we anticipate that we will be able to comply on a timely basis with these requirements, unforeseen delays may occur which could prevent us from achieving timely compliance. If we fail to complete our evaluation on a timely basis and in a satisfactory manner, or if our external auditors are unable to attest on a timely basis to the adequacy of our internal control, we may be subject to additional scrutiny surrounding our internal control over financial reporting.

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 or investment portfolio. As of September 30, 2004, 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 our fixed interest rate debt.

ITEM 4 - CONTROLS AND PROCEDURES

(a) EVALUATION OF DISCLOSURE CONTROLS AND PROCEDURES. Our management, with the participation of our chief executive officer and chief financial officer,

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evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of September 30, 2004. In designing and evaluating our disclosure controls and procedures, our 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 September 30, 2004, our disclosure controls and procedures were (1) designed to ensure that material information relating to us, including our consolidated subsidiaries, is made known to our chief executive officer and chief financial officer by others within those entities, particularly during the period in which this report was being prepared and (2) effective, in that they provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

(b) CHANGES IN INTERNAL CONTROLS. 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 September 30, 2004 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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LIMITATIONS ON THE EFFECTIVENESS OF CONTROLS

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal controls will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. The inherent limitations in all control systems include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

In September 2004, we announced the settlement of a patent infringement suit against us and C.R. Bard Inc. for an agreed-upon payment, without any admission of fault or liability. Immunomedics filed suit on February 17, 2000 against us and Bard, alleging that use of our ProstaScint product infringed U.S. Patent No. 4,460,559, which claims a method for detecting and localizing tumors. The settlement with Immunomedics is on behalf of Cytogen and Bard.

In connection with a recent review of certain of our intellectual property, it was determined that we were the recipient, beginning in 1998, of correspondence from legal counsel representing the former employer of Dr. Julius Horoszewicz, the sole inventor on the principal United States patent covering ProstaScint. Such correspondence alleged that the patent rights to Dr. Horoszewicz's discoveries were the property of such former employer and that Dr.

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Horoszewicz had no right to assign them to us. We vigorously disputed those allegations, and we have no record of the matter having been pursued by such former employer subsequent to August 2000. We believe that in view of the marketing of the technology covered by the patent through the sale of ProstaScint by us, our right to use the underlying technology in our continuing production and sale of ProstaScint should not be at risk. However, if such claims were reasserted, and if it were to be concluded that Dr. Horoszewicz in fact had no right to assign the patent to us, a court could determine that we have no right to use the technology covered by the patent or that any royalties paid by or payable by us in respect of the use of the patent should have been paid in the past, and should in the future be payable, to Dr. Horoszewicz's former employer in lieu of Dr. Horoszewicz. The amount of any such payments, and our liability for them, if any, is not presently determinable, and we cannot give any assurance that an adverse determination could not result in a material expenditure to us or have a material adverse effect on our financial condition, results of operations or liquidity.

We have certain rights to indemnification against litigation and litigation expenses from the inventor of technology used in ProstaScint, which may be offset against royalty payments on sales of ProstaScint. We cannot give any assurance that litigation expenses will not exceed any offsetting royalty payments.

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In addition, we are, from time to time, subject to claims and suits arising in the ordinary course of business. In the opinion of management, the ultimate resolution of any such matters would not have a material effect on our financial condition, results of operations or liquidity.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

CHANGES IN SECURITIES

The following information relates to all of the securities sold by us during the third quarter of 2004 that were not registered under the securities laws at the time of grant, issuance and/or sale:

OPTION GRANTS

During the third quarter of 2004, we granted stock options pursuant to our 2004 Stock Incentive Plan. Such options were not registered under the Securities Act of 1933, as amended. We intend to file a registration statement on Form S-8 with the Securities and Exchange Commission to register the shares of our common stock underlying option grants under the 2004 Stock Incentive Plan. All of such option grants were granted at the then current market value of the common stock. The following table sets forth certain information regarding such grants during the quarter:

| Plan ---- | Number of Shares ----- | Weighted Average Exercise Price Per Share ----- |
|--------------------------------|------------------------------|---|
| 2004 Stock Incentive Plan..... | 34,000 | \$11.617 |

We did not employ an underwriter in connection with the issuance of the securities described above. We believe that the issuance of the foregoing securities was exempt from registration under either (i) Section 4(2) of the Securities Act as transactions not involving any public offering and such securities having been acquired for investment and not with a view to distribution, or (ii) Rule 701 under the Securities Act as transactions made

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pursuant to a written compensatory benefit plan or pursuant to a written contract relating to compensation. All recipients had adequate access to information about the Company.

ITEM 5. OTHER INFORMATION

CLOSURE OF AXCELL BIOSCIENCES FACILITIES

In July 2004, as part of our continuing efforts to reduce non-strategic expenses, we initiated the closure of facilities at our AxCell BioSciences subsidiary. Research projects through academic, governmental and corporate collaborators will continue to be supported and additional applications for the intellectual property and technology at AxCell are being pursued.

APPOINTMENT OF SENIOR VICE PRESIDENT AND GENERAL COUNSEL

On August 23, 2004, William J. Thomas, Esq. joined the Company as Senior Vice President and General Counsel. In connection with Mr. Thomas' commencement of

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employment with the Company, we entered into a Change of Control Severance Agreement, in the form we utilize with our executive officers, with Mr. Thomas.

APPOINTMENT OF TRANSFER AGENT

On September 1, 2004, American Stock Transfer & Trust Company was appointed as the new registrar and transfer agent for the Company, replacing Mellon Investor Services LLC. In connection with our engagement of AST, we executed an Agreement for Substitution and Amendment of Rights Agreement with AST, dated as of September 1, 2004, pursuant to which, among other things, AST replaces Mellon as rights agent under our Rights Agreement, as amended to date.

RESIGNATION OF DIRECTOR

On September 3, 2004, we announced that H. Joseph Reiser, Ph.D. tendered his resignation from our Board of Directors, effective immediately. Dr. Reiser's resignation letter contained no disagreement with management concerning any matter relating to our operations, policies or practices.

MANUFACTURING AGREEMENT WITH LAUREATE PHARMA, L.P.

On September 10, 2004, we entered into a non-exclusive Manufacturing Agreement with Laureate Pharma, L.P. for our ProstaScint product. The agreement was effective immediately and shall terminate, unless earlier terminated pursuant to the terms thereof, upon Laureate's completion of the production campaign and shipment of the resulting products from Laureate's facility in Princeton, NJ. It is intended 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.

PATENT INFRINGEMENT LITIGATION SETTLED

On September 29, 2004, we announced the settlement of a patent infringement suit against us and C.R. Bard Inc. for an agreed-upon payment, without any admission of fault or liability. Immunomedics filed suit on February 17, 2000 against us and Bard, alleging that use of our ProstaScint product infringed U.S. Patent No. 4,460,559, which claims a method for detecting and localizing tumors. The settlement with Immunomedics is on behalf of Cytogen and Bard.

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ADVANCED MAGNETICS SUBMITS COMPLETE RESPONSE TO APPROVABLE LETTER FOR COMBIDEX

On October 19, 2004, we jointly announced with Advanced Magnetics, Inc. that Advanced Magnetics has submitted a complete response to the approvable letter received from the FDA for Combix, Advanced Magnetics' investigational molecular imaging agent, to which we have exclusive United States marketing rights. The September 30, 2004 submission was accepted and assigned a user fee goal date of March 30, 2005.

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ITEM 6. EXHIBITS.

| Exhibit No. ----- | Description ----- |
|----------------------|---|
| 4.1 | Agreement for Substitution and Amendment of Rights Agreement by and between the Company and American Stock Transfer & Trust Company dated as of September 1, 2004. Filed as an exhibit to the Company's Current Report on Form 8-K, filed with the Commission on September 2, 2004. |
| 10.1* | Manufacturing Agreement dated September 10, 2004 by and between the Company and Laureate Pharma, L.P. Filed as an exhibit to the Company's Current Report on Form 8-K, filed with the Commission on September 14, 2004. |
| 14.1 | Code of Business Conduct and Ethics of Cytogen Corporation, as amended. Filed herewith. |
| 31.1 | Certification of President and Chief Executive Officer 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 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. Filed herewith. |
| 32.2 | Certification of Senior Vice President and Chief Financial Officer pursuant to 18 U.S.C. Section 1350. Filed herewith. |

* The Company has submitted an application for confidential treatment with the Securities and Exchange Commission with respect to certain provisions contained in this exhibit. The copy filed as an exhibit omits the information subject to the confidentiality application.

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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: November 9, 2004

By: /s/ Michael D. Becker

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

Date: November 9, 2004

By: /s/ Christopher P. Schnittker

Christopher P. Schnittker
Senior Vice President and
Chief Financial Officer
(Principal Financial and Accounting Officer)