

Edgar Filing: CYTOGEN CORP - Form 10-Q

CYTOGEN CORP  
Form 10-Q  
May 14, 2003

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 March 31, 2003  
-----

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, CN 5308, 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 checkmark whether the registrant is an accelerated filer (as  
defined in Rule 12b-2 of the Exchange Act). Yes X No .  
--- ---

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

Class -----	Outstanding at May 1, 2003 -----
Common Stock, \$.01 par value	8,813,832

Edgar Filing: CYTOGEN CORP - Form 10-Q

CYTOGEN CORPORATION AND SUBSIDIARIES  
INDEX TO FORM 10-Q

Part I. FINANCIAL INFORMATION.....	1
Item 1. Financial Statements.....	1
Consolidated Balance Sheets as of March 31, 2003 (unaudited) and December 31, 2002.....	1
Consolidated Statements of Operations for the three months ended March 31, 2003 and 2002 (unaudited).....	2
Consolidated Statements of Cash Flows for the three months ended March 31, 2003 and 2002 (unaudited).....	3
Notes to Consolidated Financial Statements (unaudited).....	4
Item 2. Management's Discussion And Analysis Of Financial Condition And Results of Operations.....	9
Item 3. Quantitative And Qualitative Disclosures About Market Risk.....	17
Item 4. Controls and Procedures.....	18
Part II. OTHER INFORMATION.....	19
Item 6. Exhibits And Reports On Form 8-K.....	19
SIGNATURES.....	20
CERTIFICATIONS.....	21

(i)

PART I - FINANCIAL INFORMATION  
Item 1 - Consolidated Financial Statements

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

	March 31, 2003	December 31, 2002
	-----	-----
ASSETS:		
Current Assets:		
Cash and cash equivalents .....	\$ 11,131	\$ 14,725
Accounts receivable, net .....	1,419	1,778
Inventories .....	1,838	1,262

Edgar Filing: CYTOGEN CORP - Form 10-Q

Other current assets .....	1,104	643
	-----	-----
Total current assets .....	15,492	18,408
Property and Equipment, net .....	917	1,072
Other Assets .....	1,047	414
	-----	-----
	\$ 17,456	\$ 19,894
	=====	=====
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current Liabilities:		
Current portion of long-term liabilities .....	\$ 75	\$ 80
Accounts payable and accrued liabilities .....	4,017	4,427
Deferred revenue .....	354	385
	-----	-----
Total current liabilities .....	4,446	4,892
	-----	-----
Long-Term Liabilities .....	2,614	2,614
	-----	-----
Deferred Revenue .....	1,735	1,800
	-----	-----
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, 8,764,074 and 8,758,235 shares issued and outstanding at March 31, 2003 and December 31, 2002, respectively .....	88	88
Additional paid-in capital .....	366,906	366,884
Deferred compensation .....	(2)	(4)
Accumulated deficit .....	(358,331)	(356,380)
	-----	-----
Total stockholders' equity .....	8,661	10,588
	-----	-----
	\$ 17,456	\$ 19,894
	=====	=====

The accompanying notes are an integral part of these statements.

1

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

Three Months Ended March 31,	
2003	2002
-----	-----

Revenues:

Edgar Filing: CYTOGEN CORP - Form 10-Q

Product related:		
ProstaScint .....	\$ 1,620	\$ 2,076
Others .....	265	506
	-----	-----
Total product sales .....	1,885	2,582
Quadramet royalties .....	449	499
	-----	-----
Total product related .....	2,334	3,081
License and contract .....	143	215
	-----	-----
Total revenues .....	2,477	3,296
	-----	-----
Operating Expenses:		
Cost of product related revenues .....	910	1,054
Research and development .....	833	3,799
Equity loss in PSMA LLC .....	880	513
Selling and marketing .....	1,302	1,453
General and administrative .....	1,076	1,510
	-----	-----
Total operating expenses .....	5,001	8,329
	-----	-----
Operating loss .....	(2,524)	(5,033)
Interest income .....	36	77
Interest expense .....	(47)	(42)
	-----	-----
Loss before income taxes .....	(2,535)	(4,998)
Income tax benefit .....	(584)	-
	-----	-----
Net loss .....	\$ (1,951)	\$ (4,998)
	=====	=====
Basic and diluted net loss per share .....	\$ (0.22)	\$ (0.62)
	=====	=====
Weighted average common shares outstanding.....	8,763	8,122
	=====	=====

The accompanying notes are an integral part of these statements.

2

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

Three Months Ended March 31,	
2003	2002
-----	-----

Edgar Filing: CYTOGEN CORP - Form 10-Q

CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss .....	\$ (1,951)	\$ (4,998)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization .....	163	194
Stock-based compensation expenses .....	5	501
Amortization of deferred revenue .....	(96)	(215)
Stock-based milestone payment .....	-	2,000
Changes in assets and liabilities:		
Receivables, net .....	359	961
Inventories .....	(576)	200
Other assets .....	(1,102)	189
Accounts payable and accrued liabilities .....	(396)	(1,380)
Other liabilities .....	39	39
	-----	-----
Net cash used in operating activities .....	(3,555)	(2,509)
	-----	-----
CASH FLOWS FROM INVESTING ACTIVITIES:		
Net proceeds from sale of equipment .....	-	100
Purchases of property and equipment .....	-	(24)
	-----	-----
Net cash provided by investing activities .....	-	76
	-----	-----
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock .....	5	7,991
Payment of long-term liabilities .....	(44)	(24)
	-----	-----
Net cash provided by (used in) financing activities ....	(39)	7,967
	-----	-----
Net increase (decrease) in cash and cash equivalents .....	(3,594)	5,534
Cash and cash equivalents, beginning of period .....	14,725	11,309
	-----	-----
Cash and cash equivalents, end of period .....	\$ 11,131	\$ 16,843
	=====	=====

The accompanying notes are an integral part of these statements.

3

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

1. THE COMPANY AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

The Company

Cytogen Corporation ("Cytogen" or the "Company") of Princeton, New Jersey is a product-driven, oncology-focused biopharmaceutical company. Cytogen markets proprietary and licensed oncology products through its in-house

## Edgar Filing: CYTOGEN CORP - Form 10-Q

specialty sales force: ProstaScint(R) (a monoclonal antibody-based imaging agent used to image the extent and spread of prostate cancer) and NMP22(R) BladderChek(TM) (a point-of-care, in vitro diagnostic test for bladder cancer). Cytogen has also developed Quadramet(R), a skeletal targeting therapeutic radiopharmaceutical for the relief of bone pain in prostate and other types of cancer, for which the Company receives royalties on product sales through Berlex Laboratories, the U.S. affiliate of Schering AG Germany, which markets the product in the United States. Cytogen's pipeline comprises product candidates at various stages of clinical development, including fully human monoclonal antibodies and cancer vaccines based on PSMA (prostate specific membrane antigen) technology, which was exclusively licensed from Memorial Sloan-Kettering Cancer Center. Cytogen also conducts research in cellular signaling through its AxCell Biosciences research subsidiary in Newtown, PA.

In August 2000, the Company expanded its product pipeline by entering into marketing, license and supply agreements with Advanced Magnetics, Inc. for Combidex(R), which is an investigational magnetic resonance imaging (MRI) contrast agent that assists in the differentiation of metastatic from non-metastatic lymph nodes. Cytogen holds exclusive United States marketing rights to Combidex. Advanced Magnetics is continuing its discussions with the FDA relating to outstanding issues regarding an approvable letter received from the FDA dated June 2000, in an effort to bring Combidex to market.

### Basis of Consolidation

The consolidated financial statements include the accounts of Cytogen and its subsidiaries. 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 accounting principles generally accepted in the United States of America and should be read in conjunction with the consolidated financial statements and notes thereto included in the Company's Annual Report on Form

4

10-K, as amended, filed with the Securities and Exchange Commission, which includes financial statements as of and for the year ended December 31, 2002. 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.

### 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.

### Inventories

The Company's inventories are primarily related to ProstaScint and NMP22 BladderChek. Inventories are stated at the lower of cost or market using the first-in, first-out method and consisted of the following:

Edgar Filing: CYTOGEN CORP - Form 10-Q

	March 31, 2003	December 31, 2002
	-----	-----
Raw materials.....	\$ 780,000	\$ 506,000
Work-in process.....	541,000	39,000
Finished goods.....	517,000	717,000
	-----	-----
	\$1,838,000	\$1,262,000
	=====	=====

Net Loss Per Share

Basic net loss per common share is based upon the weighted average common shares outstanding during each period. Diluted net loss per common share is the same as basic net loss per share, as the inclusion of common stock equivalents would be antidilutive due to the Company's losses.

Other Comprehensive Loss

Other comprehensive loss consisted of an unrealized loss on a marketable security. For the three months ended March 31, 2002, the fair market value of that security decreased \$316,000, and as a result, the comprehensive loss for the three months ended March 31, 2002 was \$5,314,000. There were no marketable securities outstanding during the first quarter of 2003 and therefore no other comprehensive gains or losses.

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.

5

The Company follows the disclosure provisions of SFAS 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:

	Three Months Ended March 31,	
	2003	2002
	----	----
Net loss, as reported .....	\$ (1,951,000)	\$ (4,998,000)
Add: Stock-based employee compensation expense included in reported net loss .....	1,000	288,000
Deduct: Total stock-based employee compensation expense determined under fair value-based method for all awards .....	(351,000)	(789,000)
	-----	-----
Pro forma net loss .....	\$ (2,301,000)	\$ (5,499,000)
	=====	=====

Edgar Filing: CYTOGEN CORP - Form 10-Q

Basic and diluted net loss per share, as reported	\$	(0.22)	\$	(0.62)
Pro forma basic and diluted net loss per share ...	\$	(0.26)	\$	(0.68)

2. EQUITY LOSS IN PSMA DEVELOPMENT CO. LLC:

In June 1999, Cytogen entered into a joint venture with Progenics Pharmaceuticals Inc. ("Progenics"), the PSMA Development Company LLC, (the "Joint Venture"), to develop vaccine and antibody-based immunotherapeutic products utilizing Cytogen's exclusively licensed PSMA technology. The Joint Venture is owned equally by Cytogen and Progenics.

The Company accounts for the Joint Venture using the equity method of accounting. Through November 2001, Progenics was obligated to fund the initial \$3.0 million of the development costs. Beginning in December 2001, Cytogen began to recognize 50% of the Joint Venture's operating results in its consolidated statement of operations. The JV is expected to continue to incur losses in future years. For the three months ended March 31, 2003 and 2002, Cytogen recognized \$880,000 and \$513,000, respectively, of such losses. As of March 31, 2003 and December 31, 2002, the carrying value of the Company's investment in the Joint Venture was \$622,000 and \$1,000, respectively, which represents Cytogen's investment to date in the Joint Venture, less its cumulative share of losses, which net investment is recorded in other assets. Selected financial statement information of the Joint Venture is as follows:

6

	March 31, 2003	December 31, 2002	
	-----	-----	
Balance Sheet Data:			
Cash .....	\$ 1,903,000	\$ 290,000	
	=====	=====	
Accounts payable .....	\$ 676,000	\$ 304,000	
Capital contributions .....	14,399,000	11,399,000	
Accumulated deficit .....	(13,172,000)	(11,413,000)	
	-----	-----	
	\$ 1,903,000	\$ 290,000	
	=====	=====	
	-----	-----	
	2003	2002	For the Period From June 15, 1999 (inception) to March 31, 2003
	-----	-----	-----
Interest income.....	\$ -	\$ -	\$ 229,000
Total expenses .....	1,759,000	1,027,000	13,401,000
	-----	-----	-----
Net loss .....	\$ (1,759,000)	\$ (1,027,000)	\$ (13,172,000)
	=====	=====	=====

3. LITIGATION:

On March 17, 2000, Cytogen was served with a complaint filed against the Company in the U.S. District Court for the District of New Jersey by M.



## Edgar Filing: CYTOGEN CORP - Form 10-Q

David Goldenberg ("Goldenberg") and Immunomedics, Inc. (collectively "Plaintiffs"). The litigation claims that ProstaScint infringes a patent purportedly owned by Goldenberg and licensed to Immunomedics. The Company believes that ProstaScint does not infringe this patent, and that the patent is invalid and unenforceable. The patent sought to be enforced in the litigation has now expired; as a result, the claim even if successful would not result in an injunction barring the continued sale of ProstaScint or affect any other of Cytogen's products or technology. In addition, the Company has 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. On December 17, 2001, Cytogen filed a motion for summary judgment of non-infringement of the asserted claims of the patent-in-suit. The Plaintiffs opposed that motion and filed their own cross-motion for summary judgment of infringement. On July 3, 2002, the Court denied both parties' summary judgment motions, with leave to renew those motions after hearing expert testimony and legal argument based upon that testimony. On April 29, 2003, Cytogen's motion for summary judgment of non-infringement of all asserted claims was granted, plaintiff's motion for summary judgment of infringement was denied and the case was ordered closed. On May 12, 2003, Plaintiffs filed a Notice of Appeal regarding this decision to the U.S. Court of Appeals for the Federal Circuit.

7

#### 4. INCOME TAXES

During the first quarter of 2003, the Company sold New Jersey State net operating loss and research and development credit carryforwards, which resulted in the recognition of \$584,000 of income tax benefit.

8

#### Item 2 - Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion 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. All statements, other than statements of historical facts, included in this Quarterly Report on Form 10-Q regarding our strategy, future operations, financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. The words "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. 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, but are not limited to those identified in the our Annual Report on Form 10-K for the year ended December 31, 2002, as amended, under the caption "Additional Factors That May Affect Future Results". Investors are cautioned not to put undue reliance on any forward looking statement.

Cautionary Statement

## Edgar Filing: CYTOGEN CORP - Form 10-Q

Our actual results may differ materially from our historical results of operations and those discussed in the forward-looking statements for various reasons, including, but not limited to, our ability to: (i) access the capital markets in the near term and in the future for continued funding of our operations including existing and new projects and to maintain the listing of our common stock on the Nasdaq National Market; (ii) attract and retain personnel needed for business operations and strategic plans; (iii) carry out our business and financial plans; (iv) attract, and the ultimate success of, strategic partnering arrangements, collaborations, and acquisition candidates; (v) successfully develop and commercialize in-licensed products such as NMP22(R) BladderChek(TM), including programs designed to facilitate the use of our products, such as the Partners in Excellence or PIE Program; (vi) establish and successfully complete clinical trials where required for product approval; (vii) obtain foreign regulatory approvals for products and to establish marketing arrangements in countries where approval is obtained; (viii) demonstrate, over time, the efficacy and safety of our products; (ix) determine and implement the appropriate strategic initiative for our AxCell Biosciences subsidiary; and (x) fund development necessary for existing products and for the pursuit of new product opportunities. Additional risks that we face include, but are not limited to: (i) the risk of whether marketable and valuable products result from our development activities; (ii) the possibility that we may not be able to adequately protect our intellectual property portfolio; (iii) the degree of competition we may face from existing or new products; (iv) the risks associated with obtaining the necessary regulatory approvals; (v) the ability of Advanced Magnetics to satisfy the conditions specified by the FDA regarding approval to market Combindex(R) in the United States; (vi) shifts in the regulatory environment affecting sale of our products such as third-party payor reimbursement issues and dependence on our partners for development of certain projects; (vii) competitive products and technologies; (viii) price pressure; and (ix) other factors discussed in our press releases and from time-to-time in our other filings with the Securities and Exchange Commission. Any forward-looking statements made by us do not reflect the potential impact of any

9

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 Financial Statements and related notes thereto contained elsewhere herein, as well as our Annual Report on Form 10-K for the year ended December 31, 2002, as amended, and from time to time in our other filings with the Securities and Exchange Commission.

### Significant Events in 2003

In January 2003, we provided Draximage Inc. with notice of termination for each of our License and Distribution Agreement and Product Manufacturing and Supply Agreement with respect to both of Draximage's BrachySeed I-125 and BrachySeed Pd-103 products. Effective January 24, 2003, we no longer accept or fill new orders for the BrachySeed products. In April 2003, we entered into an agreement with Draximage formally terminating each of these agreements.

In April 2003, NMP22 BladderChek was awarded clearance from the FDA for use in screening patients for bladder cancer, in addition to approval gained previously for the indication of monitoring patients who have a prior diagnosis of bladder cancer. In October 2002, we entered into a five-year agreement with Matritech Inc. to be the sole distributor for Matritech's NMP22 BladderChek test to urologists and oncologists in the United States. Retention of exclusivity

## Edgar Filing: CYTOGEN CORP - Form 10-Q

rights depends upon meeting certain minimum annual purchases. NMP22 BladderChek is an in-vitro point of care diagnostic test for bladder cancer that requires only a few drops of a patient's urine. NMP22 BladderChek returns results in thirty minutes and provides urologists with a new tool to improve detection and early diagnosis when used in combination with cytoscopy, a clinical procedure for the visual identification of tumors in the bladder. We are in the early-phase of launching NMP22 BladderChek and are promoting the product to urologists in the U.S. using our in-house sales force.

### Results of Operations

#### Three Months Ended March 31, 2003 and 2002

Revenues. Total revenues for the first quarter of 2003 were \$2.5 million compared to \$3.3 million for the same period in 2002. The decrease from the prior year period is due primarily to lower product related revenues resulting from lower ProstaScint sales and from the discontinuation of selling and marketing the brachytherapy products as of January 24, 2003 and OncoScint as of December 31, 2002. Product related revenues, which included product sales and royalties, accounted for 94% and 93% of total revenues for the first quarters of 2003 and 2002, respectively. License and contract revenues accounted for the remainder of revenues.

Product related revenues for the first quarter of 2003 were \$2.3 million compared to \$3.1 million for the same period in 2002. Sales of ProstaScint accounted for 69% and 67% of product related revenues in the first quarters of 2003 and 2002, respectively, while Quadramet royalties accounted for 19% and 16% of product related revenues for such quarters, respectively. Sales of ProstaScint were \$1.6 million for the first quarter of 2003, a decrease of \$456,000 from \$2.1 million in the first quarter of 2002. We believe that the

10

year-over-year decline in first quarter ProstaScint sales was largely due to changes in radiopharmacy wholesaler buying patterns. Year-over-year declines in first quarter ProstaScint sales also occurred during 2001 and 2002, while annual product sales increased during these periods, although historical performance may not be indicative of future results. We also believe future growth for ProstaScint is dependent upon, among other things, the implementation and continued research of the following:

- Advances in imaging technology
  - Fusion imaging - an image processing technique that combines functional information from a ProstaScint scan with anatomic images provided by CT (computed tomography) or MR (magnetic resonance) scans in a digital overlay to provide information that cannot be achieved with separate imaging modalities alone, which may improve diagnostic interpretation; and
  - Image enhancements - improving the quality of ProstaScint images through reconstruction and attenuation-correction methods to address inherent limitations of single photon emission computed tomography (SPECT) imaging by correcting for the effects of radiation scatter and/or inherent collimator/detector blur.
- New product applications
  - Utilization of ProstaScint scans to guide therapy ("image-guided therapy"), to enhance therapy targeting for treatments such as brachytherapy, cryotherapy and external beam radiation, such as intensity modulated radiation therapy (IMRT); and
  - Utilization of ProstaScint scans to guide biopsy ("image-guided biopsy"), which could be facilitated by future advances in image acquisition technology.

## Edgar Filing: CYTOGEN CORP - Form 10-Q

There can be no assurance, however, that the achievement of any of the above will significantly increase the sales of ProstaScint.

Other product sales include sales from NMP22 BladderChek, BrachySeed (ended January 2003) and OncoScint (ended December 2002). Sales of NMP22 BladderChek during the first quarter 2003 were \$25,000. NMP22 BladderChek is one of only two immunoassay fluid tests approved by the FDA for screening patients for cancer; the other is the prostate specific antigen (PSA) test for prostate cancer. We began promoting NMP22 BladderChek to urologists in the United States in November 2002 using our in-house sales force. The NMP22 BladderChek test is currently approved for use in two clinical settings:

- Monitoring - In July 2002, Matritech, Inc. received FDA approval to market the NMP22 BladderChek test for monitoring patients previously diagnosed with bladder cancer; and
- Screening - In April 2003, Matritech received FDA approval to market the NMP22 BladderChek test to aid in the diagnosis of patients with bladder cancer.

There can be no assurance however, as to the market acceptance of NMP22 BladderChek or whether the sale of NMP22 BladderChek will significantly increase our revenues.

11

Sales of BrachySeed during the first quarter of 2003 were \$240,000 and accounted for 10% of product related revenues, compared to \$452,000, or 15% of product related revenues, in the first quarter of 2002. As described above, effective January 24, 2003, we no longer accept or fill new orders for the BrachySeed I-125 and BrachySeed Pd-103 products. In April 2003, we entered into an agreement with Draximage to formally terminate our agreements with Draximage with respect to these products.

We discontinued selling OncoScint CR/OV(R) in December 2002 in order to focus on our other oncology products, since the market for OncoScint CR/OV for colorectal cancer diagnosis has been negatively affected by positron emission tomography or "PET" scans which have shown the same or higher sensitivity than OncoScint CR/OV. Sales of OncoScint CR/OV during the first quarter of 2002 were \$54,000.

Quadramet royalties for the first quarter of 2003 were \$449,000, a decrease of \$50,000 from \$499,000 in the first quarter of 2002. Quadramet is currently marketed in the U.S. by the Company's marketing partner, Berlex Laboratories. We believe that the future growth and market penetration of Quadramet is dependent upon, among other things:

- New clinical data supporting the expanded and earlier use of Quadramet in various cancers;
- Novel research supporting combination uses with other therapies, such as chemotherapy and bisphosphonates;
- Establishing the use of Quadramet at higher doses to target and treat primary bone cancers; and
- Increased marketing and sales penetration to physicians.

There can be no assurance that Quadramet will achieve greater market penetration on a timely basis or result in significant revenues for Cytogen.

License and contract revenues for the first quarter of 2003 were \$143,000 compared to \$215,000 for the same period of 2002. As a result of our adoption of Securities and Exchange Commission's Staff Accounting Bulletin No.101 ("SAB 101") in 2000, license revenues from certain up-front,

## Edgar Filing: CYTOGEN CORP - Form 10-Q

non-refundable license fees previously recognized in prior years were deferred and are being amortized over the estimated performance period. In the first quarter of 2003, we recognized \$96,000 of deferred license revenue compared to \$215,000 for the same period in 2002. In the first quarter of 2003, we performed limited research and development services for the PSMA Development Company LLC, our joint venture with Progenics Pharmaceuticals Inc. resulting in \$47,000 of contract revenue. The level of future revenues from the joint venture will be dependent upon the extent of the research and development services required by the joint venture.

**Operating Expenses.** Total operating expenses for the first quarter of 2003 were \$5.0 million compared to \$8.3 million in the same quarter of 2002. The decrease from the prior year period is attributable primarily to a non-cash milestone payment of \$2.0 million in 2002 related to the progress of dendritic cell prostate cancer clinical trials at Northwest Biotherapeutics, Inc. and cost-saving measures implemented in September 2002 as a result of the restructuring at our subsidiary AxCell Biosciences.

12

Cost of product related revenues for the first quarter of 2003 were \$910,000 compared to \$1.1 million in the same period of 2002. The decrease from the prior year period is primarily due to the lower product sales and to a reversal of \$133,000 related to lower royalty expenses on the 2002 BrachySeed sales as a result of a termination agreement entered into with Draximage with respect to the BrachySeed products.

Research and development expenses for the first quarter of 2003 were \$833,000 compared to \$3.8 million in the same period of 2002. The decrease from the prior year period is attributable primarily to a non-cash milestone payment of \$2.0 million in 2002 related to the progress of dendritic cell prostate cancer clinical trials at Northwest Biotherapeutics, Inc., and cost-saving measures implemented in September 2002 as a result of the restructuring at our subsidiary AxCell Biosciences. During the first quarters of 2003 and 2002, we invested \$450,000 and \$1.3 million, respectively, in AxCell's signal transduction research activities.

Our share in the equity loss in the PSMA Development LLC ("Joint Venture") was \$880,000 during the first quarter of 2003 compared to \$513,000 in the same quarter of 2002 and represented 50% of the Joint Venture's operating results. The Joint Venture is equally owned by Cytogen and Progenics. We account for the Joint Venture using the equity method of accounting. We and Progenics share equally the costs of the Joint Venture. We expect to incur significant and increasing costs in the future to fund our share of the development costs from the Joint Venture. As of May 2003, we and Progenics are in the process of negotiating the 2003 annual budget for the joint venture and have agreed that the operating budget for 2003 will be no less than the 2002 operating expenses for the Joint Venture.

Selling and marketing expenses for the first quarter of 2003 were \$1.3 million compared to \$1.5 million in the same period of 2002. The decrease from the prior year is primarily due to the discontinuation of the selling and marketing activities related to the brachytherapy products effective January 2003.

General and administrative expenses for the first quarter of 2003 were \$1.1 million compared to \$1.5 million in the same period of 2002. The decrease from the prior year period is due primarily to a reduction in personnel at the end of 2002 and a non-cash charge in 2002 for stock-based compensation for a key employee.

## Edgar Filing: CYTOGEN CORP - Form 10-Q

Interest Income/Expense. Interest income for the first quarter of 2003 was \$36,000 compared to \$77,000 in the same period of 2002. The decrease from the prior year period is due to a lower average yield on investments and lower average cash balances in 2003. Interest expense for the first quarter of 2003 was \$47,000 compared to \$42,000 in the same period of 2002. Interest expense includes interest on outstanding debt and finance charges related to various equipment leases.

Income tax benefit. During the first quarter of 2003, we sold New Jersey State net operating loss and research and development credit carryforwards, which resulted in the recognition of \$584,000 income tax benefit. Assuming the State of New Jersey continues to fund this program, which is uncertain, the future amount of net operating losses and tax credits which we may sell will also depend upon the allocation among qualifying companies of an annual pool established by the State of New Jersey. We did not recognize any such benefits during the first quarter of 2002.

13

Net Loss. Net loss for the first quarter of 2003 was \$2.0 million compared to \$5.0 million reported in the first quarter of 2002. The net loss per share for the first quarter of 2003 was \$0.22 based on weighted average common shares outstanding of 8.8 million, compared to a net loss per share of \$0.62 based on the weighted average common shares outstanding of 8.1 million for the same period in 2002.

### Liquidity and Capital Resources

Our cash and cash equivalents were \$11.1 million as of March 31, 2003, compared to \$14.7 million as of December 31, 2002. Cash used for operating activities for the three months ended March 31, 2003 was \$3.6 million compared to \$2.5 million in the same period of 2002. The increase from the prior year period is due primarily to our build-up of ProstaScint inventory in the first quarter of 2003 and to our first quarter 2003 capital contribution of \$1.5 million to the PSMA Development Company LLC, our joint venture with Progenics Pharmaceuticals, Inc.

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.

In January 2003, we received \$584,000 relating to a sale of New Jersey State net operating losses and research and development credits. Assuming the State of New Jersey continues to fund this program, which is uncertain, the future amount of net operating losses and tax credits which we may sell will also depend upon the allocation among qualifying companies of an annual pool established by the State of New Jersey.

Because the market value of our common stock held by non-affiliates of the Company is less than \$75 million, we are ineligible to utilize a registration statement on Form S-3 for primary offerings in which our common stock is offered for cash on our behalf. We cannot guarantee you that the market value of our common stock held by non-affiliates will ever increase above \$75 million, and as a result, that we will thereby regain eligibility to utilize a Form S-3 registration statement for such primary offerings.

We have historically relied upon revenues from sales of the BrachySeed products to partially fund ongoing operations. For the three months ended March 31, 2003 and 2002, revenue from the sale of BrachySeed products was \$240,000 and \$452,000, respectively. In December 2002, we served notice of termination of our

## Edgar Filing: CYTOGEN CORP - Form 10-Q

agreements with Draximage, and in April 2003, entered into an agreement with Draximage to formally terminate each of our License and Distribution Agreement and Product Manufacturing and Supply Agreement with respect to both the BrachySeed I-125 and BrachySeed Pd-103 products. As of January 24, 2003, we no longer accept or fill new orders for the BrachySeed products.

14

Beginning in December 2001, we began to equally share the costs of the PSMA Development Company LLC, with Progenics. We expect our share of losses and funding in the joint venture to continue at an even higher level in the subsequent periods. The joint venture is funded by equal capital contributions from each of Progenics and Cytogen in accordance with an annual budget approved by the joint venture's management committee. As of May 2003, we and Progenics are in the process of negotiating the 2003 annual budget for the joint venture and have agreed that the operating budget for 2003 will be no less than the 2002 operating expenses for the joint venture.

Our capital and operating requirements may change depending upon various factors, including: (i) whether we and our strategic partners achieve success in manufacturing, marketing and commercialization of our products; (ii) the amount of resources which we devote to clinical evaluations and the expansion of marketing and sales capabilities; (iii) results of clinical trials and research and development activities; and (iv) competitive and technological developments, in particular, we expect to incur significant costs for the development of our PSMA technologies.

Our financial objectives are to meet our capital and operating requirements through revenues from existing products and licensing arrangements. To achieve our strategic objectives, we may enter into research and development partnerships and acquire, in-license and develop other technologies, products or services. Certain of these strategies may require payments by us in either cash or stock in addition to the costs associated with developing and marketing a product or technology. However, we believe that, if successful, such strategies may increase long-term revenues. There can be no assurance as to the success of such strategies or that resulting funds will be sufficient to meet cash requirements until product revenues are sufficient to cover operating expenses, if ever. To fund these strategic and operating activities, we may sell equity 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 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 the first quarter of 2004. 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

## Edgar Filing: CYTOGEN CORP - Form 10-Q

(viii) the expansion of strategic alliances for the sales, marketing,

15

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.

### 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 this Quarterly Report on Form 10-Q and Note 1 to our Consolidated Financial Statements in our Annual Report on Form 10-K for the year ended December 31, 2002, as amended, include 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

We recognize revenue from the sale of our products upon shipment. We do not grant price protection to customers. Quadramet royalties are recognized when earned. The Securities and Exchange Commission has issued Staff Accounting Bulletin (SAB) No. 101, "Revenue Recognition", which provides guidance on the recognition of up-front, non-refundable license fees. Accordingly, we defer up-front license fees and recognize them over the estimated performance period of the related agreement, when we have continuing involvement. Since the term of the performance periods is subject to management's estimates, future revenues to be recognized could be affected by changes in such estimates.

#### Accounts Receivable

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

16



## Edgar Filing: CYTOGEN CORP - Form 10-Q

### Inventories

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

### Carrying Value of Fixed and Intangible Assets

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

In October 2002, we entered into a five-year agreement with Matritech Inc. to be the sole distributor for Matritech's NMP22 BladderChek point-of-care test to urologists and oncologists in the United States. Retention of exclusivity rights depends upon meeting certain minimum annual purchases. We paid Matritech \$150,000 upon the execution of the agreement, which was recorded as other assets in the accompanying consolidated balance sheet for the respective period and is being amortized over the five year estimated performance period of the agreement. We determined that we did not have any impairment regarding Matritech's license fee at March 31, 2003.

### 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 March 31, 2003, 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. Changes in interest rates could expose us to market risk associated with a fixed interest rate debt. We do not believe that this note will have material exposure to market risks associated with interest rates.

17

### Item 4 - Controls and Procedures

a) Evaluation of disclosure controls and procedures. Based on their evaluation of the Company's disclosure controls and procedures (as defined in Rules 13a-14(c) and 15d-14(c) under the Securities Exchange Act of 1934) as of a date within 90 days of the filing date of this Quarterly Report on Form 10-Q, the Company's Chief Executive Officer and the Company's Vice President, Finance have concluded that the Company's disclosure controls and procedures are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and are operating in an effective manner.

b) Changes in internal controls. There were no significant changes in the

## Edgar Filing: CYTOGEN CORP - Form 10-Q

Company's internal controls or in other factors that could significantly affect these controls subsequent to the date of their most recent evaluation.

18

### PART II - OTHER INFORMATION

#### Item 6 - Exhibits and Reports on Form 8-K

##### (a) Exhibits:

3.1 - By-Laws of Cytogen Corporation, as amended. Filed herewith.

99.1 - Certification pursuant to 18 U.S.C. Section 1350. Filed herewith.

##### (b) Reports on Form 8-K

During the three months ended March 31, 2003, the Company filed two Current Reports on Form 8-K with the Securities and Exchange Commission. On January 17, 2003, the Company filed a Current Report on Form 8-K, under "Item 5. Other Events", on which the Company reported that the production and sale of the Palladium version of BrachySeed had been halted for an unspecified period of time. On January 24, 2003, the Company filed a Current Report on Form 8-K, under "Item 5. Other Events", on which the Company announced that it provided Draximage with notice of termination of each of its License and Distribution Agreement and Product Manufacturing and Supply Agreement with respect to both of Draximage's BrachySeed I-125 and BrachySeed PD-103 products.

19

### 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 May 14, 2003

By: /s/ Michael D. Becker

Edgar Filing: CYTOGEN CORP - Form 10-Q

-----  
Michael D. Becker  
President and Chief Executive Officer

-----  
Date May 14, 2003

-----  
By /s/ Thu A. Dang

-----  
Thu A. Dang  
Vice President, Finance  
(Principal Financial and Accounting Officer)

20

Certification

I, Michael D. Becker, President and Chief Executive Officer of Cytogen Corporation, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Cytogen Corporation;
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
  - a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
  - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
  - c) Presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons

Edgar Filing: CYTOGEN CORP - Form 10-Q

performing the equivalent function):

- a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
- b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

21

- 6. The registrant's other certifying officer and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: May 14, 2003

/s/ Michael D. Becker

-----  
Michael D. Becker  
President and Chief Executive Officer

22

Certification

I, Thu A. Dang, Vice President, Finance of Cytogen Corporation, certify that:

- 1. I have reviewed this quarterly report on Form 10-Q of Cytogen Corporation;
- 2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
  - a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

Edgar Filing: CYTOGEN CORP - Form 10-Q

- b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
  - c) Presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
- a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

23

6. The registrant's other certifying officer and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: May 14, 2003

/s/ Thu A. Dang

-----  
Thu A. Dang  
Vice President, Finance

24