CYTOGEN CORP
Form 8-K
May 14, 2003

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 8-K

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

Date of report (Date of earliest event reported): May 14, 2003

CYTOGEN CORPORATION
(Exact Name of Registrant as Specified in Charter)

Delaware	000-14879	222322400
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

650 College Road East, Suite 3100, Princeton, NJ	08540
(Address of Principal Executive Offices)	(Zip Code)

(609) 750-8200
(Registrant's telephone number, including area code)

(Former Name or Former Address, if Changed Since Last Report)

Item 7. Financial Statements, Pro Forma Financial Information and Exhibits.

(a) Not applicable.

(b) Not applicable.

(c) Exhibits.

Exhibit No.	Description of Exhibit

99.1 Press release dated May 14, 2003.

Item 9. Regulation FD Disclosure (Information furnished pursuant to Item 12, "Results of Operations and Financial Condition").

On May 14, 2003, Cytogen Corporation (the "Company") announced its financial results for the quarter ended March 31, 2003. The full text of the press release issued in connection with the announcement is attached as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

In accordance with the procedural guidance in SEC Release Nos. 33-8216 and 34-47583, the information in this Form 8-K and the Exhibit attached hereto is being furnished under "Item 9. Regulation FD Disclosure" rather than under "Item 12. Results of Operations and Financial Condition." The information shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

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 hereunto duly authorized.

Cytogen Corporation

By: /s/ Michael D. Becker

Michael D. Becker,
President and Chief Executive Officer

Date: May 14, 2003

EXHIBIT 99.1

[CYTOGEN LOGO]

Company contact:

Cytogen Corporation
Stacy Shearer
Investor Relations
(609) 750-8289
sshearer@cytogen.com

Cytogen Reports First Quarter 2003 Financial Results

Marketed product portfolio, recent launch of NMP22(R) BladderChek(TM), and anticipated introduction of Combidex(R) expected to drive future sales

Princeton, N.J., (May 14, 2003) -- Cytogen Corporation (Nasdaq: CYTO), a product-driven, oncology-focused biopharmaceutical company, today reported its consolidated financial results for the quarter ended March 31, 2003.

Total revenues were $2.48 million in the first quarter of 2003, representing a decrease of 25% from the $3.30 million reported in the first quarter of 2002. Net loss for the first quarter of 2003 was $1.95 million or $0.22 per share compared to a net loss of $5.00 million or $0.62 per share for the first quarter of 2002, representing a decrease of 61%. The net loss in the quarter ended March 31, 2002 included a non-cash milestone expense of $2.0 million related to the progress of ex vivo dendritic cell prostate cancer clinical trials at Northwest Biotherapeutics, Inc.

"We made great strides in positioning the Company for future growth by reducing operating expenses and redirecting the Company's sales and marketing infrastructure, which was largely completed during the first quarter of 2003," said Michael D. Becker, President and Chief Executive Officer of Cytogen Corporation. "After exiting the brachytherapy business earlier this year, we transitioned our selling, marketing, and training activities to focus on ProstaScint(R) and NMP22(R) BladderChek(TM), the newest addition to our marketed product portfolio. We were pleased that regulatory approval for expanded use of NMP22 BladderChek to screen for bladder cancer in high risk and symptomatic individuals coincided with the annual American Urological Association (AUA) meeting, where Cytogen officially debuted the product to urologists in April 2003. In the future, we remain cautiously optimistic for approval of Combidex(R), a novel lymph node imaging agent developed by Advanced Magnetics, Inc., which we will market pending clearance by the U.S. Food and Drug Administration."

Product Sales

Marketed product sales were $1.89 million in the first quarter of 2003 compared to $2.58 million in the first quarter of 2002, representing a decline of 27% that was driven in part by the previously announced discontinuation of brachytherapy products since January 24, 2003, and OncoScint(R) (Satumomab pendetide) since December 31, 2002. Total revenues associated with the brachytherapy product line and OncoScint were $240,000 for the first quarter of 2003 compared to $506,000 in the first quarter of 2002. Marketed product sales during the first quarter of 2003 included initial sales of NMP22 BladderChek, which Cytogen began introducing to urologists in the United States in November 2002 and is in the early phase of product launch.

Sales of ProstaScint (Capromab pendetide), Cytogen's first monoclonal antibody-based product targeting prostate specific membrane antigen, or PSMA, were $1.62 million in the first quarter of 2003 compared to $2.08 million in the first quarter of 2002, representing a decline of 22%. Cytogen believes that the 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.

Future potential growth for ProstaScint is largely 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 and 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.

Royalty revenue from the sale of Quadramet(R) (Samarium Sm-153 lexidronam injection) in the first quarter of 2003 was $449,000, representing a decrease of 10% from the $499,000 reported in the first quarter of 2002. Quadramet is a skeletal targeting therapeutic radiopharmaceutical developed by Cytogen Corporation based on technology licensed from Dow Chemical and marketed by Berlex Laboratories, the U.S. affiliate of Schering AG Germany, in the United States for the relief of pain in patients with confirmed osteoblastic metastatic bone lesions that enhance on a radionuclide bone scan. Cytogen believes that future growth and market penetration of Quadramet is largely 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 bisphophonates;
- Establishing the use of Quadramet at higher doses to target and treat primary bone cancers; and
- Increased marketing and sales penetration to physicians.

Brachytherapy product sales in the first quarter of 2003 were $240,000 compared to $452,000 in the first quarter of 2002. Effective January 24, 2003, Cytogen discontinued selling and marketing brachytherapy products.

Initial sales of NMP22 BladderChek (Nuclear matrix protein-22), a point-of-care, in vitro diagnostic test for bladder cancer, were $25,000 in the first quarter of 2003 compared to $14,000 in the fourth quarter of 2002. In October 2002, Cytogen entered into a five-year agreement with Matritech, Inc. to be the sole distributor of Matritech's NMP22 BladderChek device to urologists and oncologists in the United States. During November 2002, Cytogen began promoting NMP22 BladderChek to urologists in the United States using its in-house specialty sales force.

Developed by Matritech, Inc., 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. NMP22 BladderChek returns results in thirty minutes and provides urologists with a complement to cystoscopy, a clinical procedure for the visual identification of tumors in the bladder. By placing four drops of urine on the NMP22 BladderChek test cassette, a physician is able to detect the presence of elevated NMP22, a nuclear matrix protein correlated with bladder cancer. A colored line appears to indicate bladder cancer.

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 help diagnose patients with bladder cancer.

"With Cytogen's proprietary and licensed products, such as ProstaScint, Quadramet and NMP22 BladderChek; as well as late-stage opportunities, such as Combidex; and our evolving development pipeline based on prostate specific membrane antigen (PSMA), Cytogen has achieved a position that relatively few in our industry ever attain - an established, product-driven biopharmaceutical company with its own sales and marketing infrastructure. We believe that our marketed product portfolio, the promise of Combidex, and our development pipeline, collectively represent a tremendous opportunity for future growth," Mr. Becker concluded.

Costs and Expenses

Operating expenses in the first quarter of 2003 were $5.00 million compared to $8.33 million in the first quarter of 2002, representing a decline of 40%. Operating expenses in first quarter of 2002 included a $2.0 million non-cash milestone payment related to the progress of the ex vivo dendritic cell prostate cancer therapy. Operating expenses include costs associated with the PSMA Development Company LLC, a joint venture between Cytogen Corporation and Progenics Pharmaceuticals, Inc. for the development of in vivo immunotherapies utilizing prostate specific membrane antigen, or PSMA. Cytogen's share of development costs associated with the PSMA Development Company LLC were $880,000 for the first quarter of 2003 compared to $513,000 in the first quarter of 2002. Operating expenses also include research in cellular signaling through our AxCell Biosciences subsidiary, which were $450,000 in the first quarter of 2003 compared to $1.27 million for the first quarter of 2002.

Cytogen's cash and cash equivalents as of March 31, 2003 were $11.13 million compared to $14.73 million as of December 31, 2002.

Additional information

On May 12, 2003, Milton D. Goldenberg and Immunomedics, Inc., plaintiffs in a previously announced lawsuit filed against the Company in the U.S. District Court for the District of New Jersey, filed a notice of appeal to the U.S. Court of Appeals for the Federal Circuit from the District Court's April 30, 2003 ruling denying plaintiffs' motion for summary judgment of infringement, granting the Company's motion for summary judgment of non-infringement and dismissing the complaint. The litigation claims that our Prostascint product infringes a patent purportedly owned by Goldenberg and licensed to Immunomedics. We believe 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 our products or technology. In addition, 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. However, given the uncertainty associated with litigation, we cannot give any assurance that the litigation could not result in a material expenditure to us.

About Cytogen Corporation

Cytogen Corporation of Princeton, NJ is a product-driven, oncology-focused biopharmaceutical company. Cytogen markets proprietary and licensed oncology products through its in-house 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 has exclusive U.S. marketing rights to Combidex(R), an ultrasmall superparamagnetic iron oxide (USPIO) contrast agent for magnetic resonance imaging of lymph nodes that is pending clearance by the U.S. Food and Drug Administration. 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 division in Newtown, PA. For more information, please visit the Company's website at www.cytogen.com, which is not part of this press release.

This press release contains certain "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 press release 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. The Company cannot guarantee that the Company will actually achieve the plans, intentions or expectations disclosed in any such forward-looking statements. The Company's actual results may differ materially from the Company's historical results of operations and those discussed in the forward-looking statements for various reasons, including, but not limited to, the Company's ability to carry out its business and financial plans, to determine and implement the appropriate strategic initiative for its AxCell Biosciences subsidiary, to fund development necessary for existing products and to pursue new product opportunities, the risk of whether products result from development activities, protection of its intellectual property portfolio, ability to integrate in-licensed products such as NMP22(R) BladderChek(TM), ability to establish and successfully complete clinical trials where required for product approval, the risk associated with obtaining the necessary regulatory approvals, shifts in the regulatory environment affecting sales of the Company's products such as third-party payor

reimbursement issues, dependence on the Company's partners for development of certain projects, the ability to obtain foreign regulatory approvals for products and to establish marketing arrangements in countries where approval is obtained, and other factors discussed in the Company's Form 10-K for the year ended December 31, 2002, as amended, and from time-to-time in the Company's other filings with the Securities and Exchange Commission. Any forward-looking statements made by the Company do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments the Company may make. The Company does not assume, and specifically disclaims, any obligation to update any forward-looking statements, and these statements represent the Company's current outlook only as of the date given.

###

CYTOGEN CORPORATION & SUBSIDIARIES
(All amounts in thousands except per share data)
(Unaudited)

CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS

	THREE MONTHS ENDED MARCH 31,	
	2003	2002
Revenues:		
Marketed Product Sales	$ 1,885	$ 2,582
Royalty Revenue	449	499
License and Contract	143	215
Total Revenues	2,477	3,296
Operating Expenses:		
Cost of Product Related Revenues	910	1,054
Ongoing Research and Development	833	1,799
Equity Loss in PSMA LLC	880	513
Selling and Marketing	1,302	1,453
General and Administrative	1,076	1,510
Milestone Payment Related to Research and Development*	-	2,000
Total Operating Expenses	5,001	8,329
Non-Operating Income (Expense), net	(11)	35
Income Tax Benefit	(584)	-
Net Loss	$(1,951)	$(4,998)
Basic and Diluted Net Loss Per Share	$ (0.22)	$ (0.62)
Weighted Average Common Share Outstanding	8,763	8,122

* In 2002, the Company recorded a non-cash milestone payment related to the progress of the cancer clinical trials.

CONDENSED CONSOLIDATED BALANCE SHEETS

	MARCH 31, 2003	DECEMBER 31, 2002
Assets		
Cash and Cash Equivalents	$11,131	$14,725
Accounts Receivable, net	1,419	1,778
Inventories	1,838	1,262
Property and Equipment, net	917	1,072
Other Assets	2,151	1,057
Total Assets	$17,456	$19,894
Liabilities & Stockholders' Equity		
Accounts Payable & Accrued Liabilities	$ 4,017	$ 4,427
Other Current Liabilities	75	80
Long-Term Liabilities & Deferred Revenues	4,703	4,799
Stockholders' Equity	8,661	10,588
Total Liabilities & Stockholders' Equity	$17,456	$19,894