

Edgar Filing: CYTOGEN CORP - Form 10-Q

CYTOGEN CORP
Form 10-Q
November 13, 2001

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, 2001

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)

600 College Road East, CN 5308, 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 ☒ 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 November 1, 2001 -----
Common Stock, \$.01 par value	79,386,800

PART I - FINANCIAL INFORMATION
Item 1 - Consolidated Financial Statements

Edgar Filing: CYTOGEN CORP - Form 10-Q

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

	September 30, 2001 -----	December 31, 2000 -----
ASSETS:		
Current Assets:		
Cash and cash equivalents	\$ 14,548	\$ 11,993
Receivable on income tax benefit sold	-	1,625
Accounts receivable, net	2,198	1,841
Inventories	1,712	883
Other current assets	575	377
	-----	-----
Total current assets	19,033	16,719
Property and Equipment, net	1,794	2,193
Other Assets	1,855	1,504
	-----	-----
	\$ 22,682	\$ 20,416
	=====	=====
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current Liabilities:		
Current portion of long-term debt	\$ 89	\$ 151
Accounts payable and accrued liabilities	4,890	7,218
Deferred revenue	685	859
	-----	-----
Total current liabilities	5,664	8,228
	-----	-----
Long-Term Debt	2,336	2,374
	-----	-----
Deferred Revenue	2,125	2,596
	-----	-----
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, 250,000,000 shares authorized, 78,887,000 and 75,594,000 shares issued and outstanding at September 30, 2001 and December 31, 2000, respectively	789	756
Additional paid-in capital	350,476	335,938
Deferred compensation	(608)	(895)
Accumulated deficit	(338,100)	(328,581)
	-----	-----
Total stockholders' equity	12,557	7,218

Edgar Filing: CYTOGEN CORP - Form 10-Q

\$ 22,682
=====

\$ 20,416
=====

The accompanying notes are an integral part of these statements.

2

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

	Three Months Ended September 30,	
	2001	2000
	-----	-----
Revenues:		
Product related:		
ProstaScint	\$ 1,679	\$ 1,849
Others	317	130
	-----	-----
Total product sales	1,996	1,979
Quadramet royalties	579	523
	-----	-----
Total product related	2,575	2,502
License and contract	225	231
	-----	-----
Total revenues	2,800	2,733
	-----	-----
Operating Expenses:		
Cost of product	1,400	1,136
Research and development	2,661	2,005
Acquisition of marketing and technology rights	-	13,241
Selling and marketing	1,489	1,242
General and administrative	1,147	1,716
	-----	-----
Total operating expenses	6,697	19,340
	-----	-----
Operating loss	(3,897)	(16,607)
Interest income	162	182
Interest expense	(44)	(24)
	-----	-----
Loss before cumulative effect of accounting change	(3,779)	(16,449)
Cumulative effect of accounting change	-	-
	-----	-----

Edgar Filing: CYTOGEN CORP - Form 10-Q

Net loss	\$ (3,779)	\$ (16,449)
	=====	=====
Net loss per share:		
Basic and diluted net loss before cumulative		
effect of accounting change	\$ (0.05)	\$ (0.22)
Cumulative effect of accounting change	-	-
	-----	-----
Basic and diluted net loss	\$ (0.05)	\$ (0.22)
	=====	=====
Weighted average common shares outstanding	78,866	73,632
	=====	=====

The accompanying notes are an integral part of these statements.

3

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

	Nine Months Ended September 30,	
	2001	2000
	-----	-----
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (9,519)	\$ (24,881)
	-----	-----
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	885	679
Imputed interest	(32)	(66)
Stock based compensation	480	284
Amortization of deferred revenue	(645)	(645)
Cumulative effect of accounting change	-	4,314
Acquisition of marketing and technology rights	-	13,079
Gain on sale of equipment	-	(148)
Changes in assets and liabilities:		
Accounts receivable, net	1,300	(169)
Inventories	(829)	54
Other assets	(49)	(91)
Accounts payable and accrued liabilities	(2,138)	(495)
Other liabilities	-	117
	-----	-----
Total adjustments	(1,028)	16,913
	-----	-----
Net cash used in operating activities	(10,547)	(7,968)
	-----	-----
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of product rights	(500)	-
Purchase of property and equipment	(486)	(751)
Net proceeds from sale of equipment	-	148
Redemption of short-term investments	-	1,593

Edgar Filing: CYTOGEN CORP - Form 10-Q

	-----	-----
Net cash (used in) provided by investing activities	(986)	990
	-----	-----
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock	14,188	10,411
Payment of long-term liabilities	(100)	(56)
	-----	-----
Net cash provided by financing activities	14,088	10,355
	-----	-----
Net increase in cash and cash equivalents	2,555	3,377
Cash and cash equivalents, beginning of period	11,993	10,801
	-----	-----
Cash and cash equivalents, end of period	\$ 14,548	\$ 14,178
	=====	=====

The accompanying notes are an integral part of these statements.

4

CYTOGEN CORPORATION AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. THE COMPANY AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

The Company

Cytogen Corporation ("Cytogen" or the "Company") is a biopharmaceutical company with an established and growing product line in prostate cancer and other areas of oncology, and a leadership position in proteomics research designed to accelerate drug discovery and development. In oncology, FDA-approved products include ProstaScint(R) (a monoclonal antibody-based imaging agent used to image the extent and spread of prostate cancer); BrachySeed(TM) (a uniquely designed next-generation radioactive seed implant for the treatment of localized prostate cancer), Quadramet(R) (a therapeutic agent marketed for the relief of bone pain in prostate and other types of cancer), and OncoScint CR/OV(R) (a monoclonal antibody-based imaging agent for colorectal and ovarian cancer). Cytogen is evolving a pipeline of oncology product candidates by exploiting its prostate specific membrane antigen, or PSMA, technologies, which are exclusively licensed from Memorial Sloan-Kettering Cancer Center. In addition, Cytogen plans to use AxCell's proteomics technology to research and develop novel drug targets independently or via collaborative ventures.

AxCell Biosciences, a subsidiary of Cytogen Corporation, is a pioneer in the effort to chart protein signaling pathways in the human proteome to accelerate the discovery of new drug targets and facilitate efficient pharmaceutical and biotechnology research and development. Through the systematic and industrialized application of proteomics, AxCell provides a growing portfolio of protein pathway solutions based on its proprietary Genetic Diversity Library(TM), Cloning of Ligand Targets(TM), and affinity screening technologies. In conjunction with InforMax, Inc., AxCell is developing a proprietary protein pathway database, called ProChart(TM), which is commercially

Edgar Filing: CYTOGEN CORP - Form 10-Q

available as a discovery and development tool for subscribers in the pharmaceutical, biotechnology and agricultural industries. AxCell is also seeking to develop alliances for the development of custom protein pathway information and intends to leverage its proteomic capabilities to identify novel drug targets for internal use.

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

5

CYTOGEN CORPORATION NOTES TO CONSOLIDATED FINANCIALS STATEMENTS (Cont'd)

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 generally accepted accounting principles and should be read in conjunction with the consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission, which includes financial statements as of and for the year ended December 31, 2000. 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.

Net Loss Per Share

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

Inventories

The Company's inventories are primarily related to ProstaScint and OncoScint CR/OV. Inventories are stated at the lower of cost or market using the

Edgar Filing: CYTOGEN CORP - Form 10-Q

first-in, first-out method and consisted of the following:

	September 30, 2001	December 31, 2000
	-----	-----
Raw materials.....	\$1,383,000	\$718,000
Work-in process.....	135,000	59,000
Finished goods.....	194,000	106,000
	-----	-----
	\$1,712,000	\$883,000
	=====	=====

Revenue Recognition

Effective January 1, 2000, the Company adopted U.S. Securities and Exchange Commission Staff Accounting Bulletin No. 101 "Revenue Recognition in Financial Statements" ("SAB 101"), which, as applied to the Company, requires up-front, non-refundable license fees to be deferred and recognized over the performance period. The cumulative effect of adopting SAB 101 resulted in a one-time, non-cash charge of \$4.3 million or \$0.06 per share, which reflects the deferral of an up-front license fee received from Berlex Laboratories, Inc., net of associated costs, related to the licensing of Quadramet recognized in October

6

CYTOGEN CORPORATION NOTES TO CONSOLIDATED FINANCIALS STATEMENTS (Cont'd)

1998 and a license fee for certain applications of PSMA to a joint venture formed by Cytogen and Progenics Pharmaceuticals Inc. recognized in June 1999. Previously, the Company had recognized up-front license fees when the Company had no obligations to return the fees under any circumstances. Under SAB 101, these payments are recorded as deferred revenue to be recognized over the remaining term of the related agreements.

2. DRAXIMAGE INC.:

In December 2000, the Company entered into a Product Manufacturing and Supply Agreement with Draximage Inc. ("Draximage") to market and distribute BrachySeed(TM) implants for prostate cancer therapy in the U.S. Under the terms of the agreement, Draximage will supply radioactive iodine and palladium seeds to Cytogen in exchange for royalties on sales and certain milestone payments. Accordingly, Cytogen paid Draximage \$500,000 upon the execution of the contract in 1999 and \$500,000 upon the first sale of the Iodine-125 BrachySeeds in 2000. These payments have been recorded as other assets in the accompanying consolidated balance sheet and are being amortized over the ten year term of the Draximage agreement. In addition, pursuant to the agreement, Cytogen will pay Draximage \$1.0 million upon the first sale of the Palladium-103 BrachySeeds. Other payments are due Draximage upon the achievement of certain other milestones. The Company launched the radioactive Iodine BrachySeed in the U.S. in February 2001.

3. SALES OF CYTOGEN COMMON STOCK:

Under the terms of a \$70 million equity financing facility (the "Equity

Edgar Filing: CYTOGEN CORP - Form 10-Q

Financing Facility") entered into between the Company and Acqua Wellington North American Equities Fund, Ltd. ("Acqua Wellington") in October 2000, Cytogen could, at its discretion, sell shares of its common stock to Acqua Wellington at a small discount to the market price. Pursuant to this Equity Financing Facility, in February 2001, the Company sold to Acqua Wellington 1,276,557 shares of its common stock at an aggregate price of \$6.5 million or \$5.092 per share. The Equity Financing Facility was terminated in June 2001.

In June 2001, the Company entered into a Share Purchase Agreement (the "Agreement") with the State of Wisconsin Investment Board ("SWIB"), pursuant to which the Company sold 1,820,000 shares of Cytogen common stock to SWIB for an aggregate purchase price of \$8.2 million, before transaction costs, or \$4.50 per share. In connection with the Agreement, the Company was required to discontinue the use of the Equity Financing Facility and such agreement was terminated.

7

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

The following discussion contains historical information as well as forward looking statements that involve a number of risks and uncertainties. Statements contained or incorporated by reference in this Quarterly Report on Form 10-Q that are not based on historical fact are "forward-looking statements" within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended. Generally, forward looking statements can be identified by the use of phrases like "believe", "expect", "anticipate", "plan", "may", "will", "could", "estimate", "potential", "opportunity" and "project" and similar terms. The Company's actual results could differ materially from the Company's historical results of operations and those discussed in the forward looking statements. Factors that could cause actual results to differ materially, include, but are not limited to those identified in the Company's Annual Report on Form 10-K for the year ended December 31, 2000 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

In addition to the risks discussed under the caption referred to above, among other factors that could cause actual results to differ materially from expected results are the following: (i) the Company's ability to access the capital markets in the near term and in the future for continued funding of its operations including existing projects and for the pursuit of new projects; (ii) the ability to attract and retain personnel needed for business operations and strategic plans; (iii) the timing and results of clinical studies, and regulatory approvals; (iv) market acceptance of the Company's products, including programs designed to facilitate use of the products, such as the Partners in Excellence or PIE Program; (v) demonstration over time of the efficacy and safety of the Company's products; (vi) the degree of competition from existing or new products; (vii) the decision by the majority of public and private insurance carriers on whether to reimburse patients for the Company's products; (viii) the ability of the Company to comply with applicable governmental regulations and changes thereto; (ix) the profitability of its products; (x) the ability to attract, and the ultimate success of, strategic partnering arrangements, collaborations, and acquisition candidates; (xi) the ability of the Company and its partners to identify new products as a result of those collaborations that are capable of achieving FDA approval, that are cost-effective alternatives to existing products and that are ultimately accepted by the key users of the product; (xii) the success of the Company in

Edgar Filing: CYTOGEN CORP - Form 10-Q

obtaining marketing approvals for its products in Canada and Europe; (xiii) the ability of the Company to protect its proprietary technology, trade secrets or know-how under the patent and other intellectual property laws of the United States and other countries; and (xiv) the ability of Advanced Magnetics Inc. to satisfy the conditions specified by the FDA regarding approval to market Combindex in the United States.

The following discussion and analysis should be read in conjunction with the Financial Statements and related notes thereto contained elsewhere herein, as well as the Company's Annual Report on Form 10-K for the year ended December 31, 2000 and from time to time the Company's other filings with the Securities and Exchange Commission.

8

Item 2 - Management's Discussion and Analysis of Financial Condition and Results of Operations (Cont'd)

Significant Events in 2001

In the first half of 2001, the Company launched the iodine version of BrachySeed(TM), a second generation radioactive implant for treatment of localized prostate cancer, which was in-licensed by the Company from Draximage Inc. The Company expects to introduce, during the fourth quarter of 2001, the palladium version of BrachySeed, a uniquely designed next generation radioactive seed implant, which recently received marketing clearance from the U.S. Food and Drug Administration. The Company is utilizing its existing oncology sales force to market BrachySeed. There can be no assurance, however, as to the market acceptance of these products or whether these products will significantly increase the revenues of the Company.

AxCell Biosciences Corporation, a subsidiary of the Company, began marketing the ProChart database with its marketing partner InforMax, Inc. during the second quarter of 2001. ProChart is a proprietary protein pathway database which measures protein domain-ligand interactions in a high-throughput manner. ProChart is being marketed by InforMax using its Protein-Protein Interaction module, a new addition to its GenoMax(TM) enterprise software package. There can be no assurance, however, as to the market acceptance of this product or whether this product will significantly increase the revenues for the Company.

Results of Operations

Three Months Ended September 30, 2001 and 2000

Revenues. Total revenues for the third quarter of 2001 were \$2.8 million compared to \$2.7 million for the same period in 2000. The increase from the prior year period is due to higher product related revenues. Product related revenues, which included product sales and royalties, accounted for 92% of total revenues in each of year 2000 and 2001. License and contract revenues accounted for the remainder of revenues in such periods.

Product related revenues for the third quarter of 2001 were \$2.6 million compared to \$2.5 million for the same period in 2000. Sales of ProstaScint accounted for 65% and 74% of product related revenues in the third quarters of 2001 and 2000, respectively, while Quadramet royalties accounted for 22% and 21% of product related revenues, respectively, for such periods. Sales of ProstaScint were \$1.7 million in the third quarter of 2001, which is slightly below the \$1.8 million recorded in the third quarter of 2000. Beginning in July 2000, the Company assumed sole responsibility for selling and marketing

Edgar Filing: CYTOGEN CORP - Form 10-Q

ProstaScint from the Bard Urological Division of C.R. Bard Inc. ("Bard"), its former co-marketing partner. The Company took this step because it believed that a highly trained and dedicated internal sales force would be able to market its products most effectively and to build a marketing capability for future products. There can be no assurance, however, the Company's internal sales force will be able to significantly increase the sale of ProstaScint.

9

Item 2 - Management's Discussion and Analysis of Financial Condition and Results of Operations (Cont'd)

Other product revenues include sales of BrachySeed and OncoScint CR/OV. Sales of BrachySeed were \$244,000 in the third quarter of 2001. Since the launch of BrachySeed in February 2001, the Company has increased its market penetration for the treatment of localized prostate cancer using its radioactive seed product. This has contributed to a positive sales trend and consistent quarter-over-quarter growth since the launch. The Company plans to launch the palladium version of BrachySeed in the fourth quarter of 2001. Sales of OncoScint were \$73,000 in the third quarter of 2001 compared to \$130,000 in the same period of 2000. 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. Accordingly, the Company is emphasizing marketing of OncoScint for the recurrent ovarian cancer setting. There can be no assurance, however, as to the market acceptance of the BrachySeed products or whether these new products along with a different strategy for OncoScint will significantly increase the revenues of the Company.

Quadramet royalties for the third quarter of 2001 increased to \$579,000 from \$523,000 in the same period of 2000. Quadramet is currently marketed by the Company's marketing partner, Berlex Laboratories ("Berlex"). Although Cytogen believes that Berlex is an advantageous partner, 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 third quarter of 2001 were \$225,000 compared to \$231,000 for the same period of 2000. As a result of the adoption of SAB 101 (see Note 1 to the Consolidated Financial Statements), license revenues for both 2000 and 2001 include the recognition of \$215,000 of deferred revenues from certain up-front, non-refundable license fees previously recognized in prior years.

Operating Expenses. Total operating expenses for the third quarter of 2001 were \$6.7 million compared to \$19.3 million recorded in the same quarter of 2000. The decrease from the prior year period is attributable primarily to charges in 2000 for the acquisition of the marketing and technology rights to two product candidates (Combidex and Code 7228) in the amount of \$13.2 million and costs associated with the termination of the Company's proposed merger with Advanced Magnetics Inc. The decrease during the current year is partially offset by costs associated with the development of new manufacturing and purification processes for ProstaScint, costs associated with the launch of BrachySeed and higher cost of goods.

Cost of product for the third quarter of 2001 was \$1.4 million compared to \$1.1 million recorded in the same period of the prior year. The increase from the prior year period is primarily due to costs associated with the purchase of the BrachySeed product from Draximage Inc.

Edgar Filing: CYTOGEN CORP - Form 10-Q

Research and development expenses for the third quarter of 2001 were \$2.7 million compared to \$2.0 million recorded in the same period of 2000. The increase from the prior year period is due to increased funding for the proteomics research program and to costs associated with the development of new manufacturing and purification processes to enable the Company to outsource the manufacturing of ProstaScint. During the third quarter of 2001, the Company invested \$1.2 million in its proteomics research compared to \$924,000 for the

10

Item 2 - Management's Discussion and Analysis of Financial Condition and Results of Operations (Cont'd)

third quarter of 2000. The Company anticipates that funding for this research and the manufacturing process development will continue to at its current trend over the remainder of this year.

Acquisition of marketing and technology rights of \$13.2 million in the third quarter of 2000 represents a charge related to the acquisition of certain rights to product candidates Combindex and Code 7228 from Advanced Magnetics Inc., of which \$13.1 million was non-cash.

Selling and marketing expenses were \$1.5 million for the third quarter of 2001 compared to \$1.2 million in the same period of 2000. The current year expenses reflect the Company's efforts to expand its in-house sales force related to the selling and marketing of ProstaScint and BrachySeed.

General and administrative expenses for the third quarter 2001 were \$1.1 million compared to \$1.7 million for the comparable period in 2000. The decrease from the prior year period is due primarily to legal expenses incurred relating to the termination of the Company's proposed merger with Advanced Magnetics Inc. and relocation expenses for certain key employees.

Interest Income/Expense. Interest income for the third quarter of 2001 was \$162,000 compared to \$182,000 recorded in the same period of 2000. The decrease from the prior year period is due to a lower average yield on investments for the period in 2001. Interest expense for the third quarter of 2001 was \$44,000 compared to \$24,000 recorded in the same period of 2000. The interest expenses included finance charges related with various equipment leases.

Net Loss. Net loss for the third quarter of 2001 was \$3.8 million compared to \$16.4 million recorded in the same period of 2000. The net loss per share for the third quarter of 2001 was \$0.05 based on average common shares outstanding of 78.9 million compared to a net loss per share of \$0.22 based on average common shares outstanding of 73.6 million for the same period in 2000. The 2000 net loss included a \$13.2 million one-time charge for the acquisition of certain product rights to two product candidates as described above.

Nine months ended September 30, 2001 and 2000

Revenues. Total revenues for the nine months ended September 30, 2001 and 2000 were \$8.6 million and \$7.8 million, respectively. The increase from the prior year period is due to higher product related revenues, partially offset by lower license and contract revenues. Product related revenues, which included product sales and royalties, accounted for 92% of total revenues in 2001 compared to 90% from the comparable period of 2000. License and contract revenues accounted for the remainder of revenues.

Edgar Filing: CYTOGEN CORP - Form 10-Q

Product related revenues for the nine months ended September 30, 2001 and 2000 were \$7.9 million and \$7.0 million, respectively. Sales of ProstaScint accounted for 72% of product related revenues for each of the nine months ended September 30, 2001 and 2000, respectively, while Quadramet royalties accounted for 20% and 22% of product related revenues, respectively. Sales of ProstaScint were \$5.7 million in the nine months ended September 2001, compared to \$5.0 million in the same period of 2000, due primarily to a price increase which

11

Item 2 - Management's Discussion and Analysis of Financial Condition and Results of Operations (Cont'd)

became effective in January 2001. Beginning in July 2000, the Company assumed sole responsibility for the selling and marketing of ProstaScint from Bard. Royalties from Quadramet were \$1.6 million and \$1.5 million in the nine months ended September 30, 2001 and 2000, respectively. Quadramet royalties are based on net sales of Quadramet by Berlex.

Other revenues include sales of BrachySeed and OncoScint CR/OV. For the nine months ended September 30, 2001, sales of BrachySeed were \$347,000. This product was launched in February 2001. The Company also plans to introduce to market the palladium version of BrachySeed in the fourth quarter of 2001. Sales of OncoScint during the nine months ended September 30, 2001 were \$296,000 in 2001 compared to \$437,000 in the same period of 2000. 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. Accordingly, the Company is emphasizing marketing of OncoScint for the recurrent ovarian cancer setting. There can be no assurance, however, as to the market acceptance of the BrachySeed products or whether these new products along with a different strategy for OncoScint will significantly increase the revenues of the Company.

License and contract revenues for the nine months ended September 30, 2001 and 2000 were \$697,000 and \$809,000, respectively. As a result of the adoption of SAB 101 (see Note 1 to the Consolidated Financial Statements), license revenues for both 2001 and 2000 include the recognition of \$645,000 of deferred revenues from certain up-front non-refundable license fees previously recognized in prior years.

Operating Expenses. Total operating expenses for the nine months ended September 30, 2001 were \$18.5 million compared to \$28.8 million recorded in the same period of 2000. The current year operating expenses reflect costs associated with the proteomics research program, the development of new manufacturing and purification processes for ProstaScint, the expansion of Cytogen's in-house sales force to assume sole responsibility of marketing and sales of ProstaScint and the 2001 launch of BrachySeed. The decrease in operating expenses from the prior year period is attributable primarily to charges in 2000 for the acquisition of marketing and technology rights to two product candidates (Combidex and Code 7228) in the amount of \$13.2 million and costs associated with the termination of the Company's proposed merger with Advanced Magnetics Inc. The decrease is partially offset by 2001 costs associated with the development of new manufacturing and purification processes for ProstaScint, the launch of BrachySeed and higher cost of goods.

Cost of product for the nine months ended September 30, 2001 was \$3.2 million compared to \$3.0 million recorded in the same period of the prior year. The increase from the prior year period is due primarily to the 2001 costs associated with the purchase of BrachySeed.

Edgar Filing: CYTOGEN CORP - Form 10-Q

Research and development expenses for the nine months ended September 2001 were \$6.9 million compared to \$5.0 million recorded in the same period of 2000. The increase from the prior year period is due to increased funding for the proteomics research program and costs associated with the development of new manufacturing and purification processes to enable the Company to outsource the manufacturing of ProstaScint to another contract manufacturer. During the nine months ended September 30, 2001, the Company invested \$3.6 million in the

12

Item 2 - Management's Discussion and Analysis of Financial Condition and Results of Operations (Cont'd)

proteomics research compared to \$2.2 million for the same period of 2000. The Company anticipates that funding for this research and manufacturing process development will continue at its current trend for the remainder of this year.

Acquisition of marketing and technology rights of \$13.2 million in the third quarter of 2000 represents a charge related to the acquisition of certain rights to product candidates Combindex and Code 7228 from Advanced Magnetics, of which \$13.1 million was non-cash.

Selling and marketing expenses were \$4.8 million for the nine months ended September 30, 2001 compared to \$3.7 million in the same period of 2000. The current year expenses reflect the Company's efforts to expand its in-house sales force for the selling and marketing of ProstaScint and the launch costs associated with the BrachySeed.

General and administrative expenses for the nine months ended September 30, 2001 were \$3.7 million compared to \$3.8 million for the comparable period in 2000. The decrease from the prior year period is due primarily to legal expenses incurred relating to the termination of the Company's proposed merger with Advanced Magnetics Inc. and relocation expenses for certain key employees, partly offset by higher costs in 2001 for stock based compensation and professional fees.

Interest Income/Expense. Interest income for the nine months ended September 30, 2001 was \$538,000 compared to \$545,000 recorded in the same period of 2000. The decrease from the prior year period is due to a lower average yield on investments, partly offset by income resulting from a higher average cash balance during 2001. Interest expense for the nine months ended September 30, 2001 was \$136,000 compared to \$133,000 recorded in the same period of 2000. The interest expenses included finance charges related with various equipment leases.

Net Loss. Net loss for the nine months ended September 30, 2001 was \$9.5 million compared to \$24.9 million recorded in the same period of 2000. The net loss per share for the nine months ended September 30, 2001 was \$0.12 based on average common shares outstanding of 77.4 million compared to a net loss per share of \$0.34 based on average common shares outstanding of 72.7 million for the same period in 2000. The 2000 net loss included a \$13.2 million one-time charge for the acquisition of certain product rights to two product candidates as described above and \$4.3 million or \$0.06 per share for the cumulative effect of an accounting change as a result of the adoption of SAB 101 (see Note 1 to the Consolidated Financial Statements).

Liquidity and Capital Resources

Edgar Filing: CYTOGEN CORP - Form 10-Q

The Company's cash and cash equivalents were \$14.5 million as of September 30, 2001, compared to \$12.0 million as of December 31, 2000. The cash used for operating activities for the nine months ended September 30, 2001 was \$10.5 million compared to \$8.0 million in the same period of 2000. The increase from the prior year period is due primarily to the increased funding for the proteomics program at AxCell, the Company's expansion of its in-house sales force, the inventory build-up of the Company's antibody products, the reduction in accounts payable and accrued liabilities and milestone payments to Draximage Inc. related to the 2001 launch of BrachySeed.

13

Item 2 - Management's Discussion and Analysis of Financial Condition and Results of Operations (Cont'd)

Historically, the Company's primary sources of cash have been proceeds from the issuance and sale of its stock through public offerings and private placements, product related revenues, revenues from research services, fees received under license agreements and interest earned on cash and short-term investments.

In January 2001, the Company received cash of \$1.6 million relating to the December 2000 sale of New Jersey State net operating losses and research and development credits. Under the current legislation, the Company may be able to sell a minimum \$977,000 of the remaining approved \$3.7 million of tax benefits in 2001. The actual amount of tax credits the Company may sell will depend upon the allocation among qualifying companies of an annual pool established by the State of New Jersey.

Under the terms of a \$70 million equity financing facility (the "Equity Financing Facility") entered into between the Company and Acqua Wellington North American Equities Fund, Ltd. ("Acqua Wellington") the Company sold to Acqua Wellington 1,276,557 shares of its common stock in February 2001 at an aggregate price of \$6.5 million or \$5.092 per share. The Equity Financing Facility was terminated in June 2001.

In June 2001, the Company entered into a Share Purchase Agreement (the "Agreement") with the State of Wisconsin Investment Board ("SWIB"), pursuant to which the Company sold 1,820,000 shares of Cytogen common stock to SWIB for an aggregate purchase price of \$8.2 million before transaction costs or \$4.50 per share. In connection with the Agreement, the Company was required to discontinue the use of the Equity Financing Facility and such arrangement was terminated.

In October 2001, the Company filed a shelf Registration Statement on Form S-3 to register 10,000,000 shares of its common stock. Such Registration Statement was declared effective by the Securities and Exchange Commission in November 2001. The Company may issue such registered shares of common stock from time to time and may use the proceeds thereof for general corporate purposes, including, but not limited to, continued development and commercialization of its proteomics technologies, research and development of additional products and expansion of its sales and marketing capabilities.

The Company's capital and operating requirements may change depending upon various factors, including: (i) whether the Company and its strategic partners achieve success in manufacturing, marketing and commercialization of its products; (ii) the amount of resources which the Company devotes 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, the Company expects to incur significant costs for the development of its proteomics and PSMA technologies.

Item 2 - Management's Discussion and Analysis of Financial Condition and Results of Operations (Cont'd)

The Company's financial objectives are to meet its capital and operating requirements through revenues from existing products and licensing arrangements. To achieve its strategic objectives, the Company 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 the Company in either cash or stock in addition to the costs associated with developing and marketing a product or technology. However, the Company believes 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, the Company may sell equity or debt securities as market conditions permit or enter into credit facilities.

The Company has incurred negative cash flows from operations since its inception, and has expended, and expects to continue to expend in the future, substantial funds to implement its planned product development efforts, including acquisition of products and complementary technologies, research and development, clinical studies and regulatory activities, and to further its marketing and sales programs. The Company expects that its existing capital resources should be adequate to fund the Company's operations for the foreseeable future. The Company cannot be certain that it will not consume a significant amount of its currently available resources and reasonably expects that it will have additional requirements for debt or equity capital, irrespective of whether and when it reaches profitability, for further product development costs, product and technology acquisition costs, and working capital.

The Company's future capital requirements and the adequacy of available funds will depend on numerous factors, including the successful commercialization of its products, the costs associated with the acquisition of complementary products and technologies, progress in its product development efforts, the magnitude and scope of such efforts, progress with clinical trials, progress with regulatory affairs activities, the cost of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights, competing technological and market developments, and the expansion of strategic alliances for the sales, marketing, manufacturing and distribution of its products. To the extent that the currently available funds and revenues are insufficient to meet current or planned operating requirements, the Company 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 the Company. If adequate funds are not available, the Company may be required to delay, further scale back or eliminate certain aspects of its operations or attempt to obtain funds through arrangements with collaborative partners or others that may require the Company to relinquish rights to certain of its technologies, product candidates, products or potential markets. If adequate funds are not available, the Company's business, financial condition and results of operations will be materially and adversely affected.

Edgar Filing: CYTOGEN CORP - Form 10-Q

Item 3 - Quantitative and Qualitative Disclosures About Market Risk

The Company does not have operations subject to risks of foreign currency fluctuations, nor does it use derivative financial instruments in its operations or investment portfolio. The Company does not have exposure to market risks associated with changes in interest rates, as it has no variable interest rate debt outstanding. The Company does not believe it has any other material exposure to market risks associated with interest rates.

16

PART II - OTHER INFORMATION

Item 5 - Other Events

In October 2001, the Company filed a shelf Registration Statement on Form S-3 to register 10,000,000 shares of its common stock. Such Registration Statement was declared effective by the Securities and Exchange Commission in November 2001. The Company may issue such registered shares of common stock from time to time and may use the proceeds thereof for general corporate purposes, including, but not limited to, continued development and commercialization of its proteomics technologies, research and development of additional products and expansion of its sales and marketing capabilities.

In connection with the closing of the SWIB financing, the Company was obligated to adopt certain amendments to its Bylaws and option plans. Such amendments are attached hereto as exhibits.

At the Annual Meeting of Shareholders, the Company obtained shareholder approval for certain amendments to the Employee Stock Purchase Plan and the 1999 Non-Employee Directors Plan. Such amendments are attached hereto as exhibits.

Item 6 - Exhibits and Reports on Form 8-K

(a) Exhibits:

- 3.1 Amended Bylaws of Cytogen Corporation
- 10.1 Amended and Restated 1995 Stock Option Plan
- 10.2 Amended and Restated 1999 Stock Option Plan for Non-Employee Directors
- 10.3 Amended Employee Stock Purchase Plan of Cytogen Corporation

(b) Reports on Form 8-K:

None

17

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.

Edgar Filing: CYTOGEN CORP - Form 10-Q

CYTOGEN CORPORATION

Date November 13, 2001

By /s/ H. Joseph Reiser

H. Joseph Reiser
President and Chief Executive Officer

Date November 13, 2001

By /s/ Lawrence R. Hoffman

Lawrence R. Hoffman
Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)