

Edgar Filing: CYTOGEN CORP - Form 10-K

CYTOGEN CORP  
Form 10-K  
March 28, 2002

SECURITIES AND EXCHANGE COMMISSION  
Washington, DC 20549

FORM 10-K  
FOR ANNUAL AND TRANSITION REPORTS  
PURSUANT TO SECTIONS 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934

(Mark One)

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

For the fiscal year ended December 31, 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 No.)

600 College Road East, CN5308, Princeton New Jersey

08540-5308  
-----

(Address of Principal Executive Offices)

(Zip Code)

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

Securities registered pursuant to Section 12(b) of the Act: None  
-----

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, \$0.01 par value  
-----

(Title of Class)

Indicate by check mark whether the registrant: (1) has filed all reports  
required to be filed by Section 13 or 15(d) of the Securities Exchange Act of  
1934 during the preceding 12 months (or for such shorter period that the  
registrant was required to file such reports), and (2) has been subject to such  
filing requirements for the past 90 days.

Yes X No

--

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405  
of Regulation S-K is not contained herein, and will not be contained, to the  
best of registrant's knowledge, in definitive proxy or information statements  
incorporated by reference in Part III of this Form 10-K or any amendment to this  
Form 10-K.

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

The aggregate market value of the registrant's voting shares of Common Stock held by non-affiliates of the registrant on March 1, 2002, based on \$2.27 per share, the last reported sale price on the NASDAQ National Market on that date, was \$187 million.

The number of shares of Common Stock, \$.01 par value, of the registrant outstanding as of March 1, 2002 was 82,508,739 shares.

The following documents are incorporated by reference into the Annual Report on Form 10-K: Portions of the registrant's definitive Proxy Statement for its 2002 Annual Meeting of Stockholders are incorporated by reference into Part III of this Report.

### TABLE OF CONTENTS

	Item	Page
	----	---
PART I	1. Business.....	
	2. Properties.....	3
	3. Legal Proceedings.....	3
	4. Submission of Matters to a Vote of Security Holders.....	3
PART II	5. Market for the Company's Common Equity and Related Stockholder Matters.....	3
	6. Selected Financial Data.....	3
	7. Management's Discussion and Analysis of Financial Condition and Results of Operations.....	4
	7A. Quantitative and Qualitative Disclosures about Market Risk.....	4
	8. Financial Statements and Supplementary Data.....	4
	9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.....	4
PART III	10. Directors and Executive Officers of the Company.....	4
	11. Executive Compensation.....	4
	12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.....	4
	13. Certain Relationships and Related Transactions.....	4
PART IV	14. Exhibits, Financial Statement Schedules, and Reports on Form 8-K.....	5
	EXHIBIT INDEX.....	5
	SIGNATURES.....	5
	INDEX TO CONSOLIDATED FINANCIAL STATEMENTS.....	5

### PART I

Item 1. Business

Business

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

### Overview

Cytogen is an established biopharmaceutical company with a growing product line in prostate cancer and other areas of oncology, along with functional proteomics solutions and proprietary signal transduction pathway information through its AxCell Biosciences subsidiary. We are extending our expertise in antibodies and molecular recognition to the development of new products and a signal transduction-driven drug discovery platform. We have established a pipeline of product candidates based upon our proprietary antibody and our exclusively licensed prostate specific membrane antigen, or PSMA, technologies. We are also engaged in the research and development of novel biopharmaceutical products using our growing portfolio of functional proteomics solutions and collection of proprietary signal transduction pathway information.

Our portfolio of prostate cancer products and development pipeline reflect Cytogen's reputation for bringing novelty and innovation to patients and physicians. FDA-approved products include ProstaScint(R) (a monoclonal antibody-based imaging agent used to image the extent and spread of prostate cancer); BrachySeed(TM) I-125 and Pd-103 (uniquely designed, next-generation radioactive seed implants for the treatment of localized prostate cancer); and Quadramet(R) (a therapeutic agent marketed for the relief of bone pain in prostate and other types of cancer).

In August 2000, we expanded our product pipeline by entering into marketing, license and supply agreements with Advanced Magnetics, Inc. for Combidex(R) and for Code 7228, which are investigational magnetic resonance imaging (MRI) contrast agents. We have exclusive U.S. rights to Combidex for the detection of lymph node metastases and exclusive U.S. rights to Code 7228 for oncology applications. Following a priority review, Combidex received an approvable letter from the U.S. Food and Drug Administration (FDA) in June 2000. Cytogen and Advanced Magnetics have established project teams to cooperate on the development of Combidex.

We have integrated our expertise in molecular and cellular biology, biochemistry, bioinformatics, pharmacology and clinical development to create two exciting and distinct technologies:

#### 1) PROSTATE SPECIFIC MEMBRANE ANTIGEN

Prostate specific membrane antigen, or PSMA, is a cell-surface protein that is abundantly expressed on prostate cancer cells at all stages of disease, including advanced or metastatic disease. The PSMA gene was first discovered by scientists at Memorial Sloan-Kettering Cancer Center and is exclusively licensed to Cytogen. From this technology, we have put one product on the market (ProstaScint) and built a robust pipeline of products in development, of which one should enter Phase I clinical trials in 2002. These pipeline products are focused primarily on novel vaccine and antibody cancer therapy, initially in the area of prostate cancer.

PSMA is also present at high levels on the newly formed blood vessels (neovasculature) needed for the growth and survival of many types of solid tumors. If PSMA-targeted therapies can destroy or prevent formation of these new blood vessels, the therapies may prove valuable in treating a broad range of cancers.

#### 2) SIGNAL TRANSDUCTION INHIBITORS

Our AxCell Biosciences subsidiary is engaged in the research and development of novel biopharmaceutical products using its growing portfolio of functional proteomics solutions and collection of proprietary signal transduction pathway information. Through the systematic and industrialized measurement of protein-to-protein interactions, AxCell is assembling ProChart(TM), a

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

proprietary database of signal transduction pathway information that is relevant in a number of therapeutically important classes of molecules including growth factors, receptors and other potential protein therapeutics or drug targets. In early 2001, scientists at AxCell were the first to successfully identify all of the known domain/ligand interactions in the known WW domain family, which is believed to play a role in the onset and progression of muscular dystrophy and Alzheimer's disease. Throughout 2001, AxCell identified approximately half of the domain/ligand interactions in the known SH3 and PDZ domain families and made continued progress in mapping the SH2 domain family. AxCell is expanding and accelerating its research activities to further elucidate the role of novel proteins and pathways in ProChart, through both external collaborations and internal data mining.

-1-

AxCell uses its proprietary technology as a tool to provide collaborators with vital information about signal transduction pathways that these collaborators are interested in targeting for drug discovery. We provide this information rapidly and efficiently, using the proprietary methods and systems that we developed to identify signal transduction inhibitors as drugs. We have successfully leveraged our technology through collaborations with Mount Sinai School of Medicine, National Cancer Institute, Kimmel Cancer Center at Thomas Jefferson University, and Pluvita Corporation. These collaborations increase our resources, improve our technological strength and establish valuable development relationships with commercial opportunities.

Signal transduction inhibitors may be marketed as drugs because the inhibitor, once it binds to the target protein, prevents the activation of a specific disease-causing pathway, resulting in a therapeutic benefit to the patient. We believe signal transduction inhibitors are also useful as a tool to understand a protein's function and its value as a drug target. Understanding the function of a protein helps prioritize targets for drug discovery. AxCell's map of domain and ligand interactions is an efficient technology to convert peptide sequence information into drugs. In addition, because signal transduction inhibitors are designed to bind specifically to a target, and as a result, do not inhibit unintended protein products, we believe signal transduction inhibitors are safer and more effective than traditional drugs. By using medicinal chemistry, we can design chemical mimetics to our peptide-based signal transduction inhibitors, which will support methods of dosing drugs that are more convenient for patients, including methods of oral delivery.

The Company was incorporated in Delaware on March 3, 1980 under the name Hybridex, Inc. and changed its name to Cytogen Corporation on April 1, 1980. Our executive offices are located at 600 College Road East, Princeton, New Jersey 08540 and our telephone number is 609-750-8200.

### PROSTATE CANCER AND ONCOLOGY

#### Background

Approximately one in every six men will develop prostate cancer. It is the second leading cause of cancer death among men in the United States, exceeded only by lung cancer. The American Cancer Society estimates that nearly 200,000 new cases of prostate cancer will be diagnosed this year in the U.S., and that 31,500 men will die of the disease. Fundamentals of the prostate cancer segment of the oncology market that are particularly encouraging include:

- accelerated approval procedures adopted by the FDA to shorten the development process and review time for cancer drugs;
- in-licensing opportunities created by a trend among large

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

pharmaceutical companies to concentrate on products with larger market potential than most anticancer drugs;

- favorable pricing and reimbursement for oncology drugs; and
- a highly concentrated population of urology healthcare professionals which we believe allows a smaller sales force to be effective.

-2-

Our marketed oncology products and pipeline are comprised of the following:

Product	Indication	Status	Development
ProstaScint	Monoclonal antibody diagnostic imaging agent for staging the spread of prostate cancer	Approved and marketed in the United States. Regulatory approval in Canada	Cytogen (United States and Canada)
BrachySeed (TM)	Treatment of localized tumors such as tumors of the neck, lung, pancreas, breast, uterus and prostate	Iodine 125 approved and marketed in the United States	Cytogen (United States and Canada)
		Palladium 103 approved in the United States and marketing initiated in the first half of 2002	
OncoScint CR/OV	Monoclonal antibody diagnostic imaging agent for spread of colorectal and ovarian cancer	Approved for sale in eleven European countries, Canada and the United States	Cytogen (United States and Canada)
Quadramet	Relief of bone pain from cancer spread to the bone from primary tumor	Approved in the United States and Canada	Berlex (United States) and Cytogen (Canada)
	Treatment of primary bone tumors.	Phase I results recently published	Berlex (United States) and Cytogen (Canada)
PSMA Development	In vivo immunotherapeutic product for cancer vaccine utilizing gene and protein-based therapy	Pre-clinical development	Progenics/Cytogen
		Phase I clinical development in 2002	
	Prostate cancer antibody-based therapy	Pre-clinical development	Progenics/Cytogen
	In vitro diagnostic tests for prostate cancer	Development of a trial assay	Cytogen to partner

Edgar Filing: CYTOGEN CORP - Form 10-K

-----  
Ex vivo dendritic cell  
processing

Phase III clinical trials

Northwest Bio  
Inc.  
-----

Pipeline--PSMA technology

Prostate specific membrane antigen, or PSMA, is a transmembrane protein that can be used as an important marker associated with prostate cancer. PSMA has also been found to be present in new blood vessel formation associated with other major solid tumors. It is over expressed in primary prostate cancer, but it is expressed most highly in the more aggressive forms of prostate cancer, including those that do not express prostate specific antigen, or PSA, and those that do not respond to hormone therapy. Memorial Sloan-Kettering Cancer Center identified PSMA using a monoclonal antibody supplied by us. A patent entitled "Prostate Specific Membrane Antigen" was issued to Sloan-Kettering Institute for Cancer Research, an affiliate of Memorial Sloan-Kettering Cancer Center, and we have the exclusive worldwide license covering this technology. Subsequently, the antibody for PSMA was the basis of our FDA-approved ProstaScint imaging product. We believe that technology utilizing PSMA can yield novel products for the treatment and diagnosis of cancer because of the unique characteristics of this antigen.

-3-

In 1999, Cytogen entered into a joint venture with Progenics Pharmaceuticals, Inc. ("Progenics") to develop in vivo immunotherapeutic products utilizing PSMA. The first of these product candidates is a therapeutic prostate cancer vaccine utilizing the PSMA gene and a vector delivery system and the PSMA protein as a basis of immune stimulation. We are also developing through this venture an antibody-based immunotherapy for prostate cancer. We believe that these product candidates, if successfully developed, could play an important role in the treatment of prostate cancer. We believe there are significant unmet needs for treatment and monitoring of this disease. In addition, we intend to evaluate the utility of these therapies, as an anti-angiogenesis approach, in other cancers where PSMA is expressed in association with tumor neovasculature e.g., breast, colon, etc.

The joint venture is owned equally by Progenics Pharmaceuticals, Inc. and us. We have exclusively licensed to the joint venture certain immunotherapeutic applications of our PSMA patent rights and know-how. Progenics has funded the first \$3 million of pre-clinical development costs of the program. Beginning in December 2001, we and Progenics are sharing costs of the program in excess of the initial \$3 million for clinical development. We have certain North American marketing rights to products developed by the venture and a right of first negotiation with respect to marketing activities in any territory outside North America. We anticipate marketing any products developed upon approval by the FDA or requisite foreign regulatory bodies, as applicable. If approved, we anticipate marketing these products with our own sales force and will be reimbursed by the joint venture for these costs. We will split the net profit equally with Progenics on any products developed by the venture. In connection with the licensing of the PSMA technology to the joint venture, we received \$2 million in payments, of which \$1 million was received during 1999, \$500,000 during 2000, and \$500,000 during 2001. We have exclusively licensed in vivo immunotherapy rights to PSMA to this joint venture. During 2001, the joint venture entered into a worldwide exclusive licensing agreement with AlphaVax Human Vaccines, Inc. to use the AlphaVax Replicon Vector (ArV(TM)) system to create a therapeutic prostate cancer vaccine incorporating the PSMA antigen. Also in 2001, the joint venture entered into a collaboration with Abgenix, Inc. to use the company's XenoMouse(TM) technology for generating fully human

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

antibodies to PSMA. As a result of such collaboration, the joint venture successfully created human monoclonal antibodies that target PSMA.

We licensed PSMA through our subsidiary, Prostagin, Inc., to Northwest Biotherapeutics, Inc., for development of in vitro dendritic cell based immunotherapy of prostate cancer. Prostagin also licensed exclusive PSMA manufacturing rights for immunotherapy to Northwest Clinicals, LLC, a corporation formed and co-owned by Northwest Biotherapeutics and Prostagin. In 2000, we executed a new sublicense agreement with Northwest Biotherapeutics Inc. clarifying their rights to make and use PSMA for ex vivo prostate cancer immunotherapy. The license agreement with Northwest Clinicals, LLC was terminated and the manufacturing rights thereunder returned to Cytogen except for those granted under the newly-executed license with respect to ex vivo immunotherapy. Last year we reported that we and Progenics had a dispute regarding the timely reacquisition of the PSMA manufacturing rights. We have reached a mutually satisfactory agreement with Progenics with respect to this matter.

We obtained exclusive, world-wide licenses from Molecular Staging, Inc. for technology to be used in developing in vitro diagnostic tests using both PSMA and PSA. Molecular Staging's Rolling Circle Amplification Technology is a novel, patented process that creates new diagnostic opportunities. Rolling Circle Amplification Technology is a highly sensitive, quantitative and efficient amplification method that allows the user to detect the presence of target molecules in a wide array of testing formats. It offers a practical method that allows solid phase recognition and detection of target molecules either directly, on a cell or on a biochip. Our initial goal is to deploy Molecular Staging's technology in a new diagnostic kit for managing prostate cancer based on detection of PSA and PSMA. We have established the proof of concept of using the RCAT technology in a PSA serving assay and are investigating the optional contribution of reagents (i.e. monoclonal antibody pairs) using a similar approach for PSMA. We also plan to deploy such assays for diagnosis of other tumors where PSMA is found in associated neovasculature.

### Market potential

#### Diagnostic Screening Tests

The measurement of prostate specific antigen, or PSA, levels in the circulation is the only in vitro test approved for the monitoring of prostate cancer in the United States. The American Cancer Society, American College of Radiology and American Urologic Association have recommended PSA for use in screening of asymptomatic men, in combination with a digital rectal examination. However, in 1997, the American College of Physicians concluded that there was no evidence of benefit from routine screening using PSA and recommended against regular screening using this test. The American Urologic Association, which supports screening tests for eligible men over 50 years of age, claims that PSA and digital rectal examination screening increases the rate of early cancer diagnosis from 30% to 40% for those not screened to 70% to 85% for those

-4-

screened with PSA. Even though a PSA test combined with a digital rectal exam increases the chances of detection, the method generates a high number of false positives that often lead to unnecessary biopsies. We believe new and more accurate tests based on PSA and PSMA may offer higher specificity and prognostic information in diagnosing primary and recurrent prostate cancer.

An estimated 23.8 million PSA tests were performed in 1998 yielding a market value of \$286 million. It was expected that this market would reach nearly \$400 million in 2001 according to the 1999 Medical Data International Report. Current estimates of the world-wide market are \$400-600 million with approximately 60

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

million men being screened for PSA levels in the United States. In addition, over one million biopsies are performed annually in the United States to confirm the presence of prostate cancer following a screening. Furthermore, the correlation of PSA values and prostatic biopsy results has failed to achieve a level of predictability which avoids unnecessary biopsies.

A serum test for PSMA, representing a novel marker associated with more aggressive disease, may provide more relevant prognostic value and improve the accuracy of evaluating prostate cancer. We anticipate providing both tests together to help gain entrance to this important market.

### Immunotherapy/Vaccines

We are developing, as part of our collaboration with Progenics, immunotherapeutics for treatment of prostate cancer. We believe immunotherapy is a particularly attractive alternative for the treatment of prostate cancer and for prevention of recurrent disease by eliminating metastases. Because PSMA has been identified as a unique antigen linked to prostate and other cancers, it may serve as an excellent immunotherapy target.

As part of our joint venture with Progenics, we are developing both vaccine and antibody-based immunotherapies directed to PSMA. Additionally, antibody-based applications may also include radio labeled or toxic-conjugated agents.

We believe that there are approximately one million men annually in the United States who are at risk for recurrent disease and/or have advanced prostate cancer. We estimate that the potential market for a vaccine or antibody-based treatment is greater than \$500 million annually in the United States.

### Our approved products

We have four marketed products, each of which has been approved by the FDA: ProstaScint, used as an imaging agent in the diagnosis of the extent and spread of prostate cancer; BrachySeed, a second generation radioactive implant for prostate cancer therapy; OncoScint CR/OV, marketed as a diagnostic imaging agent for colorectal and ovarian cancer; and Quadramet, used for relief of bone pain from cancer that has spread to the bone from the primary tumor.

### Cancer diagnostic imaging products

Our cancer diagnostic products, ProstaScint and OncoScint CR/OV, are murine-based monoclonal antibody-based imaging agents for prostate, colorectal and ovarian cancers. These products utilize our proprietary targeted delivery system, employing whole monoclonal antibodies, which directs the radioisotope Indium/111/ to malignant tumor sites. A radioisotope is an element which, because of nuclear instability, undergoes radioactive decay and emits radiation. The imaging products are supplied to hospitals, diagnostic imaging centers and radiopharmacies.

During an imaging procedure, the radiolabeled monoclonal antibody product is administered intravenously into the patient. The antibody travels through the bloodstream and binds to specific antigens expressed by the tumors being studied. The radioactivity from the isotope that has been attached to the antibody can be detected from outside the body by a gamma camera. Gamma cameras are universally found in all nuclear medicine departments. The image captured by the camera identifies the existence, location and extent of the radiolabeled pharmaceutical thus identifying the sites of tumor. Based on clinical studies conducted to date by physicians on our behalf, the imaging agents may provide new and useful information not available from other diagnostic modalities regarding the existence, location and extent of a specific disease throughout the body. We believe that this information has the potential to affect the way physicians manage their patients' individual treatments.



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

### ProstaScint

ProstaScint is a diagnostic monoclonal antibody linked to Indium/111/ which specifically targets PSMA. Due to the selective expression of PSMA, the ProstaScint imaging procedure can detect the extent and spread of prostate cancer in the body. ProstaScint is approved by the FDA for marketing in two clinical settings: as a diagnostic imaging agent in newly diagnosed patients

-5-

with biopsy-proven prostate cancer thought to be clinically localized after standard diagnostic evaluation and who are at high risk for spread of their disease to pelvic lymph nodes and for use in post-prostatectomy patients in whom there is a high suspicion that the cancer has recurred.

According to the American Cancer Society, nearly 200,000 American men were diagnosed with prostate cancer in 2000, of whom approximately 11% are at high risk for metastatic spread of their disease. In addition, estimates indicate that in 2000, 40,000 to 60,000 patients previously treated for prostate cancer developed symptoms of recurrent cancer which had not yet progressed to the point of skeletal involvement. We believe that there are approximately 60,000 to 70,000 patients with prostate cancer in the United States who are candidates, based on current indications, to receive a ProstaScint scan each year.

When deciding on an initial course of therapy for diagnosed prostate cancer, physicians must first determine the extent of disease in the patient. The accuracy of this information is vital in deciding upon an appropriate course of therapy. Prior to the availability of ProstaScint, determining whether newly diagnosed disease was limited to the prostate or had spread beyond the gland was based upon statistical inference from the biopsy appearance of the tumor and the patient's serum level of PSA. Conventional imaging methods such as CT or MRI are all relatively insensitive because they rely on identifying significant changes to normal anatomic structure to indicate the presence of disease. The ProstaScint disease scan images are based upon expression of the PSMA molecule and, therefore, can identify disease not readily detectable with conventional procedures.

In the United States, following initial therapy, prostate cancer patients are monitored to ascertain changes in the level of PSA. In this setting, a rise in PSA is evidence of recurrence of the patient's prostate cancer. Knowledge of the extent and location of disease recurrence is important in choosing the most appropriate form of treatment. The National Comprehensive Cancer Network (NCCN), a consortium of leading cancer hospitals, in 2000 included ProstaScint in its Practice Guidelines for Prostate Cancer. These guidelines are published to serve as the practice standard for the oncology community.

We also believe that ProstaScint may be useful for imaging the extent of prostate cancer within the prostate gland. ProstaScint guided therapy may be useful to help guide specific treatments such as prostate brachytherapy or highly targeted external beam radiation. Brachytherapy is a treatment which implants radiation sources into the site of the tumor; while external beam radiation utilizes a beam of radiation directed at the cancer from a source outside the body. We estimate that approximately half of newly diagnosed prostate cancer patients will undergo a form of radiation treatment. The current generation of imaging technologies enables physicians to view ProstaScint scans incorporated with conventional imaging modalities. We believe these technologies will create greater acceptance of ProstaScint. We are unaware of any other agents approved for the imaging and diagnosis of prostate cancer.

### OncoScint CR/OV

OncoScint CR/OV is approved by the FDA for sale in the United States with other

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

appropriate, commercially available diagnostic tests, to locate malignancies outside the liver in patients with known colorectal or ovarian cancer. OncoScint CR/OV is also approved for sale in eleven European countries and Canada. However, this product has not received wide market acceptance by physicians for patients with these conditions. We market OncoScint CR/OV in the United States directly through our own sales force. The market for OncoScint CR/OV for colorectal cancer diagnosis has been negatively affected by positron emission tomography, or "PET", scans. The sensitivity of the PET scan in colon cancer appears to be similar or higher than the OncoScint CR/OV scan. Consequently, we are de-emphasizing the marketing of OncoScint CR/OV.

### Cancer therapeutic products

#### Quadramet

Quadramet, a cancer therapeutic agent, is approved by the FDA for the relief of pain in patients with metastatic bone lesions that image on conventional bone scan, a routinely performed nuclear medicine procedure. Quadramet consists of a radioactive isotope, Samarium/153/, which emits beta radiation, and a chelating agent, EDTMP, which targets the drug to sites of new bone formation.

Once tumors have metastasized to the skeleton, they continue to grow and cause destruction of the adjacent bone. This erosion of bone stimulates new bone formation which encircles the metastatic tumor. By targeting these areas of bone formation, Quadramet delivers site-specific radiation which may result in significant pain reduction.

-6-

According to American Cancer Society and National Cancer Institute statistics, about half of all people with cancer (other than skin cancer) will have bone metastasis at some point in the course of their disease. Bone metastasis is one of the most frequent causes of pain in people with cancer. We believe that over 200,000 patients each year will suffer from bone pain that is severe enough to require intervention. Based on this information, we believe that the potential market for Quadramet is approximately \$50 - \$80 million in the United States based on 20% of this patient population.

Quadramet has many characteristics which we believe are advantageous for the treatment of cancer bone pain, including early onset of pain relief, lasting up to four months with a single injection; predictability of recovery from bone marrow toxicity; ease of administration and length of pain relief. In addition, due to its pharmacokinetic properties, the radioactive plasma half-life is only five to six hours. Quadramet is administered as a single intravenous injection on an outpatient basis and directly targets sites of new bone formation which include those areas in the skeleton that have been invaded by metastatic tumors. Quadramet exhibits high and very selective uptake in bone with little or no detectable accumulation in soft tissue.

A Phase I/II clinical study not sponsored by us was carried out by the Mayo Clinic to investigate the use of high doses of Quadramet for the treatment of primary bone tumors. The results of that study have recently been published in the peer-reviewed literature and suggested that Quadramet may have a beneficial role in this treatment.

Current competitive treatments for severe bone cancer pain include narcotic analgesics, external beam radiation therapy, Metastron and Novantrone.

#### BrachySeed

Of the nearly 200,000 men diagnosed with prostate cancer in 2000, approximately 60% to 70% will have localized disease (cancer confined to the prostate gland).

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

The most common treatment options for localized disease are prostatectomy, the surgical removal of the prostate, or brachytherapy, the implantation of small radioactive pellets or "seeds" into the prostate. Approximately 100 seeds are implanted during a brachytherapy procedure.

BrachySeed is a unique, second generation radioactive brachytherapy implant developed by Draxis Health, Inc. and its subsidiary, Draximage, Inc. ("Draxis") and marketed in the United States by Cytogen. BrachySeed's unique, single-weld design brings a new level of accuracy, precision and safety to sealed source implant surgery. Each BrachySeed is robotically manufactured and undergoes six separate quality control checks to ensure uniformity.

While brachytherapy has been available since the 1970s, it has only started to gain prominence and greater acceptance within recent years, coinciding with the development of advanced technologies to aid seed placement. Brachytherapy is the fastest growing treatment for localized prostate cancer and offers a number of potential benefits compared to alternative treatments such as prostatectomy, including rapid patient recovery, lower costs and reduced incidence of complications such as impotency and incontinence. Given this improved side-effect profile, the market for brachytherapy seeds has grown substantially over the last three years. According to the 1999 Medical Data International Report, by 2003, it is estimated that approximately half of all newly diagnosed prostate cancer patients will opt for brachytherapy, while radical prostatectomies will be performed on less than 15% of patients. Independent estimates place the current brachytherapy market at \$220 million in the United States and growing by approximately \$100-200 million in three to four years.

During 2001, we introduced the iodine version of the BrachySeed product and we are currently seeking to grow our market position in this segment of the brachytherapy market. We are preparing to launch a palladium version of BrachySeed during the first half of 2002. Following the palladium launch, we will be among a select group of companies offering both an iodine and palladium version of the brachytherapy product.

### Oncology Product Sales, Marketing and Distribution

We currently employ a dedicated field sales force targeting approximately 10,000 healthcare professionals. The primary objective of the sales force is to promote our products to urologists, radiation oncologists and nuclear medicine physicians. Within this field force are technical specialists who assist in the training of nuclear medicine technologists and nuclear medicine physicians, and qualify nuclear imaging centers to conduct ProstaScint imaging. We depend on our own sales force for the sale and marketing of ProstaScint, BrachySeed and OncoScint CR/OV products and on Berlex for United States sales, marketing and distribution of Quadramet. Distribution of ProstaScint and OncoScint CR/OV is handled by outside contractors and Berlex and DuPont handle the distribution of Quadramet. We are the exclusive United States distributor for BrachySeed.

-7-

During 2000, we terminated our co-marketing arrangement with the Bard Urological Division of CR Bard Company, Inc. ("Bard"). Historically, ProstaScint has been marketed under a co-marketing arrangement with the urological division of Bard, a marketer of a broad range of urology products. In 1999, we reached an agreement with Bard to phase out the co-marketing agreement so that we could undertake direct marketing responsibility for the product. We took this step because of our view that a highly trained and dedicated internal sales force will be able to market our high technology products most effectively and to build a marketing capability for possible future products. The transition was completed by mid-year 2000.

ProstaScint is a technique-dependent product that requires a high degree of

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

proficiency in nuclear imaging technology in order to interpret the scan. We have established a network of accredited nuclear medicine imaging centers through our PIE, or Partners In Excellence Program. Each PIE site receives rigorous training, undergoes proficiency testing and is subject to ongoing quality assurance protocols. As of December 31, 2001, there were over 350 PIE sites, including a majority of the National Cancer Institute-designated Comprehensive Cancer Centers. ProstaScint may only be used at PIE sites. We plan to add PIE sites on a selective basis in order to ensure that new sites are adequately qualified and committed to a minimum number of scans for maintaining a high level of competence. At the present time, we bear partial expense of the qualification of each site.

In 1999, we reacquired rights to our ProstaScint and OncoScint CR/OV products in Canada, which were to be marketed by Faulding (Canada), Inc. We did not pay for the return of these rights. OncoScint CR/OV is approved by the Canadian Health Care Branch and ProstaScint was approved for sale in Canada in March of 2002. We believe these products will be marketed to major cancer centers in Canada and will not require a significant level of resources. However, we cannot be certain that these products will be reimbursable under the Canadian health care system or reimbursed on favorable economic terms, or that they will be accepted by physicians.

Since May 1994, we have been the sole marketer of OncoScint CR/OV in the United States. In 1996, we entered into a distribution agreement with CIS biointernational, granting to CIS biointernational the exclusive right to distribute and sell OncoScint CR/OV worldwide, except for in the United States and Canada. This Agreement was terminated effective in March 2001 by mutual agreement of the parties.

In October 1998, we entered into an exclusive agreement with Berlex Laboratories, Inc. for the marketing of Quadramet, after terminating our previous marketing relationship with the DuPont Merck radiopharmaceutical division. Berlex re-launched Quadramet in March 1999. Berlex maintains a sales force that targets its sales efforts on the oncological community. Pursuant to our agreement with Berlex, we are entitled to royalty payments based on net sales of the Quadramet product and milestone payments based upon sales levels achieved.

During the first year of launch, Quadramet was marketed principally to the nuclear medicine community, which administers the treatment to patients. However, the treatment is more typically prescribed by care giving physicians, including medical oncologists, radiation oncologists and urologists. We believe that successful commercialization of Quadramet will depend upon marketing to these referring physicians.

We plan to market Quadramet in Canada. We paid no costs to obtain these marketing rights. We are evaluating whether to market Quadramet directly in Canada or through a marketing partner.

We have no significant foreign revenues. Although we plan to sell our products internationally, we cannot assure you that the products will be accepted by the foreign medical community or regulators or that we will be able to sell at adequate prices. We will incur expenses if we sell our products in foreign countries, and if our products do not generate adequate revenues we may not be able to recover these expenses.

### Strategic Alliances and License Agreements

Our strategy is to use alliances with other companies to increase our financial resources, reduce risk and retain an appropriate level of ownership of products currently in development. In addition, through alliances with other pharmaceutical and biotechnology companies, we may obtain funding, expand

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

existing programs, learn of new technologies, and gain additional expertise in developing and marketing products.

Abgenix, Inc.

During 2001, the PSMA development Company LLC, a joint venture between us and Progenics Pharmaceuticals, Inc. entered into an Agreement with Abgenix, Inc. regarding the development of fully human antibodies to PSMA using Abgenix's XenoMouse(TM) technology.

-8-

Advanced Magnetics, Inc.

In August 2000, Cytogen and Advanced Magnetics, Inc. mutually terminated a previously negotiated agreement pursuant to which Cytogen was to acquire Advanced Magnetics. Instead, the two companies entered into marketing, licensing and supply agreements (the "AVM Agreements"). Under the AVM Agreements, the Company acquired exclusive United States rights to two product candidates, Combidex and imaging agent Code 7228 for oncology applications. Combidex, a MRI contrast agent for the detection of lymph node metastases, received an approvable letter in June 2000 subject to certain conditions by the FDA, following a priority review. Code 7228 is being developed for oncology and magnetic resonance angiography applications and is expected to enter Phase II clinical development during this year. The Company has rights to Code 7228 for oncology applications only.

Under the terms of our License and Marketing Agreement with Advanced Magnetics, we issued to Advanced Magnetics, 2,000,000 shares of common stock. Of such 2,000,000 shares, 500,000 are being held in escrow pending the achievement of certain milestones relating to Combidex and Code 7228. The remaining 1,500,000 shares were transferred to Advanced Magnetics, subject to certain restrictions, with such restrictions expiring at a rate of 300,000 shares per month, each month after the effective date of the agreement.

The License and Marketing Agreement will continue until August 25, 2010, and shall thereafter automatically renew for successive five year renewal periods, unless notice of non-renewal or termination is given by us or Advanced Magnetics 90 days prior to the commencement of any renewal period, and unless and until terminated pursuant to the terms thereof.

There can be no assurance that Advanced Magnetics will receive FDA approval to market Combidex or Code 7228 in the United States.

AlphaVax

In 2001, the PSMA Development Company, LLC entered into a development and license agreement with AlphaVax to utilize their proprietary viral vector technology to deliver the PSMA gene systemically. This agreement contains both milestone and royalty payments. We believe that this technology, if successfully deployed, may have important advantages in targeting immune stimulating cells in vivo which impact on the progression of cancer.

Berlex Laboratories, Inc.

In October 1998, we entered into a License Agreement with Berlex Laboratories, Inc. regarding the marketing of Quadramet, a radiopharmaceutical product used to provide pain relief from cancer spreading to the bone. As consideration for the rights granted, Berlex Laboratories agreed to pay Cytogen royalties based on net sales, as defined in the Agreement.

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

This Agreement will expire twenty years from the date of execution or on the date of expiration of the last to expire, licensed patent, whichever is later.

Draxis Health, Inc.

In December 2000, we entered into a Product Manufacturing and Supply Agreement and a License and Distribution Agreement with Draxis to, among other things, market and distribute BrachySeed implants for prostate cancer therapy in the United States. Under the agreement, Draxis will supply radioactive iodine and palladium seeds to us in exchange for royalties on sales and certain milestone payments. The FDA granted marketing approval for BrachySeed in September 2000. We launched the radioactive iodine BrachySeed in the United States in February 2001. We expect to begin selling the palladium version of BrachySeed in the United States during the first half of 2002. We cannot be certain, however, of the market acceptance of these products or whether these products will significantly increase our revenues.

-9-

We agreed to pay Draxis an aggregate of \$2,000,000 in milestone payments, as follows: (i) \$500,000 upon the execution of the License and Distribution and the product manufacturing and supply agreement, (ii) \$500,000 upon the first sale, as defined therein, of iodine BrachySeed from Draxis to Cytogen, and (iii) \$1,000,000 upon the first sale, as defined therein, of palladium BrachySeed from Draxis to Cytogen. We have paid the first two milestone payments. The License and Distribution Agreement will expire on December 31, 2010, unless earlier terminated pursuant to the provisions thereof.

The Product Manufacturing and Supply Agreement, pursuant to which Draxis has agreed to manufacture and supply iodine and palladium BrachySeed to us, will terminate on December 31, 2010. We are currently negotiating a new manufacturing and supply agreement with Draxis. In the interim both parties are operating under the terms of the existing agreement.

Elan Corporation, plc

We entered into a license agreement granting Elan worldwide rights to a group of peptides and associated technology for orally administered drugs that are transported across the gastrointestinal epithelium, as well as rights to other orally delivered drugs derived from the research program. Elan is responsible for the further development and commercialization of this technology. We are entitled to royalties from sales of any product developed and commercialized based on this technology.

Memorial Sloan-Kettering Cancer Center

In 1993, we began a development program with Memorial Sloan-Kettering Cancer Center involving PSMA and our proprietary monoclonal antibody. In November 1996, we exercised an option for and obtained an exclusive worldwide license to this technology.

Molecular Staging, Inc.

We obtained an exclusive, world-wide license from privately held Molecular Staging, Inc. for technology to be used in developing in vitro diagnostic tests utilizing PSMA and PSA. We anticipate initiating a clinical trial of the PSA assay and determining proof of concept for the PSMA test during 2003.

Northwest Biotherapeutics, Inc.

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

We licensed PSMA through our subsidiary, Prostagin, Inc., to Northwest Biotherapeutics, Inc., for development of in vitro dendritic cell processing immunotherapy to prostate cancer. Prostagin also licensed exclusive PSMA manufacturing rights for immunotherapy to Northwest Clinicals, LLC, a corporation formed and co-owned by Northwest Biotherapeutics and Prostagin. In 2000, we executed a new sublicense agreement with Northwest Biotherapeutics Inc. clarifying their rights to make and use PSMA for ex vivo prostate cancer immunotherapy. The license agreement with Northwest Clinicals, LLC was terminated and the manufacturing rights thereunder returned to Cytogen except for those granted under the newly-executed license with respect to ex vivo immunotherapy.

Progenics Pharmaceuticals, Inc.

In 1999, we entered into a joint venture with Progenics Pharmaceuticals, Inc. to develop products utilizing our PSMA technology. The first of these products, currently under development, is a therapeutic prostate cancer vaccine utilizing a PSMA protein/adjuvant approach. Our current plans are that this approach, if successful in pre-clinical development, should proceed to human clinical trials in 2002. We are also developing through this venture antibody based immunotherapy for prostate cancer. We believe that these drugs, if successfully developed, could play an important role in the treatment or prevention of advanced prostate cancer and other cancers where PSMA is expressed (e.g. breast, colon, etc.).

The Dow Chemical Company

In March 1993, we obtained an exclusive license from The Dow Chemical Company to North American rights to use Quadramet as a therapeutic radiopharmaceutical for metabolic bone disease or tumor regression for cancer caused by metastatic or primary cancer in bone in humans, and for the treatment of disease characterized by osteoblastic response in humans. In November 1998, Dow also extended our exclusive rights for use of Quadramet in treating advanced rheumatoid arthritis to Europe, Japan and other countries in addition to North America.

### SIGNAL TRANSDUCTION INHIBITORS

#### Background

The last decade of research has led to an increased understanding of how cells communicate with each other to coordinate the growth and maintenance of the multitude of tissues within the human body. A key element of this communication network is the transmission of a signal from the exterior of a cell to its

-10-

interior, resulting in the activation of specific intracellular processes. Many such signaling pathways culminate in the nucleus, which results in the activation or suppression of specific genes. This process is called signal transduction. An integral part of signal transduction is the interaction of ligands, receptors and intracellular signal transduction molecules ("downstream signaling molecules").

In general terms, chemical messengers may be released by one cell to communicate with a target cell by binding to specific receptors on the target cell's surface. A receptor generally takes the form of a protein that straddles a cell's membrane, with its "ligand-binding domain" protruding out of the cell and its "intracellular domain" anchored inside the cell. When a ligand binds to its receptor, the newly formed receptor/ligand complex triggers the activation of a cascade of downstream signaling molecules, thereby transmitting the message from

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

the exterior of the cell to its interior. The intracellular response may take the form of various structural or biochemical alterations facilitating a specific response to the extracellular message. If the intracellular signal propagates to the nucleus, it dictates the activation or suppression of specific genes, resulting in the production of proteins that carry out a specific biological response. Depending on the specific ligand, receptor and downstream signaling molecules, the resulting signalling cascade controls diverse and distinct cellular processes. For example, metabolic changes can be effected by a ligand such as insulin, which, after binding to the insulin receptor, activates a specific set of downstream signaling molecules within the cell, ultimately leading to the regulation of glucose uptake and other insulin-associated functions.

Functional proteomics has proven to be an effective drug-discovery platform and mapping key signaling molecules in biochemical pathways will be central to future drug discovery efforts. Because of their link to disease, most major pharmaceutical and biotechnology companies have active drug discovery programs based on understanding signal transduction pathways.

The application of functional proteomics in signal transduction-based target identification and validation is an important area of research and development at present. Various genomic and proteomic approaches are contributing toward mapping signal transduction and linking it to disease, and this platform promises to have a very significant future in drug discovery.

### Drug discovery

The traditional drug discovery process involves testing or screening compounds in disease models. Researchers often engage in the process with little knowledge of the intracellular processes underlying the disease or the specific drug target within the cell. Thus, companies must screen a very large number of arbitrarily selected compounds to obtain a desired change in a disease model. While this approach sometimes produces drugs successfully, we believe it has the following limitations:

- inefficiency: it is capital intensive and time consuming in identifying and validating targets;
- low productivity: it yields relatively few new drug candidates;
- lack of information: it provides little information about the intracellular processes or targets, to guide target selection and subsequent drug development; and
- risk of side effects: it often results in drug candidates with a risk of serious side effects.

In an effort to overcome some of the difficulties associated with traditional drug discovery, some scientists have turned to genomics as a means of better understanding the roots of disease. These scientists believe that a comprehensive knowledge of an organism's genetic makeup may lead to more efficient drug discovery. While useful, DNA sequence analysis alone does not lead efficiently to new target identification, because one cannot easily infer the functions of gene products, or proteins, and protein pathways from DNA sequence.

Functional proteomic technologies offer significant opportunities to improve the drug discovery process. By focusing on protein activity levels, or expression levels, researchers are able to learn more about the role proteins play in causing and treating disease. Functional proteomics also aids in deciphering the mechanisms of disease and increasing both the opportunity to develop drugs with reduced side effects and an increased probability of clinical trial success. We



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

believe functional proteomics has the potential to increase substantially the number of drug targets and thereby the number of novel new drugs.

-11-

### DRUG DISCOVERY AND DEVELOPMENT PROCESS

Early Discovery..... Compound Discovery and Development.....

Target Identification	Target Validation	Screen Development	Primary Screening	Secondary Screening	Lead Compound Optimization	Pre-clinical Studies
-----------------------	-------------------	--------------------	-------------------	---------------------	----------------------------	----------------------

### OUR TECHNOLOGY IS AIMED AT ACCELERATING FOUR STEPS IN THE DRUG DISCOVERY AND DEVELOPMENT PROCESS.

We believe that target identification, validation and optimization may be facilitated by the use of AxCell's proprietary signal transduction pathway information and functional proteomics tools. We anticipate that this technology platform will allow identification of disease-related alterations in protein pathways by comparing protein pathways in cells and tissues associated with a disease model with pathways in normal tissue. We believe that this technology will also enable researchers to more efficiently identify potential drug targets.

We also develop high-throughput screens for drug development in cases where targets are proprietary to us. Customers may license these targets and receive the components necessary for a high-throughput screen.

Finally, we believe that we can accelerate lead compound optimization through the supply of related protein-component family members, or protein arrays. We believe that these protein arrays contain the proteins with which a researcher can test a lead compound for cross-protein interaction. Such cross-protein interactions may also represent the side effects which the lead compound might invoke. We believe that modifications of the structure of the lead compound followed by further testing with the target array will lead to more efficient lead compound optimization.

Our technology

Our core proteomics technology is based on an understanding of the principles of the binding, or molecular recognition, of antibodies to antigens. Through a sponsored research program at the University of North Carolina at Chapel Hill, coupled with our internal research, we studied the interactions between peptide ligands and proteins. This research led to a better understanding of protein-protein interactions, and ultimately to proprietary methods for identifying and quantifying such interactions. We have a portfolio of patents and patent applications based on inventions generated both internally and at the University of North Carolina at Chapel Hill, relating to methods for identification of proteins which interact in cellular pathways, and the compositions of such proteins. Certain patents and patent applications filed on behalf of the University of North Carolina at Chapel Hill are the subject of a worldwide, exclusive license to us. We established AxCell Biosciences Corporation as a subsidiary to harness the commercial potential of this proprietary platform technology in the area of proteomics.

We have developed several integrated, high-throughput technologies designed to determine protein pathways quickly and cost effectively. The identification of

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

protein pathways is a critical step in drug discovery.

-12-

[GRAPHIC OF TECHNOLOGY FLOW CHART OMITTED]

As part of functional signaling pathways, protein interaction is mediated through binding of a ligand sequence on one protein and a domain on another, similar to the relationship between a lock and a key. Domains are functional recognition sites on proteins where the actual interaction occurs with another protein. Ligands are the regions of the other proteins that interact with the domains. In the human proteome, domains are classified in families such as WW or PDZ.

As seen in the above illustration, we identify domain-ligand interactions through the use of proprietary phage display libraries. The process begins with a domain from a known protein family such as WW. A library of peptides, which are short sequences of amino acids (the building blocks of proteins), is exposed to this domain to identify those peptides that act as ligands and have binding affinity to the domain (Step 1).

We then use these ligands as probes to find other proteins that contain a domain which exhibits an affinity to the ligands. This technique identifies the complete family of domains that interacts with a set of ligands (Step 2). Once a set of ligands and domains are identified, we measure the strength of affinity between each domain and ligand (Step 3). These steps are repeated with all signaling domains and their corresponding ligands. This approach allows us to create the database of ligand-domain binding interactions and thus establish a functional relationship between the set of ligands and domains (Step 4).

Using this database and computational methods, or bioinformatics, we define the rules of interaction between domains and ligands. Using bioinformatic analyses, each interacting protein can be identified, and through ligand-domain pairing biological pathways can be constructed (Step 5). These biological pathways are analogous to a circuit diagram of intracellular communication.

Analyses of the aberrations in the interaction of proteins with one another can then be studied to identify those proteins that play a role in causing or preventing disease and can be targeted for drug development (Step 6).

Proprietary algorithm development

Through the use of our platform technologies described above and the data generated with them, we plan to develop proprietary modeling and characterization algorithms. In addition, we believe that ProChart contains comprehensive protein interaction and pathway data that we believe will allow the modeling and characterization of ligands using connections to the corresponding domains. We also plan to develop pathway models using the data in ProChart. AxCell's ProChart database content and functional proteomics tools are available on a non-exclusive basis to biotechnology, pharmaceutical and academic researchers. AxCell is expanding and accelerating its research activities to further elucidate the role of novel proteins and pathways in ProChart, through both external collaborations and internal data mining.

-13-

Our products, technologies and services

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

### ProChart

ProChart is a proprietary database of signal transduction pathway information, created using AxCell's patented, high-throughput technology, which differs from the most widely used method for identifying protein interactions, such as yeast two-hybrid. Using data contained in ProChart, researchers may be better able to design drugs that target pathways related to a specific disease while avoiding those pathways associated with unwanted side effects. ProChart allows drug discovery researchers to evaluate a large number of targets and select a logical subset for experimentation. ProChart became commercially available in June 2001, although subscriptions to the database have been limited to one customer that entered into a three-year, non-exclusive agreement and that will commence a research program with AxCell. To date, we have not generated any revenues from ProChart.

### Genetic Diversity Library (GDL(TM))

AxCell identifies domain-ligand interactions through the use of patented M13 phage libraries. Although GDL is specifically patented, AxCell maintains a license from Dyax Corporation for the general technique of phage display technology conducted in M13 bacteriophage. The difference between AxCell's GDL libraries and phage display library technology as applied by others is based on the unusually large inserts in the GDL libraries. While AxCell expresses the usual linear and cyclic oligopeptides, the Company has also created libraries containing inserts of 38- and 45mer linear and cyclic peptides. These longer inserts allow AxCell to study phenomena that depend on longer peptide sequences and the folded structures they can assume.

### Cloning of Ligand Targets (CLT(TM))

AxCell uses ligands in GDL and others identified using bioinformatics as probes to find other proteins that contain a domain, which exhibits binding affinity to the ligands. Using cloned DNA (cDNA) libraries, the CLT process identifies the complete family of domains that interacts with a set of ligands. CLT exploits the cross-reactive binding inherent in domain-ligand interactions to systematically identify novel domains. The expression and purification system to create protein domains at AxCell is the Glutathione-S-Transferase (GST) Gene Fusion System in E. coli. Occasionally, other expression and purification systems like Hexa-His or Maltose gene fusion systems are used. Domains range from about 30-120 amino acids in length. When fused with GST for expression they are about 22-40kDa in size.

### Affinity Screens

Once ligands and domains are identified, synthesized and cloned, they are screened using a high throughput screening (HTS) assay based on technology similar to ELISA. In it, domains are adsorbed to microplates, and subsequent binding of peptide ligands is detected by means of the N-terminal biotin included in the peptide ligand. After screening in this HTS format, a second assay is performed to generate a binding saturation curve. This second assay provides a quantitative measurement of binding strength for individual pairs of domain-ligand interactions. The GDL and CLT steps are repeated with all signaling domains and their corresponding ligands. This approach allows AxCell to create the ProChart database of ligand-domain binding interactions and thus establish a functional relationship between the set of ligands and domains. Using this database and computational methods, or bioinformatics, AxCell defines the rules of interaction between domains and ligands. This key feature of AxCell's technology allows researchers to evaluate relative binding strength of interactions in silico.

### Bioinformatics

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

Bioinformatics (BFX) is AxCell's most high throughput discovery technology. We apply algorithms developed by our BFX group to publicly available human proteomic data in order to identify previously uncharacterized binding domains and candidate ligand peptides for our "wet bench" operations, including HTS assays as well as GDL and CLT discovery technologies. Most of these algorithms are based on recognition of homology of uncharacterized sequence data to proteomic and genomic data from the peer-reviewed literature. AxCell searches public databases for such sequences and catalogs them for synthesis and use in its HTS assays.

### Peptide Synthesis

AxCell currently produces more than 1,000 synthetic peptide ligands per month. The consensus sequences provided by our BFX algorithms are generally only 1-4 amino acids in length. But in manufacturing our fragments of human proteins, we include 4 to 6 amino acids on either side of the consensus, in order to achieve appropriate specificity. Thus the ligands average approximately 12 amino acids.

-14-

With the addition of a spacer sequence and a biotin tag, the peptides achieve an average length of 17 amino acids total, with a range from 14-29 amino acids in length. In support of AxCell's high throughput parallel peptide synthesis, a high throughput method for validation and quantitation of synthetic peptides has been developed. This method includes automated LC-MS analysis, data processing, and sample purification steps.

### Marketing

We previously established a collaboration with InforMax, Inc., a publicly held bioinformatics provider. InforMax is a leader in the development of bioinformatics software for accelerated drug discovery and has a proven track record in software development. We are jointly designing an interface for ProChart with InforMax that will be integrated with InforMax's GenoMax (TM) product. GenoMax is a bioinformatics system that offers high-speed analysis of both public and proprietary genetic databases within the security of a corporate firewall. This system is designed to allow the subscriber to evaluate data in ProChart, while accessing other public and private databases. We have also developed an application programming interface for ProChart, to permit integration with other bioinformatics platforms, including those developed by the customers themselves. By taking advantage of an existing bioinformatic platform, we plan to concentrate our efforts on the development of tools specific to protein pathway data. InforMax will also market ProChart. InforMax has developed a Protein-Protein Interaction (PPI) module for the GenoMax enterprise bioinformational system, a modular platform of advanced analysis programs for genomic and proteomic applications, and successfully integrated ProChart.

We are marketing ProChart as multi-year subscriptions allowing access to ProChart inside the customers' corporate firewall. This subscription delivery is facilitated using InforMax's GenoMax product into which ProChart has been integrated. These subscriptions may include collaborative bioinformatics research projects to analyze specific pathways as requested by a customer. Such collaborations may provide additional revenues, and may also include milestone payments and royalty-based revenues from any products emerging from the collaborative research and developed by our partner.

### RESEARCH COLLABORATIONS

AxCell is currently negotiating a Cooperative Research and Development Agreement with the National Cancer Institute (NCI) to research two major signal

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

transduction families and how they impact signaling pathways within cells, which could lead to the development of new drugs to treat cancer and other diseases. Under the terms of the agreement, relevant data resulting from this collaboration will be added to AxCell's ProChart database of protein interaction information. The research at the NCI will be led by Stephen Shaw, M.D., chief of the Human Immunology Section at the Experimental Immunology Branch of the NCI. Dr. Shaw is an immunologist who has been primary or senior author on more than 150 scientific publications and is a recipient of the Institute for Scientific Information Highly Cited Researchers award.

AxCell entered into a Research Collaboration Agreement with Mount Sinai School of Medicine to research protein interactions in the WW protein domain family, which is believed to play a role in the development of muscular dystrophy and neurodegenerative diseases, such as Alzheimer's disease. The principal goals of the research program will be to research the binding of ligands to the WW domain of dystrophin, utrophin, beta-dystroglycan, FE65 and FE65-like proteins, which could accelerate drug discovery for muscular dystrophy and certain neurodegenerative diseases. The collaboration will use specific data from AxCell's ProChart database, which includes the first and only complete map of the known WW protein domain family. The WW protein domain family is the first of approximately 60-80 protein domain families involved in signal transduction to be mapped successfully. The collaboration will be led by Marius Sudol, Ph.D., associate professor in the Medicine Department at the Mount Sinai School of Medicine in New York.

AxCell signed a letter of intent with Kimmel Cancer Center at Thomas Jefferson University to research protein interactions associated with an undisclosed gene believed to play a role as a tumor suppressor in multiple cancers. Upon execution of the final agreement, the research will be led by Kay Huebner,

-15-

Ph.D., professor of microbiology and immunology at Jefferson Medical College and Carlo Croce, M.D., professor and chair of microbiology and immunology at Jefferson Medical College of Thomas Jefferson University in Philadelphia and director of Jefferson's Kimmel Cancer Center. Dr. Huebner's laboratory focuses on finding and studying genes that are frequently altered in cancers, and whose alteration, usually leading to loss of expression of the encoded protein, contributes to development and progression of the cancers.

AxCell signed a binding term sheet with Pluvita Corporation for a pilot program to research protein interactions associated with a specific protein-based drug target. Upon execution of the final agreement, the principal goals of the pilot research program will be to identify the full-length peptides (amino acid chains) that bind to Pluvita's compound; identify apparent consensus sequences; and analyze the representation of those sequences within the human proteome. AxCell will also determine apparent affinities of compound binding observed with the isolated peptides. Based on current expectations, the research program with Pluvita will not begin until late 2002. In addition to this research program, Pluvita Corporation entered into a three-year, non-exclusive agreement to use AxCell's ProChart in a range of drug discovery initiatives.

Our proteomics patents and proprietary rights position

Overall, our patent strategy has focused on composition and use of the proteins and peptides which we are discovering, thus avoiding the uncertainty and controversy associated with the patenting of genes. We believe such composition and use claims should be important because we believe it is likely that proteins rather than genes will be the targets for new drugs. This strategy has resulted in eleven patents.

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

Among our patents are two issued U.S. patents relating to peptides that bind to certain molecules expressed on cancer cells. We also co-own with the University of North Carolina at Chapel Hill an issued U.S. patent covering certain polypeptides that contain a WW domain U.S. Patent No. 6,309,820 was issued to AxCell in 2001, entitled "Polypeptides Having a Functional Domain of Interest and Methods of Identifying and Using Same," for our proprietary Cloning of Ligand Targets(TM) (CLT) proteomics technology.

We will market our protein targets under arrangements that we anticipate would include licensing fees, milestone payments and royalty payments as our customers develop products based on these targets. We plan to market protein arrays under a license for use and, where possible, obtain commitments for milestone payments and royalty-based payments if the arrays contain novel protein targets proprietary to us.

We intend to pursue aggressively patent protection for novel synthetic peptides and novel naturally occurring polypeptides that we identify as binding to ligands of interest, as well as for products and methods relating to the use of these polypeptides and their respective genes as possible drug targets in screening assays. We also intend to seek patent protection for methods and products relating to our data analysis procedures.

We are the exclusive licensee of certain patents and patent applications owned by the University of North Carolina at Chapel Hill, covering parts of the proteomics technology. These include eight issued U.S. patents relating to our phage display libraries, methods of using phage display libraries to identify peptides that bind to a target molecule of interest, as well as peptides that bind to certain molecules.

### Competition

We are subject to significant and increasing competition in the field of proteomics. Many companies compete in the overall effort to understand the complex flow from gene sequence, to transcription into messenger ribonucleic acid, to protein expression and finally to biological activity. In addition, most major pharmaceutical and biotechnology companies have some level of internal activity and high interest in these areas.

The technology for analyzing the functions of proteins in a disease setting, and for mapping interactions between proteins, is relatively new. This technology is evolving rapidly and developments by competitors, including potential customers, could make our technology obsolete. A number of companies compete with our approach to analyzing the proteome, and others compete with our technology for identification of novel proteins and use of proteins for possible drug targets.

Of the several approaches used commercially to analyze the proteome, the main direct competitor with our technology is the yeast two-hybrid system. Three companies, Myriad Genetics, Inc. (NASDAQ: MYGN), CuraGen Corporation (NASDAQ: CRGN) and Hybrigenics Inc. use this method to perform large-scale cataloging of protein-protein interactions.

AxCell believes that its in vitro approach to detecting protein pathways is complimentary to yeast two-hybrid and other functional proteomics technologies. AxCell's in vitro approach offers the following synergies: simplicity, higher throughput data generation, quantitative protein interaction affinity measurement, fewer false positives, the rapid formatting of high-throughput screening assays, and the identification of specific ligands, which provide a starting point for rational drug design.

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

The marriage of AxCell's high throughput domain-ligand interaction technology (and the resulting ProChart database) and yeast two-hybrid technology offers an opportunity for significant synergy. AxCell's technology rapidly yields maps of protein-to-protein interactions based upon in vitro measurements. On a selected basis, key interactions could be validated using yeast two-hybrid methods to show that these interactions do indeed occur using an in vivo model.

### Strategic alliances

#### InforMax, Inc.

In September 1999, AxCell and InforMax, Inc. concluded an agreement to market ProChart as part of an enterprise bioinformatics solution to the pharmaceutical and biotechnology industries. The three year agreement also provides for technology development by InforMax to link our database to InforMax's GenoMax, a new generation of molecular biology and genetics software. In February 2001, AxCell and InforMax announced the development of the Protein-Protein Interaction (PPI) module for the GenoMax enterprise bioinformatics system and successfully integrated ProChart, AxCell's growing database of human protein interactions. AxCell has developed technology that provides both qualitative and quantitative information about a wide range of protein-protein interactions. The integration of ProChart with GenoMax was demonstrated publicly for the first time at the CHI Genome Tri-Conference in San Francisco, CA, in March of 2001.

#### Compaq Computer Corporation

In December 1999, AxCell entered into a developer partnership with Compaq Computer Corporation. This development program will be facilitated by Compaq's proven Alpha architecture, high performance 64-bit systems that deliver speed and scalability advantages. Under the agreement, Compaq has provided us with hardware for the development of our proteomics database. In December 2000, AxCell furthered its strategic relationship with Compaq, adding additional hardware provided by Compaq to continue the development of ProChart. Due to increasing laboratory data output, AxCell's computing requirements have more than doubled and Compaq's AlphaServer cluster technology facilitated the required expansion.

#### University of North Carolina

We sponsored research at, and are the exclusive licensee of certain patent and patent applications and technology owned by the University of North Carolina at Chapel Hill, covering the creation of long peptides that may fold to form three-dimensional functional structures, and of libraries composed of these peptides. The technology covered by this collaboration has been utilized, with other technology we developed, in our proteomics program.

### PRODUCT CONTRIBUTION TO REVENUES

Our currently marketed products and other sources of income constitute a single business segment. ProstaScint and Quadramet account for a significant percentage of our product-related revenues. For the years ended December 31, 2001, 2000 and 1999, revenues related to ProstaScint accounted for approximately 65%, 66% and 57%, respectively, of our total revenues while revenues related to Quadramet accounted for approximately 18%, 19% and 9%, respectively, of our total revenues.

### RESEARCH AND DEVELOPMENT

Our research and development expenditures include payments we made to customer sponsored research programs, the costs incurred to develop PSMA through our joint venture with Progenics Pharmaceuticals, payments to DSM Biologics for the

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

development and manufacture of ProstaScint and the cost to develop the functional proteomics program at AxCell. Our expenses for research and development activities were:

- 2001-- \$ 10.3 million
- 2000 -- \$7.0 million
- 1999 -- \$3.8 million

-17-

We intend to pursue research and development activities having commercial potential and to review all of our programs to determine whether possible market opportunities, near and longer term, provide an adequate return to justify the commitment of human and economic resources to their initiation or continuation. We incurred a significant increase of \$3.3 million in our research and development expenditures during 2001. We expect to incur a significant amount of expenses in future years for our share of the development of immunotherapies for prostate and other cancers through our joint venture with Progenics. During 2001, we recognized \$332,000 of expenses related to the joint venture with Progenics, \$3.2 million for the DSM development program and \$4.9 million for the proteomics program at AxCell.

### COMPETITION

The biotechnology and pharmaceutical industries are subject to intense competition, including competition from large pharmaceutical companies, biotechnology companies and other companies, universities and research institutions. Our existing therapeutic products compete with the products of a wide variety of other firms, including firms that provide products used in more traditional treatments or therapies, such as external beam radiation, chemotherapy agents and narcotic analgesics. In addition, our existing and potential competitors may be able to develop technologies that are as effective as, or more effective than those offered by us, which would render our products noncompetitive or obsolete. Moreover, many of our existing and potential competitors have substantially greater financial, marketing, sales, manufacturing, distribution and technological resources than we do. Our existing and potential competitors may be in the process of seeking FDA or foreign regulatory approval for their respective products or may also enjoy substantial advantages over us in terms of research and development expertise, experience in conducting clinical trials, experience in regulatory matters, manufacturing efficiency, name recognition, sales and marketing expertise and distribution channels. We believe that competition for our products is based upon several factors, including product efficacy, safety, cost-effectiveness, ease of use, availability, price, patent position and effective product promotion.

We expect competition to intensify in the fields in which we are involved as technical advances in such fields are made and become more widely known. We cannot assure you, however, that we or our collaborative partners will be able to develop our products successfully or that we will obtain patents to provide protection against competitors. Moreover, we cannot assure you that our competitors will not succeed in developing therapeutic products that circumvent our products or that these competitors will not succeed in developing technologies or products that are more effective than those developed by us. Notably, Nycomed-Amersham, a company with substantially greater resources than ours, is dominant in brachytherapy. In addition, many of these companies may have more experience in establishing third-party reimbursement for their products. Accordingly, we cannot assure you that we will be able to compete



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

effectively against existing or potential competitors or that competition will not have a material adverse effect on our business, financial condition and results of operations.

### MANUFACTURING

Our products must be manufactured in compliance with regulatory requirements and at commercially acceptable costs. ProstaScint and OncoScint CR/OV were manufactured at a current good manufacturing practices, or cGMP, compliant manufacturing facility in Princeton, New Jersey which is operated by Bard BioPharma L.P., a subsidiary of Purdue BioPharma ("Purdue"). An Establishment License Application for the facility was approved by the FDA for the manufacture of ProstaScint in October 1996 and for OncoScint CR/OV in December 1992. Our manufacturing agreement with Purdue expired in January 2002. In July 2000, we entered into a Development and Manufacturing Agreement with DSM Biologics Company B.V. ("DSM"), pursuant to which DSM will conduct certain development activities with respect to ProstaScint for testing and evaluation purposes. Our intention is that DSM would replace the arrangement with Purdue, with respect to the manufacture of ProstaScint. Under the terms of such agreement, and subject to the regulatory approvals for the manufacturing of ProstaScint, the parties are obligated to negotiate in good faith a long term supply agreement. Notwithstanding the parties' obligations to perform under the agreement or to negotiate a supply agreement in good faith, we cannot be certain that DSM will satisfactorily perform its obligations thereunder or that the parties will be able to negotiate a supply agreement on commercially satisfactory terms, if at all. Our failure to negotiate a supply agreement on commercially reasonable terms will have a material adverse effect on our business, financial condition and results of operations. At December 31, 2001 we have sufficient level of ProstaScint inventory on hand for 2 years while working to secure a supply arrangement for ProstaScint.

With regard to OncoScint CR/OV, we have a sufficient level of inventory on hand for the foreseeable future.

-18-

Any new manufacturing arrangement will be subject to FDA oversight, and qualification of a new manufacturer with the FDA could take a significant amount of time. Any failure to obtain such regulatory approvals will have a material adverse effect on our business, financial condition and results of operations.

### Raw materials and suppliers

The active raw materials used for the manufacture of our products include antibodies. We anticipate that our existing supply of OncoScint CR/OV will be able to meet our needs for commercial quantities of the product for the foreseeable future. We are de-emphasizing the marketing of this product.

We do not have arrangements with any outside suppliers for the monoclonal antibody for ProstaScint. This material will be supplied by the same third party manufacturer that will make ProstaScint. We are currently working to secure such an arrangement.

Quadramet is manufactured by DuPont pursuant to an agreement with both Berlex and Cytogen. Some components of Quadramet, particularly Samarium153 and EDTMP, are provided to DuPont by outside suppliers. DuPont obtains its requirements for Samarium153 from one supplier. Alternative sources for these components may not be readily available. If DuPont cannot obtain sufficient quantities of the components on commercially reasonable terms, or in a timely manner, it would be unable to manufacture Quadramet on a timely and cost-effective basis which could have a material adverse effect on our business, financial condition and results

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

of operations.

Pursuant to the terms of our Product Manufacturing and Supply Agreement with Draxis, we rely on Draxis as the sole supplier of BrachySeed, a second-generation radioactive pellet used in the treatment of prostate cancer. If Draxis fails or is unable to perform under such agreement, we could experience a material adverse effect on our business, financial condition and results of operations.

### PATENTS AND PROPRIETARY RIGHTS

Consistent with industry practice, we have a policy of using patent and trade secret protection to preserve our right to exploit the results of our research and development activities and, to the extent it may be necessary or advisable, to exclude others from appropriating our proprietary technology.

Our policy is to aggressively protect our proprietary technology by selectively seeking patent protection in a worldwide program. In addition to the United States, we file patent applications in Canada, major European countries, Japan and additional foreign countries on a selective basis to protect inventions important to the development of our business. We believe that the countries in which we have obtained and are seeking patent coverage for our proprietary technology represent the major focus of the pharmaceutical industry in which we and certain of our licensees will market our respective products.

We hold, or are the licensee of, 41 current United States patents and 45 current foreign patents. We have filed and currently have pending a number of additional United States and foreign patent applications, relating to certain aspects of our technology for diagnostic and therapeutic products, and the methods for their production and use. We intend to file patent applications with respect to subsequent developments and improvements, when we believe such protection is in our best interest.

We are the exclusive licensee of certain patents and patent applications owned by the University of North Carolina at Chapel Hill, covering parts of the proteomics technology. These include eight issued United States patents relating to our phage display libraries, methods of using phage display libraries to identify peptides that bind to a target molecule of interest, as well as peptides that bind to certain molecules. We hold an exclusive license under certain patents and patent applications held by the Memorial Sloan-Kettering Institute covering PSMA. We are the exclusive licensee of certain United States patents and applications held by Dow covering Quadramet.

Among our patents are two issued United States patents relating to peptides that bind to certain molecules expressed on cancer cells. We also co-own with the University of North Carolina at Chapel Hill an issued United States patent covering certain polypeptides that contain a WW domain.

We may be entitled under certain circumstances to seek extension of the terms of our patents.

-19-

We also rely upon, and intend to continue to rely upon, trade secrets, unpatented proprietary know-how and continuing technological innovation to develop and maintain our competitive position. We typically enter into confidentiality agreements with our licensees and any scientific consultants, and each of our employees has entered into agreements requiring that they forbear from disclosing confidential information, and in some cases assign to us all rights in any inventions made while in our employ. We believe that our valuable proprietary information is protected to the fullest extent practicable;

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

however, we cannot assure you that:

- additional patents will be issued to us in any or all appropriate jurisdictions;
- litigation will not be commenced seeking to challenge our patent protection or that challenges will not be successful;
- our processes or products do not or will not infringe upon the patents of third parties; or
- the scope of patents issued will successfully prevent third parties from developing similar and competitive products.

The technology applicable to our products is developing rapidly. A substantial number of patents have been issued to other biotechnology companies. In addition, competitors have filed applications for, or have been issued, patents and may obtain additional patents and proprietary rights relating to products or processes that are competitive with ours. In addition, others may have filed patent applications and may have been issued patents to products and to technologies potentially useful to us or necessary to commercialize our products or to achieve our business goals. We cannot assure you that we will be able to obtain licenses of patents on acceptable terms.

We cannot predict how any patent litigation will affect our efforts to develop, manufacture or market our products.

We are defendants in litigation filed against us in the United States Federal Court for the District of New Jersey with respect to claims that our ProstaScint product infringes a third-party patent and we have disclosed certain information regarding such lawsuit under the caption "Legal Proceedings", herein.

### GOVERNMENT REGULATION AND PRODUCT TESTING

The development, manufacture and sale of medical products utilizing our technology are governed by a variety of statutes and regulations in the United States and by comparable laws and agency regulations in most foreign countries.

The Food, Drug and Cosmetic Act requires that our products be manufactured in FDA registered facilities subject to inspection. The manufacturer must be in compliance with current Good Manufacturing Practice (cGMP) which imposes certain procedural and documentation requirements upon us and our manufacturing partners with respect to manufacturing and quality control activities. Noncompliance with cGMP can result in, among other things, fines, injunctions, civil penalties, recalls or seizures of products, total or partial suspension of production, failure of the government to grant premarket clearance or premarket approval for drugs, withdrawal of marketing approvals and criminal prosecution. Any failure by us or our manufacturing partners to comply with the requirements of cGMP could have a material adverse effect on our business, financial condition and results of operations.

Diagnostic and therapeutic products in the United States are regulated by the Food Drug and Cosmetic Act and the Public Health Service Act, and by FDA rules and regulations promulgated thereunder. These laws and regulations require carefully controlled research and testing of products, government notification, review and/or approval prior to marketing the products, inspection and/or licensing of manufacturing and production facilities, adherence to cGMP, compliance with product specifications, labeling, and other applicable regulations.

Medical products that we develop or intend to market are subject to substantial governmental regulation and may be classified as new drugs or biologics under

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

the Food Drug and Cosmetic Act. The FDA and similar health authorities in most other countries must approve or license the diagnostic and therapeutic products before they can be commercially marketed. In order to obtain FDA approval, an applicant must submit, as relevant for the particular product, proof of safety, purity, potency and efficacy. In most cases this proof entails extensive pre-clinical, clinical and laboratory studies. Both the studies and the preparation and prosecution of those applications by the FDA are expensive and time consuming, and each may take several years to complete. Difficulties or unanticipated costs may be encountered by us or our licensees in their respective efforts to secure necessary governmental approval or licenses, which could delay or preclude us or our licensees from marketing their products.

-20-

Limited indications for use or other conditions could also be placed on any approvals that could restrict the commercial applications of products. With respect to patented products or technologies, delays imposed by the government approval process may materially reduce the period during which we will have the exclusive right to exploit them, because patent protection lasts only for a limited time, beginning on the date the patent is first granted in the case of United States patent applications filed prior to June 6, 1995, and when the patent application is first filed in the case of patent applications filed in the United States after June 6, 1995, and applications filed in the European Economic Community. We intend to seek to maximize the useful life of our patents under the Patent Term Restoration Act of 1984 in the United States and under similar laws if available in other countries.

The majority of our diagnostic and therapeutic products will likely be classified as new drugs or biologics and will be evaluated in a series of in vitro, non-clinical and human clinical testing. Typically, clinical testing is performed in three phases to further evaluate the safety and efficacy of the drug. In Phase I, a product is tested in a small number of patients primarily for safety at one or more dosages. Phase II evaluates, in addition to safety, the efficacy of the product against particular diseases in a patient population that is generally somewhat larger than Phase I. Clinical trials of certain diagnostic and cancer therapeutic agents frequently combine Phase I and Phase II into a single Phase I/II study. In Phase III, the product is evaluated in a larger patient population sufficient to generate data to support a claim of safety and efficacy within the meaning of the Food Drug and Cosmetic Act. Permission by the FDA must be obtained before clinical testing can be initiated within the United States. This permission is obtained by submission of an Investigational New Drug application which typically includes the results of in vitro and non-clinical testing and any previous human testing done elsewhere. The FDA has 30 days to review the information submitted and makes a final decision whether to permit clinical testing with the drug or biologic. However, this process can take longer if the FDA raises questions or asks for additional information regarding the Investigational New Drug application. A similar procedure applies to medical device and diagnostic products.

After completion of in vitro, non-clinical and clinical testing, authorization to market a drug or biologic must be granted by FDA. The FDA grants permission to market through the review and approval of either a New Drug Application for drugs or a Biologic License Application for biologics. These applications provide detailed information on the results of the safety and efficacy of the drug conducted both in animals and humans. Additionally, information is submitted describing the facilities and procedures for manufacturing the drug or biologic.

The Prescription Drug User Fee Act and subsequently, the Food and Drug Administration Modernization Act of 1997 have established application review times for both New Drug Applications and Biologic License Applications. For the

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

majority of new drugs and biologics, FDA is to review and make a recommendation for approval within 12 months. For drugs and biologics designated as "priority," the review time is six months. This review process, however, can and frequently does exceed these targets.

Once a drug or biologic is approved, we are required to maintain approval status of the products by providing certain updated safety and efficacy information at specified intervals. Additionally, we are required to meet other requirements specified by the Food Drug and Cosmetic Act including but not limited to the manufacture of products, labeling and promotional materials and the maintenance of other records and reports. Failure to comply with these requirements or the occurrence of unanticipated safety effects from the products during commercial marketing, could lead to the need for product recall, or FDA initiated action, which could delay further marketing until the products are brought into compliance. Similar laws and regulations apply in most foreign countries where these products are likely to be marketed.

### Orphan Drug Act

The Orphan Drug Act is intended to provide incentives to manufacturers to develop and market drugs for rare diseases or conditions affecting fewer than 200,000 persons in the United States at the time of application for orphan drug designation. A drug that receives orphan drug designation and is the first product to receive FDA marketing approval for a particular indication is entitled to orphan drug status, a seven-year exclusive marketing period in the United States for that indication. Clinical testing requirements for orphan drugs are the same as those for products that have not received orphan drug designation. OncoScint CR/OV has received an orphan drug designation for the detection of ovarian carcinoma. Under the Orphan Drug Act, the FDA cannot approve any application by another party to market an identical product for treatment of an identical indication unless the party has a license from the holder of orphan drug status, or the holder of orphan drug status is unable to assure an adequate supply of the drug. However, a drug that is considered by FDA to be different from a particular orphan drug is not barred from sale in the United States during the seven-year exclusive marketing period even if it receives marketing approval for the same product claim.

-21-

### Fraud and Abuse

We are subject to various federal and state laws pertaining to health care fraud and abuse, including anti-kickback laws and physician self-referral laws. Violations of these laws are punishable by criminal and/or civil sanctions, including, in some instances, imprisonment and exclusion from participation in federal and state health care programs, including Medicare, Medicaid and VA health programs. Because of the far-reaching nature of these laws, there can be no assurance that the occurrence of one or more violations of these laws would not result in a material adverse effect on our financial condition and results of operations.

**Anti-Kickback Laws.** Our operations are subject to federal and state anti-kickback laws. Certain provisions of the Social Security Act, that are commonly known collectively as the Medicare Fraud and Abuse Statute, prohibit entities, such as us, from offering, paying, soliciting or receiving any form of remuneration in return for the referral of Medicare or state health program patients or patient care opportunities, or in return for the recommendation, arrangement, purchase, lease or order of items or services that are covered by Medicare or state health programs. Violation of the Medicare Fraud and Abuse Statute is a felony, punishable by fines up to \$25,000 per violation and imprisonment for up to five years. In addition, the Department of Health and

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

Human Services may impose civil penalties of up to \$50,000 per act plus three times the remuneration offered and exclude violators from participation in Medicare or state health programs. Many states have adopted similar prohibitions against payments intended to induce referrals to Medicaid and other third party payor patients.

Physician Self-Referral Laws. We are also subject to federal and state physician self-referral laws. Federal physician self-referral legislation (known as the Stark law) prohibits, subject to certain exceptions, a physician or a member of his immediate family from referring Medicare or Medicaid patients to an entity providing "designated health services" in which the physician has an ownership or investment interest, or with which the physician has entered into a compensation arrangement. The Stark law also prohibits the entity receiving the referral from billing any good or service furnished pursuant to an unlawful referral. The penalties for violations include a prohibition on payment by these government programs and civil penalties of as much as \$15,000 for each violative referral and \$100,000 for participation in a circumvention scheme." Various state laws also contain similar provisions and penalties.

False Claims Laws. Under separate statutes, submission of claims for payment that are "not provided as claimed" may lead to civil money penalties, criminal fines and imprisonment, and/or exclusion from participation in Medicare, Medicaid and other federally funded state health programs. These false claims statutes include the Federal False Claims Act, which allows any person to bring suit alleging false or fraudulent Medicare or Medicaid claims or other violations of the statute and to share in any amounts paid by the entity to the government in fines or settlement. Such suits, known as qui tam actions, have increased significantly in recent years causing greater numbers of health care companies to have to defend a false claim action, pay fines or be excluded from the Medicare, Medicaid or other federal or state health care programs as a result of any investigation arising out of such action.

### Other regulations

In addition to regulations enforced by FDA, we are also subject to regulation under the state and local authorities and other federal statutes and agencies including the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and the Nuclear Regulatory Commission.

### Foreign regulatory approval

The regulatory approval process in Europe has changed over the past few years. There are two regulatory approval processes in Europe for products developed by us. Beginning in 1995, the centralized procedure became mandatory for all biotechnology products. Under this regulatory scheme, the application is reviewed by two scientific project leaders referred to as the rapporteur and co-rapporteur, respectively. Their roles are to prepare assessment reports of safety and efficacy and for recommending the approval for full European Union marketing.

The second regulatory scheme, referred to as the Mutual Recognition Procedure, is a process whereby a product's national registration in one member state within the European Union may be "mutually recognized" by other member states within the European Union.

Substantial requirements, comparable in many respects to those imposed under the

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

Food Drug and Cosmetic Act, will have to be met before commercial sale is permissible in most countries. There can be no assurance, however, as to whether or when governmental approvals, other than those already obtained, will be obtained or as to the terms or scope of those approvals.

### HEALTH CARE REIMBURSEMENT

Our business, financial condition and results of operations will continue to be affected by the efforts of governments and third-party payors to contain or reduce the costs of healthcare through various means. There have been, and we expect that there will continue to be, federal and state proposals to implement government control of pricing and profitability of therapeutic and diagnostic imaging agents. In addition, an increasing emphasis on managed care has and will continue to increase the pressure on pricing of these products. While we cannot predict whether legislative or regulatory proposals will be adopted or the effects proposals or managed care efforts may have on our business, the announcement of proposals and the adoption of proposals or efforts could have a material adverse effect on our business, financial condition and results of operations. Further, to the extent proposals or efforts have a material adverse effect on other companies that are our prospective corporate partners, our ability to establish strategic alliances may be materially and adversely affected. In certain foreign markets, the pricing and profitability of our products generally are subject to government controls.

Sales of our products depend in part on the availability of reimbursement to the consumer from third-party payors, including Medicare, Medicaid, and private health insurance plans. Third-party payors are increasingly challenging the prices charged for medical products and services. To the extent we succeed in bringing products to market, we cannot assure you that these products will be considered cost-effective and that reimbursement to consumers will be available or sufficient to allow us to sell our products on a competitive basis. Reimbursement by a third-party payor may depend on a number of factors, including the payor's determination that our products are clinically useful and cost-effective, medically necessary and not experimental or investigational. Since reimbursement approval is required from each payor individually, seeking approvals can be a time consuming and costly process which could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to each payor separately. If we or our collaborators are unable to secure adequate third party reimbursement for our products, there would be material adverse effect on its business, financial condition and results of operations.

### CUSTOMERS

During the year ended December 31, 2001, we received 63% of our total revenues from four customers, Berlex Laboratories, Inc. (20%) and the radiopharmacy chains of Mallinckrodt Medical, Inc. (20%), Medi-Physics (12%) and Syncor International Corporation (11%).

### EMPLOYEES

As of March 1, 2002, we employed 74 persons, 73 of which are employed full-time and 1 part-time. Of such 74 persons, 26 were in our proteomics subsidiary, AxCell, 1 in regulatory, 5 in clinical activities, 15 in administration and management, and 27 in marketing and sales. We believe that we have been successful in attracting skilled and experienced employees. None of our employees is covered by a collective bargaining agreement. All of our employees have executed confidentiality agreements. We consider relations with our employees to be excellent.

### ADDITIONAL FACTORS THAT MAY AFFECT FUTURE RESULTS

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

Investing in the Company's Common Stock involves a high degree of risk. You should carefully consider the following risks and uncertainties described below together with the other information included or incorporated by reference in this Annual Report on Form 10-K in your decision as to whether to invest in our Common Stock. If any of the following risks or uncertainties actually occur, our business, financial condition and operating results could be significantly and adversely affected. If that happens, the price of our Common Stock could decline, and you could lose all or part of your investment.

We Have A History Of Operating Losses And An Accumulated Deficit And Expect To Incur Losses In The Future.

We have a history of operating losses since our inception. We had a net loss of \$12.1 million for the year ended December 31, 2001. We had a net loss of \$27.3 million for the year ended December 31, 2000 which included one-time, non-cash charges of \$13.1 million for the acquisition of product candidate rights and \$4.3 million for the cumulative effect of an accounting change following the adoption of Securities and Exchange Commission Staff Accounting Bulletin No. 101. We had net income of \$729,000 for the year ended December 31, 1999 which

-23-

included a \$3.3 million non-operating gain. We had an accumulated deficit of \$340.7 million as of December 31, 2001. In order to develop and commercialize our technologies, particularly our functional proteomics program and our prostate specific membrane antigen, or PSMA, technology, and expand our oncology products, we expect to incur significant increases in our expenses over the next several years. As a result, we may need to generate significant additional revenue to become profitable.

Our ability to generate and sustain significant additional revenues or achieve profitability will depend upon the factors discussed elsewhere in this "Risk Factors" Section, as well as numerous other factors outside of our control, including:

- development of competing products that are more effective or less costly than ours;
- our ability to develop and commercialize our own products and technologies; and
- our ability to achieve increased sales for our existing products and sales for any new products.

As a result, we may never be able to generate or sustain significant additional revenue or achieve profitability.

We Are Heavily Dependent On Market Acceptance Of ProstaScint, Quadramet and BrachySeed For Near-Term Revenues.

We expect ProstaScint and Quadramet to account for a significant percentage of our product-related revenues in the near future. For the year ended December 31, 2001, revenues from ProstaScint and Quadramet accounted for approximately 89% of our product related revenues.

Because these products contribute the majority of our product-related revenues, our business, financial condition and results of operations depend on their acceptance as safe, effective and cost-efficient alternatives to other available treatment and diagnostic protocols by the medical community, including:

- health care providers, such as hospitals and physicians; and



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

- third-party payors, including Medicare, Medicaid, private insurance carriers and health maintenance organizations.

Our customers, including technologists and physicians, must successfully complete our Partners in Excellence Program, or PIE Program, a proprietary training program designed to promote the correct acquisition and interpretation of ProstaScint images. This product is technique dependent and requires a learning commitment on the part of users. We cannot assure you that additional technologist's and physicians will make this commitment or otherwise accept this product as part of their treatment practices.

Berlex Laboratories, Inc. markets Quadramet in the United States through an agreement with us entered into in October 1998. We cannot assure you that Berlex will be able to successfully market Quadramet or that this agreement will result in significant revenues for us. We recently obtained marketing rights to Quadramet in Canada, but have not yet implemented a selling program. We cannot assure you that Quadramet can be marketed effectively in Canada, or that it will contribute significantly to our revenues.

We cannot assure you that Quadramet will be approved for additional indications, due to uncertainty as to efficacy or safety for other purposes, regulatory obstacles and physician preferences for existing or competing practices.

Accordingly, we cannot assure you that ProstaScint, Quadramet or BrachySeed will achieve market acceptance on a timely basis, or at all. If ProstaScint, Quadramet or BrachySeed do not achieve broader market acceptance, we may not be able to generate sufficient revenue to become profitable.

Our Functional Proteomics Program Is At An Early Stage Of Development.

We are developing a functional proteomics program. This technology involves new approaches to drug research and development and remains commercially unproven. Our technology and development focus is primarily directed toward offering an infrastructure to companies for the development of drugs to treat a variety of complex human diseases. There is limited understanding generally relating to the role of proteins in diseases, and few products based on protein interaction discoveries have been developed and commercialized. Even if our proteomics

-24-

program is successful in identifying and validating biological targets, there is no certainty that we or our customers will be able to develop or commercialize products to improve human health. We have developed and intend to continue to develop a proteomics program. This technology involves new approaches to drug research and development and remains commercially unproven. Our technology and development focus is primarily directed toward offering an infrastructure to companies for the development of drugs to treat a variety of complex human diseases. There is limited understanding generally relating to the role of proteins in diseases, and few products based on protein interaction discoveries have been developed and commercialized. Even if our proteomics program is successful in identifying and validating biological targets, there is no certainty that we or our customers will be able to develop or commercialize products to improve human health.

Our technology program for proteomics is still in the early stages of development. We may not be able to populate our ProChart with information that is useful to potential customers in a timely manner. Even if we complete and develop successfully our proteomics technology, the technology may not be accepted by, or be useful to, our potential customers.

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

In addition, the success of our proteomics technology will depend upon our ability to use software tools to generate data that relates protein signaling pathways to a variety of other bioinformatic data. Because of the complexity of this data, we may not be able to detect and remedy any design defects or software errors in our existing or future technologies, including databases.

We may not be successful in addressing or mitigating these risks and uncertainties, and, if we are not, our business could be significantly and adversely affected.

### There Is A Limited Market For Our Functional Potential Proteomics Products

Due to the specialized nature and anticipated cost of our proteomics technology and services, there are a limited number of pharmaceutical and biotechnology companies that are potential customers. In addition, demand for our functional proteomics technology and services is limited because:

- our potential customers may decide to conduct in-house research rather than subscribe to our ProChart database;
- our competitors may offer similar services at competitive prices;
- we may not be able to service satisfactorily the needs of our potential or actual customers;
- others may publicly disclose or patent proprietary information contained in our ProChart (including information related to protein signaling pathways or target candidates) or relating to prostate antigens or antibodies; and
- technological innovations may be discovered that are more advanced than those used by or available to us.

We may not be successful in addressing or mitigating these risks and uncertainties, and, if we are not, our business could be significantly and adversely affected.

### We Have Experienced Fluctuating Results Of Operations.

Our results of operations have fluctuated on an annual and quarterly basis and may fluctuate significantly from period to period in the future, due to, among other factors:

- variations in revenue from sales of and royalties from our products;
- timing of regulatory approvals and other regulatory announcements relating to our products;
- variations in our marketing, manufacturing and distribution channels;
- timing of the acquisition and successful integration of complementary products and technologies;
- timing of new product announcements and introductions by us and our competitors; and

-25-

- product obsolescence resulting from new product introductions by us or our competitors.

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

Many of these factors are outside our control. Due to one or more of these factors, our results of operations may fall below the expectations of securities analysts and investors in one or more future quarters. If this happens, the market price of our Common Stock could decline.

We May Need To Raise Additional Capital Which May Not Be Available.

We have incurred negative cash flows from operations since inception. We expended, and will need to continue to expend, substantial funds to complete our planned product development efforts, including our proteomics and PSMA programs. Our future capital requirements and the adequacy of our available funds depend on many factors, including:

- successful commercialization of our products;
- acquisition of complementary products and technologies;
- magnitude, scope and results of our product development efforts;
- progress of preclinical studies and clinical trials;
- progress toward regulatory approval for our products;
- costs of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights;
- competing technological and market developments; and
- expansion of strategic alliances for the sale, marketing and distribution of our products.

We may raise additional capital through public or private equity offerings, debt financings or additional collaborations and licensing arrangements. Additional financing may not be available to us when needed, or, if available, we may not be able to obtain financing on terms favorable to us or our stockholders. If we raise additional capital by issuing equity securities, the issuance will result in ownership dilution to our stockholders. If we raise additional funds through collaborations and licensing arrangements, we may be required to relinquish rights to certain of our technologies or product candidates or to grant licenses on unfavorable terms. If we relinquish rights or grant licenses on unfavorable terms, we may not be able to develop or market products in a manner that is profitable to us. If adequate funds are not available, we may not be able to conduct research activities, preclinical studies, clinical trials or other activities relating to the successful commercialization of our products on a timely basis, if at all, with the result that our business could be significantly and adversely affected.

Our Products, Generally, Are In The Early Stages Of Development And Commercialization And We May Never Achieve The Revenue Goals Set Forth In Our Business Plan.

We began operations in 1980 and have been engaged primarily in research directed toward the development, commercialization and marketing of products to improve diagnosis and treatment of cancer and other diseases. In December 1992, we introduced for commercial use our OncoScint imaging agent. In October 1996, we introduced for commercial use our ProstaScint imaging agent. In March 1997, we introduced for commercial use our Quadramet therapeutic product. In 2001, we launched BrachySeed. These products have not yet achieved significant commercial success. In 1998, we undertook a restructuring to focus on the development of our PSMA and proteomics technologies as well as the marketing of these existing products.

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

Our PSMA and proteomics technologies are still in the early stages of development. We have only recently begun to incorporate our proteomics technology into commercialized products. We may be unable to continue to successfully develop or commercialize these products and technologies.

-26-

Our business is therefore subject to the risks inherent in the development of an early stage biopharmaceutical business enterprise, such as the need:

- to obtain sufficient capital to support the expenses of developing our technology and commercializing our products;
- to ensure that our products are safe and effective;
- to obtain regulatory approval for the use and sale of our products;
- to manufacture our products in sufficient quantities and at a reasonable cost;
- to develop a sufficient market for our products; and
- to attract and retain qualified management, sales, technical and scientific staff.

The problems frequently encountered using new technologies and operating in a competitive environment also may affect our business. If we fail to properly address these risks and attain our business objectives, our business could be significantly and adversely affected.

Our PSMA Product Development Program Is Novel And, Consequently, Inherently Risky.

We are subject to the risks of failure inherent in the development of product candidates based on new technologies, including our PSMA technology. These risks include the possibility that:

- the technologies we use will not be effective;
- our product candidates will be unsafe;
- our product candidates will fail to receive the necessary regulatory approvals;
- the product candidates will be hard to manufacture on a large scale or will be uneconomical to market; and
- we will not successfully overcome technological challenges presented by our potential new products.

Our objectives include developing our PSMA technology into novel cancer therapeutics, including a cancer vaccine. To our knowledge, no therapeutic cancer vaccine has been demonstrated effective or approved for marketing. Our other research and development programs involve similarly novel approaches to human therapeutics. Consequently, there is no precedent for the successful commercialization of therapeutic products based on our PSMA technologies. We cannot assure you that any products will be successfully developed from our PSMA technology. If we fail to develop such products for the reasons set forth above or for any other reason, our business could be significantly and adversely

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

affected.

All of Our Potential Oncology Products Will Be Subject To The Risks Of Failure Inherent In The Development Of Diagnostic Or Therapeutic Products Based On New Technologies.

Product development for cancer treatment involves a high degree of risk. We cannot assure you that the product candidates we develop, pursue or offer will prove to be safe and effective, will receive the necessary regulatory approvals, will not be precluded by proprietary rights of third parties or will ultimately achieve market acceptance. These product candidates will require substantial additional investment, laboratory development, clinical testing and regulatory approvals prior to their commercialization. We cannot assure you that we will not experience difficulties that could delay or prevent the successful development, introduction and marketing of new products.

Before we obtain regulatory approvals for the commercial sale of any of our products under development, we must demonstrate through preclinical studies and clinical trials that the product is safe and efficacious for use in each target indication. The results from preclinical studies and early clinical trials may not be predictive of results that will be obtained in large-scale testing. We cannot assure you that our clinical trials will demonstrate the safety and efficacy of any products or will result in marketable products. A number of companies in the biotechnology industry have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. Clinical trials or marketing of any potential diagnostic or therapeutic products

-27-

may expose us to liability claims for the use of these diagnostic or therapeutic products. We may not be able to maintain product liability insurance or sufficient coverage may not be available at a reasonable cost. In addition, as we develop diagnostic or therapeutic products internally, we will have to make significant investments in diagnostic or therapeutic product development, marketing, sales and regulatory compliance resources. We will also have to establish or contract for the manufacture of products, including supplies of drugs used in clinical trials, under the current Good Manufacturing Practices of the FDA. We also cannot assure you that product issues will not arise following successful clinical trials and FDA approval.

The rate of completion of clinical trials also depends on the rate of patient enrollment. Patient enrollment depends on many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites and the eligibility criteria for the study. Delays in planned patient enrollment may result in increased costs and delays, which could have a harmful effect on our ability to develop the products in our pipeline. If we are unable to develop and commercialize products on a timely basis or at all, our business could be significantly and adversely affected.

Competition In Our Field Is Intense And Likely To Increase.

We face, and will continue to face, intense competition from one or more of the following entities:

- pharmaceutical companies;
- biotechnology companies;
- bioinformatics companies;
- diagnostic companies;

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

- academic and research institutions; and
- government agencies.

All of our lines of business are subject to significant competition from organizations that are pursuing technologies and products that are the same as or similar to our technology and products. Many of the organizations competing with us have greater capital resources, research and development staffs and facilities and marketing capabilities.

Before we recover development expenses for our products and technologies, the products or technologies may become obsolete as a result of technological developments by us or others. Our products could also be made obsolete by new technologies which are less expensive or more effective. We may not be able to make the enhancements to our technology necessary to compete successfully with newly emerging technologies and failure to do so could significantly and adversely affect our business.

We Rely Heavily On Our Collaborative Partners.

Our success depends in significant part upon the success of our collaborative partners. We have entered into the following agreements for the sale, marketing, distribution and manufacture of our products, product candidates and technologies:

- license from The Dow Chemical Company relating to the Quadramet technology;
- sub-license and marketing agreement with Berlex Laboratories, Inc. relating to the Quadramet technology which we licensed from The Dow Chemical Company;
- agreement for manufacture of Quadramet by The DuPont Pharmaceuticals Company (formerly the radiopharmaceuticals division of The DuPont Merck Company);
- marketing and platform development agreement with InforMax, Inc. related to our proteomics program;
- joint venture with Progenics Pharmaceuticals for the development of PSMA for in vivo immunotherapy for prostate and other cancers;

-28-

- licensing agreement with Molecular Staging for technology to be used in developing in vitro diagnostic tests using PSMA and prostate specific antigen, or PSA;
- marketing and distribution agreement with Draxis Health, Inc. and its subsidiary, Draximage, Inc. to market and distribute BrachySeed; and
- marketing, license and supply agreements with Advanced Magnetics, Inc. related to our oncology product line for products currently subject to regulatory approval.

Because our collaborative partners are responsible for certain of our sales, marketing, manufacturing and distribution activities, these activities are outside our direct control. We cannot assure you that our partners will perform their obligations under these agreements with us. In the event that our collaborative partners do not successfully market and sell our products or

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

breach their obligations under our agreements, our products may not be commercially successful, any success may be delayed and new product development could be inhibited with the result that our business could be significantly and adversely affected.

Our Business Could Be Harmed If Our Collaborative Arrangements Expire Or Are Terminated Early.

We cannot assure you that we will be able to maintain our existing collaborative arrangements. If they expire or are terminated, we cannot assure you that they will be renewed or that new arrangements will be available on acceptable terms, if at all. In addition, we cannot assure you that any new arrangements or renewals of existing arrangements will be successful, that the parties to any new or renewed agreements will perform adequately or that any former or potential collaborators will not compete with us.

We cannot assure you that our existing or future collaborations will lead to the development of product candidates or technologies with commercial potential, that we will be able to obtain proprietary rights or licenses for proprietary rights for our product candidates or technologies developed in connection with these arrangements or that we will be able to ensure the confidentiality of proprietary rights and information developed in such arrangements or prevent the public disclosure thereof.

The Termination Of One Or More License Agreements That Are Important In The Manufacture Of Our Current Products And New Product Research And Development Activities Would Harm Our Business.

We are a party to license agreements under which we have rights to use technologies owned by other companies in the manufacture of our products and in our proprietary research, development and testing processes. We are the exclusive licensee of certain patents and patent applications held by the University of North Carolina at Chapel Hill covering part of the technology used in the proteomics program and of certain patents and patent applications held by the Memorial Sloan-Kettering Institute covering PSMA. We also depend upon the enforceability of our license with The Dow Chemical Company with respect to Quadramet. If the licenses were terminated, we may not be able to find suitable alternatives to this technology on a timely basis or on reasonable terms, if at all. The loss of the right to use these technologies that we have licensed would significantly and adversely affect our business.

We Have Limited Sales, Marketing And Distribution Capabilities For Our Products.

We have only recently established a sales force and have limited internal sales, marketing and distribution capabilities for our products. We depend on Berlex Laboratories, Inc. for the sale, marketing and distribution of Quadramet in the United States. In locations outside the United States, we have not established a selling presence. If we are unable to establish and maintain significant sales, marketing and distribution efforts, either internally or through arrangements with third parties, our business may be significantly and adversely affected.

There Are Risks Associated With The Manufacture And Supply Of Our Products.

If we are to be successful, our products will have to be manufactured through third-party manufacturers in compliance with regulatory requirements and at costs acceptable to us. We cannot assure you that we will be able to arrange for the manufacture of our products on commercially reasonable terms. If we are unable to successfully arrange for the manufacture of our products and product candidates, we will not be able to successfully commercialize our products and our business will be significantly and adversely affected.

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

ProstaScint and OncoScint CR/OV are manufactured at a cGMP compliant manufacturing facility operated by Purdue. We have access to the facility for continued manufacturing of these products until January 2002. We expect that this facility will allow us to meet our projected production requirements for ProstaScint and OncoScint CR/OV in the short term. We entered into a Development and Manufacturing Agreement with DSM which we intend would replace the arrangement with Purdue with respect to ProstaScint and OncoScint CR/OV prior to January 2002. Notwithstanding the parties obligations to perform under the agreement with DSM or to negotiate a supply agreement in good faith, we cannot be certain that DSM will satisfactorily perform its obligations thereunder or that the parties will be able to negotiate a supply agreement on commercially reasonable terms, if at all. Our failure to negotiate a long term supply agreement on commercially reasonable terms will have a material adverse effect on our business, financial condition and results of operations.

Quadramet is manufactured by DuPont pursuant to an agreement with both Berlex and Cytogen. Some components of Quadramet, particularly Samarium153 and EDTMP, are provided to DuPont by outside suppliers. Due to radioactive decay, Samarium153 must be produced on a weekly basis. DuPont obtains its requirements for Samarium153 from one supplier. Alternative sources for these components may not be readily available. If DuPont cannot obtain sufficient quantities of the components on commercially reasonable terms, or in a timely manner, it would be unable to manufacture Quadramet on a timely and cost-effective basis which could have a material adverse effect on our business, financial condition and results of operations.

We rely on Draxis as the sole supplier of BrachySeed. If Draxis fails to or is unable to timely supply BrachySeed, we could experience a material adverse effect on our business, financial condition and results of operations.

We and our third-party manufacturers are required to adhere to United States Food & Drug Administration regulations setting forth requirements for current Good Manufacturing Practices, or cGMP, and similar regulations in other countries, which include extensive testing, control and documentation requirements. Ongoing compliance with cGMP, labeling and other applicable regulatory requirements are monitored through periodic inspections and market surveillance by state and federal agencies, including the FDA, and by comparable agencies in other countries. Failure of our third-party manufacturers or us to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of the government to grant premarket clearance or premarket approval of drugs, delays, suspension or withdrawal of approvals, seizures or recalls of products, operating restrictions and criminal prosecutions any of which could significantly and adversely affect our business.

Failure Of Consumers To Obtain Adequate Reimbursement From Third-Party Payors Could Limit Market Acceptance And Affect Pricing Of Our Products.

Our business, financial condition and results of operations will continue to be affected by the efforts of governments and other third-party payors to contain or reduce the costs of healthcare. There have been, and we expect that there will continue to be, a number of federal and state proposals to implement government control of pricing and profitability of therapeutic and diagnostic imaging agents such as our products. In addition, an emphasis on managed care increases possible pressure on pricing of these products. While we cannot predict whether these legislative or regulatory proposals will be adopted, or the effects these proposals or managed care efforts may have on our business, the announcement of these proposals and the adoption of these proposals or efforts could affect our stock price or our business. Further, to the extent these proposals or efforts have an adverse effect on other companies that are



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

our prospective corporate partners, our ability to establish necessary strategic alliances may be harmed.

Sales of our products depend in part on reimbursement to the consumer from third-party payors, including Medicare, Medicaid and private health insurance plans. Third-party payors are increasingly challenging the prices charged for medical products and services. We cannot assure you that our products will be considered cost-effective and that reimbursement to consumers will continue to be available, or will be sufficient to allow us to sell our products on a competitive basis. Approval of our products for reimbursement by a third-party payor may depend on a number of factors, including the payor's determination that our products are clinically useful and cost-effective, medically necessary and not experimental or investigational. Reimbursement is determined by each payor individually and in specific cases. The reimbursement process can be time consuming. If we cannot secure adequate third-party reimbursement for our products, our business could be significantly and adversely affected.

-30-

If We Are Unable To Comply With Applicable Governmental Regulations, We May Not Be Able To Continue Our Operations.

Any products tested, manufactured or distributed by us or on our behalf pursuant to FDA clearances or approvals are subject to pervasive and continuing regulation by numerous regulatory authorities, including primarily the FDA. We may be slow to adapt, or we may never adapt to changes in existing requirements or adoption of new requirements or policies. Our failure to comply with regulatory requirements could subject us to enforcement action, including product seizures, recalls, withdrawal of clearances or approvals, restrictions on or injunctions against marketing our products based on our technology, and civil and criminal penalties. We cannot assure you that we will not be required to incur significant costs to comply with laws and regulations in the future or that laws or regulations will not create an unsustainable burden on our business.

Numerous federal, state and local governmental authorities, principally the FDA, and similar regulatory agencies in other countries, regulate the preclinical testing, clinical trials, manufacture and promotion of any compounds or agents we or our collaborative partners develop, and the manufacturing and marketing of any resulting drugs. The drug development and regulatory approval process is lengthy, expensive, uncertain and subject to delays.

The regulatory risks we face also include the following:

- any compound or agent we or our collaborative partners develop must receive regulatory agency approval before it may be marketed as a drug in a particular country;
- the regulatory process, which includes preclinical testing and clinical trials of each compound or agent in order to establish its safety and efficacy, varies from country to country, can take many years and requires the expenditure of substantial resources;
- in all circumstances, approval of the use of previously unapproved radioisotopes in certain of our products requires approval of either the Nuclear Regulatory Commission or equivalent state regulatory agencies. A radioisotope is an unstable form of an element which undergoes radioactive decay, thereby emitting radiation which may be used, for example, to image or destroy harmful growths or tissue. We cannot assure you that such approvals will be obtained on a timely basis, or at all;

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

- data obtained from preclinical and clinical activities are susceptible to varying interpretations which could delay, limit or prevent regulatory agency approval; and
- delays or rejections may be encountered based upon changes in regulatory agency policy during the period of drug development and/or the period of review of any application for regulatory agency approval. These delays could adversely affect the marketing of any products we or our collaborative partners develop, impose costly procedures upon our activities, diminish any competitive advantages we or our collaborative partners may attain and adversely affect our ability to receive royalties.

We cannot assure you that, even after this time and expenditure, regulatory agency approvals will be obtained for any compound or agent developed by or in collaboration with us. Moreover, regulatory agency approval for a drug or agent may entail limitations on the indicated uses that could limit the potential market for any such drug. Furthermore, if and when such approval is obtained, the marketing, manufacture, labeling, storage and record keeping related to our products would remain subject to extensive regulatory requirements. Discovery of previously unknown problems with a drug, its manufacture or its manufacturer may result in restrictions on such drug, manufacture or manufacturer, including withdrawal of the drug from the market. Failure to comply with regulatory requirements could result in fines, suspension of regulatory approvals, operating restrictions and criminal prosecution.

The United States Food, Drug and Cosmetics Act requires (i) that our products be manufactured in FDA registered facilities subject to inspection, and (ii) that we comply with cGMP, which imposes certain procedural and documentation requirements upon us and our manufacturing partners with respect to manufacturing and quality assurance activities. If we or our manufacturing partners do not comply with cGMP we may be subject to sanctions, including fines, injunctions, civil penalties, recalls or seizures of products, total or partial suspension of production, failure of the government to grant premarket clearance or premarket approval for drugs, withdrawal of marketing approvals and criminal prosecution.

-31-

We Could Be Negatively Impacted By Future Interpretation Or Implementation Of Federal And State Fraud And Abuse Laws, Including Anti-kickback Laws, The Federal Stark Law And Other Federal And State Anti-referral Laws.

We are subject to various federal and state laws pertaining to health care fraud and abuse, including anti-kickback laws and physician self-referral laws. Violations of these laws are punishable by criminal and/or civil sanctions, including, in some instances, imprisonment and exclusion from participation in federal and state health care programs, including Medicare, Medicaid and Veterans Administration health programs. We have not been challenged by a governmental authority under any of these laws and believe that our operations are in compliance with such laws. However, because of the far-reaching nature of these laws, we may be required to alter one or more of our practices to be in compliance with these laws. Health care fraud and abuse regulations are complex and even minor, inadvertent irregularities in submissions can potentially give rise to claims that the statute has been violated. Any violations of these laws could result in a material adverse effect on our business, financial condition and results of operations. If there is a change in law, regulation or administrative or judicial interpretations, we may have to change our business practices or our existing business practices could be challenged as unlawful, which could have a material adverse effect on our business, financial condition

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

and results of operations.

We could become subject to false claims litigation under federal statutes, which can lead to civil money penalties, criminal fines and imprisonment, and/or exclusion from participation in Medicare, Medicaid and other federal and state health care programs. These false claims statutes include the False Claims Act, which allows any person to bring suit alleging false or fraudulent Medicare or Medicaid claims or other violations of the statute and to share in any amounts paid by the entity to the government in fines or settlement. Such suits, known as qui tam actions, have increased significantly in recent years and have increased the risk that a health care company will have to defend a false claim action, pay fines or be excluded from the Medicare program, Medicaid programs or other federal and state health care programs as a result of an investigation arising out of such action. We cannot assure you that we will not become subject to such litigation or, if we are not successful in defending against such actions, that such actions will not have a material adverse effect on our business, financial condition and results of operations.

We Depend On Attracting And Retaining Key Personnel.

We are highly dependent on the principal members of our management and scientific staff. The loss of their services might significantly delay or prevent the achievement of development or strategic objectives. Our success depends on our ability to retain key employees and to attract additional qualified employees. Competition for personnel is intense, and we cannot assure you that we will be able to retain existing personnel or attract and retain additional highly qualified employees in the future.

We have an employee retention agreement with our President and Chief Executive Officer, H. Joseph Reiser, Ph.D., which provides for vesting of stock options for the purchase of shares of our Common Stock based on continued employment and on the achievement of performance objectives defined by the board of directors. We do not have similar retention agreements with its other key personnel. If we are unable to hire and retain personnel in key positions, our business could be significantly and adversely affected unless qualified replacements can be found.

Our Business Exposes Us To Potential Liability Claims That May Exceed Our Financial Resources, Including Our Insurance Coverage, And May Lead To The Curtailment Or Termination Of Our Operations.

Our business is subject to product liability risks inherent in the testing, manufacturing and marketing of our products. We cannot assure you that product liability claims will not be asserted against us, our collaborators or our licensees. While we currently maintain product liability insurance in amounts we believe are adequate, we cannot assure you that such coverage will be adequate to protect us against future product liability claims or that product liability insurance will be available to us in the future on commercially reasonable terms, if at all. Furthermore, we cannot assure you that we will be able to avoid significant product liability claims and adverse publicity. If liability claims against us exceed our financial resources we may have to curtail or terminate our operations.

Our Business Involves Environmental Risks That May Result In Liability.

We are subject to a variety of local, state, federal and foreign government regulations relating to storage, discharge, handling, emission, generation, manufacture and disposal of toxic, infectious or other hazardous substances used to manufacture our products. If we fail to comply with these regulations, we could be liable for damages, penalties or other forms of censure and our business could be significantly and adversely affected.

Our Intellectual Property Is Difficult To Protect.

Our business and competitive positions are dependent upon our ability to protect our proprietary technology. Because of the substantial length of time and expense associated with development of new products, we, like the rest of the biopharmaceutical industry, place considerable importance on obtaining and maintaining patent and trade secret protection for new technologies, products and processes. We have filed patent applications for our technology for diagnostic and therapeutic products and the methods for its production and use.

The patent positions of pharmaceutical, biopharmaceutical and biotechnology companies, including us, are generally uncertain and involve complex legal and factual questions. Our patent applications may not protect our technologies and products because, among other things:

- there is no guarantee that any of our pending patent applications will result in issued patents;
- we may develop additional proprietary technologies that are not patentable;
- there is no guarantee that any patents issued to us, our collaborators or our licensors will provide a basis for a commercially viable product;
- there is no guarantee that any patents issued to us or our collaborators will provide us with any competitive advantage;
- there is no guarantee that any patents issued to us or our collaborators will not be challenged, circumvented or invalidated by third parties; and
- there is no guarantee that any patents previously issued to others or issued in the future will not have an adverse effect on our ability to do business.

In addition, patent law in the technology fields in which we operate is uncertain and still evolving, and we cannot assure you as to the degree of protection that will be afforded any patents we are issued or license from others. Furthermore, we cannot assure you that others will not independently develop similar or alternative technologies, duplicate any of our technologies, or, if patents are issued to us, design around the patented technologies developed by us. In addition, we could incur substantial costs in litigation if we are required to defend ourselves in patent suits by third parties or if we initiate such suits. We cannot assure you that, if challenged by others in litigation, the patents we have been issued, or which have been assigned or have been licensed from others will not be found invalid. We cannot assure you that our activities would not infringe patents owned by others. Defense and prosecution of patent matters can be expensive and time-consuming and, regardless of whether the outcome is favorable to us, can result in the diversion of substantial financial, managerial and other resources. An adverse outcome could:

- subject us to significant liability to third parties;
- require us to cease any related research and development activities and product sales; or
- require us to obtain licenses from third parties.

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

We cannot assure you that any licenses required under any such third-party patents or proprietary rights would be made available on commercially reasonable terms, if at all. Moreover, the laws of certain countries may not protect our proprietary rights to the same extent as the laws of the United States. We cannot predict whether us or our competitors' pending patent applications will result in the issuance of valid patents which may significantly and adversely affect our business.

We Cannot Be Certain That Our Security Measures Protect Our Unpatented Proprietary Technology.

We also rely upon trade secret protection for some of our confidential and proprietary information that is not subject matter for which patent protection is available. To help protect our rights, we require all employees, consultants, advisors and collaborators to enter into confidentiality agreements that require disclosure, and in most cases, assignment to us, of their ideas, developments, discoveries and inventions, and that prohibit the disclosure of confidential

-33-

information to anyone outside Cytogen or our subsidiaries. We cannot assure you, however, that these agreements will provide adequate protection for our trade secrets, know-how or other proprietary information or prevent any unauthorized use or disclosure.

We Are Currently Subject To Patent Litigation.

We are a defendant in a lawsuit filed against us in the United States Federal Court for the District of New Jersey by M. David Goldenberg and Immunomedics, Inc. This lawsuit was filed on March 16, 2000. The litigation claims that our ProstaScint product infringes a patent purportedly owned by Dr. Goldenberg and licensed to Immunomedics. The patent sought to be enforced in the litigation has now expired. As a result, the claim, even if successful, would not result in a bar of the continued sale of ProstaScint or affect any other of our products or technology. However, given the uncertainty associated with litigation, we cannot give any assurance that the litigation will not result in a material expenditure to us.

If We Make Any Acquisitions, We Will Incur A Variety Of Costs And May Never Realize The Anticipated Benefits.

If appropriate opportunities become available, we may attempt to acquire businesses, technologies, services or products that we believe are a strategic fit with our business. We currently have no commitments or agreements with respect to any acquisitions. If, however, we do undertake any transaction of this sort, the process of integrating an acquired business, technology, service or product may result in operating difficulties and expenditures and may absorb significant management attention that would otherwise be available for ongoing development of our business. Moreover, we may never realize the anticipated benefits of any acquisition. Future acquisitions could result in potentially dilutive issuances of equity securities, the incurrence of debt, contingent liabilities and amortization expenses related to intangible assets. These factors could adversely affect our results of operations and financial condition, which could cause a decline in the market price of our Common Stock.

Our Stock Price Has Been And May Continue To Be Volatile, And Your Investment In Our Stock Could Decline In Value.

The market prices for securities of biotechnology and pharmaceutical companies have historically been highly volatile, and the market has from time to time experienced significant price and volume fluctuations that are unrelated to the

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

operating performance of particular companies. The market price of our Common Stock has fluctuated over a wide range and may continue to fluctuate for various reasons, including, but not limited to, announcements concerning our competitors or us regarding:

- results of clinical trials;
- technological innovations or new commercial products;
- changes in governmental regulation or the status of our regulatory approvals or applications;
- changes in earnings;
- changes in health care policies and practices;
- developments or disputes concerning proprietary rights;
- litigation or public concern as to safety of the our potential products; and
- changes in general market conditions.

We Have Adopted Various Anti-Takeover Provisions Which May Affect The Market Price Of Our Common Stock.

Our Board of Directors has the authority, without further action by the holders of Common Stock, to issue from time to time, up to 5,400,000 shares of preferred stock in one or more classes or series, and to fix the rights and preferences of the preferred stock. Pursuant to these provisions, we have implemented a stockholder rights plan by which one preferred stock purchase right is attached to each share of Common Stock, as a means to deter coercive takeover tactics and to prevent an acquirer from gaining control of us without some mechanism to secure a fair price for all of our stockholders if an acquisition was completed. These rights will be exercisable if a person or group acquires beneficial ownership of 20% or more of our Common Stock and can be made exercisable by action of our board of directors if a person or group commences a tender offer which would result in such person or group beneficially owning 20% or more of

-34-

our Common Stock. Each right will entitle the holder to buy one one-thousandth of a share of a new series of our junior participating preferred stock for \$20. If any person or group becomes the beneficial owner of 20% or more of our Common Stock (with certain limited exceptions), then each right not owned by the 20% stockholder will entitle its holder to purchase, at the right's then current exercise price, common shares having a market value of twice the exercise price. In addition, if after any person has become a 20% stockholder, we are involved in a merger or other business combination transaction with another person, each right will entitle its holder (other than the 20% stockholder) to purchase, at the right's then current exercise price, common shares of the acquiring company having a value of twice the right's then current exercise price.

We are subject to provisions of Delaware corporate law which, subject to certain exceptions, will prohibit us from engaging in any "business combination" with a person who, together with affiliates and associates, owns 15% or more of our Common Stock for a period of three years following the date that the person came to own 15% or more of our Common Stock unless the business combination is approved in a prescribed manner.

These provisions of the stockholder rights plan, our certificate of

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

incorporation, and of Delaware law may have the effect of delaying, deterring or preventing a change in control of Cytogen, may discourage bids for our Common Stock at a premium over market price and may adversely affect the market price, and the voting and other rights of the holders, of our Common Stock.

A Large Number Of Our Shares Are Eligible For Future Sale Which May Adversely Impact The Market Price Of Our Common Stock.

A large number of shares of our common stock are already outstanding, issuable upon exercise of options and warrants, or the achievement of certain milestones under previously completed acquisitions and may be eligible for resale, which may adversely affect the market price of our common stock. As of March 1, 2002 we had 82,011,156 shares of common stock outstanding, which number of shares: (i) includes an aggregate of 2,417 shares of common stock to be issued to prior holders of securities of CytoRad Incorporated and Cellcor, Inc., which we acquired in 1995, upon each such holders respective exchange of such securities; (ii) excludes 500,000 shares of common stock previously issued by us and currently held in escrow pending release, upon certain conditions, to Advanced Magnetics, who currently maintains voting control of such securities; and (iii) excludes 355,497 shares previously issued by us and currently held for issuance by the custodian of our Employee Stock Purchase Plan to the participants thereunder, in the event they elect to purchase such shares. An additional 4,855,929 shares of common stock are issuable upon the exercise of outstanding stock options and an additional 393,630 shares of common stock are issuable upon the exercise of outstanding warrants. Substantially all of such shares subject to outstanding options and warrants will, when issued upon exercise thereof, be available for immediate resale in the public market pursuant to either a currently effective registration statement under the Securities Act of 1933 (the "Securities Act"), as amended, or pursuant to Rule 144 or Rule 701 promulgated thereunder. In addition, there are 1,091,827 additional shares of common stock reserved for future issuance under our current stock options plans, 154,363 additional shares of common stock reserved for issuance under our 401(k) Plan and 227,518 additional shares of common stock reserved for the future issuance under our employee bonus plan. All such reserved shares have been registered with the Securities and Exchange Commission pursuant to currently effective Registration Statements. In addition, there are 929,757 additional shares of common stock, subject to certain adjustments, reserved for future issuance in connection with the issuance of a convertible promissory note, having a seven (7) year maturity, to ELAN Corporation, plc in August 1998.

In connection with our acquisition of Prostagin, Inc. in June 1999, we issued 2,050,000 unregistered shares of our common stock to the then stockholders of Prostagin, which shares may be sold from time to time pursuant to Rule 144 under the Securities Act. Such stockholders also have certain piggyback registration rights with respect to these shares of common stock. An additional 950,000 shares may be issued as contingent payment upon the happening of certain events and up to \$4.0 million worth of Cytogen common stock may be issued if certain milestones are achieved in the dendritic cell therapy and PSMA development programs.

In addition, on March 28, 2000, we filed with the Securities and Exchange Commission a shelf registration statement on Form S-3 covering six million (6,000,000) shares of our common stock. 1,500,000 of such registered shares were issued to Advanced Magnetics, Inc. in connection with the parties entering into a License and Marketing Agreement in August 2000. An additional 500,000 of the shares registered on that Form S-3 are currently being held in escrow and may be released to Advanced Magnetics in the future in accordance with the terms of such License and Marketing Agreement. An additional 902,601 of the shares registered on that form S-3 were issued to Acqua Wellington North American Equities Fund, Ltd. on September 29, 2000 in a private placement transaction. An additional 1,276,557 of the shares registered on that Form S-3 were issued to Acqua Wellington on February 5, 2001 pursuant to an equity financing facility

-35-

with Acqua Wellington that was subsequently terminated. An additional 1,820,000 of the shares registered on that Form S-3 were issued to the State of Wisconsin Investment Board on June 19, 2001 in a private placement transaction. We are contractually obligated to maintain the effectiveness of such registration statement.

On October 25, 2001, we filed with the Securities and Exchange Commission a shelf registration statement on Form S-3 covering ten million (10,000,000) shares of our common stock. 2,970,665 of such registered shares were issued to the State of Wisconsin Investment Board in another private placement transaction in January 2002.

Availability of a significant number of additional shares of our common stock could depress the price of our common stock.

Because We Do Not Intend to Pay Any Cash Dividends On Our Shares of Common Stock, Our Stockholders Will Not Be Able to Receive a Return on Their Shares Unless They Sell Them.

We have never paid or declared any cash dividends on our Common Stock or other securities and intend to retain any future earnings to finance the development and expansion of our business. We do not anticipate paying any cash dividends on our Common Stock in the foreseeable future. Unless we pay dividends, our stockholders will not be able to receive a return on their shares unless they sell them.

Our Stock Price Is Highly Volatile, And Therefore The Value Of Your Investment May Fluctuate Significantly.

The market price of our Common Stock has fluctuated and may continue to fluctuate as a result of variations in our business and our quarterly operating results. These fluctuations may be exaggerated if the trading volume of our Common Stock is low. In addition, the stock market in general has experienced dramatic price and volume fluctuations from time to time. These fluctuations may or may not be based upon any business or operating results. Our Common Stock may experience similar or even more dramatic price and volume fluctuations which may continue indefinitely. Please see Item 5 herein, Market for the Company's Common Equity and Related Stockholder Matters, for additional information on the volatility of our Common Stock.

#### Item 2. Properties

We currently lease approximately 20,000 square feet of administrative space in Princeton, New Jersey. The lease on this space expires in August 2002. We intend to remain in Princeton, New Jersey for the foreseeable future and are reviewing our lease situation.

We also lease approximately 9,000 square feet of laboratory and office space in Newtown, Pennsylvania, which is occupied by our AxCell Biosciences subsidiary, under a lease expiring in 2004. In February 2001, we expanded the AxCell facility by amending the lease to include approximately an additional 5,000 square feet, which additional lease space will expire in July 2006. We own substantially all of the equipment used in our laboratories and offices. We believe our facilities are adequate for our operations at present.

#### Item 3. Legal Proceedings

On March 17, 2000, we were served with a complaint filed against us in the



Edgar Filing: CYTOGEN CORP - Form 10-K

United States Federal Court for the District of New Jersey by M. David Goldenberg ("Goldenberg") and Immunomedics, Inc. (collectively "Plaintiffs") 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. 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. In addition, 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. However, given the uncertainty associated with litigation, we cannot give any assurance that the litigation could not result in a material expenditure to us. On December 17, 2001, we filed a motion for summary judgment of non-infringement of the asserted claims of the patent-in-suit. The Plaintiffs have indicated that they will file a cross-motion for summary judgment with their opposition to our motion. A hearing on these motions is likely to take place in the Spring of 2002.

-36-

Item 4. Submission of Matters to a Vote of Security Holders

None.

-37-

PART II

Item 5. Market for the Company's Common Equity and Related Stockholder Matters

Our Common Stock is traded on the NASDAQ National Market (the "NNM") under the trading symbol "CYTO."

The table below sets forth the high and low bid information for our Common Stock for each of the calendar quarters indicated, as reported on the NNM. Such quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not represent actual transactions.

2000	High	Low
-----	-----	---
First Quarter.....	\$ 21.69	\$ 2.63
Second Quarter.....	10.56	2.00
Third Quarter.....	11.31	5.50
Fourth Quarter.....	7.13	1.00
2001		
-----		
First Quarter.....	6.53	2.31
Second Quarter.....	6.09	2.19
Third Quarter.....	5.38	1.90
Fourth Quarter.....	4.46	2.05

As of March 1, 2002, there were approximately 4,357 holders of record of the Common Stock and there were approximately 51,346 beneficial holders of the Common Stock.

We have never paid any cash dividends on our Common Stock and we do not anticipate paying any cash dividends on our Common Stock in the foreseeable

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

future. We intend to retain any future earnings to fund the development and growth of our business. Any future determination to pay dividends will be at the discretion of the board of directors.

On January 17, 2001, we granted 10,000 options to purchase shares of our Common Stock at an exercise price of \$6.13, to Kevin G. LoKay, upon his appointment to our Board of Directors. Such options were granted outside of any of our stock option plans, and will vest in full upon the one year anniversary of the date of grant. We granted such option to Mr. LoKay in a transaction exempt from the registration requirements of the Securities Act of 1933, as amended, as a transaction by an issuer not involving any public offering under Section 4(2) thereof.

On November 1 and December 1 of 2001, we issued two warrants to purchase 7,000 and 7,000 shares of our Common Stock, respectively, at an exercise price per share of \$3.12 and \$4.98, respectively, to SCO Financial Group LLC ("SCO"). Such warrants, which vest immediately, were issued in consideration of SCO providing certain financial consultancy and advisory services to us. Such warrants have a term of three (3) years. We granted such warrants to purchase shares of our Common Stock in a transaction exempt from registration under the Securities Act of 1933, as amended, as a transaction by an issuer not involving a public offering under Section 4(2) thereof.

-38-

### Item 6. Selected Financial Data

The following selected financial information has been derived from the consolidated financial statements of the Company for each of the five years in the period ended December 31, 2001, which have been audited by Arthur Andersen LLP, our independent public accountants. The selected financial data set forth below should be read in conjunction with the consolidated financial statements, including the notes thereto, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and other information provided elsewhere in this report.

	Year Ended December		
	2001	2000	1999
Statements of Operations Data:	(All amounts in thousands, except p		
Revenues:			
Product sales .....	\$ 8,692	\$ 7,424	\$ 6,971
Royalties .....	2,063	2,004	1,060
License and contract .....	912	1,024	3,171
	-----	-----	-----
Total revenues .....	11,667	10,452	11,202
	-----	-----	-----
Operating Expenses:			
Cost of product and contract			
manufacturing revenues .....	4,126	4,414	4,111
Research and development .....	10,340	6,957	3,849
Acquisition of marketing and technology rights (1) ....	-	13,241	1,214
Selling and marketing .....	6,314	6,126	4,210

Edgar Filing: CYTOGEN CORP - Form 10-K

General and administrative .....	4,947	4,934	3,501	
Equity loss in Targon subsidiary .....	-	-	-	
	-----	-----	-----	-----
 Total operating expenses .....	 25,727	 35,672	 16,885	
	-----	-----	-----	-----
 Operating loss .....	 (14,060)	 (25,220)	 (5,683)	
Gain on sale of laboratory and manufacturing facilities..	-	-	3,298	
Gain on sale of Targon subsidiary .....	-	-	-	
Other income (expense) .....	857	611	412	
	-----	-----	-----	-----
 Loss before income taxes and cumulative effect of accounting change .....	 (13,203)	 (24,609)	 (1,973)	
Income tax benefit .....	(1,103)	(1,625)	(2,702)	
	-----	-----	-----	-----
 Income (loss) before cumulative effect of accounting change .....	 (12,100)	 (22,984)	 729	
Cumulative effect of accounting change .....	-	(4,314)	-	
	-----	-----	-----	-----
Net income (loss) .....	(12,100)	\$ (27,298)	729	
Dividends, including deemed dividends on preferred stock .....	-	-	-	
	-----	-----	-----	-----
Net income (loss) to common stockholders .....	\$ (12,100)	\$ (27,298)	\$ 729	\$ (
	=====	=====	=====	=====
 Net income (loss) per common share: Basic and diluted net income (loss) before cumulative effect of accounting change .....	\$ (0.16)	\$ (0.31)	\$ 0.01	\$
Cumulative effect of accounting change (2) .....	-	(0.06)	-	
	-----	-----	-----	-----
Basic and diluted net income (loss) .....	\$ (0.16)	\$ (0.37)	\$ 0.01	\$
	=====	=====	=====	=====
 Weighted average common shares outstanding: Basic .....	 77,783	 73,337	 67,179	
	=====	=====	=====	=====
Diluted .....	77,783	73,337	68,187	
	=====	=====	=====	=====
 Pro forma amounts assuming accounting change is applied retroactively: Net loss to common stockholders .....		\$ (22,984)	\$ (484)	\$ (
		=====	=====	=====
Basic and diluted net loss per common share .....		\$ (0.31)	\$ (0.01)	\$
		=====	=====	=====

-39-

			December 31,
			-----
Consolidated Balance Sheet Data:	2001	2000	1999

Edgar Filing: CYTOGEN CORP - Form 10-K

(in thousands)

Cash, short-term investments and restricted cash...	\$ 11,309	\$ 11,993	\$ 12,394
Total assets.....	21,492	20,416	18,605
Long-term debt.....	2,291	2,374	2,416
Accumulated deficit.....	(340,681)	(328,581)	(301,283)
Stockholders' equity.....	11,214	7,218	10,549

- (1) In August 2000, the Company licensed product rights from Advanced Magnetics, Inc. In June 1999, the Company acquired Prostagren, Inc.
- (2) In 2000, the Company recorded a non-cash charge for the cumulative effect related to the adoption of SEC Staff Accounting Bulletin No. 101. See Note 1 of the Consolidated Financial Statements.

-40-

Item 7. 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 Annual Report on Form 10-K that are not based on historical facts 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 under the caption "Additional Factors That May Affect Future Results", provided elsewhere in this report. 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 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

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

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 and its partners 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 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 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 from time to time the Company's other filings with the Securities and Exchange Commission.

### Significant Events in 2001

In 2001, the Company launched BrachySeed I-125 (iodine version), a second generation radioactive implant for treatment of localized prostate cancer, which was in-licensed by the Company from Draximage Inc. Since the launch, the Company has increased its market penetration resulting in a positive sales trend and consistent quarter-over-quarter growth. The Company expects to begin selling BrachySeed Pd-103 (palladium version) in the first half of 2002, a uniquely designed next generation radioactive implant. BrachySeed Pd-103 recently received marketing clearance from the U.S. Food and Drug Administration. The Company expects to utilize its existing oncology sales force to market the BrachySeed products. 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.

Also in 2001, AxCell Biosciences Corporation, a subsidiary of the Company, began marketing the ProChart database with its marketing partner InforMax. ProChart is a proprietary protein pathway database which measures protein domain-ligand interactions in a high-through put 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.

In December 2001, Progenics Pharmaceuticals, our partner in the PSMA LLC, filed a Biological Master File with the FDA for recombinant subunit PSMA vaccine, which is preparing to enter Phase I clinical trials in patients with recurrent prostate cancer in the first half of 2002. The Company expects to incur significant costs going forward to fund its share of developing the PSMA LLC pipeline (see Note 6 to the Consolidated Financial Statements).

-41-

### RESULTS OF OPERATIONS

Years ended December 31, 2001, 2000 and 1999

Revenues

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

Total revenues were \$11.7 million in 2001, \$10.5 million in 2000 and \$11.2 million in 1999. The increase in 2001 from 2000 and 1999 was primarily due to higher product related revenues, partially offset by lower license and contract revenues. Product related revenues, including product sales and royalty revenues, accounted for 92%, 90% and 72% of revenues in 2001, 2000 and 1999, respectively. License and contract revenues accounted for the remainder of revenues.

Product related revenues were \$10.8 million, \$9.4 million and \$8.0 million in 2001, 2000 and 1999, respectively. The increase in 2001 from 2000 and 1999 was due to a price increase for ProstaScint at the beginning of the year and the market introduction and commercial launch of BrachySeed I-125 during 2001, partially offset by a slight decrease in sales volume for ProstaScint. Sales from ProstaScint were \$7.6 million, \$6.9 million and \$6.4 million in 2001, 2000 and 1999, respectively, and accounted for 70%, 73% and 79% of the product related revenues, respectively. Beginning in July 2000, the Company assumed sole responsibility for selling and marketing ProstaScint from Bard Urological Division of C.R. Bard Inc. ("Bard"), its former co-marketing partner. Future growth of ProstaScint is dependent upon increased marketing and sales initiatives by Cytogen's in-house sales force, entry into additional markets and the implementation of new product applications, such as using ProstaScint scans to guide the placement of brachytherapy seeds and/or external beam radiation. There can be no assurance, however, that the Company's internal sales force or any of its new marketing strategy will be able to significantly increase the sale of ProstaScint. The Company plans to utilize Cytogen's sales and marketing organization for the launch of BrachySeed Pd-103 during the first half of 2002 and later Combidex, subject to the receipt of final marketing approval of Combidex by FDA.

Sales from BrachySeed were \$773,000 for 2001 and accounted for 7% of the product related revenues. Since the market introduction of BrachySeed I-125 in February 2001, the Company has increased its market penetration of the brachytherapy iodine market which has contributed to the quarter-over-quarter growth. The Company plans to begin selling BrachySeed Pd-103 during 2002. There can be no assurance, however as to the market acceptance of the BrachySeed products or whether these new products will significantly increase the revenues of the Company.

Royalties from Quadramet were \$2.1 million, \$2.0 million and \$1.1 million in 2001, 2000 and 1999, respectively, and accounted for 19%, 21% and 13% of product related revenues. Quadramet is currently marketed by the Company's marketing partner, Berlex Laboratories Inc. Although Cytogen believes that Berlex is an advantageous marketing partner, there can be no assurance that Quadramet will achieve greater market penetration on a timely basis or result in significant revenues for Cytogen.

Sales from OncoScint CR/OV were \$358,000, \$512,000 and \$620,000 in 2001, 2000 and 1999, respectively. The market for OncoScint CR/OV for colorectal cancer diagnostic has been negatively affected by positron emission tomography or "PET" scans which have shown the same or higher sensitivity than OncoScint CR/OV. Consequently, the Company is decreasing its emphasis on OncoScint in order to focus on its prostate cancer products.

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 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 in 2000, which reflects the deferral of an up-front license fee received from Berlex, net of associated costs, related to the licensing of Quadramet recognized in 1998 and a license fee for certain applications of PSMA to a joint venture formed by Cytogen and Progenics recognized in 1999.

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

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. In 2001 and 2000, the Company recognized \$860,000 and \$859,000, respectively, of license revenue that was included in the cumulative effect adjustment as of January 1, 2000. The Company's 1999 results have not been restated to apply SAB 101 retroactively.

-42-

License revenues for 2001, 2000 and 1999 were \$869,000, \$859,000 and \$2.0 million, respectively. License revenues have fluctuated in the past and may fluctuate in the future. In 1999, the Company recorded \$1.8 million for the licensing of certain applications of PSMA to a joint venture formed by Cytogen and Progenics Pharmaceuticals Inc. Had the Company been subject to SAB 101 prior to 2000, license revenue would have been \$834,000 in 1999.

Revenues from contract manufacturing and research services were \$43,000, \$165,000 and \$1.2 million in 2001, 2000 and 1999, respectively. Revenues from contract manufacturing were \$604,000 in 1999. The Company discontinued its contract manufacturing services business in 2000 as a result of the sale of its laboratory and manufacturing facilities.

### Operating Expenses

Total operating expenses were \$25.7 million, \$35.7 million and \$16.9 million in 2001, 2000 and 1999, respectively. The current year operating expenses reflect costs associated with the proteomics research program at AxCell, the development of new manufacturing and purification processes for ProstaScint, the pre-clinical development of the PSMA technologies, and the 2001 launch of BrachySeed. The decrease in 2001 from 2000 was due primarily to charges in 2000 for the acquisition of marketing and technology rights to Combidex and Code 7228 from Advanced Magnetics, partially offset by increased development efforts in 2001 for the proteomics programs and the new manufacturing and purification processes for ProstaScint and the 2001 launch of BrachySeed. The increase in 2000 from 1999 was due to the acquisition of Combidex and Code 7228, increased development efforts for the proteomics programs and the expansion of our in-house sales force. The 2000 operating expenditures included a \$13.2 million charge related to the acquisition of the marketing and technology rights to Combidex and Code 7228, of which \$13.1 million was non-cash as the Company issued its Common Stock as consideration. The 1999 operating expenditures included a \$1.2 million non-cash charge for the acquisition of exclusive technology rights for immunotherapy to PSMA from Prostagene Inc. ("Prostagene").

Costs of product and contract manufacturing revenues were \$4.1 million, \$4.4 million and \$4.1 million in 2001, 2000 and 1999, respectively. The decrease in 2001 from 2000 was due to lower manufacturing costs resulted from better manufacturing yields for ProstaScint, partially offset by costs associated with the purchase of BrachySeeds, which became commercially available in 2001. The increase in 2000 from 1999 was due to increased product manufacturing costs.

Research and development expenses were \$10.3 million in 2001, \$7.0 million in 2000 and \$3.8 million in 1999. The increase in 2001 from 2000 and 1999 was due to increased funding for the proteomics programs at AxCell, costs associated with the development of new manufacturing and purification processes by DSM Biologics Company B.V. ("DSM") with respect to ProstaScint (see Note 2 to the Consolidated Financial Statements) and the product development efforts related to the PSMA technologies. In 2001, 2000 and 1999 the Company invested \$4.9 million, \$3.4 million and \$1.1 million, respectively, in the proteomics research programs and \$3.2 million, \$559,000 and \$0, respectively, in the manufacturing process development. The Company anticipates to incur comparable amounts of

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

expenses for both programs in 2002. During 2001, the Company recognized \$332,000 of expenses related to its share of losses for The PSMA Development Company LLC. The Company expects to incur significant costs going forward to fund its share of development costs from this joint venture (see Note 6 to the Consolidated Financial Statements).

Acquisition of marketing and technology rights of \$13.2 million in 2000 represents a non-cash charge of \$13.1 million related to the acquisition of certain rights to product candidates Combidx and Code 7228 from AVM (see Note 3 to the Consolidated Financial Statements). In 1999, the acquisition of technology rights was \$1.2 million and represents a non-cash charge related to the acquisition of Prostagin (see Note 5 to the Consolidated Financial Statements).

Selling and marketing expenses were \$6.3 million, \$6.1 million and \$4.2 million in 2001, 2000 and 1999, respectively. The increase in 2001 from 2000 and 1999 was due to the expansion of the Company's in-house sales force and costs associated with the 2001 launch of BrachySeed I-125. CytoGen assumed sole responsibility for the selling and marketing of ProstaScint in July 2000. The 1999 marketing expenses reflect efforts to develop and maintain the Partners in Excellence ("PIE") program which established a network of qualified nuclear medicine sites and physicians which are trained and certified for acquiring, processing and interpreting antibody-derived images.

General and administrative expenses were \$4.9 million, \$4.9 million and \$3.5 million in 2001, 2000 and 1999, respectively. The increase in 2000 from 1999 was due to expenses related to the termination of the proposed merger with Advanced Magnetics, stock based compensation for a key employee, additional staffing and related costs.

-43-

### Gain on sale of laboratory and manufacturing facilities--

The Company recorded a gain of \$3.3 million during 1999 resulting from a sale of certain of the Company's laboratory and manufacturing facilities to Purdue Bio Pharma for net proceeds of \$3.6 million in January 1999.

### Insurance Reimbursement--

During 2001, the Company received a one-time payment of \$402,000 from an insurance claim filed by the Company in 2000 to recover the loss of product resulting from the rupture of a tube during the manufacture of a batch of ProstaScint.

### Interest Income/Expense--

Interest income was \$635,000, \$774,000 and \$441,000 for 2001, 2000 and 1999, respectively. The decrease in 2001 from 2000 was due to a lower average yield on investments, partially offset by increased income resulting from a higher than average cash balance in 2001. The increase in 2000 from 1999 was due to higher average cash balances during 2000.

Interest expense was \$180,000, \$163,000 and \$29,000 in 2001, 2000 and 1999, respectively. The increase in 2001 from 2000 and 1999 was due to finance charges related to various equipment leases.

### Income tax benefit--

During 2001, 2000 and 1999, the Company sold New Jersey State net operating loss carryforwards and research and development credits which resulted in the recognition of a \$1.1 million, \$1.6 million and \$2.7 million income tax benefit, respectively. Under the current legislation, the Company may be able to sell a minimum \$634,000 of the remaining approved \$2.4 million of tax benefits in 2002,



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

assuming the State of New Jersey continues to fund this program, which is uncertain. The actual amount of net operating losses and tax credits the Company may sell will also depend upon the allocation among qualifying companies of an annual pool established by the State of New Jersey.

### Net Income/Loss--

Net loss was \$12.1 million in 2001 and \$27.3 million in 2000 compared to a net income of \$729,000 in 1999. Net loss per share in 2001 and 2000 was \$0.16 and \$0.37 based on weighted average common shares outstanding of 77.8 million and 73.3 million, respectively. The 2000 net loss included \$4.3 million or \$0.06 per share for the cumulative effect of accounting change as a result of the adoption of SAB 101. The basic and diluted net income per common share in 1999 was \$0.01 based on weighted average common shares outstanding of 67.2 million for basic and 68.2 million for diluted.

### LIQUIDITY AND CAPITAL RESOURCES

The Company's cash and cash equivalents were \$11.3 million as of December 31, 2001, compared to \$12.0 million as of December 31, 2000. The cash used for operating activities in 2001 was \$13.4 million compared to \$9.0 million in the same period of 2000. The increase in cash used for operating activities in 2001 was primarily due to increased development efforts in the proteomics programs, expenses relating to the manufacturing and purification processes for ProstaScint and the PSMA technologies, as well as to marketing costs associated with the 2001 launch of BrachySeed iodine prostate cancer product.

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 contract manufacturing and research services, fees paid under license agreements and interest earned on cash and short-term investments. In October 2000, the Company entered into an equity financing facility with Acqua Wellington for up to \$70 million of Common Stock. Under the terms of the agreement, 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 with Acqua Wellington and such agreement was terminated.

-44-

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 January 2002, the Company sold 2,970,665 shares of Cytogen common stock to SWIB for an aggregate purchase price of \$8.0 million or \$2.69 per share.

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

In connection with our stock issuances to SWIB, we agreed not to enter into equity line arrangements in the future, issue certain securities at less than fair market value or undertake certain other securities issuances without requisite stockholder approval.

In January 2002, the Company received cash of \$1.1 million relating to the December 2001 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 \$634,000 of the remaining approved \$2.4 million of tax benefits in 2002 assuming the State of New Jersey continues to fund for this program. The actual amount of net operating losses and tax credits the Company may sell will also depend upon the allocation among qualifying companies of an annual pool established by the State of New Jersey.

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.

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, Management 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 assure you that its business or operations will not change in a manner that would consume available resources more rapidly than anticipated. The Company 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

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

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

-45-

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.

### CRITICAL ACCOUNTING POLICIES

Financial Reporting Release No. 60, which was recently released by the Securities and Exchange Commission, requires all companies to include a discussion of critical accounting policies or methods used in the preparation of financial statements. Note 1 of the Notes to our Consolidated Financial Statements includes a summary of our significant accounting policies and methods used in the preparation of our Consolidated Financial Statements. The following is a brief discussion of the more significant accounting policies and methods used by us. The preparation of our Consolidated Financial Statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Our actual results could differ from those estimates. In addition, Financial Reporting Release No. 61 was recently released by the Securities and Exchange Commission to require all companies to include a discussion to address, among other things, liquidity, off-balance sheet arrangements, contractual obligations and commercial commitments.

#### 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. 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 doubtful accounts if our future bad debt expense exceeds our estimated reserve. We are subject to concentration risks as a limited number of our customers provide a high percent of total revenues, and corresponding receivables.

#### Inventories

Inventories are stated at the lower of cost or market, as determined using the

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

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 our 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 those assets. In accordance with SFAS No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed of," 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.

-46-

### COMMITMENTS

As outlined in Note 7, 10 and 16 of the Notes to our Consolidated Financial Statements, we have entered into various contractual obligations and commercial commitments. The following table summarizes our contractual obligations as of December 31, 2001:

Contractual Obligation	Less than 1 year	1 to 3 years	4 to 5 years	After 5 years	To
Long-term debt	\$ 160,000	\$2,700,000	-	-	2,86
Capital lease obligations	85,000	13,000	-	-	9
Facility leases	624,000	825,000	104,000	-	1,55
Other operating leases	124,000	64,000	-	-	18
Research and development contracts	559,000	515,000	260,000	515,000	1,84
Minimum royalty payments	1,000,000	3,000,000	2,000,000	5,000,000	11,00

In addition to the above, we are obligated to make certain royalty payments based on sales of the related product. We also are obligated to make certain milestone payments if our collaborative partners achieved specific development milestones or commercial milestones as outlined in Note 4 of the Notes to our

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

### Consolidated Financial Statements.

In connection with the acquisition of Prostagin, Inc. (see Note 5 to the Consolidated Financial Statements), the Company may issue up to \$4.0 million worth of Cytogen Common Stock if certain milestones are achieved in the dendritic cell therapy and PSMA development programs. The Company is currently determining whether the initial \$2.0 million milestone has been met in the first quarter of 2002 based on the progress of the dendritic cell prostate cancer clinical trials being conducted by Northwest Biotherapeutics Inc. (NWBT, NASDAQ).

-47-

### Item 7a. 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.

### Item 8. Financial Statements and Supplementary Data

The response to Item 8 is submitted as a separate section of this Form 10-K.

### Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

-48-

## PART 111

### Item 10. Directors and Executive Officers of the Company.

The information relating to the Company's directors, nominees for election as directors and executive officers under the headings "Election of Directors", "Executive Officers" and "Compliance with Section 16(a) of the Exchange Act" in the Company's definitive proxy statement for the 2002 Annual Meeting of Stockholders is incorporated herein by reference to such proxy statement.

### Item 11. Executive Compensation.

The discussion under the heading "Executive Compensation" in the Company's definitive proxy statement for the 2002 Annual Meeting of Stockholders is incorporated herein by reference to such proxy statement.

### Item 12. Security Ownership of Certain Beneficial Owners and Management and

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

Related Stockholder Matters.

The discussion under the heading "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters" in the Company's definitive proxy statement for the 2002 Annual Meeting of Stockholders is incorporated herein by reference to such proxy statement.

Item 13. Certain Relationships and Related Transactions.

The discussion under the heading "Certain Relationships and Related Transactions" in the Company's definitive proxy statement for the 2002 Annual Meeting of Stockholders is incorporated herein by reference to such proxy statement.

-49-

### PART IV

Item 14. Exhibits, Financial Statement Schedules, and Reports on Form 8-K

(a) Documents filed as a part of the Report:

(1) and (2)

The response to this portion of Item 14 is submitted as a separate section of this Form 10-K.

(3) Exhibits -

Exhibit No.

-----

- 3.1 - Certificate of Incorporation of Cytogen Corporation, as amended. Filed as an exhibit to Form 10-Q Quarterly Report for the quarter ended June 30, 1996, and incorporated herein by reference.
- 3.2 - Certificate of Amendment to the Restated Certificate of Incorporation of Cytogen Corporation, as amended. Filed as an exhibit to Form 10-Q Quarterly Report for the quarter ended June 30, 2000, and incorporated herein by reference.
- 3.3 - By-Laws of Cytogen Corporation, as amended. Filed as an exhibit to Form 10-Q Quarterly Report for the quarter ended September 30, 2001, and incorporated herein by reference.
- 4.1 - Amended and Restated Rights Agreement, dated as of October 19, 1998 between Cytogen Corporation and Chase Mellon Shareholder Services, L.L.C., as Rights Agent. The Amended and Restated Rights Agreement includes the Form of Certificate of Designations of Series C Junior Participating Preferred Stock as Exhibit A, the form of Right Certificate as Exhibit B and the Summary of Rights as Exhibit C. Filed as an exhibit to Form 10-Q Quarterly Report for the quarter ended September 30, 1998, and incorporated herein by reference.

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

- 4.2 - Certificate of Designations of Series C Junior Participating Preferred Stock of Cytogen Corporation. Filed as an exhibit to the Company's Registration Statement on Form S-8 (File No. 333-59718), filed with the Commission on April 27, 2001, and incorporated herein by reference.
  - 10.1 - Lease Agreement, dated as of March 16, 1987, by and between Peregrine Investment Partners I, as lessor, and Cytogen Corporation, as lessee. Filed as an exhibit to Form 10-K Annual Report for Year Ended January 2, 1988, and incorporated herein by reference.
  - 10.2. - Amendment, dated as of October 16, 1987, to Lease Agreement between Peregrine Investment Partners I and Cytogen Corporation. Filed as an exhibit to Form S-8 Registration Statement (No. 33-30595), and incorporated herein by reference.
  - 10.3 - 1989 Employee Stock Option Plan. Filed as an exhibit to Form S-8 Registration Statement (No. 33-30595), and incorporated herein by reference. +
  - 10.4.1 - 1988 Stock Option Plan for Non-Employee Directors. Filed as an exhibit to Form S-8 Registration Statement (No. 33-30595), and incorporated herein by reference. +
  - 10.4.2 - Amendment to the Cytogen Corporation 1988 Stock Option Plan for Non-Employee Directors dated May 22, 1996. Filed as an exhibit to Form 10-Q Quarterly Report for the quarter ended June 30, 1996, and incorporated herein by reference. +
- 50-
- 10.5 - Standard Form of Indemnification Agreement entered into between Cytogen Corporation and its officers, directors, and consultants. Filed as an exhibit to Amendment No. 1 to Form S-1 Registration Statement (No. 33-31280), and incorporated herein by reference. +
  - 10.6 - 1989 Stock Option Policy for Outside Consultants. Filed as an exhibit to Amendment No. 1 to Form S-1 Registration Statement (No. 33-31280), and incorporated herein by reference. +
  - 10.7.1 - License Agreement dated as of March 31, 1993 between Cytogen Corporation and The Dow Chemical Company. Filed as an exhibit to Form 10-Q/A-1 Amendment to Quarterly Report for the quarter ended July 3, 1993, and incorporated herein by reference.\*
  - 10.7.2 - Amendment of the License Agreement between Cytogen Corporation and The Dow Chemical Company dated September 5, 1995. Filed as an exhibit to Form 10-Q Quarterly Report for the quarter ended March 31, 1996, and incorporated herein by reference.\*
  - 10.7.3 - Second Amendment to the License Agreement between Cytogen Corporation and The Dow Chemical Company dated May 20, 1996. Filed as an exhibit to Form 10-Q/A-1 Amendment to Quarterly Report for the quarter ended June 30, 1996, and incorporated herein by reference.\*
  - 10.8 - 1992 Cytogen Corporation Employee Stock Option Plan II, as amended. Filed as an exhibit to Form S-4 Registration Statement (No. 33-88612), and incorporated herein by reference. +
  - 10.9 - License Agreement, dated March 10, 1993, between Cytogen Corporation and The University of North Carolina at Chapel Hill, as amended. Filed as an exhibit to Form 10-K Annual Report for the year ended December

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

31, 1994, and incorporated herein by reference.\*

- 10.10 - Option and License Agreement, dated July 1, 1993, between Cytogen Corporation and Sloan-Kettering Institute for Cancer Research. Filed as an exhibit to Form 10-K Annual Report for the year ended December 31, 1994, and incorporated herein by reference.\*
  - 10.11 - Cytogen Corporation Amended and Restated 1995 Stock Option Plan. Filed as an exhibit to Form 10-Q Quarterly Report for the quarter ended September 30, 2001, and incorporated herein by reference. +
  - 10.12 - Horosziewicz - Cytogen Agreement, dated April 20, 1989, between Cytogen Corporation and Julius S. Horosziewicz, M.D., DMSc. Filed as an exhibit to Form 10-K Annual Report for the year ended December 31, 1995, and incorporated herein by reference.\*
  - 10.13 - Marketing and Co-Promotion Agreement between Cytogen Corporation and C.R. Bard, Inc. effective August 1, 1996. Filed as an exhibit to Form 10-Q Quarterly Report for the quarter ended September 30, 1996, and incorporated herein by reference.\*
  - 10.14 - Severance Agreement effective as of March 26, 1996 between Cytogen Corporation and John D. Rodwell, Ph.D. Filed as an exhibit to Form 10-K Annual Report for the year ended December 31, 1996, and incorporated herein by reference. +
  - 10.15 - Cytogen Corporation Employee Stock Purchase Plan, as amended. Filed as an exhibit to Form 10-Q Quarterly Report for the quarter ended September 30, 2001, and incorporated herein by reference. +
  - 10.16 - License Agreement between Targon Corporation and Elan Corporation, plc dated July 21, 1997. Filed as an exhibit to Form 10-Q Quarterly Report for the quarter ended June 30, 1997, and incorporated herein by reference.\*
- 51-
- 10.17 - Employment Agreement effective as of December 23, 1996 between Cytogen Corporation and Dr. Graham S. May. Filed as an exhibit to Form 10-K/A-1 Amendment to Annual Report for the Year Ended December 31, 1997, and incorporated herein by reference. +
  - 10.18 - Convertible Promissory Note dated as of August 12, 1998 between Cytogen Corporation and Elan International Services, Ltd. Filed as an exhibit to Form 10-Q Quarterly Report for the quarter ended June 30, 1998, and incorporated herein by reference.
  - 10.19 - Employment agreement effective as of August 20, 1998 between Cytogen Corporation and H. Joseph Reiser. Filed as an exhibit to Form 10-Q Quarterly Report for the quarter ended September 30, 1998, and incorporated herein by reference. +
  - 10.20 - License Agreement by and between Berlex Laboratories, Inc. and Cytogen Corporation dated as of October 28, 1998. Filed as an exhibit to Form 10-Q/A-1 Amendment to Quarterly Report for the quarter ended September 30, 1998, and incorporated herein by reference.
  - 10.21 - Manufacturing Space Agreement between Bard BioPharma L.P. and Cytogen Corporation dated as of January 7, 1999. Filed as an exhibit to Form S-1/A-1 Amendment to Registration Statement, filed with the Commission on January 27, 1999, and incorporated herein by reference.



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

- 10.22 - Employment Agreement effective as of June 10, 1997 between Cytogen Corporation and Donald F. Crane, Jr. Filed as an exhibit to Form 10-K Annual Report for the year ended December 31, 1999, and incorporated herein by reference. +
  - 10.23 - Amended and Restated 1999 Stock Option Plan for Non-Employee Directors. Filed as an exhibit to Form 10-Q Quarterly Report for the quarter ended September 30, 2001, and incorporated herein by reference. +
  - 10.24 - Strategic Alliance Agreement between AxCell Biosciences Corporation and InforMax, Inc. dated as of September 15, 1999. Filed as an exhibit to Form 10-K Annual Report for the year ended December 31, 1999, and incorporated herein by reference.\*
  - 10.25 - AxCell Biosciences Corporation Employee Stock Option Plan. Filed as an exhibit to Form 10-K Annual Report for the year ended December 31, 1999, and incorporated herein by reference. +
  - 10.26 - Master Loan and Security Agreement No. S7600 among Cytogen Corporation, AxCell Biosciences Corporation and Finova Capital Corporation dated December 30, 1999. Filed as an exhibit to Form 10-K Annual Report for the year ended December 31, 1999, and incorporated herein by reference.
  - 10.27 - Amendment No. 1 to Marketing and Co-Promotion Agreement effective as of January 1, 2000 by and between Cytogen Corporation and C.R. Bard, Inc. Filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2000, and incorporated herein by reference.
  - 10.28 - License and Marketing Agreement by and between Cytogen Corporation and Advanced Magnetics, Inc. dated August 25, 2000. Filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2000, and incorporated herein by reference.\*
  - 10.29 - Development and Manufacturing Agreement by and between Cytogen Corporation and DSM Biologics Company B.V. dated July 12, 2000. Filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2000, and incorporated herein by reference.\*
- 52-
- 10.30 - Common Stock Purchase Agreement, dated September 29, 2000, by and between Cytogen Corporation and Acqua Wellington North American Equities Fund, Ltd. Filed as an exhibit to the Company's Current Report on Form 8-K, filed with the Commission on October 5, 2000, and incorporated herein by reference.
  - 10.31 - Common Stock Purchase Agreement, dated October 4, 2000, by and between Cytogen Corporation and Acqua Wellington North American Equities Fund, Ltd. Filed as an exhibit to the Company's Current Report on Form 8-K, filed with the Commission on October 12, 2000, and incorporated herein by reference.
  - 10.32 - Written Compensatory Agreement by and between Cytogen Corporation and H. Joseph Reiser dated August 24, 1998, as revised on July 11, 2000. Filed as an exhibit to the Company's Registration Statement on Form S-8 (File No. 333-48454), filed with the Commission on October

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

23, 2000, and incorporated herein by reference. +

- 10.33 - Written Compensatory Agreement by and between Cytogen Corporation and Lawrence Hoffman dated July 10, 2000. Filed as an exhibit to the Company's Registration Statement on Form S-8 (File No. 333-48454), filed with the Commission on October 23, 2000, and incorporated herein by reference. +
- 10.34 - Product Manufacturing and Supply Agreement by and between Cytogen Corporation and Draximage Inc. dated December 5, 2000. Filed as an exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 2000. \*
- 10.35 - License and Distribution Agreement by and between Cytogen Corporation and Draximage Inc. dated December 5, 2000. Filed as an exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 2000. \*
- 10.36 - Form of Executive Change of Control Severance Agreement by and between the Company and each of its Executive Officers. Filed as an exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 2001. Filed herewith. +
- 10.37.1- Lease Agreement by and between Newtown Associates, L.P. and AxCell Biosciences Corporation dated as of July 23, 1999. Filed as an exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 2001. Filed herewith.
- 10.37.2- First Amendment to the Lease Agreement by and between 826 Newtown Associates, L.P. and AxCell Biosciences Corporation dated as of March 16, 2001. Filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2001, and incorporated herein by reference.
- 10.38 - Cytogen Corporation Stock Payment Bonus Plan Program. Filed as an exhibit to the Company's Registration Statement on Form S-8 (File No. 333-58384), filed with the Commission on April 6, 2001, and incorporated herein by reference. +
- 10.39 - MFS Fund Distributors, Inc. 401(K) Profit Sharing Plan and Trust. Filed as an exhibit to the Company's Registration Statement on Form S-8 (File No. 333-59718), filed with the Commission on April 27, 2001, and incorporated herein by reference. +
- 10.40 - Adoption Agreement for MFS Fund Distributors, Inc. Non-Standardized 401(K) Profit Sharing Plan and Trust, with amendments. Filed as an exhibit to the Company's Registration Statement on Form S-8 (File No. 333-59718), filed with the Commission on April 27, 2001, and incorporated herein by reference.
- 10.41 - Cytogen Corporation Performance Bonus Plan with Stock Payment Program. Filed as an exhibit to Company's Registration Statement on Form S-8 (File No. 333-75304), filed with the Commission on December 17, 2001, and incorporated herein by reference. +
- 10.42 - Share Purchase Agreement by and between Cytogen Corporation and the State of Wisconsin Investment Board dated as of June 18, 2001. Filed as an exhibit to the Company's Current Report on Form 8-K, filed with the Commission on June 19, 2001, and incorporated herein by reference.

Edgar Filing: CYTOGEN CORP - Form 10-K

- 10.43 - Share Purchase Agreement by and between Cytogen Corporation and the State of Wisconsin Investment Board dated as of January 18, 2002. Filed as an exhibit to the Company's Current Report on Form 8-K, filed with the Commission on January 24, 2002, and incorporated herein by reference.
- 21 - Subsidiaries of Cytogen Corporation. Filed herewith.
- 23 - Consent of Arthur Andersen LLP. Filed herewith.
- 99.1 - Letter regarding certain representation of Arthur Andersen LLP, dated as of March 28, 2002. Filed as an exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 2001. Filed herewith.

+ Management contract or compensatory plan or arrangement.

\* We have received confidential treatment of certain provisions contained in this exhibit pursuant to an order issued by the Securities and Exchange Commission. The copy filed as an exhibit omits the information subject to the confidentiality grant.

(b) Reports on Form 8-K:

We did not file any Current Reports on Form 8-K during the quarter ended December 31, 2001.

On January 24, 2002, we filed a Current Report on Form 8-K relating to the issuance and sale of 2,970,665 shares of our Common Stock to the State of Wisconsin Investment Board for an aggregate purchase price of approximately \$8.0 million pursuant to a share purchase agreement dated January 18, 2002.

(c) Exhibits:

The Exhibits filed with this Form 10-K are listed above in response to Item 14(a)(3).

(d) Financial Statement Schedules:

None.

-54-

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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 on the 28th day of March 2002.

Cytogen Corporation

By: /s/ H. Joseph Reiser

-----  
H. Joseph Reiser, President and Chief Executive Officer

Edgar Filing: CYTOGEN CORP - Form 10-K

-55-

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ H. Joseph Reiser ----- H. Joseph Reiser	Chief Executive Officer and President (Principal Executive Officer), and Director	March 28, 2002
/s/ Lawrence R. Hoffman ----- Lawrence R. Hoffman	Vice President & Chief Financial Officer Treasurer and Secretary (Principal Financial and Accounting Officer)	March 28, 2002
/s/ John E. Bagalay, Jr. ----- John E. Bagalay, Jr.	Director	March 28, 2002
/s/ Stephen K. Carter ----- Stephen K. Carter	Director	March 28, 2002
/s/ James A. Grigsby ----- James A. Grigsby	Director and Chairman of the Board	March 28, 2002
/s/ Robert F. Hendrickson ----- Robert F. Hendrickson	Director	March 28, 2002
/s/ Kevin G. Lokay ----- Kevin G. Lokay	Director	March 28, 2002

-56-

Form 10-K Item 14(a)(1) and (2)

CYTOGEN CORPORATION AND SUBSIDIARIES

(1) Index to Consolidated Financial Statements

Edgar Filing: CYTOGEN CORP - Form 10-K

-----  
The following consolidated financial statements of Cytogen Corporation and Subsidiaries together with the related notes and report of Arthur Andersen LLP, independent public accountants.

Report of Independent Public Accountants.....  
Consolidated Balance Sheets as of December 31, 2001 and 2000.....  
Consolidated Statements of Operations--Years Ended December 31, 2001, 2000 and 1999 .....  
Consolidated Statements of Stockholders' Equity--Years Ended December 31, 2001, 2000 and 1999....  
Consolidated Statements of Cash Flows--Years Ended December 31, 2001, 2000 and 1999.....  
Notes to Consolidated Financial Statements.....

-57-

REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS

To Cytogen Corporation:

We have audited the accompanying consolidated balance sheets of Cytogen Corporation (a Delaware Corporation) and Subsidiaries as of December 31, 2001 and 2000, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2001. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Cytogen Corporation and Subsidiaries as of December 31, 2001 and 2000 and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2001, in conformity with accounting principles generally accepted in the United States.

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

As explained in Note 1 to the consolidated financial statements, effective January 1, 2000, the Company changed its method of accounting for revenue recognition.

ARTHUR ANDERSEN LLP

Philadelphia, Pennsylvania  
February 5, 2002

-58-

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

	December 31,	
	2001	2000
<b>ASSETS:</b>		
<b>Current Assets:</b>		
Cash and cash equivalents .....	\$ 11,309	\$ 11,309
Marketable securities .....	1,376	1,376
Receivable on income tax benefit sold .....	1,103	1,103
Accounts receivable, net .....	1,621	1,621
Inventories .....	1,889	1,889
Other current assets .....	508	508
	17,806	16,806
Total current assets .....		
Property and Equipment, net .....	1,831	2,000
Other Assets .....	1,855	1,855
	\$ 21,492	20,661
	21,492	20,661
<b>LIABILITIES AND STOCKHOLDERS' EQUITY:</b>		
<b>Current Liabilities:</b>		
Current portion of long-term debt .....	\$ 77	\$ 77
Accounts payable and accrued liabilities .....	5,315	7,000
Deferred revenue .....	534	534
	5,926	7,611
Total current liabilities .....		
Long-Term Debt .....	2,291	2,291
Deferred Revenue .....	2,061	2,061
Commitments and Contingencies (Note 16)		

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

### 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, 78,937,000 and 75,594,000 shares issued and outstanding at December 31, 2001 and 2000, respectively .....	789	
Additional paid-in capital .....	350,867	335,
Deferred compensation .....	(621)	(
Accumulated other comprehensive income .....	860	
Accumulated deficit .....	(340,681)	(328,
	11,214	7,
Total stockholders' equity .....	\$ 21,492	\$ 20,
	=====	=====

The accompanying notes are an integral part of these statements.

-59-

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

	Year Ended December 31	
	2001	2000
Revenues:		
Product related:		
ProstaScint .....	\$ 7,561	\$ 6,912
BrachySeed .....	773	-
OncoScint .....	358	512
Total product sales .....	8,692	7,424
Quadramet royalties .....	2,063	2,004
Total product related .....	10,755	9,428
License and contract .....	912	1,024
Total revenues .....	11,667	10,452
Operating Expenses:		
Cost of product and contract manufacturing revenues .....	4,126	4,414
Research and development .....	10,340	6,957
Acquisition of marketing and technology rights .....	-	13,241
Selling and marketing .....	6,314	6,126
General and administrative .....	4,947	4,934

Edgar Filing: CYTOGEN CORP - Form 10-K

Total operating expenses .....	25,727	35,672	
	-----	-----	
Operating loss .....	(14,060)	(25,220)	
Insurance reimbursement .....	402	-	
Gain on sale of laboratory and manufacturing facilities .....	-	-	
Interest income .....	635	774	
Interest expense .....	(180)	(163)	
	-----	-----	
Loss before income taxes and cumulative effect of accounting change .....	(13,203)	(24,609)	
Income tax benefit .....	(1,103)	(1,625)	
	-----	-----	
Income (loss) before cumulative effect of accounting change .....	(12,100)	(22,984)	
Cumulative effect of accounting change (Note 1) .....	-	(4,314)	
	-----	-----	
Net income (loss) .....	\$ (12,100)	\$ (27,298)	\$
	=====	=====	=====
Net income (loss) per share:			
Basic and diluted net income (loss) before cumulative effect of accounting change .....	\$ (0.16)	\$ (0.31)	\$
Cumulative effect of accounting change .....	-	(0.06)	
	-----	-----	
Basic and diluted net income (loss) .....	\$ (0.16)	\$ (0.37)	\$
	=====	=====	=====
Weighted average common shares outstanding:			
Basic .....	77,783	73,337	
	=====	=====	
Diluted .....	77,783	73,337	
	=====	=====	

The accompanying notes are an integral part of these statements.

-60-

CYTOGEN CORPORATION AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY  
(All amounts in thousands, except share data)

	Common Stock	Additional Paid-in Capital	Deferred Compen- sation	Accum Ot Com hen Inc
	-----	-----	-----	-----
Balance, December 31, 1998	\$ 619	\$ 301,836	\$ -	\$
Issuance of 2,050,000 shares of common stock in connection with the acquisition of Prostagen Inc. ....	21	1,824	-	
Sale of 6,527,002 shares of common stock .....	65	7,244	-	
Issuance of options and warrants to purchase				



Edgar Filing: CYTOGEN CORP - Form 10-K

shares of common stock .....	-	221	-
Deferred compensation related to			
stock options .....	-	84	(84)
Amortization of deferred compensation .....	-	-	2
Net income .....	-	-	-
	-----	-----	-----
Balance, December 31, 1999 .....	705	311,209	(82)
Sale of 3,567,771 shares of			
common stock .....	36	10,342	-
Issuance of 1,500,000 shares of common stock			
in connection with the acquisition of			
product candidates marketing rights .....	15	13,064	-
Issuance of options to purchase			
shares of common stock .....	-	261	-
Deferred compensation related to			
stock options .....	-	1,062	(1,062)
Amortization of deferred compensation .....	-	-	249
Net loss .....	-	-	-
	-----	-----	-----
Balance, December 31, 2000 .....	756	335,938	(895)
Sale of 3,241,485 shares of			
common stock .....	32	14,206	-
Issuance of stock and stock options related			
to compensation .....	1	281	-
Issuance of options and warrants to purchase			
shares of common stock .....	-	201	-
Deferred compensation related to			
stock options .....	-	241	(241)
Amortization of deferred compensation .....	-	-	515
Comprehensive loss:			
Net loss .....	-	-	-
Unrealized gain on marketable securities .....	-	-	-
Total comprehensive loss .....	-----	-----	-----
Balance, December 31, 2001 .....	\$ 789	\$ 350,867	\$ (621)
	=====	=====	=====

The accompanying notes are an integral part of these statements.

-61-

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

	Year Ended Decemb	
	2001	2000
	-----	-----
Cash Flows From Operating Activities:		
Net income (loss).....	\$ (12,100)	\$ (27,298)

Edgar Filing: CYTOGEN CORP - Form 10-K

Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization .....	1,186	1,027
Imputed interest (income) expense .....	(43)	29
Warrant, stock and stock option grants .....	201	261
Stock based compensation expenses .....	608	249
Amortization of deferred revenue .....	(860)	(859)
Acquisition of marketing and technology rights .....	-	13,079
Cumulative effect of accounting change .....	-	4,314
Write down of property and equipment .....	-	-
Gain on sale of laboratory and manufacturing facilities .....	-	-
Gain on sale of other property and equipment .....	-	(148)
Changes in assets and liabilities:		
Accounts receivable, net .....	263	397
Inventories .....	(1,006)	(198)
Other assets .....	24	(1,631)
Accounts payable and accrued liabilities .....	(1,714)	1,740
	-----	-----
Total adjustments .....	(1,341)	18,260
	-----	-----
Net cash used in operating activities .....	(13,441)	(9,038)
	-----	-----
Cash Flows From Investing Activities:		
Purchases of property and equipment .....	(813)	(1,209)
Purchase of product rights .....	(500)	(500)
Net cash acquired from Prostagren, Inc. ....	-	-
Net proceeds from sale of laboratory and manufacturing facilities...	-	-
Net proceeds from sale of other property and equipment .....	-	148
(Increase) decrease in short-term investments .....	-	1,593
	-----	-----
Net cash provided by (used in) investing activities .....	(1,313)	32
	-----	-----
Cash Flows From Financing Activities:		
Proceeds from sale of common stock .....	14,238	10,378
Payments of long-term liabilities .....	(168)	(180)
	-----	-----
Net cash provided by financing activities .....	14,070	10,198
	-----	-----
Net increase (decrease) in cash and cash equivalents .....	(684)	1,192
Cash and cash equivalents, beginning of year .....	11,993	10,801
	-----	-----
Cash and cash equivalents, end of year .....	\$ 11,309	\$ 11,993
	=====	=====

The accompanying notes are an integral part of these statements.

-62-

CYTOGEN CORPORATION AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Business

Cytogen Corporation ("Cytogen" or the "Company") is a biopharmaceutical company

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

with an established and growing product line in prostate cancer and other areas of 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) I-125 and Pd-103, (uniquely designed, next-generation radioactive seed implants for the treatment of localized prostate cancer); and Quadramet(R) (a therapeutic agent marketed for the relief of bone pain in prostate and other types of cancer). Cytogen is evolving a pipeline of oncology product candidates by developing its prostate specific membrane antigen, or PSMA technologies, which are exclusively licensed from Memorial Sloan-Kettering Cancer Center.

AxCell, a subsidiary of Cytogen Corporation, is engaged in the research and development of novel biopharmaceutical products using its growing portfolio of functional proteomics solutions and collection of proprietary signal transduction pathway information. Through the systematic and industrialized measurement of protein-to-protein interactions, AxCell is assembling ProChart(TM), a proprietary database of signal transduction pathway information that is relevant in a number of therapeutically important classes of molecules including growth factors, receptors and other potential protein therapeutics or drug targets. AxCell's database content and functional proteomics tools are available on a non-exclusive basis to biotechnology, pharmaceutical and academic researchers. AxCell is expanding and accelerating its research activities to further elucidate the role of novel proteins and pathways in ProChart(TM), through both external collaborations and internal data mining.

### Basis of Consolidation

The consolidated financial statements include the accounts of Cytogen and its wholly-owned subsidiaries. Intercompany balances and transactions have been eliminated in consolidation.

### Use of Estimates

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

### Statements of Cash Flows

Cash and cash equivalents include cash on hand, cash in banks and all highly liquid investments with maturity of three months or less at the time of purchase. Cash paid for interest expense was \$180,000, \$99,000 and \$44,000 in 2001, 2000 and 1999, respectively. During 2001, 2000 and 1999, the Company purchased \$11,000, \$49,000 and \$223,000, respectively, of equipment under various capital leases.

### Marketable Securities

In connection with the acquisition of Prostagin Inc. in June 1999 (see Note 5), the Company received 275,350 shares of Northwest Biotherapeutics, Inc. common stock. The Company has classified this investment as available-for-sale securities in accordance with Statement of Financial Accounting Standards ("SFAS") No. 115, "Accounting for Certain Investments in Debt and Equity Securities." Available-for-sale securities are carried at fair value, based on quoted market prices, with unrealized gains or losses reported as a separate component of stockholders' equity. As of December 31, 2001, the Company had an unrealized gain of \$860,000 related to this investment. There is no assurance, however that the Company can sell these securities within a reasonable amount of time without negatively effecting the price of the stock since the daily trading

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

volume has been low.

-63-

### CYTOGEN CORPORATION AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

#### Receivables

At December 31, 2001 and 2000, accounts receivable were net of an allowance for doubtful accounts of \$30,000 and \$35,000, respectively. The Company charged to expense \$0, \$0 and \$10,000 as a provision for doubtful accounts and wrote off \$5,000, \$47,000 and \$0 of uncollectible accounts in 2001, 2000 and 1999, respectively. At December 31, 2001 and 2000, the Company had a \$1.1 million and \$1.6 million receivable, respectively, due from Public Service Electric and Gas Company relating to the sales of New Jersey state operating loss carryforwards and research and development credits. The Company received the proceeds from these receivables in January 2002 and 2001, respectively.

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

	December 31,	
	2001	2000
	----	----
Raw materials.....	\$ 506,000	\$718,000
Work-in process.....	1,371,000	59,000
Finished goods.....	12,000	106,000
	\$1,889,000	\$883,000
	=====	=====

#### Property and Equipment

Property and equipment are stated at cost, net of depreciation. Leasehold improvements are amortized on a straight-line basis over the lease period or the estimated useful life, whichever is shorter. Equipment and furniture are depreciated on a straight-line basis over three to five years. Expenditures for repairs and maintenance are charged to expense as incurred. Property and equipment consisted of the following:

	December 31,	
	2001	2000
	----	----
Leasehold improvements.....	\$3,425,000	\$ 3,211,000
Equipment and furniture.....	6,224,000	5,668,000
	9,649,000	8,879,000
Less - accumulated depreciation and amortization	(7,818,000)	(6,686,000)
	\$1,831,000	\$ 2,193,000

=====

In 1999, the Company sold certain of its laboratory and manufacturing facilities to Bard BioPharma L.P., a subsidiary of Purdue Pharma L.P. ("Purdue"), for \$3.6 million, net of approximately \$300,000 of transaction costs. As a result of the sale, the Company recognized a gain of approximately \$3.3 million during 1999.

Fair Value of Financial Instruments

The Company's financial instruments consist primarily of cash and cash equivalents, marketable securities, accounts receivable, accounts payable, accrued expenses and long-term debt. The Company believes the carrying value of these assets and liabilities are considered to be representative of their fair market value.

Impairment of Long-Lived Assets

In accordance with SFAS No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed of," if indicators of impairment exist, Management assesses the recoverability of the affected long-lived assets by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows. If impairment is indicated

-64-

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

Management measures the amount of such impairment by comparing the carrying value of the assets to the present value of the expected future cash flows associated with the use of the asset. Management believes the future cash flows to be received from the long-lived assets will exceed the assets' carrying value, and, accordingly, the Company has not recognized any impairment losses through December 31, 2001.

Other Assets

Other assets consists of the following:

	December 31,	
	2001	2000
	----	----
Investment in Northwest Biotherapeutics, Inc.....	\$ -	\$ 516,000
BrachySeed Marketing Rights (Note 4).....	903,000	496,000
Investment in PSMA Development Co. LLC (Note 6).....	588,000	20,000
Other .....	364,000	472,000
	-----	-----
	\$1,855,000	\$1,504,000
	=====	=====

Revenue Recognition

Product related revenues include product sales by Cytogen to its customers and Quadramet royalties. Product sales are recognized upon shipment of the finished goods. The Company does not grant price protection to its customers. Royalties are recognized as revenue when earned.

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

License and contract revenues include milestone payments and fees under collaborative agreements with third parties, revenues from contract manufacturing and research services, and revenues from other miscellaneous sources. In 2000, the Company discontinued contract manufacturing services, concurrent with the sale of the manufacturing and laboratory facilities (see Property and Equipment above) and therefore received no revenue from this source since 2000.

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. ("Berlex"), net of associated costs, related to the licensing of Quadramet recognized in October 1998 and a license fee for certain applications of PSMA to a joint venture formed by Cytogen and Progenics Pharmaceuticals Inc. ("Progenics") recognized in June 1999 (see Note 6). 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. For the years ended December 31, 2001 and 2000, the Company recognized \$860,000 and \$859,000 in revenues, respectively, that were included in the cumulative effect adjustment as of January 1, 2000.

Prior year financial statements have not been restated to apply SAB 101 retroactively; however, the following pro forma amounts present the net loss to common stockholders and net loss per share assuming the Company had retroactively applied SAB 101.

	Year Ended December 31,	
	2000	1999
Net income (loss), as reported.....	\$(27,298,000)	\$ 729,000
Net income (loss) per share, as reported....	\$ (0.37)	\$ 0.01
Pro forma net loss .....	\$(22,984,000)	\$ (484,000)
Pro forma net loss per share.....	\$ (0.31)	\$ (0.01)

-65-

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

### Research and Development

Research and development expenditures consist of projects conducted by the Company and payments made to sponsored research programs and consultants. All

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

research and development costs are charged to expense as incurred. Research and development expenditures for customer sponsored programs were \$17,000, \$45,000 and \$194,000 in 2001, 2000 and 1999, respectively.

### Patent Costs

Patent costs are charged to expense as incurred.

### Net Income (Loss) Per Share

Basic net income (loss) per common share is based upon the weighted average common shares outstanding during each period. Diluted net income per common share in 1999 is based upon the weighted average common shares outstanding and common stock equivalents, which represent the incremental common shares that would have been outstanding under certain employee stock options and warrants, upon assumed exercise of dilutive stock options and warrants. Diluted net loss per share for 2001 and 2000 is the same as basic net loss per share, as the inclusion of common stock equivalents would be antidilutive (see Note 12).

### Other Comprehensive Income

The Company follows SFAS No. 130, "Reporting Comprehensive Income." This statement requires the classification of items of other comprehensive income by their nature and disclose of the accumulated balance of other comprehensive income separately from retained earnings and additional paid-in capital in the equity section of the balance sheet.

### 2. DSM BIOLOGICS COMPANY B.V.

In July 2000, the Company entered into a Development and Manufacturing Agreement with DSM Biologics Company B.V. ("DSM"), pursuant to which DSM will conduct certain development activities with respect to ProstaScint, including the delivery of a limited number of batches of ProstaScint for testing and evaluation purposes. Under the terms of such agreement, and subject to the satisfactory performance thereof by DSM and the achievement of certain regulatory approvals for the manufacturing of ProstaScint, the parties are obligated to negotiate in good faith a long term supply agreement. Notwithstanding the parties' obligations to perform under the agreement or to negotiate a supply agreement in good faith, the Company cannot be certain that DSM will satisfactorily perform its obligations thereunder or that the parties will be able to negotiate a supply agreement on commercially satisfactory terms, if at all. Alternatively, the Company has the option, but not the obligation, to enter into certain licensing arrangements with DSM for the technology developed on terms and conditions to be agreed upon by the parties. In 2001 and 2000, the Company recorded \$3.2 million and \$559,000, respectively, of development expenses related to this agreement.

### 3. ADVANCED MAGNETICS, INC.

In August 2000, the Company and Advanced Magnetics, Inc. ("Advanced Magnetics"), a developer of novel diagnostic pharmaceuticals for use in magnetic resonance imaging (MRI), entered into marketing, license and supply agreements ("AVM Agreements"). Under the AVM Agreements, Cytogen acquired certain rights to Advanced Magnetics' product candidates: Combidx(R), MRI contrast agent for the detection of lymph node metastases and imaging agent Code 7228 for oncology applications. Advanced Magnetics will be responsible for all costs associated with the clinical development, supply and manufacture of Combidx and Code 7228 and will receive royalties based upon product sales.

In exchange for the future marketing rights to Combidx and Code 7228, Cytogen issued 1.5 million shares of its Common Stock to Advanced Magnetics at closing and may issue an additional 500,000 shares, which are currently in escrow,

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

subject to the achievement of certain milestones. Since the Advanced Magnetics' product candidates have not yet received FDA approval, the Company recorded a \$13.2 million charge in the December 31, 2000 consolidated statement of operations for the acquisition of marketing and technology rights, of which \$13.1 million was non-cash and represented the fair value of the 1.5 million shares of Common Stock issued. There can be no assurance that Advanced Magnetics will receive FDA approval to market Combidex or Code 7228 in the United States.

#### 4. DRAXIMAGE INC.

In December 2000, the Company entered into a Product Manufacturing and Supply Agreement with Draximage, Inc. ("Draximage") to market and distribute BrachySeed 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 product transfer payments, royalties on sales and certain milestone payments. Cytogen paid Draximage \$500,000 upon execution of

-66-

### CYTOGEN CORPORATION AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

the contract in 2000 and \$500,000 upon the first sale of the Iodine-125 BrachySeeds in 2001. These payments have been recorded as other assets in the accompanying consolidated balance sheet (see Note 1) and are being amortized over the ten year term of the Draximage agreement. Amortization of these rights was \$93,000 and \$4,000 in 2001 and 2000, respectively. Pursuant to the agreement, Cytogen will pay Draximage \$1.0 million upon the first sale of the palladium-103 BrachySeeds. The Company launched the radioactive iodine BrachySeed in the U.S. in the first half of 2001.

#### 5. ACQUISITION OF PROSTAGEN, INC.

In June 1999, Cytogen reacquired the rights for immunotherapy to its PSMA technology by acquiring 100% of the outstanding capital stock of Prostagene, Inc. ("Prostagene") for 2,050,000 shares of Cytogen Common Stock, plus transaction costs. The acquisition was accounted for using the purchase method of accounting, whereby the purchase price was allocated to the assets acquired and liabilities assumed from Prostagene based on the respective estimated fair values at the acquisition date. The excess of the purchase price over the fair value of the net tangible assets of approximately \$1.2 million was assigned to acquired technology rights and has been recorded as a non-cash charge to operations in the accompanying financial statements. Acquired technology rights reflects the value of the PSMA technology development projects underway at the time of the Prostagene acquisition. The Company may issue up to an additional 450,000 shares of Cytogen Common Stock upon the satisfactory termination of lease obligations assumed in the Prostagene acquisition.

The Company had sublicensed PSMA to Prostagene for prostate cancer immunotherapy in 1996. In connection with the acquisition, Cytogen acquired approximately \$550,000 in cash, a minority ownership in Northwest Biotherapeutics, Inc., which is developing PSMA for dendritic cell therapy, and a contract with Velos, Inc. for marketing a cancer patient software management program for hospitals and health care payors. In addition, the Company may issue up to an additional \$4.0 million worth of Cytogen Common Stock if certain milestones are achieved in the dendritic cell therapy and PSMA development programs. The Company may also issue up to 500,000 shares of Cytogen Common Stock upon beneficial resolution of other contractual arrangements entered into by Prostagene.

#### 6. PROGENICS PHARMACEUTICALS, INC. JOINT VENTURE



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

In June 1999, Cytogen entered into a joint venture with Progenics, PSMA Development Co. LLC (the "Joint Venture"), to develop vaccine and antibody-based immunotherapeutic products utilizing Cytogen's proprietary PSMA technology. The Joint Venture is owned equally by Cytogen and Progenics. Through November 2001, Progenics funded the first \$3.0 million of development costs of the Joint Venture. Beginning in December 2001, the Company and Progenics began to equally share the future costs of the Joint Venture. Cytogen has the exclusive North American marketing rights on products developed by the Joint Venture.

The Company accounts for the Joint Venture using the equity method of accounting. As discussed above, 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, expected to be losses, in its consolidated statement of operations. For the year ended December 31, 2001, Cytogen recognized \$332,000 of these losses. As of December 31, 2001, the carrying value of the Company's investment in the Joint Venture was \$588,000 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 (see Note 1).

In connection with the licensing of the PSMA technology to the Joint Venture in June 1999, Cytogen recognized approximately \$1.8 million in license fee revenue. In connection with the adoption of SAB 101, effective January 1, 2000 (see Note 1), the Company deferred approximately \$1.5 million of this previously recognized license fee and recognized \$599,000 of the deferred revenue as license and contract revenue in each of the years in 2001 and 2000. The remaining \$275,000 of deferred revenue will be recognized on a straight-line basis through June 2002, the estimated term of the development program.

### 7. THE DOW CHEMICAL COMPANY

In 1993, Cytogen acquired from The Dow Chemical Company ("Dow") an exclusive license for the treatment of osteoblastic bone metastases in the U.S. for Quadramet. This license was amended in 1995 and 1998 to expand the territory to include Canada, Latin America, Europe and Japan, in 1996 to expand the field to include all osteoblastic diseases, and in 1998 to include rheumatoid arthritis. The agreement also requires the Company to pay Dow royalties based on a percentage of net sales of Quadramet, or a guaranteed contractual minimum payments, whichever is greater, and future payments upon achievement of certain milestones. The Company recorded \$824,000, \$802,000 and \$500,000, in royalty expense for 2001, 2000 and 1999, respectively. Future annual minimum royalties due to Dow are \$1.0 million per year in 2002 through 2012.

-67-

### CYTOGEN CORPORATION AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

### 8. REVENUES FROM MAJOR CUSTOMERS

Revenues from major customers (greater than 10%) as a percentage of total revenues were as follows:

	Year Ended December 31,		
	2001	2000	1999
Berlex Laboratories Inc.....	20%	22%	9%
Progenics Pharmaceuticals, Inc. (see Note 6).....	5	6	16

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

Mallinckrodt Medical Inc.....	20	19	16
Medi-Physics.....	12	7	15
Syncor International Corporation.....	11	11	10

Mallinckrodt Medical Inc., Medi-Physics and Syncor International Corporation are chains of radiopharmacies, which distribute ProstaScint and OncoScint CR/OV kits.

Revenues from Berlex and Progenics in 2001 and 2000 include the recognition of deferred revenue following the adoption of SAB 101.

### 9. ACCOUNTS PAYABLE AND ACCRUED LIABILITIES

	December 31,	
	2001	2000
Accounts payable.....	\$1,166,000	\$2,700,000
Accrued payroll and related expenses.....	989,000	1,791,000
Accrued research contracts and materials.....	831,000	218,000
Accrued commission and royalties.....	250,000	205,000
Accrued professional and legal.....	1,061,000	755,000
Facility payable.....	462,000	1,125,000
Other accruals.....	556,000	424,000
	\$5,315,000	\$7,218,000
	=====	=====

### 10. LONG-TERM DEBT

	December 31,	
	2001	2000
Due to Elan Corporation, plc.....	\$2,280,000	\$2,280,000
Capital lease obligations.....	88,000	245,000
	2,368,000	2,525,000
Less: Current portion.....	(77,000)	(151,000)
	\$2,291,000	\$2,374,000
	=====	=====

In August 1998, Cytogen received \$2.0 million from Elan Corporation, plc ("Elan") in exchange for a convertible promissory note. The note is convertible into shares of Cytogen Common Stock at \$2.80 per share, subject to adjustments, and matures in August 2005. The note bears annual interest of 7%, compounded semi-annually, however, such interest is not payable in cash but is added to the principal for the first 24 months; thereafter, interest is payable in cash. In 2001, 2000 and 1999, the Company recorded \$160,000 and \$141,000 and \$146,000, respectively, in interest expense on this note.

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

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

The Company leases certain equipment under capital lease obligations, which will expire on various dates through 2004. Property and equipment leased under non-cancellable capital leases have a net book value of \$210,000 at December 31, 2001. Payments to be made under capital lease obligations (including total interest of \$11,000) are \$85,000 in 2002, \$9,000 in 2003 and \$4,000 in 2004.

#### 11. COMMON STOCK

In January 1999, the Company sold 2,666,667 shares of Cytogen Common Stock to a subsidiary of The Hillman Company for an aggregate price of \$2.0 million, or \$0.75 per share. Also in January, the Company exercised a put right granted to Cytogen under a \$12.0 million equity line agreement with an institutional investor, for the sale of 475,342 shares of Common Stock at an aggregate price of \$500,000 or \$1.0519 per share.

In August 1999, the Company sold to the State of Wisconsin Investment Board ("SWIB") 3,105,590 shares of Cytogen Common Stock at an aggregate price of \$5.0 million, or \$1.61 per share.

In 2000, the Company sold 1.0 million shares of Cytogen Common Stock to Berlex for \$1.0 million or \$1.00 per share upon an exercise of a warrant and approximately 1.7 million additional shares of Cytogen Common Stock for total proceeds of \$3.5 million at an average price of \$2.12 per share upon the exercises of employee stock options and other warrants.

In September 2000, the Company sold to Acqua Wellington North American Equities Fund, Ltd. ("Acqua Wellington") 902,601 registered shares of Cytogen Common Stock at an aggregate price of \$6.0 million or \$6.647 per share. In October 2000, the Company entered into an equity financing facility with Acqua Wellington for up to \$70 million of Common Stock. Under the terms of the agreement, 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 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.

In January 2002, the Company sold 2,970,665 shares of Cytogen Common Stock to SWIB for an aggregate purchase price of \$8.0 million or \$2.69 per share pursuant to a January 2002 Share Purchase Agreement between SWIB and the Company. In connection with our stock issuances to SWIB, the Company agreed not to enter into equity line arrangements in the future, issue certain securities at less than fair market value or undertake certain other securities issuances without requisite stockholder approval.

#### 12. STOCK OPTIONS

The Company has various stock option plans that provide for the issuance of incentive and non-qualified stock options to purchase Cytogen Common Stock ("Cytogen Options") to employees, non-employee directors and outside consultants, for which an aggregate of 6,078,888 shares of Common Stock have been reserved. The persons to whom Cytogen Options may be granted and the

Edgar Filing: CYTOGEN CORP - Form 10-K

number, type, and terms of the Cytogen Options vary among the plans. Cytogen Options are granted with an exercise term of 10 years and generally become exercisable in installments over periods of up to 5 years at an exercise price determined either by the plan or equal to the fair market value of the Cytogen Common Stock at the date of grant. Under certain circumstances, vesting may accelerate. Activity under these plans was as follows:

-69-

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

	Number of Cytogen Options	Price Range Per Share	Aggregate Exercise Price
	-----	-----	-----
Balance at December 31, 1998	6,042,295	\$ 0.70 - 16.63	\$15,449,915
Granted	536,155	0.95 - 2.67	1,068,223
Exercised	(231,842)	0.81 - 2.69	(306,507)
Cancelled	(1,266,609)	0.80 - 8.06	(5,963,368)
	-----		-----
Balance at December 31, 1999	5,079,999	0.70 - 16.63	10,248,263
Granted	1,340,500	2.47 - 16.94	8,530,540
Exercised	(1,343,439)	0.83 - 16.63	(3,210,282)
Cancelled	(380,766)	0.95 - 16.94	(1,024,568)
	-----		-----
Balance at December 31, 2000	4,696,294	0.70 - 16.94	14,543,953
Granted	747,360	2.56 - 6.13	2,845,773
Exercised	(130,904)	0.70 - 2.84	(217,478)
Cancelled	(370,269)	0.83 - 16.94	(1,627,480)
	-----		-----
Balance at December 31, 2001	4,942,481	\$ 0.70 - 16.94	\$15,544,768
	=====		=====

The following table summarizes information about Cytogen stock options at December 31, 2001:

Outstanding Cytogen Stock Options			Exercisable Cytogen Stock Options		
Range of Exercise Prices	Outstanding Shares	Weighted-Average Remaining Contractual Life	Weighted-Average Exercise Price	Exercisable Shares	Weighted-Average Exercise Price
-----	-----	-----	-----	-----	-----
\$ 0.70 - 1.83	2,348,452	6.6	\$ 1.09	1,510,052	
1.84 - 3.67	1,363,896	8.1	2.76	657,845	
3.68 - 5.50	418,300	7.0	4.86	190,300	
5.51 - 7.33	251,333	5.9	5.98	184,567	

Edgar Filing: CYTOGEN CORP - Form 10-K

7.34 - 9.17	45,500	4.8	7.80	43,100
9.18 -11.00	501,000	8.5	10.14	167,067
16.50 -16.94	14,000	1.9	16.56	12,800
	-----			-----
\$ 0.70 -16.94	4,942,481	7.2	\$ 3.35	2,765,731
	=====			=====

At December 31, 2001, Cytogen Options to purchase 2,765,731 shares of Cytogen Common Stock were exercisable and 1,136,407 shares of Cytogen Common Stock were available for issuance under approved plans of additional options that may be granted under the plans.

Included in the above tables is a Cytogen Option granted to a key employee in 1998 to purchase 2,250,000 shares of Cytogen Common Stock at an exercise price of \$1.0937 per share, of which, the vesting of 1,350,000 shares ("Performance Options") are subject to the completion of certain performance based milestones as determined by the Board of Directors (the "Board"). During 2000 and 1999, the Board approved the commencement of vesting for 225,000 and 675,000 of the Performance Options, respectively, upon the achievement of certain milestones. In 2000 and 1999, the Company recorded \$1.1 million and \$84,000, respectively, of deferred compensation related to the vesting of the Performance Options, which represents the fair market value of Cytogen's Common Stock in excess of the exercise price of the option on the date, which the Board determined the performance milestones had been met. Deferred compensation is being amortized over the three-year vesting period of the Performance Options.

AxCell, a subsidiary of Cytogen Corporation, also has a stock option plan that provides for the issuance of incentive and non-qualified stock options to purchase AxCell Common Stock ("AxCell Options") to employees, for which 2,000,000 shares of AxCell common stock have been reserved. As of December 31, 2001, 8,000,000 shares of AxCell Common Stock are outstanding; all of which are held by Cytogen. AxCell Options are granted with an exercise term of 10 years and generally become exercisable in installments over periods of up to 5 years at an exercise price determined either by the plan or equal to the fair market

-70-

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

value of AxCell Common Stock at the date of grant. The Company granted AxCell Options to purchase 438,365 and 229,028 shares of AxCell Common Stock during 2001 and 1999, respectively. The exercise prices range from \$0.63 to \$4.63 (weighted average of \$3.69) in 2001 and \$0.63 to \$0.80 (weighted average of \$0.68) in 1999. As of December 31, 2001, options to purchase 578,602 shares of AxCell Common Stock were outstanding, of which 349,208 shares were exercisable and 1,421,398 shares were available for future grant. During 2001, in connection with the grant of AxCell Options, the Company recorded deferred compensation of \$241,000, representing the estimated fair value of AxCell Common Stock in excess of the exercise price of the options on the date such options were granted. The deferred compensation is being amortized over the vesting period of the options.

The Company adopted an employee stock purchase plan under which eligible employees may elect to purchase shares of Cytogen Common Stock at the lower of 85% of fair market value as of the first trading day of each quarterly participation period, or as of the last trading day of each quarterly

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

participation period. In 2001, 2000 and 1999, employees purchased 12,869, 32,385 and 29,209 shares, respectively, for aggregate proceeds of \$28,000, \$80,000 and \$29,000, respectively. The Company has reserved 355,497 shares for future issuance under its employee stock purchase plan.

The Company applies Accounting Principle Board Opinion No. 25, "Accounting for Stock Issued to Employees," and the related interpretations in accounting for its stock options to employees. The Company follows the disclosure requirement of Statement of Financial Accounting Standards ("SFAS") No. 123, "Accounting for Stock-Based Compensation". Had compensation cost of the Company's stock options to employees been determined under SFAS No. 123, the Company's net loss would have been increased to the following pro forma amounts:

	Year Ended December 31,	
	2001	2000
Net income (loss), as reported	\$(12,100,000)	\$(27,298,000)
Pro forma net loss	\$(17,423,000)	\$(30,689,000)
Basic and diluted net income (loss) per share, as reported	\$(0.16)	\$(0.37)
Basic and diluted pro forma net loss per share	\$(0.22)	\$(0.42)

The weighted average fair value of the options granted under the Cytogen stock option plans during 2001, 2000 and 1999 is estimated as \$3.07, \$5.40 and \$1.29 per option, respectively, on the date of grant using the Black-Scholes pricing model with the following assumptions for 2001, 2000 and 1999: dividend yield of zero, volatility of 124.95%, 120.39% and 87.99%, respectively, risk-free interest rate of 4.55%, 5.98% and 5.85%, respectively, and an expected life ranging from 4 to 5 years. The average fair value per option ascribed to the employee stock purchase plan during 2001, 2000 and 1999 is estimated at \$1.47, \$1.35 and \$0.40, respectively, on the date of grant using the Black-Scholes option pricing model with the following assumptions for 2001, 2000 and 1999: dividend yield of zero, volatility of 125.41%, 109.83% and 111.48%, respectively, risk free interest rate of 4.12%, 5.52% and 4.46%, respectively, and expected life of three months. The weighted average fair value of AxCell Options granted during 2001 and 1999 is estimated at \$4.06 and \$0.49, respectively, on the date of grant using the Black-Scholes pricing model with the following assumptions for 2001 and 1999: dividend yield of zero, volatility of 124.91% and 88.61%, respectively, risk-free interest rate of 4.59% and 5.81%, respectively, and an expected life of 5 years.

### 13. RELATED PARTY TRANSACTION

Consulting services have been provided to the Company under an agreement with the Chairman of the Board of Directors related to time spent in that function on Company matters. Fees and expenses under this agreement were \$53,000, \$54,000 and \$136,000 in 2001, 2000 and 1999, respectively.

### 14. RETIREMENT SAVINGS PLAN

The Company maintains a defined contribution plan for its employees. The contribution is determined by the Board of Directors each year and is based upon a percentage of gross wages of eligible employees. The plan provides for vesting over four years, with credit given for prior service. The Company also makes contributions under a 401(k) plan in amounts, which match up to 50% of the salary deferred by the participants. Matching is capped at 6% of deferred

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

salaries. Total expense was \$140,000, \$95,000 and \$182,000 for 2001, 2000 and 1999, respectively.

-71-

### CYTOGEN CORPORATION AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

#### 15. INCOME TAXES

As of December 31, 2001, Cytogen had federal net operating loss carryforwards of approximately \$241 million. The Company also had federal and state research and development tax credit carryforwards of approximately \$6.8 million. These net operating loss and credit carryforwards will expire through 2021. In addition, certain operating loss and credit carryforwards began to expire in 1995.

The Tax Reform Act of 1986 contains provisions that limit the utilization of net operating loss and tax credit carryforwards if there has been an "ownership change". Such an "ownership change", as described in Section 382 of the Internal Revenue Code may limit the Company's utilization of its net operating loss and tax credit carryforwards.

Deferred income taxes reflect the net tax effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amount used for income tax purposes. Based upon the Company's loss history, a valuation allowance for deferred tax assets has been provided:

	2001 ----	2000 ----
Deferred tax assets:		
Net operating loss carryforwards	\$ 81,860,000	\$ 74,800,000
Capitalized research and development expenses	11,808,000	15,800,000
Research and development credit	6,800,000	6,800,000
Acquisition of in-process technology	720,000	800,000
Other, net	9,738,000	5,800,000
	-----	-----
Total deferred tax assets	110,926,000	104,000,000
Valuation allowance for deferred tax assets	(110,926,000)	(104,000,000)
	-----	-----
Net deferred tax assets	\$ -	\$ -
	=====	=====

In 1995, Cytogen acquired CytoRad and Cellcor, both of which had net operating loss carryforwards. Due to Section 382 limitations, approximately \$10 million of CytoRad and \$12.0 million of Cellcor carryforwards may be available to offset future taxable income. A full valuation allowance was established on the acquisition dates as realization of these tax assets is uncertain.

During 2001 and 2000, the Company sold New Jersey state operating loss carryforwards and research and development credits, resulting in the recognition of a \$1.1 million and \$1.6 million tax benefit, respectively.

#### 16. COMMITMENTS AND CONTINGENCIES

The Company leases its facilities and certain equipment under non-cancellable operating leases that expire at various times through 2006. Rent expense on

Edgar Filing: CYTOGEN CORP - Form 10-K

these leases was \$1.6 million, \$1.3 million and \$998,000 in 2001, 2000 and 1999, respectively. Minimum future obligations under the operating leases are \$1.7 million as of December 31, 2001 and will be paid as follows: \$748,000 in 2002, \$408,000 in 2003, \$344,000 in 2004, \$137,000 in 2005 and \$104,000 in 2006.

The Company is obligated to make minimum future payments under research and development contracts that expire at various times. As of December 31, 2001, the minimum future payments under contracts are \$559,000 in 2002, \$213,000 in 2003, \$172,000 in 2004 and \$130,000 each year from 2005 and thereafter. In addition, the Company is obligated to pay royalties on revenues from commercial product sales including certain guaranteed minimum payments.

On March 17, 2000, we were served with a complaint filed against us in the United States Federal Court for the District of New Jersey by M. David Goldenberg ("Goldenberg") and Immunomedics, Inc. (collectively "Plaintiffs") 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. 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. In addition, 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. However, given the uncertainty associated with litigation, we cannot give any assurance that the litigation could not result in a material expenditure to us. On December 17, 2001, we filed a motion for summary judgment of non-infringement of the asserted claims of the patent-in-suit. The Plaintiffs have indicated that they will file a cross-motion for summary judgment with their opposition to our motion. A hearing on these motions is likely to take place in the Spring of 2002.

-72-

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

17. CONSOLIDATED QUARTERLY FINANCIAL DATA - UNAUDITED

The following table provides quarterly data for the years ended December 31, 2001 and 2000.

	Three Months Ended		
	March 31, 2001	June 30, 2001	Sept. 30, 2001
	(amounts in thousands except per share)		
Total revenues.....	\$ 2,991	\$ 2,834	\$ 2,800
Total operating expenses .....	5,817	6,031	6,697
Operating loss .....	(2,826)	(3,197)	(3,897)



Edgar Filing: CYTOGEN CORP - Form 10-K

Other income, net .....	172	112	118
	-----	-----	-----
Loss before income taxes .....	(2,654)	(3,085)	(3,779)
Income tax benefit .....	-	-	-
	-----	-----	-----
Net loss .....	\$ (2,654)	\$ (3,085)	\$ (3,779)
	=====	=====	=====
Basic and diluted net loss per share .....	\$ (0.03)	\$ (0.04)	\$ (0.05)
	=====	=====	=====
Weighted average common share outstanding....	76,244	77,444	78,866
	=====	=====	=====

-73-

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

	Three Months En		
	March 31, 2000	June 30, 2000	Sept 2
	-----	-----	-----
	(amounts in thousands except		
Total revenues.....	\$ 2,643	\$ 2,435	\$ 2
Total operating expenses .....	4,500	4,951	19
	-----	-----	-----
Operating loss .....	(1,857)	(2,516)	(16
Other income, net.....	111	144	-----
	-----	-----	-----
Loss before income taxes and cumulative effect of accounting change.....	(1,746)	(2,372)	(16
Income tax benefit .....	-	-	-----
	-----	-----	-----
Loss before cumulative effect of accounting change.....	(1,746)	(2,372)	(16
Cumulative effect of accounting change .....	(4,314)	-	-----
	-----	-----	-----
Net loss .....	\$ (6,060)	\$ (2,372)	\$ (16
	=====	=====	=====

Edgar Filing: CYTOGEN CORP - Form 10-K

Net loss per share:			
Basic and diluted net loss before cumulative			
effect of accounting change .....	\$ (0.02)	\$ (0.03)	\$ (
Cumulative effect of accounting change .....	(0.06)	-	
	-----	-----	-----
Basic and diluted net loss .....	\$ (0.08)	\$ (0.03)	\$ (
	=====	=====	=====
Weighted average common shares outstanding .....	71,630	72,779	73
	=====	=====	=====