CYTOGEN CORP
Form 10-K
March 16, 2005
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UNITED STATES

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)

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2004

OR

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

For the transition period from _____ to _____

Commission File Number 000-14879

CYTOGEN CORPORATION

(Exact Name of Registrant as Specified in Its Charter)

Delaware	22-2322400
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
650 College Road East, Suite 3100 Princeton, New Jersey	08540
(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 per share

(Title of Class)

Preferred Stock Purchase Rights, $0.01 par value per share

(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. x

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2). Yes x No ¨

The aggregate market value of the registrant s voting shares of Common Stock held by non-affiliates of the registrant on June 30, 2004, based on $15.90 per share, the last reported sale price on the NASDAQ National Market on that date, was $203,110,973.

The number of shares of Common Stock, $.01 par value, of the registrant outstanding as of March 1, 2005 was 15,521,229 shares.

The following documents are incorporated by reference into this Annual Report on Form 10-K: Portions of the registrant s definitive Proxy Statement for its 2005 Annual Meeting of Stockholders are incorporated by reference into Part III hereof.

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PART I

Item 1. Business

OVERVIEW

Founded in 1980, Cytogen Corporation of Princeton, NJ is a product-driven biopharmaceutical company that develops and commercializes innovative molecules that can be used to build leading franchises across multiple markets. Our marketed products include QUADRAMET® (samarium Sm-153 lexidronam injection) and PROSTASCINT® (capromab pendetide) kit for the preparation of Indium In-111 capromab pendetide in the United States. We have exclusive United States marketing rights to COMBIDEX® (ferumoxtran-10) for all applications, and the exclusive right to market and sell ferumoxytol (formerly Code 7228) for oncology applications in the United States. COMBIDEX, an investigational functional molecular imaging agent consisting of iron oxide nanoparticles, is currently being developed for use in conjunction with magnetic resonance imaging to aid in the differentiation of cancerous from non-cancerous lymph nodes, and is under review by the U.S. Food and Drug Administration (FDA). We are also developing therapeutics targeting prostate-specific membrane antigen (PSMA), a protein highly expressed on the surface of prostate cancer cells and the neovasculature of solid tumors.

Our proprietary and licensed products, product candidates and technologies are as follows:

Marketed Products:

Product	Description	Status
QUADRAMET® (samarium Sm-153 lexidronam injection)	Fast-acting, long-lasting non-opioid treatment for the relief of pain due to metastatic bone disease arising from prostate, breast, multiple myeloma and other types of cancer	Developed by Cytogen based upon technology licensed from the Dow Chemical Company Marketed in the United States by Cytogen as of August 1, 2003, and previously by Berlex Laboratories from May 1999 until July 2003
PROSTASCINT® (capromab pendetide)	Kit for the preparation of Indium In-111 capromab pendetide, the first and only commercial monoclonal antibody-based agent targeting prostate-specific membrane antigen (PSMA) to image the extent and spread of prostate cancer	Developed and marketed by Cytogen in the United States

Product Candidates and Pipeline:

Product	Description	Status
COMBIDEX® (ferumoxtran-10)	Investigational functional molecular imaging agent consisting of iron oxide nanoparticles used in conjunction with magnetic resonance imaging to aid in the differentiation of cancerous from non-cancerous lymph nodes	Developed by Advanced Magnetics, Inc. and exclusively licensed by Cytogen for marketing in the United States Under review by FDA

	Received an approvable letter in June 2000; On March 3, 2005, FDA advisory committee voted to not recommend approval of proposed broad indication; Assigned a user fee goal date of March 30, 2005

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Product	Description	Status
rs PSMA protein vaccine	An *in vivo* vaccine consisting of recombinant soluble PSMA combined with an immune stimulant to induce an immune response	Phase I*
PSMA viral vector vaccine	An *in vivo* vaccine that utilizes viral vectors designed to deliver the PSMA gene to immune system cells in order to generate potent and specific immune response	Preclinical*
PSMA monoclonal antibodies	Novel fully-human monoclonal antibodies that bind to the three-dimensional structure of PSMA as presented on cancer cells, including naked, toxin-linked and radio-labeled approaches	Preclinical*

* Jointly developed with Progenics Pharmaceuticals, Inc.

We market QUADRAMET and PROSTASCINT in the United States through our in-house specialty sales and marketing organization, consisting of approximately 59 employees, directly to medical oncologists, radiation oncologists, nuclear medicine professionals, radiologists and urologists.

We were incorporated in Delaware on March 3, 1980 under the name Hybridex, Inc. and changed our name to Cytogen Corporation on April 1, 1980. Our executive offices are located at 650 College Road East, Suite 3100, Princeton, New Jersey 08540 and our telephone number is 609-750-8200.

QUADRAMET®, PROSTASCINT® and ONCOSCINT® are registered United States trademarks of Cytogen Corporation. All other trade names, trademarks or servicemarks appearing in this Annual Report on Form 10-K are the property of their respective owners, and not the property of Cytogen Corporation or any of our subsidiaries.

We also maintain a website at www.cytogen.com, which is not a part of this Annual Report on Form 10-K. References to our website in this Annual Report on Form 10-K are intended as an inactive textual reference only. We provide an internet link on our website to the Securities and Exchange Commission s website where you can find documents that we file with the SEC, including our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to such reports filed pursuant to Section 13(a) or 15(d) of the Exchange Act. These documents are posted as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Alternatively, we will provide electronic or paper copies of our filings free of charge upon request.

MARKETED PRODUCTS AND PRODUCT CANDIDATES PENDING APPROVAL

THERAPEUTICS

QUADRAMET

Overview

QUADRAMET is an oncology product that pairs the targeting ability of a small molecule, bone-seeking phosphonate (EDTMP) with the therapeutic potential of radiation (samarium Sm-153). Combined, these agents form an innovative molecule with a short radioactive half-life that selectively concentrates in osteoblastic sites (areas of new bone formation). Skeletal invasion by prostate, breast, multiple myeloma, and other cancers often

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creates an imbalance between the normal process of bone destruction and formation. QUADRAMET selectively targets such sites of imbalance, thereby delivering radioactivity to areas of the skeleton that have been invaded by metastatic tumor.

QUADRAMET has many characteristics which we believe are advantageous for the treatment of metastatic bone disease including early onset of pain relief, predictable and reversible bone marrow toxicity or myelosuppression, ease of administration, and length of pain relief, lasting, on average, four months with a single injection. QUADRAMET is administered as an intravenous injection on an outpatient basis, and exhibits selective uptake in bone with little or no detectable accumulation in soft tissue.

Further Clinical Development Related to QUADRAMET

We believe the unique combination of nuclear, chemical, and biologic properties possessed by QUADRAMET makes it an attractive candidate for addition of a skeletal targeted therapeutic component to a number of systemic therapies currently utilized in the treatment of patients with cancers originating in, or metastasizing to, bone. We believe that future QUADRAMET growth is, in part, dependent upon:

- clinical investigations to develop new data supporting the expanded and earlier use of QUADRAMET in various cancers;
- conducting novel research supporting combination uses of QUADRAMET with other therapies, such as chemotherapy and bisphophonates;
- establishing the use of QUADRAMET at higher doses and earlier in the course of the disease to target and treat primary bone cancers;
- obtaining FDA marketing approval for these expanded indications, where appropriate; and
- increasing marketing and sales penetration to radiation and medical oncologists.

Our products, including QUADRAMET, are subject to significant regulation by governmental agencies, including the FDA, as is more fully described under the section entitled Government Regulation herein. We cannot assure you that we will be able to complete any of our market expansion strategies set forth above.

QUADRAMET is currently being evaluated both at higher doses and in a series of combination therapy trials in order to assess potential synergies with chemotherapeutics, bisphosphonates and other agents. Currently active clinical studies in this regard include:

- TAXSAM studies (TAXoid-based chemotherapy and SAMarium Sm-153 lexidronam injection)

  A Phase I/II study at The University of Texas M. D. Anderson Cancer Center in Houston evaluating the potential benefits of treatments including multiple doses of QUADRAMET in combination with weekly dosing of docetaxel in patients whose

cancer has progressed after receiving hormonal therapy.

A Phase I/II study at Johns Hopkins Kimmel Cancer Center to investigate the use of QUADRAMET in combination with standard docetaxel dosing every three weeks for the treatment of metastatic bone disease arising from prostate cancer. The clinical study will evaluate the safety profile and preliminary incidence and duration of clinical benefits of novel escalating dose and administration schedules of docetaxel in combination with multiple doses of QUADRAMET in hormone refractory prostate cancer patients.

A Phase I/II study at Northwestern University in Illinois using QUADRAMET, paclitaxel (Taxol®), and estramustine phosphate sodium (Emcyt®) in hormone refractory prostate cancer patients. The study utilizes escalating single doses of QUADRAMET in combination with paclitaxel and estramustine phosphate sodium in order to evaluate the dose level at which dose limiting toxicity is obtained.

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NEOSAM studies (NEOadjuvant use of SAMarium Sm-153 lexidronam injection)

A Phase I study at Thomas Jefferson University in Pennsylvania using escalating single doses of QUADRAMET combined with ongoing hormonal therapy prior to external beam radiation therapy in men with high risk clinically localized prostate cancer. The objectives of this study are to assess the safety of QUADRAMET and determine the maximum tolerated dose of QUADRAMET in this clinical setting. The goal of this type of therapy is to prevent or delay the progression of metastatic bone disease.

A Phase I/II study at a leading medical institution evaluating the use of QUADRAMET in the adjuvant treatment of osteogenic sarcoma. The objective of this study is to determine the maximum tolerated dose of QUADRAMET in this clinical setting that will result in marrow recovery in a time frame that does not significantly delay further chemotherapy.

SAMBIS studies (SAMarium Sm-153 lexidronam injection and BISphosphonates)

Two Phase I/II studies at the University of Maryland in Baltimore evaluating the potential benefits of combination treatments including QUADRAMET and zoledronic acid (Zometa®) in patients with advanced prostate cancer. One study involves patients who are chemotherapy naïve while the other involves patients who have previously received chemotherapy.

A Phase I/II study at the Mayo Clinic evaluating the use of QUADRAMET in combination with bisphosphonates for the treatment of pain associated with metastatic bone disease in patients with recurrent or refractory multiple myeloma. The escalating dose clinical study will evaluate both the safety profile and effects on painful symptoms and analgesic use. In addition, preliminary information regarding the effect of QUADRAMET on the underlying disease will be determined by monitoring levels of M-protein, a marker for multiple myeloma activity.

In addition to these clinical studies, in November 2004 we also announced the initiation of our National Bone Pain Registry for QUADRAMET. As of March 1, 2005, more than 50 oncology sites were participating in the registry, and we expect to collect data regarding both the use of QUADRAMET and best practices in bone pain management from more than 500 patients. Results of this initiative are expected to be presented at key medical meetings following the conclusion of the program in 2005. We cannot give any assurances regarding the rate of patient accrual in the registry.

During 2004, we reported that clinical investigators from cancer research centers around the world presented new clinical data regarding QUADRAMET as follows:

Clinical investigators from the Stanley S. Scott Cancer Center at Louisiana State University Medical School reported data from two studies of QUADRAMET. In a Phase IV clinical study, patients with metastatic bone disease received multiple administrations of QUADRAMET based on a recurrence of painful symptoms. In a separate Phase I clinical study, patients with hormone sensitive prostate cancer received both multiple and higher doses of QUADRAMET at fixed time intervals. Additional details regarding the conduct and results of these studies were presented at the Eleventh Prostate Cancer Foundation Scientific Retreat held in Lake Tahoe, Nevada.

Clinical investigators from the Mayo Clinic reported data on the use of high dose QUADRAMET in conjunction with chemotherapy for the treatment of acute myeloid leukemia (AML). Additional details regarding the conduct and results of this study are available in *Pediatr Transplant* 9(1):122-6, 2005.

Clinical investigators from the University of Pisa Medical School in Italy reported data on the safety and efficacy of QUADRAMET in conjunction with chemotherapy for the treatment of bone metastases secondary to prostate cancer. Additional details regarding the conduct and results of this study were presented at the 2004 Society of Nuclear Medicine Meeting held in Philadelphia, Pennsylvania.

Clinical investigators from Northwestern University in Illinois reported data on the use of QUADRAMET, paclitaxel (Taxol®), and estramustine phosphate sodium (Emcyt®) in hormone refractory prostate cancer patients. The purpose of the study was to evaluate the dose level at which dose limiting toxicity is obtained. Additional details regarding the conduct and results of this study are available in the *Proceedings of the American Society of Clinical Oncology,* 23:438, 2004.

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Clinical investigators from Magee-Womens Hospital in Pittsburgh reported data on the use of chemotherapy and external beam radiotherapy with QUADRAMET and chemotherapy for the treatment of bone metastases secondary to breast cancer. Additional details regarding the conduct and results of this study are available in *Proceedings of the American Society of Clinical Oncology,* 22:14S, 2004.

QUADRAMET is indicated for the relief of pain in patients with confirmed osteoblastic metastatic bone lesions that enhance on a radionuclide bone scan. The foregoing discussion describes investigational clinical applications that differ from that reported in the QUADRAMET package insert, and that have not been reviewed or approved by FDA. A copy of the full prescribing information for QUADRAMET may be obtained in the United States from us by calling us toll free at 800-833-3533 or by visiting our web site at http://www.cytogen.com, which is not part of this Annual Report on Form 10-K. We are sponsoring or supporting the clinical investigations described in the foregoing discussion to explore potential new indications for the use of QUADRAMET.

Intellectual Property Position Related to QUADRAMET

In May 1993, we obtained an exclusive license from The Dow Chemical Company to use QUADRAMET, in North America, 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. Our license was expanded to include Latin America in 1995, and will remain in effect, unless earlier terminated, for a period of 20 years from May 30, 1993 or until the last to expire of the related patents. We currently anticipate such termination date to be May 30, 2013.

Under our agreement with Dow, we are the licensee of five issued United States patents and certain corresponding foreign patents. Dow is responsible, at its own cost and expense, for prosecuting and maintaining any patents or patent applications included in our agreement. One of these, U.S. Pat. No. 4,898,724, includes claims directed to the QUADRAMET product and methods for its use in the treatment of calcific tumors and bone pain. We have obtained an extension of the term of this U.S. patent, which will now expire March 28, 2011. Other patents licensed to us under this agreement are: (i) U.S. Pat. No. 4,897,254, which expires on January 30, 2007; (ii) U.S. Pat. No. 4,937,333, which expires August 4, 2009; (iii) U.S. Pat. No. 5,300,279, which expires on November 19, 2008; and (iv) U.S. Pat. No. 5,066,478 which expires on November 19, 2008. Additional patents have been issued, including U.S. Pat. No. 5,714,604, which expires on February 3, 2015, and U.S. Pat. No. 5,762,907, which expires November 21, 2006, which include claims directed to the QUADRAMET product, methods for its manufacture, and methods for its preparation and administration. We are the owner of a registered United States trademark relating to QUADRAMET.

Upon execution of our agreement with Dow, we issued warrants to Dow to purchase shares of our common stock, which have since expired. As of December 31, 2004, we have paid an aggregate of $5.2 million to Dow in milestone payments. We remain obligated to pay Dow additional milestone payments as, and if, our sales of QUADRAMET increase and royalties, which are subject to certain minimum amounts, based on future sales of QUADRAMET.

Manufacturing, Supply and Distribution of QUADRAMET

QUADRAMET is manufactured by Bristol-Myers Squibb Medical Imaging, Inc. (BMSMI), pursuant to the terms of a manufacturing and supply agreement with us which became effective on January 1, 2004. Under this agreement, BMSMI has agreed to manufacture, supply and distribute QUADRAMET for us in exchange for a minimum payment of at least $4.2 million annually, subject to future annual price adjustment, through 2008. The agreement will then renew for five successive one year periods. The agreement is terminable by either us or BMSMI, at any time, upon two years notice to the other. We also pay BMSMI a variable amount per month for each order placed to cover the costs of customer service.

The two primary components of QUADRAMET, particularly Samarium-153 and EDTMP, are provided to BMSMI by outside suppliers. BMSMI obtains its supply of Samarium-153 from a sole supplier, and EDTMP from another sole supplier. Alternative sources for these components may not be readily available, and any

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alternate suppliers would have to be identified and qualified, subject to all applicable regulatory guidelines. If BMSMI cannot obtain sufficient quantities of these components on commercially reasonable terms, or in a timely manner, it would be unable to manufacture QUADRAMET on a timely and cost-effective basis. Additionally, QUADRAMET must be manufactured in compliance with regulatory requirements. Any inability on the part of BMSMI to manufacture QUADRAMET, or any failure by BMSMI to comply with all applicable regulatory guidelines, including FDA requirements, and those of the U.S. Nuclear Regulatory Commission, could have a material adverse effect on our business, financial condition and results of operations.

Marketing of QUADRAMET

We currently market QUADRAMET through our in-house specialty sales force.

In October 1998, we entered into an exclusive agreement with Berlex pursuant to which Berlex would market QUADRAMET for us in the United States. Berlex re-launched QUADRAMET in March 1999, and maintained a sales force that targeted its sales efforts on the oncological community. Pursuant to our agreement with Berlex, we received royalty payments based on net sales of QUADRAMET and milestone payments based upon sales levels that were achieved.

In June 2003, we entered into an agreement with Berlex to reacquire marketing rights to QUADRAMET in North America and Latin America in exchange for an upfront payment of $8.0 million and royalties based on future sales of QUADRAMET, subject to our receipt of necessary financing for the reacquisition. On August 1, 2003, we reacquired these marketing rights and began recording product revenue from our sales of QUADRAMET. We no longer receive royalty revenue from Berlex.

Dow is the owner of the technology upon which we developed QUADRAMET. As such, under our license agreement with Dow, we are required to pay Dow royalties or guaranteed contractual minimum payments, whichever is greater, and certain future payments upon the achievement of certain milestones.

Competition Related to Quadramet

Current competitive treatments for bone cancer pain include narcotic analgesics, external beam radiation therapy, bisphosphonates, and other skeletal targeting therapeutic radiopharmaceuticals such as Strontium-89 chloride and Phosphorus-32.

QUADRAMET primarily competes with Strontium-89 chloride in the radiopharmaceutical pain palliation market. Strontium-89 chloride is manufactured and marketed either as Metastron®, by GE Healthcare, or in a generic form by Bio-Nucleonics Pharma, Inc. GE Healthcare manufactures Metastron and sells the product through its wholly owned network of radiopharmacies, direct to end-users and through other radiopharmacy distributors. The generic version is distributed directly by the manufacturer, or is sold through radiopharmacy distributors such as Cardinal Health and AnazaoHealth (formerly Custom Care Pharmacy). The first radiopharmaceutical introduced as a metastatic bone cancer pain palliation agent, Phosphorus-32 (P-32), is no longer routinely utilized clinically in the United States.

To meet future competitive challenges to QUADRAMET, we continue to, among other things, focus our efforts on managing radiopharmacy distributor relationships. We also plan to continue to focus on research supporting additional applications and by documenting the safe and effective use of QUADRAMET when used in conjunction with metastatic disease therapies such as bisphosphonates, chemotherapeutics and hormonal therapy.

MOLECULAR IMAGING/DIAGNOSTIC PRODUCTS AND PRODUCT CANDIDATES

PROSTASCINT

Overview

Our PROSTASCINT molecular imaging agent is the first, and currently the only, commercial product targeting PSMA, a transmembrane protein that is expressed on prostate cancer cells at all stages of disease,

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including advanced or metastatic disease. PROSTASCINT consists of a murine monoclonal antibody (7E11-C5) directed against PSMA that is linked to the radioisotope Indium-111. A radioisotope is an element, which, because of nuclear instability, undergoes radioactive decay and emits radiation. Due to the selective expression of PSMA by prostate cancer cells, PROSTASCINT can image the extent and spread of prostate cancer using a common gamma camera.

PROSTASCINT is approved for marketing in the United States in two clinical settings: (i) as a diagnostic imaging agent in newly diagnosed patients 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 (ii) for use in post-prostatectomy patients with a rising PSA and a negative or equivocal standard metastatic evaluation in whom there is a high clinical suspicion of occult metastatic disease.

During the molecular imaging procedure, PROSTASCINT is administered intravenously into the patient. The 7E11 antibody in PROSTASCINT travels through the bloodstream and binds to PSMA. 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 found in the nuclear medicine departments of most hospitals. The image captured by the camera assists in the identification of the location of the radiolabeled pharmaceutical thus identifying the sites of tumors.

When deciding on a course of therapy for newly diagnosed prostate cancer, physicians must determine the extent of disease in the patient. Patients are most likely to benefit from local treatment options, such as surgical removal of the prostate gland, when disease has not spread beyond the prostate gland. Patients diagnosed with distant disease (not confined to the prostate gland), have a poorer chance of five-year survival than those with disease confined to the gland, and require systemic therapy.

Prior to the availability of PROSTASCINT, determining whether newly diagnosed disease was limited to the prostate or had spread beyond the gland, for instance to lymph nodes, was based upon statistical inference from the biopsy appearance of the tumor, the patient s level of serum PSA, and the stage of other primary tumors. Conventional imaging methods such as computed tomography (CT) or magnetic resonance (MR) are all relatively insensitive because they rely on identifying significant changes to normal anatomic structure to indicate the presence of disease. PROSTASCINT images are based upon expression of the PSMA molecule and, therefore, may identify disease not readily detectable with conventional procedures, such as CT or MR imaging alone. Clinical studies conducted to date by physicians on our behalf indicate that PROSTASCINT may provide new and useful information not available from other conventional diagnostic modalities regarding the existence, location and extent of a specific disease throughout the body.

In addition, in the United States, following initial therapy, prostate cancer patients are monitored to ascertain changes in the level of serum PSA. In this setting, a consistent 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.

Partners In Excellence Sites

PROSTASCINT is a technique-dependent product that requires a high degree of proficiency in nuclear imaging technology in order to correctly obtain and interpret the scan. We have established a network of accredited nuclear medicine imaging centers through our Partners In Excellence, or PIE, program. Since PROSTASCINT images are traditionally difficult to interpret, due to inherent limitations of nuclear medicine imaging as opposed to product performance, each PIE site receives initial training and proficiency evaluations. We only sell PROSTASCINT to qualified PIE sites. As of December 31, 2004, there were approximately 400 PIE sites qualified to perform PROSTASCINT imaging. We plan to add PIE sites on a selective basis and, at the present time, we bear part of the expense of qualifying new sites. We expect to review and requalify existing PIE site on a selective basis.

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Market Expansion Strategies for PROSTASCINT

We believe that future growth and market penetration of PROSTASCINT is largely dependent upon the implementation and continued research of:

- using PROSTASCINT in conjunction with fusion imaging procedures;
- image enhancement technologies;
- imaging other cancers expressing PSMA;
- image guided applications, such as therapy, biopsy and combinations of the foregoing; and
- monitoring response to cytotoxic therapy.

Fusion imaging. Fusion (or hybrid) imaging is an *in vivo* diagnostic technique that combines anatomic and functional information directly from patient studies to provide information that cannot be obtained with separate imaging modalities. Anatomical information derived from either computed tomography (CT) or magnetic resonance (MR) imaging can be fused with functional information obtained using single-photon emission computed tomography (SPECT) and novel molecular imaging agents, such as PROSTASCINT. SPECT imaging focuses on metabolic abnormalities that may be present earlier than the anatomical changes otherwise seen with CT or MR imaging alone. Registering both anatomic and functional images provides a complete pathology picture in a single exam, helping physicians eliminate guesswork and enabling them to plan better patient treatment. Approximately 90 of our current PIE sites are proficient in performing fusion imaging with PROSTASCINT, which can be accomplished through either software or hardware solutions. Through alliances discussed in the Strategic Relationships and Collaborations Related to PROSTASCINT section that follows, we believe that we may increase the use of fusion imaging with PROSTASCINT.

Image Enhancement Technologies. Gamma cameras used in nuclear medicine have advanced in recent years. Some manufacturers now sell cameras with wider segmented crystals, providing advantages in medium and high energy imaging of isotopes (e.g., Indium-labeled agents, such as PROSTASCINT); thus providing enhanced system sensitivity. System enhancements allow improved image quality or reduced scan time, thereby reducing potential risk of patient motion. Equipment vendors have also recently introduced advanced single-photon emission computed tomography (SPECT) reconstruction algorithms, as well as three dimensional iterative reconstruction techniques which potentially increase image contrast with inherent system gains in image quality. These prominent new nuclear medicine imaging algorithms enable advances in image quality as compared to conventional Filtered Back Projection techniques. In addition, nuclear medicine SPECT images of agents such as PROSTASCINT may now be co-registered with an anatomic image obtained with either CT or MR imaging. Device manufacturers generally offer two methods to achieve co-registration between metabolic and anatomical images. Some manufacturers merge information in a single SPECT/CT system, while others utilize fusion software, which has become more widely available in the past few years, as computer workstations have become powerful enough to achieve co-registration.

Imaging Other Cancers Expressing PSMA. PSMA was originally thought to be strictly expressed in prostate tissue, but studies have demonstrated PSMA protein expression in the newly forming blood vessels associated with a variety of nonprostatic tumors. The formation of new blood vessels (angiogenesis) is essential for the growth and development of both primary and metastatic tumors and may represent a unique target for the treatment and diagnosis of a variety of diverse tumors. PSMA may be a unique antiangiogenesis target because it is selectively and

consistently expressed in nonprostatic tumor-associated neovasculature but not in normal vessels in benign tissue. A renal cell carcinoma discovered through PROSTASCINT imaging forms the basis upon which we believe PSMA s role as a molecular imaging target may be expanded. The PROSTASCINT scan revealed suspicious uptake in a kidney, which subsequent conventional imaging revealed to be a solid renal mass with necrosis. This example might have demonstrated recognition of tumor-associated neovasculature by the PROSTASCINT monoclonal antibody. Detection of other malignancies such as non-Hodgkin s lymphoma, neurofibromatosis, and meningioma have also been reported with PROSTASCINT imaging. Accordingly, we are planning additional research to determine the role of PROSTASCINT imaging in nonprostatic primary and metastatic malignancies.

Image Guided Therapy. Recent advances in nuclear medicine imaging SPECT equipment, computer workstation power, as well as software enhancements allow researchers to utilize cutting-edge imaging

technology to explore novel applications of the enhanced PROSTASCINT image. With fusion of an enhanced SPECT, the PROSTASCINT image is registered with CT and/or MR anatomic images; the resulting images have been applied to clinical research in areas of guided brachytherapy (or radioactive seeds), guided external beam radiation therapy (EBRT), intensity modulated radiation therapy (IMRT) and image guided biopsy. An example of this type of application was described in a 2003 publication reporting four-year biochemical outcome after radioimmunoguided (PROSTASCINT) brachytherapy published in the *International Journal of Radiation Oncology Biology Physics*, Vol. 57, No. 2, pp. 362-370, 2003.

Monitoring Response to Cytotoxic Therapy. The molecular basis of cancer is widely believed to involve mutations that lead to deregulated cellular proliferation and suppression of mechanisms controlling programmed cell death (apoptosis). Tumor sensitivity to any given therapeutic regimen is commonly mediated by the initiation of apoptosis. Many therapeutically effective anticancer drugs act to interfere with DNA synthesis and cell division, thereby inducing apoptosis in susceptible target tumors. The specific segment of PSMA recognized by the PROSTASCINT monoclonal antibody is located in the internal cellular domain, which may only be accessible in dead or dying cells within tumor sites, although this has not been confirmed. Accordingly, we are planning additional research to determine the effectiveness of various anticancer regimens on a patient-by-patient basis by assessing the degree of apoptosis in target tumors soon after the initial treatment using PROSTASCINT imaging. Assessment of response to cytotoxic therapy would support the decision to continue treatment in responding patients because this group benefits from an improved prognosis. By identifying nonresponding patients, PROSTASCINT could potentially help to avoid ineffective therapy and, therefore, reduce toxic side effects in these patients.

Our products, including PROSTASCINT, are subject to significant regulation by governmental agencies, including the FDA, as is more fully described under the section entitled Government Regulation herein. We cannot assure you that we will be able to complete any of our market expansion strategies set forth above.

Further Clinical Development Related to PROSTASCINT

To support our market expansion strategies for PROSTASCINT, we are sponsoring or supporting several active clinical studies including:

Researchers at Case Western University and University Hospital in Cleveland are comparing uptake of PROSTASCINT within the prostate gland of prostate cancer patients with histopathologic findings of the distribution of cancer in the gland based on whole mount pathology specimens prepared following radical prostatectomy. Some of the patients have also been imaged via positron emission tomography (in addition to PROSTASCINT) to provide for additional comparisons between these two imaging methodologies.

Researchers at The Mayo Clinic in Scottsdale, Arizona are using images of PROSTASCINT distribution within the prostate gland to guide the use of intensity modulated radiation therapy (IMRT) for the treatment of prostate cancer. The purpose of this study is to evaluate whether the use of PROSTASCINT in guiding IMRT allows for delivery of increased doses of radiation specifically to the areas of cancer within the prostate without increasing the level of side effects experienced by the patient.

Researchers at Aultman Hospital, Case Western University and University Hospital in Cleveland are using images of PROSTASCINT distribution within the prostate gland to guide the placement of both I-125 and Pd-103 brachytherapy sources (seeds) for the treatment of prostate cancer. The purpose of this work is to evaluate whether the use of PROSTASCINT in guiding brachytherapy implantation allows for delivery of increased doses of radiation specifically to the areas of cancer within the prostate without increasing the level of side effects experienced by the patient.

During 2004, we reported that clinical investigators from cancer research centers throughout the country presented new clinical data regarding PROSTASCINT as follows:

Clinical investigators at the University of Chicago Hospitals, Illinois, reported that the use of PROSTASCINT imaging in patients with recurrent prostate cancer undergoing radiation therapy of their

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disease resulted in significant changes in the regions to which the doses of radiation were planned to be delivered. Additional details regarding the conduct and results of this study are available in the *Journal of Nuclear Medicine*, Vol. 45, pages 238-246 (2004).

Clinical investigators at Johns Hopkins University School of Medicine in Baltimore reported on imaging results obtained using PROSTASCINT and other agents acquired with the GE Infinia™ Hawkeye®, a combined nuclear medicine/computed tomography (CT) camera system. Additional details regarding the conduct and results of this study were presented at 2004 Radiological Society of North America Annual Meeting held in Chicago, Illinois, *Radiology* (Supplement); 372, 2004.

Clinical investigators at the University of Illinois at Chicago reported on a study evaluating the safety and efficacy of external beam radiation therapy aided by advanced molecular imaging with PROSTASCINT in recurrent prostate cancer patients following definitive surgical treatment. Additional details regarding the conduct and results of this study are available in *The Journal of Nuclear Medicine*, Vol. 45, No. 8, pp. 1315-1322.

Clinical investigators at the Johns Hopkins Medical Institutions in Baltimore, working in conjunction with Emory University in Atlanta, performed fusion imaging using PROSTASCINT to obtain improved image quality and quantitative information about patient s disease. Additional details regarding the conduct and results of this study were presented at 2004 Society of Nuclear Medicine Meeting held in Philadelphia, Pennsylvania.

Clinical investigators reported data showing that overexpression of PSMA in primary prostate cancer correlates with other adverse traditional prognostic factors and independently predicts disease recurrence. Overexpression of PSMA was determined by immunohistochemical staining using the same monoclonal antibody utilized in PROSTASCINT. Additional details regarding the conduct and results of this study are available in *Clinical Cancer Research*, Volume 9, No. 17, pp. 6357-6362.

The foregoing discussion describes clinical applications that differ from that reported in the PROSTASCINT package insert, and that have not been reviewed or approved by FDA. A copy of the full prescribing information for PROSTASCINT may be obtained in the United States from us by calling us toll free at 800-833-3533 or by visiting our web site at www.cytogen.com, which is not part of this Annual Report on Form 10-K. We are sponsoring or supporting the clinical investigations described in the foregoing discussion to explore potential indications for the use of PROSTASCINT.

Intellectual Property Related to PROSTASCINT

In 1987, Dr. Julius S. Horosziewicz first identified PSMA in a prostate cancer cell line, known as LNCaP, by generating a monoclonal antibody against the protein. That monoclonal antibody, known as 7E11-C5, is conjugated via a proprietary linker technology to the radioisotope Indium-111 to produce the PROSTASCINT product. Dr. Horosziewicz s original patent claiming the 7E11-C5 antibody, as well as additional patents relating to the PROSTASCINT product and commercialization rights thereto, were assigned to us in 1989. Under our agreement, we have made, and may continue to make, certain payments to Dr. Horosziewicz, which obligation will remain in effect until the expiration of the last related patent in 2015.

As of December 31, 2004, we were the owner of several issued United States patents and certain corresponding foreign patents relating to PROSTASCINT. One of these, U.S. Pat. No. 5,162,504, is the original Horosziewicz patent and includes claims directed to the monoclonal antibody and the cell line that produces it. We have obtained an extension of the term for this U.S. patent, which will now expire October 28, 2010. U.S. Pat. No. 4,671,958 and U.S. Pat. No. 4,741,900, both of which expired on June 9, 2004, included claims directed to antibody conjugates such as PROSTASCINT, methods for preparing such conjugates, methods for using such conjugates for *in vivo* imaging, testing and therapeutic treatment, and methods for delivering radioisotopes by linking them to such antibodies. U.S. Pat. No. 4,867,973, which also expired on June 9, 2004, included claims directed to antibody conjugates such as PROSTASCINT, and methods for preparing such conjugates. The

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foregoing patents, which will expire in 2010 or expired in 2004, provided or provide the primary patent protection for PROSTASCINT. We also currently own the trademark PROSTASCINT®. We are responsible for the costs of prosecuting and maintaining this intellectual property.

In September 2004, we announced the settlement of a patent infringement suit against us and C.R. Bard Inc. for an agreed-upon payment, without any admission of fault or liability. Immunomedics, Inc. filed suit on February 17, 2000 against us and Bard, alleging that use of our PROSTASCINT product infringed U.S. Patent No. 4,460,559, which claims a method for detecting and localizing tumors. Under our agreement with Dr. Horosziewicz, we may offset our litigation expenses against payments we make to Dr. Horosziewicz. The settlement with Immunomedics was on behalf of Cytogen and Bard. We have included certain information regarding this lawsuit in this Annual Report on Form 10-K under the caption Legal Proceedings.

Manufacturing, Supply and Distribution of PROSTASCINT

In September 2004, we entered into a non-exclusive manufacturing agreement with Laureate Pharma, L.P. for the manufacture and supply of our PROSTASCINT product. Laureate is the sole manufacturer of PROSTASCINT and its primary raw materials, which are antibodies. Our agreement with Laureate will terminate, unless terminated earlier pursuant to its terms, upon Laureate s completion of the specified production campaign for PROSTASCINT and shipment of the resulting products from Laureate s facility in Princeton, New Jersey. We believe that the agreement will provide us with a sufficient supply of PROSTASCINT to satisfy our commercial requirements for approximately the next four years, based upon current sales levels.

In October 2004, Laureate was acquired by Safeguard Scientifics, Inc. Laureate has continued to operate as a full service contract manufacturing organization and we have not experienced any disruption in Laureate s performance of its obligations under our agreement. We currently have no alternative manufacturer or supplier for PROSTASCINT or any of its components. As of December 31, 2004, we had a sufficient level of PROSTASCINT inventory on hand to satisfy our requirements through the second quarter of 2005.

Any failure on Laureate s part to perform its obligations under the agreement with respect to the supply of PROSTASCINT will have a material adverse effect on our business, financial condition and results of operations. Additionally, PROSTASCINT must be manufactured in compliance with regulatory requirements and at commercially acceptable costs.

PROSTASCINT is distributed for us by Cardinal Health 105, Inc., formerly CORD Logistics, Inc., under the terms of a distribution services agreement dated March 1, 1999. Pursuant to the agreement, Cardinal Health is the exclusive distributor of PROSTASCINT in the United States. The agreement will remain in effect until May 19, 2005, and is terminable by us upon 30 days notice prior to the end of the term.

Any arrangement that we enter into with respect to the manufacture, supply or distribution of PROSTASCINT will also be subject to FDA oversight. Any failure on our part, or the part of our business partners, to comply with all applicable regulations and FDA requirements will have a material adverse effect on our business, financial condition and results of operations.

Marketing of PROSTASCINT

We market PROSTASCINT using our in-house specialty sales force to hospitals, diagnostic imaging centers, radiopharmacies, urologists, radiation oncologists and nuclear medicine physicians. We also employ technical specialists who are a part of this sales force and who assist in the training of nuclear medicine technologists and nuclear medicine physicians. These technical specialists also administer the PIE site qualification process for nuclear imaging centers to perform PROSTASCINT imaging.

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Competition Related to PROSTASCINT

The spread of prostate cancer to lymph nodes may be evaluated using a number of imaging modalities, including computed tomography, magnetic resonance imaging, or positron emission tomography.

Strategic Relationships and Collaborations Related to PROSTASCINT

In June 2003, we entered into a relationship with Siemens Medical Solutions and the University Hospitals of Cleveland to promote advances in prostate cancer imaging. Through this arrangement, physicians at the University Hospitals of Cleveland are using the Siemens e.cam gamma camera with Flash 3D iterative reconstruction and CT attenuation correction technology in combination with PROSTASCINT. We hope to explore advances in the use and application of imaging software through our relationship with Siemens.

Also, in June 2003, we entered into an alliance with GE Medical Systems, a unit of the General Electric Company, to market a total molecular imaging system to help evaluate the extent and spread of prostate cancer by integrating GE Medical s Infinia Hawkeye® imaging system with our PROSTASCINT imaging agent. GE s Infinia Hawkeye imaging system combines the anatomic detail of computed tomography (CT) with the molecular imaging data provided by nuclear medicine cameras using products such as PROSTASCINT. The Infinia Hawkeye provides CT-based attenuation correction and localization for single-photon emission computed tomography (SPECT) studies that can help address the inherent limitations of SPECT imaging. Our agreement with GE provides that Cytogen and GE will work together to advance patient and physician awareness of fusion imaging. GE Medical Systems will maintain installation and customer service activities, while Cytogen will provide technical support for PROSTASCINT fusion imaging.

COMBIDEX

Overview

COMBIDEX (ferumoxtran-10), which was developed by Advanced Magnetics, Inc., is currently under review by the FDA. We cannot market or sell COMBIDEX until Advanced Magnetics receives the appropriate regulatory approvals, and we cannot assure you that Advanced Magnetics will receive such approvals on a timely basis, or at all.

On October 19, 2004, Advanced Magnetics and Cytogen announced that Advanced Magnetics had submitted a complete response to an approvable letter received in June 2000 from the FDA for COMBIDEX. On March 3, 2005, the FDA s Oncologic Drugs Advisory Committee (ODAC) voted 15 to 4 to not recommend approval of the proposed broad indication for COMBIDEX. A decision by the FDA on COMBIDEX is expected by the user fee goal date of March 30, 2005.

COMBIDEX is an investigational functional molecular imaging agent consisting of iron oxide nanoparticles which is currently being developed for use in conjunction with magnetic resonance imaging to aid in the differentiation of cancerous from non-cancerous lymph nodes. COMBIDEX is administered via a 30 minute infusion and accumulates preferentially in non-cancerous lymph node tissue, thus facilitating the

differentiation between malignant and non-malignant lymph nodes.

Lymph nodes are frequently the site for metastases of different types of cancer, particularly breast cancer and prostate cancer. Lymph node imaging plays a role in staging patients and determining appropriate patient management. The cross-sectional imaging modalities currently used for imaging lymph nodes are computed tomography (CT) and MRI without contrast. CT and MRI without contrast cannot distinguish between nodes enlarged due to inflammation and enlarged cancerous nodes, nor can they identify cancerous nodes that are not enlarged. Therefore, the current practice is to assume that enlarged nodes (typically greater than ten millimeters in size) are cancerous and to perform biopsy or surgery to establish their true status. Clinical studies have

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demonstrated that COMBIDEX accumulates in macrophage cells associated with non-cancerous lymph node tissue and can therefore facilitate differentiation between cancerous nodes and other nodes. We believe that COMBIDEX could enable doctors using MRI to have improved diagnostic confidence in differentiating between normal and cancerous lymph nodes, irrespective of node size.

According to the American Cancer Society, approximately 900,000 new cases of cancer that could spread to the lymph nodes were diagnosed in 2004. Many of these patients may require, and benefit from, diagnostic tools such as COMBIDEX-enhanced magnetic resonance imaging, to help differentiate normal from cancerous lymph nodes, irrespective of node size.

Clinical Data Related to COMBIDEX

In October 2004, Advanced Magnetics and Cytogen announced the publication of certain clinical data relating to COMBIDEX in the journal *Radiology*. The data showed that magnetic resonance imaging (MRI) in conjunction with COMBIDEX improves the sensitivity for detecting the spread of cancer to lymph nodes in patients with urinary bladder cancer. COMBIDEX was shown to improve the ability to detect lymph node metastases, particularly in normal-sized nodes. The article contains the results of a clinical research study conducted by radiologists at the University Medical Center Sint Radboud, the Netherlands; Charite Hospital, Berlin; and Massachusetts General Hospital, Boston. Overall, 172 lymph nodes from 58 bladder cancer patients were evaluated by MRI both prior to and after the administration of COMBIDEX. The imaging results were then compared to the pathology findings following surgical removal of the nodes. The data revealed that current anatomic imaging techniques, which rely on insensitive size criteria, correctly identified the presence of cancer in lymph nodes 76% of the time. Following the administration of COMBIDEX, the sensitivity for detection of cancer in the same lymph nodes was increased to 96%. As described in the *Radiology* article, normal and cancerous nodal tissues have different signal intensities on COMBIDEX-enhanced MRI. This difference allows detection of metastases even in normal-sized nodes. Additional details regarding the conduct and results of this study are available in *Radiology*, 233(2): 449-56, 2004.

Agreements with Advanced Magnetics, Inc.

In August 2000, we entered into a license and marketing agreement with Advanced Magnetics, Inc. for COMBIDEX, for all applications, and ferumoxytol (formerly referred to as Code 7228), for oncology applications only. Pursuant to the terms of the license agreement, we have the exclusive right to market, distribute and sell COMBIDEX in the United States. The license agreement will continue until August 25, 2010, and will thereafter automatically renew for successive five year 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.

Upon execution of our agreements with Advanced Magnetics in 2000, we issued 200,000 shares of common stock to Advanced Magnetics. Of such 200,000 shares, 25,000 shares are being held in escrow pending the achievement of certain milestones relating to COMBIDEX and 25,000 shares are being held in escrow pending the achievement of certain milestones relating to ferumoxytol. The remaining 150,000 shares were transferred to Advanced Magnetics, subject to certain restrictions. Such restrictions have since expired. We remain obligated to make royalty payments, which are subject to certain minimum amounts, to Advanced Magnetics on sales of COMBIDEX we may make.

In 2000, we also entered into a supply agreement with Advanced Magnetics for COMBIDEX. Under the terms of the supply agreement, Advanced Magnetics has agreed to manufacture and supply us with COMBIDEX at fixed prices, subject to certain adjustments. The supply agreement is coterminous with the license agreement.

DISCONTINUED PRODUCTS

NMP22® BLADDERCHEK®

In October 2002, we entered into an agreement with Matritech, Inc. to be the sole distributor for NMP22 BLADDERCHEK to urologists and oncologists in the United States. NMP22 BLADDERCHEK is a point-of-care *in vitro* diagnostic test for bladder cancer developed by Matritech. Matritech retained rights to market

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NMP22 BLADDERCHEK directly to physicians other than oncologists, such as primary care physicians. In October 2003, we executed an amendment to our agreement which provided that, as of November 8, 2003, we had the non-exclusive right to market and sell NMP22 BLADDERCHEK to urologists until December 31, 2003 and the exclusive right to continue to sell NMP22 BLADDERCHEK to oncologists until December 31, 2004. The amended agreement terminated as of December 31, 2004 and we have no further obligations to Matritech with respect to NMP22 BLADDERCHEK.

BRACHYSEED®

In December 2000, we entered into a 10-year agreement with Draximage Inc., the radiopharmaceutical subsidiary of Draxis Health, Inc. to market and distribute Draximage s BRACHYSEED implants in the United States. On January 24, 2003, we provided Draximage with notice of termination for each of our license and distribution agreement and product manufacturing and supply agreement with respect to both of Draximage s BRACHYSEED Iodine-125 and BRACHYSEED Palladium-103 products and, as of January 2003, we no longer accepted or filled new orders for the BRACHYSEED products. On April 8, 2003, we formally terminated these agreements and announced the amicable resolution of all open matters with Draximage. We also agreed with Draximage to maintain the confidentiality of each other s proprietary information, released each other from all other liability with respect to any claims under such agreements, and agreed to certain indemnification obligations with respect to third party claims.

ONCOSCINT CR/OV

In December 2002, we discontinued marketing, selling and producing ONCOSCINT CR/OV, a monoclonal antibody diagnostic imaging agent for the detection of the spread of colorectal and ovarian cancer. The market for ONCOSCINT CR/OV for colorectal cancer diagnosis was negatively affected by positron emission tomography, or PET , scans, which have been shown to have similar or higher sensitivity than the ONCOSCINT CR/OV scan.

RESEARCH AND DEVELOPMENT

AGGREGATE EXPENDITURES

Our research and development expenses, including our equity in the loss of the PSMA Development Company, LLC, over the past three years were:

2004 $ 6.1 million

2003 $ 5.8 million

2002 $ 10.5 million

We intend to pursue research and development activities having commercial potential and to review all of our programs to determine whether possible market opportunities provide an adequate return to justify the commitment of human and economic resources to their initiation or continuation. The major components of our research and development programs and expenditures are set forth below.

TECHNOLOGY

Prostate-Specific Membrane Antigen (PSMA)

PSMA is a transmembrane protein that is an important marker associated with prostate cancer. Dr. Julius S. Horosziewicz identified the PSMA protein using a monoclonal antibody in 1987. The antibody technology developed by Dr. Horosziewicz was assigned to us. Later, researchers at the Sloan-Kettering Institute for Cancer Research identified and sequenced the gene encoding PSMA, and we acquired an exclusive worldwide license to that and related technologies. From these technologies, we have put one product on the market, PROSTASCINT, and we are building a pipeline of potential new products which are currently in research and development. These pipeline products are focused primarily on novel vaccine and antibody therapies for prostate and other cancers.

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PSMA has also been found to be present at high levels in the new blood vessels or neovasculature formed in association with a variety of major solid tumors other than prostate cancers. Such neovasculature is necessary for the growth and survival of many types of solid tumors. We believe that, due to the unique characteristics of this antigen, technologies utilizing PSMA can yield novel products for the treatment and diagnosis of cancer. If PSMA-targeted therapies can destroy or prevent formation of these new blood vessels, we believe that such therapies may prove valuable in treating a broad range of cancers.

In 1993, we entered into an option and license agreement with the Sloan Kettering Institute for Cancer Research (SKICR), and began a development program with SKICR involving PSMA and our proprietary monoclonal antibody. In November 1996, we exercised our option and obtained an exclusive worldwide license to this technology. Under our agreement with SKICR, we received, or subsequently obtained, rights to patents and patent applications including: U.S. Pat. Nos. 5,538,866 (expiring July 23, 2013), 5,935,818 (expiring August 10, 2016), and 6,569,432 (expiring February 24, 2015), and U.S. Pat. Appln. Nos. 08/403,803 (filed March 17, 1995), 08/466,381 (filed June 6, 1995), 08/470,735 (filed June 6, 1995), 08/481,916 (filed June 7, 1995), 08/894,583 (filed February 23, 1998), 09/724,026 (filed November 28, 2000), 09/990,595 (November 21, 2001), 10/012,169 (filed October 24, 2001), 10/443,694 (filed May 21, 2003), and 10/614,625 (filed July 2, 2003). The filing, prosecution and maintenance of licensed patents, as defined in the agreement, is the responsibility of SKICR, but is at our discretion and expense. In the event that we decide not to file, prosecute or maintain any part of the licensed patents, SKICR may do so at its own expense.

The license shall terminate on the date of expiration of the last to expire of the licensed patents unless it is terminated earlier in accordance with the terms of the agreement. The license agreement is also terminable by us upon 60 days notice to SKICR. Upon execution of our agreement with SKICR, we paid to SKICR an option fee, a license fee and a reimbursement for patent expenses paid by SKICR. We are obligated to make certain royalty payments, which are subject to certain minimum amounts and other annual payments to SKICR, for the term of the agreement.

In 2000, we executed a sublicense agreement with Northwest Biotherapeutics Inc. pursuant to which we granted Northwest the right to make and use PSMA for *ex vivo* prostate cancer immunotherapy. In December 2002, we announced that we had regained our rights to *ex vivo* prostate cancer immunotherapy using PSMA, in connection with the termination of our agreement with Northwest.

PSMA Development Company LLC

In 1999, we entered into a joint venture with Progenics Pharmaceuticals, Inc. to develop *in vivo* immunotherapeutic products utilizing PSMA. These product candidates currently include antibody-based immunotherapies for prostate cancer, a therapeutic prostate cancer vaccine utilizing the PSMA gene and a vector delivery system, and a recombinant form of the PSMA protein as a basis for immune stimulation. 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.

We are currently pursuing three research and development programs through the joint venture:

Monoclonal Antibody Program. The PSMA monoclonal antibody program is currently in the preclinical development stage. The joint venture is utilizing fully human monoclonal antibodies, derived from Abgenix s Xenomouse technology, in conjunction with naked, radio-labeled and toxin-labeled approaches, to treat prostate cancer.

Viral Vector Vaccine Program. The joint venture is developing a novel, *in vivo* alphavirus vaccine for prostate cancer that is designed to induce both antibodies and cytotoxic T cells against PSMA. The joint venture is currently working with AlphaVax and Greer Laboratories to use the Alphavax Replicon Vector(ArV) system to develop a prostate cancer vaccine using the PSMA antigen. To date, preclinical and clinical batches have been manufactured and stability and preclinical toxicology studies have been initiated and are ongoing.

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Recombinant Soluble PSMA Vaccine Program. The joint venture is developing an *in vivo* therapeutic recombinant protein vaccine, which is designed to stimulate a patient s immune response system to recognize and destroy prostate cancer cells. The vaccine combines the PSMA cancer antigen with an immune stimulant to induce an immune response against prostate cancer cells. The genetically engineered PSMA vaccine generated potent immune responses in preclinical animal testing. The Phase I clinical trial was designed to evaluate the safety and immune-stimulating properties of the vaccine in patients with either newly diagnosed or recurrent prostate cancer. Enrollment in such clinical trial is now complete.

The joint venture is owned equally by Progenics 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 $3.0 million of development costs, in addition to $2.0 million in supplemental capital contributions funded at certain dates prior to December 2001. Beginning in December 2001, we began sharing costs of the programs with Progenics.

In 2004, we incurred expenses of $2.9 million relating to our half of the expenses for the programs at the joint venture, compared to $3.5 million in 2003. The joint venture is funded by equal capital contributions from each of Progenics and Cytogen in accordance with an annual budget approved by the joint venture representatives from each such party. As of March 15, 2005, we and Progenics are in the process of negotiating the work plan and annual budget for 2005 for the joint venture. We cannot give any assurances that agreement will be reached on such matters in the near future, if at all. The failure to reach agreement with Progenics on these matters could significantly and adversely affect the development of PSMA technologies and products.

Contract research and development services were provided by Progenics and Cytogen to the joint venture during 2004. We are discussing the terms of a new services agreement with Progenics pursuant to which the parties will provide services to the joint venture. We believe that if mutual agreement is not achieved with respect to a new service agreement, the parties can successfully negotiate with outside third parties for necessary services.

In 2004, $8.0 million of grants were awarded over four years from the National Institutes of Health (NIH). The awards were made under the National Cancer Institute s FLAIR program, or Flexible System to Advance Innovative Research for Cancer Drug Discovery by Small Business. The NIH grants are in the form of two Phase II Small Business Innovation Research grants, and will be used to develop novel immunotherapies for prostate cancer based on PSMA. The failure of Cytogen and Progenics to reach agreement on the 2005 annual work plan and budget for the joint venture, could adversely effect the joint venture s ability to access the NIH grants.

We have North American marketing rights to products developed by the joint venture and a right of first negotiation with respect to marketing activities in any territory outside North America. We anticipate initiation of marketing efforts for any product 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 for any products developed by the joint venture, assuming there is no change in our existing ownership interests.

Clinical Data Related to PSMA

In December 2002, the joint venture announced the initiation of a Phase I clinical trial for the testing of a novel therapeutic prostate cancer vaccine directed against PSMA. This trial is being conducted through a physician s IND by the Memorial Sloan Kettering Cancer Center. Requisite follow-up of the last patient, which will conclude the Phase I trial, is expected in March 2005.

Strategic Relationships, Collaborations and Licensing Arrangements Related to PSMA

AlphaVax Human Vaccines, Inc. During 2001, the joint venture entered into a worldwide exclusive licensing agreement with AlphaVax Human Vaccines, Inc. to use the Alphavax Replicon Vector(ArV) system to create a therapeutic prostate cancer vaccine incorporating the PSMA antigen. In consideration for the license, the joint

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venture paid a nonrefundable, noncreditable license fee and is obligated to pay additional payments upon the occurrence of certain defined milestones associated with the development and commercialization program for products incorporating the ArV technology. In addition, the joint venture is required to pay an annual maintenance fee until the commencement of commercial sales of products and then royalties based on net sales of products. The joint venture has the right to terminate this agreement upon 30 days prior written notice. 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.

Abgenix, Inc. During 2001, the joint venture entered into an agreement with Abgenix, Inc. regarding the development of fully human antibodies to PSMA using Abgenix s Xenomouse™ technology. In consideration for the license, the joint venture paid a nonrefundable, noncreditable license fee and is obligated to pay additional license fees on each of the first three anniversary dates and milestone payments upon the occurrence of certain defined milestones associated with the development and commercialization program for products incorporating an antibody generated utilizing the Xenomouse technology. In addition, the joint venture is required to pay royalties based upon net sales of antibody products sold thereunder. If not terminated early, the agreement continues until the expiration of the joint venture s obligation to pay royalties under the agreement to Abgenix. The joint venture has the right to terminate this agreement upon 30 days prior written notice. In August 2003, the joint venture entered into a manufacturing agreement with Abgenix for the production of clinical supplies for the PSMA human monoclonal antibody program. Such agreement has been terminated and the joint venture is currently pursuing alternative manufacturing arrangements for the monoclonal antibody program.

In connection with the agreements discussed above, the joint venture has recognized contractual payments, including license fees, which are included in research and development expenses, totaling approximately $550,000, $300,000, and $200,000 for the years ended December 31, 2004, 2003, and 2002, respectively. In addition, as of December 31, 2004, remaining potential payments associated with milestones and defined objectives with respect to the existing agreements total approximately $11.6 million. Future annual minimum royalties under the existing agreements described above are not significant.

AxCell Biosciences

In 1993, we licensed from the University of North Carolina at Chapel Hill (UNC) exclusive worldwide rights to novel reagents and technology for identifying targeting peptides that were developed under sponsored research funded by us. This process utilizes random peptide libraries (Genetic Diversity Library, GDL) expressing an extensive collection of long peptides that, unlike conventional drugs or short peptides, can mimic natural proteins in terms of their folding and their corresponding molecular recognition functions. This is similar to the ability of antibody molecules to selectively bind to antigens, or enzymes to bind to their substrates. This proprietary approach facilitated the screening of a more diverse family of compounds than was practical with previous methods and yielded several novel reagents (totally synthetic affinity reagents, TSAR s). Originally, we expected to utilize these libraries to discover specific binding molecules that would represent attractive alternatives to monoclonal antibodies for diagnostic and therapeutic products.

In 1996, we entered into a research and licensing agreement with Elan Corporation, plc, which marked our first external collaboration in which GDL-derived products would be utilized for their ability to target drugs to specific sites within the body. The research program with Elan was designed to discover GDL-derived peptides that could be used to target therapeutic agents to receptors expressed within the lining of the intestinal tract known to be involved in certain cellular uptake and transport processes. In contrast to most biotechnology drugs that cannot be administered orally due to the fact that they break down prior to reaching the bloodstream, such peptides could be administered orally. Under the agreement, Elan had the option for worldwide licensing rights to any products developed collaboratively and we would receive royalties based on the sale of any such products. We recently assumed ownership and responsibility for Elan s pending patent portfolio related to GDL-derived peptides that could be used to target therapeutic agents to receptors expressed within the lining of the intestinal tract known to be involved in certain cellular uptake and transport processes. We are seeking strategic partners for this program.

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Our subsidiary, AxCell Biosciences was incorporated in 1996 to further commercialize the GDL technology in the field of accelerated new target discovery and validation. Based on the prevalence of modular protein domains, such as Src homology domain 3 and 2 (SH3 and SH2), among many other important signaling molecules known to mediate protein-protein interactions, UNC researchers advanced the use of ligands generated using GDL as probes to systematically isolate entire repertoires of modular domain-containing proteins from cloned DNA expression libraries. This became AxCell s Cloning of Ligand Targets (CLT™) technology.

As an initial proof of concept for the automation and application of GDL and CLT technologies to rapidly and efficiently identify protein signaling pathways, AxCell created a comprehensive database (ProChart) of domain and ligand interactions throughout 2001. Because protein signaling pathways play a role in many diseases, researchers are working to develop drugs that specifically target these pathways. While some interactions are likely to have positive clinical results, others can lead to unwanted drug side effects and toxicity. By referring to a comprehensive map of the body s protein interactions, researchers may be better able to identify drugs that target a specific disease related interaction while avoiding those unspecific interactions associated with unwanted side effects.

Beginning in 2002, AxCell began applying its existing protein interaction data in several major areas of scientific interest by entering into academic, governmental, and corporate research collaborations designed to both provide *in vivo* validation of novel protein-protein interactions discovered using its *in vitro* approach and the discovery of novel drug targets. In most circumstances, AxCell has an exclusive option to negotiate an exclusive, worldwide, royalty-bearing license for inventions that result from the research collaboration.

In March 2004, the first *in vivo* validation of a novel interaction discovered using AxCell s technology was published (Functional association between Wwox tumor suppressor protein and p73, a p53 homolog. *Proceedings of the National Academy of Sciences* March 30, 2004: vol. 101; no. 13 pp. 4401 4406). In November 2004, a second demonstration of *in vivo* validation for a novel interaction discovered using AxCell s technology was published (Physical and functional interactions between the Wwox tumor suppressor protein and the AP-2gamma transcription factor. Cancer Res. November 2004: vol. 64; no. 22 pp. 8256-61).

In addition to research done under collaboration with AxCell, other groups also validated AxCell s technology via publications confirming interactions contained in the ProChart database. One such example is the publication of The RING-H2 protein RNF11 is differentially expressed in breast tumours and interacts with HECT-type E3 ligases. (Biochim Biophys Acta. 2003 Oct 15;1639(2):104-12.). This paper was published nearly two years after the RNF11/AIP4 interaction data was deposited into ProChart.

In view of recent biological validation and progress through both internal data mining efforts and external research collaborations, we are currently considering strategic transactions for AxCell to create value. AxCell has a proprietary high-throughput platform for the systematic identification and characterization of domain-mediated intracellular pathways, which can be combined with many levels of biological information to understand how they work together in a systems biology approach. AxCell has made technical progress over the past several years by applying its proprietary protein pathway content and knowledge to accelerate the development of targeted drugs in certain therapeutic categories through both internal efforts and external research collaborations with corporate, governmental and academic partners.

The application of AxCell s technology may accelerate research and drug development by:

- discovering novel signal transduction pathways and their relevant protein-protein interactions;
- rapidly identifying qualified drug targets;

identifying structure and activity relationship (SAR) information regarding domain and ligand interactions that can facilitate small molecule drug design; and

providing high throughput screening reagents (eg, cloned domains and ligands).

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The patents and patent applications we have licensed from UNC include: U.S. Pat. Nos. 5,498,538 (expiring March 12, 2013), 5,625,033 (expiring April 29, 2014), 5,747,334 (expiring May 5, 2015), 5,844,076 (expiring December 1, 2015), 5,852,167 (expiring December 22, 2015), 5,935,823 (expiring August 10, 2016), 6,011,137 (expiring April 3, 2016), 6,184,205 (expiring July 22, 2014), 6,303,574 (expiring July 22, 2014), 6,309,820 (expiring April 7, 2015), 6,432,920 (expiring July 22, 2014), 6,703,482 (expiring July 22, 2014), and 6,709,821 (expiring April 7, 2015), and U.S. Pat. Appln. Nos. 10/161,791 (filed May 31, 2002), and 10/185,050 (filed June 28, 2002). We are responsible for the costs of filing, prosecuting and maintaining domestic and foreign patents and patent applications under our agreement with UNC.

The agreement commenced on March 10, 1993 and will expire, unless earlier terminated as provided therein, upon the expiration of the last to expire of the licensed patents that cover a licensed product. Under the agreement, we are required to make certain milestone and royalty payments to UNC, which are subject to certain minimum amounts.

In September 2002, we significantly reduced AxCell s workforce to reduce the cash expenditures relating to AxCell in order to leverage our oncology franchise. Further, in July 2004, as part of our continuing efforts to reduce non-strategic expenses, we initiated the closure of AxCell s facilities. Research projects through academic, governmental and corporate collaborators to be supported and additional applications for the intellectual property and technology at AxCell are being pursued.

OTHER STRATEGIC RELATIONSHIPS

We frequently enter into alliances with other companies to, among other things, 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 and other collaborators, we may obtain funding, expand existing programs, learn of new technologies and gain additional expertise in developing and marketing products.

Antisoma Research Limited. In September 2003, Antisoma Research Limited acquired certain royalty rights to its lead product, R1549 (formerly Pemtumomab), from us. In connection with Antisoma s acquisition of these rights, Antisoma made a cash payment to us of $500,000 and agreed to make an additional payment of $500,000 to us upon the first commercial sale, if any, of the R1549 product. In return, we relinquished our right to receive royalties of 1.65% on future net sales, if any, of the R1549 product. In April 2004, Antisoma and Roche announced that the R1549 product did not meet the primary endpoints in a Phase III study in ovarian cancer, and that it is unlikely that development of R1549 will continue.

Elan Corporation, plc. In December 1995, 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 related research programs. 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. In July 2004, we were assigned rights to certain patents and patent applications developed under the agreement, including U.S. Pat. No. 6,703,362 (expiring May 15, 2018), and U.S. Pat. Appln. Nos. 09/079,678 (filed May 15, 1998) and 09/079,819 (filed May 15, 1998).

Northwest Biotherapeutics, Inc. In August 2002, we entered into an agreement with Northwest Biotherapeutics that gave Northwest Biotherapeutics a license to develop and commercialize *ex vivo* immunotherapy products for prostate cancer that are produced by pulsing isolated populations of a patient s antigen presenting cells, such as dendritic cells, with PSMA. Northwest Biotherapeutics advanced their program to the initiation of Phase III clinical trials before terminating the program in November 2002, which resulted in a termination of the license agreement and Cytogen regaining rights to *ex vivo* prostate cancer immunotherapy using PSMA. Based on data demonstrating a

favorable safety and clinical response in prostate cancer patients treated to date using PSMA-based *ex vivo* immunotherapy, we are pursuing other collaborations or partnerships to realize the clinical and commercial potential of this approach.

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PRODUCT CONTRIBUTION TO REVENUES

PROSTASCINT and QUADRAMET account for, and, prior to its discontinuation in January 2003, BRACHYSEED accounted for substantially all of our total revenues. For the years ended December 31, 2004, 2003 and 2002, revenues related to PROSTASCINT accounted for approximately 49%, 47% and 61%, respectively, of our total revenues; and revenues related to QUADRAMET accounted for approximately 50%, 28% and 14%, respectively, of our total revenues. Prior to its discontinuation in January 2003, BRACHYSEED accounted for approximately 2% and 19% of our total revenues for the years ended December 31, 2003 and December 31, 2002, respectively. In April 2003, we announced the termination of our agreements with Draximage with respect to the BRACHYSEED products.

CONCENTRATION OF SALES

During the year ended December 31, 2004, we received 68% of our total revenues from three customers, as follows: 46% from Cardinal Health (formerly Syncor International Corporation); 12% from Mallinckrodt Inc., and 10% from GE Healthcare (formerly Amersham Health).

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 and imaging/diagnostic products compete with the products of a wide variety of other firms, including firms that provide products used in more traditional therapies or procedures, such as external beam radiation, chemotherapy agents, narcotic analgesics and other imaging/diagnostics. 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 established 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 or imaging/diagnostic 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. 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 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.

INTELLECTUAL PROPERTY

We believe that our success depends, in part, on our ability to protect our products and technology through patents and trade secrets. Accordingly, our policy is to pursue a vigorous program of securing and maintaining 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.

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We 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 will market our respective products.

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. It is our policy to require our employees, consultants, licensees, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements also provide that all confidential information developed or made known to the individual during the course of the individual s relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual shall be our exclusive property. There can be no assurances, however, that these agreements will provide meaningful protection or adequate remedies for our trade secrets in the event of unauthorized use or disclosure of such information.

We believe that our valuable proprietary information is protected to the fullest extent commercially reasonable; 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 relating to PSMA. In addition, competitors have filed applications for, have been issued, or may otherwise obtain patents and other 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 relating to products and 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 to such patents on commercially reasonable terms if at all. The failure to obtain licenses to such patents could prevent us from commercializing products or services covered by such patents.

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

GOVERNMENT REGULATION

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

products consist of a biologic (PROSTASCINT) and a drug (QUADRAMET). Future applications for these may include expanded indications and could result in additional drugs, biologics, devices or combination products. Our product development pipeline contains various other products, the majority of which will likely be classified as new drugs or biologics.

In the United States, medical products that we currently market or intend to develop are regulated by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (FDC Act) and the Public Health Service Act (PHS Act), and the rules and regulations promulgated thereunder. These laws and

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regulations require, among other things, carefully controlled research and preclinical and clinical testing of products, government notification, review and/or approval or clearance prior to investigating or marketing the product, inspection of manufacturing and production facilities, adherence to current Good Manufacturing Practices (cGMP), and compliance with product and manufacturer specifications or standards, and requirements for reporting, advertising, promotion, export, packaging, and labeling, and other applicable regulations.

The FDC Act requires that our products be manufactured in FDA registered facilities subject to inspection. The manufacturer must be in compliance with cGMP, which imposes certain procedural, substantive, and recordkeeping requirements upon us and our manufacturing partners with respect to manufacturing and quality control activities, and, for devices, product design. To ensure full technical compliance with such regulations, a manufacturer must spend funds, time and effort in the areas of production and quality control. These regulations may also apply to Cytogen. 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.

FDA approval of our proposed products, including a review of the manufacturing processes, controls and facilities used to produce such products, will be required before such products may be marketed in the United States. The process required by the FDA before drug, biological or medical device products may be approved for marketing in the United States generally involves:

- preclinical laboratory and animal tests that are conducted consistent with the FDA s good laboratory practice regulations;
- submission to the FDA of an Investigational New Drug Application (IND) (for a drug or biologic) or Investigational Device Exemption (IDE) (for a device), which must become effective before clinical trials may begin; further, approval of the investigation by an Institutional Review Board (IRB) must also be obtained before the investigational product may be given to human subjects;
- human clinical trial(s) to establish the safety and efficacy of the product for its intended indication;
- submission to the FDA of a marketing application-New Drug Application (NDA) for a drug, Biologics License Application (BLA) for a biologic, and a premarket approval application (PMA) or premarket notification (510(k)) for a device; and
- FDA review and approval or clearance of the marketing application. Radiopharmaceutical drugs are subject to additional requirements pertaining to the description and support of their indications for use, and the evaluation of product effectiveness and safety, including, radiation safety. There is no assurance that the FDA review of marketing applications will result in product approval or clearance on a timely basis, or at all.

Clinical trials for drugs, devices, and biologics typically are performed in three phases to evaluate the safety and efficacy of the product. In Phase I, a product is tested in a small number of healthy subjects or 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 may 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 FDC Act or PHS 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 IND/IDE application which typically includes, among other things, 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, biologic or device. However, this process can take longer if the FDA raises questions or asks for additional information regarding the IND/IDE application. Unless the FDA notifies the sponsor that the IND/IDE is subject to a clinical hold during the 30 day review period, the IND/IDE is considered effective and the trial may commence.

There can be no assurance that submission of an IND or IDE will result in the ability to commence clinical trials. In addition, after a trial begins, the FDA may place it on hold or terminate it if, among other reasons, it

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concludes that clinical subjects are being exposed to an unacceptable health risk. In addition, clinical trials require IRB approval before the drug may be given to subjects and are subject to continuing IRB review. An IRB may suspend or terminate approval if the IRB s requirements are not followed or if unexpected serious harm to subjects is associated with the trial. The FDA may decide not to consider, in support of an application for approval or clearance, any data that was collected in a trial without IRB approval and oversight. After completion of *in vitro*, non-clinical and clinical testing, authorization to market a drug, biologic or device must be granted by the FDA. The FDA grants permission to market through the review and approval or clearance of either an NDA, BLA, PMA, or 510(k). Historically, monoclonal antibodies have been regulated through the FDA s Center for Biologics Evaluation and Research (CBER). As of late 2003, monoclonal antibodies, which include ProstaScint, were transferred to the Center for Drug Evaluation and Research (CDER), for regulation, review and approval.

An NDA is an application to the FDA to market a new drug. A BLA is an application to the FDA to market a biological product. An NDA or BLA, depending on the submission, must contain, among other things, information on chemistry, manufacturing controls and potency and purity; nonclinical pharmacology and toxicology; human pharmacokinetics and bioavailability; and clinical data. The new drug or biologic may not be approved for marketing in the United States until the FDA has determined that the NDA product is safe and effective or that the BLA product is safe, pure, and potent and the facility in which it is manufactured, processed, packed or held meets standards designed to assure its continued safety, purity, and potency. For both NDAs and BLAs, the application will not be approved until the FDA conducts a manufacturing inspection and approves the applicable manufacturing process for the drug or biologic. A PMA is an application to the FDA to market certain medical devices, which must be approved in order for the product to be marketed. It must be supported by valid scientific evidence, which typically includes extensive data, including pre-clinical data and clinical data from well-controlled clinical trials to demonstrate the safety and effectiveness of the device. Product testing, manufacturing, controls, specifications and information must also be provided, and a pre-approval inspection is normally conducted. NDA, BLA, and PMA submissions may be refused review if they do not meet submission requirements.

Conducting the studies, preparing these applications and securing approval from the FDA is expensive and time consuming, and takes 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. There can be no assurance that approvals of our proposed products, processes or facilities will be granted on a timely basis, or at all. 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 lives of our patents under the Patent Term Restoration Act of 1984 in the United States and under similar laws if available in other countries.

Our new drug products may be subject to generic competition. Once a NDA is approved, the product covered thereby becomes a listed drug which can, in turn, be cited by potential competitors in support of approval of an abbreviated new drug application (ANDA). An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. Federal law provides for a period of three years of exclusivity following approval of a listed drug that contains previously approved active ingredients but is approved in a new dosage, dosage form, route of administration or combination, or for a new use, the approval of which was required to be supported by new clinical trials conducted by or for the sponsor. Federal law also provides a period of five years following approval of a drug containing no previously approved active ingredients, during which ANDAs for generic versions of those drugs cannot be submitted unless the submission accompanies a challenge to a listed patent, in which case the submission may be made four years

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following the original product approval. Additionally, in the event that the sponsor of the listed drug has properly informed the FDA of patents covering its listed drug, applicants submitting an ANDA referencing that drug are required to make certifications including that it believes one or more listed patents are invalid or not infringed. If the ANDA applicant certifies that it does not intend to market its generic product before some or all listed patents on the listed drug expire, then the FDA cannot grant effective approval of the ANDA until those patents expire. The first of the abbreviated new drug applicant(s) submitting substantially complete applications certifying that listed patents for a particular product are invalid or not infringed may qualify for a period of 180 days exclusivity running from when the generic product is first marketed, during which subsequently submitted ANDAs cannot be granted effective approval.

Certain of our future products may be regulated by the FDA as combination products. Combination products are products comprised of a combination of two or more different types of components, *(e.g.,* drug/device, device/biologic, drug/device/biologic), or are comprised of two or more separate different types of products packaged together for use, or two or more different types of products packaged separately but labeled for use in combination with one another. The regulation of a combination product is determined by the product s primary mode of action. For example, a combination drug/device that has a primary mode of action as a drug would be regulated by the Center for Drug Evaluation and Research under an NDA. In some cases, however, consultative reviews and/or separate approvals by each agency Center with jurisdiction over a component may be required. The product designation, approval pathway, and submission requirements for a combination product may be difficult to predict, and the approval process may be fraught with unanticipated delays and difficulties. In addition, post-approval requirements may be more extensive than for single entity products. Even if products such as ProstaScint or Quadramet that we intend to develop for use with other separately regulated products are not regulated as combination products, they may be subject to similar multi-Center consultative reviews and additional post-market requirements.

Once the FDA approves a product, we are required to maintain approval status of the product by providing certain updated safety and efficacy information at specified intervals. Most product or labeling changes to drugs or biologics as well as any change in a manufacturing process or equipment that has a substantial potential to adversely affect the safety or effectiveness of the product for a drug or biologic, or, for a device, changes that affect safety and effectiveness, would necessitate additional FDA review and approval. Post approval changes in packaging or promotional materials may also necessitate further FDA review and approval. Additionally, we are required to meet other requirements specified by the FDC Act, including but not limited to, cGMPs, enforced by periodic inspections, adverse event reporting, requirements governing labeling and promotional materials and, for drugs, biologics and restricted and PMA devices, requirements regarding advertising, and the maintenance of records. Failure to comply with these requirements or the occurrence of unanticipated safety effects from the products during commercial marketing could result in product marketing restrictions, product withdrawal or recall and/or public notifications, or other voluntary 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 may be marketed.

Violations of the FDC Act, PHS Act, or regulatory requirements at any time during the product development process, approval process, or after approval may result in agency enforcement actions, including voluntary or mandatory recall, license suspension or revocation, new drug approval suspension or withdrawal, pre-market approval withdrawal, seizure of products, fines, injunction and/or civil or criminal penalties. Any agency enforcement action could have a material adverse effect on our business, financial condition and results of operations.

Orphan Drug Act

The Orphan Drug Act is intended to provide incentives to pharmaceutical companies to develop and market drugs and biologics 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

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product to receive FDA marketing approval for a particular indication is entitled to orphan drug status, which confers 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 but pharmaceutical companies may receive grants or tax credits for research, as well as protocol assistance. Under the Orphan Drug Act, the FDA cannot approve any application by another party to market the same drug for treatment of an identical indication unless the holder consents, 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, or it has been shown to be clinically superior to the approved orphan drug. However, a drug that is considered by the 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. In addition, holders of orphan drug status must notify the FDA of any decision to discontinue active pursuit of drug approval or biologics license, or, if such approval or license is in effect, notify the FDA at least one year prior to any discontinuance of product production. If the holder of an orphan designation cannot assure the availability of sufficient quantities of the product to meet the needs of affected patients, the FDA may withdraw orphan drug status.

Fraud and Abuse

We are subject to various federal and state laws pertaining to health care fraud and abuse, including anti-kickback laws, false claims laws and physician self-referral laws. Violations of these laws are punishable by criminal, civil and/or administrative sanctions, including, in some instances, imprisonment and exclusion from participation in federal and state health care programs, including Medicare, Medicaid and veterans 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 business, 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 prohibit entities such as us from knowingly and willingly offering, paying, soliciting or receiving any form of remuneration (including any kickbacks, bribes or rebates) in return for the referral of items or services for which payment may be made under a federal health care program, or in return for the recommendation, arrangement, purchase, lease or order of items or services for which payment may be made under a federal health care program. Violation of the federal anti-kickback law is a felony, punishable by criminal fines and imprisonment for up to five years or both. In addition, the Department of Health and Human Services may impose civil penalties and exclude violators from participation in federal health care programs such as Medicare and Medicaid. Many states have adopted similar prohibitions against payments intended to induce referrals of products or services paid by Medicaid or other third party payors.

Physician Self-Referral Laws. We also may be subject to federal and/or state physician self-referral laws. Federal physician self-referral legislation (known as the Stark law) prohibits, subject to certain exceptions, a physician from referring Medicare or Medicaid patients to an entity to provide designated health services, including, among other things, certain radiology and radiation therapy services and clinical laboratory services in which the physician or a member of his immediate family has an ownership or investment interest or has entered into a compensation arrangement. The Stark law also prohibits the entity receiving the improper referral from billing any good or service furnished pursuant to the 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 improper referral and $100,000 for participation in a circumvention scheme. Various state laws also contain similar provisions and penalties.

False Claims. The federal False Claims Act imposes civil and criminal liability on individuals or entities who submit (or cause the submission of) false or fraudulent claims for payment to the government. Violations of the federal False Claims Act may result in penalties equal to three times the damages which the government sustained, an assessment of between $5,000 and $10,000 per claim, civil monetary penalties and exclusion from participation in the Medicare and Medicaid programs.

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The federal False Claims Act also allows a private individual to bring a *qui tam* suit on behalf of the government against an individual or entity for violations of the False Claims Act. In a *qui tam* suit, the private plaintiff is responsible for initiating a lawsuit that may eventually lead to the government recovering money of which it was defrauded. In return for bringing the suit on the government s behalf, the statute provides that the private plaintiff is entitled to receive up to 30% of the recovered amount from the litigation proceeds if the litigation is successful plus reasonable expenses and attorneys fees. Recently, the number of *qui tam* suits brought against entities in the health care industry has increased dramatically. In addition, a number of states have enacted laws modeled after the False Claims Act that allow those states to recover money which was fraudulently obtained from the state.

Other Fraud and Abuse Laws. The Health Insurance Portability and Accountability Act of 1996 created, in part, two new federal crimes: (i) Health Care Fraud; and (ii) False Statements Relating to Health Care Matters. The Health Care Fraud statute prohibits the knowing and willful execution of a scheme or artifice to defraud any health care benefit program. A violation of the statute is a felony and may result in fines and/or imprisonment. The False Statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact by any trick, scheme or device or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services. A violation of this statute is a felony and may result in fines and/or imprisonment.

We currently maintain several programs designed to minimize the likelihood that we would engage in conduct or enter into contracts in violation of the fraud and abuse laws. Contracts of the types subject to these laws are reviewed and approved by legal department personnel. We also maintain various educational programs designed to keep our managers updated and informed on developments with respect to the fraud and abuse laws and to reinforce to all employees the policy of strict compliance in this area. While we believe that all of our applicable agreements, arrangements and contracts comply with the various fraud and abuse laws and regulations, we cannot provide assurance that further administrative or judicial interpretations of existing laws or legislative enactment of new laws will not have a material adverse impact on our business.

Other regulations

In addition to regulations enforced by the FDA, and federal and state laws pertaining to health care fraud and abuse, 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. 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 FDC 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.

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HEALTH CARE REIMBURSEMENT

Sales of our products depend in part on the coverage status of our products and the availability of reimbursement by various payers, including federal health care programs, such as Medicare and Medicaid, as well as private health insurance plans. Whether a product receives favorable coverage depends upon a number of factors, including the payer s determination that the product is medically reasonable and necessary for the diagnosis or treatment of the illness or injury for which it is administered and not otherwise excluded from coverage by law or regulation. There may be significant delays in obtaining coverage for newly-approved products, and coverage may be limited or expanded outside the purpose(s) for which the product is approved by the FDA.

Eligibility for coverage does not imply that any product will be reimbursed in all cases or at a rate that allows us or any health care provider to make a profit or even cover costs, including research, development, production, sales, and distribution costs. Although new laws provide for expedited coverage for new technology, interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the approved and covered use of the product and the place of service in which it is used, may be based on payments allowed for lower-cost products that are already reimbursed, may be incorporated into existing payments for other products or services, and may reflect budgetary constraints and/or imperfections in Medicare or Medicaid claims data. Net prices for products may be reduced by mandatory discounts or rebates required by law under government health care programs or by any future relaxation of laws that restrict imports of certain medical products from countries where they may be sold at lower prices than in the U.S.

In December 2003, the Medicare Prescription Drug, Improvement and Modernization Act of 2003 was signed into law. This Act includes provisions that reduced Medicare reimbursement for many drugs and biologicals from a reimbursement rate of 95% of the average wholesale price to 80% of the average wholesale price, effective January 1, 2004. As of January 2005, the general reimbursement methodology for many drugs and biologicals is now based on average sales price , as defined by the Act, plus 6%.

Third party payers often mirror Medicare coverage policy and payment limitations in setting their own reimbursement payment and coverage policy and may have sufficient market penetration to demand significant price reductions. Even if successful, securing reimbursement coverage at adequate payment levels from government and third party payers can be a time consuming and costly process that could require us to provide additional supporting scientific, clinical and cost-effectiveness data to permit payment and coverage of our products to payers. Our inability to promptly obtain product coverage and profitable reimbursement rates from government-funded and private payers could have a material adverse effect on our business, financial condition and our results of operations.

Although health care funding has and will continue to be closely monitored by the government, the ability to diagnose patients quickly and more effectively has been one of the few areas where the government has increased health care spending. Approval of payment for new technology has been another area with required spending outlined in the 2004 legislative requirements.

The Centers for Medicare and Medicaid Services (CMS) continually monitor and update product descriptors, coverage policies, product and service codes, payment methodologies, and reimbursement values. Although it is not possible to predict or identify all of the risks relating to such changes, we believe that such risks include, but are not limited to: (i) increasing price pressures (including those imposed by regulations and practices of managed care groups and institutional and governmental purchasers); and (ii) judicial decisions and government laws related to health care reform including radiopharmaceutical, pharmaceutical and device reimbursement. In addition, an increasing emphasis on managed care has and will continue to increase the pressure on pricing of these products and services.

Our business, financial condition and results of operations will continue to be affected by the efforts of governmental and third-party payers to contain or reduce the costs of health care. There have been, and we

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expect that there will continue to be, federal and state proposals to constrain expenditures for medical products and services, which may affect payments for therapeutic and diagnostic imaging agents. We rely heavily on the ability to monitor changes in reimbursement and coverage and proactively influence policy and legislative changes in the areas of health care that directly impact our products. We have proven our ability to monitor changes that impact our products and have worked with the government and private payers to take advantage of the opportunities offered by legislative and policy changes for our products. While we cannot predict if legislative or regulatory proposals will be adopted or the effects managed care may have on our business, the changes in reimbursement and the adoption of new health care proposals could have a material adverse effect on our business, financial condition and results of operations. Further, to the extent that changes in health care reimbursement have a material adverse effect on other 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 are generally subject to governmental controls.

KEY EMPLOYEES

Michael D. Becker currently serves as our President and Chief Executive Officer. Mr. Becker joined Cytogen in April 2001 and has served in positions of increasing responsibility, including Chief Executive Officer of our AxCell Biosciences subsidiary and Vice President, Business Development and Industry Relations. Prior to joining Cytogen, Mr. Becker was with Wayne Hummer Investments LLC, a Chicago-based regional brokerage firm from July 1996 to April 2001, where he held senior positions as a biotechnology analyst, investment executive and portfolio manager in addition to participating in sales management activities. From October 1998 to April 2001, Mr. Becker also served on the board of directors for the Chicago Biotech Network, a nonprofit trade association for the biotechnology industry in Illinois. Mr. Becker attended DePaul University in Chicago, Illinois. Mr. Becker continues to serve on the board of, and is Vice Chairman of, the Biotechnology Council of New Jersey.

William F. Goeckeler, Ph.D. was promoted to Senior Vice President, Operations in December 2003. Previously, he served as Vice President, Operations since January 2003 and Vice President of Research and Development since June 2001. He joined Cytogen in March of 1994 as the Assistant Director, Pharmaceutical Development. In 1995, he was promoted to Associate Director, Technical Support Operations and in June 1997 became our Director, Pharmaceutical Development, a position he held until June 2001. Before joining us, Dr. Goeckeler spent nine years as a scientist in the Bioproducts Laboratory of Central Research and Development at The Dow Chemical Company. Dr. Goeckeler did his undergraduate and graduate work at the University of Missouri where he received his Ph.D. in Radiochemistry for research that involved the discovery of QUADRAMET and other skeletal targeting radiopharmaceuticals.

Christopher P. Schnittker, CPA, joined Cytogen in September 2003 and currently serves as our Senior Vice President and Chief Financial Officer. Prior to joining Cytogen, Mr. Schnittker served as Chief Financial Officer of Genaera Corporation (formerly Magainin Pharmaceuticals, Inc.) from June 2000 to August 2003. Prior to Genaera, Mr. Schnittker served as Director of Finance from August 1999 to May 2000 and Controller from December 1997 to August 1999 at GSI Commerce, Inc., a publicly-traded technology company. From June 1995 to December 1997, Mr. Schnittker held several positions of increasing responsibility at Rhône-Poulenc Rorer, Inc. (now Aventis). Prior to that, Mr. Schnittker held various positions at Price Waterhouse LLP s (now PricewaterhouseCoopers LLP) Life Sciences audit practice from 1990 to 1995. Mr. Schnittker received his Bachelor of Arts Degree from Lafayette College, and is a certified public accountant licensed in the State of New Jersey.

Thomas S. Lytle joined Cytogen in April 2004 as our Senior Vice President, Sales and Marketing. Prior to joining Cytogen, Mr. Lytle was with Amgen, Inc. from 1997 to January 2004 where he held senior marketing positions, including Vice President of Strategic Marketing and Business Development, and Vice President of New Products Marketing. Mr. Lytle began his career in the health care industry when he joined Pfizer, Inc. in 1971 and, during more than 20 years with Pfizer, he gained a broad range of industry experience in a series of sales, marketing and marketing management positions in several therapeutic categories. Further, as Vice

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President of Marketing for Lederle Laboratories, a division of American Cyanamid, from 1989 to 1991, he had responsibility for a broad range of anti-infective, oncology, cardiovascular, and anti-inflammatory products. Mr. Lytle holds an MBA in Marketing from LaSalle University, and a BBA in Marketing from Western Michigan University. In 1993, he retired from the United States Army Reserve as a Colonel.

William J. Thomas joined Cytogen in August 2004 as our Senior Vice President and General Counsel. Prior to joining Cytogen, Mr. Thomas was a senior partner at Wilmer Cutler Pickering Hale and Dorr LLP. From 1994 through 2001, Mr. Thomas was a partner at Buchanan Ingersoll P.C. His law practice concentrated on emerging growth and high technology business issues, including securities law compliance, strategic alliances and mergers and acquisitions. Mr. Thomas received a J.D. degree from Fordham University School of Law where he was an associate editor of the Law Review. He holds a B.A. degree in Political Science from Rutgers University where he graduated with highest honors.

Michael J. Manyak, M.D., joined Cytogen in January 2005 as our Vice President of Medical Affairs. Prior to joining Cytogen, Dr. Manyak was Professor of Urology, Microbiology, and Tropical Medicine at The George Washington University Medical Center (GWUMC) where he was also Chairman of the Department of Urology. After completing his urological residency at GWUMC, Dr. Manyak became an American Foundation for Urological Disease (AFUD) Scholar at the National Cancer Institute (NCI), completed a fellowship in Biotechnology in 1988, and joined the urological staff at GWUMC. Dr. Manyak has also served on the Medicare Coverage Advisory Committee for the Center for Medicare and Medicaid Services (CMS) where he was a member of the Imaging Subcommittee. In addition, he received a presidential appointment to the National Kidney and Urological Disease Advisory Board. He was formerly a voting member of the Food and Drug Administration (FDA) Regulatory Panel for Genitourinary and Gastrointestinal Devices. He has been a reviewer for the NIH Special Study Section for Small Business Grants and several professional journals. Dr. Manyak received his Bachelor of Arts Degree from the University of Notre Dame and his medical degree from the University of the East, Manila, Phillipines.

Thu A. Dang has served as our Vice President, Finance since January 2003. Ms. Dang joined Cytogen in September 1988 as our Senior Financial Reporting Accountant, and was promoted to Director of Finance in May 2000. Prior to joining Cytogen, Ms. Dang held numerous positions with Harrisburg Dairies for six years, serving ultimately as their Controller. Ms. Dang received her Bachelor of Science Degree in Accounting from Elizabethtown College.

Rita A. Auld has served as our Vice President, Human Resources and Administration since January 2003 and as Corporate Secretary since March 2003. Ms. Auld joined Cytogen as our Director of Human Resources in October 2000. For a period of six years prior to joining Cytogen, Ms. Auld was the Director of Human Resources of Flexpaq Corporation, where she established the Human Resources Department, developing procedures, handbooks and benefit and safety programs. Ms. Auld has over 20 years of experience with sales, manufacturing, accounting and engineering organizations, directing the activities of human resources and administrative functions, specializing in small-sized companies, both public and private. Ms. Auld holds Associates and Bachelor of Science Degrees in Business Administration from Thomas A. Edison State College and is certified as a Human Resources Professional.

EMPLOYEES

As of February 25, 2005, we employed 89 persons, 88 of whom are employed full-time and one of whom is employed part-time. Of such 89 persons, 59 were employed in sales and marketing, five in medical affairs, two in regulatory, and 23 in administration and management. The employees in sales and marketing included nine Clinical Oncology Specialists and 39 Regional Managers, Professional Oncology Representatives, Senior Professional Oncology Representatives and Senior Account Managers. In comparison, 36 persons were employed in sales and marketing as of March 1, 2004. 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.

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ADDITIONAL FACTORS THAT MAY AFFECT FUTURE RESULTS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below together with other information included or incorporated by reference in this Annual Report on Form 10-K in your decision as to whether or not to invest in our common stock. If any of the following risks or uncertainties actually occur, our business, financial condition or results of operations would likely suffer. In that case, the trading price of our common stock could fall, and you may lose all or part of the money you paid to buy our common stock.

We have a history of operating losses and an accumulated deficit and expect to incur losses in the future.

Given the high level of expenditures associated with our business and our inability to generate revenues sufficient to cover such expenditures, we have had a history of operating losses since our inception. We had net losses of $20.5 million, $9.4 million and $15.7 million for the years ended December 31, 2004, 2003 and 2002, respectively. We had an accumulated deficit of $386.3 million as of December 31, 2004.

In order to develop and commercialize our technologies, particularly our prostate-specific membrane antigen technology, and expand our products, we expect to incur significant increases in our expenses over the next several years. As a result, we will need to generate significant additional revenue to become profitable.

To date, we have taken affirmative steps to rationalize our trend of operating losses. Such steps include, among other things:

- undergoing steps to realign and implement our focus as a product-driven biopharmaceutical company;
- establishing and maintaining our in-house specialty sales force;
- reacquiring North American and Latin American marketing rights to QUADRAMET from Berlex Laboratories in August 2003; and
- enhancing our marketed product portfolio through marketing alliances and strategic arrangements.

Although we have taken these affirmative steps, we may never be able to successfully implement them, and our ability to generate and sustain significant additional revenues or achieve profitability will depend upon the factors discussed elsewhere in this section entitled, Additional Factors That May Affect Future Results. As a result, we may never be able to generate or sustain significant additional revenue or achieve profitability.

We depend on sales of QUADRAMET and PROSTASCINT for substantially all of our near-term revenues.

We expect QUADRAMET and PROSTASCINT to account for substantially all of our product related revenues in the near future. For the year ended December 31, 2004, revenues from QUADRAMET and PROSTASCINT each accounted for approximately 50% of our product related revenues. For the year ended December 31, 2003, royalty and product revenues from QUADRAMET and sales revenues from PROSTASCINT accounted for approximately 35% and 60%, respectively, of our product related revenues. If QUADRAMET or PROSTASCINT does not achieve broader market acceptance, either because we fail to effectively market such products or our competitors introduce competing products, we may not be able to generate sufficient revenue to become profitable.

A Small Number of Customers Account for the Majority of Our Sales, and the Loss of One of Them, or Changes in Their Purchasing Patterns, Could Result in Reduced Sales, Thereby Adversely Affecting Our Operating Results.

We sell most of our products to a small number of radiopharmacies. During the year ended December 31, 2004, we received 68% of our total revenues from three customers, as follows: 46% from Cardinal Health (formerly Syncor International Corporation); 12% from Mallinckrodt Inc.; and 10% from GE Healthcare (formerly Amersham Health). During the year ended December 31, 2003, we received 69% of our total revenues from four customers, as follows: 24% from Cardinal Health (formerly Syncor International Corporation); 23% from Berlex Laboratories Inc.; 14% from Mallinckrodt Inc., and 8% from GE Healthcare (formerly Amersham Health).

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The small number of radiopharmacies, consolidation in this industry or financial difficulties of these radiopharmacies could result in the combination or elimination of customers for our products. We anticipate that our results of operations in any given period will continue to depend to a significant extent upon sales to a small number of customers. As a result of this customer concentration, our revenues from quarter to quarter and business, financial condition and results of operations may be subject to substantial period-to-period fluctuations. In addition, our business, financial condition and results of operations could be materially adversely affected by the failure of customer orders to materialize as and when anticipated. None of our customers have entered into an agreement requiring on-going minimum purchases from us. There can be no assurance that our principal customers will continue to purchase products from us at current levels, if at all. The loss of one or more major customers could have a material adverse effect on our business, financial condition and results of operations.

We depend on acceptance of our products by the medical community for the continuation of our revenues.

Our business, financial condition and results of operations depend on the acceptance of our marketed products 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

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

With respect to PROSTASCINT, our customers, including technologists and physicians, must successfully complete our Partners in Excellence, 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 by technologists and physicians and their acceptance of this product as part of their treatment practices. With respect to QUADRAMET, we believe that challenges we may encounter in generating market acceptance for this product include the need to further educate patients and physicians about QUADRAMET s properties, approved uses and how QUADRAMET may be differentiated from other radiopharmaceuticals and used in combination with other treatments for the palliation of pain due to metastatic bone disease, such as analgesics, opioids, bisphosphonates, and chemotherapeutics. If we are unable to educate our existing and future customers about PROSTASCINT and QUADRAMET, our revenues may decrease. If PROSTASCINT or QUADRAMET does not achieve broader market acceptance, we may not be able to generate sufficient revenue to become profitable.

Generating market acceptance and sales of our products has proven difficult, time consuming and uncertain. We launched ONCOSCINT CR/OV in December 1992, PROSTASCINT in October 1996, QUADRAMET in March 1997, a brachytherapy product in February 2001 and NMP22 BLADDERCHEK in November 2002. Revenues for PROSTASCINT grew from $55,000 in 1996 to $7.2 million in 2004. Royalties from sales and product revenues for QUADRAMET grew from $3.3 million in 1997 to $7.3 million in 2004. Royalties from sales of QUADRAMET in the initial years of sales were supported by a guaranteed minimum revenue arrangement with the third party licensor of QUADRAMET. We discontinued selling ONCOSCINT CR/OV in December 2002, brachytherapy products in January 2003 and NMP22 BLADDERCHEK in December 2004. Currently, substantially all of our revenues are derived from sales of PROSTASCINT and QUADRAMET.

We rely heavily on our collaborative partners.

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

a license agreement with The Dow Chemical Company relating to the QUADRAMET technology;

a manufacturing and supply agreement for the manufacture of QUADRAMET with Bristol-Myers Squibb Medical Imaging, Inc.;

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a manufacturing agreement for the manufacture of PROSTASCINT with Laureate Pharma, L.P.;

marketing, license and supply agreements with Advanced Magnetics, Inc. related to COMBIDEX and ferumoxytol (formerly Code 7228);

a distribution services agreement with Cardinal Health 105, Inc. (formerly Cord Logistics, Inc.) for PROSTASCINT;

various agreements which form and control our joint venture with Progenics Pharmaceuticals, Inc. for the development of PSMA for *in vivo* immunotherapy for prostate and other cancers; and

a license agreement between our joint venture and AlphaVax Human Vaccines, Inc.

Because our collaborative partners are responsible for certain manufacturing and distribution activities, among others, these activities are outside our direct control and we rely on our partners to perform their obligations. In the event that our collaborative partners are entitled to enter into third party arrangements that may economically disadvantage us, or do not perform their obligations as expected under our agreements, our products may not be commercially successful. As a result, any success may be delayed and new product development could be inhibited with the result that our business, financial condition and results of operation could be significantly and adversely affected.

Our business could be harmed if certain agreements expire or are terminated.

If our collaborative agreements expire or are terminated and we cannot renew or replace them on commercially reasonable terms, our business and financial results may suffer. If the licenses and/or agreements described below expire or are terminated, we may not be able to find suitable alternatives to them on a timely basis or on reasonable terms, if at all. The loss of the right to use these technologies that we have licensed or the loss of any services provided to us under these agreements would significantly and adversely affect our business, financial condition and results of operations. For example, in January 2003, we provided Draximage Inc. with notice of our intent to terminate our product manufacturing and supply agreement and license agreement with Draximage relating to the brachytherapy products which represented 20% of our product-related revenues for the year ended December 31, 2002. In April 2003, we entered into an agreement with Draximage formally terminating each of these agreements. We no longer market and sell the brachytherapy products.

We currently depend on the following agreements for our present and future operating results:

Dow Chemical. In May 1993, we obtained an exclusive license from The Dow Chemical Company to use QUADRAMET, in North America, 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. Our license was expanded to include Latin America in 1995. Our license agreement with Dow with respect to QUADRAMET will remain in effect, unless earlier terminated, for a period of twenty (20) years from May 30, 1993 or until the last to expire of the related patents. We anticipate such termination date to be May 30, 2013.

Bristol-Myers Squibb Medical Imaging, Inc. QUADRAMET is manufactured by BMSMI pursuant to the terms of a manufacturing and supply agreement with us which became effective on January 1, 2004. Under this agreement, BMSMI has agreed to manufacture, supply and distribute QUADRAMET for us in exchange for a minimum payment of at least $4.2 million annually, subject to future annual price adjustment, through 2008. After 2008, the agreement will then renew for five successive one-year periods. The agreement is terminable by either party, at any time,

upon two years notice to the other. We also pay BMSMI a variable amount per month for each order placed to cover the cost of customer service.

Agreement with Dr. Horosziewicz regarding PROSTASCINT. In 1989, we entered into an agreement with Dr. Julius S. Horosziewicz pursuant to which we were assigned certain rights to the patent claiming the 7E11-C5 antibody, as well as additional patents relating to the PROSTASCINT product and commercialization rights thereto. Under this agreement, we have made, and may continue to make, certain payments to Dr. Horosziewicz, which obligation will remain in effect until the expiration of the last related patent in 2015.

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Laureate Pharma, L.P. In September 2004, we entered into a non-exclusive manufacturing agreement with Laureate Pharma, L.P., pursuant to which Laureate is manufacturing PROSTASCINT for us in exchange for expected payments of at least an aggregate of $5.1 million through 2006. This agreement will terminate, unless terminated earlier pursuant to its terms, upon Laureate s completion of the production campaign of PROSTASCINT and shipment of the resulting products from Laureate s facility in Princeton, NJ. We believe that this agreement will provide us with a sufficient supply of PROSTASCINT to satisfy our commercial requirements for approximately the next four years, based upon current sales levels. In October 2004, Laureate was acquired by Safeguard Scientifics, Inc. Laureate has continued to operate as a full service contract manufacturing organization and we have not experienced any disruption in Laureate s performance of its obligations to produce PROSTASCINT.

Advanced Magnetics, Inc. In August 2000, we entered into a license and marketing agreement with Advanced Magnetics, Inc. for COMBIDEX, for all applications, and ferumoxytol (formerly Code 7228) for oncology applications only. In 2000, we also entered into a supply agreement with Advanced Magnetics for COMBIDEX. We have exclusive United States marketing rights to COMBIDEX for all applications. COMBIDEX (ferumoxtran-10) is an investigational functional molecular imaging agent consisting of iron oxide nanoparticles, which is currently being developed for use in conjunction with magnetic resonance imaging to aid in the differentiation of cancerous from non-cancerous lymph nodes, and is currently under review by the U.S. Food and Drug Administration. In September 2004, Advanced Magnetics submitted a complete response to an approvable letter received in June 2000 from the FDA for COMBIDEX. On March 3, 2005, the FDA s Oncologic Drugs Advisory Committee (ODAC) voted 15 to 4 to not recommend approval of the proposed broad indication for COMBIDEX. A decision by the FDA on COMBIDEX is expected by the user fee goal date of March 30, 2005. There can be no assurance that Advanced Magnetics will receive FDA approval for COMBIDEX or ferumoxytol (for oncology applications). Our license and marketing agreement with Advanced Magnetics will continue until August 25, 2010, and will thereafter automatically renew for successive five year 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.

Sloan Kettering Institute for Cancer Research. In 1993, we began a development program with SKICR involving PSMA and our proprietary monoclonal antibody. In November 1996, we exercised an option for, and obtained, an exclusive worldwide license from the SKICR to its PSMA-related technology. The license shall terminate on the date of expiration of the last to expire of the licensed patents unless it is terminated earlier.

Our intellectual property is difficult to protect.

In addition to our key agreements referenced above, our business and competitive positions are also dependent upon our ability to protect our proprietary technology. Because of the substantial length of time and expense associated with the 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 certain aspects of our technology for diagnostic and therapeutic products and/or the methods for their production and use.

In addition, the protection afforded by a duly issued patent is limited in duration. With respect to our PROSTASCINT product, we rely or have relied primarily on United States patent numbers 5,162,504 (expiring October 28, 2010), 4,741,900 (expired June 9, 2004), 4,671,958 (expired June 9, 2004), and 4,867,973 (expired June 9, 2004). With respect to QUADRAMET, we rely primarily on United States patent numbers 4,898,724 (expiring March 28, 2011), 4,937,333 (expiring August 4, 2009), 4,897,254 (expiring January 30, 2007), 5,066,478 (expiring November 19, 2008), and 5,300,279 (expiring November 19, 2008), which were licensed to us by The Dow Chemical Company. In addition, we rely on United States patent number 5,495,042 (expiring November 4, 2013), which is assigned to us, and United States patent numbers 5,714,604 (expiring February 3, 2015) and 5,762,907 (expiring November 21, 2006).

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The patent positions of pharmaceutical, biopharmaceutical and biotechnology companies, including us, are generally uncertain and involve complex legal and factual questions. Our patents and 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. The degree of protection that may be afforded by any patents we are issued or license from others may not be sufficient to protect our commercial interests. Furthermore, others may independently develop similar or alternative technologies, duplicate our technologies, or, if patents are issued to us, design around the patented technologies developed by us. 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. In addition, if challenged by others in litigation, the patents we have been issued, which we have been assigned or we have licensed from others may be found invalid. It is also possible that our activities may 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.

Any licenses required under any such third-party patents or proprietary rights may not be 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 our or our competitors pending patent applications will result in the issuance of valid patents which may significantly and adversely affect our business, financial condition and results of operations.

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 by contract manufacturers in compliance with regulatory requirements and at costs acceptable to us. If we are unable to successfully arrange for the manufacture of our products and product candidates, either because potential manufacturers are not cGMP compliant, are not available or charge excessive amounts, we will not be able to successfully commercialize our products and our business, financial condition and results of operations will be significantly and adversely affected.

PROSTASCINT is currently manufactured at a current Good Manufacturing Practices, or cGMP, compliant manufacturing facility operated by Laureate Pharma, L.P. We entered into a development and manufacturing agreement with DSM Biologics Company B.V. in July 2000, which we intended would replace an earlier arrangement we had with Laureate with respect to PROSTASCINT. Our relationship with DSM was subsequently terminated. Although we entered into another agreement with Laureate in September 2004 pursuant to which Laureate is manufacturing PROSTASCINT for us, our failure to maintain a long term supply agreement on commercially reasonable terms will have a material adverse effect on our business, financial condition and

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results of operations. In October 2004, Laureate was acquired by Safeguard Scientifics, Inc. Laureate has continued to operate as a full service contract manufacturing organization and we have not experienced any disruption in Laureate s performance of its obligations to produce PROSTASCINT.

QUADRAMET is manufactured by BMSMI, pursuant to an agreement with us. Both primary components of QUADRAMET, particularly Samarium-153 and EDTMP, are provided to BMSMI by outside suppliers. Due to radioactive decay, Samarium-153 must be produced on a weekly basis. BMSMI obtains its requirements for Samarium-153 from a sole supplier and EDTMP from another sole supplier. Alternative sources for these components may not be readily available, and any alternative supplier would have to be identified and qualified, subject to all applicable regulatory guidelines. If BMSMI 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 would have a material adverse effect on our business, financial condition and results of operations.

The Company, our contract manufacturers and testing laboratories are required to adhere to FDA regulations setting forth requirements for 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 is 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 contract vendors 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 pre-market clearance or pre-market 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, financial condition and results of operations.

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 since been engaged primarily in research directed toward the development, commercialization and marketing of products to improve the diagnosis and treatment of cancer and other diseases. 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 August, 2000, we entered into a license and marketing agreement with Advanced Magnetics for COMBIDEX, for all applications, and ferumoxytol (formerly Code 7228) for oncology applications only. We have exclusive United States marketing rights to COMBIDEX. In September 2004, Advanced Magnetics submitted a complete response to an approvable letter received in June 2000 from the FDA for COMBIDEX. On March 3, 2005, the FDA s Oncologic Drugs Advisory Committee (ODAC) voted 15 to 4 to not recommend approval of the proposed broad indication for COMBIDEX. A decision by the FDA on COMBIDEX is expected by the user fee goal date of March 30, 2005.

To date, we have allocated, and expect to continue to allocate, significant amounts of time and resources in preparation for the commercial launch of COMBIDEX. We cannot assure you, however, that Advanced Magnetics will obtain approval from the FDA for COMBIDEX on a timely basis, if at all. If Advanced Magnetics does not secure regulatory approval for COMBIDEX, we will not be permitted to sell and market COMBIDEX as we have anticipated and we will not realize any return on the significant amount of time and resources we have allocated to COMBIDEX. Ferumoxytol is in the early stage of development and there can be no assurance that it will be developed for oncology applications.

In July 2004, as part of our continuing efforts to reduce non-strategic expenses, we initiated the closure of facilities at our AxCell Biosciences subsidiary. Research projects through academic, governmental and corporate collaborators will continue to be supported and additional applications for the intellectual property and technology at AxCell are being pursued. We may be unable to further develop or commercialize any of these products and technologies in the future.

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Further, our PSMA technologies are still in the early stages of development. All of our PSMA programs are either in preclinical or Phase I stages.

Our business is therefore subject to the risks inherent in 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, financial condition and results of operations. If we fail to properly address these risks and attain our business objectives, our business could be significantly and adversely 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. The product candidates we develop, pursue or offer may not prove to be safe and effective, may not receive the necessary regulatory approvals, may be precluded by proprietary rights of third parties or may not ultimately achieve market acceptance. These product candidates will require substantial additional investment, laboratory development, clinical testing and regulatory approvals prior to their commercialization. We may experience difficulties, such as the inability to agree with our collaborative partners on development, initiate clinical trials or receive timely regulatory approvals, 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 effective for use in each target indication. The results from preclinical studies and early-stage clinical trials may not be predictive of results that will be obtained in large-scale, later-stage testing. Our clinical trials may not demonstrate safety and efficacy of a proposed product, and therefore, may not result in marketable products. A number of companies in our 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 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, internal development of diagnostic or therapeutic products will require significant investments in 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 cGMP of the FDA. We 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, financial condition and results of operations could be significantly and adversely affected.

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Competition in our field is intense and likely to increase.

All of our products and product candidates 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.

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

- pharmaceutical companies;
- biotechnology companies;
- diagnostic companies;
- medical device companies;
- radiopharmaceutical distributors;
- academic and research institutions; and
- government agencies.

QUADRAMET primarily competes with Strontium-89 chloride in the radiopharmaceutical pain palliation market. Strontium-89 chloride is manufactured and marketed either as Metastron, by GE HealthCare, or in a generic form by Bio-Nucleonics Pharma, Inc. GE HealthCare manufactures Metastron and sells the product through its wholly-owned network of radiopharmacies, direct to end-users and through other radiopharmacy distributors. The generic version is distributed directly by the manufacturer or is sold through radiopharmacy distributors such as Cardinal Health and AnazaoHealth (formerly Custom Care Pharmacy). The first radiopharmaceutical introduced as a metastatic bone cancer pain palliation agent, Phosphorus-32 (P-32), is no longer routinely utilized clinically in the United States.

Competitive imaging modalities to PROSTASCINT include computed tomography (CT), magnetic resonance (MR) imaging, and position emission tomography (PET).

Additionally, we face competition in the development of PSMA-related technology and products primarily from Millennium Pharmaceuticals, Inc. and Medarex, Inc.

Before we recover development expenses for our products and technologies, the products or technologies may become obsolete as a result of technological developments by others or us. 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, financial condition and results of operations.

We have limited sales, marketing and distribution capabilities for our products.

We have established an internal sales force that is responsible for marketing and selling PROSTASCINT and QUADRAMET. Although we are continuing to expand our internal sales force, it still has limited sales, marketing and distribution capabilities compared to those of many of our competitors. Effective August 1, 2003, we reacquired marketing rights to QUADRAMET from Berlex Laboratories, Inc. in North and Latin America, for an upfront payment of $8.0 million and the obligation to pay royalties to Berlex on future sales of QUADRAMET. If our internal sales force is unable to successfully market QUADRAMET and PROSTASCINT, our business and financial condition may be adversely affected. If we are unable to establish and maintain significant sales, marketing and distribution efforts within the United States, either internally or through arrangements with third parties, our business may be significantly and adversely affected. In locations outside of the United States, we have not established a selling presence. To the extent that our sales force, from time to time, markets and sells additional products, we cannot be certain that adequate resources or sales capacity will be available to effectively accomplish these tasks.

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Failure of third party payors to provide adequate coverage and reimbursement for our products could limit market acceptance and affect pricing of our products and affect our revenues.

Sales of our products depend in part on the availability of favorable coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid as well as private health insurance plans. Each payor has its own process and standards for determining whether and, if so, to what extent it will cover and reimburse a particular product or service. Whether and to what extent a product may be deemed covered by a particular payor depends upon a number of factors, including the payor s determination that the product is reasonable and necessary for the diagnosis or treatment of the illness or injury for which it is administered according to accepted standards of medical practice, cost effective, not experimental or investigational, not found by the FDA to be less than effective, and not otherwise excluded from coverage by law, regulation, or contract. There may be significant delays in obtaining coverage for newly-approved products, and coverage may not be available or could be more limited than the purposes for which the product is approved by the FDA.

Moreover, eligibility for coverage does not imply that any product will be reimbursed in all cases or at a rate that allows us to make a profit or even cover our costs, which include, for example, research, development, production, sales, and distribution costs. Interim payments for new products, if applicable, also may not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower-cost products that are already reimbursed, may be incorporated into existing payments for other products or services, and may reflect budgetary constraints and/or imperfections in Medicare or Medicaid data. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs, or other payors, or by any future relaxation of laws that restrict imports of certain medical products from countries where they may be sold at lower prices than in the United States.

Third party payors often follow Medicare coverage policy and payment limitations in setting their own coverage policies and reimbursement rates, and may have sufficient market power to demand significant price reductions. Even if successful, securing coverage at adequate reimbursement rates from government and third party payors can be a time consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products among other data and materials to each payor. Our inability to promptly obtain favorable coverage and profitable reimbursement rates from government-funded and private payors for our products could have a material adverse effect on our business, financial condition and results of operations, and our ability to raise capital needed to commercialize products.

Our business, financial condition and results of operations will continue to be affected by the efforts of governmental and 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 regulate expenditures for medical products and services, which may affect payments for therapeutic and diagnostic imaging agents such as our products. In addition, an emphasis on managed care increases possible pressure on the 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 our prospective corporate partners, our ability to establish necessary strategic alliances may be harmed.

If we are unable to comply with applicable governmental regulation we may not be able to continue our operations.

Any products tested, manufactured or distributed by us or on our behalf pursuant to FDA 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, suspension, or revocation of approvals, restrictions on or

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injunctions against marketing our products based on our technology, and civil and criminal penalties. We may incur significant costs to comply with laws and regulations in the future or compliance with laws or regulations may 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 product 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, including generics, 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 the Nuclear Regulatory Commission and/or equivalent state regulatory agencies, which may be a lengthy process. 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;

- 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 product 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.

Regulatory agency approval for a product or agent may not be received and may entail limitations on the indicated uses that could limit the potential market for any such product. For example, as disclosed in our press releases and periodic filings, we have exclusive United States marketing rights to COMBIDEX, an investigational functional molecular imaging agent consisting of iron oxide nanoparticles, which is currently being developed for use in conjunction with magnetic resonance imaging to aid in the differentiation of cancerous from non-cancerous lymph nodes, and is under review by the FDA. In June 2000, Advanced Magnetics received an approvable letter from the FDA with respect to COMBIDEX. An approvable letter is a written communication to an applicant from the FDA stating that the agency will approve the application or abbreviated application if specific and satisfactory additional information or material is submitted or specific conditions are met. An approvable letter does not constitute approval of any part of an application or abbreviated application and does not permit marketing of the drug that is the subject of the application or abbreviated application. In September 2004, Cytogen and Advanced Magnetics announced that Advanced Magnetics submitted a complete response to the approvable letter for COMBIDEX. The September 30, 2004 submission was accepted and assigned a user fee goal date of March 30, 2005. On March 3, 2005, the FDA s Oncologic Drugs Advisory Committee (ODAC) voted 15 to 4 to not recommend approval of the proposed broad indication for COMBIDEX. A decision by the FDA on COMBIDEX is expected by the user fee goal date of March 30, 2005.

If and when we obtain approval or clearance for our products, the marketing, manufacture, labeling, packaging, adverse event and other reporting, storage, advertising and promotion 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.

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The Food, Drug and Cosmetics Act and the Public Health Service Act require: (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 contract partners do not comply with cGMP or we do not comply with any of the FDA s other postmarket requirements we may be subject to sanctions, including fines, injunctions, civil penalties, recalls or seizures of products, total or partial suspension of production, product recalls, failure of the government to grant clearance or premarket approval for devices or premarket approval for drugs or biologics, suspension, revocation or withdrawal of marketing approvals and criminal prosecution.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance or interpretations changed, or what the impact of such changes, if any, may be.

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 therefore we may not be able to retain existing personnel or attract and retain additional highly qualified employees in the future.

On December 17, 2002, we entered into a letter agreement with Michael D. Becker in connection with Mr. Becker s promotion to President and Chief Executive Officer of the Company. Mr. Becker s annual base salary for 2005 is $300,000. Mr. Becker is also eligible to participate in our Cytogen Corporation Performance Bonus Plan, as and if approved by our Board of Directors, with a target bonus rate of 35% of base salary based upon performance objectives. Mr. Becker is also entitled to all existing Company benefits, at the sole discretion of the Board of Directors. In addition, Mr. Becker was granted options to purchase 200,000 shares of our common stock under our 1995 Stock Option Plan, of which options to purchase 150,000 shares are performance-based and will vest, if at all, upon the achievement of milestones as determined by our Board of Directors. Mr. Becker has subsequently received additional options to purchase shares of our common stock. Pursuant to the terms of the letter agreement, in the event we terminate Mr. Becker s employment for reasons other than for cause, as defined therein, Mr. Becker shall be entitled to receive twelve months base pay and continuation of benefits under COBRA, and a pro rata portion of any incentive benefits earned through the date of termination.

We do not carry key person life insurance policies and we do not typically enter into long-term arrangements with our key personnel. If we are unable to hire and retain personnel in key positions, our business, financial condition and results of operations could be significantly and adversely affected unless qualified replacements can be found.

Our business exposes us to product 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 and product liability claims may be asserted against us, our collaborators or our licensees. While we currently maintain product liability insurance in the amount of $10.0 million, such coverage may not be adequate to protect us against future product liability claims. In addition, product liability insurance may not be available to us in the future on commercially reasonable terms, if at all. Although we have not had a history of claims payments that have

exceeded our insurance coverage or available financial resources, if liability claims against us exceed our financial resources or coverage amounts, we may have to curtail or terminate our operations. In

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addition, while we currently maintain directors and officers liability insurance in the amount of $25.0 million, such coverage may not be available on commercially reasonable terms or be adequate to cover any claims that we may be required to satisfy in the future. Our insurance coverage is subject to industry standard and certain other limitations.

Our security measures may not 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 information to anyone outside Cytogen or our subsidiaries. Although we are unaware of any unauthorized use or disclosure of our unpatented proprietary technology to date, these agreements may not provide adequate protection for our trade secrets, know-how or other proprietary information or prevent such unauthorized use or disclosure.

We may not be able to implement AxCell s business plan.

In September 2002, we began the restructuring of our subsidiary, AxCell Biosciences Corporation, in an effort to reduce expenses and position Cytogen for stronger long-term growth in oncology. In July 2004, as part of our continuing efforts to reduce non-strategic expenses, we initiated the closure of facilities at our AxCell Biosciences subsidiary. Research projects through academic, governmental and corporate collaborators will continue to be supported and additional applications for the intellectual property and technology at AxCell are being pursued. We may be unable to further develop or commercialize any of AxCell s technologies in the future.

We may need to raise additional capital, which may not be available.

Our cash, cash equivalents and short-term investments were $35.8 million at December 31, 2004. We expect that our existing capital resources should be adequate to fund our operations and commitments into early 2006.

We have incurred negative cash flows from operations since our inception and have expended, and expect to continue to expend in the future, substantial funds based upon the:

- success of our product commercialization efforts;
- success of any future acquisitions of complementary products and technologies we may make;
- magnitude, scope and results of our product development and research and 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.

Our business or operations may change in a manner that would consume available resources more rapidly than anticipated. We expect that we will have additional requirements for debt or equity capital, irrespective of whether and when we reach profitability, for further product development costs, product and technology acquisition costs and working capital. To the extent that our currently available funds and revenues are insufficient to meet current or planned operating requirements, we will be required to obtain additional funds through equity or debt financing, strategic alliances with corporate partners and others, or through other sources.

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These financial sources may not be available when we need them or they may be available, but on terms that are not commercially acceptable to us. If adequate funds are not available, we may be required to delay, further scale back or eliminate certain aspects of our operations or attempt to obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to certain of our technologies, product candidates, products or potential markets. If adequate funds are not available, our business, financial condition and results of operations will be materially and adversely affected.

Our capital raising efforts may dilute stockholder interests.

If we raise additional capital by issuing equity securities or convertible debentures, including the securities registered pursuant to this prospectus, such issuance will result in ownership dilution to our existing stockholders, and new investors could have rights superior to those of our existing stockholders. The extent of such dilution will vary based upon the amount of capital raised.

We may need to raise funds other than through the issuance of equity securities.

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.

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 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. If we fail to develop such products, our business

financial condition and results of operations could be significantly and adversely affected.

We could be negatively impacted by future interpretation or implementation of federal and state fraud and abuse laws, including anti-kickback laws, false claims laws and 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, false claims 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 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 can potentially give rise to claims that the law 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 and results of operations.

We could become subject to false claims litigation under federal or state statutes, which can lead to civil money penalties, criminal fines and imprisonment, and/or exclusion from participation in federal health care programs. These false claims statutes include the federal False Claims Act, which allows any person to bring suit alleging the false or fraudulent submission of claims for payment under federal programs 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 companies like us may have to defend a false claim action. We could also become subject to similar false claims litigation under state statutes. If we are unsuccessful in defending any such action, such action may have a material adverse effect on our business, financial condition and results of operations.

The healthcare fraud and abuse laws to which we are subject include the following, among others:

Federal and State Anti-Kickback Laws and Safe Harbor Provisions. The federal anti-kickback law makes it a felony to knowingly and willfully offer, or pay remuneration to induce a person to refer an individual or to recommend or arrange for the purchase, lease or ordering of any item or service for which payment may be made under the Medicare or state healthcare programs. The anti-kickback prohibitions apply regardless of whether the remuneration is provided directly or indirectly, in cash or in kind. Interpretations of the law have been very broad. Under current law, courts and federal regulatory authorities have stated that this law is violated if even one purpose, as opposed to the sole or primary purpose, of the arrangement is to induce referrals. Violations of the anti-kickback law carry potentially severe penalties including imprisonment of up to five years, criminal fines, civil money penalties and exclusion from the Medicare and Medicaid programs.

The U.S. Department of Health and Human Services Office of Inspector General, or OIG, has published safe harbors that exempt some arrangements from enforcement action under the anti-kickback statute. These statutory and regulatory safe harbors protect various bona fide employment relationships, personal service arrangements, certain discount arrangements, among other things, provided that certain conditions set forth in the statute and regulations are satisfied. The safe harbor regulations, however, do not comprehensively describe all lawful arrangements, and the failure of an arrangement to satisfy all of the requirements of a particular safe harbor does not mean that the arrangement is unlawful. Failure to comply with the safe harbor provisions, however, may mean that the arrangement will be subject to scrutiny by the OIG.

Many states have adopted similar prohibitions. Some of these state laws lack specific safe harbors that may be available under federal law. Sanctions under these state anti-kickback laws may include civil money penalties, license suspension or revocation, exclusion from Medicare or Medicaid, and criminal fines or imprisonment.

We believe that our contracts and arrangements are not in violation of applicable anti-kickback or related laws. We cannot assure you, however, that these laws will ultimately be interpreted in a manner consistent with our practices.

False Claims Acts. We are subject to state and federal laws that govern the submission of claims for reimbursement. The Federal Civil False Claims Act imposes civil liability on individuals or entities that submit, or cause to be submitted, false or fraudulent claims for payment to the government. Violations of the Civil False Claims Act may result in treble damages, civil monetary penalties for each false claim submitted and exclusion from the Medicare and Medicaid programs. In addition, we could be subject to criminal penalties under a variety of federal statutes to the extent that we knowingly violate legal requirements under federal health programs or otherwise present or cause the presentation of false or fraudulent claims or documentation to the

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government. In addition, the OIG may impose extensive and costly corporate integrity requirements upon entities and individuals subject to a false claims judgment or settlement. These requirements may include the creation of a formal compliance program, the appointment of an independent review organization, and the imposition of annual reporting requirements and audits conducted by an independent review organization to monitor compliance with the terms of the agreement and relevant laws and regulations.

The Federal Civil False Claims Act also allows a private individual to bring a qui tam suit on behalf of the government for violations of the Civil False Claims Act, and if successful, the qui tam relator shares in the government s recovery. A qui tam suit may be brought by, with only a few exceptions, any private citizen who has material information of a false claim that has not yet been previously disclosed. Recently, the number of qui tam suits brought in the healthcare industry has increased dramatically. In addition, several states have enacted laws modeled after the Federal Civil False Claims Act.

Civil Monetary Penalties. The Civil Monetary Penalties Statute states that civil penalties ranging between $10,000 and $50,000 per claim or act may be imposed on any person or entity that knowingly submits, or causes the submission of, improperly filed claims for federal health benefits, or makes payments to induce a beneficiary or provider to reduce or limit the use of healthcare services or to use a particular provider or supplier. Civil monetary penalties may be imposed for violations of the anti-kickback statute and for the failure to return known overpayments, among other things.

Prohibition on Employing or Contracting with Excluded Providers. The Social Security Act and federal regulations state that individuals or entities that have been convicted of a criminal offense related to the delivery of an item or service under the Medicare or Medicaid programs or that have been convicted, under state or federal law, of a criminal offense relating to neglect or abuse of residents in connection with the delivery of a healthcare item or service cannot participate in any federal healthcare programs, including Medicare and Medicaid.

Health Insurance Portability and Accountability Act of 1996. HIPAA created new healthcare related crimes, and granted authority to the Secretary of the Department of Health and Human Services (HHS) to impose certain civil penalties. Particularly, the Secretary may now exclude from Medicare any individual with a direct or indirect ownership interest in an entity convicted of healthcare fraud or excluded from the program. Under HIPAA and other healthcare laws, it is a crime to knowingly and willfully commit a healthcare fraud, and knowingly and willfully falsify, or conceal material information or make any materially false or fraudulent statements in connection with claims and payment for healthcare services by a healthcare benefit plan. HIPAA also created new programs to control fraud and abuse, and requires new investigations, audits and inspections.

We believe that our operations materially comply with applicable regulatory requirements. There can be no assurance that the outcome of any inquiry audit or investigation will be undertaken by HHS, OIG or DOJ. If we are ever found to have engaged in improper practices, we could be subjected to civil, administrative or criminal fines, penalties or restitutionary relief, and suspension or exclusion of the entity or individuals from participation in federal and state healthcare programs.

Patient Information and Privacy. HIPAA also mandates, among other things, the establishment of regulatory standards addressing the electronic exchange of health information, standards for the privacy and security of health information maintained or exchanged electronically, and standards for assigning unique health identifiers to healthcare providers. Sanctions for failure to comply with HIPAA standards include civil and criminal penalties. The Security Standards require us to implement certain security measures to protect certain individually identifiable health information, called protected health information, or PHI, in electronic format. The Standards for Privacy of Individually Identifiable Information restrict use and disclosure of PHI unless patient authorization for such disclosures are obtained. These Privacy Standards not only require our compliance with standards restricting the use and disclosure of PHI, but also require us to obtain satisfactory assurances that any business associate of ours who has access to our PHI similarly will safeguard such PHI.

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We have evaluated these rules to determine the effects of the rules on our business, and we believe that we have taken the appropriate steps to ensure that we will comply with these standards in all material respects by their respective compliance deadlines.

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. We currently do not carry insurance for contamination or injury resulting from the use of such materials.

PROSTASCINT and QUADRAMET utilize radioactive materials. PROSTASCINT is not manufactured or shipped as a radioactive material because the radioactive component is not added until the product has arrived at its final destination (a radiopharmacy). Laureate Pharma, our contract manufacturer of PROSTASCINT, holds a radioactive materials license because such license is required for certain release and stability tests of the product.

QUADRAMET, however, is manufactured and shipped as radioactive, and therefore, the manufacturing and distribution of this product must comply with regulations promulgated by the U.S. Nuclear Regulatory Commission. BMSMI manufacturers and distributes QUADRAMET, and is, therefore, subject to these regulations.

We have been and may, in the future be, subject to patent litigation.

On March 17, 2000, we were served with a complaint filed against us in the United States District Court for the District of New Jersey by M. David Goldenberg and Immunomedics, Inc. The litigation claimed that our PROSTASCINT product infringes a patent purportedly owned by Goldenberg and licensed to Immunomedics. We believe that PROSTASCINT did not infringe this patent, and that the patent was invalid and unenforceable. In June 2004, the U.S. Court of Appeals for the Federal Circuit affirmed the district court s grant of summary judgment of no literal infringement. Regarding infringement under the doctrine of equivalents, however, the U.S. Court of Appeals for the Federal Circuit disagreed with the district court s conclusion that there was no issue of material fact and reversed the district court s grant of summary judgment on this point and remanded for further proceedings on the issue. In September 2004, we settled the patent infringement suit for an undisclosed payment, without any admission of fault or liability.

We cannot give any assurance that we will not become subject to additional patent litigation in the future, which could result in material expenditures to us.

Our stock price has been and may continue to be volatile, and your investment in our stock could decline in value or fluctuate significantly.

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 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;

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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.

These fluctuations may be exaggerated if the trading volume of our common stock is low. These fluctuations may or may not be based upon any of our business or operating results. Our common stock may experience similar or even more dramatic price and volume fluctuations which may continue indefinitely.

We have adopted various anti-takeover provisions which may affect the market price of our common stock and prevent or frustrate attempts by our stockholders to replace or remove our management team.

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 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 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. In addition, these provisions make it more difficult to replace or remove our current management team in the event our stockholders believe this would be in the best interest of the Company and our stockholders.

The liquidity of our common stock could be adversely affected if we are delisted from The Nasdaq National Market.

In the event that we are unable maintain compliance with all relevant Nasdaq Listing Standards, our securities may be subject to delisting from the Nasdaq National Market. If such delisting occurs, the market price and market liquidity of our common stock may be adversely affected. Such listing standards include, among other things, requirements related to the market value of our listed securities and publicly-held shares, the minimum bid price for such shares. On March 3, 2005, the closing sale price of our common stock as reported by Nasdaq was $6.26.

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If faced with delisting, we may submit an application to transfer the listing of our common stock to the Nasdaq SmallCap Market. Alternatively, if our common stock is delisted by Nasdaq, our common stock would be eligible to trade on the OTC Bulletin Board maintained by Nasdaq, another over-the-counter quotation system, or on the pink sheets where an investor may find it more difficult to dispose of or obtain accurate quotations as to the market value of our common stock. In addition, we would be subject to a rule promulgated by the Securities and Exchange Commission that, if we fail to meet criteria set forth in such rule, imposes various practice requirements on broker-dealers who sell securities governed by the rule to persons other than established customers and accredited investors. Consequently, such rule may deter broker-dealers from recommending or selling our common stock, which may further affect the liquidity of our common stock.

Delisting from Nasdaq would make trading our common stock more difficult for investors, potentially leading to further declines in our share price. It would also make it more difficult for us to raise additional capital. Further, if we are delisted, we would also incur additional costs under state blue sky laws in connection with any sales of our securities. These requirements could severely limit the market liquidity of our common stock and the ability of our shareholders to sell our common stock in the secondary market.

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. This availability of a significant number of additional shares of our common stock for future sale and issuance could depress the price of our common stock.

Because we do not intend to pay, and have not paid, any cash dividends on our shares of common stock, our stockholders will not be able to receive a return on their shares unless the value of our shares appreciates and 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. Therefore, our stockholders will not be able to receive a return on their shares unless the value of our shares appreciates and they sell them.

Item 2. Properties

In August 2002, we moved our main offices from 600 College Road East to 650 College Road East in Princeton, New Jersey. On February 10, 2004, we entered into an amendment to our existing sublease agreement for these premises to increase the amount of space we occupy from approximately 11,500 square feet to approximately 16,100 square feet. This amendment also extended the expiration date of our sublease to October 2007, with a two year option to renew thereafter. We intend to remain headquartered in Princeton, New Jersey for the foreseeable future.

We also leased approximately 14,900 square feet of laboratory and office space in Newtown, Pennsylvania, which was occupied by our AxCell Biosciences subsidiary. In December 2004, we terminated the lease for this facility.

We own substantially all of the equipment used in our offices and we believe that our facilities are adequate for our operations at present.

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Item 3. Legal Proceedings

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

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

Not applicable.

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PART II

Item 5. Market for the Company s Common Equity, Related Stockholder Matters and Company Purchases of Equity Securities

Our common stock is traded on the Nasdaq National Market 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 Nasdaq National Market. Such quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not represent actual transactions.

2003	High	Low
First Quarter	$ 3.89	$ 2.51
Second Quarter	$ 8.59	$ 2.63
Third Quarter	$ 14.46	$ 7.78
Fourth Quarter	$ 13.40	$ 9.26
2004		
First Quarter	$ 15.25	$ 10.88
Second Quarter	$ 16.46	$ 10.39
Third Quarter	$ 16.65	$ 9.90
Fourth Quarter	$ 11.67	$ 9.17

As of March 1, 2005, there were approximately 2,958 holders of record of our common stock and there were approximately 35,200 beneficial holders of our 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 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 our board of directors.

CHANGES IN SECURITIES

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

Option Grants

During the fourth quarter of 2004, we granted an aggregate of 9,400 stock options pursuant to our 2004 Stock Incentive Plan. Of such 9,400 options, 7,400 were not registered under the Securities Act of 1933, as amended, at the time they were granted. On December 16, 2004, we filed a registration statement on Form S-8 (Reg. No. 333-121320) with the Securities and Exchange Commission to register, among other things, the shares of our common stock underlying options previously granted and to be granted, under the 2004 Stock Incentive Plan. All of such option grants were granted at the then current market value of the common stock. The following table sets forth certain information regarding such grants during the quarter:

Plan	Number of Shares	Weighted-Average Exercise Price Per Share
2004 Stock Incentive Plan	7,400*	$ 10.26

* Unregistered at the time of grant.

We did not employ an underwriter in connection with the issuance of the unregistered securities described above. We believe that the issuance of the foregoing securities was exempt from registration under either: (i) Section 4(2) of the Securities Act as transactions not involving any public offering and such securities having been acquired for investment and not with a view to distribution, or (ii) Rule 701 under the Securities Act as transactions made pursuant to a written compensatory benefit plan or pursuant to a written contract relating to compensation. All recipients had adequate access to information about the Company.

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Item 6. Selected Financial Data

The following selected financial information has been derived from our audited consolidated financial statements for each of the five years in the period ended December 31, 2004. 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 31,				
	2004	2003	2002	2001	2000
Statements of Operations Data:	(All amounts in thousands, except per share data)				
Revenues:					
Product revenues	$ 14,480	$ 9,823	$ 10,626	$ 8,782	$ 7,523
Royalties		1,105	1,842	2,063	2,004
License and contract	139	2,914	463	912	1,024
Total revenues	14,619	13,842	12,931	11,757	10,551
Operating Expenses:					
Cost of product related	9,309	6,268	4,748	4,216	4,513
Selling, general and administrative	20,318	11,867	11,272	11,427	11,370
Research and development	3,206	2,342	7,580	9,842	6,647
Equity in loss of joint venture	2,896	3,452	2,886	332	
Impairment of intangible assets[1]		115	1,729		
Acquisition of marketing and technology rights[2]					13,241
Total operating expenses	35,729	24,044	28,215	25,817	35,771
Operating loss	(21,110)	(10,202)	(15,284)	(14,060)	(25,220)
Loss on investment			(516)		
Other income (expense), net	263	(44)	101	857	611
Loss before income taxes and cumulative effect of accounting change	(20,847)	(10,246)	(15,699)	(13,203)	(24,609)
Income tax benefit	(307)	(888)		(1,103)	(1,625)
Loss before cumulative effect of accounting change	(20,540)	(9,358)	(15,699)	(12,100)	(22,984)
Cumulative effect of accounting change[3]					(4,314)
Net loss	$ (20,540)	$ (9,358)	$ (15,699)	$ (12,100)	$ (27,298)
Net loss per share:					
Basic and diluted net loss before cumulative effect of accounting change	$ (1.40)	$ (0.92)	$ (1.85)	$ (1.56)	$ (3.13)
Cumulative effect of accounting change[3]					(0.59)
Basic and diluted net loss	$ (1.40)	$ (0.92)	$ (1.85)	$ (1.56)	$ (3.72)
Weighted-average common shares outstanding:					
Basic	14,654	10,205	8,466	7,778	7,334

Diluted	14,654	10,205	8,466	7,778	7,334
Pro forma amounts assuming accounting change is applied retroactively:					
Net loss					$ (22,984)
Basic and diluted net loss per share					$ (3.13)

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Consolidated Balance Sheet Data:	December 31,				
	2004	2003	2002	2001	2000
			(in thousands)		
Cash, cash equivalents and short-term investments	$ 35,825	$ 30,215	$ 14,725	$ 11,309	$ 11,993
Total assets	50,413	43,695	19,894	21,492	20,416
Long-term liabilities	47	2,454	2,614	2,291	2,374
Accumulated deficit	(386,278)	(365,738)	(356,380)	(340,681)	(328,581)
Stockholders equity	40,030	36,040	10,588	11,214	7,218

(1) Reflects a non-cash charge to write off the carrying value of the licensing fees associated with NMP22 BLADDERCHEK in 2003 and BRACHYSEED in 2002.

(2) In August 2000, the Company licensed product rights from Advanced Magnetics, Inc.

(3) In 2000, the Company recorded a non-cash charge for the cumulative effect related to the adoption of SEC Staff Accounting Bulletin No. 101.

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Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations

Cautionary Statement

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements regarding future events and our future results are based on current expectations, estimates, forecasts, and projections and the beliefs and assumptions of our management including, without limitation, our expectations regarding results of operations, selling, general and administrative expenses, research and development expenses and the sufficiency of our cash for future operations. Forward-looking statements may be identified by the use of forward-looking terminology such as may, will, expect, estimate, anticipate, continue, or similar terms, variations of such terms or the neg of those terms. These forward-looking statements include statements regarding our intent to hold our investments until maturity, additional funding of the PSMA technologies, potential charges resulting from the closure of AxCell Biosciences, growth and market penetration for QUADRAMET and PROSTASCINT, revenues, if any, from our joint venture with Progenics Pharmaceuticals Inc., increased expenses resulting from our sales force and marketing expansion, including sales and marketing expenses for PROSTASCINT and QUADRAMET and expenses in preparation for the launch of COMBIDEX upon final regulatory approval, the sufficiency of our capital resources and supply of products for sale, the continued cooperation of our contractual and collaborative partners, our need for additional capital and other statements included in this Annual Report on Form 10-K that are not historical facts. Such forward-looking statements involve a number of risks and uncertainties and investors are cautioned not to put any undue reliance on any forward-looking statement. We cannot guarantee that we will actually achieve the plans, intentions or expectations disclosed in any such forward-looking statements. Factors that could cause actual results to differ materially, include, market acceptance of our products, the results of our clinical trials, our ability to hire and retain employees, economic and market conditions generally, our receipt of requisite regulatory approvals for our products and product candidates, the continued cooperation of our marketing and other collaborative and strategic partners, our ability to protect our intellectual property, and the other risks identified under the caption Additional Factors That May Affect Future Results provided elsewhere in this in our Annual Report on Form 10-K and those under the caption Risk Factors, as included in certain of our other filings, from time to time, with the Securities and Exchange Commission.

Any forward-looking statements made by us do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make. We do not assume, and specifically disclaim, any obligation to update any forward-looking statements, and these statements represent our current outlook only as of the date given.

The following discussion and analysis should be read in conjunction with the consolidated financial statements and related notes thereto contained elsewhere herein, as well as from time to time in our other filings with the Securities and Exchange Commission.

Overview

Founded in 1980, Cytogen Corporation of Princeton, NJ is a product-driven biopharmaceutical company that develops and commercializes innovative molecules that can be used to build leading franchises across multiple markets. Our marketed products include QUADRAMET® (samarium Sm-153 lexidronam injection) and PROSTASCINT® (capromab pendetide) kit for the preparation of Indium In-111 capromab pendetide in the United States. We have exclusive United States marketing rights to COMBIDEX® (ferumoxtran-10) for all applications, and the exclusive right to market and sell ferumoxytol (formerly Code 7228) for oncology applications in the United States. COMBIDEX, an investigational functional molecular imaging agent consisting of iron oxide nanoparticles, which is currently being developed for use in conjunction with magnetic resonance imaging to aid in the differentiation of cancerous from non-cancerous lymph nodes, and is under review by the U.S. Food and Drug Administration. We are also developing therapeutics targeting prostate-specific membrane antigen (PSMA), a protein highly expressed on the surface of prostate cancer cells and the neovasculature of solid tumors.

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Significant Events in 2004

Advanced Magnetics Submits Complete Response To Approvable Letter For COMBIDEX

On October 19, 2004, we jointly announced with Advanced Magnetics, Inc. that Advanced Magnetics submitted a complete response to the approvable letter received from the FDA for COMBIDEX, Advanced Magnetics investigational functional molecular imaging agent, to which we have exclusive United States marketing rights. The September 30, 2004 submission was accepted and assigned a user fee goal date of March 30, 2005. On March 3, 2005, the FDA s Oncologic Drugs Advisory Committee (ODAC) voted 15 to 4 to not recommend approval of the proposed broad indication for COMBIDEX. A decision by the FDA on COMBIDEX is expected by the user fee goal date of March 30, 2005.

Capital Raising and Shelf Registration Statement

In April 2004, we issued and sold 2,570,000 shares of our common stock for $10.10 per share through a registered direct offering resulting in net proceeds of approximately $23.9 million after the payment of placement agency fees and expenses related to the offering. The shares in this transaction were registered under our existing shelf registration statement on Form S-3 (File No. 333-110040), which was declared effective by the Securities and Exchange Commission on October 30, 2003.

On November 5, 2004, we filed another shelf registration statement on Form S-3 (File No. 333-120262) with the Securities and Exchange Commission relating to the registration of up to an aggregate of $70.0 million of our common stock, preferred stock, debt securities, warrants and units. The Securities and Exchange Commission declared the registration statement effective on November 19, 2004. No securities have been issued under this registration statement.

Initiation of QUADRAMET National Bone Pain Registry

In November 2004, we initiated our National Bone Pain Registry for QUADRAMET. As of March 1, 2005, more than 50 oncology sites are participating in the registry, and we expect to collect data regarding both the use of QUADRAMET and best practices in bone pain management from more than 500 patients. Results of this initiative are expected to be presented at key medical meetings following the conclusion of the program in 2005. We cannot give any assurances regarding the rate of patient accrual in the registry.

Manufacturing Agreement With Laureate Pharma, L.P.

On September 10, 2004, we entered into a non-exclusive Manufacturing Agreement with Laureate Pharma, L.P. for our PROSTASCINT product. We intend that the agreement will provide us with a sufficient supply of PROSTASCINT to satisfy our commercial requirements for approximately the next four years, based upon current sales levels.

Additions To Senior Management

In April 2004, we announced that Thomas S. Lytle joined us as Senior Vice President of Sales and Marketing, a newly-created position at Cytogen. Mr. Lytle has over 25 years of experience in the pharmaceutical industry and has held senior level positions at Amgen, Inc., Pfizer and Lederle Laboratories. Mr. Lytle is responsible for overseeing strategic sales and marketing initiatives for our existing and future products.

In August 2004, we announced that William J. Thomas, Esq. joined us as Senior Vice President and General Counsel. Mr. Thomas was formerly a senior partner with the law firm of Wilmer Cutler Pickering Hale and Dorr, and has almost 20 years of experience in representing emerging growth and high technology businesses in the areas of, among others, general corporate issues, securities law compliance, venture capital, underwriting, strategic alliances and mergers and acquisitions. Mr. Thomas has represented numerous public and private companies in the software, pharmaceutical, telecommunications and e-commerce industries. Mr. Thomas is responsible for all legal matters at Cytogen.

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In December 2004, we announced that Michael J. Manyak, MD joined us as Vice President of Medical Affairs. Prior to joining Cytogen, Dr. Manyak was Professor of Urology, Microbiology, and Tropical Medicine at The George Washington University Medical Center (GWUMC) where he was also Chairman of the Department of Urology. Dr. Manyak s corporate medical experience includes service on the scientific advisory boards of, and as a consultant to, more than 25 biomedical technology and pharmaceutical companies. In these capacities, he has been involved in business development, strategic planning for the regulatory approval of products, intellectual property development, protocol construction, and clinical trials. He is also a founder of Metastatin Pharmaceuticals, a biopharmaceutical company developing anti-metastatic therapies. At Cytogen, Dr. Manyak acts as primary liaison with the medical community and is responsible for the Company s clinical science and medical affairs functions.

Patent Infringement Litigation Settled

On September 29, 2004, we announced the settlement of a patent infringement suit against us and C.R. Bard Inc. for an agreed-upon payment, without any admission of fault or liability. The charge related to this settlement was recorded in the accompanying statements of operations for the year ended December 31, 2004. Immunomedics filed suit on February 17, 2000 against us and Bard, alleging that use of our PROSTASCINT product infringed U.S. Patent No. 4,460,559, which claims a method for detecting and localizing tumors. The settlement with Immunomedics was on behalf of Cytogen and Bard.

RESULTS OF OPERATIONS

Year Ended December 31, 2004 as Compared to December 31, 2003

Revenues

			Increase/(Decrease)	
	2004	2003	$	%
	(All amounts in thousands, except percentage data)			
PROSTASCINT	$ 7,186	$ 6,523	$ 663	10 %
QUADRAMET:				
Product Sales (commenced August 2003)	7,293	2,765	4,528	164 %
Royalties (ceased July 2003)		1,105	(1,105)	(100)%
NMP22 BLADDERCHEK (ceased December 2004)	1	295	(294)	(100)%
BRACHYSEED (ceased January 2003)		240	(240)	(100)%
License and Contract	139	2,914	(2,775)	(95)%
	$ 14,619	$ 13,842	$ 777	6 %

Total revenues for the year ended December 31, 2004 were $14.6 million compared to $13.8 million for the same period in 2003. Product related revenues, which include product sales and royalties, accounted for 99% and 79% of total revenues in 2004 and 2003, respectively. License and

contract revenues accounted for the remainder of revenues. If QUADRAMET or PROSTASCINT does not achieve broader market acceptance, either because we fail to effectively market such products or our competitors introduce competing products, we may not be able to generate sufficient revenue to become profitable. Further, if COMBIDEX does not receive regulatory approval, we will not be permitted to sell and market COMBIDEX as we have anticipated and we will not realize any return on the significant amount of time and resources we have allocated to COMBIDEX.

PROSTASCINT. PROSTASCINT sales were $7.2 million for the year ended December 31, 2004, an increase of $663,000 from $6.5 million for the same period of 2003. Sales of PROSTASCINT accounted for 50% and 60% of product related revenues for 2004 and 2003, respectively. We believe that such increase in PROSTASCINT sales was due to increased demand associated with our focused marketing programs, a higher PROSTASCINT reimbursement value established for 2004 compared to 2003 and our identification of new

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distribution channels to better accommodate customer needs. We believe that demand for PROSTASCINT was consistently higher during 2004 than 2003 as evidenced by the higher annual sales in 2004. PROSTASCINT has historically been a challenging product for physicians and technologists to use, in part due to inherent limitations in nuclear medicine imaging. We believe that future growth and market penetration of PROSTASCINT is dependent upon, among other things, the implementation and continued research relating to advances in imaging technology, new product applications and the validation of PSMA as an independent prognostic indicator. We cannot provide any assurance that we will be able to successfully market PROSTASCINT, or that PROSTASCINT will achieve greater market penetration on a timely basis or result in significant revenues for us.

QUADRAMET. We recorded QUADRAMET sales of $7.3 million for the year ended December 31, 2004. In 2003, we recorded royalty revenue of $1.1 million from sales of QUADRAMET from January 1, 2003 to July 31, 2003 and sales revenue of $2.8 million from August 1, 2003 to December 31, 2003. QUADRAMET sales and royalties accounted for 50% and 35% of product related revenues for 2004 and 2003, respectively. Berlex Laboratories marketed QUADRAMET in the United States from May 1999 through July 31, 2003. On August 1, 2003, we reacquired marketing rights to QUADRAMET from Berlex and began marketing QUADRAMET through our internal specialty sales force. Upon the reacquisition of these marketing rights, we no longer receive royalty revenue from Berlex for QUADRAMET and we pay royalties to Berlex on our sales of QUADRAMET. On August 1, 2003, we began recognizing product revenue from our sales of QUADRAMET. Currently, we market QUADRAMET only in the United States and have no rights to market QUADRAMET in Europe. We believe that the future growth and market penetration of QUADRAMET is dependent upon, among other things: (i) new clinical data supporting the expanded and earlier use of QUADRAMET in various cancers; (ii) novel research supporting combination uses with other therapies, such as chemotherapeutics and bisphosphonates; and (iii) establishing the use of QUADRAMET at higher doses to target and treat primary bone cancers. We cannot provide any assurance that we will be able to successfully market QUADRAMET or that QUADRAMET will achieve greater market penetration on a timely basis or result in significant revenues for us.

NMP22 BLADDERCHEK. NMP22 BLADDERCHEK sales for the year ended December 31, 2004 were $1,000 compared to $295,000 in 2003. We began promoting NMP22 BLADDERCHEK to both urologists and oncologists in the United States in November 2002 using our internal sales force. On October 30, 2003, we entered into an amended and restated distribution agreement with Matritech whereby, effective November 8, 2003, we had the right to non-exclusively market NMP22 BLADDERCHEK to urologists through December 31, 2003 and also to exclusively market NMP22 BLADDERCHEK to oncologists through the term of the amended agreement, which was December 31, 2004. Effective December 31, 2004, we stopped promoting NMP22 BLADDERCHEK and we have no further obligations to Matritech with respect to this product.

BRACHYSEED. There were no BRACHYSEED sales during 2004. Effective January 24, 2003, we stopped accepting and filling new orders for the BRACHYSEED I-125 and BRACHYSEED Pd-103 products. In April 2003, we entered into an agreement with Draximage to formally terminate our agreements with respect to these products. Sales of BRACHYSEED products in 2003 totaled $240,000, or 2% of product related revenues.

License and Contract Revenues. License and contract revenues were $139,000 and $2.9 million for the years ended December 31, 2004 and 2003, respectively. Such decrease from the prior year period is due primarily to our recognition of the previously deferred license revenue. Under SAB 101, which we adopted in 2000, license revenues from certain up-front, non-refundable license fees previously recognized in prior years were deferred and were being amortized over the estimated performance period. In 2003, we recognized $2.2 million of previously deferred license revenue which included our recognition of the remaining unamortized deferred revenue in the amount of $1.9 million related to an up-front license payment, net of associated costs, which we received from Berlex Laboratories in 1998 for granting them the marketing rights to QUADRAMET. In August 2003, the 1998 license agreement was terminated and we reacquired those rights from Berlex. In addition, during 2003, we recognized $500,000 from Antisoma Research Limited in connection with Antisoma s acquisition of certain royalty rights to its lead product, R1549 (formerly Pemtumomab), because we have no continuing involvement in this arrangement. We also recognized $106,000 of contract revenues in 2004,

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compared to $214,000 in 2003, for limited research and development services provided by us to the PSMA Development Company LLC, our joint venture with Progenics Pharmaceuticals Inc. The level of future revenues, if any, for contract services provided to the joint venture may vary and will depend upon the extent of research and development services required by the joint venture.

Operating Expenses

			Increase/(Decrease)	
	2004	2003	$	%
	(All amounts in thousands, except percentage data)			
Cost of product related revenues	$ 9,309	$ 6,268	$ 3,041	49 %
Selling, general and administrative	20,318	11,867	8,451	71 %
Research and development	3,206	2,342	864	37 %
Equity in loss of joint venture	2,896	3,452	(556)	(16)%
Impairment of intangible assets		115	(115)	(100)%
	$ 35,729	$ 24,044	$ 11,685	49 %

Total operating expenses for the year ended December 31, 2004 were $35.7 million compared to $24.0 million for the same period of 2003.

Cost of Product Related Revenues. Cost of product related revenues for the year ended December 31, 2004 was $9.3 million compared to $6.3 million for the same period of 2003. The increase from the prior year was due primarily to our assumption, in August 2003, of the responsibility for manufacturing costs for QUADRAMET including contractual increases in 2004 related to our new agreement with Bristol-Myers Squibb Medical Imaging, royalties to Berlex on our sales of QUADRAMET and the amortization of the up-front payment to Berlex to reacquire QUADRAMET.

Selling, General and Administrative. Selling, general and administrative expenses for the year ended December 31, 2004 were $20.3 million compared to $11.9 million for the same period of 2003. The increase from the prior year was due primarily to the expansion of our sales force and the implementation of other marketing initiatives for our planned and existing products, including QUADRAMET, which we reacquired from Berlex in August 2003. The selling, general and administrative expenses in 2004 also include increased legal and professional fees as well as a payment related to the settlement, in September 2004, of a patent infringement suit filed by Immunomedics, Inc. against us and C.R. Bard Inc. in February 2000. The selling, general and administrative expenses in 2003 include $497,000 in stock-based compensation expenses related to warrants granted to certain consultants in 2003. As of February 25, 2005, we employed 59 people in sales and marketing. The employees in sales and marketing included nine Clinical Oncology Specialists and 39 Regional Managers, Professional Oncology Representatives, Senior Professional Oncology Representatives and Senior Account Managers. By comparison, we had 36 employees in sales and marketing as of March 1, 2004. We anticipate that expenditure levels will continue to increase as we continue this expansion in our sales force.

Research and Development. Research and development expenses for the year ended December 31, 2004 were $3.2 million compared to $2.3 million for the same period of 2003. The 2004 expenses reflect, primarily, costs associated with our product development efforts in support of new and expanded uses for Quadramet and PROSTASCINT and savings from the recent closure of our AxCell Biosciences facility. The 2004 expenses also included a $497,000 charge related to the issuance of shares of our common stock in November 2004, to the stockholders and debtholders of Prostagen Inc. made pursuant to the terms of an addendum to our Stock Exchange Agreement dated June 15, 1999, related to the

progress of certain PSMA development programs. Research and development expenses in 2003 included a net credit of $580,000 associated with our termination of an agreement with DSM Biologics Company BV relating to the development of a new manufacturing process for PROSTASCINT. In 2005, we expect to expand the development programs for our market products beyond the current indications through new and ongoing clinical studies which may increase current expenditure levels.

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In 2004 and 2003, we incurred $621,000 and $1.4 million, respectively, in expenses relating to AxCell s operations. In September 2002, we significantly reduced AxCell s workforce to reduce the cash expenditures relating to AxCell in order to leverage our oncology franchise. Further, in July 2004, as part of our continuing efforts to reduce non-strategic expenses, we initiated the closure of AxCell s facilities. Research projects through academic, governmental and corporate collaborators to be supported and additional applications for the intellectual property and technology at AxCell are being pursued.

Equity in Loss of Joint Venture. Our share of the loss of the PSMA Development Company LLC, our joint venture with Progenics Pharmaceuticals, Inc., was $2.9 million in 2004 compared to $3.5 million for the same period of 2003, and represented 50% of the joint venture s operating losses. We equally share ownership and costs of the joint venture with Progenics and account for the joint venture using the equity method of accounting. As of March 15, 2005, we and Progenics are in the process of negotiating the work plan and annual budget for 2005 for the joint venture. We cannot give any assurances that agreement will be reached on such matters in the near future, if at all. The failure to reach agreement with Progenics on these matters could significantly and adversely affect the development of PSMA technologies and products. In 2004, $8.0 million of grants were awarded over four years from the National Institutes of Health that will be used to develop novel immunotherapies for prostate cancer based upon PSMA. The failure of Cytogen and Progenics to reach agreement on the 2005 annual work plan and budget for the joint venture could adversely effect the joint venture s ability to access the NIH grants. We may incur significant and increasing costs in the future to fund our share of the development costs of the joint venture, although we cannot provide any assurance that any further agreements between us and Progenics will be reached regarding the joint venture.

Impairment of Intangible Assets. In 2003, we recorded a non-cash charge of $115,000 for the impairment of the carrying value of an up-front license fee associated with NMP22 BLADDERCHEK, which was not recoverable.

Interest Income/Expense. Interest income for the year ended December 31, 2004 was $448,000 compared to $141,000 for the same period of 2003. The increase from the prior year period was due to higher average cash and short-term investment balances in 2004. Interest expense was $185,000 for each of 2004 and 2003. Interest expense includes interest on outstanding debt and finance charges related to various equipment leases that are accounted for as capital leases.

Income Tax Benefit. During 2004, we sold a portion of our New Jersey state net operating loss carryforwards, which resulted in the recognition of $307,000 in income tax benefits. In 2003, we recognized $888,000 in such income tax benefits. Assuming the State of New Jersey continues to fund this program, which is uncertain, the future amount of net operating loss and research and development credit carryforwards which we may sell will also depend upon the allocation among qualifying companies of an annual pool established by the State of New Jersey.

Net Loss. Net loss for the year ended December 31, 2004 was $20.5 million compared to $9.4 million for the same period of 2003. The basic and diluted net loss per share for 2004 was $1.40 based on 14.7 million weighted-average common shares outstanding, compared to a basic and diluted net loss per share of $0.92 based on 10.2 million weighted-average common shares outstanding for the same period in 2003.

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Year Ended December 31, 2003 as Compared to December 31, 2002

Revenues

			Increase/(Decrease)	
	2003	2002	$	%
	(All amounts in thousands, except percentage data)			
PROSTASCINT	$ 6,523	$ 7,923	$ (1,400)	(18)%
QUADRAMET:				
Product Sales (commenced August 2003)	2,765		2,765	n/a
Royalties (ceased July 2003)	1,105	1,842	(737)	(40)%
NMP22 BLADDERCHEK (commenced November 2002)	295	14	281	2,007 %
BRACHYSEED (ceased January 2003)	240	2,507	(2,267)	(90)%
ONCOSCINT (ceased December 2002)		182	(182)	(100)%
License and Contract	2,914	463	2,451	529 %
	$ 13,842	$ 12,931	$ 911	7 %

Total revenues for the year ended December 31, 2003 were $13.8 million compared to $12.9 million for the same period in 2002. Product related revenues, which include product sales and royalties, accounted for 79% and 96% of total revenues in 2003 and 2002, respectively. License and contract revenues accounted for the remainder of revenues.

PROSTASCINT. PROSTASCINT sales were $6.5 million for the year ended December 31, 2003, a decrease of $1.4 million from $7.9 million for the same period of 2002. Sales of PROSTASCINT accounted for 60% and 64% of product related revenues for 2003 and 2002, respectively. PROSTASCINT has historically been a challenging product for physicians and technologists to use, in part due to inherent limitations in nuclear medicine imaging. While we believe that the period to period decrease in PROSTASCINT sales that we have experienced is due, to a large degree, to such challenge, we also believe that such decline in PROSTASCINT revenue may be reversed depending upon, among other things, the implementation and continued research relating to the following: (i) advances in imaging technology; (ii) new product applications; and (iii) improvements in healthcare reimbursement practices. We cannot assure you that we will be able to successfully market PROSTASCINT or that PROSTASCINT will achieve greater market penetration on a timely basis or result in significant revenues for us.

QUADRAMET. Berlex Laboratories marketed QUADRAMET in the United States through July 31, 2003. On August 1, 2003, we reacquired marketing rights to QUADRAMET from Berlex and began marketing QUADRAMET through our internal specialty sales force. Effective upon the reacquisition of such marketing rights, we no longer receive royalty revenue from Berlex for QUADRAMET and we pay royalties to Berlex on our sales of QUADRAMET. On August 1, 2003, we began recognizing product revenue from our sales of QUADRAMET. Royalty revenue from sales of QUADRAMET for the year ended December 31, 2003 was $1.1 million from January 1, 2003 through July 31, 2003 compared to $1.8 million in the full year 2002. In 2003, Cytogen recorded QUADRAMET sales of $2.8 million from August 1, 2003 through December 31, 2003. QUADRAMET product sales and royalties combined accounted for 35% and 15% of product related revenues for 2003 and 2002, respectively. Currently, we market QUADRAMET only in the United States. Schering AG, Germany, through its subsidiary CIS Bio International, will continue to market QUADRAMET in Europe as a direct licensee of Dow Chemical Company. We believe that the future growth and market penetration of QUADRAMET is dependent upon, among other things: (i) new clinical data supporting the expanded and earlier use of QUADRAMET in various cancers; (ii) novel research supporting combination uses with other therapies, such as

chemotherapeutics and bisphophonates; and (iii) establishing the use of QUADRAMET at higher doses to target and treat primary bone cancers. We cannot assure you that we will be able to successfully market QUADRAMET or that QUADRAMET will achieve greater market penetration on a timely basis or result in significant revenues for us.

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NMP22 BLADDERCHEK. NMP22 BLADDERCHEK sales for the year ended December 31, 2003 were $295,000, which represented 3% of our total product related revenues compared to $14,000 in 2002. We began promoting NMP22 BLADDERCHEK to both urologists and oncologists in the United States in November 2002 using our internal sales force. On October 30, 2003, we entered into an amended and restated distribution agreement with Matritech whereby, effective November 8, 2003, we had the right to non-exclusively market NMP22 BLADDERCHEK to urologists through December 31, 2003 and also to exclusively market NMP22 BLADDERCHEK to oncologists through the term of the amended agreement, which is December 31, 2004. Effective December 31, 2004, we stopped promoting NMP22 BLADDERCHEK and we have no further obligations to Matritech with respect to this product.

BRACHYSEED. Effective January 24, 2003, we stopped accepting and filling new orders for the BRACHYSEED I-125 and BRACHYSEED Pd-103 products. In April 2003, we entered into an agreement with Draximage to formally terminate our agreements with respect to these products. Sales of BRACHYSEED products in 2003 totaled $240,000, or 2% of product related revenues. BRACHYSEED sales for the year ended December 31, 2002 were $2.5 million, which represented 20% of our product related revenues.

ONCOSCINT CR/OV. We stopped selling ONCOSCINT CR/OV in December 2002 in order to focus our efforts on other oncology products, primarily because the market for ONCOSCINT CR/OV for colorectal cancer diagnosis was negatively affected by positron emission tomography, or PET , scans which have shown the same or higher sensitivity than ONCOSCINT CR/OV. ONCOSCINT CR/OV sales for the year ended December 31, 2002 were $182,000.

License and Contract Revenues. License and contract revenues were $2.9 million and $463,000 for the years ended December 31, 2003 and 2002, respectively. Under SAB 101, which we adopted in 2000, license revenues from certain up-front, non-refundable license fees previously recognized in prior years were deferred and were being amortized over the estimated performance period. In 2003, we recognized $2.2 million of previously deferred license revenue compared to $410,000 for the same period in 2002. Such increase from the prior year period is due primarily to our recognition of the remaining unamortized deferred revenue in the amount of $1.9 million related to an up-front license payment, net of associated costs, which we received from Berlex Laboratories in 1998 for granting them the marketing rights to QUADRAMET. In August 2003, the 1998 license agreement was terminated and we reacquired those rights from Berlex. In addition, during 2003, we recognized $500,000 from Antisoma Research Limited in connection with Antisoma s acquisition of certain royalty rights to its lead product, R1549 (formerly Pemtumomab), because we have no continuing involvement in this arrangement. We also recognized $214,000 of contract revenues in 2003, compared to $53,000 in 2002, for limited research and development services provided by us to the PSMA Development Company LLC, our joint venture with Progenics Pharmaceuticals Inc. The level of future revenues, if any, for contract services provided to the joint venture may vary and will depend upon the extent of research and development services required by the joint venture.

Operating Expenses

			Increase/(Decrease)	
	2003	2002	$	%
	(All amounts in thousands, except percentage data)			
Cost of product related revenues	$ 6,268	$ 4,748	$ 1,520	32 %
Selling, general and administrative	11,867	11,272	595	5 %
Research and development	2,342	7,580	(5,238)	(69)%
Equity in loss of joint venture	3,452	2,886	566	20 %
Impairment of intangible assets	115	1,729	(1,614)	(93)%
	$ 24,044	$ 28,215	$ (4,171)	(15)%

Total operating expenses for the year ended December 31, 2003 were $24.0 million compared to $28.2 million for the same period of 2002.

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Cost of Product Related Revenues. Cost of product related revenues for the year ended December 31, 2003 was $6.3 million compared to $4.7 million for the same period of 2002. The increase from the prior year is due to our August 2003 assumption of responsibility for manufacturing costs for QUADRAMET and royalties to Berlex on our sales of QUADRAMET. Also included in the 2003 cost of product related revenues is the amortization of the up-front payment to Berlex to reacquire QUADRAMET and inventory writedowns for excess PROSTASCINT and NMP22 BLADDERCHEK due to shelf-life expiration issues. These increases are partially offset by lower costs associated with our discontinuation of BRACHYSEED products in January 2003 and ONCOSCINT in December 2002.

Selling, General and Administrative. Selling, general and administrative expenses for the year ended December 31, 2003 were $11.9 million compared to $11.3 million for the same period of 2002. The increase from the prior year is primarily due to the selling and marketing efforts for NMP22 BLADDERCHEK and QUADRAMET in 2003 as well as increased insurance, legal, and professional fees. Also included in selling, general and administrative expenses are $497,000 in stock-based compensation expenses related to warrants granted to certain consultants in 2003. These increases are partially offset by the discontinuation of selling and marketing activities related to BRACHYSEED products in January 2003, the 2002 AxCell restructuring charge of $869,000, and non-recurring stock-based compensation expenses for a key employee in 2002. As of March 1, 2004, we employed 61 persons, 60 of whom are employed full-time and 1 of whom is employed part-time. Of such 61 persons, 4 were employed in our AxCell subsidiary, 2 in regulatory, 5 in clinical activities, 14 in administration and management, and 36 in sales and marketing. The employees in sales and marketing included 8 Regional Oncology Specialists and 23 Regional and Territory Managers. We had 31 employees in sales and marketing as of December 31, 2003 and 27 as of December 31, 2002.

Research and Development. Research and development expenses for the year ended December 31, 2003 were $2.3 million compared to $7.6 million for the same period of 2002. The 2003 expenses reflect, primarily, costs associated with our efforts to explore new applications for PROSTASCINT such as image guided therapies and imaging enhancements. The 2003 decrease from the prior year is attributable primarily to a non-cash milestone expense of $2.0 million occurring only in 2002 related to the progress of dendritic cell prostate cancer clinical trials at Northwest Biotherapeutics. Also contributing to this decrease were decreases in AxCell research and development expenditures as a result of the September 2002 restructuring and the 2003 settlement and termination of a 2000 agreement with DSM Biologics relating to the development of a new manufacturing process for PROSTASCINT, which resulted in a net credit of $580,000 to manufacturing development costs in 2003. In 2003 and 2002, we incurred $1.4 million and $3.6 million, respectively, in expenses relating to AxCell s operations. In September 2002, we significantly reduced AxCell s workforce to reduce the cash expenditures relating to AxCell in order to leverage our oncology franchise.

Equity in Loss of Joint Venture. Our 50% share of the equity loss in the PSMA Development Company LLC, our joint venture with Progenics Pharmaceuticals, Inc., was $3.5 million in 2003 compared to $2.9 million for the same period of 2002. We equally share ownership and costs of the joint venture with Progenics and account for the joint venture using the equity method of accounting. The joint venture s work plan, budget, and other operational and financial matters relating to 2004 were approved by us and Progenics. We expect to incur significant and increasing costs in the future to fund our share of the development costs of the joint venture.

Impairment of Intangible Assets. In 2003, we recorded a non-cash charge of $115,000 for the impairment of the carrying value of an up-front license fee associated with NMP22 BLADDERCHEK, which we believe will not be recoverable given our projected sales volumes. During 2002, we recorded a non-cash charge of $1.7 million to impairment of intangible assets which represented the write-off of the carrying value of the up-front license fees associated with BRACHYSEED I-125 and BRACHYSEED Pd-103, as the carrying value would not have been recoverable. In January 2003, we served notice of termination for each of our license and distribution agreement and product manufacturing and supply agreement with Draximage with respect to the BRACHYSEED products. As of January 24, 2003, we no longer accept or fill new orders for either BRACHYSEED product.

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Interest Income/Expense. Interest income for the year ended December 31, 2003 was $141,000 compared to $274,000 for the same period of 2002. The decrease from the prior year is due to a lower average yield on investments. Interest expense for 2003 was $185,000 compared to $173,000 for the same period of 2002. Interest expense includes interest on outstanding debt and finance charges related to various equipment leases.

Loss on Investment. We recorded a non-cash charge of $516,000 during 2002 for a complete impairment in the carrying value of our investment in shares of common stock of Northwest Biotherapeutics Inc., which we had received as part of our acquisition of Prostagen in 1999. The fair value of such investment, based on the quoted market prices, had dramatically decreased from its original carrying value of $516,000. Based on an evaluation of the financial condition of Northwest and the then current stock price, we concluded that the decline was other than temporary and that the carrying amount of this investment would not be recoverable.

Income Tax Benefit. During 2003, we sold a portion of our New Jersey state net operating loss carryforwards, which resulted in the recognition of $888,000 in income tax benefits. Assuming the State of New Jersey continues to fund this program, which is uncertain, the future amount of net operating loss and research and development credit carryforwards which we may sell will also depend upon the allocation among qualifying companies of an annual pool established by the State of New Jersey. We did not recognize any such benefits in 2002.

Net Loss. The net loss for the year ended December 31, 2003 was $9.4 million compared to $15.7 million reported for the same period of 2002. The net loss per share for the year ended December 31, 2003 was $0.92 based on weighted-average common shares outstanding of 10.2 million, compared to a net loss per share of $1.85 based on weighted-average common shares outstanding of 8.5 million for the same period in 2002.

COMMITMENTS

We have entered into various contractual and commercial commitments. The following table summarizes our obligations with respect to these commitments as of December 31, 2004:

Contractual Obligation	Less than 1 year	1 to 3 years	4 to 5 years	More than 5 years	Total
	(All amounts in thousands)				
Long-term debt[1]	$ 2,380	$	$	$	$ 2,380
Capital lease obligations	16	42	5		63
Facility leases	338	620			958
Research and development and other obligations	397	166	152	625	1,340
Manufacturing contracts[2]	6,159	5,473			11,632
Capital contribution to joint venture[3]	500				500
Minimum royalty payments[4]	1,000	2,000	2,000	3,833	8,833
Total	$ 10,790	$ 8,301	$ 2,157	$ 4,458	$ 25,706

(1) In August 1998, we received $2.0 million from Elan Corporation, plc in exchange for a convertible promissory note. The note is convertible into shares of our common stock at $28 per share, subject to adjustments, and matures in August 2005. The note bears annual

interest of 7%, compounded semi-annually, however, such interest was not payable in cash but was added to the principal of the note through August 2000. For subsequent periods, interest is payable in cash. The note contains certain non-financial covenants, with which we were in compliance as of December 31, 2004.

(2) Effective January 1, 2004, we entered into a new manufacturing and supply agreement with BMSMI for QUADRAMET whereby BMSMI manufactures, distributes and provides order processing and customer services for us relating to QUADRAMET. Under the terms of our agreement, we are obligated to pay at least $4.2 million annually, subject to future annual price adjustment, through 2008, unless terminated by BMSMI or us on a two year prior written notice. This agreement will automatically renew for five successive one-year periods unless terminated by BMSMI or us on a two-year prior written notice. Accordingly, we have not included commitments beyond December 31, 2006.

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Additionally, in September 2004, we entered into a non-exclusive manufacturing agreement with Laureate Pharma, L.P. pursuant to which Laureate shall manufacture ProstaScint for us in its Princeton, New Jersey facility. The agreement will terminate, unless earlier terminated pursuant to its terms, upon Laureate s completion of the production campaign for PROSTASCINT and shipment of the resulting products from Laureate s facility. Under the terms of the agreement, we are obligated to pay at least an aggregate of $5.1 million through 2006, of which $2.3 million was incurred in 2004. We intend that the agreement will provide us with a sufficient supply of ProstaScint to satisfy our commercial requirements for approximately the next four years, based upon current sales levels.

(3) As of March 15, 2005, we and Progenics are in the process of negotiating the work plan and annual budget for 2005 for the joint venture. We cannot give any assurances that agreement will be reached on such matters in the near future, if at all. Cytogen and Progenics each made a capital contribution of $500,000 to the joint venture in January 2005, for 2004 expenditures. We may incur significant and increasing costs in the future to fund our share of the development costs from the joint venture, although we cannot be sure that any further agreements between us and Progenics will be reached regarding the joint venture.

(4) We acquired an exclusive license from The Dow Chemical Company for QUADRAMET for the treatment of osteoblastic bone metastases in certain territories. The agreement requires us to pay Dow royalties based on a percentage of net sales of QUADRAMET, or a guaranteed contractual minimum payment, whichever is greater, and future payments upon achievement of certain milestones. Future annual minimum royalties due to Dow are $1.0 million per year in 2005 through 2012 and $833,000 in 2013.

In addition to the above, we are obligated to make certain royalty payments based on sales of the related product and certain milestone payments if our collaborative partners achieve specific development milestones or commercial milestones.

LIQUIDITY AND CAPITAL RESOURCES

Condensed Statement of Cash Flows:

	2004
	(All amounts in thousands)
Net loss	$ (20,540)
Adjustments to reconcile net loss to net cash used in operating activities	2,867
Net cash used in operating activities	(17,673)
Net cash used in investing activities	(6,834)
Net cash provided by financing activities	23,923
Net decrease in cash and cash equivalents	$ (584)

Our cash and cash equivalents were $13.0 million as of December 31, 2004, compared to $13.6 million as of December 31, 2003. As of December 31, 2004, our total cash, cash equivalents and short-term investments were $35.8 million compared to $30.2 million as of December 31, 2003. The increase in cash, cash equivalents and short term investments from the December 31, 2003 balance was primarily due to our receipt of net proceeds of approximately $23.9 million from a registered direct offering of our common stock in April 2004, offset by increased cash used for operating activities in 2004, including inventory built up for PROSTASCINT and increased costs to manufacture, promote and support our existing oncology products and to expand our internal sales force. During 2004 and 2003, net cash used for operating activities was $17.7 million and $10.5 million, respectively. In 2005, we expect operating expenditures to increase over 2004 levels.

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

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2004 Capital Raising

In April 2004, we sold 2,570,000 shares of our common stock for $10.10 per share through a registered direct offering resulting in net proceeds of approximately $23.9 million after the payment of placement agency fees and expenses related to the offering. The shares in this transaction were registered under our existing shelf registration statement on Form S-3 (File No. 333-110040), which was declared effective by the Securities and Exchange Commission on October 30, 2003.

On November 5, 2004, we filed another shelf registration statement on Form S-3 (File No. 333-120262) with the Securities and Exchange Commission relating to the registration of up to an aggregate of $70.0 million of our common stock, preferred stock, debt securities, warrants and units. The Securities and Exchange Commission declared the registration statement effective on November 19, 2004.

Other Liquidity Events

In September 2004, we entered into a non-exclusive manufacturing agreement with Laureate Pharma, L.P. pursuant to which Laureate is manufacturing PROSTASCINT for us in its Princeton, New Jersey facility. Our agreement will terminate, unless terminated earlier pursuant to its terms, upon Laureate s completion of the production campaign and shipment of the resulting products from Laureate s facility. Under the terms of the agreement, we are obligated to pay at least an aggregate of $5.1 million through 2006, of which $2.3 million was incurred in 2004. We intend that the agreement will provide us with a sufficient supply of PROSTASCINT to satisfy our commercial requirements for approximately the next four years, based upon current sales levels. In October 2004, Laureate was acquired by Safeguard Scientifics, Inc. Laureate has continued to operate as a full service contract manufacturing organization and we have not experienced any disruption in Laureate s performance of its obligations to produce PROSTASCINT.

In 2003, we reacquired the marketing rights to QUADRAMET from Berlex. Accordingly, effective August 1, 2003, we began recording all revenue from sales of QUADRAMET. Effective upon the reacquisition of such marketing rights, we no longer receive royalty revenue from Berlex and pay Berlex royalties on our sales of QUADRAMET. As a result of the reacquisition, we assumed all of Berlex s obligations under a manufacturing and supply agreement with BMSMI. Effective January 1, 2004, we entered into a new manufacturing and supply agreement with BMSMI whereby BMSMI manufactures, distributes and provides order processing and customer services for us relating to QUADRAMET. Under the terms of the new agreement, we are obligated to pay at least $4.2 million annually, subject to future annual price adjustment, through 2008, unless terminated by BMSMI or us on two years prior written notice. For 2004, we incurred $4.2 million of manufacturing costs for QUADRAMET. This agreement will automatically renew for five successive one-year periods unless terminated by BMSMI or us on a two year prior written notice. We also pay BMSMI a variable amount per month for each QUADRAMET order placed to cover the costs of customer service. In addition, we expect our QUADRAMET sales and marketing expenses to increase in 2005.

Beginning in December 2001, we began to equally share the costs of the joint venture with Progenics. In 2004, Cytogen and Progenics each provided funding of $2.0 million to the joint venture. As of March 15, 2005, we and Progenics are in the process of negotiating the work plan and annual budget for 2005 for the joint venture. We cannot give any assurances that agreement will be reached on such matters in the near future, if at all. Cytogen and Progenics each made a capital contribution of $500,000 to the joint venture in January 2005, for 2004 expenditures. We may incur significant and increasing costs in the future to fund our share of the development costs from the joint venture although we cannot provide any assurance that any further agreements between us and Progenics will be reached regarding the joint venture. Any funding amount in subsequent periods may vary dependent upon, among other things, the results of the clinical trials and research and development activities, competitive and technological developments, and market opportunities.

Our financial objectives are to meet our capital and operating requirements through revenues from existing products and licensing arrangements. To achieve these objectives, we may enter into research and development partnerships and acquire, in-license and develop other technologies, products or services. Certain of these

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strategies may require payments by us in either cash or stock in addition to the costs associated with developing and marketing a product or technology. However, we believe that, if successful, such strategies may increase long-term revenues. There can be no assurance as to the success of such strategies or that resulting funds will be sufficient to meet cash requirements until product revenues are sufficient to cover operating expenses, if ever. To fund these strategic and operating activities, we may sell equity, debt or other securities as market conditions permit or enter into credit facilities.

We have incurred negative cash flows from operations since our inception, and have expended, and expect to continue to expend in the future, substantial funds to implement our planned product development efforts, including acquisition of products and complementary technologies, research and development, clinical studies and regulatory activities, and to further our marketing and sales programs. We expect that our existing capital resources should be adequate to fund our operations and commitments at least into early 2006. We cannot assure you that our business or operations will not change in a manner that would consume available resources more rapidly than anticipated. We expect that we will have additional requirements for debt or equity capital, irrespective of whether and when we reach profitability, for further product development costs, product and technology acquisition costs, and working capital.

Our future capital requirements and the adequacy of available funds will depend on numerous factors, including: (i) the successful commercialization of our products; (ii) the costs associated with the acquisition of complementary products and technologies; (iii) progress in our product development efforts and the magnitude and scope of such efforts; (iv) progress with clinical trials; (v) progress with regulatory affairs activities; (vi) the cost of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights; (vii) competing technological and market developments; and (viii) the expansion of strategic alliances for the sales, marketing, manufacturing and distribution of our products. To the extent that the currently available funds and revenues are insufficient to meet current or planned operating requirements, we will be required to obtain additional funds through equity or debt financing, strategic alliances with corporate partners and others, or through other sources. There can be no assurance that the financial sources described above will be available when needed or at terms commercially acceptable to us. If adequate funds are not available, we may be required to delay, further scale back or eliminate certain aspects of our operations or attempt to obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to certain of our technologies, product candidates, products or potential markets. If adequate funds are not available, our business, financial condition and results of operations will be materially and adversely affected.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Financial Reporting Release No. 60 requires all companies to include a discussion of critical accounting policies or methods used in the preparation of financial statements. Note 1 to our Consolidated Financial Statements in our Annual Report on Form 10-K for the year ended December 31, 2004 includes a summary of our significant accounting policies and methods used in the preparation of our Consolidated Financial Statements. The following is a brief discussion of the more significant accounting policies and methods used by us. The preparation of our Consolidated Financial Statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Our actual results could differ materially from those estimates.

Revenue Recognition

Product related revenues include product sales by us to our customers and QUADRAMET royalties earned by us prior to August 2003. Product sales are recognized when the customer takes ownership of the products and assumes risk of loss, collection of the relevant receivable is probable, persuasive evidence of an agreement exists and the sales price is fixed and determinable. Product returns are accepted under limited circumstances and are estimated based upon historical experience. We may provide rebates and volume discounts to our customers from time to time. Such rebates and discounts are recorded as a reduction of product sales when earned by the customer.

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

License and contract revenues include milestone payments and fees under collaborative agreements with third parties, revenues from research services, and revenues from other miscellaneous sources.

In 2003, Staff Accounting Bulletin No. 104, Revenue Recognition (SAB 104) replaced Staff Accounting Bulletin No. 101, Revenue Recognition In Financial Statements (SAB 101), which the Company adopted in 2000. The provisions related to non-refundable, up-front license fees were unchanged in SAB 104 compared to SAB 101. Accordingly, we defer up-front license fees and recognize them over the estimated performance period of the related agreement, when we have continuing involvement. Since the term of the performance periods is subject to management s estimates, future revenues to be recognized could be affected by changes in such estimates.

Accounts Receivable

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

Inventories

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

Carrying Value of Fixed and Intangible Assets

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

New Accounting Pronouncements

Abnormal Inventory Costs

In November 2004, the FASB issued SFAS No. 151, Inventory Costs, an amendment of ARB No. 43, Chapter 4 (SFAS 151), to clarify that abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage) should be recognized as current period charges, and that fixed production overheads

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should be allocated to inventory based on the normal capacity of production facilities. This statement is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. Accordingly, we will adopt SFAS 151 in our fiscal year beginning January 1, 2006. We are currently in the process of evaluating the impact of adopting this statement.

Share-Based Payment

In December 2004, the FASB issued SFAS No. 123(R), Share-Based Payment , which revised SFAS No. 123 and superseded APB Opinion No. 25, Accounting for Stock Issued to Employees. SFAS No. 123(R) requires that companies recognize compensation expense associated with grants of stock options and other equity instruments to employees in the financial statements effective as of the first interim reporting period that begins after June 15, 2005. Compensation cost will be measured based on the fair value of the instrument on the grant date and will be recognized over the vesting period. This pronouncement applies to all grants after the effective date and to the unvested portion of stock options outstanding as of the effective date. SFAS No. 123(R) eliminates the ability to account for such transactions using the intrinsic method currently used by us. SFAS No. 123(R) also requires that companies recognize compensation expense associated with purchases of shares of common stock by employees at a discount to market value under employee stock purchase plans that meet certain criteria. Accordingly, we will adopt SFAS No. 123(R) in the quarterly period beginning July 1, 2005. Although management has not yet determined the impact of the adoption of this standard, it is expected to have a material effect on our consolidated financial statements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

We do not have operations subject to risks of foreign currency fluctuations, nor do we use derivative financial instruments in our operations. Our exposure to market risk is principally confined to interest rate sensitivity. Our cash equivalents and short-term investments are conservative in nature, with a focus on preservation of capital. Due to the short-term nature of our investments and our investment policies and procedures, we have determined that the risks associated with interest rate fluctuations related to these financial instruments are not material to our business. As of December 31, 2004, we had $2.3 million of debt outstanding with a fixed interest rate of 7%. We do not have exposure to market risks associated with changes in interest rates, as we have no variable interest rate debt outstanding. However, downward changes in interest rates could expose us to market risk associated with any fixed interest rate debt.

Item 8. Financial Statements and Supplementary Data

The financial statements required to be disclosed under this Item are submitted as a separate section of this Annual Report on Form 10-K.

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

Not applicable.

Item 9A. Controls and Procedures

(a) Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2004. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported, within the time periods specified in the SEC s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Securities

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Exchange Act of 1934 is accumulated and communicated to the company s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applied its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our chief executive officer and chief financial officer concluded that, as of December 31, 2004, our disclosure controls and procedures were effective.

(b) Internal Controls Over Financial Reporting

(1) Management s Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) of the Exchange Act. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based upon the framework in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on that evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2004.

KPMG LLP, an independent registered public accounting firm, has audited the consolidated financial statements included in this Annual Report on Form 10-K and, as part of their audit, has issued their report, included herein, (1) on our management s assessment of the effectiveness of our internal controls over financial reporting and (2) on the effectiveness of our internal control over financial reporting.

(2) Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended as of December 31, 2004 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders

Cytogen Corporation:

We have audited management s assessment, included in the accompanying Management s Annual Report on Internal Control over Financial Reporting, that Cytogen Corporation maintained effective internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Cytogen Corporation s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management s assessment and an opinion on the effectiveness of the Company s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management s assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management s assessment that Cytogen Corporation maintained effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Also, in our opinion, Cytogen Corporation maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on the criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Cytogen Corporation and subsidiaries as of December 31, 2004 and 2003, and the related consolidated statements of operations, stockholders equity and comprehensive loss, and cash flows for each of the years in the three-year period ended December 31, 2004, and our report dated March 15, 2005 expressed an unqualified opinion on those consolidated financial statements.

/s/ KPMG LLP

Princeton, New Jersey

March 15, 2005

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Item 9B. Other Information

Not applicable.

PART III

Item 10. Directors and Executive Officers of the Company

The information relating to our directors, nominees for election as directors and executive officers under the headings Election of Directors , Executive Officers and Key Employees and Section 16(a) Beneficial Ownership Reporting Compliance in our definitive proxy statement for the 2005 Annual Meeting of Stockholders is incorporated herein by reference to such proxy statement.

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. We have made our code of business conduct and ethics available free of charge through our website which is located at www.cytogen.com, which is not part of this Annual Report on Form 10-K. We intend to disclose any amendments to, or waivers from, our code of business conduct and ethics that are required to be publicly disclosed pursuant to rules of the Securities and Exchange Commission and Nasdaq by filing such amendment or waiver with the Securities and Exchange Commission and by posting it on our website.

Item 11. Executive Compensation

The discussion under the heading Executive Compensation in our definitive proxy statement for the 2005 Annual Meeting of Stockholders is incorporated herein by reference to such proxy statement.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The discussion under the heading Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters in our definitive proxy statement for the 2005 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 our definitive proxy statement for the 2005 Annual Meeting of Stockholders is incorporated herein by reference to such proxy statement.

Item 14. Principal Accountant s Fees and Services

The discussion under the heading Independent Auditors Fees and Services in our definitive proxy statement for the 2005 Annual Meeting of Stockholders is incorporated herein by reference to such proxy statement.

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PART IV

Item 15. 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 15 is submitted as a separate section of this Annual Report on Form 10-K, beginning on page F-1.

(3) Exhibits

Exhibit No.	
3.1.1	Restated Certificate of Incorporation of Cytogen Corporation, as amended. Filed as an exhibit to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 1996, filed with the Commission on August 2, 1996, and incorporated herein by reference.
3.1.2	Certificate of Amendment to the Restated Certificate of Incorporation of Cytogen Corporation, as amended. Filed as an exhibit to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2000, filed with the Commission on August 11, 2000, and incorporated herein by reference.
3.1.3	Certificate of Amendment to the Restated Certificate of Incorporation, as amended, as filed with the Secretary of State of the State of Delaware on October 25, 2002. Filed as an exhibit to the Company s Current Report on Form 8-K, dated October 25, 2002, filed with the Commission on October 25, 2002, and incorporated herein by reference.
3.1.4	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 (Reg. No. 333-59718), filed with the Commission on April 27, 2001, and incorporated herein by reference.
3.2	By-Laws of Cytogen Corporation, as amended. Filed as an exhibit to the Company s Quarterly Report on Form 10-Q for the quarter ended March 31, 2003, filed with the Commission on May 14, 2003, and incorporated herein by reference.
4.1.1	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 the Company s Quarterly Report on Form 10-Q for the quarter ended September 30, 1998, filed with the Commission on November 13, 1998, and incorporated herein by reference.
4.1.2	Agreement for Substitution and Amendment of Rights Agreement by and between Cytogen Corporation and American Stock Transfer & Trust Company dated September 1, 2004. Filed as an exhibit to the Company s Current Report on Form 8-K, dated September 1, 2004, filed with the Commission on September 2, 2004, and incorporated herein by reference.
10.1.1	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 the Company s Annual Report on Form 10-K for the year ended January 2, 1988, filed with the Commission on April 1, 1988, and incorporated herein by reference.
10.1.2	Amendment, dated as of October 16, 1987, to Lease Agreement between Peregrine Investment Partners I and Cytogen Corporation. Filed as an exhibit to the Company s Registration Statement on Form S-8 (Reg. No. 33-30595), filed with the Commission on August 18, 1989, and incorporated herein by reference.

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Exhibit No.	
10.2	1989 Employee Stock Option Plan. Filed as an exhibit to Company s Registration Statement on Form S-8 (Reg. No. 33-30595), filed with the Commission on August 18, 1989, and incorporated herein by reference. +
10.3.1	1988 Stock Option Plan for Non-Employee Directors. Filed as an exhibit to the Company s Registration Statement on Form S-8 (Reg. No. 33-30595), filed with the Commission on August 18, 1989, and incorporated herein by reference. +
10.3.2	Amendment No. 2 to the Cytogen Corporation 1988 Stock Option Plan for Non-Employee Directors dated May 22, 1996. Filed as an exhibit to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 1996, filed with the Commission on August 2, 1996, and incorporated herein by reference. +
10.4	1989 Stock Option Policy for Outside Consultants. Filed as an exhibit to Amendment No. 1 to the Company s Registration Statement on Form S-1 (Reg. No. 33-31280), and incorporated herein by reference. +
10.5.1	License Agreement dated March 31, 1993 between Cytogen Corporation and The Dow Chemical Company. Filed as an exhibit to Amendment No. 1 to the Company s Quarterly Report on Form 10-Q for the quarter ended July 3, 1993, filed with the Commission on October 13, 1993, and incorporated herein by reference.*
10.5.2	Amendment of the License Agreement between Cytogen Corporation and The Dow Chemical Company dated September 5, 1995. Filed as an exhibit to the Company s Quarterly Report on Form 10-Q for the quarter ended March 31, 1996, filed with the Commission on May 9, 1996, and incorporated herein by reference.*
10.5.3	Second Amendment to the License Agreement between Cytogen Corporation and The Dow Chemical Company dated May 20, 1996. Filed as an exhibit to Amendment No. 1 to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 1996, filed with the Commission on August 2, 1996, and incorporated herein by reference.*
10.6	1992 Cytogen Corporation Employee Stock Option Plan II, as amended. Filed as an exhibit to the Company s Registration Statement on Form S-4 (Reg. No. 33-88612), filed with the Commission on January 19, 1995, and incorporated herein by reference. +
10.7	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 the Company s Annual Report on Form 10-K for the year ended December 31, 1994, filed with the Commission on March 17, 1995, and incorporated herein by reference.*
10.8	Option and License Agreement, dated July 1, 1993, between Cytogen Corporation and Sloan-Kettering Institute for Cancer Research. Filed as an exhibit to the Company s Annual Report on Form 10-K for the year ended December 31, 1994, filed with the Commission on March 17, 1995, and incorporated herein by reference.*
10.9	Horosziewicz-Cytogen Agreement, dated April 20, 1989, between Cytogen Corporation and Julius S. Horosziewicz, M.D., DMSe. Filed as an exhibit to the Company s Annual Report on Form 10-K for the year ended December 31, 1995, filed with the Commission on March 28, 1996, and incorporated herein by reference.*
10.10	Severance Agreement effective as of March 26, 1996 between Cytogen Corporation and John D. Rodwell, Ph.D. Filed as an exhibit to the Company s Annual Report on Form 10-K for the year ended December 31, 1996, filed with the Commission on March 24, 1997, and incorporated herein by reference. +

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Exhibit No.	
10.11	License Agreement between Targon Corporation and Elan Corporation, plc dated July 21, 1997. Filed as an exhibit to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 1997, filed with the Commission on August 6, 1997, and incorporated herein by reference.*
10.12	Convertible Promissory Note dated as of August 12, 1998 between Cytogen Corporation and Elan International Services, Ltd. Filed as an exhibit to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 1998, filed with the Commission on August 14, 1998, and incorporated herein by reference.
10.13	Employment agreement effective as of August 20, 1998 between Cytogen Corporation and H. Joseph Reiser. Filed as an exhibit to the Company s Quarterly Report on Form 10-Q for the quarter ended September 30, 1998, filed with the Commission on November 13, 1998, and incorporated herein by reference. +
10.14	License Agreement by and between Berlex Laboratories, Inc. and Cytogen Corporation dated as of October 28, 1998. Filed as an exhibit to the Company s Quarterly Report on Form 10-Q for the quarter ended September 30, 1998, filed with the Commission on November 13, 1998, and incorporated herein by reference.
10.15	Manufacturing Space Agreement between Bard BioPharma L.P. and Cytogen Corporation dated as of January 7, 1999. Filed as an exhibit to Amendment No. 1 to the Company s Registration Statement on form S-1 (Reg. No. 333-67947), filed with the Commission on January 27, 1999, and incorporated herein by reference.
10.16.1	Limited Liability Company Agreement of PSMA Development Company LLC by and among Cytogen Corporation, Progenics Pharmaceuticals, Inc. and the PSMA Development Company LLC dated June 15, 1999. Filed as an exhibit to the Company s Registration Statement on Form S-3 (Reg. No. 333-83215), filed with the Commission on July 20, 1999, and incorporated herein by reference.
10.16.2	Amendment No. 1 to Limited Liability Company Agreement of PSMA Development Company LLC by and among Cytogen Corporation, Progenics Pharmaceuticals, Inc. and PSMA Development Company LLC dated as of March 22, 2002. Filed as an exhibit to the Company s Quarterly Report on Form 10-Q for the quarter ended March 31, 2002, filed with the Commission on May 14, 2002, and incorporated herein by reference.
10.17.1	Stock Exchange Agreement among Cytogen Corporation and the Stockholders and Debtholders of Prostagen, Inc. Filed as an exhibit to the Company s Registration Statement on Form S-3 (Reg. No. 333-83215) dated July 19, 1999, as amended, filed with the Commission on July 20, 1999, and incorporated herein by reference.
10.17.2	Addendum to Stock Exchange Agreement among Cytogen Corporation and the Shareholders and Debtholders of Prostagen, Inc. dated as of May 14, 2002, and amended as of August 13, 2002. Filed as an exhibit to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, filed with the Commission on August 14, 2002, and incorporated herein by reference.
10.17.3	Addendum No. 2 to Stock Exchange Agreement among Cytogen Corporation and the Stockholders and Debtholders of Prostagen, Inc. Filed as an exhibit to the Company s Current Report on Form 8-K dated November 19, 2004, filed with the Commission on November 22, 2004, and incorporated herein by reference.
10.18	Strategic Alliance Agreement between AxCell Biosciences Corporation and InforMax, Inc. dated as of September 15, 1999. Filed as an exhibit to the Company s Annual Report on Form 10-K for the year ended December 31, 1999, filed with the Commission on March 28, 2000, and incorporated herein by reference.*

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Exhibit No.	
10.19	AxCell Biosciences Corporation Stock Option Plan. Filed as an exhibit to the Company s Annual Report on Form 10-K for the year ended December 31, 1999, filed with the Commission on March 28, 2000, and incorporated herein by reference. +
10.20	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 the Company s Annual Report on Form 10-K for the year ended December 31, 1999, filed with the Commission on March 28, 2000, and incorporated herein by reference.
10.21	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 (Reg. No. 333-48454), filed with the Commission on October 23, 2000, and incorporated herein by reference. +
10.22	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 (Reg. No. 333-48454), filed with the Commission on October 23, 2000, and incorporated herein by reference. +
10.23	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, filed with the Commission on November 14, 2000, and incorporated herein by reference.*
10.24	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, filed with the Commission on November 14, 2000, and incorporated herein by reference.*
10.25	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, filed with the Commission on March 30, 2001, and incorporated herein by reference. *
10.26	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, filed with the Commission on March 30, 2001, and incorporated herein by reference. *
10.27	Cytogen Corporation Stock Payment Program Bonus Plan. Filed as an exhibit to the Company s Registration Statement on Form S-8 (Reg. No. 333-58384), filed with the Commission on April 6, 2001, and incorporated herein by reference. +
10.28	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 (Reg. No. 333-59718), filed with the Commission on April 27, 2001, and incorporated herein by reference. +
10.29	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 (Reg. No. 333-59718), filed with the Commission on April 27, 2001, and incorporated herein by reference.
10.30	Cytogen Corporation Performance Bonus Plan with Stock Payment Program. Filed as an exhibit to Company s Registration Statement on Form S-8 (Reg. No. 333-75304), filed with the Commission on December 17, 2001, and incorporated herein by reference. +

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Exhibit No.	
10.31	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, dated January 18, 2002, filed with the Commission on January 24, 2002, and incorporated herein by reference.
10.32	Form of Executive Change of Control Severance Agreement by and between Cytogen Corporation 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 with the Commission on March 28, 2002, and incorporated herein by reference. +
10.33.1	Office Space Lease by and between Yardley 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 with the Commission on March 28, 2002, and incorporated herein by reference.
10.33.2	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, filed with the Commission on May 14, 2001, and incorporated herein by reference.
10.34.1	Sublease Agreement by and between Cytogen Corporation and Hale and Dorr LLP dated as of May 23, 2002. Filed as an exhibit to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, filed with the Commission on August 14, 2002, and incorporated herein by reference.
10.34.2	First Amendment to Sublease Agreement by and between Cytogen Corporation and Hale and Dorr LLP dated February 10, 2004. Filed as an exhibit to the Company s Quarterly Report on Form 10-Q for the quarter ended March 31, 2004, filed with the Commission on May 7, 2004, and incorporated herein by reference.
10.35	Cytogen Corporation Amended and Restated 1995 Stock Option Plan. Filed as an exhibit to the Company s Annual Report on Form 10-K for the year ended December 31, 2002, filed with the Commission on March 31, 2003, and incorporated herein by reference. +
10.36	Amended and Restated 1999 Stock Option Plan for Non-Employee Directors. Filed as an exhibit to the Company s Annual Report on Form 10-K for the year ended December 31, 2002, filed with the Commission on March 31, 2003, and incorporated herein by reference.
10.37	Distribution Agreement by and between Cytogen Corporation and Matritech Inc. dated October 18, 2002. Filed as an exhibit to the Company s Annual Report on Form 10-K for the year ended December 31, 2002, filed with the Commission on March 31, 2003, and incorporated herein by reference. *
10.38	Written Compensatory Agreement by and between Cytogen Corporation and Michael D. Becker dated December 17, 2002. Filed as an exhibit to the Company s Annual Report on Form 10-K for the year ended December 31, 2002, filed with the Commission on March 31, 2003, and incorporated herein by reference. +
10.39	Contract Manufacturing Agreement by and between Cytogen Corporation and Laureate Pharma, L.P. dated January 15, 2003. Filed as an exhibit to the Company s Annual Report on Form 10-K for the year ended December 31, 2002, filed with the Commission on March 31, 2003, and incorporated herein by reference. *
10.40	Quality Agreement by and between Cytogen Corporation and Laureate Pharma, L.P. dated January 15, 2003. Filed as an exhibit to the Company s Annual Report on Form 10-K for the year ended December 31, 2002, filed with the Commission on March 31, 2003, and incorporated herein by reference. *

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Exhibit No.	
10.41	Securities Purchase Agreement by and among Cytogen Corporation and certain purchasers of the Company s common stock dated June 6, 2003. Filed as an exhibit to the Company s Current Report on Form 8-K dated June 6, 2003, filed with the Commission on June 9, 2003, and incorporated herein by reference.
10.42	Form of Common Stock Purchase Warrant issued by the Company in favor of certain purchasers of the Company s common stock dated June 6, 2003. Filed as an exhibit to the Company s Current Report on Form 8-K dated June 6, 2003, filed with the Commission on June 9, 2003, and incorporated herein by reference.
10.43	Registration Rights Agreement by and among the Company and certain purchasers of the Company s common stock dated June 6, 2003. Filed as an exhibit to the Company s Current Report on Form 8-K dated June 6, 2003, filed with the Commission on June 9, 2003, and incorporated herein by reference.
10.44	Securities Purchase Agreement by and among Cytogen Corporation and certain purchasers of the Company s common stock dated July 10, 2003. Filed as an exhibit to the Company s Current Report on Form 8-K dated July 10, 2003, filed with the Commission on July 11, 2003, and incorporated herein by reference.
10.45	Form of Common Stock Purchase Warrant issued by Cytogen Corporation in favor of certain purchasers of the Company s common stock dated July 10, 2003. Filed as an exhibit to the Company s Current Report on Form 8-K dated July 10, 2003, filed with the Commission on July 11, 2003, and incorporated herein by reference.
10.46	Registration Rights Agreement by and among Cytogen Corporation and certain purchasers of the Company s common stock dated July 10, 2003. Filed as an exhibit to the Company s Current Report on Form 8-K dated July 10, 2003, filed with the Commission on July 11, 2003, and incorporated herein by reference.
10.47	Share Purchase Agreement by and among Cytogen Corporation and certain purchasers of the Company s common stock dated November 6, 2003. Filed as an exhibit to the Company s Current Report on Form 8-K dated November 6, 2003, filed with the Commission on November 7, 2003, and incorporated herein by reference.
10.48	Manufacturing and Supply Agreement by and among Cytogen Corporation, Berlex Laboratories, Inc. and DuPont Pharmaceuticals Company dated November 13, 1998 and effective as of January 1, 1999. Filed as an exhibit to the Company s Quarterly Report on Form 10-Q for the quarter ended September 30, 2003, filed with the Commission on November 12, 2003, and incorporated herein by reference. **
10.49	Termination Agreement between Cytogen Corporation and Berlex Laboratories, Inc., dated June 16, 2003. Filed as an exhibit to the Company s Quarterly Report on Form 10-Q for the quarter ended September 30, 2003, filed with the Commission on November 12, 2003, and incorporated herein by reference. **
10.50	Assignment Agreement between Cytogen Corporation and Berlex Laboratories, Inc., dated August 1, 2003. Filed as an exhibit to the Company s Quarterly Report on Form 10-Q for the quarter ended September 30, 2003, filed with the Commission on November 12, 2003, and incorporated herein by reference. **
10.51	Placement Agency Agreement by and among Cytogen Corporation, CIBC World Markets Corp., JMP Securities LLC and ThinkEquity Partners LLC dated April 14, 2004. Filed as an exhibit to the Company s Current Report on Form 8-K dated April 14, 2004, filed with the Commission on April 15, 2004, and incorporated herein by reference.

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Exhibit No.	
10.52	Manufacturing and Supply Agreement by and between Cytogen Corporation and Bristol-Myers Squibb Medical Imaging, Inc. effective as of January 1, 2004. Filed as an exhibit to the Company s Quarterly Report on Form 10-Q for the quarter ended March 31, 2004, filed with the Commission on May 7, 2004, and incorporated herein by reference. **
10.53	Cytogen Corporation 2004 Stock Incentive Plan. Filed as an exhibit to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2004, filed with the Commission on August 9, 2004, and incorporated herein by reference. +
10.54	Cytogen Corporation 2004 Non-Employee Director Stock Incentive Plan. Filed as an exhibit to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2004, filed with the Commission on August 9, 2004, and incorporated herein by reference. +
10.55	Manufacturing Agreement dated September 10, 2004 by and between Cytogen Corporation and Laureate Pharma, L.P. Filed as an exhibit to the Company s Current Report on Form 8-K dated September 10, 2004, filed with the Commission on September 14, 2004, and incorporated herein by reference.**
10.56	Warrant Agreement, dated June 10, 2003, between Cytogen Corporation and Howard Soule, Ph.D. Filed as an exhibit to the Company s Registration Statement on Form S-8 (Reg. No. 333-121320), filed with the Commission on December 16, 2004, and incorporated herein by reference. +
10.57	Cytogen Corporation Employee Stock Purchase Plan, amended as of February 2005. Filed as an exhibit to the Company s Current Report on Form 8-K dated February 8, 2005, filed with the Commission on February 10, 2005, and incorporated herein by reference. +
14.1	Code of Business Conduct and Ethics of Cytogen Corporation, as amended. Filed as an exhibit to the Company s Quarterly Report on Form 10-Q for the quarter ended September 30, 2004, filed with the Commission on November 9, 2004, and incorporated herein by reference.
16.1	Letter from Arthur Andersen LLP to the Securities and Exchange Commission dated May 20, 2002. Filed as an exhibit to the Company s Current Report on Form 8-K dated May 20, 2002, filed with the Commission on May 20, 2002, and incorporated herein by reference.
16.2	Letter from Arthur Andersen LLP to the Securities and Exchange Commission dated May 22, 2002. Filed as an exhibit to the Company s Current Report on Form 8-K/A dated May 20, 2002, filed with the Commission on May 22, 2002, and incorporated herein by reference.
16.3	Letter from Arthur Andersen LLP to the Securities and Exchange Commission dated May 24, 2002. Filed as an exhibit to the Company s Current Report on Form 8-K, filed with the Commission on May 24, 2002, and incorporated herein by reference.
21	Subsidiaries of Cytogen Corporation. Filed herewith.
23.1	Consent of KPMG LLP. Filed herewith.
23.2	Consent of PricewaterhouseCoopers. Filed herewith.
31.1	Certification of President and Chief Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. Filed herewith.
31.2	Certification of Senior Vice President and Chief Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. Filed herewith.
32.1	Certification of President and Chief Executive Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. Filed herewith.

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Exhibit No.	
32.2	Certification of Senior Vice President and Chief Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. 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.

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

(b) Exhibits:

The Exhibits filed with this Form 10-K are listed above in response to Item 15(a)(3).

(c) Financial Statement Schedules:

None.

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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 16th day of March 2005.

CYTOGEN CORPORATION

By: /s/ MICHAEL D. BECKER

Michael D. Becker,

President and Chief Executive Officer

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SIGNATURES AND POWER OF ATTORNEY

We, the undersigned officers and directors of Cytogen Corporation, hereby severally constitute and appoint Michael D. Becker and Christopher P. Schnittker and each of them singly, our true and lawful attorneys with full power to any of them, and to each of them singly, to sign for us and in our names in the capacities indicated below, the Annual Report on Form 10-K filed herewith and any and all amendments to said Annual Report on Form 10-K and generally to do all such things in our name and behalf in our capacities as officers and directors to enable Cytogen Corporation to comply with the provisions of the Securities Exchange Act of 1934, as amended, and all requirements of the Securities and Exchange Commission, hereby ratifying and confirming our signatures as they may be signed by our said attorneys, or any of them, to said Annual Report on Form 10-K and any and all amendments thereto.

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
By:	/s/ Michael D. Becker	Chief Executive Officer and President (Principal Executive Officer and Director)	March 16, 2005
	Michael D. Becker		
By:	/s/ Christopher P. Schnittker	Senior Vice President, Chief Financial Officer (Principal Financial and Accounting Officer)	March 16, 2005
	Christopher P. Schnittker		
By:	/s/ John E. Bagalay, Jr.	Director	March 16, 2005
	John E. Bagalay, Jr.		
By:	/s/ Allen Bloom	Director	March 16, 2005
	Allen Bloom		
By:	/s/ Stephen K. Carter	Director	March 16, 2005
	Stephen K. Carter		
By:	/s/ James A. Grigsby	Director and Chairman of the Board	March 16, 2005
	James A. Grigsby		
By:	/s/ Robert F. Hendrickson	Director	March 16, 2005
	Robert F. Hendrickson		
By:	/s/ Kevin G. Lokay	Director	March 16, 2005
	Kevin G. Lokay		

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Form 10-K Item 15(a)(1) and (2)

CYTOGEN CORPORATION AND SUBSIDIARIES

Index to Consolidated Financial Statements

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders

Cytogen Corporation:

We have audited the accompanying consolidated balance sheets of Cytogen Corporation and subsidiaries as of December 31, 2004 and 2003, and the related consolidated statements of operations, stockholders equity and comprehensive loss, and cash flows for each of the years in the three-year period ended December 31, 2004. These consolidated financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We did not audit the financial statements of PSMA Development Company LLC (a development stage enterprise), a 50% owned unconsolidated investee company. The Company s equity interest in the loss of PSMA Development Company LLC was $2.9 million, $3.5 million and $2.9 million for the years ended December 31, 2004, 2003 and 2002, respectively. The Company s investment in PSMA Development Company LLC was ($396,000) and $550,000 as of December 31, 2004 and 2003, respectively. The financial statements of PSMA Development Company LLC were audited by other auditors whose report has been furnished to us, and our opinion, insofar as it relates to the amounts included for PSMA Development Company LLC, is based solely on the report of the other auditors. The report of the other auditors on the financial statements of PSMA Development Company LLC contains an explanatory paragraph that states that PSMA Development Company LLC has suffered recurring losses from operations and has a net capital deficiency that raise substantial doubt about its ability to continue as a going concern, and that its financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (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 and the report of the other auditors provide a reasonable basis for our opinion.

In our opinion, based on our audits and the report of the other auditors, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Cytogen Corporation and subsidiaries as of December 31, 2004 and 2003, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2004, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Cytogen Corporation s internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated March 15, 2005 expressed an unqualified opinion on management s assessment of, and the effective operation of, internal control over financial reporting.

/s/ KPMG LLP

Princeton, New Jersey

March 15, 2005

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Management Committee and Members of

PSMA Development Company LLC (a development stage enterprise):

In our opinion, the accompanying balance sheets and the related statements of operations, of Members (deficit) equity and of cash flows present fairly, in all material respects, the financial position of PSMA Development Company LLC (the Company) (a development stage enterprise) at December 31, 2003 and 2004, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2004, and, cumulatively, for the period from June 15, 1999 (date of inception) to December 31, 2004 in conformity with accounting principles generally accepted in the United States of America. 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 of these statements in accordance with the standards of the Public Company Accounting Oversight Board (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, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations and has a net capital deficiency that raise substantial doubt about its ability to continue as a going concern. Management s plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ PricewaterhouseCoopers LLP

New York, New York

March 14, 2005

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CYTOGEN CORPORATION AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(All amounts in thousands, except share and per share data)

	December 31,	
	2004	**2003**
ASSETS:		
Current assets:		
Cash and cash equivalents	$ 13,046	$ 13,630
Short-term investments	22,779	16,585
Accounts receivable, net	1,406	1,445
Inventories	3,623	1,887
Prepaid expenses	1,242	958
Other current assets	258	17
Total current assets	42,354	34,522
Property and equipment, net	787	595
QUADRAMET license fee, net	7,024	7,720
Other assets	248	858
	$ 50,413	$ 43,695
LIABILITIES AND STOCKHOLDERS EQUITY:		
Current liabilities:		
Current portion of long-term liabilities	$ 2,296	$ 76
Liability related to joint venture	396	
Accounts payable and accrued liabilities	7,644	5,125
Total current liabilities	10,336	5,201
Long-term liabilities	47	2,454
Commitments and contingencies (Note 20)		
Stockholders equity:		
Preferred stock, $.01 par value, 5,400,000 shares authorized Series C Junior Participating Preferred Stock, $.01 par value, 200,000 shares authorized, none issued and outstanding		
Common stock, $.01 par value, 25,000,000 shares authorized, 15,489,116 and 12,857,488 shares issued and outstanding at December 31, 2004 and December 31, 2003, respectively	155	129
Additional paid-in capital	426,153	401,649
Accumulated deficit	(386,278)	(365,738)
Total stockholders equity	40,030	36,040
	$ 50,413	$ 43,695

The accompanying notes are an integral part of these statements.

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CYTOGEN CORPORATION AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

(All amounts in thousands, except per share data)

	Year Ended December 31,		
	2004	2003	2002
Revenues:			
Product related:			
PROSTASCINT	$ 7,186	$ 6,523	$ 7,923
QUADRAMET	7,293	2,765	
NMP22 BLADDERCHEK	1	295	14
BRACHYSEED		240	2,507
ONCOSCINT			182
Total product revenues	14,480	9,823	10,626
QUADRAMET royalties		1,105	1,842
Total product related revenues	14,480	10,928	12,468
License and contract	139	2,914	463
Total revenues	14,619	13,842	12,931
Operating expenses:			
Cost of product related revenues	9,309	6,268	4,748
Selling, general and administrative	20,318	11,867	11,272
Research and development	3,206	2,342	7,580
Equity in loss of joint venture	2,896	3,452	2,886
Impairment of intangible assets		115	1,729
Total operating expenses	35,729	24,044	28,215
Operating loss	(21,110)	(10,202)	(15,284)
Interest income	448	141	274
Interest expense	(185)	(185)	(173)
Loss on investment			(516)
Loss before income taxes	(20,847)	(10,246)	(15,699)
Income tax benefit	(307)	(888)	
Net loss	$ (20,540)	$ (9,358)	$ (15,699)
Basic and diluted net loss per share	$ (1.40)	$ (0.92)	$ (1.85)
Weighted-average common shares outstanding	14,654	10,205	8,466

The accompanying notes are an integral part of these statements.

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CYTOGEN CORPORATION AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY AND COMPREHENSIVE LOSS

(All amounts in thousands, except share data)

	Common Stock		Additional Paid-in Capital	Deferred Compensation	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders Equity
	Shares	Amount					
Balance, December 31, 2001	7,893,734	$ 79	$ 351,577	$ (621)	$ 860	$ (340,681)	$ 11,214
Sale of shares of common stock including exercise of stock options	716,290	7	12,966				12,973
Issuance of shares of common stock and stock options related to compensation	20,512	1	736				737
Issuance of shares of common stock in connection with Prostagen	127,699	1	2,038				2,039
Reversal of deferred compensation related to stock options			(433)	433			
Amortization of deferred compensation				184			184
Comprehensive loss:							
Net loss						(15,699)	(15,699)
Unrealized loss on marketable securities					(860)		(860)
Total comprehensive loss							(16,559)
Balance, December 31, 2002	8,758,235	88	366,884	(4)		(356,380)	10,588
Sale of shares of common stock	4,094,187	41	34,240				34,281
Issuance of shares of common stock and warrants related to compensation	5,066		526				526
Reversal of deferred compensation related to stock options			(1)	1			
Amortization of deferred compensation				3			3
Net loss and comprehensive loss						(9,358)	(9,358)
Balance, December 31, 2003	12,857,488	129	401,649			(365,738)	36,040
Sale of shares of common stock including exercise of stock options	2,580,755	26	23,992				24,018
Issuance of shares of common stock and amendment of options related to compensation	873		15				15
Issuance of shares of common stock in connection with Prostagen	50,000		497				497
Net loss and comprehensive loss						(20,540)	(20,540)
Balance, December 31, 2004	15,489,116	$ 155	$ 426,153	$	$	$ (386,278)	$ 40,030

The accompanying notes are an integral part of these statements.

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CYTOGEN CORPORATION AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

(All amounts in thousands)

	Year Ended December 31,		
	2004	**2003**	**2002**
Cash Flows From Operating Activities:			
Net loss	$ (20,540)	$ (9,358)	$ (15,699)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	984	822	779
Stock-based compensation expenses	15	515	655
Stock-based milestone payment	497		2,033
Amortization of deferred revenue		(2,185)	(410)
Amortization of premium on investments	132		
Asset impairment	67	115	2,446
Deferred rent	15	(5)	(1)
Loss on investment			516
(Gain) loss on disposition of assets	(2)	28	
Changes in assets and liabilities:			
Receivables, net	39	333	946
Inventories	(1,736)	(625)	627
Other assets	25	(921)	548
Liability related to joint venture	396		
Accounts payable and accrued liabilities	2,435	738	(691)
Net cash used in operating activities	(17,673)	(10,543)	(8,251)
Cash Flows From Investing Activities:			
Purchases of product rights		(8,000)	(1,150)
Purchases of property and equipment	(695)	(84)	(148)
Net proceeds from sale of property and equipment	187		100
Maturities of short-term investments	16,700		
Purchases of short-term investments	(23,026)	(16,585)	
Net cash used in investing activities	(6,834)	(24,669)	(1,198)
Cash Flows From Financing Activities:			
Proceeds from issuance of common stock	24,018	34,281	12,973
Payments of long-term liabilities	(95)	(164)	(108)
Net cash provided by financing activities	23,923	34,117	12,865
Net increase (decrease) in cash and cash equivalents	(584)	(1,095)	3,416
Cash and cash equivalents, beginning of year	13,630	14,725	11,309
Cash and cash equivalents, end of year	$ 13,046	$ 13,630	$ 14,725

Supplemental disclosure of non-cash information:			
Capital lease of equipment	$ 73	$	$ 189
Supplemental disclosure of cash information:			
Cash paid for interest	$ 185	$ 185	$ 169

The accompanying notes are an integral part of these statements.

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CYTOGEN CORPORATION AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Business

Founded in 1980, Cytogen Corporation (the Company or Cytogen) of Princeton, NJ is a product-driven biopharmaceutical company that develops and commercializes innovative molecules that can be used to build leading franchises across multiple markets. The Company s marketed products include QUADRAMET® (samarium Sm-153 lexidronam injection) and PROSTASCINT® (capromab pendetide) kit for the preparation of Indium In-111 capromab pendetide in the United States. The Company has exclusive United States marketing rights to COMBIDEX® (ferumoxtran-10) for all applications, and the exclusive right to market and sell ferumoxtol (formerly Code 7228) for oncology applications in the United States. COMBIDEX, an investigational functional molecular imaging agent consisting of iron oxide nanoparticles, is currently being developed for use in conjunction with magnetic resonance imaging to aid in the differentiation of cancerous from non-cancerous lymph nodes, and is under review by the U.S. Food and Drug Administration. On March 3, 2005, the FDA s Oncologic Drugs Advisory Committee (ODAC) voted 15 to 4 to not recommend approval of the proposed broad indication for COMBIDEX. A decision by the FDA on COMBIDEX is expected by the FDA-designated date of March 30, 2005.

The Company is also developing therapeutics targeting prostate-specific membrane antigen (PSMA), a protein highly expressed on the surface of prostate cancer cells and the neovasculature of solid tumors.

Cytogen has had a history of operating losses since its inception. The Company currently relies on two products, PROSTASCINT and QUADRAMET, for substantially all of its revenues. In addition, the Company has, from time to time, stopped selling certain products, such as NMP22 BLADDERCHEK, BRACHYSEED and ONCOSCINT, that the Company previously believed would generate significant revenues. The Company s products are subject to significant regulatory review by the FDA and other federal and state agencies, which requires significant time and expenditures in seeking, maintaining and expanding product approvals. In addition, the Company relies on collaborative partners to a significant degree, among other things, to manufacture its products, to secure raw materials, and to provide licensing rights to their proprietary technologies for the Company to sell and market to others.

The Company has incurred negative cash flows from operations since its inception, and has expended, and expects to continue to expend 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 the Company s marketing and sales programs. The Company expects that it will have additional requirements for debt or equity capital, irrespective of whether or when it reaches profitability, for further product development costs, product and technology acquisition costs and working capital.

Basis of Consolidation

The consolidated financial statements include the financial statements of Cytogen and its subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

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

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CYTOGEN CORPORATION AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Cash and Cash Equivalents

Cash and cash equivalents include cash on hand, cash in banks and all highly-liquid investments with a maturity of three months or less at the time of purchase.

Short-Term Investments

Short-term investments at December 31, 2004 and December 31, 2003 were $22.8 million and $16.6 million, respectively, and consisted of investments in U.S. government agency notes. The Company has the ability and intent to hold these investments until maturity and therefore has classified the investments as held-to-maturity. Held-to-maturity investments are recorded at amortized cost, adjusted for the accretion of discounts or premiums. Discounts or premiums are accreted into interest income over the life of the related investment using the straight-line method, which approximates the effective yield method. Dividend and interest income are recognized when earned. These investments mature at various times through June 15, 2005.

At December 31, 2004 $19.7 million of the Company s short term investments has unrealized losses of $37,000 and has been in a continuous loss position for less than twelve months. Due to the short-term nature of these investments, the unrealized losses have been deemed temporary and not recognized in the accompanying consolidated financial statements.

Accounts Receivable

Accounts receivable are recorded at the invoiced amount and do not bear interest. The allowance for doubtful accounts is the Company s best estimate of the amount of probable credit losses in the Company s existing accounts receivable. The Company determines the allowance based on historical write-off experience. The Company reviews its allowance for doubtful accounts quarterly. Past due balances over 90 days and any specific customers with collection issues are reviewed for collectibility. Account balances are charged off against the allowance after all means of collection have been exhausted and the potential for recovery is considered remote. The Company is subject to credit concentration risks as a limited number of its customers provide a high percentage of total revenues and corresponding receivables (see Note 12). The Company does not have any off-balance-sheet credit exposure related to its customers.

At December 31, 2004 and 2003, accounts receivable were net of an allowance for doubtful accounts of $60,000 and $67,000, respectively. Expense charged to the provision for doubtful accounts during 2003 was $37,000. No such expense was charged in 2004 or 2002. The Company wrote off $7,000 of uncollectible accounts in 2004 and none in 2003 and 2002.

Inventories

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

	December 31,	
	2004	2003
	(All amounts in thousands)	
Raw materials	$ 427	$ 11
Work-in process	2,345	1,089
Finished goods	851	787
	$ 3,623	$ 1,887

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CYTOGEN CORPORATION AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Property and Equipment

Property and equipment are stated at cost, net of accumulated depreciation or amortization. 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,	
	2004	2003
	(All amounts in thousands)	
Leasehold improvements	$ 142	$ 103
Equipment and furniture	1,301	2,383
	1,443	2,486
Less: Accumulated depreciation and amortization	(656)	(1,891)
	$ 787	$ 595

In August 2004, the Company sold equipment and furniture remaining at the AxCell facility which had a net book value of $182,000 for net proceeds of approximately $187,000, resulting in a $5,000 gain.

Depreciation expense was $288,000, $512,000 and $600,000 in 2004, 2003 and 2002, respectively.

Fair Value of Financial Instruments

The Company s financial instruments consist primarily of cash and cash equivalents, short-term investments, accounts receivable, accounts payable, accrued expenses and long-term debt. Management believes the carrying value of these assets and accrued expenses are representative of their fair value because of the short-term nature of these instruments. The fair value of long-term debt is estimated by discounting the future cash flows of each instrument at rates currently offered to the Company for similar debt instruments of comparable maturities by the Company s bankers. The resulting fair value of long-term debt approximates its carrying amount.

Impairment of Long-Lived Assets

In accordance with Statement of Financial Accounting Standards (SFAS) No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets, if indicators of impairment exist, management assesses the recoverability of the affected long-lived assets by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows and eventual disposition of the asset. If impairment is indicated, management measures the amount of such impairment by comparing the carrying value of the assets to the present value of the expected future cash flows associated with the use of the asset.

In July 2004, as part of the Company s continuing effort to reduce non-strategic expenses, the Company initiated the closure of its AxCell Biosciences facilities. In connection with such closure, the Company recorded a charge of $100,000 for equipment impairment to write down the carrying value of the assets to fair value based on prices of similar assets and similar conditions. This charge is included in selling, general and administrative expenses for 2004 in the accompanying consolidated statement of operations. During 2003, the Company recorded a charge of $115,000 for the asset impairment associated with a licensing fee previously paid by the Company for NMP22 BLADDERCHEK (see Note 11). During 2002, the Company recorded a charge of $1.7 million for the asset impairment associated with licensing fees paid by the Company related to BRACHYSEED products (see Note 4).

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CYTOGEN CORPORATION AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Costs Associated with Exit or Disposal Activities

In accordance with the SFAS No. 146, Accounting for Costs Associated with Exit or Disposal Activities, the Company is required to record a liability for costs associated with an exit or disposal activity, measured at fair value, in the period in which the liability is incurred. A liability related to one-time termination benefits provided to severed employees as a result of the exit or disposal activity is recorded when certain criteria have been met and the employees are notified of the details of the plan. A liability for costs to terminate a lease or other contract before the end of its term is recognized and measured at its fair value when the Company terminates the contract in accordance with the contract terms. If the contract is an operating lease, the fair value of the liability at the cease-use date is determined based on the remaining lease rentals, reduced by estimated sublease rentals that could be reasonably obtained for the property, even if the Company does not intend to enter into a sublease.

In July 2004, as part of our continuing effort to reduce non-strategic expenses, the Company initiated the closure of its AxCell Biosciences facilities, which was accounted for pursuant to SFAS No. 146 (see Note 14).

QUADRAMET License Fee

In August 2003, Cytogen reacquired marketing rights to QUADRAMET in North America and Latin America in exchange for an upfront payment of $8.0 million which was capitalized as a QUADRAMET license fee and is being amortized on a straight-line basis over approximately 12 years, the estimated performance period of the agreement. The balance is comprised as follows:

	December 31,	
	2004	2003
	(All amounts in thousands)	
QUADRAMET license fee	$ 8,000	$ 8,000
Less: Accumulated amortization	(976)	(280)
	$ 7,024	$ 7,720

During 2004 and 2003, Cytogen recorded $696,000 and $280,000, respectively, of such amortization as cost of product related revenues in the accompanying consolidated statements of operations. Estimated amortization expense is $696,000 for each of the next fiscal years through 2014 and $64,000 in 2015.

Other Assets

Other assets consisted of the following:

	December 31,	
	2004	2003
	(All amounts in thousands)	
Investment in PSMA Development Company LLC (Note 6)	$	$ 550
Other	248	308
	$ 248	$ 858

Other assets in 2004 and 2003 each include $48,000 of restricted cash which is used as collateral for a letter of credit required by a facility lease as a security deposit. The letter of credit is automatically renewed annually but not beyond the term of the lease.

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CYTOGEN CORPORATION AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Revenue Recognition

Product related revenues include product sales by Cytogen to its customers and QUADRAMET royalties earned by Cytogen prior to August 2003. Product sales are recognized when the customer takes ownership of the products and assumes risk of loss, collection of the relevant receivable is probable, persuasive evidence of an agreement exists and the sales price is fixed and determinable. Product returns are accepted under limited circumstances and are estimated based upon historical experience. The Company may provide rebates and volume discounts to its customers from time to time. Such rebates and discounts are recorded as a reduction of product sales when earned by the customer.

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

License and contract revenues include milestone payments and fees under collaborative agreements with third parties, revenues from research services, and revenues from other miscellaneous sources.

In accordance with U.S. Securities and Exchange Commission Staff Accounting Bulletin No. 104, Revenue Recognition (SAB 104), non-refundable, up-front license fees are recorded as deferred revenue to be recognized over the estimated performance period of the related agreements. In 2003, SAB 104 replaced Staff Accounting Bulletin No. 101, Revenue Recognition In Financial Statements (SAB 101), which the Company adopted in 2000. The provisions related to non-refundable, up-front license fees were unchanged in SAB 104 compared to SAB 101. For the years ended December 31, 2003 and 2002, the Company recognized $2.2 million and $410,000, respectively, in revenues that were included in the cumulative effect adjustment recorded upon the adoption of SAB 101 as of January 1, 2000. The 2003 amount included $1.9 million related to the acceleration of the previously deferred revenue resulting from the termination of the 1998 license agreement with Berlex.

In accordance with Emerging Issues Task Force (EITF) No. 00-10, the Company records shipping and handling charges billed to customers as revenue and the related costs as cost of product related revenues.

Research and Development

Research and development expenditures consist of projects conducted by the Company and payments made for sponsored research programs and consultants. All research and development costs are charged to expense as incurred.

Advertising Costs

Advertising costs are charged to expense as incurred.

Patent Costs

Patent costs are charged to expense as incurred.

Income Taxes

The Company accounts for income taxes under the asset and liability method in accordance with SFAS No. 109, Accounting for Income Taxes. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and

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CYTOGEN CORPORATION AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

Net Loss Per Share

Basic net loss per common share is calculated by dividing the Company s net loss by the weighted-average common shares outstanding during each period. Diluted net loss per common share is the same as basic net loss per share for each of the three years ended December 31, 2004, 2003 and 2002, because the inclusion of common stock equivalents, which consist of warrants and options to purchase shares of the Company s common stock, would be antidilutive due to the Company s losses (see Notes 15 and 16).

Variable Interest Entities

In December 2003, the Financial Accounting Standards Board (FASB) revised FASB Interpretation No. 46 (FIN 46R), Consolidation of Variable Interest Entities (VIEs), which addresses how a business enterprise should evaluate whether it has a controlling financial interest in an entity through means other than voting rights and accordingly should consolidate the entity. FIN 46R replaced FASB Interpretation No. 46 (FIN 46) which was issued in January 2003. The Company was required to apply FIN 46R to variable interests in VIEs created after December 31, 2003. For variable interests in VIEs created before January 1, 2004, FIN 46R applied beginning on March 31, 2004. For any VIEs that must be consolidated under FIN 46R that were created before January 1, 2004, the assets, liabilities and noncontrolling interests of the VIE initially are measured at their carrying amounts with any difference between the net amount added to the balance sheet and any previously recognized interest being recognized as the cumulative effect of an accounting change. If determining the carrying amounts is not practicable, fair value at the date FIN 46R first applies may be used to measure the assets, liabilities and noncontrolling interest of the VIE.

In June 1999, Cytogen entered into a joint venture with Progenics Pharmaceuticals Inc. (Progenics, and collectively with Cytogen, the Members) to form the PSMA Development Company LLC (the Joint Venture). The Joint Venture is currently developing antibody-based and vaccine immunotherapeutic products utilizing Cytogen s exclusively licensed prostate-specific membrane antigen (PSMA) technology. The Joint Venture is owned equally by the Members (see Note 6). Cytogen accounts for the Joint Venture using the equity method of accounting. The Company is not required to consolidate the Joint Venture under the requirements of FIN 46R.

Stock-Based Compensation

The Company follows the intrinsic value method of accounting for stock-based employee compensation in accordance with APB Opinion No. 25, Accounting for Stock Issued to Employees , and related interpretations. The Company records deferred compensation for option grants to employees for the amount, if any, by which the market price per share exceeds the exercise price per share at the measurement date, which is generally the grant date.

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CYTOGEN CORPORATION AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The Company follows the disclosure provisions of SFAS No. 123, Accounting for Stock-Based Compensation , as amended by SFAS No. 148 Accounting for Stock-Based Compensation Transition and Disclosure. Had compensation cost for options been recognized in the consolidated statements of operations using the fair value method of accounting, the Company s net loss and net loss per share would have been as follows:

	Year Ended December 31,		
	2004	2003	2002
	(All amounts in thousands, except per share data)		
Net loss, as reported	$ (20,540)	$ (9,358)	$ (15,699)
Add: Stock-based employee compensation expense included in reported net loss	15	3	184
Deduct: Total stock-based employee compensation expense determined under fair value-based method for all awards	(2,152)	(1,506)	(4,000)
Pro forma net loss	$ (22,677)	$ (10,861)	$ (19,515)
Basic and diluted net loss per share, as reported	$ (1.40)	$ (0.92)	$ (1.85)
Pro forma basic and diluted net loss per share	$ (1.55)	$ (1.06)	$ (2.31)

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 disclosure 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.

Recent Accounting Pronouncements

Abnormal Inventory Costs

In November 2004, the FASB issued SFAS No. 151, Inventory Costs, an amendment of ARB No. 43, Chapter 4 (SFAS No. 151), to clarify that abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage) should be recognized as current period charges, and that fixed production overheads should be allocated to inventory based on the normal capacity of production facilities. This statement is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. Accordingly, the Company will adopt SFAS No. 151 in its fiscal year beginning January 1, 2006. The Company is currently in the process of evaluating the impact of adopting this statement.

Share-Based Payment

In December 2004, the FASB issued SFAS No. 123(R), Share-Based Payment , which revised SFAS No. 123 and superseded APB Opinion No. 25, Accounting for Stock Issued to Employees. SFAS No. 123(R) requires that companies recognize compensation expense associated with grants of stock options and other equity instruments to employees in the financial statements effective as of the first interim or annual reporting period that begins after June 15, 2005. Compensation cost will be measured based on the fair value of the instrument on the grant date and will be recognized over the vesting period. This pronouncement applies to all grants after the effective date and to the unvested portion of stock options outstanding as of the effective date. SFAS No. 123(R)

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

eliminates the ability to account for such transactions using the intrinsic method currently used by the Company. SFAS No. 123(R) also requires that companies recognize compensation expense associated with purchases of shares of common stock by employees at a discount to market value under employee stock purchase plans that meet certain criteria. Accordingly, the Company will adopt SFAS No. 123(R) in the quarterly period beginning July 1, 2005. Although management has not yet determined the impact of the adoption of this standard, it is expected to have a material effect on the Company s consolidated financial statements.

Reclassification

Certain amounts in prior years consolidated financial statements have been reclassified to conform to current year presentation.

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 was to conduct certain development activities with respect to PROSTASCINT, including the delivery of a limited number of batches of PROSTASCINT for testing and evaluation purposes. During 2002, the parties ceased to operate under the terms of such agreement. In 2002, the Company recorded $551,000 of development expenses related to this agreement.

In November 2003, the Company entered into a settlement agreement and mutual release with DSM to terminate the development and manufacturing agreement (the Settlement Agreement). As a result of the Settlement Agreement, Cytogen recorded an expense reversal of $580,000 to research and development expense in the fourth quarter of 2003 and a corresponding reduction in accounts payable and accrued expenses.

3. ADVANCED MAGNETICS, INC.

In August 2000, the Company and Advanced Magnetics, Inc., a developer of superparamagnetic iron oxide nanoparticles used in pharmaceutical products, entered into marketing, license and supply agreements (the AVM Agreements). Under the AVM Agreements, Cytogen acquired certain rights in the United States to Advanced Magnetics product candidates: COMBIDEX®, an investigational functional molecular imaging agent for all applications; and ferumoxytol (formerly referred to as Code 7228) for oncology applications only. Advanced Magnetics will be responsible for all costs associated with the clinical development of, and if approved by the FDA, the supply and manufacture of COMBIDEX and ferumoxytol and will receive product transfer payments and royalties based upon product sales or certain minimum payments from Cytogen, whichever is greater.

Pursuant to the AVM Agreements, Cytogen may release 50,000 shares of its Common Stock to Advanced Magnetics, which are currently in escrow, upon the achievement of certain milestones. Of such 50,000 shares, 25,000 shares are being held in escrow pending the achievement of certain milestones relating to COMBIDEX and 25,000 shares are being held in escrow pending the achievement of certain milestones relating to ferumoxytol. There can be no assurance that Advanced Magnetics will receive FDA approval to market COMBIDEX or ferumoxytol for oncology applications in the United States. Advanced Magnetics has stated that it does not intend to develop ferumoxytol for oncology imaging.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

4. DRAXIMAGE, INC.

In December 2000, the Company entered into a product manufacturing and supply agreement and a license and distribution agreement with Draximage, Inc. to market and distribute BRACHYSEED implants for prostate cancer therapy in the United States (the Draximage Agreements). Under the terms of the Draximage Agreements, Draximage supplied radioactive iodine and palladium seeds to Cytogen in exchange for product transfer payments, royalty payments on sales and certain milestone payments. Cytogen paid Draximage an aggregate of $2.0 million in connection with Draximage Agreements. These payments were recorded as other assets and were being amortized over the ten year term of the Draximage Agreements. In January 2003, the Company served notice of termination of the Draximage Agreements. As a result, in 2002 the Company recorded a non-cash charge of $1.7 million to write off the carrying values of the licensing fees paid for BRACHYSEED products. Prior to the write-off of such licensing rights, amortization expense was $174,000 in 2002. The Company also recorded $503,000 in royalty expense for 2002. In April 2003, the Company entered into an agreement with Draximage to formally terminate each of the Draximage Agreements.

5. ACQUISITION OF PROSTAGEN, INC.

Pursuant to a Stock Exchange Agreement (the Prostagen Agreement) related to the Company s acquisition of Prostagen Inc. (Prostagen) in June 1999, the Company agreed to issue up to an additional $4.0 million worth of Cytogen Common Stock to the shareholders and debtholders of Prostagen (the Prostagen Partners), if certain milestones are achieved in the dendritic cell therapy and PSMA development programs. During 2002, the Company and the Prostagen Partners agreed that a milestone was achieved based on the progress of the dendritic cell prostate cancer clinical trials at Northwest Biotherapeutics, Inc. As a result, the Company recorded a $2.0 million charge to research and development expense which represented the fair value of the 122,699 shares of Common Stock issued. In May 2002, the Company entered into an Addendum to the Prostagen Agreement (the Addendum), which clarifies the future milestone payments to be made under the Prostagen Agreement, as well as the timing of such payments. Pursuant to the Addendum, the Company may be obligated to pay two additional milestone payments of $1.0 million each, upon certain clinical achievements regarding the PSMA development programs. In November 2004, the Company entered into Addendum No. 2 to the Prostagen Agreement (the Second Addendum), which further clarifies the future milestone payments to be made under the Prostagen Agreement. Pursuant to the Second Addendum, the Company issued 50,000 shares of Common Stock to the Prostagen Partners and the Company may be obligated to pay two additional milestone payments of an aggregate of $1.5 million, upon certain clinical achievements regarding the PSMA development programs. As a result, in 2004, the Company recorded a $497,000 charge to research and development expense which represented the fair value of the shares of Common Stock issued to Prostagen Partners. Any future milestone payments are payable in shares of Cytogen Common Stock. In addition, the Company issued 5,000 shares of Common Stock to the Prostagen Partners in 2002 upon the satisfactory termination of a lease obligation originally assumed by the Company.

6. PSMA DEVELOPMENT COMPANY LLC

In June 1999, Cytogen entered into a joint venture with Progenics Pharmaceuticals Inc., a development stage enterprise (Progenics, and collectively with Cytogen, the Members), to form the PSMA Development Company LLC (the Joint Venture). The Joint Venture is currently developing antibody-based and vaccine immunotherapeutic products utilizing Cytogen s 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 exclusive North American marketing rights for products developed by the Joint Venture.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The Company accounts for the Joint Venture using the equity method of accounting. Beginning in December 2001, Cytogen began to recognize 50% of the Joint Venture s losses in its consolidated statement of operations. For the years ended December 31, 2004, 2003 and 2002, Cytogen recognized $2.9 million, $3.5 million and $2.9 million, respectively, in losses of the Joint Venture. As of December 31, 2003, the carrying value of the Company s investment in the Joint Venture was $550,000, which represents Cytogen s investment in the Joint Venture, less its cumulative share of losses, which net investment is recorded in other assets (see Note 1). As of December 31, 2004, Cytogen s cumulative share of losses exceeded its investment in the Joint Venture resulting in a liability to the Joint Venture of $396,000 as reported in Liability related to Joint Venture in the accompanying consolidated balance sheet. In January 2005, the Members made a capital contribution of $500,000 each to cover such deficit. As of March 15, 2005, the Company and Progenics are negotiating the work plan and annual budget for 2005 for the Joint Venture. In the absence of an agreement by the Members, funding from the Members could be reduced or eliminated and the Joint Venture s research and development programs, as well as all other operations, could be halted. The report of the independent auditors on the financial statements of the Joint Venture contains an explanatory paragraph which states that the Joint Venture has suffered recurring losses from operations and has a net capital deficiency that raise substantial doubt about its ability to continue as a going concern, and that its financial statements do not include any adjustments that might result from the outcome of that uncertainty. Selected financial statement information of the Joint Venture, is as follows:

Balance Sheet Data:

	December 31,	
	2004	**2003**
	(All amounts in thousands)	
ASSETS:		
Cash	$	$ 1,173
Prepaid expenses	12	
Accounts receivable from Progenics Pharmaceuticals Inc., a related party		108
	$ 12	$ 1,281
LIABILITIES AND MEMBERS EQUITY:		
Accounts payable to Cytogen Corporation, a related party	$ 4	$
Accounts payable to Progenics Pharmaceuticals Inc., a related party	189	
Accounts payable and accrued expenses	629	199
Total liabilities	822	199
Capital contributions	23,298	19,398
Deficit accumulated during the development stage	(24,108)	(18,316)
Total members equity (deficit)	(810)	1,082
Total liabilities and members equity (deficit)	$ 12	$ 1,281

Income Statement Data:

	For the Year Ended			For the Period From June 15, 1999 (inception) to December 31, 2004
	2004	2003	2002	
	(All amounts in thousands)			
Interest income	$ 7	$ 5	$ 13	$ 241
Total expenses	5,799	6,908	5,786	24,349
Net loss	$ (5,792)	$ (6,903)	$ (5,773)	$ (24,108)

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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 in 2000, the Company deferred approximately $1.5 million of this previously recognized license fee and recognized $125,000 and $150,000 of the deferred revenue as license and contract revenue in 2003 and 2002, respectively. The deferred revenue had been fully recognized as of December 31, 2003. The Company also provided limited research and development services to the Joint Venture. During 2004, 2003 and 2002, the Company recorded revenue of $106,000, $214,000 and $53,000, respectively, for such services as contract revenue in the accompanying statements of operations.

7. THE DOW CHEMICAL COMPANY

In 1993, Cytogen acquired an exclusive license from The Dow Chemical Company for QUADRAMET for the treatment of osteoblastic bone metastases in the United States. This license was amended in 1995 to expand the territory to include Canada and Latin America and again in 1996 to expand the field to include all osteoblastic diseases. The agreement requires the Company to pay Dow royalties based on a percentage of net sales of QUADRAMET, or a guaranteed annual minimum payment, whichever is greater, and future payments upon the achievement of certain milestones. The Company recorded $1.0 million in royalty expense for each of 2004, 2003 and 2002. Future annual minimum royalties due to Dow are $1.0 million per year in 2005 through 2012 and $833,000 in 2013.

8. BERLEX LABORATORIES INC.

In June 2003, the Company announced that it had entered into an agreement with Berlex Laboratories Inc. (Berlex) to reacquire marketing rights to QUADRAMET in North America and Latin America in exchange for an upfront payment of $8.0 million and royalties based on future sales of QUADRAMET, subject to Cytogen obtaining any necessary financing for the reacquisition. Cytogen reacquired marketing rights to QUADRAMET on August 1, 2003 and, in accordance with that agreement, began recording product revenue from the sales of QUADRAMET. Cytogen no longer receives royalty revenue from Berlex. The up-front license payment of $8.0 million was capitalized in 2003 as the QUADRAMET license fee in the accompanying consolidated balance sheet and is being amortized on a straight-line basis over approximately twelve years, which is the estimated performance period of the agreement (see Note 1). Cytogen also recorded $1.2 million and $455,000 of royalty expenses to Berlex based on its sales of QUADRAMET in 2004 and 2003, respectively, as cost of product related revenues.

In 1998, under a separate agreement, the Company licensed the marketing rights to QUADRAMET to Berlex in exchange for, among other things, an up-front, non-refundable license fee. In connection with the adoption of SAB No. 101 in 2000, the Company deferred $2.8 million of such license fee net of associated costs, to be recognized over the estimated performance period. In August 2003, the 1998 license was terminated and, as a result, the remaining unamortized deferred revenue of $1.9 million was recognized as license and contract revenue in the accompanying consolidated statement of operations. Prior to the acceleration of the remaining unamortized deferred revenues in August 2003, the Company recognized $152,000 and $260,000 of the deferred revenues in 2003 and 2002, respectively.

9. BRISTOL-MYERS SQUIBB MEDICAL IMAGING, INC.

As a result of the Company s 2003 reacquisition of marketing rights to QUADRAMET, the Company assumed all of Berlex s obligations under a manufacturing and supply agreement with Bristol-Myers Squibb Medical Imaging, Inc. (BMSMI), which were met through December 31, 2003. Effective January 1, 2004, the Company entered into a new manufacturing and supply agreement with BMSMI whereby BMSMI will manufacture, distribute and provide order processing and customer service for Cytogen relating to QUADRAMET. Under the terms of the new agreement, Cytogen is obligated to pay at least $4.2 million annually, subject to future annual price adjustment, through 2008, unless terminated by BMSMI or Cytogen on

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

two years prior written notice. This agreement will automatically renew for five successive one-year periods unless terminated by BMSMI or Cytogen on two years prior written notice. During 2004 and 2003, Cytogen incurred $4.2 million and $1.5 million, respectively, of manufacturing costs for QUADRAMET, all of which is included in cost of product related revenues. The Company also pays BMSMI a variable amount per month for each QUADRAMET order placed to cover the costs of customer service which is included in selling, general and administrative expenses.

The two primary components of QUADRAMET, particularly Samarium-153 and EDTMP, are provided to BMSMI by outside suppliers. BMSMI obtains its supply of Samarium-153 from a sole supplier, and EDTMP from another sole supplier. Alternative sources for these components may not be readily available, and any alternate suppliers would have to be identified and qualified, subject to all applicable regulatory guidelines. If BMSMI cannot obtain sufficient quantities of these components on commercially reasonable terms, or in a timely manner, it would be unable to manufacture QUADRAMET on a timely and cost-effective basis.

10. LAUREATE PHARMA, L.P.

In September 2004, the Company entered into a non-exclusive manufacturing agreement with Laureate Pharma, L.P. pursuant to which Laureate shall manufacture PROSTASCINT and its primary raw materials for Cytogen in Laureate s Princeton, New Jersey facility. The agreement will terminate, unless terminated earlier pursuant to its terms, upon Laureate s completion of the specified production campaign for PROSTASCINT and shipment of the resulting products from Laureate s facility. Under the terms of the agreement, the Company is obligated to pay at least an aggregate of $5.1 million through 2006, of which $2.3 million was incurred in 2004 and is recorded as inventory in the accompanying balance sheet.

11. MATRITECH, INC.

In October 2002, the Company entered into a distribution agreement with Matritech Inc. (Matritech) to be the sole distributor for Matritech s NMP22 BLADDERCHEK test to urologists and oncologists in the United States. In October 2003, Matritech and Cytogen executed an amended and restated distribution agreement (the Restated Distribution Agreement) modifying the original distribution agreement. Under the terms of the Restated Distribution Agreement, which took effect in November 2003, Cytogen had a non-exclusive right to sell NMP22 BLADDERCHEK to urologists until December 31, 2003 and an exclusive right to continue to sell NMP22 BLADDERCHEK to oncologists for the term of the Restated Distribution Agreement. The Restated Distribution Agreement expired on December 31, 2004 and the Company has no further obligations with respect to NMP22 BLADDERCHEK.

The Company paid Matritech a non-refundable licensing fee of $150,000 upon the execution of the original distribution agreement in 2002, which was recorded as other assets and was being amortized over the five year estimated performance period of the original distribution agreement. Amortization expense of $30,000 and $5,000 was recorded in 2003 and 2002, respectively. As a result of entering into the Restated Distribution Agreement, the Company recorded a non-cash charge of $115,000 to impairment of intangible assets in 2003 to write off the carrying value of the upfront license fee which was deemed not recoverable.

12. REVENUES FROM MAJOR CUSTOMERS

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

	Year Ended December 31,		
	2004	2003	2002
Cardinal Health (formerly Syncor International Corporation)	46%	24%	9%
Mallinckrodt Inc.	12	14	18
GE Healthcare (formerly Amersham Health)	10	8	12
Berlex Laboratories Inc.		23	16

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Cardinal Health, Mallinckrodt Inc. and GE Healthcare are chains of radiopharmacies, which distribute PROSTASCINT and QUADRAMET.

Revenues from Berlex Laboratories Inc. include the recognition of deferred revenue following the adoption of SAB 101. In 2003, the Company recorded $1.9 million related to the acceleration of previously deferred revenue resulting from the termination of the 1998 license agreement with Berlex. As a result of the reacquisition of marketing rights to QUADRAMET in August 2003, the Company no longer receives royalty revenue from Berlex for QUADRAMET.

As of December 31, 2004 and 2003, the receivables from the above-mentioned major customers accounted for 55% and 63%, respectively, of gross accounts receivable.

13. ACCOUNTS PAYABLE AND ACCRUED LIABILITIES

Significant components of the accounts payable and accrued liabilities were as follows:

	December 31,	
	2004	2003
	(All amounts in thousands)	
Accounts payable	$ 3,514	$ 2,041
Accrued payroll, sales commission and related expenses	1,157	714
Accrued royalty expense	770	705
Accrued professional and legal expenses	627	649
Accrued research contracts and materials	218	218
Accrued manufacturing costs	387	
Accrued marketing expenses	246	148
Accrued facilities costs	93	93
Other accruals	632	557
	$ 7,644	$ 5,125

14. LONG-TERM LIABILITIES

Components of long-term liabilities were as follows:

	December 31,	
	2004	2003
	(All amounts in thousands)	
Due to Elan Corporation, plc	$ 2,280	$ 2,280
Capital lease obligations	63	82
Facility lease obligation		163
Other		5
	2,343	2,530
Less: Current portion of long-term liabilities	(2,296)	(76)
	$ 47	$ 2,454

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 $28.00 per share, subject to adjustments, and matures in August 2005. The note bears annual interest of 7%, compounded semi-annually, however, such interest was not payable in cash but was added to the principal for the first 24 months;

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thereafter, interest is payable in cash. The Company recorded $160,000 in interest expense on this note for each of the years 2004, 2003 and 2002. The note contains certain non-financial covenants with which the Company was in compliance as of December 31, 2004.

The Company leases certain equipment under capital lease obligations, which will expire on various dates through 2008. Property and equipment leased under non-cancellable capital leases have a net book value of $64,000 at December 31, 2004. Amortization of assets held under capital leases is included with depreciation expense. Payments to be made under capital lease obligations (including total interest of $18,000) are $25,000 in 2005, $25,000 in 2006, $25,000 in 2007, and $6,000 in 2008. The Company has the option to purchase this leased equipment at its fair value at the end of the lease.

As part of the Company s continuing efforts to reduce non-strategic expenses, the Company restructured AxCell in September 2002 by reducing 75% of AxCell s workforce, initiated the closure of the AxCell facility in July 2004 and terminated early an operating lease in December 2004. As a result, during 2004 and 2002, the Company recorded a gross charge of $100,000 and $869,000, respectively, related to employee severance costs, the impairment of property, and equipment and future rental payments on leased facilities that will no longer be used in operations. Such charge is included in selling, general and administrative expense in the accompanying consolidated statement of operations. As of December 31, 2003, the Company had a remaining accrued liability for future lease payments of $246,000, of which $163,000 was considered long-term as of December 31, 2003. In December 2004, the Company terminated early the lease for the AxCell facilities and as of December 31, 2004 was obligated to pay a termination fee of $130,000 which was paid in January 2005. As a result, the remaining liability for future lease payments of $163,000 was eliminated in 2004. The resulting gain of $33,000 is recorded in selling, general and administrative expense in the accompanying consolidated statement of operations, for a net charge in 2004 of $67,000.

15. COMMON STOCK AND WARRANTS

In April 2004, the Company issued and sold 2,570,000 shares of its common stock for $10.10 per share through a registered direct offering resulting in net proceeds of approximately $23.9 million after the payment of placement agency fees and expenses related to the offering.

In November 2003, the Company sold 1,863,637 shares of its common stock to certain institutional investors at $11.00 per share resulting in net proceeds to the Company of approximately $20.4 million.

In July 2003, the Company sold 1,172,332 shares of its common stock to certain institutional investors at $8.53 per share resulting in net proceeds of approximately $9.3 million. In connection with the sale, the Company issued to the investors warrants to purchase 1,172,332 shares of its common stock with an exercise price of $12.80 per share. In addition, the Company also issued: (i) warrants to purchase 100,000 shares of its common stock at an exercise price of $12.80 per share to a consultant as part of its compensation for services rendered in connection with this financing; and (ii) warrants to purchase an aggregate of 250,000 shares of its common stock at an exercise price of $10.97 per share, to certain stockholders, in connection with such stockholders waiver of certain rights in connection with this financing. All warrants issued in connection with this financing are exercisable until July 10, 2008 and become automatically exercised in full if the closing price of the Company s common stock is at least 130% of the exercise price then in effect ($16.64 or $14.26, as applicable) for 30 consecutive trading days. Upon receipt of a written notice by the Company of such automatic exercise, the holders of the warrants must exercise such warrants by paying the Company the exercise price times the number of shares of common stock issuable upon exercise.

In June 2003, the Company issued to consultants warrants to purchase an aggregate of 100,000 shares of its common stock at an exercise price of $5.65 per share for consulting services. The warrants are exercisable in 12 equal installments on each monthly anniversary from the date of issuance and are exercisable through June 10, 2006. The

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Company recorded a charge to selling, general and administrative expense for the fair value of these warrants in the amount of $497,000 in its consolidated statement of operations for 2003 using a Black-Scholes pricing model.

In June 2003, the Company sold 1,052,632 shares of its common stock to certain institutional investors at $4.75 per share resulting in net proceeds of approximately $4.6 million. In connection with the sale, the Company issued to the investors warrants to purchase 315,790 shares of its common stock with an exercise price of $6.91 per share. The warrants are exercisable until June 6, 2008.

In January 2002, the Company sold 297,067 shares of its common stock to the State of Wisconsin Investment Board (SWIB) for an aggregate purchase price of $8.0 million, or consideration equal to $26.90 per share. In connection with the 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. The Company sold an additional 416,670 shares of its common stock to SWIB in June 2002 for an aggregate purchase price of $5.0 million, or consideration equal to $12.00 per share.

In 2004, 2003 and 2002, the Company issued to certain members of Cytogen s Board of Directors an aggregate total of 873, 1,127 and 3,541 shares, respectively, of its common stock as compensation for their services as directors of the Company.

See Note 5 for information regarding Cytogen common stock issued to the Prostagen Partners, and Notes 16 and 18 for information regarding Cytogen common stock issued to employees under the stock option and employee stock purchase plans and 401(k) plan, respectively.

As of December 31, 2004, 2003 and 2002, the Company has outstanding warrants to purchase 1,938,122, 1,944,485 and 32,363 shares, respectively, of Cytogen common stock at exercise prices ranging from $5.65 to $12.80 per share in 2004, $5.65 to $49.80 per share in 2003, and $16.25 to $49.80 per share in 2002. The warrants outstanding as of December 31, 2004 are exercisable and expire at various times through July 2008. During 2004 and 2003, warrants to purchase 6,363 and 26,000 shares of the Company s common stock, respectively, expired. Some warrants may become automatically exercised, in full, subject to certain conditions.

16. STOCK OPTIONS AND EMPLOYEE STOCK PURCHASE PLAN

Cytogen 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 Stock Options) to employees, non-employee directors and outside consultants. At the Company s 2004 Annual Meeting of Stockholders held on June 15, 2004, the stockholders of the Company approved the adoption of the Company s 2004 Stock Incentive Plan (the 2004 Plan) and the Company s 2004 Non-Employee Director Stock Incentive Plan (the 2004 Director Plan and together with the 2004 Plan,

collectively the 2004 Incentive Plans). An aggregate of 1,200,000 and 375,000 shares of the Company s common stock have been reserved for issuance upon the exercise of option grants or restricted stock awards (as applicable) under the 2004 Plan and 2004 Director Plan, respectively. The 2004 Plan provides for the grant of incentive stock options, non-qualified stock options or restricted stock to the Company s employees, officers, consultants and advisors. The 2004 Director Plan provides for the grant of non-qualified stock options and shares of the Company s common stock, in certain circumstances, to members of the Company s Board of Directors who are not employees of the Company. The Company has filed a registration statement on Form S-8 with the Securities and Exchange Commission to register the shares of the Company s common stock underlying option grants or other awards under the 2004 Incentive Plans. Furthermore, upon

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approval of the 2004 Incentive Plans by the Company s stockholders, no further option grants or awards were, or will be, made under the Company s existing 1995 Stock Option Plan or 1999 Non-Employee Director Stock Option Plan. Any unissued and unallocated options previously reserved under these plans were released from reserves. An aggregate of 2,056,119 shares of common stock have been reserved for issuance in connection with grants under the Company s option plans. The persons to whom Cytogen Stock Options may be granted and the number, type, and terms of the Cytogen Stock Options vary among the plans. Cytogen Stock Options are granted with a term of up to 10 years and generally become exercisable in installments over periods of up to 5 years. The exercise price of Cytogen Stock Options is determined in accordance with the terms of the applicable plan. Under certain circumstances, vesting may accelerate. Activity under these plans was as follows:

	Number of Cytogen Stock Options	Price Range Per Share	Weighted-Average Exercise Price Per Share	Aggregate Exercise Price
Balance at December 31, 2001	494,248	$ 7.00 169.38	$ 31.45	$ 15,544,768
Granted	102,063	3.48 23.30	4.32	440,688
Exercised	(905)	8.13 20.00	18.87	(17,077)
Cancelled	(123,300)	8.28 165.00	42.87	(5,285,848)
Balance at December 31, 2002	472,106	3.48 169.38	22.63	10,682,531
Granted	266,569	2.75 11.48	6.17	1,645,623
Exercised				
Cancelled	(254,065)	3.48 101.41	24.90	(6,325,910)
Balance at December 31, 2003	484,610	2.75 169.38	12.39	6,002,244
Granted	383,000	9.83 14.58	11.47	4,391,356
Exercised	(5,648)	3.54 9.20	4.48	(25,285)
Cancelled	(32,143)	2.75 169.38	19.49	(626,564)
Balance at December 31, 2004	829,819	$ 2.84 89.38	$ 11.74	$ 9,741,751

The following table summarizes information about Cytogen Stock Options at December 31, 2004:

	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
$ 2.84 8.28	248,477	7.9	$ 3.69	82,993	$ 3.94
8.29 10.00	30,870	7.9	9.20	12,702	8.87

10.01	11.14	84,000	8.3	10.92	21,854	10.78
11.15	11.50	249,456	8.9	11.50	16,747	11.49
11.51	18.33	119,150	8.6	11.67	17,700	12.11
18.34	36.66	68,983	4.9	26.12	68,908	26.13
36.67	54.99	15,100	5.2	47.09	15,100	47.09
55.00	73.32	11,383	5.1	58.40	11,383	58.40
73.33	89.38	2,400	2.1	77.65	2,400	77.65
$ 2.84	89.38	829,819	8.0	$ 11.74	249,787	$ 17.79

At December 31, 2004, Cytogen Stock Options to purchase 249,787 shares of Cytogen common stock were exercisable and the weighted-average exercise price of these options was $17.79. At December 31, 2004, 1,226,300 shares of Cytogen common stock were available for issuance under approved option plans.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Included in the above tables is an option granted to a key employee in 1998 to purchase 135,000 shares of Cytogen common stock (Performance Options) at an exercise price of $10.94 per share. The vesting of the Performance Options was subject to the completion of certain performance-based milestones as determined by the Company s Board of Directors. The Company recorded approximately $1.1 million of deferred compensation upon the commencement of the vesting of the Performance Options, which represented the fair value of Cytogen s common stock in excess of the exercise price of the option on the date which the Board of Directors determined the performance milestones had been met. Deferred compensation was amortized over the three-year vesting period of the Performance Options. Upon the resignation of the key employee in December 2002, $354,000 of the deferred compensation related to unvested options was reversed.

Also included in the above table are options to purchase 150,000 shares of Cytogen common stock granted to our Chief Executive Officer under the Company s approved stock option plans at an exercise price of $3.54 per share. This option has three separate and equal tranches which will each vest based upon the achievement of certain milestones established by the Company s Board of Directors. If the fair value of the common stock is greater than the exercise price of the option when such milestones are met, the Company will record compensation expense.

On September 3, 2004, H. Joseph Reiser tendered his resignation from the Company s Board of Directors. In connection with Dr. Reiser s resignation, the Company accelerated the vesting of options to purchase 20,000 shares of the Company s common stock held by Dr. Reiser such that these options became immediately exercisable as of September 3, 2004. In addition, the expiration dates of an aggregate of 21,000 options to purchase shares of the Company s common stock held by Dr. Reiser were amended to September 3, 2005. As a result of the foregoing, the Company recorded a charge for the change in the intrinsic value of these modified options in the amount of $5,000 in its consolidated statement of operations for the year ended December 31, 2004.

AxCell Stock 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 Stock Options) to employees, for which 2,000,000 shares of AxCell common stock have been reserved. In 2002, the Company granted 20,000 shares of AxCell common stock to members of AxCell s Scientific Advisory Board. The Company recorded $93,000 of expense related to these grants, based upon the estimated fair value of those shares on the date of grant. As of December 31, 2004 and 2003, 8,035,000 shares of AxCell common stock were outstanding, 8,000,000 of which are held by Cytogen. AxCell Stock Options are granted with a term of 10 years and generally become exercisable in installments over periods of up to 5 years. The Company granted AxCell Stock Options to purchase 183,035 shares of AxCell common stock during 2002 at a weighted-average exercise price of $4.63 per share. No such options were granted in 2003 or 2004. In 2004, 2003 and 2002, 81,416, 39,710 and 561,106 of AxCell Stock Options were cancelled, respectively. The weighted-average exercise price per share for AxCell Stock Options cancelled in 2004, 2003 and 2002 were $2.52, $4.13 and $3.11, respectively. In 2002, 15,000 of AxCell Stock Options with an exercise price of $0.63 per share were exercised. The weighted-average exercise price per share for all outstanding AxCell Stock Options was $4.34, $3.36 and $3.52 at December 31, 2004, 2003 and 2002, respectively. As of December 31, 2004, options to purchase 69,405 shares of AxCell common stock were outstanding, of which 51,394 shares were exercisable, and 1,915,595 shares were available for future grants. Of the outstanding AxCell Stock Options at December 31, 2004, 5,000 AxCell Stock Options have a weighted-average remaining contractual life of 2.4 years with a weighted-average exercise price of $0.63 per share; and the remaining 64,405 AxCell Stock Options have a weighted-average remaining contractual life of 7.2 years with a weighted-average exercise price of $4.63 per share. During 2001, in connection with the grant of AxCell Stock Options, the Company recorded deferred compensation of $241,000,

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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 resultant deferred compensation was being amortized over the vesting period of the options. Due to employee terminations, primarily as a result of the restructuring at AxCell in September 2002, $1,000 and $79,000 of deferred compensation related to unvested options were reversed in 2003 and 2002, respectively. The deferred compensation was fully amortized at December 31, 2003.

Employee Stock Purchase Plan

Cytogen adopted an employee stock purchase plan under which eligible employees may elect to purchase shares of Cytogen common stock at 85% of the lower of fair market value as of the first or last trading day of each quarterly participation period. In 2004, 2003 and 2002, employees purchased 6,695, 4,211 and 4,911 shares, respectively, for aggregate proceeds to the Company of $64,000, $17,000 and $24,000, respectively. The Company has reserved 19,733 shares for future issuance under its employee stock purchase plan.

Fair Value

The weighted-average fair value per share of the options granted under the Cytogen stock option plans during 2004, 2003 and 2002 is estimated as $8.74, $8.12 and $3.70 per share, respectively, on the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions for 2004, 2003 and 2002:

Valuation Assumptions	2004	2003	2002
Dividend yield	0%	0%	0%
Volatility	109.66%	141.17%	143.46%
Risk-free interest rate	3.766%	2.81%	2.94%
Expected life	4.6 yrs	4 yrs	4 yrs

The weighted-average fair value per share ascribed to the shares purchased under the employee stock purchase plan during 2004, 2003 and 2002 is estimated at $3.81, $1.51 and $5.72 per share, respectively, on the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions for 2004, 2003 and 2002:

Valuation Assumptions	2004	2003	2002
Dividend yield	0%	0%	0%
Volatility	52.63%	115.12%	20.83%
Risk-free interest rate	1.26%	1.10%	1.67%
Expected life	3 months	3 months	3 months

The weighted-average fair value per share of AxCell Stock Options granted during 2002 is estimated at $4.16 per share on the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions for 2002:

Valuation Assumptions	2002
Dividend yield	0%
Volatility	142.07%
Risk-free interest rate	4.02%
Expected life	5 yrs

17. 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 $38,000 and $52,000 in 2003 and 2002, respectively. This agreement was terminated in October 2003.

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18. RETIREMENT SAVINGS PLAN

The Company maintains a defined contribution 401(k) plan for its employees. The contribution is determined by the Board of Directors 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 in cash or its common stock, at the Company s discretion, under the 401(k) plan in amounts which match up to 50% of the salary deferred by the participants up to 6% of total salary. During 2003 and 2002, the Company issued 3,939 and 9,646 shares, respectively, of its common stock under the 401(k) plan. No such shares were issued in 2004. Total expense was $136,000, $79,000 and $98,000 for 2004, 2003 and 2002, respectively.

19. INCOME TAXES

As of December 31, 2004, Cytogen had federal and state net operating loss carryforwards of approximately $281.8 million and $178.8 million, respectively. The Company also had federal and state research and development tax credit carryforwards of approximately $5.7 million and $441,000, respectively. These net operating loss and credit carryforwards have begun to expire and will continue to expire through 2024. At December 31, 2004, the net current and non-current deferred tax assets were $1.3 million and $127.1 million, respectively, compared to $1.1 million and $124.3 million, respectively, at December 31, 2003.

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 on the Company s net loss before income taxes during 2004, 2003 and 2002, the Company would have recorded a tax benefit. During 2004, 2003 and 2002, there were increases of $3,114,000, $2,466,000 and $11,232,000, respectively, in the valuation allowance, due to the Company s loss history, and uncertainty regarding the realization of deferred tax assets. These increases to the valuation allowance reduced the actual benefit to $307,000, $888,000 and $0 in 2004, 2003 and 2002, respectively, which amounts are related to the sales of New Jersey state operating loss carryforwards as discussed below. Deferred tax assets have been fully reserved as of December 31, 2004 and 2003.

A portion of the Company s net operating loss carryforward relates to tax deductions from stock option exercises and disqualifying dispositions that would be accounted for as capital contributions for financial reporting purposes to the extent such deductions could be utilized by the Company. The valuation allowance includes approximately $676,000 pertaining to tax deductions relating to stock option exercises for which any subsequently recognized tax benefit will be recorded as an increase to additional paid-in capital.

	2004	2003

	(All amounts in thousands)	
Deferred tax assets:		
Net operating loss carryforwards	$ 106,119	$ 102,786
Capitalized research and development expenses	3,425	4,367
Research and development credit	6,095	7,251
Acquisition of in-process technology	831	868
Other, net	11,961	10,045
Total deferred tax assets	128,431	125,317
Valuation allowance	(128,431)	(125,317)
Net deferred tax assets	$	$

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 2004 and 2003, the Company sold New Jersey state operating loss carryforwards, resulting in the recognition of $307,000 and $888,000 of income tax benefit, respectively.

20. COMMITMENTS AND CONTINGENCIES

The Company leases its facilities and certain equipment under non-cancellable operating leases that expire at various times through October 2007. Rent expense on these leases was $510,000, $694,000 and $832,000 in 2004, 2003 and 2002, respectively. Minimum future obligations under the operating leases are $958,000 as of December 31, 2004 and will be paid as follows: $338,000 in 2005, $338,000 in 2006 and $282,000 in 2007.

The Company is obligated to make minimum future payments under contracts for research and development, investor relations, and consulting services that expire at various times. As of December 31, 2004, the minimum future payments under these contracts are $1.3 million and will be paid as follows: $397,000 in 2005, $85,000 in 2006, $81,000 in 2007, $76,000 each year from 2008 to 2009, $75,000 each year from 2010 to 2017, and $25,000 in 2018. In addition, under the BMSMI agreement, the Company is obligated to pay at least $4.2 million annually, subject to future annual price adjustment, through 2008. The Company may terminate this agreement on two years prior written notice (see Note 9). The Company is also obligated to pay milestone payments upon achievement of certain milestones and royalties on revenues from commercial product sales including certain guaranteed minimum payments. Such obligations include payments to Dow (see Note 7) and Berlex Laboratories (see Note 8). As of December 31, 2004, under the Laureate Pharma, L.P. agreement, the Company is obligated to pay at least an aggregate of $2.8 million through 2006, estimated as follows: $1.8 million in 2005 and $1.0 million in 2006.

In January 2005, the Company made a $500,000 capital contribution to the joint venture to cover the 2004 expenditures. As of March 15, 2005, the Company and Progenics are in the process of negotiating the work plan and annual budget for 2005 for the joint venture. The Company cannot give any assurances that agreement will be reached on such matters in the near future, if at all. The failure to reach agreement with Progenics on these matters could significantly and adversely affect the development of PSMA technologies and products. Such funding amount in subsequent periods may vary dependent upon, among other things, the results of the clinical trials and research and development activities, competitive and technological developments, and market opportunities.

Each of the Company s executive officers is currently party to an Executive Change of Control Severance Agreement with Cytogen. Such agreements provide, generally, for the payment of twelve months base salary, a pro rata portion of such officer s bonus compensation, the continuation of all benefits, reasonable Company-paid outplacement assistance and certain other accrued rights, in the event such officer s employment with the Company is terminated in connection with certain changes in control.

In the ordinary course of business, the Company enters into agreements with third parties that include indemnification provisions which, in its judgment, are normal and customary for companies in its industry sector. These agreements are typically with business partners, clinical sites, and suppliers. Pursuant to these agreements, the Company generally agrees to indemnify, hold harmless and reimburse the indemnified parties for losses suffered or incurred by the indemnified parties with respect to the Company s products or product candidates, use of such products or other actions taken or omitted by the Company. The maximum potential amount of future payments the Company could be required to make under these indemnification provisions is unlimited. The Company has not incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. As a result, the current estimated liabilities relating to this provision are minimal. Accordingly, the Company has no liabilities recorded for these provisions as of December 31, 2004 and 2003.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

21. ANTISOMA RESEARCH LIMITED

In September 2003, Antisoma Research Limited (Antisoma) acquired certain royalty rights to Antisoma s lead product, R1549 (formerly Pemtumomab), from Cytogen. In connection with Antisoma s acquisition of such rights, Antisoma made a cash payment to Cytogen of $500,000 which the Company recognized as revenue because it has no continuing involvement in this arrangement. Antisoma has agreed to make an additional payment of $500,000 upon the first commercial sale, if any, of the R1549 product. In return, Cytogen relinquished its right to receive royalties equivalent to 1.65% of future net sales, if any, of the R1549 product.

22. CONSOLIDATED QUARTERLY FINANCIAL DATA UNAUDITED

The following tables provide quarterly data for the years ended December 31, 2004 and 2003.

	Three Months Ended			
	March 31, 2004	June 30, 2004	Sept. 30, 2004	Dec. 31, 2004
	(amounts in thousands except per share data)			
Total revenues	$ 3,601	$ 3,952	$ 3,261	$ 3,805
Total operating expenses	7,903	8,393	8,944	10,489
Operating loss	(4,302)	(4,441)	(5,683)	(6,684)
Other income, net	20	57	87	99
Loss before income taxes	(4,282)	(4,384)	(5,596)	(6,585)
Income tax benefit				(307)
Net loss	$ (4,282)	$ (4,384)	$ (5,596)	$ (6,278)
Basic and diluted net loss per share	$ (0.33)	$ (0.30)	$ (0.36)	$ (0.41)
Weighted-average common shares outstanding	12,860	14,848	15,435	15,454
Product related gross margin	$ 1,183	$ 1,532	$ 1,044	$ 1,412

	Three Months Ended

	March 31, 2003	June 30, 2003	Sept. 30, 2003	Dec. 31, 2003
	(amounts in thousands except per share data)			
Total revenues	$ 2,477	$ 2,326	$ 5,505	$ 3,534
Total operating expenses	5,001	5,671	6,401	6,971
Operating loss	(2,524)	(3,345)	(896)	(3,437)
Other income (expense), net	(11)	(23)	(14)	4
Loss before income taxes	(2,535)	(3,368)	(910)	(3,433)
Income tax benefit	(584)			(304)
Net loss	$ (1,951)	$ (3,368)	$ (910)	$ (3,129)
Basic and diluted net loss per share	$ (0.22)	$ (0.37)	$ (0.08)	$ (0.26)
Weighted-average common shares outstanding	8,763	9,051	10,866	12,087
Product related gross margin	$ 1,424	$ 1,262	$ 946	$ 1,028

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

23. LITIGATION AND RELATED MATTERS

In September 2004, the Company announced the settlement of a patent infringement suit brought by Immunomedics Inc. against Cytogen and C.R. Bard Inc. for an agreed-upon payment without any admission of fault or liability. The charge related to this settlement is recorded in the accompanying statements of operations for the year ended December 31, 2004. Immunomedics, Inc. filed suit on February 17, 2000 against Cytogen and Bard, alleging that use of Cytogen s PROSTASCINT product infringed U.S. Patent No. 4,460,559, which claims a method for detecting and localizing tumors. The settlement with Immunomedics was on behalf of Cytogen and Bard.

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