CYTOGEN CORP
Form 10-K
March 15, 2004
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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, 2003

OR

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

For the transition period from _____ to _____

Commission File Number 000-14879

CYTOGEN CORPORATION

(Exact Name of Registrant as Specified in Its Charter)

Delaware	22-2322400
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification 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. ¨

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, 2003, based on $8.33 per share, the last reported sale price on the NASDAQ National Market on that date, was $61,787,175.

The number of shares of Common Stock, $.01 par value, of the registrant outstanding as of March 1, 2004 was 12,935,910 shares.

The following documents are incorporated by reference into the Annual Report on Form 10-K: Portions of the registrant s definitive Proxy Statement for its 2004 Annual Meeting of Stockholders are incorporated by reference into Part III of this Report.

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PART I

Item 1. Business

OVERVIEW

Founded in 1980, Cytogen Corporation of Princeton, NJ is a product-driven, oncology-focused biopharmaceutical company that licenses, develops and commercializes both therapeutic and molecular imaging/diagnostic products that address the unmet medical needs of physicians and the patients they serve. We directly market QUADRAMET (samarium Sm-153 lexidronam injection), PROSTASCINT® (capromab pendetide) kit for the preparation of Indium In-111 capromab pendetide, and NMP22® BLADDERCHEK® (nuclear matrix protein-22) in the United States. We also have exclusive United States marketing rights to COMBIDEX® (ferumoxtran-10), which 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.

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

Therapeutics:

Product	Description	Status
QUADRAMET (samarium Sm-153 lexidronam injection)	Third-generation skeletal targeting therapeutic radiopharmaceutical for the relief of pain in patients with confirmed osteoblastic metastatic bone lesions	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
PSMA rs protein vaccine	A vaccine consisting of recombinant soluble PSMA combined with an immune stimulant to induce an immune response	Phase I Jointly developed with Progenics Pharmaceuticals, Inc.
PSMA viral vector vaccine	A 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 Jointly developed with Progenics Pharmaceuticals, Inc.
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.

Molecular Imaging/Diagnostic:

Product	Description	Status
PROSTASCINT® (capromab pendetide)	Monoclonal antibody-based imaging agent targeting PSMA used to image the extent and spread of prostate cancer in previously diagnosed patients	Developed and marketed by Cytogen in the United States

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Molecular Imaging/Diagnostic:

Product	Description	Status
NMP22® BLADDERCHEK® (nuclear matrix protein-22)	A point-of-care *in vitro* diagnostic test for bladder cancer	Developed by Matritech, Inc., marketed to oncologists by Cytogen in the United States
COMBIDEX® (ferumoxtran-10)	Investigational molecular imaging agent consisting of lymphotropic superparamagnetic nanoparticles used in conjunction with magnetic resonance imaging to detect metastatic tumor in local and distant lymph nodes	Developed by Advanced Magnetics, Inc. and exclusively licensed by Cytogen for marketing in the United States
		Under review by the United States Food and Drug Administration
		Received an approvable letter in June 2000

As of March 1, 2004, we market QUADRAMET, PROSTASCINT and NMP22 BLADDERCHEK in the United States through our in-house specialty sales organization, consisting of approximately 36 employees, directly to medical oncologists, radiation oncologists, nuclear medicine professionals, radiologists and urologists.

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

PROSTASCINT and ONCOSCINT® are registered United States trademarks of Cytogen Corporation. We are the owner of a pending United States trademark application, Serial No. 78374967, relating to QUADRAMET. 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. 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

THERAPEUTIC PRODUCT

QUADRAMET

Overview

QUADRAMET is a third-generation skeletal targeting therapeutic radiopharmaceutical for relief of pain due to bone metastases arising from prostate, breast, multiple myeloma and other cancers. QUADRAMET is indicated for relief of pain in patients with confirmed osteoblastic metastatic bone lesions that enhance on a radionuclide bone scan. QUADRAMET consists of a radioactive isotope, Samarium-153, which emits both beta and gamma radiation, and a chelating agent, ethylenediaminetetramethylenephosphonic acid (EDTMP), which selectively targets and delivers the drug to sites of new bone formation associated with tumor invasion.

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Once tumors have metastasized to the skeleton, they continue to grow and cause destruction of the adjacent bone. This erosion of bone stimulates new bone formation which encircles the metastatic tumor. By targeting these areas of bone formation, QUADRAMET delivers site-specific radiation, which may result in significant pain reduction. According to American Cancer Society and National Cancer Institute statistics, about half of all people with cancer (other than skin cancer) will have bone metastasis at some point in the course of their disease. Bone metastasis is one of the most frequent causes of cancer related pain.

QUADRAMET has many characteristics which we believe are advantageous for the treatment of cancer bone pain, including early onset of pain relief; predictable and reversible bone marrow toxicity or myelosuppression; ease of administration; and length of pain relief, lasting up to 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 make 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:

- publishing new clinical 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 a desired indication; 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 United States Food and Drug Administration, 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 anti-tumor drugs and other bone seeking agents such as bisphosphonates. Currently active clinical studies sponsored or supported by us in this regard include:

- A Phase I/II study is ongoing at Northwestern University in Illinois using QUADRAMET, paclitaxel (Taxol®), and estramustine phosphate sodium (Emcyt®) in hormone refractory prostate cancer patients. The initial Phase I component of the study will utilize 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. The Phase II portion of the study will expand the number of patients treated at the maximum tolerated dose obtained in the Phase I portion in order to assess the clinical response to treatment.

A Phase I study is ongoing 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 the current study are to assess the safety 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 bone metastases.

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Two Phase I studies are ongoing at the University of Maryland 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 is for patients who have previously received chemotherapy.

During 2003, we reported that independent investigators from cancer research centers around the world presented new clinical data as follows:

Clinical investigators from the Department of Radiation Sciences at University Umea in Sweden reported data from a pilot study of QUADRAMET in combination with docetaxel (Taxotere®) in hormone refractory prostate cancer patients. The purpose of the study was to evaluate the optimal time frame for co-administration of docetaxel with QUADRAMET. Additional details regarding the conduct and results of this study are available in the *Proc. Am. Soc. Clin. Oncol.,* vol. 22, page 433, 2003 (abstract # 1739).

Clinical investigators from Cantanzaro and Rome in Italy studied the toxicity, clinical impact, and quality of life from sequential doses of QUADRAMET and zoledronic acid (Zometa®) in symptomatic chemorefractory multiple myeloma patients. The purpose of the study was to evaluate the effect of this combination of treatments on pain scores and markers of disease in this patient population. Additional details regarding the conduct and results of this study are available in the *Proc. Am. Soc. Clin. Oncol.,* vol. 22, page 603, 2003 (abstract # 2425) and in the journal *Blood*, vol. 102, no. 11, page 446a, 2003 (abstract # 1630).

Clinical investigators from The Mayo Clinic in Minneapolis reported data on the use of high dose QUADRAMET in combination with high dose melphalan (Alkeran®) as part of a preparative regimen prior to stem cell transplant for the treatment of multiple myeloma. The study consisted of a Phase I component in which the safety of escalating single doses of QUADRAMET was evaluated and a Phase II component in which the response rate of the procedure was evaluated. Additional details regarding the conduct and results of this study are available in the journal *Blood*, vol. 102, no. 11, page 928a, 2003 (abstract # 3656) and *J. Nucl. Med.,* 44j Suppl. 174p, (2003) (abstract # 569).

Clinical investigators from Hadassah University Hospital in Israel reported data on the use of high dose QUADRAMET in combination with chemotherapy followed by non-myeloablative allogeneic stem cell transplantation in patients with a variety of resistant hematologic malignancies including acute leukemia, myelodysplastic syndrome and multiple myeloma. Additional details regarding the conduct and results of this study are available in the *Proc. Am. Soc. Clin. Oncol.,* vol. 22, page 839, 2003 (abstract # 3372).

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 may describe 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.

Intellectual Property Position Related to QUADRAMET

In May 1993, we obtained an exclusive license from The Dow Chemical Company to North American rights to use QUADRAMET as a therapeutic radiopharmaceutical for metabolic bone disease or tumor regression for cancer caused by metastatic or primary cancer in bone in humans, and for the treatment of disease characterized by osteoblastic response in humans. Our license was expanded to include Latin America in 1995. Our license agreement with Dow with respect to QUADRAMET shall remain in effect, unless earlier terminated pursuant to the terms thereof, for a term of twenty (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.

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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, 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 pending United States trademark application, Serial No. 78374967, relating to QUADRAMET.

Upon execution of this agreement with Dow, we issued warrants to purchase shares of our common stock, which have since expired. As of December 31, 2003, 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 effective as of January 1, 2004. Under the manufacturing and supply 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 through 2008. The agreement shall thereafter 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 costs of customer service and distribution. Upon our reacquisition of marketing rights to QUADRAMET from Berlex Laboratories, Inc., on August 1, 2003, we assumed certain obligations under a previous exclusive manufacturing and supply agreement among Cytogen, Berlex and BMSMI, which were met through December 31, 2003. This agreement was replaced by the manufacturing and supply agreement with BMSMI as of January 1, 2004.

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. 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 were entitled to royalty payments based on net sales of QUADRAMET and milestone payments based upon sales levels that were achieved.

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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 we began recording product revenue from the 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 royalties or guaranteed contractual minimum payments, whichever is greater, and certain future payments upon the achievement of certain milestones, to Dow.

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 Amersham Health, or in a generic form by Bio-Nucleonics Pharma, Inc. Amersham 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 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 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, 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

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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.

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, each PIE site receives initial training and proficiency evaluations. We only sell PROSTASCINT to qualified PIE sites. As of December 31, 2003, 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.

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; and

image guided applications, such as therapy, biopsy and combinations of the foregoing.

Fusion imaging. Fusion 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. Fusion imaging can combine CT or MR with radionuclide imaging using single-photon emission computed tomography (SPECT) to image a radio-labeled agent, such as PROSTASCINT. Approximately 74 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

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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.

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.

Our products, including PROSTASCINT, are subject to significant regulation by governmental agencies, including the United States Food and Drug Administration, 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.

Clinical Studies Related to PROSTASCINT

To support the foregoing market expansion strategies for PROSTASCINT we currently have active clinical studies sponsored or supported by us which include:

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 work 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

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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 2003, we reported that clinical investigators from cancer research centers throughout the country had presented new clinical data indicating that:

PROSTASCINT-guided prostate brachytherapy results in a high probability of actuarial four-year biochemical disease-free survival for patients with localized prostate cancer. Additional details regarding the conduct and results of this study are available in the *International Journal of Radiation Oncology Biology Physics*, Vol. 57, No. 2, pp. 362-370, 2003.

In a retrospective outcomes study sponsored by us, patients exhibiting a certain pattern of PROSTASCINT distribution, namely uptake in the central abdominal lymph nodes, a finding exhibited in approximately 20% of patients in this study, were significantly more likely to have died in the follow-up period of 4-5 years than patients not exhibiting that pattern of uptake. Additional details regarding the conduct and results of this study are available in the journal *Radiology* 2003; Suppl. 576p (abstract #1076).

In a study supported partially by us, researchers 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 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 *J. Nucl. Med*., Vol. 45, pages 238-246 (2004).

PROSTASCINT is indicated 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 thought to be at high risk for pelvic lymph node metastases. PROSTASCINT is also indicated 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.

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.

Intellectual Property Position Related to PROSTASCINT

In 1987, Dr. Julius S. Horoszewicz 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. Horoszewicz 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, which we believe will remain in effect until the expiration of the last related patent, we have made, and may continue to make, certain payments to Dr. Horoszewicz.

As of December 31, 2003, 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 Horoszewicz 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 expire June 9, 2004, include 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 expires June 9, 2004, includes claims directed to antibody conjugates such as PROSTASCINT, and methods for preparing such conjugates. The

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foregoing patents, which expire in 2004, do not 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.

We are defendants in litigation filed against us by Immunomedics, Inc. in the United States Federal Court for the District of New Jersey with respect to claims that PROSTASCINT infringes a third-party patent. Under our agreement with Dr. Horoszewicz, we may offset our litigation expenses against payments we make to Dr. Horoszewicz. We have disclosed certain information regarding this lawsuit under the caption Legal Proceedings , herein.

Manufacturing, Supply and Distribution of PROSTASCINT

In January 2003, we entered into a contract manufacturing and supply agreement with Laureate Pharma L.P., pursuant to which Laureate manufactured and supplied us with PROSTASCINT through December 31, 2003, at which time the agreement expired. Laureate was the sole manufacturer of PROSTASCINT and its primary raw materials, which are antibodies. We currently have no alternative manufacturer or supplier for PROSTASCINT or any of its components. As of December 31, 2003, we had a sufficient level of PROSTASCINT inventory on hand to satisfy our requirements into 2005. We intend to negotiate and engage Laureate or another suitable manufacturer to supply us with PROSTASCINT for subsequent periods. Our failure to procure a sufficient supply of PROSTASCINT, or our failure to procure such a supply on commercially reasonable terms, 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. Prior to January 2004, PROSTASCINT was manufactured at a current good manufacturing practices, or cGMP, compliant manufacturing facility in Princeton, New Jersey which is operated by Laureate. In July 2000, we entered into a development and manufacturing agreement with DSM Biologics Company B.V., pursuant to which DSM conducted certain development activities with respect to PROSTASCINT for testing and evaluation purposes. Our relationship with DSM was subsequently terminated.

PROSTASCINT is distributed for us by CORD Logistics, Inc., a subsidiary of Cardinal Health Inc. under the terms of a distribution services agreement dated March 1, 1999. Pursuant to the agreement, CORD is the exclusive distribution agent of PROSTASCINT in the United States. The initial term of the agreement was for three years. Upon completion of the initial three year term, the agreement was renewed for a one year period, and pursuant to the terms of a May 2003 amendment thereto, will remain in effect until May 19, 2005.

Any arrangement that we enter into with respect to the manufacture, supply or distribution of PROSTASCINT will 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. Within this sales force are technical specialists who assist in the training of nuclear medicine technologists and nuclear medicine physicians who administer the PIE site qualification process for nuclear imaging centers to perform PROSTASCINT imaging.

Competition Related to PROSTASCINT

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

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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.

NMP22 BLADDERCHEK

Overview

NMP22 BLADDERCHEK is a point-of-care *in vitro* diagnostic test for bladder cancer developed by Matritech, Inc.

In October 2002, we entered into a five-year agreement with Matritech to be the sole distributor for NMP22 BLADDERCHEK to urologists and oncologists in the United States. Matritech has retained rights to market NMP22 BLADDERCHEK directly to physicians other than oncologists, such as primary care physicians. In October 2003, we executed an amendment to our agreement that provides 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 is renewable annually upon the mutual consent of the parties. We are not subject to any minimum sales targets or other similar obligations under our agreement with Matritech, as amended.

Polymedco manufactures BTAStat®, a point of care urine-based test approved for monitoring bladder cancer patients. BTAStat, marketed by Mentor, competes with NMP22 BLADDERCHEK. NMP22 BLADDERCHEK is, however, the only point of care urine-based test approved for both monitoring and diagnosis of bladder cancer.

COMBIDEX

Overview

COMBIDEX (ferumoxtran-10), which was developed by Advanced Magnetics, Inc., is currently under review by the United States Food and Drug Administration. 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 in a timely basis, or at all.

COMBIDEX is an ultrasmall superparamagnetic iron oxide nanoparticle designed to facilitate the differentiation between malignant and non-malignant lymph nodes using magnetic resonance (MR) imaging. 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.

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Numerous cancers spread via the lymphatic system. Common imaging modalities currently used for imaging lymph nodes are CT and MR imaging. Under these existing modalities, normal nodes are distinguished from cancerous nodes solely on the basis of size. Lymph nodes less than ten millimeters in size are often assumed to be normal and lymph nodes greater than ten millimeters in size are often presumed cancerous. Contrast imaging with COMBIDEX, which is not based on size of the lymph nodes, may prove more effective in distinguishing cancerous from non-cancerous lymph nodes.

The American Cancer Society estimated that there would be 900,800 newly diagnosed patients with cancers that potentially metastasize in this manner in 2003. Many of these patients may require, and benefit from, diagnostic tools such as COMBIDEX-enhanced magnetic resonance imaging, to help differentiate malignant from non-malignant lymph nodes, irrespective of node size.

Clinical Data Related to COMBIDEX

In May 2003, Advanced Magnetics and Cytogen announced the presentation of data showing that MR imaging using COMBIDEX helps in the determination of the spread of testicular cancer to lymph nodes. This data, from a study conducted at Massachusetts General Hospital, showed improved accuracy for lymph node characterization, potentially resulting in better patient management. The data involved 13 lymph nodes from 11 patients with proven testicular cancer, all of whom were scheduled for CT guided nodal biopsy. The researchers performed MR imaging of lymph nodes within 24 to 36 hours after the administration of COMBIDEX. When imaging evaluation results were compared to histopathologic analysis, lymph node staging with COMBIDEX was 92% accurate in identifying malignant disease.

In June 2003, Advanced Magnetics and Cytogen announced the publication of clinical data in the *New England Journal of Medicine* (2003, Vol. 348, No. 25, pages 2491-2499) showing that MR imaging with COMBIDEX may aid in the non-invasive evaluation of lymph nodes in patients with prostate cancer. Researchers at Massachusetts General Hospital and the University Medical Center Nijmegen in the Netherlands, concluded that the use of COMBIDEX-enhanced MR imaging allows for the detection of small and otherwise undetectable lymph node metastases in patients with prostate cancer. The study involved 40 patients from MGH and 40 patients from UMCN with prostate cancer, who were scheduled either for surgical lymph node resection or nodal biopsy. The researchers performed MR imaging before and 24 hours after the administration of COMBIDEX. In one of the evaluations done, the researchers determined whether or not each patient had any metastatic nodes. For these evaluations on a patient-by-patient basis, when the before and after MR scans were compared to pathology, the use of COMBIDEX-enhanced MR imaging improved accuracy from 65% to 98% and improved the positive predictive value from 60% to 94%. Sensitivity, the probability that the diagnosis is positive given the presence of disease, increased from 45% to 100%. Specificity, the likelihood that given the absence of disease the diagnosis is negative, increased from 79% to 96%. Of the 33 patients in whom metastatic disease was found, the researchers noted that 9 of those patients had metastatic lymph nodes outside of the standard area for surgical exploration that would not have been found by current standard diagnostic procedures. Additionally, the researchers analyzed the results based on the diagnosis of each individual node. Results of the node-by-node diagnoses with COMBIDEX showed accuracy of 97%, sensitivity of 91%, specificity of 98% and a positive predictive value of 95%. Of the nodes that were determined malignant by pathology, 71% were 10 millimeters or less in size and therefore did not fulfill the traditional imaging criteria for malignancy. Nodal evaluation using COMBIDEX-enhanced images for nodes between 5 millimeters and 10 millimeters in size resulted in accuracy of 99%, sensitivity of 96%, specificity of 99% and an increase in the positive predictive value compared to unenhanced MR images from 29% to 96%.

In September 2003, Advanced Magnetics and Cytogen announced that data from a Phase III clinical study of COMBIDEX in lymph nodes was published in the journal *Radiology*. The data showed that MR imaging with COMBIDEX may aid in the non-invasive evaluation of metastatic lymph nodes in patients with head and neck, chest, breast, abdominal, and pelvic cancers. This study included 147 patients with primary malignancies who were suspected of having nodal metastases of which 29 had head and neck cancer, 32 had lung or mediastinal

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cancer, 23 had breast cancer, 25 had abdominal cancer, 38 had pelvic cancer, and 2 patients had both abdominal and pelvic cancers. For each patient, MR imaging was performed before the administration of COMBIDEX and 24-36 hours after COMBIDEX administration. The MR imaging results were correlated with pathology. No serious adverse events were reported. Overall the data demonstrated that COMBIDEX-enhanced MR imaging improved diagnostic accuracy from 68% to 85% as compared to MR imaging prior to the administration of COMBIDEX.

In April 2003, Advanced Magnetics and Cytogen announced the presentation of data from two separate studies with results suggesting that imaging with COMBIDEX may be useful in defining the periphery of residual and primary brain, head and neck tumors.

The first study, conducted at the University of Washington, reported MR imaging of 15 patients with primary head and neck cancers 24 hours after the administration of COMBIDEX. In 7 of 15 patients, a dark rim was clearly visible at the tumor margin on the post-COMBIDEX images. When imaging evaluation results were compared to histopathologic analysis, iron deposition within macrophages or other inflammatory cells was found predominantly at the periphery of the tumor, and to a lesser extent within the tumor. Researchers found that COMBIDEX may be valuable not only for detecting lymph node metastatsis but also for defining the margin of primary head and neck tumors.

Another study, conducted at Oregon Health and Sciences University, involved 7 patients in whom researchers investigated the value of both Gadolinium-enhanced and COMBIDEX-enhanced MR imaging in assessing malignant brain tumors pre- and post-operatively. The MR imaging with Gadolinium was done at least 24 hours prior to COMBIDEX administration. MR images were then obtained 24 hours after COMBIDEX administration followed by surgery on the same day. Post-operative MR was performed approximately 18 hours after surgery. All malignant tumors showed COMBIDEX accumulation around the periphery of the tumor, which was shown to be in the inflammatory cells on histological analysis. In 5 of the 7 patients there were tumors enhanced by COMBIDEX, but not by Gadolinium. In 1 case available for follow-up, Gadolinium enhancement did develop and progressed in these areas. In 4 of the 7 cases, comparison of the pre- and post-operative COMBIDEX-enhanced MR imaging revealed residual COMBIDEX enhancement, thus avoiding the need to re-administer contrast during post-operative MR imaging to evaluate residual disease.

Agreement with Advanced Magnetics, Inc.

In August 2000, we entered into a license and marketing agreement and a supply agreement with Advanced Magnetics, Inc. for COMBIDEX, for all applications, and ferumoxytol (formerly referred to as Code 7228), for oncology applications only. At this time Advanced Magnetics does not intend to develop ferumoxytol for oncology imaging. Pursuant to the terms of the license agreement, we obtained the exclusive right in the United States to market, distribute and sell COMBIDEX. Advanced Magnetics is continuing its discussions with the FDA relating to outstanding issues regarding an approvable letter received from the FDA dated June 2000, in an effort to bring COMBIDEX to market. The license agreement will continue until August 25, 2010, and shall 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 are being held in escrow pending the achievement of certain milestones relating to COMBIDEX and 25,000 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 having subsequently 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, upon the receipt of all requisite regulatory approvals.

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 coterminus with the license agreement.

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There can be no assurance that Advanced Magnetics will receive FDA approval for COMBIDEX or ferumoxytol.

DISCONTINUED PRODUCTS

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 over the past three years were:

2003 $ 6.1 million

2002 $ 10.5 million

2001 $ 10.4 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 genetic marker associated with prostate cancer. Dr. Julius S. Horoszewicz identified the PSMA protein using a monoclonal antibody in 1987. The antibody technology developed by Dr. Horoszewicz 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 in research and development.

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These pipeline products are focused primarily on novel vaccine and antibody therapies for prostate and other cancers.

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 shall be at the discretion and expense of Cytogen. 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 term of the license shall end on the date of expiration of the last to expire of the licensed patents unless it earlier terminates by operation of law or by acts of the parties in accordance with the terms of the agreement. The license agreement is also terminable by Cytogen upon 60 days notice to SKICR. Additionally, upon execution of an agreement with SKICR, we paid to SKICR an option fee, a license fee and reimbursement for patent expenses paid by SKICR. We remain 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.

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. In connection with the licensing of our PSMA technology to the joint venture in June 1999, we recognized approximately $1.8 million in license fee revenue. Beginning in December 2001, we and Progenics began sharing costs of the program.

In 2003, we incurred expenses of $3.5 million relating to our half of the expenses for the programs at the joint venture, compared to $2.9 million in 2002. The joint venture is funded by equal capital contributions from

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each of Progenics and Cytogen in accordance with an annual budget approved by the joint venture representatives from each such party. In January 2004, we and Progenics: (i) agreed to a work plan governing the activities of the joint venture for the remainder of 2004; and (ii) agreed to a budget for the joint venture s operations for 2004 and certain related capital contributions of the parties. The joint venture s work plan, budget, and other operational and financial matters relating to periods after 2004 will require the further agreement of Progenics and us. During 2004, we expect to incur expenses of approximately $4.6 million relating to our half of the expenses for the joint venture. We have not committed to fund the joint venture beyond December 31, 2004 at this time, but for existing contractual commitments as of that date. Contract research and development services provided by Progenics to the joint venture during 2003 were in accordance with a services agreement between the parties which expired on January 31, 2004. Cytogen also provided minimal services to the joint venture. We are discussing the terms of a new services agreement with Progenics and we and Progenics continue to perform research and development in accordance with the approved annual budget and work plan for 2004. 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.

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 November 2003, the joint venture announced publication of new findings, published in the November 2003 issue of the *Proceedings of the National Academy of Sciences USA*, that PSMA exists on human cancer cells as a homodimer, a protein complex consisting of two identical PSMA chains. Importantly, researchers also found that when recombinant soluble PSMA (rsPSMA) was used as a cancer vaccine in an animal model, dimer but not monomer efficiently elicited antibodies that recognized PSMA-expressing tumor cells. In addition, researchers at the joint venture reported the discovery of fully human monoclonal antibodies that specifically recognize dimeric but not monomeric rsPSMA. Such antibodies represent candidates for therapy by virtue of their specificity for dimeric PSMA as found on tumor cells. The joint venture is currently conducting a Phase 1 clinical study of a therapeutic prostate cancer vaccine based on a novel proprietary form of dimeric rsPSMA.

We are currently pursuing three research and development programs at 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, alphavirus vaccine for prostate cancer that induces both antibodies and cytotoxic T cells. 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.

Recombinant Soluble PSMA Vaccine Program. 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.

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

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to create a therapeutic prostate cancer vaccine incorporating the PSMA antigen. In consideration for the license, the joint 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. In August 2003, the joint venture entered into a manufacturing agreement with Abgenix for the production of clinical supplies in the PSMA human monoclonal antibody program. The joint venture has the right to terminate either of these agreements upon 30 days prior written notice.

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 $300,000, $200,000, and $400,000 for the years ended December 31, 2003, 2002, and 2001, respectively. In addition, as of December 31, 2003, remaining potential payments associated with milestones and defined objectives with respect to the above agreements total approximately $13.5 million. Future annual minimum royalties under the agreements described above are not significant.

AxCell Biosciences

Further research and development efforts are carried out through our subsidiary, AxCell Biosciences Corporation, which remains engaged in the research and development of novel biopharmaceutical products using its collection of proprietary signal transduction pathway information, despite significant reductions in AxCell s workforce in 2002.

AxCell uses its proprietary technology as a tool to provide academic, governmental and commercial collaborators with vital information about signal transduction pathways that can be used for drug discovery and development. AxCell provides this information rapidly and efficiently, using the proprietary methods and systems that AxCell developed to identify signal transduction pathways. We have successfully leveraged our technology through research collaborations with Mount Sinai School of Medicine, National Cancer Institute, Kimmel Cancer Center at Thomas Jefferson University, University of Muenster in Germany and Celgene Corporation. These collaborations increase our research resources, improve our technological strength and establish valuable development relationships with potential commercial opportunities.

A majority of the drugs on the market today are agents that interact with cell surface receptors. Surface receptors, however, are generally associated with multiple intracellular signaling pathways and, as a result, drugs targeting these receptors are less specific to the disease, which may lead to reduced efficacy and/or unwanted side effects. By targeting intracellular proteins downstream from the surface receptor, a drug can more precisely initiate the desired cellular response, which may lead to treatments with greater efficacy and fewer side effects. Many proteins along these intracellular pathways communicate with each other through structurally and functionally defined modules, called domains, and their respective binding partners called ligands. The

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modular and well-defined nature of these domain-ligand interactions makes them ideal drug targets for developing small inhibitory molecules.

One of the historical challenges to design small molecule inhibitors for domain-ligand interactions is the fact that domains are highly homologous within each domain family making it difficult to develop a highly specific inhibitor for a particular interaction. AxCell overcomes this problem through the exact determination of specificity boundaries for each domain-ligand interaction. This biochemical approach integrates parallel synthesis of peptides, protein expression and high-throughput screening methodology combined with tools of bioinformatics.

AxCell has the only 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. Using its proprietary technologies, AxCell has made significant technical progress over the past several years and is currently applying its 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, government and academic institutions.

In March 1993, we entered into a license agreement with The University of North Carolina at Chapel Hill, pursuant to which UNC granted us an exclusive world-wide license with respect to certain technology, patents and patent applications which relate to certain aspects of proteomics technology, including phage display. These patents 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), and 6,432,920 (expiring July 22, 2014), and U.S. Pat. Appln. Nos. 09/879,957 (filed June 13, 2001), 09/938,315 (filed August 23, 2001), 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 an 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, which are subject to certain minimum amounts, to UNC.

OTHER STRATEGIC RELATIONSHIPS

Our strategy is to use alliances with other companies to increase our financial resources, reduce risk and retain an appropriate level of ownership of products currently in development. In addition, through alliances with other pharmaceutical and biotechnology companies, we may obtain funding, expand 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 Cytogen. In connection with Antisoma s acquisition of these rights, Antisoma made a cash payment to us of $500,000. Antisoma also 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 equivalent to 1.65% of future net sales, if any, of the R1549 product.

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 addition, we are the co-owners with Elan of patents and patent applications developed under the agreement,

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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, Cytogen is pursuing other collaborations or partnerships to realize the clinical and commercial potential of this approach.

PRODUCT CONTRIBUTION TO REVENUES

PROSTASCINT and QUADRAMET account for, and, prior to its discontinuation in January 2003, BRACHYSEED accounted for, a significant percentage of our total revenues. For the years ended December 31, 2003, 2002 and 2001, revenues related to PROSTASCINT accounted for approximately 47%, 61% and 65%, respectively, of our total revenues; revenues related to QUADRAMET accounted for approximately 28%, 14% and 18%, respectively, of our total revenues; and revenues related to BRACHYSEED accounted for approximately 2%, 19% and 7%, respectively, of our total revenues. 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, 2003, we received 69% of our total revenues from four customers, as follows: 23% from Berlex Laboratories, Inc., 14% from Mallinckrodt Inc., 8% from Amersham Health (formerly Medi-Physics), and 24% from Cardinal Health (formerly Syncor International Corporation).

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

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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.

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.

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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, and the rules and regulations promulgated thereunder. These laws and 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 under 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

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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. 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 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.

Both the studies and the preparation and prosecution of these applications in front of the FDA are expensive and time consuming, and each may take several years to complete. Difficulties or unanticipated costs may be encountered by us or our licensees or us 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

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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. There is no requirement, other than the requirement for bioequivalence testing, for an ANDA applicant to conduct or submit results of pre-clinical or clinical tests to prove the safety or effectiveness of its drug product. Drugs approved in this way are commonly referred to as generic equivalents to the listed drug, are listed as such by the FDA, and can often be substituted by pharmacists under prescriptions written for the original 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. During such three-year exclusivity period the FDA cannot grant approval of an ANDA to commercially distribute a generic version of the drug based on that listed drug. However, the FDA can approve generic equivalents of that listed drug based on other listed drugs, *(e.g.*, a generic that is the same in every way but its indication for use), and thus the value of such exclusivity may be undermined. 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 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 one of four certifications including that it believes one or more listed patents are invalid or not infringed. If a generic applicant certifies invalidity or non-infringement, it is required to provide notice of its filing to the NDA sponsor and the patent holder. If the patent holder then initiates a suit for patent infringement against the ANDA sponsor within 45 days of receipt of the notice, the FDA cannot grant effective approval of the ANDA until either 30 months has passed or there has been a court decision holding that the patents in question 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.

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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, Public Health Service 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 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 an identical product 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. 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 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. 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

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receiving any form of remuneration in return for the referral of items or services reimbursable by any federal health care program, or in return for the recommendation, arrangement, purchase, lease or order of items or services that are covered by federal health care programs. 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 are also subject to federal and state physician self-referral laws. Federal physician self-referral legislation (known as the Stark law) prohibits, subject to certain exceptions, a physician from referring Medicare or Medicaid patients to an entity providing 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 Laws. Under separate federal statutes, submission of claims for payment that are false or fraudulent may 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 false or fraudulent claims against a federal program such as Medicare or Medicaid or other violations of the statute and to share in any amounts paid by the entity to the government in fines or settlement. Such suits, known as *qui tam* actions, have increased significantly in recent years, causing greater numbers of health care companies to face false claim actions, pay fines or be excluded from Medicare, Medicaid or other federal health care programs. Various state laws also contain similar prohibitions, penalties, and *qui tam* action mechanisms.

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 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 such coverage depends upon a number of factors, including the payer 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, safe, effective, 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 healthcare provider to make a profit or even cover costs, including research, development, production, sales, and distribution costs. Although new laws require 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.

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 healthcare 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 healthcare spending. Approval in payment of 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 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

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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 healthcare proposals could have a material adverse effect on our business, financial condition and results of operations. Further, to the extent that changes in healthcare 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, Vice President, Business Development and Industry Relations, and Vice President, Investor Relations Officer. Prior to joining Cytogen, he 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 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 as our 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 is a certified public accountant licensed in the State of New Jersey.

Thu A. Dang was promoted to Vice President, Finance in 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 was promoted to Vice President, Human Resources and Administration in January 2003 and became our Corporate Secretary in 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,

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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 and is certified as a Human Resources Professional.

June Gobern, MBA, was promoted to Senior Director of Marketing in January 2003. She previously served as Director of Marketing. Ms. Gobern joined Cytogen in 1992 as Supervisor of Technical Services, in 1994 was promoted to Assistant Director of Marketing Services and in July of 1996 to Director of Sales and Marketing. Prior to joining Cytogen, Ms. Gobern worked for Bristol-Myers Squibb as a Technical Sales Associate for the Metro Region. She spent over 10 years in the hospital setting where she functioned in various Nuclear Medicine, MRI and Ultrasound supervisory roles and served on the Board of Directors for Putman Credit Union. She received both a BS in Medical Technology and a MBA in Management from Fairleigh Dickinson University. She also holds a Certificate in International Business from Wroxton College, England and a Nuclear Medicine AMA Certification, from the JFK School of Nuclear Medicine. Ms. Gobern is also a certified Nuclear Medicine Technologist.

Corey Jacklin, MBA, joined Cytogen in January 2003 as our Director of Business Development and in March 2003 became our Senior Director of Sales. He has held various sales and marketing positions in the biotechnology industry for the past 15 years including co-founding Polyprobe (now Genisphere), marketing bioreactors and fermenters for New Brunswick Scientific, selling contract research services for MDS Panlabs, and lastly as a Director of Business Development with Gene Logic, a provider of genomics and toxicogenomics information products. He received his Bachelor s degree in Molecular Biology from the University of California at Berkeley and his MBA in Industrial Marketing from Baruch College, CUNY.

EMPLOYEES

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, 36 were employed in sales and marketing, 5 in clinical activities, 2 in regulatory, 4 in our AxCell subsidiary and 14 in administration and management. The employees in sales and marketing included 8 Regional Oncology Specialists and 23 Regional and Territory Managers. We believe that we have been successful in attracting skilled and experienced employees. None of our employees is covered by a collective bargaining agreement. All of our employees have executed confidentiality agreements. We consider relations with our employees to be excellent.

ADDITIONAL FACTORS THAT MAY AFFECT FUTURE RESULTS

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 research and development and related 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 $9.4 million, $15.7 million, and $12.1 million for the years ended December 31, 2003, 2002 and 2001, respectively. We had an accumulated deficit of $366 million as of December 31, 2003.

In order to develop and commercialize our technologies, particularly our prostate specific membrane antigen technology, and expand our oncology 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.

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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, oncology-focused biopharmaceutical company;
- the establishment and maintenance of our in-house specialty sales force;
- the reacquisition of North American and Latin American marketing rights to QUADRAMET from Berlex Laboratories in August 2003;
- enhancing our marketed product portfolio through marketing alliances and strategic arrangements such as we have done with the COMBIDEX product, which we intend to market if this product is approved by the FDA; and
- the effective monitoring and management of expenses relating to research and development, selling and marketing, and other general and administrative matters.

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 PROSTASCINT and QUADRAMET for the majority of our near-term revenues.

We expect QUADRAMET and PROSTASCINT to account for a significant percentage of our product related revenues in the near future. 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. For the year ended December 31, 2002, royalties from QUADRAMET and product revenues from PROSTASCINT accounted for approximately 15% and 64%, respectively, of our product related revenues. If PROSTASCINT or QUADRAMET 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.

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

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

- health care providers, such as hospitals and physicians; and
- 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 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 bone metastases, such as analgesics, opioids, bisphosphonates, and chemotherapeutics. If PROSTASCINT or QUADRAMET do not achieve broader market acceptance, we may not be able to generate sufficient revenue to become profitable.

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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, BRACHYSEED I-125 in February 2001, BRACHYSEED Pd-103 in May 2002 and NMP22 BLADDERCHEK in November 2002. Revenues for PROSTASCINT grew from $55,000 in 1996 to $6.5 million in 2003. Royalties from sales and product revenues for QUADRAMET grew from $3.3 million in 1997 to $3.9 million in 2003. 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. ONCOSCINT CR/OV selling activity was discontinued in December 2002 and selling activities for the BRACHYSEED products were discontinued in January 2003. We began marketing NMP22 BLADDERCHEK in November 2002 and sales of this product have been minimal to date. Currently, most of our revenues are derived from sales of PROSTASCINT and QUADRAMET, as well as certain license and contract revenues.

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 BMSMI;
- marketing, license and supply agreements with Advanced Magnetics, Inc. related to COMBIDEX;
- a distribution services agreement with CORD Logistics, Inc. for PROSTASCINT;
- various agreements which form and control our joint venture with Progenics Pharmaceuticals for the development of PSMA for *in vivo* immunotherapy for prostate and other cancers;
- a collaboration and manufacturing agreement between our joint venture and Abgenix, Inc.; 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 breach their obligations 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 early.

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. 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 BRACHYSEED 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 BRACHYSEED 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 North American rights to use QUADRAMET as a therapeutic radiopharmaceutical for metabolic bone disease or tumor regression for cancer caused by metastatic or primary cancer in bone in humans, and for the treatment of disease characterized by osteoblastic response in humans. Our license was expanded to include Latin America in 1995.

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Our license agreement with Dow with respect to QUADRAMET shall remain in effect, unless earlier terminated pursuant to the terms thereof, for a term of twenty (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.

Bristol-Myers Squibb Medical Imaging, Inc. QUADRAMET is manufactured by BMSMI pursuant to the terms of a manufacturing and supply agreement with us effective as of 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 through 2008. The agreement shall thereafter renew for five successive one-year periods unless terminated by either party upon two years notice, or earlier terminated pursuant to the terms thereof. 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 and distribution.

Advanced Magnetics, Inc. In August 2000, we entered into a license and marketing agreement and a supply agreement with Advanced Magnetics, Inc. for COMBIDEX, an investigational magnetic resonance imaging contrast agent that assists in the differentiation of metastatic from non-metastatic lymph nodes. We hold exclusive United States marketing rights to COMBIDEX. Advanced Magnetics is continuing its discussions with the FDA relating to outstanding issues regarding an approvable letter received from the FDA dated June 2000, in an effort to bring COMBIDEX to market. Our license and marketing agreement with Advanced Magnetics will continue until August 25, 2010, and shall 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 term of the license shall end on the date of expiration of the last to expire of the licensed patents unless it earlier terminates by operation of law or by acts of the parties in accordance with the terms of the agreement.

Agreement with Dr. Horoszewicz regarding PROSTASCINT. In 1989, we entered into an agreement with Dr. Julius S. Horoszewicz pursuant to which we 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 our agreement, which we believe will remain in effect until the expiration of the last related patent, we have made, and may continue to make, certain payments to Dr. Horoszewicz.

The University of North Carolina at Chapel Hill. In March 1993, we entered into a license agreement with The University of North Carolina at Chapel Hill, pursuant to which UNC granted us and our affiliates an exclusive world-wide license with respect to certain technology, patents and patent applications related to certain aspects of proteomics technology, including phage display. 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.

Laureate Pharma, L.P. In January 2003, we entered into a contract manufacturing agreement with Laureate Pharma L.P., pursuant to which Laureate was obligated to manufacture PROSTASCINT for us through December 31, 2003. Although we do not plan to manufacture any PROSTASCINT in 2004, we do intend to negotiate with Laureate or another suitable contract manufacturer to supply us with PROSTASCINT in subsequent periods.

If the licenses and/or agreements described above 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.

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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 primarily on United States patent numbers 5,162,504 (expiring October 28, 2010), 4,741,900 (expiring June 9, 2004), 4,671,958 (expiring June 9, 2004), and 4,867,973 (expiring 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).

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

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

In addition, patent law in the technology fields in which we operate is uncertain and still evolving. The degree of protection that may be afforded 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.

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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 was manufactured at a cGMP compliant manufacturing facility operated by Laureate Pharma L.P. We had access to Laureate s facility for continued manufacturing of the product until December 31, 2003. We entered into a development and manufacturing agreement with DSM Biologics Company B.V. in July 2000, which we intended would replace our arrangement with Laureate with respect to PROSTASCINT. Our relationship with DSM has subsequently terminated. 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 results of operations.

QUADRAMET is manufactured by BMSMI, pursuant to an agreement with Cytogen. 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 could 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 United States Food and Drug Administration 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 November 2002, we began promoting NMP22 BLADDERCHEK to urologists in the United States, and now promote NMP22 BLADDERCHEK solely to

oncologists.

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Our PSMA technologies are still in the early stages of development. We have significantly reduced operations at our AxCell subsidiary, which is responsible for the development certain of our technologies. We may be unable to develop or commercialize these products and technologies in the future.

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 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 efficacious 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 the biotechnology industry have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. Clinical trials or marketing of any potential diagnostic or therapeutic products may expose us to liability claims for the use of these diagnostic or therapeutic products. We may not be able to maintain product liability insurance or sufficient coverage may not be available at a reasonable cost. In addition, as we develop diagnostic or therapeutic products internally, we will have to make significant investments in diagnostic or therapeutic product development, marketing, sales and regulatory compliance resources. We will also have to establish or contract for the manufacture of

products, including supplies of drugs used in clinical trials, under the current Good Manufacturing Practices of the FDA. We 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

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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.

Competition in our field is intense and likely to increase.

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

- pharmaceutical companies;
- biotechnology companies;
- diagnostic companies;
- bioinformatics companies;
- academic and research institutions; and
- government agencies.

All of our products and product candidate 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.

The markets for therapeutic and molecular imaging/diagnostic products that address prostate and bladder cancers are large. Our most significant competitors include various pharmaceutical and medical device companies, radiopharmaceutical distributors and biotechnology companies.

QUADRAMET primarily competes with Strontium-89 chloride in the radiopharmaceutical pain palliation market. Strontium-89 chloride is manufactured and marketed either as Metastron, by Amersham Health, or in a generic form by Bio-Nucleonics Pharma, Inc. Amersham 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 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).

Polymedco manufactures BTAStat, a point of care urine-based test approved for monitoring bladder cancer patients. BTAStat, marketed by Mentor, competes with NMP22 BLADDERCHEK (a product of Matritech for which we are the sole distributor to oncologists in the United States). NMP22 BLADDERCHEK is, however, the only point of care urine-based test approved for both monitoring and diagnosis of bladder cancer. Matritech has retained rights to market NMP22 BLADDERCHEK directly to physicians other than oncologists, such as primary care physicians.

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.

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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, QUADRAMET and NMP22 BLADDERCHEK. However, such internal sales force has limited sales, marketing and distribution capabilities for our products, 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, 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.

Failure of consumers to obtain adequate reimbursement from third-party payors could limit market acceptance and affect pricing of our products.

Sales of our products depend in part on the availability of reimbursement by federal health care programs such as Medicare and Medicaid as well as private health insurance plans. Whether a product receives such coverage 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 or regulation. There may be significant delays in obtaining coverage for newly-approved products, and coverage may 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, including research, development, production, sales, and distribution costs. 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 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 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 United States.

Third party payors often follow Medicare coverage policy and payment limitations in setting their own 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 to each payor. Our inability to promptly obtain 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 governments and third-party payors to contain or reduce the costs of health care. 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

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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 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 either the Nuclear Regulatory Commission 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 ultrasmall superparamagnetic iron oxide contrast agent for magnetic resonance imaging of lymph nodes, that is pending clearance by the United States Food and Drug Administration. 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

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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. We are awaiting further information from the FDA regarding COMBIDEX.

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.

The United States Food, Drug and Cosmetics Act requires: (i) that our products be manufactured in FDA registered facilities subject to inspection; and (ii) that we comply with cGMP, which imposes certain procedural and documentation requirements upon us and our manufacturing partners with respect to manufacturing and quality assurance activities. If we or our 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. Under the terms of such letter agreement, Mr. Becker receives an annual base salary of $280,000. 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 30% 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. 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 month s 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.

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Our business exposes us to potential liability claims that may exceed our financial resources, including our insurance coverage, and may lead to the curtailment or termination of our operations.

Our business is subject to product liability risks inherent in the testing, manufacturing and marketing of our products 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 addition, while we currently maintain directors and officers liability insurance in the amount of $20.0 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.

The reduced workforce at AxCell may not be able to implement AxCell s business plan.

In September 2002, we implemented the restructuring of our subsidiary, AxCell Biosciences Corporation, in an effort to reduce expenses and position Cytogen for stronger long-term growth in oncology. As a result, we reduced our staff at AxCell by seventy-five percent, suspended certain projects at AxCell and implemented other cost-saving measures.

The technologies under development at AxCell are complex and remain commercially unproven. Even if we are able to develop and commercialize a product through AxCell, there may be fewer than 100 pharmaceutical companies and biotechnology companies that are potential customers for such technology or product.

Although we believe that we have retained the AxCell personnel who are key to achieving AxCell s goals and implementing its strategies, such reduced workforce may not be able to implement AxCell s current business plan. The further loss of any of AxCell s personnel could have a material adverse effect on AxCell s ability to achieve its goals.

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

Our cash, cash equivalents and short-term investments were $30.2 million at December 31, 2003. We expect that our existing capital resources should be adequate to fund our operations and commitments at least into the middle of 2005.

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;

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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. 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, the issuance will result in ownership dilution to 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

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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 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 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 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 False Claims Act, which allows any person to bring suit alleging false or fraudulent claims 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.

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.

Two of our marketed products, 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 most recent 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 are currently 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. (collectively Plaintiffs). The

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litigation claims that our PROSTASCINT product infringes a patent purportedly owned by Goldenberg and licensed to Immunomedics. The patent sought to be enforced in the litigation has now expired; as a result, the claim, even if successful, would not result in an injunction barring the continued sale of PROSTASCINT or affect any other of our products or technology. We believe that PROSTASCINT did not infringe this patent, and that the patent was invalid and unenforceable. The patent sought to be enforced in the litigation has now expired; as a result, the claim, even if successful, would not result in an injunction barring the continued sale of PROSTASCINT or affect any other of our products or technology. In addition, we have certain rights to indemnification against litigation and litigation expenses from the inventor of technology used in PROSTASCINT, which may be offset against royalty payments on sales of PROSTASCINT. However, given the uncertainty associated with litigation, we may incur material expenditures. On December 17, 2001, Cytogen filed a motion for summary judgment of non-infringement of the asserted claims of the patent-in-suit. The Plaintiffs opposed that motion and filed their own cross-motion for summary judgment of infringement. On July 3, 2002, the Court denied both parties summary judgment motions, with leave to renew those motions after presenting expert testimony and legal argument based upon that testimony. The parties subsequently presented expert testimony and submitted additional briefing. On April 29, 2003, our motion for summary judgment of non-infringement of all asserted claims was granted, plaintiffs motion for summary judgment of infringement was denied and the case was ordered closed. On May 12, 2003, Plaintiffs filed a Notice of Appeal regarding this decision to the U.S. Court of Appeals for the Federal Circuit, and subsequently filed their opening brief on July 28, 2003. On September 22, 2003, Cytogen filed its responsive brief. On October 23, 2003, Plaintiffs filed their reply brief in the Federal Circuit. The appeal is now fully briefed and oral argument was held on March 2, 2004. The Court has not indicated when it expects to issue a ruling, however, given the uncertainty associated with litigation, we cannot give any assurance that the litigation could not result in a material expenditure 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;
- 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

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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.

Alternatively, if faced with such delisting, we may submit an application to transfer the listing of our common stock to the Nasdaq SmallCap Market. The Nasdaq SmallCap Market also has a $1.00 minimum bid price requirement.

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

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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 to increase the amount of space we occupy from approximately 11,500 square feet to approximately 16,100 square feet. Such amendment also extended the expiration date of our sublease to October 2007, with a 2 year option to renew thereafter. We intend to remain headquartered in Princeton, New Jersey for the foreseeable future.

We also lease approximately 9,200 square feet of laboratory and office space in Newtown, Pennsylvania, which is occupied by our AxCell Biosciences subsidiary. In February 2001, we expanded the AxCell facility by amending the lease to include approximately an additional 5,700 square feet, which additional lease space will expire in September 2006. We sublease approximately 2,400 square feet of the Axcell space to another company. Such sublease will expire in August 2006.

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

Item 3. Legal Proceedings

On March 17, 2000, we were served with a complaint filed against us in the United States District Court for the District of New Jersey by M. David Goldenberg and Immunomedics, Inc. (collectively Plaintiffs). The litigation claims that our PROSTASCINT product infringes a patent purportedly owned by Goldenberg and licensed to Immunomedics. The patent sought to be enforced in the litigation has now expired; as a result, the claim, even if successful, would not result in an injunction barring the continued sale of PROSTASCINT or affect any other of our products or technology. We believe that PROSTASCINT did not infringe this patent, and that the patent was invalid and unenforceable. The patent sought

to be enforced in the litigation has now expired; as a result, the claim, even if successful, would not result in an injunction barring the continued sale of PROSTASCINT or affect any other of our products or technology. In addition, we have certain rights to indemnification against litigation and litigation expenses from the inventor of technology used in PROSTASCINT, which may be offset against royalty payments on sales of PROSTASCINT. However, given the uncertainty associated with litigation, we may incur material expenditures. On December 17, 2001, Cytogen filed

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a motion for summary judgment of non-infringement of the asserted claims of the patent-in-suit. The Plaintiffs opposed that motion and filed their own cross-motion for summary judgment of infringement. On July 3, 2002, the Court denied both parties summary judgment motions, with leave to renew those motions after presenting expert testimony and legal argument based upon that testimony. The parties subsequently presented expert testimony and submitted additional briefing. On April 29, 2003, our motion for summary judgment of non-infringement of all asserted claims was granted, plaintiffs motion for summary judgment of infringement was denied and the case was ordered closed. On May 12, 2003, Plaintiffs filed a Notice of Appeal regarding this decision to the U.S. Court of Appeals for the Federal Circuit, and subsequently filed their opening brief on July 28, 2003. On September 22, 2003, Cytogen filed its responsive brief. On October 23, 2003, Plaintiffs filed their reply brief in the Federal Circuit. The appeal is now fully briefed and oral argument was held on March 2, 2004. The Court has not indicated when it expects to issue a ruling, however given the uncertainty associated with litigation, we cannot give any assurance that the litigation could not result in a material expenditure to us.

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, may not represent actual transactions and have been adjusted to reflect the Company s one-for-ten reverse stock split executed October 25, 2002.

2002	High	Low
First Quarter	$ 34.40	$ 21.10
Second Quarter	$ 22.00	$ 9.10
Third Quarter	$ 11.00	$ 3.10
Fourth Quarter	$ 8.40	$ 3.30
2003		
First Quarter	$ 3.89	$ 2.51
Second Quarter	$ 8.59	$ 2.63
Third Quarter	$ 14.46	$ 7.78
Fourth Quarter	$ 13.40	$ 9.26

As of February 25, 2004, there were approximately 4,000 holders of record of our common stock and there were approximately 38,500 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 the board of directors.

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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, 2003. 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,				
	2003	2002	2001	2000	1999
Statements of Operations Data:	(All amounts in thousands, except per share data)				
Revenues:					
Product sales	$ 9,823	$ 10,626	$ 8,782	$ 7,523	$ 7,073
Royalties	1,105	1,842	2,063	2,004	1,060
License and contract	2,914	463	912	1,024	3,171
Total revenues	13,842	12,931	11,757	10,551	11,304
Operating Expenses:					
Cost of product related and contract manufacturing revenues	6,268	4,748	4,216	4,513	4,213
Selling, general and administrative	11,550	11,247	11,178	11,060	7,711
Research and development	2,659	7,605	10,091	6,957	3,849
Equity in loss of joint venture	3,452	2,886	332		
Impairment of intangible assets[1]	115	1,729			
Acquisition of marketing and technology rights[2]				13,241	1,214
Total operating expenses	24,044	28,215	25,817	35,771	16,987
Operating loss	(10,202)	(15,284)	(14,060)	(25,220)	(5,683)
Loss on investment		(516)			
Gain on sale of laboratory and manufacturing facilities					3,298
Other income (expense), net	(44)	101	857	611	412
Loss before income taxes and cumulative effect of accounting change	(10,246)	(15,699)	(13,203)	(24,609)	(1,973)
Income tax benefit	(888)		(1,103)	(1,625)	(2,702)
Income (loss) before cumulative effect of accounting change	(9,358)	(15,699)	(12,100)	(22,984)	729
Cumulative effect of accounting change[3]				(4,314)	
Net income (loss)	$ (9,358)	$ (15,699)	$ (12,100)	$ (27,298)	$ 729
Net income (loss) per share:					
Basic and diluted net income (loss) before cumulative effect of accounting change	$ (0.92)	$ (1.85)	$ (1.56)	$ (3.13)	$ 0.11
Cumulative effect of accounting change[3]				(0.59)	
Basic and diluted net income (loss)	$ (0.92)	$ (1.85)	$ (1.56)	$ (3.72)	$ 0.11

Weighted average common shares outstanding:					
Basic	10,205	8,466	7,778	7,334	6,718
Diluted	10,205	8,466	7,778	7,334	6,819
Pro forma amounts assuming accounting change is applied retroactively:					
Net loss				$ (22,984)	$ (484)
Basic and diluted net loss per share				$ (3.13)	$ (0.07)

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	December 31,				
	2003	2002	2001	2000	1999
Consolidated Balance Sheet Data:					
			(in thousands)		
Cash, cash equivalents and short-term investments	$ 30,215	$ 14,725	$ 11,309	$ 11,993	$ 12,394
Total assets	43,695	19,894	21,492	20,416	18,605
Long-term liabilities	2,454	2,614	2,291	2,374	2,416
Accumulated deficit	(365,738)	(356,380)	(340,681)	(328,581)	(301,283)
Stockholders equity	36,040	10,588	11,214	7,218	10,549

(1) Reflects a non-cash charge to write off the carrying value of the licensing fees associated with NMP22 BLADDERCHEK in 2003 and BRACHYSEED I-125 and BRACHYSEED Pd-103 in 2002.

(2) In August 2000, the Company licensed product rights from Advanced Magnetics, Inc. In June 1999, the Company acquired Prostagen, 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. All statements, other than statements of historical facts, included in this Annual Report on Form 10-K regarding our strategy, future operations, financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. Such forward-looking statements involve a number of risks and uncertainties and investors are cautioned not to put any undue reliance on any forward-looking statement. We cannot guarantee that we will actually achieve the plans, intentions or expectations disclosed in any such forward-looking statements. Factors that could cause actual results to differ materially, include, but are not limited to those identified under the caption Additional Factors That May Affect Future Results , provided elsewhere in this Annual Report on Form 10-K.

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 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, oncology-focused biopharmaceutical company that licenses, develops and commercializes both therapeutic and molecular imaging/diagnostic products that address the unmet medical needs of physicians and the patients they serve. We directly market QUADRAMET (samarium Sm-153 lexidronam injection), PROSTASCINT® (capromab pendetide) kit for the preparation of Indium In-111 capromab pendetide, and NMP22® BLADDERCHEK® (nuclear matrix protein-22) in the United States. We also have exclusive United States marketing rights to COMBIDEX® (ferumoxtran-10), which 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. Full prescribing information for our products is available at www.cytogen.com or by calling 1-800-833-3533. For more information, please visit our website at www.cytogen.com, which is not part of this Annual Report on Form 10-K.

The year 2003 was a transformational period for Cytogen, highlighted by the reacquisition of marketing rights to our lead therapeutic product, QUADRAMET, from Berlex and substantial balance sheet improvement from prior years, with in excess of $35 million of capital raised during the year from recognized institutional investors. Through QUADRAMET investigational clinical data presented at a number of medical meetings in 2003 and broader follow-up studies thereon planned in 2004, we hope to set the stage for potential product expansion opportunities. Our PROSTASCINT collaborations signed in 2003 with General Electric Medical Systems and Siemens and an improved reimbursement climate should help to drive future sales for this product. In addition, COMBIDEX, which we are committed to launching pending regulatory clearance, was brought to the forefront of national attention with a lead publication in the *New England Journal of Medicine* in June 2003.

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Significant Events in 2003

Draximage

In January 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 I-125 and BRACHYSEED Pd-103 products. We launched BRACHYSEED I-125 and BRACHYSEED Pd-103 in February 2001 and May 2002, respectively. Effective January 24, 2003, we no longer accept or fill new orders for either of these products. In April 2003, we entered into an agreement with Draximage to formally terminate each of these agreements.

Quadramet Reacquisition

In June 2003, we entered into an agreement with Berlex Laboratories, Inc., whereby marketing rights held by Berlex to market QUADRAMET in North America and Latin America would be returned to us in exchange for an upfront payment of $8.0 million and royalties based on future sales, subject to our receipt of requisite financing to complete the transaction. In August 2003, we paid Berlex the upfront payment of $8.0 million and reacquired such marketing rights to QUADRAMET.

Capital Raising and Shelf Registration

In June 2003, we issued and sold 1,052,632 shares of our common stock to certain institutional investors at $4.75 per share for net proceeds of $4.6 million. In connection with this financing, we also issued warrants, which are exercisable until June 6, 2008, to these investors to purchase an aggregate of 315,790 shares of our common stock with an exercise price of $6.91 per share.

In July 2003, we issued and sold an additional 1,172,332 shares of our common stock to institutional investors at $8.53 per share for net proceeds of $9.3 million. We also issued warrants, which are exercisable until July 10, 2008, to purchase: (i) 1,172,332 shares of our common stock with an exercise price of $12.80 per share to the institutional investors; (ii) 100,000 shares of our common stock at an exercise price of $12.80 per share to a consultant; and (iii) an aggregate of 250,000 shares of our common stock at an exercise price of $10.97 per share to certain of our stockholders in exchange for their waiver of certain rights in connection with this financing.

On October 29, 2003, we filed a shelf registration statement on Form S-3 (File No. 333-110040) with the Securities and Exchange Commission relating to the registration of up to an aggregate of $60.0 million in shares of our common stock. The SEC declared the registration statement effective on October 30, 2003. On November 6, 2003, we issued and sold an aggregate of 1,863,637 shares of our common stock pursuant to this shelf registration statement at a price of $11.00 per share to certain institutional investors for net proceeds of $20.4 million.

New Chief Financial Officer

In September 2003, we announced that Christopher P. Schnittker, CPA, joined the Company as Vice President and Chief Financial Officer.

Antisoma Research Limited

In September 2003, Antisoma Research Limited acquired certain royalty rights to Antisoma s lead product, R1549 (formerly Pemtumomab), from us. In connection with Antisoma s acquisition of such rights, Antisoma made a cash payment to us of $500,000 and has agreed to make an additional payment of $500,000 upon the first commercial sale, if any, of the R1549 product. In return, we relinquished our right to receive royalties equivalent to 1.65% of future net sales, if any, of the R1549 product.

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Matritech

In October 2003, we entered into an amendment and restatement of our distribution agreement with Matritech originally executed on October 18, 2002. Under the terms of this amended and restated agreement, which took effect on November 8, 2003, we had a non-exclusive right to sell NMP22 BLADDERCHEK to urologists until December 31, 2003 and have an exclusive right to continue to sell NMP22 BLADDERCHEK to oncologists through the term of the restated agreement, which is December 31, 2004. All minimum sales requirements were removed from the agreement.

RESULTS OF OPERATIONS

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

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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.

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. We cannot assure you that we will be able to successfully market NMP22 BLADDERCHEK or that NMP22 BLADDERCHEK will achieve greater market penetration on a timely basis or result in significant revenues for us.

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

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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	11,550	11,247	303	3 %
Research and development	2,659	7,605	(4,946)	(65)%
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.

Cost of Product Related Revenues. Cost of product related revenues for the year ended December 31, 2003 were $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 reserves 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 $11.6 million compared to $11.2 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. In 2004, we expect to expand our sales force and implement other marketing initiatives associated with the commercialization of our existing and anticipated oncology products which may increase current expenditure levels.

Research and Development. Research and development expenses for the year ended December 31, 2003 were $2.7 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

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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. In 2004, we expect to conduct investigational studies related to QUADRAMET product expansion which may increase current expenditure levels.

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.

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 and research and development credit 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.

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Year Ended December 31, 2002 as Compared to December 31, 2001

Revenues

			Increase/(Decrease)	
	2002	2001	$	%
	(All amounts in thousands, except percentage data)			
PROSTASCINT	$ 7,923	$ 7,640	$ 283	4 %
QUADRAMET Royalties	1,842	2,063	(221)	(11) %
NMP22 BLADDERCHEK (commenced November 2002)	14		14	n/a
BRACHYSEED	2,507	779	1,728	222 %
ONCOSCINT	182	363	(181)	(50)%
License and Contract	463	912	(449)	(49)%
	$ 12,931	$ 11,757	$ 1,174	10 %

Total revenues for the year ended December 31, 2002 and 2001 were $12.9 million and $11.8 million, respectively. Product related revenues, which included product sales and royalties, accounted for 96% of total revenues in 2002 compared to 92% in the same period of 2001. License and contract revenues accounted for the remainder of revenues.

PROSTASCINT. Sales of PROSTASCINT for the year ended December 31, 2002 were $7.9 million compared to $7.6 million for the same period of 2001. PROSTASCINT sales accounted for 64% and 70% of product related revenues for 2002 and 2001, respectively.

QUADRAMET. Royalties from QUADRAMET for the year ended December 31, 2002 were $1.8 million compared to $2.1 million for the same period of 2001. The decrease was partially due to a temporary and infrequent disruption in the supply of QUADRAMET from the manufacturer of the product during the third quarter of 2002, which was subsequently resolved.

NMP22 BLADDERCHEK. The initial sales of NMP22 BLADDERCHEK were $14,000 in 2002. During the fourth quarter of 2002, we entered into a five-year agreement with Matritech Inc. for us to be the sole distributor for Matritech s NMP22 BLADDERCHEK test to urologists and oncologists in the United States. We began marketing NMP22 BLADDERCHEK in November 2002.

BRACHYSEED. Sales of BRACHYSEED for the year ended December 31, 2002 were $2.5 million and accounted for 20% of product related revenues, compared to $779,000, or 7% of product related revenues, for the same period of 2001. The increase from the prior year is due to increased market penetration of BRACHYSEED I-125 since its market introduction in February 2001, and to the initial sales of BRACHYSEED Pd-103, which was launched in May 2002.

ONCOSCINT CR/OV. Sales of ONCOSCINT CR/OV were $182,000 in 2002 compared to $363,000 for the same period of 2001. The market for ONCOSCINT CR/OV for colorectal cancer diagnosis has been negatively affected by positron emission tomography, or PET , scans which have shown the same or higher sensitivity than ONCOSCINT CR/OV. Accordingly, we discontinued selling ONCOSCINT CR/OV at the end of 2002 in order to focus on our other oncology products.

License and Contract Revenues. License and contract revenues for the years ended December 31, 2002 and 2001 were $463,000 and $912,000, respectively. Under SAB 101, which we adopted in 2000, license revenues

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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 2002, we recognized $410,000 of previously deferred license revenue compared to $860,000 for the same period in 2001. In 2002, we performed limited research and development services for the PSMA Development Company LLC, our joint venture with Progenics Pharmaceuticals, Inc., and recorded $53,000 in revenue for such services. The level of future revenues from the joint venture will be dependent upon the extent of research and development services requested by the joint venture.

Operating Expenses

			Increase/(Decrease)	
	2002	2001	$	%
	(All amounts in thousands, except percentage data)			
Cost of product related revenues	$ 4,748	$ 4,216	$ 532	13 %
Selling, general and administrative	11,247	11,178	69	1 %
Research and development	7,605	10,091	(2,486)	(25)%
Equity in loss of joint venture	2,886	332	2,554	769 %
Impairment of intangible assets	1,729		1,729	n/a
	$ 28,215	$ 25,817	$ 2,398	9 %

Total operating expenses for the year ended December 31, 2002 were $28.2 million, compared to $25.8 million for the same period of 2001.

Cost of Product Related Revenues. Cost of product related revenues for the year ended December 31, 2002 were $4.7 million compared to $4.2 million for the same period of 2001. The increase from the prior year period is due primarily to increases in sales of our products and to a $169,000 charge to reserve for excess inventory for ONCOSCINT and PROSTASCINT, partially offset by lower facility related costs associated with the manufacturing of PROSTASCINT.

Selling, General and Administrative. Selling, general and administrative expenses of $11.2 million for the year ended December 31, 2002 were relatively flat compared to 2001. The 2002 expenses include a charge of $869,000 related to a restructuring of AxCell in September 2002 and a non-recurring stock-based compensation charge for a key employee. The 2001 expenses reflect costs associated with the launch of the BRACHYSEED I-125 product.

Research and Development. Research and development expenses for the year ended December 31, 2002 were $7.6 million compared to $10.1 million for the same period of 2001. The decrease from the prior year is due to decreased funding during 2002 for signal transduction research programs at AxCell and a reduction in expenses related to the development of a new manufacturing and purification process by DSM Biologics Company B.V. with respect to PROSTASCINT, partially offset by a stock-based milestone payment of $2.0 million in 2002 related to the progress of the dendritic cell prostate cancer clinical trials at Northwest Biotherapeutics, Inc. In 2002 and 2001, we invested $3.6 million and $4.9 million, respectively, in AxCell s research programs and $551,000 and $3.2 million, respectively, in our manufacturing process development of PROSTASCINT with DSM. We ceased working with DSM on a manufacturing process development in 2002. In connection with the AxCell restructuring plan in September 2002, cost-saving measures implemented at AxCell were expected to lower our annual operating expenses, which began in the fourth quarter of 2002.

Equity in Loss of Joint Venture. Our 50% share of the equity loss in the PSMA Development Company LLC, our joint venture with Progenics, was $2.9 million for 2002. The joint venture is equally owned by Progenics and us. We account for the joint venture using the equity method of accounting. Progenics was obligated to fund the initial $3.0 million of development costs of the joint venture, in addition to $2.0 million in

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supplemental capital contributions funded at certain defined dates, all of which they satisfied in 2001. Beginning in December 2001, we began to equally share the costs of the joint venture with Progenics. Our share of the loss of the joint venture was $332,000 for 2001.

Impairment of Intangible Assets. During 2002, we recorded a non-cash charge of $1.7 million related to the write-off of the carrying value of the up-front licensing fees associated with BRACHYSEED I-125 and BRACHYSEED Pd-103, as the carrying value will not be 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 BRACHYSEED.

Interest Income/Expense. Interest income for the year ended December 31, 2002 was $274,000 compared to $635,000 for the same period of 2001. The decrease from the prior year is due to a lower average yield on investments during the respective periods. Interest expense for 2002 was $173,000 compared to $180,000 for the same period of 2001. 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, 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.

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

Income Tax Benefit. During 2001, we sold a portion of our New Jersey state net operating loss and research and development credit carryforwards, which resulted in the recognition of $1.1 million 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, 2002 was $15.7 million compared to $12.1 million for the same period of 2001. The net loss per share for the year ended December 31, 2002 was $1.85 based on weighted average common shares outstanding of 8.5 million, compared to a net loss per share of $1.56 based on weighted average common shares outstanding of 7.8 million for the same period in 2001.

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COMMITMENTS

We have entered into various contractual obligations and commercial commitments. The following table summarizes our contractual obligations as of December 31, 2003:

Contractual Obligation	Less than 1 year	1 to 3 years	4 to 5 years	After 5 years	Total
			(All amounts in thousands)		
Long-term debt[1]	$	$ 2,280	$	$	$ 2,280
Capital lease obligations	76	6			82
Facility leases	607	395			1,002
Other operating leases	9				9
Manufacturing and research and development contracts[2]	4,649	4,507	260	1,010	10,426
Investor relations and consulting services	834	128			962
Capital contribution to joint venture[3]	4,200				4,200
Minimum royalty payments[4]	1,000	2,000	2,000	4,833	9,833
Total	$ 11,375	$ 9,316	$ 2,260	$ 5,843	$ 28,794

(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 for the first 24 months; thereafter, interest is payable in cash. The note contains certain non-financial covenants, with which we are in compliance as of December 31, 2003.

(2) As a result of our recent reacquisition of marketing rights to QUADRAMET, we assumed all of Berlex s obligations under a manufacturing and supply agreement with BMSMI, including an obligation to pay manufacturing costs. Effective January 1, 2004, we entered into a new manufacturing and supply agreement with BMSMI whereby BMSMI will manufacture, distribute and provide 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 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 2005.

(3) In 2004, we expect to provide $4.2 million in funding for the development of PSMA technologies through our joint venture with Progenics. Such funding amount in subsequent periods may vary dependent upon, among other things, the results of the joint venture s clinical trials and research and development activities, competitive and technological developments, and market opportunities.

(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 payment upon achievement of certain milestones. Future annual minimum royalties due to Dow are $1.0 million per year in 2004 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.

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LIQUIDITY AND CAPITAL RESOURCES

Condensed Statement of Cash Flows:

	2003
	(All amounts in thousands)
Net loss	$ (9,358)
Adjustment to reconcile net loss to net cash used in operating activities	(1,185)
Cash used in operating activities	(10,543)
Cash used in investing activities	(24,669)
Cash provided by financing activities	34,117
Net change in cash and cash equivalents	$ (1,095)

Our cash and cash equivalents were $13.6 million as of December 31, 2003, compared to $14.7 million as of December 31, 2002. The decrease in 2003 from 2002 was primarily due to increased operating cash usage and purchases of short term investments and product rights, partially offset by proceeds from the sales of our common stock. In 2003, 2002 and 2001, the cash used for operating activities was $10.5 million, $8.3 million, and $13.4 million, respectively. The 2003 increase from 2002 was primarily due to our build-up of PROSTASCINT inventories during 2003 and to increased funding to our joint venture, the PSMA Development Company LLC. The 2002 decrease from 2001 was primarily due to improved working capital management, which included a build-up of PROSTASCINT inventory in 2001 compared to a reduction in 2002. In 2004, we expect operating expenditures to increase over 2003 levels.

Overview

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.

2003 Capital Raising Events

In 2003, we received $888,000 relating to the sales of a portion of our New Jersey state net operating loss and research and development credit carryforwards. 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.

In June 2003, we entered into a securities purchase agreement pursuant to which we sold 1,052,632 shares of our 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, we issued to the investors warrants to purchase 315,790 shares of our common stock with an exercise price of $6.91 per share. The warrants are exercisable until June 6, 2008.

In July 2003, we entered into a securities purchase agreement pursuant to which we sold 1,172,332 shares of our 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, we issued to the investors warrants to purchase 1,172,332 shares of our common stock with an exercise price of $12.80 per share. In addition, we also issued: (i) warrants to purchase 100,000 shares of our 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 our common stock at an exercise price of $10.97 per share, to certain of our stockholders, in connection with such stockholders waiver of certain rights in connection with this financing. All warrants issued

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in connection with this financing are exercisable until July 10, 2008 and become automatically exercised, in full, if the closing price of our 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 written notice by us of such automatic exercise, the holders of the warrants must exercise such warrants by paying us the exercise price times the number of shares of common stock issuable upon exercise. The net proceeds from this financing were used for our reacquisition of QUADRAMET marketing rights from Berlex and related expenses.

On October 29, 2003, we filed a shelf registration statement on Form S-3 (File No. 333-110040) with the Securities and Exchange Commission relating to the registration of up to an aggregate of $60.0 million in shares of our common stock. The SEC declared the registration statement effective on October 30, 2003. On November 6, 2003, we issued and sold an aggregate of 1,863,637 shares of our common stock pursuant to this shelf registration statement at a price of $11.00 per share to certain institutional investors for net proceeds of $20.4 million.

As of December 31, 2003, our total cash, cash equivalents and short term investments were $30.2 million.

Other Liquidity Events

In August 2003, we paid to Berlex an up-front payment of $8.0 million to reacquire the marketing rights to QUADRAMET. Accordingly, effective August 1, 2003, we began recording product 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, which we fulfilled through December 31, 2003. Effective January 1, 2004, we entered into a new manufacturing and supply agreement with BMSMI whereby BMSMI will manufacture, distribute and provide 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 through 2008, unless terminated by BMSMI or us on two years 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. We also pay BMSMI a variable amount per month for each QUADRAMET order placed to cover the costs of customer service and distribution. In addition, we expect our QUADRAMET sales and marketing expenses to increase, which may result in an increase in our sales and product gross margin.

We have historically relied upon revenues from sales of the BRACHYSEED products to partially fund ongoing operations. For the years ended December 31, 2003 and 2002, revenue from the sale of BRACHYSEED products was $240,000 and $2.5 million, respectively. In January 2003, we served notice of termination of our agreements with Draximage, and in April 2003, entered into an agreement with Draximage to formally terminate each of our license and distribution agreement and product manufacturing and supply agreement with respect to both the BRACHYSEED I-125 and BRACHYSEED Pd-103 products. As of January 24, 2003, we no longer accept or fill new orders for the BRACHYSEED products.

In September 2003, Antisoma acquired certain royalty rights to Antisoma s lead product, R1549 (formerly Pemtumomab), from us. In connection with Antisoma s acquisition of such rights, Antisoma made a cash payment to us of $500,000 and has agreed to make an additional payment of $500,000 upon the first commercial sale, if any, of the R1549 product. In return, we relinquished our right to receive royalties equivalent to 1.65% of future net sales, if any, of the R1549 product.

Beginning in December 2001, we began to equally share the costs of the joint venture with Progenics. In 2003, we contributed an additional $4.0 million to the joint venture and expect to fund $4.2 million in 2004. We have not committed to fund the joint venture beyond December 31, 2004 at this time, but for existing contractual commitments as of that date. We may incur significant and increasing costs in the future to fund our

share of the development costs from the joint venture. Such funding amount in subsequent periods may vary depending upon, among other things, the results of the clinical trials and research and development activities, competitive and technological developments, and market opportunities.

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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 payment upon achievement of certain milestones. Future annual minimum royalties due to Dow are $1.0 million per year in 2004 through 2012 and $833,000 in 2013.

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

We have incurred negative cash flows from operations since our inception, and have expended, and expect to continue to expend in the future, substantial funds to implement our planned product development efforts, including acquisition of products and complementary technologies, research and development, clinical studies and regulatory activities, and to further our marketing and sales programs. We expect that our existing capital resources should be adequate to fund our operations and commitments at least into the middle of 2005. 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 this Annual Report on Form 10-K for the year ended December 31, 2003 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.

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Revenue Recognition

Product related revenues include product sales by Cytogen to its customers and QUADRAMET royalties. Product sales are recognized when products are shipped, which is when the customer takes ownership 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. The Company does not grant price protection to its customers.

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 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

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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.

Recently Enacted Accounting Pronouncements

In December 2003, the Financial Accounting Standards Board (FASB) issued FASB Interpretation No. 46 (revised December 2003), 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 replaces FASB Interpretation No. 46, which was issued in January 2003. We are 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, the Interpretation will be 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 would be 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. We are currently evaluating the impact, if any, that the adoption of FIN 46R will have on our consolidated financial statements.

FASB Statement No. 150, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity, was issued in May 2003. This Statement establishes standards for the classification and measurement of certain financial instruments with characteristics of both liabilities and equity. The Statement also includes required disclosures for financial instruments within its scope. For us, the Statement was effective for instruments entered into or modified after May 31, 2003. For certain mandatorily redeemable financial instruments, the Statement will be effective for us at a later date. We currently do not have any financial instruments that are within the scope of this Statement.

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 or investment portfolio. As of December 31, 2003, the Company 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. In addition, financial statements and notes thereto relating to the PSMA Development Company LLC are attached as Exhibit 99.1 to this Annual Report on Form 10-K.

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

The information required to be disclosed under this Item regarding former accountants was previously reported by us on: (i) a Current Report on Form 8-K filed with the Securities and Exchange Commission on May 20, 2002, and an amendment thereto filed with the Securities and

Exchange Commission on May 22, 2002; and (ii) a Current Report on Form 8-K filed with the Securities and Exchange Commission on May 24, 2002.

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Item 9A. Controls and Procedures

(1) *Evaluation of disclosure controls and procedures*. Our management, with the participation of our chief executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2003. In designing and evaluating our disclosure controls and procedures, our 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, 2003, our disclosure controls and procedures were (1) designed to ensure that material information relating to us, including our consolidated subsidiaries, is made known to our chief executive officer and chief financial officer by others within those entities, particularly during the period in which this report was being prepared and (2) effective, in that they provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms.

(2) *Changes in internal controls*. 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 December 31, 2003 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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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 Compliance with Section 16(a) of the Exchange Act in our definitive proxy statement for the 2004 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 will make available our code of business conduct and ethics 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 2004 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 2004 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 2004 Annual Meeting of Stockholders is incorporated herein by reference to such proxy statement.

Item 14. Principal Accountant Fees and Services

The discussion under the heading Principal Accountant Fees and Services in our definitive proxy statement for the 2004 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	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, and incorporated herein by reference.
3.2	Certificate of Amendment to the Restated Certificate of Incorporation of Cytogen Corporation, as amended. Filed as an exhibit to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2000, and incorporated herein by reference.
3.3	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, filed with the Commission on October 25, 2002, and incorporated herein by reference.
3.4	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 (File No. 333-59718), filed with the Commission on April 27, 2001, and incorporated herein by reference.
3.5	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	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, 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 Year Ended January 2, 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 (No. 33-30595), and incorporated herein by reference.
10.2	1989 Employee Stock Option Plan. Filed as an exhibit to Company s Registration Statement on Form S-8 (No. 33-30595), 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 (No. 33-30595), 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, and incorporated herein by reference. +

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Exhibit No.	
10.4	Standard Form of Indemnification Agreement entered into between Cytogen Corporation and its officers, directors, and consultants. Filed as an exhibit to Amendment No. 1 to the Company s Registration Statement on Form S-1 (No. 33-31280), and incorporated herein by reference. +
10.5	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 (No. 33-31280), and incorporated herein by reference. +
10.6.1	License Agreement dated as of 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, and incorporated herein by reference.*
10.6.2	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, and incorporated herein by reference.*
10.6.3	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, and incorporated herein by reference.*
10.7	1992 Cytogen Corporation Employee Stock Option Plan II, as amended. Filed as an exhibit to the Company s Registration Statement on Form S-4 (No. 33-88612), and incorporated herein by reference. +
10.8	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, and incorporated herein by reference.*
10.9	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, and incorporated herein by reference.*
10.10	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. +
10.11	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, and incorporated herein by reference.*
10.12.1	Marketing and Co-Promotion Agreement between Cytogen Corporation and C.R. Bard, Inc. effective August 1, 1996. Filed as an exhibit to the Company s Quarterly Report on Form 10-Q for the quarter ended September 30, 1996, and incorporated herein by reference.*
10.12.2	Amendment No. 1 to Marketing and Co-Promotion Agreement effective as of January 1, 2000 by and between Cytogen Corporation and C.R. Bard, Inc. Filed as an exhibit to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2000, and incorporated herein by reference.
10.13	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, and incorporated herein by reference. +
10.14	Cytogen Corporation Amended and Restated Employee Stock Purchase 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. +

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Exhibit No.	
10.15	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, and incorporated herein by reference.*
10.16	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, and incorporated herein by reference.
10.17	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, and incorporated herein by reference. +
10.18	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, and incorporated herein by reference.
10.19	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, filed with the Commission on January 27, 1999, and incorporated herein by reference.
10.20	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.
10.21	Strategic Alliance Agreement between AxCell Biosciences Corporation and InforMax, Inc. dated as of September 15, 1999. Filed as an exhibit to Form 10-K Annual Report for the year ended December 31, 1999, and incorporated herein by reference.*
10.22	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, and incorporated herein by reference. +
10.23	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, and incorporated herein by reference.
10.24	License and Marketing Agreement by and between Cytogen Corporation and Advanced Magnetics, Inc. dated August 25, 2000. Filed as an exhibit to the Company s Quarterly Report on Form 10-Q for the quarter ended September 30, 2000, and incorporated herein by reference.*
10.25	Development and Manufacturing Agreement by and between Cytogen Corporation and DSM Biologics Company B.V. dated July 12, 2000. Filed as an exhibit to the Company s Quarterly Report on Form 10-Q for the quarter ended September 30, 2000, and incorporated herein by reference.*
10.26	Written Compensatory Agreement by and between Cytogen Corporation and H. Joseph Reiser dated August 24, 1998, as revised on July 11, 2000. Filed as an exhibit to the Company s Registration Statement on Form S-8 (File No. 333-48454), filed with the Commission on October 23, 2000, and incorporated herein by reference. +
10.27	Written Compensatory Agreement by and between Cytogen Corporation and Lawrence Hoffman dated July 10, 2000. Filed as an exhibit to the Company s Registration Statement on Form S-8 (File No. 333-48454), filed with the Commission on October 23, 2000, and incorporated herein by reference. +

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Exhibit No.	
10.28	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, and incorporated herein by reference. *
10.29	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, and incorporated herein by reference. *
10.30	Form of Executive Change of Control Severance Agreement by and between the Company and each of its Executive Officers. Filed as an exhibit to the Company s Annual Report on Form 10-K for the year ended December 31, 2001, and incorporated herein by reference. +
10.31.1	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, and incorporated herein by reference.
10.31.2	First Amendment to the Lease Agreement by and between 826 Newtown Associates, L.P. and AxCell Biosciences Corporation dated as of March 16, 2001. Filed as an exhibit to the Company s Quarterly Report on Form 10-Q for the quarter ended March 31, 2001, and incorporated herein by reference.
10.32	Cytogen Corporation Stock Payment Program Bonus Plan. Filed as an exhibit to the Company s Registration Statement on Form S-8 (File No. 333-58384), filed with the Commission on April 6, 2001, and incorporated herein by reference. +
10.33	MFS Fund Distributors, Inc. 401(K) Profit Sharing Plan and Trust. Filed as an exhibit to the Company s Registration Statement on Form S-8 (File No. 333-59718), filed with the Commission on April 27, 2001, and incorporated herein by reference. +
10.34	Adoption Agreement for MFS Fund Distributors, Inc. Non-Standardized 401(K) Profit Sharing Plan and Trust, with amendments. Filed as an exhibit to the Company s Registration Statement on Form S-8 (File No. 333-59718), filed with the Commission on April 27, 2001, and incorporated herein by reference.
10.35	Cytogen Corporation Performance Bonus Plan with Stock Payment Program. Filed as an exhibit to Company s Registration Statement on Form S-8 (File No. 333-75304), filed with the Commission on December 17, 2001, and incorporated herein by reference. +
10.36	Share Purchase Agreement by and between Cytogen Corporation and the State of Wisconsin Investment Board dated as of June 18, 2001. Filed as an exhibit to the Company s Current Report on Form 8-K, filed with the Commission on June 19, 2001, and incorporated herein by reference.
10.37	Share Purchase Agreement by and between Cytogen Corporation and the State of Wisconsin Investment Board dated as of January 18, 2002. Filed as an exhibit to the Company s Current Report on Form 8-K, filed with the Commission on January 24, 2002, and incorporated herein by reference.
10.38.1	Limited Liability Company Agreement of PSMA Development Company LLC by and between 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, filed with the Commission on July 20, 1999, and incorporated herein by reference.
10.38.2	Amendment No. 1 to Limited Liability Company Agreement of PSMA Development Company LLC by and between 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, filed with the Commission on May 14, 2002, and incorporated herein by reference.

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Exhibit No.	
10.39.1	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, filed with the Commission on August 14, 2002, and incorporated herein by reference.
10.40	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, filed with the Commission on August 14, 2002, and incorporated herein by reference.
10.41	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. *
10.42	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. +
10.43	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. *
10.44	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. *
10.45	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, filed with the Commission on June 9, 2003, and incorporated herein by reference.
10.46	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, filed with the Commission on June 9, 2003, and incorporated herein by reference.
10.47	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, filed with the Commission on June 9, 2003, and incorporated herein by reference.
10.48	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, filed with the Commission on July 11, 2003, and incorporated herein by reference.
10.49	Form of Common Stock Purchase Warrant issued by the Company 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, filed with the Commission on July 11, 2003, and incorporated herein by reference.

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Exhibit No.	
10.50	Registration Rights Agreement by and among the Company 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, filed with the Commission on July 11, 2003, and incorporated herein by reference.
10.51	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, filed with the Commission on November 7, 2003, and incorporated herein by reference.
10.52	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, filed with the Commission on November 12, 2003, and incorporated herein by reference. **
10.53	Termination Agreement between Cytogen and Berlex Laboratories, Inc., dated June 16, 2003. Filed as an exhibit to the Company s Quarterly Report on Form 10-Q, filed with the Commission on November 12, 2003, and incorporated herein by reference. **
10.54	Assignment Agreement between Cytogen and Berlex Laboratories, Inc., dated August 1, 2003. Filed as an exhibit to the Company s Quarterly Report on Form 10-Q, filed with the Commission on November 12, 2003, and incorporated herein by reference. **
14.1	Code of Business Conduct and Ethics of Cytogen Corporation adopted by the Company as of March 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.
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, 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, 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 Section 302 of the Sarbanes-Oxley Act of 2002. Filed herewith.
31.2	Certification of Vice President and Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. Filed herewith.
32.1	Certification of President and Chief Executive Officer pursuant to pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. Filed herewith.
32.2	Certification of Vice President and Chief Financial Officer pursuant to 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.	
99.1	Financial Statements of the PSMA Development Company LLC and notes thereto. 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) Reports on Form 8-K:

On November 3, 2003, we filed a Current Report on Form 8-K with the Securities and Exchange Commission reporting the amendment of our Distribution Agreement with Matritech, Inc.

On November 5, 2003, we furnished a Current Report on Form 8-K with the Securities and Exchange Commission reporting the Company s results of operations for the quarter ended September 30, 2003.

On November 7, 2003, we filed a Current Report on Form 8-K with the Securities and Exchange Commission reporting the sale and issuance of shares of the Company s common stock to certain investors.

(c) Exhibits:

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

(d) 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 12th day of March 2004.

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 **Michael D. Becker**	Chief Executive Officer and President (Principal Executive Officer and Director)	March 12, 2004
By:	/s/ CHRISTOPHER P. SCHNITTKER **Christopher P. Schnittker**	Vice President, Chief Financial Officer (Principal Financial and Accounting Officer)	March 12, 2004
By:	/s/ JOHN E. BAGALAY, JR. **John E. Bagalay, Jr.**	Director	March 12, 2004
By:	/s/ ALLEN BLOOM **Allen Bloom**	Director	March 12, 2004
By:	/s/ STEPHEN K. CARTER **Stephen K. Carter**	Director	March 5, 2004
By:	/s/ JAMES A. GRIGSBY **James A. Grigsby**	Director and Chairman of the Board	March 8, 2004
By:	/s/ ROBERT F. HENDRICKSON **Robert F. Hendrickson**	Director	March 12, 2004
By:	/s/ KEVIN G. LOKAY **Kevin G. Lokay**	Director	March 10, 2004
By:	/s/ H. JOSEPH REISER **H. Joseph Reiser**	Director	March 12, 2004

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

CYTOGEN CORPORATION AND SUBSIDIARIES

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INDEPENDENT AUDITORS REPORT

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, 2003 and 2002 and the related consolidated statements of operations, stockholders equity and comprehensive loss, and cash flows for the years then ended. 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 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 $3.5 million and $2.9 million for the years ended December 31, 2003 and 2002, 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 consolidated financial statements of Cytogen Corporation and subsidiaries for the year ended December 31, 2001, were audited by other auditors who have ceased operations. Those auditors report dated February 5, 2002, on those consolidated financial statements was unqualified before the restatement described in Note 1 to the consolidated financial statements, and included an explanatory paragraph that described the change in Cytogen Corporation s method of accounting for revenue recognition discussed in Note 1 to the consolidated financial statements.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. 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 other auditors provide a reasonable basis for our opinion.

In our opinion, based on our audits and the report of other auditors, the 2003 and 2002 consolidated financial statements referred to above present fairly, in all material respects, the financial position of Cytogen Corporation and subsidiaries as of December 31, 2003 and 2002, and the results of their operations and their cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

As discussed above, the consolidated financial statements of Cytogen Corporation and subsidiaries for the year ended December 31, 2001, were audited by other auditors who have ceased operations. As described in Note 1, the Company implemented a reverse stock split in 2002, and the number of shares and per share amounts in the accompanying 2001 consolidated financial statements have been restated to reflect such reverse stock split. We audited the adjustments that were applied to restate the number of shares and per share amounts reflected in the 2001 consolidated financial statements for the reverse stock split. In our opinion, such adjustments are appropriate and have been properly applied. However, we were not engaged to audit, review or apply any procedures to the 2001 consolidated financial statements of Cytogen Corporation and subsidiaries, other than with respect to such adjustments and, accordingly, we do not express an opinion or any form of assurance on the 2001 consolidated financial statements taken a whole.

/s/ KPMG LLP

Princeton, New Jersey

February 26, 2004

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THE FOLLOWING IS A COPY OF A REPORT ISSUED BY ARTHUR ANDERSEN LLP, AND INCLUDED IN CYTOGEN CORPORATION S ANNUAL REPORT ON FORM 10-K FOR THE YEAR ENDED DECEMBER 31, 2001. THIS REPORT HAS NOT BEEN REISSUED BY ARTHUR ANDERSEN, AND ARTHUR ANDERSEN HAS NOT CONSENTED TO ITS USE IN THIS ANNUAL REPORT ON FORM 10-K FOR THE YEAR ENDED DECEMBER 31, 2003. ALL NUMBERS SET FORTH IN THIS FORM 10-K REFLECT THE EFFECT OF A ONE-FOR-TEN REVERSE STOCK SPLIT EFFECTIVE OCTOBER 25, 2002.

REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS

To Cytogen Corporation:

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

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

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

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

ARTHUR ANDERSEN LLP

Philadelphia, Pennsylvania

February 5, 2002

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Report of Independent Auditors

To the Members of the

PSMA Development Company LLC:

In our opinion, the accompanying balance sheets and the related statements of operations, of stockholders (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, 2002 and 2003, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2003 and the cumulative period from June 15, 1999 (inception) to December 31, 2003, 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 financial statements in accordance with auditing standards generally accepted in the United States of America which require that we plan and perform the audits 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.

/s/ PricewaterhouseCoopers LLP

New York, New York

February 26, 2004

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CYTOGEN CORPORATION AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

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

	December 31,	
	2003	**2002**
ASSETS:		
Current assets:		
Cash and cash equivalents	$ 13,630	$ 14,725
Short-term investments	16,585	
Accounts receivable, net	1,445	1,778
Inventories	1,887	1,262
Other current assets	975	643
Total current assets	34,522	18,408
Property and equipment, net	595	1,072
QUADRAMET license fee, net	7,720	
Other assets	858	414
	$ 43,695	$ 19,894
LIABILITIES AND STOCKHOLDERS EQUITY:		
Current liabilities:		
Current portion of long-term liabilities	$ 76	$ 80
Accounts payable and accrued liabilities	5,125	4,427
Deferred revenue		385
Total current liabilities	5,201	4,892
Long-term liabilities	2,454	2,614
Deferred revenue		1,800
Commitments and Contingencies (Note 19)		
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, 12,857,488 and 8,758,235 shares issued and outstanding at December 31, 2003 and 2002, respectively	129	88
Additional paid-in capital	401,649	366,884
Deferred compensation		(4)
Accumulated deficit	(365,738)	(356,380)
Total stockholders equity	36,040	10,588

	$ 43,695	$ 19,894

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,		
	2003	**2002**	**2001**
Revenues:			
Product related:			
PROSTASCINT	$ 6,523	$ 7,923	$ 7,640
QUADRAMET	2,765		
NMP22 BLADDERCHEK	295	14	
BRACHYSEED	240	2,507	779
ONCOSCINT		182	363
Total product sales	9,823	10,626	8,782
QUADRAMET royalties	1,105	1,842	2,063
Total product related	10,928	12,468	10,845
License and contract	2,914	463	912
Total revenues	13,842	12,931	11,757
Operating Expenses:			
Cost of product related revenues	6,268	4,748	4,216
Selling, general and administrative	11,550	11,247	11,178
Research and development	2,659	7,605	10,091
Equity in loss of joint venture	3,452	2,886	332
Impairment of intangible assets	115	1,729	
Total operating expenses	24,044	28,215	25,817
Operating loss	(10,202)	(15,284)	(14,060)
Interest income	141	274	635
Interest expense	(185)	(173)	(180)
Loss on investment		(516)	
Insurance reimbursement			402
Loss before income taxes	(10,246)	(15,699)	(13,203)
Income tax benefit	(888)		(1,103)
Net loss	$ (9,358)	$ (15,699)	$ (12,100)
Basic and diluted net loss per share	$ (0.92)	$ (1.85)	$ (1.56)
Weighted average common shares outstanding	10,205	8,466	7,778

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	Deferred	Accumulated Other Comprehensive	Accumulated	Total Stockholders
	Shares	Amount	Capital	Compensation	Income	Deficit	Equity
Balance, December 31, 2000	7,559,444	$ 76	$ 336,618	$ (895)	$	$ (328,581)	$ 7,218
Sale of shares of common stock including exercise of stock options	324,149	3	14,235				14,238
Issuance of shares of common stock and stock options related to compensation	10,141		282				282
Issuance of options and warrants to purchase shares of common stock			201				201
Deferred compensation related to stock options			241	(241)			
Amortization of deferred compensation				515			515
Comprehensive loss:							
Net loss						(12,100)	(12,100)
Unrealized gain on marketable securities					860		860
Total comprehensive loss							(11,240)
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						(9,358)	(9,358)
Balance, December 31, 2003	12,857,488	$ 129	$ 401,649	$	$	$ (365,738)	$ 36,040

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,		
	2003	**2002**	**2001**
Cash Flows From Operating Activities:			
Net loss	$ (9,358)	$ (15,699)	$ (12,100)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	822	779	1,186
Imputed interest income			(43)
Stock-based compensation expenses	515	655	809
Stock-based milestone payment		2,033	
Amortization of deferred revenue	(2,185)	(410)	(860)
Asset impairment	115	2,446	
Loss on investment		516	
Loss on disposition of assets	28		
Changes in assets and liabilities:			
Receivables, net	333	946	263
Inventories	(625)	627	(1,006)
Other assets	(921)	548	24
Accounts payable and accrued liabilities	733	(692)	(1,714)
Net cash used in operating activities	(10,543)	(8,251)	(13,441)
Cash Flows From Investing Activities:			
Purchases of property and equipment	(84)	(148)	(813)
Purchase of product rights	(8,000)	(1,150)	(500)
Net proceeds from sale of property and equipment		100	
Purchase of short-term investments	(16,585)		
Net cash used in investing activities	(24,669)	(1,198)	(1,313)
Cash Flows From Financing Activities:			
Proceeds from issuance of common stock	34,281	12,973	14,238
Payments of long-term liabilities	(164)	(108)	(168)
Net cash provided by financing activities	34,117	12,865	14,070
Net increase (decrease) in cash and cash equivalents	(1,095)	3,416	(684)
Cash and cash equivalents, beginning of year	14,725	11,309	11,993
Cash and cash equivalents, end of year	$ 13,630	$ 14,725	$ 11,309

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, oncology-focused biopharmaceutical company that licenses, develops and commercializes both therapeutic and molecular imaging/diagnostic products that address the unmet medical needs of physicians and the patients they serve. The Company directly markets QUADRAMET™ (samarium Sm-153 lexidronam injection), PROSTASCINT® (capromab pendetide) kit for the preparation of Indium In-111 capromab pendetide, and NMP22® BLADDERCHEK® (nuclear matrix protein-22) in the United States. The Company also has exclusive United States marketing rights to COMBIDEX® (ferumoxtran-10), which is under review by the U.S. Food and Drug Administration. 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 BRACHYSEED and ONCOSCINT CR/OV, that the Company previously believed would generate significant revenues for its business. 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 products for the Company to sell and market to others.

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

Statements of Cash Flows

Cash and cash equivalents include cash on hand, cash in banks and all highly-liquid investments with a maturity of three months or less at the time of purchase. Cash paid for interest expense was $185,000, $169,000 and $180,000 in 2003, 2002 and 2001, respectively. During 2003, 2002 and 2001, the Company purchased $0, $189,000 and $11,000, respectively, of equipment under various capital leases.

Short-Term Investments

Short-term investments at December 31, 2003 were $16.6 million and consisted of U.S. Government Agency Discount Notes. The Company has the ability and intent to hold these securities until maturity. Held-to-

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CYTOGEN CORPORATION AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

maturity securities are recorded at amortized cost, adjusted for the accretion of discounts. Discounts are accreted over the life of the related security on a straight-line basis. Dividend and interest income are recognized when earned. These securities mature at various times until December 2004.

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 monthly. Past due balances over 90 days and over a specified amount are reviewed individually 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 does not have any off-balance-sheet credit exposure related to its customers.

At December 31, 2003 and 2002, accounts receivable were net of an allowance for doubtful accounts of $67,000 and $30,000, respectively. Expense charged to the provision for doubtful accounts during 2003, 2002 and 2001 was $37,000, $0 and $0, respectively. The Company wrote off $5,000 of uncollectible accounts in 2001 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,	
	2003	2002
	(All amounts in thousands)	
Raw materials	$ 11	$ 506
Work-in process	1,089	39
Finished goods	787	717
	$ 1,887	$ 1,262

Property and Equipment

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

	December 31,	
	2003	2002
	(All amounts in thousands)	
Leasehold improvements	$ 103	$ 103
Equipment and furniture	2,383	2,420
	2,486	2,523
Less accumulated depreciation and amortization	(1,891)	(1,451)
	$ 595	$ 1,072

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CYTOGEN CORPORATION AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

In 2002, the Company wrote off approximately $1.7 million of fully depreciated property and equipment, and sold $5.3 million of its manufacturing property and equipment which had a net value of $100,000 to Bard BioPharma L.P., a subsidiary of Purdue Pharma L.P., for proceeds of $100,000. Depreciation expense was $512,000, $600,000 and $1.2 million, in 2003, 2002, and 2001, 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. 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 10). In 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 I-125 and BRACHYSEED Pd-103 (see Note 4).

Other Assets

Other assets consisted of the following:

	December 31,	
	2003	**2002**
	(All amounts in thousands)	
Investment in PSMA Development Co. LLC (Note 6)	$ 550	$ 1
NMP22 BLADDERCHEK license fee, net (Note 10)		145

Other	308	268
	$ 858	$ 414

Revenue Recognition

Product related revenues include product sales by Cytogen to its customers and QUADRAMET royalties. Product sales are recognized when products are shipped, which is when the customer takes ownership 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. The Company does not grant price protection to its customers.

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.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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, 2002 and 2001, the Company recognized $2.2 million, $410,000 and $860,000 in revenues, respectively, 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) 00-10, the Company records shipping and handling charges billed to customers as revenue and the related costs as cost of product sales.

Research and Development

Research and development expenditures consist of projects conducted by the Company and payments made to sponsored research programs and consultants. All research and development costs are charged to expense as incurred. Research and development expenditures for customer sponsored programs were $214,000, $53,000 and $17,000 in 2003, 2002 and 2001, respectively.

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 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 based upon the weighted average common shares outstanding during each period. Diluted net loss per common share is the same as basic net loss per share, because the inclusion of common stock equivalents, which consist of stock warrants and options, would be antidilutive due to the Company s losses (see Notes 14 and 15).

Reverse Stock Split

In October 2002, upon the receipt of approval of the Company s stockholders, the Company s Board of Directors authorized and implemented a reverse stock split (the Reverse Split) of Cytogen s issued,

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

outstanding and authorized shares of common stock at a ratio of one-for-ten. All references to the number of shares and per share amounts in the accompanying consolidated financial statements and notes to consolidated financial statements have been retroactively restated to reflect the Reverse Split.

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.

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

	Year Ended December 31,		
	2003	2002	2001
	(All amounts in thousands, except per share data)		
Net loss, as reported	$ (9,358)	$ (15,699)	$ (12,100)
Add: Stock-based employee compensation expense included in reported net loss	3	184	515
Deduct: Total stock-based employee compensation expense determined under fair value-based method for all awards	(1,506)	(4,000)	(5,838)
Pro forma net loss	$ (10,861)	$ (19,515)	$ (17,423)
Basic and diluted net loss per share, as reported	$ (0.92)	$ (1.85)	$ (1.56)
Pro forma basic and diluted net loss per share	$ (1.06)	$ (2.31)	$ (2.24)

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

In December 2003, the Financial Accounting Standards Board (FASB) issued FASB Interpretation No. 46 (revised December 2003), 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 replaces FASB Interpretation No. 46 which was issued in January 2003. The Company is required to apply FIN 46R to variable interests in VIEs created after December 31, 2003. For variable interests in VIEs create before January 1, 2004, the Interpretation will be applied beginning on March 31, 2004. For any VIEs that must be consolidated under FIN 46R that were

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

created before January 1, 2004, the assets, liabilities and noncontrolling interests of the VIE initially would be 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. The Company is currently evaluating the impact, if any, that the adoption of FIN 46R will have on the Company s consolidated financial statements.

FASB Statement No. 150, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity, was issued in May 2003. This Statement establishes standards for the classification and measurement of certain financial instruments with characteristics of both liabilities and equity. The Statement also includes required disclosures for financial instruments within its scope. For the Company, the Statement was generally effective for instruments entered into or modified after May 31, 2003. For certain mandatorily redeemable financial instruments, the Statement will be effective for the Company at a later date. The Company currently does not have any financial instruments that are within the scope of this Statement.

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 and 2001, the Company recorded $551,000 and $3.2 million, respectively, 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. As of December 31, 2002, Cytogen had a liability recorded of $730,000 in the accompanying consolidated balance sheet to DSM. As a result of the Settlement Agreement, Cytogen recorded an expense reversal of $580,000 to research and development 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 novel diagnostic pharmaceuticals for use in magnetic resonance imaging (MRI), entered into marketing, license and supply agreements (AVM Agreements). Under the AVM Agreements, Cytogen acquired

certain rights in the United States to Advanced Magnetics product candidates: COMBIDEX®, an MRI contrast agent for the detection of lymph node metastases (for all applications) and imaging agent ferumoxytol (formerly referred to as Code 7228) for oncology applications only. Advanced Magnetics will be responsible for all costs associated with the clinical development, 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 are being held in escrow pending the achievement of certain milestones relating to COMBIDEX and

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

25,000 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. At this time, Advanced Magnetics does not intend to develop ferumoxytol for oncology imaging.

4. DRAXIMAGE INC.

In December 2000, the Company entered into a product manufacturing and supply agreement and a license and distribution agreement (collectively, the Draximage Agreements) with Draximage, Inc. to market and distribute BRACHYSEED implants for prostate cancer therapy in the United States. 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 $500,000 upon execution of the Draximage Agreements in 2000, $500,000 upon the first sale of the Iodine-125 BRACHYSEEDs in 2001 and $1.0 million related to the first sale of BRACHYSEED Pd-103 in 2002. 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 I-125 and BRACHYSEED Pd-103. Prior to the write-off of such licensing rights, amortization expense was $174,000 and $93,000 in 2002 and 2001, respectively. The Company also recorded $503,000 and $113,000 in royalty expense for 2002 and 2001, respectively. 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. 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. (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. As discussed above, through November 2001, Progenics was obligated to fund the initial $3.0 million of the development costs. Beginning in December 2001, Cytogen began to recognize 50% of the Joint Venture s losses in its consolidated statement of operations. For the years ended December 31, 2003, 2002 and 2001, Cytogen recognized $3.5 million, $2.9 million and $332,000 in losses of the Joint Venture, respectively. As of December 31, 2003 and 2002, the carrying value of the Company s investment in the Joint Venture was $550,000 and $1,000, respectively, 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). Selected financial statement information of the Joint Venture is as follows:

Balance Sheet Data:

	December 31,	
	2003	**2002**
	(All amounts in thousands)	
Cash	$ 1,173	$ 290
Accounts receivable from Progenics Pharmaceuticals, a related party	108	
Total assets	$ 1,281	$ 290
Accounts payable to Progenics Pharmaceuticals, a related party	$	$ 304
Accounts payable and accrued expenses	199	
Total liabilities	199	304
Capital contributions	19,398	11,399
Accumulated deficit	(18,316)	(11,413)
Total stockholders equity (deficit)	1,082	(14)
Total liabilities and stockholders equity (deficit)	$ 1,281	$ 290

Income Statement Data:

	For the Year Ended			For the Period From June 15, 1999 (inception) to
	2003	**2002**	**2001**	**December 31, 2003**

	(All amounts in thousands)			
Interest income	$ 5	$ 13	$ 47	$ 234
Total expenses	6,908	5,786	2,623	18,550
Net loss	$ (6,903)	$ (5,773)	$ (2,576)	$ (18,316)

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, $150,000 and $599,000 of the deferred revenue as license and contract revenue in 2003, 2002 and 2001, respectively. The deferred revenue has been fully recognized as of December 31, 2003.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 contractual minimum payments, whichever is greater, and future payments upon achievement of certain milestones. The Company recorded $1.0 million, $1.0 million and $824,000 in royalty expense for 2003, 2002 and 2001, respectively. Future annual minimum royalties due to Dow are $1.0 million per year in 2004 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 a 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. During 2003, Cytogen recorded $280,000 of such amortization as cost of product related revenues in the accompanying consolidated statement of operations. Cytogen also recorded $455,000 of royalty expenses to Berlex based on its sales of QUADRAMET in 2003 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, $260,000 and $260,000 of the deferred revenues in 2003, 2002 and 2001, respectively.

9. BRISTOL-MYERS SQUIBB MEDICAL IMAGING, INC.

As a result of the Company s recent 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 services for Cytogen relating to QUADRAMET. Under the terms of the new agreement, Cytogen is obligated to pay at least $4.2 million annually through 2008, unless terminated by BMSMI or Cytogen on 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. The Company also pays BMSMI a variable amount per month for each order of QUADRAMET placed to cover the costs of customer service and distribution.

10. 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

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CYTOGEN CORPORATION AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

States. In October 2003, Matritech and Cytogen executed an Amended and Restated Distribution Agreement (the Restated Agreement) modifying the Distribution Agreement. Under the terms of the Restated 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 Agreement. The term of the Restated Agreement expires on December 31, 2004 and is renewable annually thereafter upon the mutual consent of the parties. The parties also have agreed to remove the requirement that Cytogen sell a minimum quantity of NMP22 BLADDERCHEK in order to maintain its exclusivity.

The Company paid Matritech a non-refundable licensing fee of $150,000 upon the execution of the Distribution Agreement in 2002, which was recorded as other assets in the accompanying consolidated balance sheet and was being amortized over the five year estimated performance period of the Distribution Agreement. The amortization expense was $30,000 and $5,000 in 2003 and 2002, respectively. As a result of entering into the Restated 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 an upfront license fee which was not deemed recoverable.

11. REVENUES FROM MAJOR CUSTOMERS

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

	Year Ended December 31,		
	2003	2002	2001
Berlex Laboratories Inc.	23%	16%	20%
Cardinal Health (formerly Syncor International Corporation)	24	9	11
Mallinckrodt Inc.	14	18	20
Amersham Health (formerly Medi-Physics)	8	12	12

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

Revenues from Berlex 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, 2003 and 2002, the receivables from four of the Company s largest customers accounted for 63% and 57%, respectively, of gross accounts receivable.

12. ACCOUNTS PAYABLE AND ACCRUED LIABILITIES

	December 31,	
	2003	**2002**
	(All amounts in thousands)	
Accounts payable	$ 2,041	$ 1,726
Accrued payroll, sales commission and related expenses	714	488
Accrued royalties	705	720
Accrued professional and legal	649	519
Accrued research contracts and materials	218	238
Facility payable	93	144
Other accruals	705	592
	$ 5,125	$ 4,427

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

13. LONG-TERM LIABILITIES

	December 31,	
	2003	2002
	(All amounts in thousands)	
Due to Elan Corporation, plc	$ 2,280	$ 2,280
Capital lease obligations	82	162
Facility lease obligation	163	246
Other	5	6
	2,530	2,694
Less current portion of long-term liabilities	(76)	(80)
	$ 2,454	$ 2,614

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 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; thereafter, interest is payable in cash. The Company recorded $160,000 in interest expense on this note for each of the years 2003, 2002 and 2001. The note contains certain non-financial covenants, and the Company was in compliance with these covenants as of December 31, 2003.

The Company leases certain equipment under capital lease obligations, which will expire on various dates through 2005. Property and equipment leased under non-cancellable capital leases have a net book value of $69,000 at December 31, 2003. Amortization of assets held under capital leases is included with depreciation expense. Payments to be made under capital lease obligations (including total interest of $2,000) are $78,000 in 2004 and $6,000 in 2005.

In an effort to reduce expenses and position Cytogen for stronger long-term growth in oncology, the Company restructured AxCell in September 2002 by reducing 75% of AxCell s workforce. As a result, during 2002, the Company recorded a charge of $869,000 related to employee severance costs, the impairment of property, and equipment and future rental payments on leased facilities that will not be used in operations, which has been included in selling, general and administrative expense in the accompanying consolidated statement of operations. As of December 31, 2003 and 2002, the Company has a remaining accrued liability for future lease payments of $246,000 and $322,000, respectively, of which $163,000 is considered long-term as of December 31, 2003 and payable through 2006.

14. COMMON STOCK AND WARRANTS

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 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 the Black-Scholes pricing model.

In June 2003, the Company entered into a securities purchase agreement pursuant to which the Company sold 1,052,632 shares of its common stock to certain institutional investors at $4.75 per share, resulting in net

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 July 2003, the Company entered into a securities purchase agreement pursuant to which 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 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 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 February 2001, the Company sold 127,656 shares of its Common Stock to an institutional investor at an aggregate price of $6.5 million or consideration equal to $50.92 per share.

In June 2001, the Company entered into a Share Purchase Agreement with the State of Wisconsin Investment Board (SWIB), pursuant to which the Company sold 182,000 shares of Cytogen Common Stock to SWIB for an aggregate purchase price of $8.2 million, before transaction costs, or consideration equal to $45.00 per share. In connection with the Share Purchase Agreement, the Company was required to discontinue the use of an equity financing facility.

In January 2002, the Company sold 297,067 shares of its Common Stock to SWIB for an aggregate purchase price of $8.0 million, or consideration equal to $26.90 per share pursuant to a January 2002 Share Purchase Agreement between SWIB and the Company. In connection with our stock issuances to SWIB, the Company agreed not to enter into equity line arrangements in the future, issue certain securities at less than fair market value or undertake certain other securities issuances without requisite stockholder approval. 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 2003 and 2002, the Company issued to certain members of Cytogen s Board of Directors an aggregate total of 1,127 and 3,541 shares of its Common Stock, respectively, 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 Note 17 for information regarding Cytogen Common Stock issued to employees under the 401(k) plan.

As of December 31, 2003, the Company has outstanding warrants to purchase 1,944,485 shares of Cytogen Common Stock, at exercise prices ranging from $5.65 to $49.80 per share. The warrants are exercisable and expire at various times through July 2008. During 2003, warrants to purchase 26,000 shares of the Company s Common Stock expired. Some warrants may become automatically exercised, in full, subject to certain conditions.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

15. STOCK OPTIONS AND EMPLOYEE STOCK PURCHASE PLAN

The Company has various stock option plans that provide for the issuance of incentive and non-qualified stock options to purchase Cytogen Common Stock (Cytogen Options) to employees, non-employee directors and outside consultants, for which an aggregate of 807,889 shares of Common Stock have been reserved. In June 2003, the Company s stockholders approved an increase in the reserve of 200,000 shares under one of its approved stock option plan which is included above. The persons to whom Cytogen Options may be granted and the number, type, and terms of the Cytogen Options vary among the plans. Cytogen Options are granted with a term of 10 years and generally become exercisable in installments over periods of up to 5 years. The exercise price of Cytogen 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 Options	Price Range Per Share	Weighted Average Exercise Price Per Share	Aggregate Exercise Price
Balance at December 31, 2000	469,629	$ 7.00 169.38	$ 30.97	$ 14,543,953
Granted	74,736	25.60 61.30	38.08	2,845,773
Exercised	(13,090)	7.00 28.40	16.61	(217,478)
Cancelled	(37,027)	8.30 169.38	43.95	(1,627,480)
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

The following table summarizes information about Cytogen stock options at December 31, 2003:

	Outstanding Cytogen Stock Options			Exercisable Cytogen Stock Options	
Range of Exercise Prices	Outstanding Shares	Weighted-Average Remaining	Weighted-Average Exercise Price	Exercisable Shares	Weighted-Average Exercise Price

			Contractual Life			
$ 2.75	10.00	287,785	8.9	$ 4.21	71,178	$ 4.08
10.01	20.00	109,903	8.3	$ 12.98	36,164	$ 16.84
20.01	30.00	35,072	6.2	$ 26.27	33,877	$ 26.31
30.01	40.00	19,456	7.7	$ 34.83	13,497	$ 34.79
40.01	50.00	17,411	6.8	$ 47.19	14,463	$ 46.80
50.01	60.00	10,150	5.7	$ 56.83	10,150	$ 56.83
60.01	70.00	2,083	6.8	$ 64.40	2,083	$ 64.40
70.01	80.00	2,000	2.4	$ 75.30	2,000	$ 75.30
80.01	90.00	550	4.9	$ 88.86	550	$ 88.86
90.01	169.38	200	6.2	$ 169.38	200	$ 169.38
$ 2.75	169.38	484,610	8.3	$ 12.39	184,162	$ 21.08

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CYTOGEN CORPORATION AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

At December 31, 2003, Cytogen Stock Options to purchase 184,162 shares of Cytogen Common Stock were exercisable and the weighted average exercise price of these options was $21.08. At December 31, 2003, 59,448 shares of Cytogen Common Stock were available for issuance under approved option plans.

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 were subject to the completion of certain performance based milestones as determined by the Company s Board of Directors (the Board). 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 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.

AxCell, a subsidiary of Cytogen Corporation, also has a stock option plan that provides for the issuance of incentive and non-qualified stock options to purchase AxCell Common Stock (AxCell Options) to employees, for which 2,000,000 shares of AxCell common stock have been reserved. 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, 2003, 8,035,000 shares of AxCell Common Stock are outstanding; 8,000,000 of which are held by Cytogen. AxCell 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 Options to purchase 0, 183,035 and 438,365 shares of AxCell Common Stock during 2003, 2002 and 2001, respectively. The weighted-average exercise price per share for all outstanding AxCell Options was $3.36, $3.52 and $3.69 in 2003, 2002 and 2001, respectively. As of December 31, 2003, options to purchase 150,821 shares of AxCell Common Stock were outstanding, of which 107,301 shares were exercisable, and 1,834,179 shares were available for future grant. During 2001, in connection with the grant of AxCell Options, the Company recorded deferred compensation of $241,000, representing the estimated fair value of AxCell Common Stock in excess of the exercise price of the options on the date such options were granted. The deferred compensation is being amortized over the vesting period of the options. 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 is fully amortized at December 31, 2003.

Cytogen adopted an employee stock purchase plan under which eligible employees may elect to purchase shares of Cytogen Common Stock at the lower of 85% of fair market value as of the first trading day of each quarterly participation period, or as of the last trading day of each quarterly participation period. In 2003, 2002 and 2001, employees purchased 4,211, 4,911 and 1,287 shares, respectively, for aggregate proceeds of $17,000, $24,000 and $28,000, respectively. The Company has reserved 26,428 shares for future issuance under its employee stock purchase plan.

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CYTOGEN CORPORATION AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The weighted-average fair value of the options granted under the Cytogen stock option plans during 2003, 2002 and 2001 is estimated as $8.12, $3.70 and $30.74 per option, respectively, on the date of grant using the Black-Scholes option pricing model with the following assumptions for 2003, 2002 and 2001:

Valuation Assumptions	2003	2002	2001
Dividend yield	0%	0%	0%
Volatility	141.17%	143.46%	124.95%
Risk-free interest rate	2.81%	2.94%	4.55%
Expected life	4 yrs	4 yrs	4 yrs

The average fair value per option ascribed to the employee stock purchase plan during 2003, 2002 and 2001 is estimated at $1.51, $5.72 and $14.73, respectively, on the date of grant using the Black-Scholes option pricing model with the following assumptions for 2003, 2002 and 2001:

Valuation Assumptions	2003	2002	2001
Dividend yield	0%	0%	0%
Volatility	115.12%	20.83%	125.41%
Risk-free interest rate	1.10%	1.67%	4.12%
Expected life	3 months	3 months	3 months

The weighted average fair value of AxCell Options granted during 2002 and 2001 is estimated at $4.16 and $4.06, respectively, on the date of grant using the Black-Scholes pricing model with the following assumptions for 2002 and 2001:

Valuation Assumptions	2002	2001
Dividend yield	0%	0%
Volatility	142.07%	124.91%
Risk-free interest rate	4.02%	4.59%
Expected life	5 yrs	5 yrs

16. 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, $52,000 and $53,000 in 2003, 2002 and 2001, respectively. This agreement was terminated in October 2003.

17. RETIREMENT SAVINGS PLAN

The Company maintains a defined contribution 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 a 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, 2002 and 2001, the Company issued 3,939, 9,646 and 2,784, respectively, shares of its Common Stock under the 401(k) plan. Total expense was $79,000, $98,000 and $140,000 for 2003, 2002 and 2001, respectively.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

18. INCOME TAXES

As of December 31, 2003, Cytogen had federal and state net operating loss carryforwards of approximately $276.6 million and $150.1 million, respectively. The Company also had federal and state research and development tax credit carryforwards of approximately $6.6 million and $693,000, respectively. These net operating loss and credit carryforwards have begun to expire and will continue to expire through 2023.

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 2003, 2002 and 2001, the Company would have recorded a tax benefit. During 2003, 2002 and 2001, there were increases of $2,466,000, $11,232,000 and $6,926,000, 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 zero. Deferred tax assets have been fully reserved as of December 31, 2003 and 2002.

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.

	2003	2002
	(All amounts are in thousands)	
Deferred tax assets:		
Net operating loss carryforwards	$ 102,786	$ 97,562
Capitalized research and development expenses	4,367	7,396
Research and development credit	7,251	7,768
Acquisition of in-process technology	868	977
Other, net	10,045	9,148
Total deferred tax assets	125,317	122,851
Valuation allowance	(125,317)	(122,851)
Net deferred tax assets	$	$

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

During 2003 and 2001, the Company sold New Jersey state operating loss carryforwards and research and development credits, resulting in the recognition of $888,000 and $1.1 million of income tax benefit, respectively.

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CYTOGEN CORPORATION AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

19. COMMITMENTS AND CONTINGENCIES

The Company leases its facilities and certain equipment under non-cancellable operating leases that expire at various times through 2006. Rent expense on these leases was $694,000, $832,000 and $1.6 million in 2003, 2002 and 2001, respectively. Minimum future obligations under the operating leases are $1.0 million as of December 31, 2003 and will be paid as follows: $616,000 in 2004, $291,000 in 2005, and $104,000 in 2006. In addition, the Company has an agreement to receive annual sublease income of $54,000 in 2004 and 2005 and $36,000 in 2006.

The Company is obligated to make minimum future payments under manufacturing, research and development and investor relations and consulting services contracts that expire at various times. As of December 31, 2003, the minimum future payments under contracts are $5.5 million in 2004, $4.5 million in 2005, $168,000 in 2006 and $130,000 each year from 2007 to 2012, $105,000 from 2013 to 2015, $75,000 from 2016 to 2017 and $25,000 in 2018. Under the BMSMI agreement, the Company is obligated to pay a minimum of $4.2 million annually through 2008. Because the Company may terminate this agreement on a two year prior written notice (see Note 9), the Company has not included such commitments beyond 2005 herein. In addition, the Company is obligated to pay milestone payments upon achievement of certain milestones and royalties on revenues from commercial product sales including certain guaranteed minimum payments.

In 2004, the Company expects to provide $4.2 million in funding for the development of the PSMA technologies through its joint venture with Progenics. 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.

On March 17, 2000, the Company was 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. (collectively Plaintiffs). The litigation claims that the Company s PROSTASCINT product infringes a patent purportedly owned by Goldenberg and licensed to Immunomedics. The patent sought to be enforced in the litigation has now expired; as a result, the claim, even if successful, would not result in an injunction barring the continued sale of PROSTASCINT or affect any other of the Company s products or technology. The Company believes that PROSTASCINT did not infringe this patent, and that the patent was invalid and unenforceable. In addition, the Company has certain rights to indemnification against litigation and litigation expenses from the inventor of technology used in PROSTASCINT, which may be offset against royalty payments on sales of PROSTASCINT. However, given the uncertainty associated with litigation, the Company may incur material expenditures. On December 17, 2001, Cytogen filed a motion for summary judgment of non-infringement of the asserted claims of the patent-in-suit. The Plaintiffs opposed that motion and filed their own cross-motion for summary judgment of infringement. On July 3, 2002, the Court denied both parties summary judgment motions, with leave to renew those motions after presenting expert testimony and legal argument based upon that testimony. The parties subsequently presented expert testimony and submitted additional briefing. On April 29, 2003, the Company s motion for summary judgment of non-infringement of all asserted claims was granted, Plaintiffs motion for summary judgment of infringement was denied and the case was ordered closed. On May 12, 2003, Plaintiffs filed a Notice of Appeal regarding this decision to the U.S. Court of Appeals for the Federal Circuit, and subsequently filed their opening brief on July 28, 2003. On September 22, 2003, Cytogen filed its responsive brief. On October 23, 2003, Plaintiffs filed their reply brief. The appeal is now fully briefed and oral argument was held on March 2, 2004. The Court has not indicated when it expects to issue a ruling, however given the uncertainty associated with litigation, the Company cannot give any assurance that the litigation could not result in a material expenditure to the Company.

Each of our 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

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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.

20. 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.

21. CONSOLIDATED QUARTERLY FINANCIAL DATA UNAUDITED

The following table provides quarterly data for the years ended December 31, 2003 and 2002.

	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

	Three Months Ended			
	March 31, 2002	June 30, 2002	Sept. 30, 2002	Dec. 31, 2002
	(amounts in thousands except per share data)			
Total revenues	$ 3,296	$ 3,167	$ 3,101	$ 3,367
Total operating expenses	8,329	6,404	6,588	6,894
Operating loss	(5,033)	(3,237)	(3,487)	(3,527)
Other income (expense), net	35	30	(484)	4
Net loss	$ (4,998)	$ (3,207)	$ (3,971)	$ (3,523)
Basic and diluted net loss per share	$ (0.62)	$ (0.39)	$ (0.46)	$ (0.40)
Weighted average common shares outstanding	8,122	8,308	8,660	8,758
Product related gross margin	$ 2,027	$ 1,861	$ 1,882	$ 1,950