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

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-K

FOR ANNUAL AND TRANSITION REPORTS

PURSUANT TO SECTIONS 13 OR 15(d) OF THE

SECURITIES EXCHANGE ACT OF 1934

(Mark One)

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

OR

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

For the transition period from _____ to _____

Commission File Number 000-14879

CYTOGEN CORPORATION

(Exact Name of Registrant as Specified in Its Charter)

Delaware	22-2322400
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
650 College Road East, Suite 3100 Princeton, New Jersey	08540
(Address of Principal Executive Offices)	(Zip Code)

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

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

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

Common Stock, $0.01 par value per share

(Title of Class)

Preferred Stock Purchase Rights, $0.01 par value per share

(Title of Class)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

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

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

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

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

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

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PART I

Item 1. Business

OVERVIEW

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

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

Marketed Products:

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

Product Candidates and Pipeline:

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

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

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

* Jointly developed with Progenics Pharmaceuticals, Inc.

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

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

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

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

MARKETED PRODUCTS AND PRODUCT CANDIDATES PENDING APPROVAL

THERAPEUTICS

QUADRAMET

Overview

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

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

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

Further Clinical Development Related to QUADRAMET

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

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

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

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

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

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

cancer has progressed after receiving hormonal therapy.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Intellectual Property Position Related to QUADRAMET

In May 1993, we obtained an exclusive license from The Dow Chemical Company to use QUADRAMET, in North America, as a therapeutic radiopharmaceutical for metabolic bone disease or tumor regression for cancer caused by metastatic or primary cancer in bone in humans, and for the treatment of disease characterized by osteoblastic response in humans. Our license was expanded to include Latin America in 1995, and will remain in effect, unless earlier terminated, for a period of 20 years from May 30, 1993 or until the last to expire of the related patents. We currently anticipate such termination date to be May 30, 2013.

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

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

Manufacturing, Supply and Distribution of QUADRAMET

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

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

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

Marketing of QUADRAMET

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

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

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

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

Competition Related to Quadramet

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

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

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

MOLECULAR IMAGING/DIAGNOSTIC PRODUCTS AND PRODUCT CANDIDATES

PROSTASCINT

Overview

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

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

PROSTASCINT is approved for marketing in the United States in two clinical settings: (i) as a diagnostic imaging agent in newly diagnosed patients with biopsy-proven prostate cancer thought to be clinically localized after standard diagnostic evaluation and who are at high risk for spread of their disease to pelvic lymph nodes; and (ii) for use in post-prostatectomy patients with a rising PSA and a negative or equivocal standard metastatic evaluation in whom there is a high clinical suspicion of occult metastatic disease.

During the molecular imaging procedure, PROSTASCINT is administered intravenously into the patient. The 7E11 antibody in PROSTASCINT travels through the bloodstream and binds to PSMA. The radioactivity from the isotope that has been attached to the antibody can be detected from outside the body by a gamma camera. Gamma cameras are found in the nuclear medicine departments of most hospitals. The image captured by the camera assists in the identification of the location of the radiolabeled pharmaceutical thus identifying the sites of tumors.

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

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

In addition, in the United States, following initial therapy, prostate cancer patients are monitored to ascertain changes in the level of serum PSA. In this setting, a consistent rise in PSA is evidence of recurrence of the patient s prostate cancer. Knowledge of the extent and location of disease recurrence is important in choosing the most appropriate form of treatment.

Partners In Excellence Sites

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

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Market Expansion Strategies for PROSTASCINT

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

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

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

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

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

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

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

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

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

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

Further Clinical Development Related to PROSTASCINT

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

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

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

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

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

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

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

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

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

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

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

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

Intellectual Property Related to PROSTASCINT

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

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

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

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

Manufacturing, Supply and Distribution of PROSTASCINT

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

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

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

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

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

Marketing of PROSTASCINT

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

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Competition Related to PROSTASCINT

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

Strategic Relationships and Collaborations Related to PROSTASCINT

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

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

COMBIDEX

Overview

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

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

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

differentiation between malignant and non-malignant lymph nodes.

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

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

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

Clinical Data Related to COMBIDEX

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

Agreements with Advanced Magnetics, Inc.

In August 2000, we entered into a license and marketing agreement with Advanced Magnetics, Inc. for COMBIDEX, for all applications, and ferumoxytol (formerly referred to as Code 7228), for oncology applications only. Pursuant to the terms of the license agreement, we have the exclusive right to market, distribute and sell COMBIDEX in the United States. The license agreement will continue until August 25, 2010, and will thereafter automatically renew for successive five year periods, unless notice of non-renewal or termination is given by us or Advanced Magnetics 90 days prior to the commencement of any renewal period.

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

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

DISCONTINUED PRODUCTS

NMP22® BLADDERCHEK®

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

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

BRACHYSEED®

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

ONCOSCINT CR/OV

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

RESEARCH AND DEVELOPMENT

AGGREGATE EXPENDITURES

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

2004 $ 6.1 million

2003 $ 5.8 million

2002 $ 10.5 million

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

TECHNOLOGY

Prostate-Specific Membrane Antigen (PSMA)

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

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

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

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

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

PSMA Development Company LLC

In 1999, we entered into a joint venture with Progenics Pharmaceuticals, Inc. to develop *in vivo* immunotherapeutic products utilizing PSMA. These product candidates currently include antibody-based immunotherapies for prostate cancer, a therapeutic prostate cancer vaccine utilizing the PSMA gene and a vector delivery system, and a recombinant form of the PSMA protein as a basis for immune stimulation. We believe that these product candidates, if successfully developed, could play an important role in the treatment of prostate cancer. We believe there are significant unmet needs for treatment and monitoring of this disease.

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

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

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

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

The joint venture is owned equally by Progenics and us. We have exclusively licensed to the joint venture certain immunotherapeutic applications of our PSMA patent rights and know-how. Progenics has funded the first $3.0 million of development costs, in addition to $2.0 million in supplemental capital contributions funded at certain dates prior to December 2001. Beginning in December 2001, we began sharing costs of the programs with Progenics.

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

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

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

We have North American marketing rights to products developed by the joint venture and a right of first negotiation with respect to marketing activities in any territory outside North America. We anticipate initiation of marketing efforts for any product developed upon approval by the FDA or requisite foreign regulatory bodies, as applicable. If approved, we anticipate marketing these products with our own sales force and will be reimbursed by the joint venture for these costs. We will split the net profit equally with Progenics for any products developed by the joint venture, assuming there is no change in our existing ownership interests.

Clinical Data Related to PSMA

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

Strategic Relationships, Collaborations and Licensing Arrangements Related to PSMA

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

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venture paid a nonrefundable, noncreditable license fee and is obligated to pay additional payments upon the occurrence of certain defined milestones associated with the development and commercialization program for products incorporating the ArV technology. In addition, the joint venture is required to pay an annual maintenance fee until the commencement of commercial sales of products and then royalties based on net sales of products. The joint venture has the right to terminate this agreement upon 30 days prior written notice. We believe that this technology, if successfully deployed, may have important advantages in targeting immune stimulating cells *in vivo* which impact on the progression of cancer.

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

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

AxCell Biosciences

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

OTHER STRATEGIC RELATIONSHIPS

We frequently enter into alliances with other companies to, among other things, increase our financial resources, reduce risk and retain an appropriate level of ownership of products currently in development. In addition, through alliances with other pharmaceutical and biotechnology companies and other collaborators, we may obtain funding, expand existing programs, learn of new technologies and gain additional expertise in developing and marketing products.

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

Elan Corporation, plc. In December 1995, we entered into a license agreement granting Elan worldwide rights to a group of peptides and associated technology for orally administered drugs that are transported across the gastrointestinal epithelium, as well as rights to other orally delivered drugs derived from related research programs. Elan is responsible for the further development and commercialization of this technology. We are entitled to royalties from sales of any product developed and commercialized based on this technology. In July 2004, we were assigned rights to certain patents and patent applications developed under the agreement, including U.S. Pat. No. 6,703,362 (expiring May 15, 2018), and U.S. Pat. Appln. Nos. 09/079,678 (filed May 15, 1998) and 09/079,819 (filed May 15, 1998).

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

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

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PRODUCT CONTRIBUTION TO REVENUES

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

CONCENTRATION OF SALES

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

COMPETITION

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

We expect competition to intensify in the fields in which we are involved, as technical advances in such fields are made and become more widely known. We cannot assure you, however, that we or our collaborative partners will be able to develop our products successfully or that we will obtain patents to provide protection against competitors. Moreover, we cannot assure you that our competitors will not succeed in developing therapeutic or imaging/diagnostic products that circumvent our products or that these competitors will not succeed in developing technologies or products that are more effective than those developed by us. In addition, many of these companies may have more experience in establishing third-party reimbursement for their products. Accordingly, we cannot assure you that we will be able to compete effectively against existing or potential competitors or that competition will not have a material adverse effect on our business, financial condition and results of operations.

INTELLECTUAL PROPERTY

We believe that our success depends, in part, on our ability to protect our products and technology through patents and trade secrets. Accordingly, our policy is to pursue a vigorous program of securing and maintaining patent and trade secret protection to preserve our right to exploit the results of our research and development activities and, to the extent it may be necessary or advisable, to exclude others from appropriating our proprietary technology.

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

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

We believe that our valuable proprietary information is protected to the fullest extent commercially reasonable; however, we cannot assure you that:

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

The technology applicable to our products is developing rapidly. A substantial number of patents have been issued to other biotechnology companies relating to PSMA. In addition, competitors have filed applications for, have been issued, or may otherwise obtain patents and other proprietary rights relating to products or processes that are competitive with ours. In addition, others may have filed patent applications and may have been issued patents relating to products and technologies potentially useful to us or necessary to commercialize our products or to achieve our business goals. We cannot assure you that we will be able to obtain licenses to such patents on commercially reasonable terms if at all. The failure to obtain licenses to such patents could prevent us from commercializing products or services covered by such patents.

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

GOVERNMENT REGULATION

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

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

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

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

The FDC Act requires that our products be manufactured in FDA registered facilities subject to inspection. The manufacturer must be in compliance with cGMP, which imposes certain procedural, substantive, and recordkeeping requirements upon us and our manufacturing partners with respect to manufacturing and quality control activities, and, for devices, product design. To ensure full technical compliance with such regulations, a manufacturer must spend funds, time and effort in the areas of production and quality control. These regulations may also apply to Cytogen. Any failure by us or our manufacturing partners to comply with the requirements of cGMP could have a material adverse effect on our business, financial condition and results of operations.

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

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

Clinical trials for drugs, devices, and biologics typically are performed in three phases to evaluate the safety and efficacy of the product. In Phase I, a product is tested in a small number of healthy subjects or patients primarily for safety at one or more dosages. Phase II evaluates, in addition to safety, the efficacy of the product against particular diseases in a patient population that is generally somewhat larger than Phase I. Clinical trials of certain diagnostic and cancer therapeutic agents may combine Phase I and Phase II into a single Phase I/II study. In Phase III, the product is evaluated in a larger patient population sufficient to generate data to support a claim of safety and efficacy within the meaning of the FDC Act or PHS Act. Permission by the FDA must be obtained before clinical testing can be initiated within the United States. This permission is obtained by submission of an IND/IDE application which typically includes, among other things, the results of *in vitro* and non-clinical testing and any previous human testing done elsewhere. The FDA has 30 days to review the information submitted and makes a final decision whether to permit clinical testing with the drug, biologic or device. However, this process can take longer if the FDA raises questions or asks for additional information regarding the IND/IDE application. Unless the FDA notifies the sponsor that the IND/IDE is subject to a clinical hold during the 30 day review period, the IND/IDE is considered effective and the trial may commence.

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

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

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

Conducting the studies, preparing these applications and securing approval from the FDA is expensive and time consuming, and takes several years to complete. Difficulties or unanticipated costs may be encountered by us or our licensees in their respective efforts to secure necessary governmental approval or licenses, which could delay or preclude us or our licensees from marketing their products. There can be no assurance that approvals of our proposed products, processes or facilities will be granted on a timely basis, or at all. Limited indications for use or other conditions could also be placed on any approvals that could restrict the commercial applications of products. With respect to patented products or technologies, delays imposed by the government approval process may materially reduce the period during which we will have the exclusive right to exploit them, because patent protection lasts only for a limited time, beginning on the date the patent is first granted (in the case of United States patent applications filed prior to June 6, 1995) and when the patent application is first filed (in the case of patent applications filed in the United States after June 6, 1995, and applications filed in the European Economic Community). We intend to seek to maximize the useful lives of our patents under the Patent Term Restoration Act of 1984 in the United States and under similar laws if available in other countries.

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

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

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

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

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

Orphan Drug Act

The Orphan Drug Act is intended to provide incentives to pharmaceutical companies to develop and market drugs and biologics for rare diseases or conditions affecting fewer than 200,000 persons in the United States at the time of application for orphan drug designation. A drug that receives orphan drug designation and is the first

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product to receive FDA marketing approval for a particular indication is entitled to orphan drug status, which confers a seven-year exclusive marketing period in the United States for that indication. Clinical testing requirements for orphan drugs are the same as those for products that have not received orphan drug designation but pharmaceutical companies may receive grants or tax credits for research, as well as protocol assistance. Under the Orphan Drug Act, the FDA cannot approve any application by another party to market the same drug for treatment of an identical indication unless the holder consents, the party has a license from the holder of orphan drug status, or the holder of orphan drug status is unable to assure an adequate supply of the drug, or it has been shown to be clinically superior to the approved orphan drug. However, a drug that is considered by the FDA to be different from a particular orphan drug is not barred from sale in the United States during the seven-year exclusive marketing period even if it receives marketing approval for the same product claim. In addition, holders of orphan drug status must notify the FDA of any decision to discontinue active pursuit of drug approval or biologics license, or, if such approval or license is in effect, notify the FDA at least one year prior to any discontinuance of product production. If the holder of an orphan designation cannot assure the availability of sufficient quantities of the product to meet the needs of affected patients, the FDA may withdraw orphan drug status.

Fraud and Abuse

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

Anti-Kickback Laws. Our operations are subject to federal and state anti-kickback laws. Certain provisions of the Social Security Act prohibit entities such as us from knowingly and willingly offering, paying, soliciting or receiving any form of remuneration (including any kickbacks, bribes or rebates) in return for the referral of items or services for which payment may be made under a federal health care program, or in return for the recommendation, arrangement, purchase, lease or order of items or services for which payment may be made under a federal health care program. Violation of the federal anti-kickback law is a felony, punishable by criminal fines and imprisonment for up to five years or both. In addition, the Department of Health and Human Services may impose civil penalties and exclude violators from participation in federal health care programs such as Medicare and Medicaid. Many states have adopted similar prohibitions against payments intended to induce referrals of products or services paid by Medicaid or other third party payors.

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

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

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

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

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

Other regulations

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

Foreign regulatory approval

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

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

Substantial requirements, comparable in many respects to those imposed under the FDC Act, will have to be met before commercial sale is permissible in most countries. There can be no assurance, however, as to whether or when governmental approvals, other than those already obtained, will be obtained or as to the terms or scope of those approvals.

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HEALTH CARE REIMBURSEMENT

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

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

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

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

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

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

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

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

KEY EMPLOYEES

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

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

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

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

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

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

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

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

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

EMPLOYEES

As of February 25, 2005, we employed 89 persons, 88 of whom are employed full-time and one of whom is employed part-time. Of such 89 persons, 59 were employed in sales and marketing, five in medical affairs, two in regulatory, and 23 in administration and management. The employees in sales and marketing included nine Clinical Oncology Specialists and 39 Regional Managers, Professional Oncology Representatives, Senior Professional Oncology Representatives and Senior Account Managers. In comparison, 36 persons were employed in sales and marketing as of March 1, 2004. We believe that we have been successful in attracting skilled and experienced employees. None of our employees is covered by a collective bargaining agreement. All of our employees have executed confidentiality agreements. We consider relations with our employees to be excellent.

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ADDITIONAL FACTORS THAT MAY AFFECT FUTURE RESULTS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

health care providers, such as hospitals and physicians; and

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

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

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

We rely heavily on our collaborative partners.

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

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

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

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

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

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

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

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

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

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

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

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

Dow Chemical. In May 1993, we obtained an exclusive license from The Dow Chemical Company to use QUADRAMET, in North America, as a therapeutic radiopharmaceutical for metabolic bone disease or tumor regression for cancer caused by metastatic or primary cancer in bone in humans, and for the treatment of disease characterized by osteoblastic response in humans. Our license was expanded to include Latin America in 1995. Our license agreement with Dow with respect to QUADRAMET will remain in effect, unless earlier terminated, for a period of twenty (20) years from May 30, 1993 or until the last to expire of the related patents. We anticipate such termination date to be May 30, 2013.

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

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

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

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

Advanced Magnetics, Inc. In August 2000, we entered into a license and marketing agreement with Advanced Magnetics, Inc. for COMBIDEX, for all applications, and ferumoxytol (formerly Code 7228) for oncology applications only. In 2000, we also entered into a supply agreement with Advanced Magnetics for COMBIDEX. We have exclusive United States marketing rights to COMBIDEX for all applications. COMBIDEX (ferumoxtran-10) is an investigational functional molecular imaging agent consisting of iron oxide nanoparticles, which is currently being developed for use in conjunction with magnetic resonance imaging to aid in the differentiation of cancerous from non-cancerous lymph nodes, and is currently under review by the U.S. Food and Drug Administration. In September 2004, Advanced Magnetics submitted a complete response to an approvable letter received in June 2000 from the FDA for COMBIDEX. On March 3, 2005, the FDA s Oncologic Drugs Advisory Committee (ODAC) voted 15 to 4 to not recommend approval of the proposed broad indication for COMBIDEX. A decision by the FDA on COMBIDEX is expected by the user fee goal date of March 30, 2005. There can be no assurance that Advanced Magnetics will receive FDA approval for COMBIDEX or ferumoxytol (for oncology applications). Our license and marketing agreement with Advanced Magnetics will continue until August 25, 2010, and will thereafter automatically renew for successive five year periods, unless notice of non-renewal or termination is given by us or Advanced Magnetics, 90 days prior to the commencement of any renewal period.

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

Our intellectual property is difficult to protect.

In addition to our key agreements referenced above, our business and competitive positions are also dependent upon our ability to protect our proprietary technology. Because of the substantial length of time and expense associated with the development of new products, we, like the rest of the biopharmaceutical industry, place considerable importance on obtaining and maintaining patent and trade secret protection for new technologies, products and processes. We have filed patent applications for certain aspects of our technology for diagnostic and therapeutic products and/or the methods for their production and use.

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

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

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

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

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

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

There are risks associated with the manufacture and supply of our products.

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

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

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

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

The Company, our contract manufacturers and testing laboratories are required to adhere to FDA regulations setting forth requirements for cGMP, and similar regulations in other countries, which include extensive testing, control and documentation requirements. Ongoing compliance with cGMP, labeling and other applicable regulatory requirements is monitored through periodic inspections and market surveillance by state and federal agencies, including the FDA, and by comparable agencies in other countries. Failure of our contract vendors or us to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of the government to grant pre-market clearance or pre-market approval of drugs, delays, suspension or withdrawal of approvals, seizures or recalls of products, operating restrictions and criminal prosecutions any of which could significantly and adversely affect our business, financial condition and results of operations.

Our products, generally, are in the early stages of development and commercialization and we may never achieve the revenue goals set forth in our business plan.

We began operations in 1980 and have since been engaged primarily in research directed toward the development, commercialization and marketing of products to improve the diagnosis and treatment of cancer and other diseases. In October 1996, we introduced for commercial use our PROSTASCINT imaging agent. In March 1997, we introduced for commercial use our QUADRAMET therapeutic product.

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

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

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

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

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

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

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

All of our potential oncology products will be subject to the risks of failure inherent in the development of diagnostic or therapeutic products based on new technologies.

Product development for cancer treatment involves a high degree of risk. The product candidates we develop, pursue or offer may not prove to be safe and effective, may not receive the necessary regulatory approvals, may be precluded by proprietary rights of third parties or may not ultimately achieve market acceptance. These product candidates will require substantial additional investment, laboratory development, clinical testing and regulatory approvals prior to their commercialization. We may experience difficulties, such as the inability to agree with our collaborative partners on development, initiate clinical trials or receive timely regulatory approvals, that could delay or prevent the successful development, introduction and marketing of new products.

Before we obtain regulatory approvals for the commercial sale of any of our products under development, we must demonstrate through preclinical studies and clinical trials that the product is safe and effective for use in each target indication. The results from preclinical studies and early-stage clinical trials may not be predictive of results that will be obtained in large-scale, later-stage testing. Our clinical trials may not demonstrate safety and efficacy of a proposed product, and therefore, may not result in marketable products. A number of companies in our industry have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. Clinical trials or marketing of any potential diagnostic or therapeutic products may expose us to liability claims for the use of these diagnostic or therapeutic products. We may not be able to maintain product liability insurance or sufficient coverage may not be available at a reasonable cost. In addition, internal development of diagnostic or therapeutic products will require significant investments in product development, marketing, sales and regulatory

compliance resources. We will also have to establish or contract for the manufacture of products, including supplies of drugs used in clinical trials, under the cGMP of the FDA. We cannot assure you that product issues will not arise following successful clinical trials and FDA approval.

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

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Competition in our field is intense and likely to increase.

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

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

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

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

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

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

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

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

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

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

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

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

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

Our business, financial condition and results of operations will continue to be affected by the efforts of governmental and third-party payors to contain or reduce the costs of healthcare. There have been, and we expect that there will continue to be, a number of federal and state proposals to regulate expenditures for medical products and services, which may affect payments for therapeutic and diagnostic imaging agents such as our products. In addition, an emphasis on managed care increases possible pressure on the pricing of these products. While we cannot predict whether these legislative or regulatory proposals will be adopted, or the effects these proposals or managed care efforts may have on our business, the announcement of these proposals and the adoption of these proposals or efforts could affect our stock price or our business. Further, to the extent these proposals or efforts have an adverse effect on other companies that are our prospective corporate partners, our ability to establish necessary strategic alliances may be harmed.

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

Any products tested, manufactured or distributed by us or on our behalf pursuant to FDA approvals are subject to pervasive and continuing regulation by numerous regulatory authorities, including primarily the FDA. We may be slow to adapt, or we may never adapt, to changes in existing requirements or adoption of new requirements or policies. Our failure to comply with regulatory requirements could subject us to enforcement action, including product seizures, recalls, withdrawal, suspension, or revocation of approvals, restrictions on or

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injunctions against marketing our products based on our technology, and civil and criminal penalties. We may incur significant costs to comply with laws and regulations in the future or compliance with laws or regulations may create an unsustainable burden on our business.

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

The regulatory risks we face also include the following:

- any compound or agent, including generics, we or our collaborative partners develop must receive regulatory agency approval before it may be marketed as a drug in a particular country;

- the regulatory process, which includes preclinical testing and clinical trials of each compound or agent in order to establish its safety and efficacy, varies from country to country, can take many years and requires the expenditure of substantial resources;

- in all circumstances, approval of the use of previously unapproved radioisotopes in certain of our products requires approval of the Nuclear Regulatory Commission and/or equivalent state regulatory agencies, which may be a lengthy process. A radioisotope is an unstable form of an element which undergoes radioactive decay, thereby emitting radiation which may be used, for example, to image or destroy harmful growths or tissue;

- data obtained from preclinical and clinical activities are susceptible to varying interpretations which could delay, limit or prevent regulatory agency approval; and

- delays or rejections may be encountered based upon changes in regulatory agency policy during the period of product development and/or the period of review of any application for regulatory agency approval. These delays could adversely affect the marketing of any products we or our collaborative partners develop, impose costly procedures upon our activities, diminish any competitive advantages we or our collaborative partners may attain and adversely affect our ability to receive royalties.

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

If and when we obtain approval or clearance for our products, the marketing, manufacture, labeling, packaging, adverse event and other reporting, storage, advertising and promotion and record keeping related to our products would remain subject to extensive regulatory requirements. Discovery of previously unknown problems with a drug, its manufacture or its manufacturer may result in restrictions on such drug, manufacture or manufacturer, including withdrawal of the drug from the market.

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

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

We depend on attracting and retaining key personnel.

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

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

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

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

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

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

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

Our security measures may not protect our unpatented proprietary technology.

We also rely upon trade secret protection for some of our confidential and proprietary information that is not subject matter for which patent protection is available. To help protect our rights, we require all employees, consultants, advisors and collaborators to enter into confidentiality agreements that require disclosure, and in most cases, assignment to us, of their ideas, developments, discoveries and inventions, and that prohibit the disclosure of confidential information to anyone outside Cytogen or our subsidiaries. Although we are unaware of any unauthorized use or disclosure of our unpatented proprietary technology to date, these agreements may not provide adequate protection for our trade secrets, know-how or other proprietary information or prevent such unauthorized use or disclosure.

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

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

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

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

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

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

progress toward regulatory approval for our products;

costs of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights;

competing technological and market developments; and

expansion of strategic alliances for the sale, marketing and distribution of our products.

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

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

Our capital raising efforts may dilute stockholder interests.

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

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

If we raise additional funds through collaborations and licensing arrangements, we may be required to relinquish rights to certain of our technologies or product candidates or to grant licenses on unfavorable terms. If we relinquish rights or grant licenses on unfavorable terms, we may not be able to develop or market products in a manner that is profitable to us.

Our PSMA product development program is novel and, consequently, inherently risky.

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

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

Our other research and development programs involve similarly novel approaches to human therapeutics. Consequently, there is no precedent for the successful commercialization of therapeutic products based on our PSMA technologies. If we fail to develop such products, our business

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

We could be negatively impacted by future interpretation or implementation of federal and state fraud and abuse laws, including anti-kickback laws, false claims laws and federal and state anti-referral laws.

We are subject to various federal and state laws pertaining to health care fraud and abuse, including anti-kickback laws, false claims laws and physician self-referral laws. Violations of these laws are punishable by criminal and/or civil sanctions, including, in some instances, imprisonment and exclusion from participation in federal and state health care programs, including Medicare, Medicaid, and veterans health programs. We have not been challenged by a governmental authority under any of these laws and believe that our operations are in compliance with such laws.

However, because of the far-reaching nature of these laws, we may be required to alter one or more of our practices to be in compliance with these laws. Health care fraud and abuse regulations are complex, and even minor, inadvertent irregularities can potentially give rise to claims that the law has been violated. Any violations

of these laws could result in a material adverse effect on our business, financial condition and results of operations. If there is a change in law, regulation or administrative or judicial interpretations, we may have to change our business practices or our existing business practices could be challenged as unlawful, which could have a material adverse effect on our business, financial condition and results of operations.

We could become subject to false claims litigation under federal or state statutes, which can lead to civil money penalties, criminal fines and imprisonment, and/or exclusion from participation in federal health care programs. These false claims statutes include the federal False Claims Act, which allows any person to bring suit alleging the false or fraudulent submission of claims for payment under federal programs or other violations of the statute and to share in any amounts paid by the entity to the government in fines or settlement. Such suits, known as qui tam actions, have increased significantly in recent years and have increased the risk that companies like us may have to defend a false claim action. We could also become subject to similar false claims litigation under state statutes. If we are unsuccessful in defending any such action, such action may have a material adverse effect on our business, financial condition and results of operations.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our business involves environmental risks that may result in liability.

We are subject to a variety of local, state, federal and foreign government regulations relating to storage, discharge, handling, emission, generation, manufacture and disposal of toxic, infectious or other hazardous substances used to manufacture our products. If we fail to comply with these regulations, we could be liable for damages, penalties, or other forms of censure and our business could be significantly and adversely affected. We currently do not carry insurance for contamination or injury resulting from the use of such materials.

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

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

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

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

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

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

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

market price of our common stock has fluctuated over a wide range and may continue to fluctuate for various reasons, including, but not limited to, announcements concerning our competitors or us regarding:

results of clinical trials;

technological innovations or new commercial products;

changes in governmental regulation or the status of our regulatory approvals or applications;

changes in earnings;

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changes in health care policies and practices;

developments or disputes concerning proprietary rights;

litigation or public concern as to safety of the our potential products; and

changes in general market conditions.

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

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

Our Board of Directors has the authority, without further action by the holders of common stock, to issue from time to time, up to 5,400,000 shares of preferred stock in one or more classes or series, and to fix the rights and preferences of the preferred stock. Pursuant to these provisions, we have implemented a stockholder rights plan by which one preferred stock purchase right is attached to each share of common stock, as a means to deter coercive takeover tactics and to prevent an acquirer from gaining control of us without some mechanism to secure a fair price for all of our stockholders if an acquisition was completed. These rights will be exercisable if a person or group acquires beneficial ownership of 20% or more of our common stock and can be made exercisable by action of our board of directors if a person or group commences a tender offer which would result in such person or group beneficially owning 20% or more of our common stock. Each right will entitle the holder to buy one one-thousandth of a share of a new series of our junior participating preferred stock for $20. If any person or group becomes the beneficial owner of 20% or more of our common stock (with certain limited exceptions), then each right not owned by the 20% stockholder will entitle its holder to purchase, at the right s then current exercise price, common shares having a market value of twice the exercise price. In addition, if after any person has become a 20% stockholder, we are involved in a merger or other business combination transaction with another person, each right will entitle its holder (other than the 20% stockholder) to purchase, at the right s then current exercise price, common shares of the acquiring company having a value of twice the right s then current exercise price.

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

These provisions of the stockholder rights plan, our certificate of incorporation, and of Delaware law may have the effect of delaying, deterring or preventing a change in control of Cytogen, may discourage bids for our common stock at a premium over market price and may adversely affect the market price, and the voting and other rights of the holders, of our common stock. In addition, these provisions make it more difficult to replace or remove our current management team in the event our stockholders believe this would be in the best interest of the Company and our stockholders.

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

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

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

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

A large number of our shares are eligible for future sale which may adversely impact the market price of our common stock.

A large number of shares of our common stock are already outstanding, issuable upon exercise of options and warrants, or the achievement of certain milestones under previously completed acquisitions and may be eligible for resale. This availability of a significant number of additional shares of our common stock for future sale and issuance could depress the price of our common stock.

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

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

Item 2. Properties

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

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

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

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Item 3. Legal Proceedings

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

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

Not applicable.

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PART II

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

Our common stock is traded on the Nasdaq National Market under the trading symbol CYTO.

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

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

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

We have never paid any cash dividends on our common stock and we do not anticipate paying any cash dividends on our common stock in the foreseeable future. We intend to retain any future earnings to fund the development and growth of our business. Any future determination to pay dividends will be at the discretion of our board of directors.

CHANGES IN SECURITIES

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

Option Grants

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

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

* Unregistered at the time of grant.

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

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Item 6. Selected Financial Data

The following selected financial information has been derived from our audited consolidated financial statements for each of the five years in the period ended December 31, 2004. The selected financial data set forth below should be read in conjunction with the consolidated financial statements, including the notes thereto, Management s Discussion and Analysis of Financial Condition and Results of Operations and other information provided elsewhere in this report.

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

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

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

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

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

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

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

Cautionary Statement

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

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

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

Overview

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

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Significant Events in 2004

Advanced Magnetics Submits Complete Response To Approvable Letter For COMBIDEX

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

Capital Raising and Shelf Registration Statement

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

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

Initiation of QUADRAMET National Bone Pain Registry

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

Manufacturing Agreement With Laureate Pharma, L.P.

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

Additions To Senior Management

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

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

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

Patent Infringement Litigation Settled

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

RESULTS OF OPERATIONS

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

Revenues

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

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

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

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

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

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

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

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

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

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

Operating Expenses

			Increase/(Decrease)	
	2004	2003	$	%
	(All amounts in thousands, except percentage data)			
Cost of product related revenues	$ 9,309	$ 6,268	$ 3,041	

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exposures. Gains and losses on these non-U.S. currency investments would generally be offset by corresponding losses and gains on the related hedging instruments, resulting in negligible net exposure.

We did not have any foreign currency contracts, or hedge instruments or contracts outstanding at December 29, 2013, or December 30, 2012.

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ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM
The Board of Directors and Stockholders

Magnetek, Inc.

We have audited the accompanying consolidated balance sheets of Magnetek, Inc. as of December 29, 2013 and December 30, 2012, and the related consolidated statements of operations, comprehensive income, stockholders' equity (deficit), and cash flows for the years ended December 29, 2013 and December 30, 2012, the six months ended January 1, 2012 and the year ended July 3, 2011. 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 the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also 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.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Magnetek, Inc. as of December 29, 2013 and December 30, 2012, and the related consolidated statements of operations, comprehensive income, stockholders' equity (deficit), and cash flows for the years ended December 29, 2013 and December 30, 2012, the six months ended January 1, 2012 and the year ended July 3, 2011, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP
Milwaukee, Wisconsin

March 21, 2014

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CONSOLIDATED STATEMENTS OF OPERATIONS

(Amounts in thousands, except per share data)	Twelve Months Ended December 29, 2013	December 30, 2012	January 1, 2012	Six Months Ended January 1, 2012	January 2, 2011	Fiscal Year Ended July 3, 2011
					(unaudited)	
Net sales	$103,316	$114,274	$117,610	$58,721	$50,943	$109,832
Cost of sales	67,991	74,430	78,134	38,388	34,929	74,675
Gross profit	35,325	39,844	39,476	20,333	16,014	35,157
Operating expenses:						
Research and development	3,246	3,834	4,394	2,103	2,069	4,360
Pension expense	6,365	6,936	5,895	2,706	3,311	6,500
Sales, general and administrative	20,939	21,052	21,187	10,644	8,308	18,851
Income (loss) from operations	4,775	8,022	8,000	4,880	2,326	5,446
Non operating income:						
Interest income	—	—	—	—	(1)	(1)
Income (loss) from continuing operations before provision for income taxes	4,775	8,022	8,000	4,880	2,327	5,447
Provision for income taxes	1,016	1,096	892	549	287	630
Income (loss) from continuing operations	3,759	6,926	7,108	4,331	2,040	4,817
Income (loss) from discontinued operations, net of tax	(627)	5,697	(660)	(39)	(533)	(1,154)
Net income (loss)	$3,132	$12,623	$6,448	$4,292	$1,507	$3,663
Earnings per common share - basic						
Income (loss) from continuing operations	$1.16	$2.18	$2.27	$1.38	$0.65	$1.54
Income (loss) from discontinued operations	$(0.19)	$1.79	$(0.21)	$(0.01)	$(0.17)	$(0.37)
Net income (loss)	$0.97	$3.97	$2.06	$1.36	$0.48	$1.17
Earnings per common share - diluted						
Income (loss) from continuing operations	$1.13	$2.14	$2.22	$1.35	$0.65	$1.51
Income (loss) from discontinued operations	$(0.19)	$1.76	$(0.21)	$(0.01)	$(0.17)	$(0.37)
Net income (loss)	$0.94	$3.90	$2.01	$1.34	$0.48	$1.15
Weighted average shares outstanding - basic	3,231	3,174	3,138	3,148	3,127	3,134
Weighted average shares outstanding - diluted	3,339	3,238	3,194	3,212	3,151	3,187

The accompanying notes are an integral part of these consolidated financial statements.

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CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(Amounts in thousands)	Twelve Months Ended			Six Months Ended		Fiscal Year Ended
	December 29, 2013	December 30, 2012	January 1, 2012 (unaudited)	January 1, 2012	January 2, 2011 (unaudited)	July 3, 2011
Net income (loss)	$3,132	$ 12,623	$ 6,448	$4,292	$ 1,507	$3,663
Change in unrecognized pension liability	35,389	(8,867)	(32,576)	(35,940)	3,491	14,613
Change in currency translation adjustments	(284)	132	(42)	(218)	109	284
Comprehensive income (loss)	$38,237	$ 3,888	$ (26,170)	$(31,866)	$ 5,107	$18,560

The accompanying notes are an integral part of these consolidated financial statements.

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CONSOLIDATED BALANCE SHEETS

As of (Amounts in thousands)	December 29, 2013	December 30, 2012
Assets		
Current assets:		
Cash	$14,960	$28,706
Restricted cash	262	262
Trade accounts receivable, less allowances for doubtful accounts	15,100	15,833
Inventories	13,322	14,868
Prepaid expenses and other current assets	814	710
Total current assets	44,458	60,379
Property, plant and equipment:		
Buildings and improvements	1,963	1,963
Machinery and equipment	21,301	20,797
Less accumulated depreciation	20,529	19,905
Net property, plant and equipment	2,735	2,855
Goodwill	30,427	30,485
Other assets	4,349	5,096
Total assets	$81,969	$98,815
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$10,403	$11,954
Accrued liabilities	4,833	6,097
Total current liabilities	15,236	18,051
Long-term pension benefit obligations	48,461	102,340
Other long-term obligations	911	1,095
Deferred income taxes	9,125	8,204
Commitments and contingencies		
Stockholders' Equity (Deficit):		
Common stock, $0.10 par value, 100,000 shares authorized; 3,260 and 3,209 outstanding at December 29, 2013, and December 30, 2012, respectively	33	32
Additional paid-in capital	142,598	141,725
Retained earnings	17,088	13,956
Accumulated other comprehensive loss	(151,483)	(186,588)
Total stockholders' equity (deficit)	8,236	(30,875)
Total liabilities and stockholders' equity (deficit)	$81,969	$98,815

The accompanying notes are an integral part of these consolidated financial statements.

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CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

(Amounts in thousands)	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Retained Earnings (Accumulated Deficit)	Accumulated Other Comprehensive Loss	Total
Balance, June 27, 2010	3,120	$31	$139,246	$(6,622)	$(156,592)	$(23,937)
Shares issued	—	—				—
Shares purchased	—	—	—			—
Stock-based compensation expense	—	—	629			629
Shares issued to trust	18	—	286			286
Net income (loss)				3,663		3,663
Translation adjustments					284	284
Pension adjustments					14,613	14,613
Comprehensive income (loss)						18,560
Balance, July 3, 2011	3,138	$31	$140,161	$(2,959)	$(141,695)	$(4,462)
Stock-based compensation expense	—	—	402			402
Shares issued to trust	20	1	180			181
Net income (loss)				4,292		4,292
Translation adjustments					(218)	(218)
Pension adjustments					(35,940)	(35,940)
Comprehensive income (loss)						(31,866)
Balance, January 1, 2012	3,158	$32	$140,743	$1,333	$(177,853)	$(35,745)
Stock-based compensation expense	—	—	824			824
Shares issued	42					—
Shares purchased	(14)	—	(151)			(151)
Shares issued to trust	23	—	309			309
Net income (loss)				12,623		12,623
Translation adjustments					132	132
Pension adjustments					(8,867)	(8,867)
Comprehensive income (loss)						3,888
Balance, December 30, 2012	3,209	$32	$141,725	$13,956	$(186,588)	$(30,875)
Exercise of stock options	8		99			99
Stock-based compensation expense	—	—	676			676
Shares issued	37	1				1
Shares purchased	(13)	—	(218)			(218)
Shares issued to trust	19	—	316			316
Net income (loss)				3,132		3,132
Translation adjustments					(284)	(284)
Pension adjustments					35,389	35,389
Comprehensive income (loss)						38,237

Balance, December 29, 2013	3,260	$33	$142,598	$17,088	$(151,483)	$8,236

The accompanying notes are an integral part of these consolidated financial statements.

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CONSOLIDATED STATEMENTS OF CASH FLOWS

(Amounts in thousands)	Twelve Months Ended			Six Months Ended		Fiscal Year Ended
	December 29, 2013	December 30, 2012	January 1, 2012	January 1, 2012	January 2, 2011	July 3, 2011
Cash flows from operating activities:			(unaudited)		(unaudited)	
Net income (loss)	$3,132	$12,623	$6,448	$4,292	$1,507	$3,663
Loss (income) from discontinued operations	627	(5,697)	660	39	533	1,154
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:						
Depreciation	663	2,082	898	423	439	914
Amortization	53	53	53	27	27	53
Stock-based compensation expense	676	824	690	402	341	629
Pension expense	6,365	6,936	5,895	2,706	3,311	6,500
Deferred income tax provision	929	950	833	477	493	849
Changes in operating assets and liabilities	164	(1,453)	5,915	3,100	(2,075)	740
Cash contribution to pension fund	(24,856)	(11,571)	(4,950)	(1,920)	(5,388)	(8,418)
Net cash provided by (used in) operating activities:						
Continuing operations	(12,247)	4,747	16,442	9,546	(812)	6,084
Discontinued operations	(1,145)	4,079	(1,403)	(605)	(838)	(1,636)
Net cash provided by (used in) operating activities	(13,392)	8,826	15,039	8,941	(1,650)	4,448
Cash flows from investing activities:						
Capital expenditures	(549)	(869)	(1,345)	(796)	(155)	(704)
Net cash provided by (used in) investing activities:						
Continuing operations	(549)	(869)	(1,345)	(796)	(155)	(704)
Discontinued operations	—	—	—	—	—	—
Net cash provided by (used in) investing activities	(549)	(869)	(1,345)	(796)	(155)	(704)
Cash flow from financing activities:						
Proceeds from issuance of common stock	416	309	325	182	143	286
Purchase and retirement of treasury stock	(218)	(151)	—	—	—	—
Principal payments under capital lease obligations	(3)	(3)	(4)	(2)	(3)	(5)
Net cash provided by (used in) financing activities:						
Continuing operations	195	155	321	180	140	281
Discontinued operations	—	—	—	—	—	—

Net cash provided by (used in) financing activities	195	155	321	180	140	281
Net increase (decrease) in cash	(13,746)	8,112	14,015	8,325	(1,665)	4,025
Cash at the beginning of the period	28,706	20,594	6,579	12,269	8,244	8,244
Cash at the end of the period	$14,960	$28,706	$ 20,594	$20,594	$ 6,579	$12,269

The accompanying notes are an integral part of these consolidated financial statements.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(All amounts in the notes to consolidated financial statements are expressed in thousands unless otherwise noted, except share and per share data)

1. Summary of Significant Accounting Policies

Profile

Magnetek, Inc. (the “Company” or “Magnetek”) is a global provider of digital power control systems that are used to control motion and power primarily in material handling, elevator, and mining applications. The Company’s products consist primarily of programmable motion control and power conditioning systems used on overhead cranes and hoists, elevators, and underground mining equipment.

Basis of Presentation

The consolidated financial statements include the accounts of Magnetek, Inc. and its subsidiaries. All significant intercompany accounts and transactions have been eliminated.

Fiscal Year

On August 4, 2011, the Company's Board of Directors approved a change in the Company's fiscal year-end from the Sunday nearest to June 30 of each calendar year to the Sunday nearest to December 31, with the change to a calendar year reporting cycle beginning January 2, 2012. The intent of the change was to align the reporting of financial results more closely with peers and to better align the Company's business cycle with suppliers and customers. Fiscal years 2013 and 2012 refer to the twelve-month periods ended December 29, 2013, and December 30, 2012, respectively, and each fiscal year contained 52 weeks. Transition period 2011 refers to the six-month transition period ended January 1, 2012, and contained 26 weeks. Fiscal year 2011 refers to the twelve-month period ended July 3, 2011, and contained 53 weeks. Supplemental financial information in these financial statements with respect to the twelve months ended January 1, 2012, and the six months ended January 2, 2011, is unaudited.

Reverse Stock Split
All references to numbers of common shares and per share information in this Annual Report on Form 10-K have been adjusted retroactively to reflect the one for ten reverse stock split effected by the Company on December 5, 2011.

Use of Estimates

The preparation of financial statements in accordance with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

Accounts Receivable

Accounts receivable represent amounts due from customers in the ordinary course of business. The Company is subject to losses from uncollectable receivables in excess of its allowances. The Company maintains allowances for doubtful accounts for estimated losses from customers’ inability to make required payments. In order to estimate the appropriate level of these allowances, the Company analyzes historical bad debts, customer concentrations, current customer creditworthiness, current economic trends, and changes in customer payment patterns. If the financial

conditions of the Company's customers were to deteriorate and impair their ability to make payments, additional allowances may be required in future periods.

Inventories

The Company's inventories are stated at the lower of cost or market. Cost is determined by the first-in, first-out ("FIFO") method, including material, labor and factory overhead. Existing inventory on hand may exceed future demand either because the product is obsolete, or the amount on hand is more than can be used to meet future needs. The Company identifies potentially obsolete and excess inventory by evaluating overall inventory levels in relation to past and anticipated usage levels. In assessing the ultimate realization of inventories, the Company is required to make judgments as to future

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demand requirements and compare those with the current or committed inventory levels. If future demand requirements are less favorable than those projected by management, additional inventory write-downs may be required.

Reserves for Litigation and Environmental Issues

The Company periodically records the estimated impacts of various conditions, situations, or circumstances involving uncertain outcomes. The accounting for such events is prescribed under ASC Topic 450, Contingencies. The Company does not record gain contingencies under any circumstances. For loss contingencies, the loss must be accrued if information is available that indicates it is probable that the loss has been incurred, given the likelihood of uncertain events, and if the amount of the loss can be reasonably estimated.

The accrual of a contingency involves considerable judgment on the part of management. The Company uses its internal expertise and outside experts, as necessary, to help estimate the probability that a loss has been incurred and the amount or range of the loss.

Income Taxes

The Company uses the liability method to account for income taxes. The preparation of consolidated financial statements involves estimating the Company's current tax exposure together with assessing temporary differences resulting from differing treatment of items for tax and accounting purposes. These differences result in deferred tax assets and liabilities, which are included in the consolidated balance sheets. An assessment of the recoverability of deferred tax assets is made, and a valuation allowance is established if necessary based upon this assessment.

Pension Benefits

The valuation of the Company's pension plan requires the use of assumptions and estimates to develop actuarial valuations of pension expense, pension assets, and pension liabilities. These assumptions include discount rates, investment returns, and mortality rates. Changes in these assumptions could potentially have a material impact on the Company's pension expense and related funding requirements.

Restricted Cash

At December 29, 2013, and December 30, 2012, the Company had $0.3 million of restricted cash related to minimum balance requirements associated with procurement of certain raw materials and supplies.

Revenue Recognition

The Company's policy is to recognize revenue when the earnings process is complete. The criteria used in making this determination are persuasive evidence that an arrangement exists, delivery has occurred, the sales price is fixed or determinable, and collectability is reasonably assured. Sales are recorded net of returns and allowances, which are estimated using historical data, at the time of sale.

Terms of shipment are free on board shipping point, and payment is not contingent upon resale or any other matter other than passage of time. As a result, title to goods passes upon shipment. Amounts billed to customers for shipping costs are reflected in net sales; shipping costs are reflected in cost of sales.

Property, Plant and Equipment

Additions and improvements are capitalized at cost, whereas expenditures for maintenance and repairs are charged to expense as incurred. Depreciation is provided over the estimated useful lives of the respective assets principally on the straight-line method (machinery and equipment normally five to ten years; buildings and leasehold improvements over the shorter of the lease term or the economic life, estimated at ten to forty years).

Goodwill

In accordance with ASC Topic 350, Goodwill and Other Intangible Assets, the Company reviews the carrying value of goodwill at least annually and more frequently if indicators of potential impairment arise. Goodwill represents the excess of the amount paid to acquire the Company over the estimated fair value of the net tangible and intangible assets acquired as of

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the acquisition date. Conditions that would trigger an impairment assessment include, but are not limited to, a significant adverse change in legal factors or business climate that could affect the value of an asset.

The Company performed the required annual impairment tests for fiscal years 2013 and 2012, transition period 2011, and fiscal year 2011, and found no impairment of goodwill. There can be no assurance that future goodwill impairment tests will not result in a charge to earnings.

Intangible Assets

Additions to intangible assets are capitalized at fair market value and the carrying value of indefinite-lived intangibles is reviewed for impairment at least annually. Intangible assets are included in other assets in the consolidated balance sheets, and are amortized over the estimated useful lives of the respective assets, principally on the straight-line method. In fiscal 2009 and fiscal 2010, the Company acquired several patents related to the design and manufacture of digital DC drives for material handling and mining applications. The cost of the patents, $533 as of December 29, 2013, and December 30, 2012, was capitalized and is included in other assets in the consolidated balance sheets. The estimated useful life of the patents is 10 years. Accumulated amortization of the patents as of December 29, 2013, and December 30, 2012, was $291 and $238, respectively, resulting in a net carrying value as of those dates of $242 and $295, respectively.

Stock-Based Compensation

The Company records stock-based compensation expenses in accordance with ASC Topic 718, Stock Compensation (formerly SFAS No. 123R, Accounting for Stock-Based Compensation). Compensation expense related to all stock-based awards for fiscal years 2013 and 2012, transition period 2011, and for fiscal year 2011 is included in selling, general and administrative expense in the consolidated statements of operations. No tax benefit was recorded on the stock compensation expense for fiscal years 2013 and 2012, transition period 2011, or fiscal year 2011 due to deferred tax valuation allowances recorded by the Company in those years.

Research and Development

Expenditures for research and development are charged to expense as incurred and totaled $3,246 for fiscal 2013, $3,834 for fiscal 2012, $2,103 for the six-month transition period 2011, and $4,360 for fiscal year 2011.

Advertising

Expenditures for advertising are charged to expense as incurred and totaled $58 for fiscal year 2013, $88 for fiscal year 2012, $26 for the six-month transition period 2011, and $74 for the fiscal year 2011.

Foreign Currency Translation

The accounts of the Company’s foreign entities are measured using local currency as the functional currency. Assets and liabilities are translated to the reporting currency (U.S. Dollar) at the exchange rate in effect at year-end. Revenues and expenses are translated at the rates of exchange prevailing during the year. Unrealized translation gains and losses arising from differences in exchange rates from period to period are included as a component of accumulated other comprehensive gain or loss in stockholders’ equity.

Earnings Per Share

In accordance with ASC Topic 260, Earnings Per Share, basic earnings per share is computed using the weighted average number of common shares outstanding during the period. Diluted earnings per common share incorporate the incremental shares issuable upon the assumed vesting of restricted stock and the exercise of stock options as if all vesting and exercises had occurred at the beginning of the fiscal year.

Recent Accounting Pronouncements

On January 2, 2012, the Company adopted Financial Accounting Standards Board Accounting Standards Update ("ASU") 2011-05, an amendment to Accounting Standards Codification 220, Comprehensive Income. ASU 2011-05 introduces a new statement, the Consolidated Statement of Comprehensive Income, which begins with net earnings and adds or deducts other recognized changes in assets and liabilities that are not included in net earnings, but are reported directly to equity. For example, unrealized changes in currency translation adjustments are included in the measure of comprehensive income but are

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excluded from net income. The amendment affects only the display of those components of equity categorized as other comprehensive income and does not change existing recognition and measurement requirements that determine net earnings.

In February 2010, the SEC approved a work plan regarding convergence of US GAAP with International Financial Reporting Standards ("IFRS") and the timeline for the preparation of financial statements by U.S. registrants under IFRS. IFRS are standards and interpretations adopted by the International Accounting Standards Board. Under the proposed roadmap, the Company would be required to prepare financial statements in accordance with IFRS no earlier than in fiscal 2016. The Company is currently assessing the potential impact of IFRS on its financial statements and will continue to follow the proposed roadmap for future developments.

2. Discontinued Operations

Certain expenses incurred related to businesses the Company no longer owns, are classified as discontinued operations. The results of discontinued operations follow:

	Fiscal Year Ended		Six Months Ended	Fiscal Year Ended
	December 29, 2013	December 30, 2012	January 1, 2012	July 3, 2011
Income (loss) from discontinued operations before interest and income taxes	$(627)	$703	$(39)	$(1,154)
Income on sale of telecom power systems business	—	32	—	—
Gain from settlement agreement, net of fees	—	4,962	—	—
Income (loss) from discontinued operations	$(627)	$5,697	$(39)	$(1,154)

The Company's loss from discontinued operations of $0.6 million in fiscal 2013 was comprised mainly of charges of $0.3 million for environmental matters and $0.2 million for legal fees related to asbestos matters from previously divested businesses (see Note 10 of Notes to Consolidated Financial Statements).

Income from discontinued operations of $5.7 million in fiscal 2012 includes a gain of $5.0 million from a settlement agreement entered into by the Company to resolve a legal matter, as well as income of $1.2 million from non-cash adjustments of liabilities related to previously owned businesses, partially offset by $0.5 million of legal fees and other costs related to previously divested businesses (see Note 10 of Notes to Consolidated Financial Statements).

The Company's loss from discontinued operations in transition period 2011 includes charges of $0.3 million for adjustments to legacy insurance reserves, $0.2 million for environmental matters, and $0.2 million for legal fees related to asbestos and other costs related to previously divested businesses, offset by a gain of $0.7 million related to the recovery of legal fees paid in a patent infringement matter pursuant to an indemnification agreement (see Note 10 of Notes to Consolidated Financial Statements).

The Company's loss from discontinued operations in fiscal 2011 includes charges of $0.5 million for environmental matters, $0.3 million for legal fees related to asbestos issues, and $0.3 million for other legal fees and other costs related to previously divested businesses.

3. Goodwill

The change in the carrying value of goodwill for the periods ended December 29, 2013, and December 30, 2012, is as follows:

	December 29, 2013	December 30, 2012
Balance at beginning of period	30,485	30,465
Currency translation	(58)	20
Balance at end of period	30,427	30,485

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4. Inventories

Inventories consist of the following:

	December 29, 2013	December 30, 2012
Raw materials	$8,531	$9,754
Work in process	1,344	1,554
Finished goods	3,447	3,560
Total inventory	$13,322	$14,868

5. Bank Borrowing Arrangements

In November 2007, the Company entered into an agreement with Associated Bank, N.A. (“Associated Bank”) providing for a $10 million revolving credit facility (the “revolving facility”). Borrowings under the revolving facility bore interest at the London Interbank Offering Rate (“LIBOR”) plus 1.5%, with borrowing levels determined by a borrowing base formula as defined in the agreement, which includes the level of eligible accounts receivable. The revolving facility also supports the issuance of letters of credit, places certain restrictions on the Company’s ability to pay dividends or make acquisitions, and includes covenants that require minimum operating profit levels and limit annual capital expenditures. Borrowings under the revolving facility were originally collateralized by the Company’s accounts receivable and inventory.

The Company has subsequently entered into several amendments to the revolving facility, mainly to increase the commitment amount to $12.5 million, to extend the maturity date of the revolving facility, to broaden the security interest of Associated Bank to collateralize all assets of the Company, and to establish or modify certain covenants with which the Company must comply under the terms of the amended revolving facility.

In June 2013, the Company and Associated Bank entered into the fifth amendment to the revolving facility, the purpose of which was to (i) extend the maturity date of the revolving facility to June 15, 2014; (ii) establish minimum adjusted earnings before interest, taxes, depreciation and amortization requirements for the three-month periods ending December 31, 2012, through March 31, 2014; and (iii) establish maximum cash amounts the Company can contribute to its defined benefit pension plan during the term of the agreement.

In December 2013, the Company and Associated Bank entered into the most recent sixth amendment to the revolving facility, the purpose of which was to increase the maximum cash amounts the Company could contribute to its defined benefit pension plan during the fourth quarter of fiscal 2013.

There were no amounts outstanding on the amended revolving facility as of December 29, 2013. The Company is currently in compliance with all covenants of the revolving facility, as amended.

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6. Earnings (Loss) Per Share

The following table sets forth the computation of basic and diluted earnings (loss) per share for the periods ended:

	Fiscal Year Ended		Six Months Ended	Fiscal Year Ended
	December 29, 2013	December 30, 2012	January 1, 2012	July 3, 2011
Numerator:				
Income (loss) from continuing operations	$3,759	$6,926	$4,331	$4,817
Income (loss) from discontinued operations	(627)	5,697	(39)	(1,154)
Net income (loss)	$3,132	$12,623	$4,292	$3,663
Denominator:				
Weighted average shares for basic income (loss) per share	3,231	3,174	3,148	3,134
Add dilutive effect of stock options outstanding	108	64	64	53
Weighted average shares for diluted income (loss) per share	3,339	3,238	3,212	3,187
Income (loss) per share - basic:				
Income (loss) per share from continuing operations	$1.16	$2.18	$1.38	$1.54
Income (loss) per share from discontinued operations	$(0.19)	$1.79	$(0.01)	$(0.37)
Net income (loss) per share - basic	$0.97	$3.97	$1.36	$1.17
Income (loss) per share - diluted:				
Income (loss) per share from continuing operations	$1.13	$2.14	$1.35	$1.51
Income (loss) per share from discontinued operations	$(0.19)	$1.76	$(0.01)	$(0.37)
Net income (loss) per share - diluted	$0.94	$3.90	$1.34	$1.15

Outstanding options to purchase 147 thousand and 174 thousand shares of common stock for fiscal years 2013 and 2012, respectively, have not been included in the Company's computation of weighted average shares for diluted earnings per share because the effect would have been anti-dilutive. Similarly, outstanding options to purchase 179 thousand and 178 thousand shares of common stock for the six-month period ended January 1, 2012 and fiscal year 2011, respectively, have not been included in the Company's computation of weighted average shares for diluted earnings per share because the effect would have been anti-dilutive.

7. Fair Values of Financial Instruments

The carrying amounts of certain financial instruments including cash, restricted cash, accounts receivable, and accounts payable approximate their fair values based on the short-term nature of these instruments. In addition, the Company's investment in an annuity contract of $3.9 million at December 29, 2013, and $4.6 million at December 30, 2012, is recorded at fair value based upon the net asset value of the contract. The annuity contract is included in other assets in the accompanying consolidated balance sheet and is classified as a level 2 asset within the fair value hierarchy (refer to Note 12 of Notes to Consolidated Financial Statements for a definition of the fair value levels).

8. Asset Impairment Charges

In the fourth quarter of fiscal 2012, the Company committed to a plan to no longer pursue new business opportunities in renewable energy, due to significantly diminished expectations for future sales of inverters into renewable energy

markets. As a result, the Company determined at that time that its fixed assets used in the manufacture and test of inverters were impaired. Accordingly, the Company recorded a non-cash, pre-tax impairment charge of $1.2 million. The charge is included in cost of sales in the accompanying consolidated statement of operations for the fiscal year ended December 30, 2012. The impairment charge reduced the net book value of the Company's renewable energy fixed assets to a negligible amount.

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9. Income Taxes

The Company's provision for income taxes, all of which relates to its continuing operations, consists of the following:

For the period ended	Fiscal Year Ended December 29, 2013	Fiscal Year Ended December 30, 2012	Six Months Ended January 1, 2012	Fiscal Year Ended July 3, 2011
Current				
Federal	$—	$—	$—	$—
State	—	45	—	—
Foreign	87	101	48	(219)
Deferred				
Federal	926	955	477	953
State and foreign	3	(5)	24	(104)
Provision for income taxes	$1,016	$1,096	$549	$630

The Company did not record any provision for income taxes related to its discontinued operations for fiscal years 2013 or 2012, transition period 2011, or for fiscal year 2011, as the Company has a full valuation allowance and available net operating losses.

A reconciliation of the Company's effective tax rate for continuing operations to the statutory Federal tax rate follows:

	Fiscal Year Ended December 29, 2013		December 30, 2012		Six Months Ended January 1, 2012		Fiscal Year Ended July 3, 2011	
	Amount	%	Amount	%	Amount	%	Amount	%
Provision (benefit) computed at the statutory rate	$1,670	35.0	$2,808	35.0	$1,708	35.0	$1,906	35.0
Losses not benefited	—	—	—	—	—	—	—	—
Use of net operating losses	(622)	(13.0)	(1,652)	(20.2)	(1,124)	(23.0)	(896)	(16.5)
Foreign tax rate differential	(32)	(0.7)	(60)	(0.8)	(35)	(0.7)	(380)	(7.0)
Total provision for income taxes	$1,016	21.3	$1,096	14.0	$549	11.3	$630	11.5

Income before provision for income taxes of the Company's foreign subsidiaries (located in Canada and the United Kingdom) included in continuing operations was approximately $368, $447, $305, and $341 for fiscal years 2013 and 2012, the six-month transition period 2011, and fiscal year 2011, respectively.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes.

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Significant components of the Company's deferred tax liabilities and assets as of December 29, 2013, and December 30, 2012, follow:

	December 29, 2013	December 30, 2012
Deferred tax liabilities		
Depreciation and amortization (including differences in the basis of acquired assets)	$(9,125)	$(8,204)
Total deferred tax liabilities	(9,125)	(8,204)
Deferred tax assets		
Inventory and other reserves	2,329	2,152
Pension benefit obligation	19,055	40,240
Net operating loss and capital loss carryforwards	88,784	85,080
Total gross deferred tax assets	110,168	127,472
Less valuation allowance	(110,090)	(127,386)
Deferred tax assets less valuation allowance	78	86
Net deferred tax liability	$(9,047)	$(8,118)

The Company records valuation allowances against its deferred tax assets, when necessary, in accordance with ASC Topic 740, Income Taxes. Realization of deferred tax assets (such as net operating loss carryforwards) is dependent on future taxable earnings and may therefore be uncertain. To the extent the Company believes that recovery is unlikely, a valuation allowance is established against its deferred tax asset, which increases the Company’s income tax expense in the period such determination is made. Due to the uncertainty surrounding the timing of realizing the benefits of its deferred tax assets in future tax returns, the Company has recorded a valuation allowance against its otherwise recognizable deferred tax assets.

The Company had net operating loss (“NOL”) carryforwards for U.S. federal tax purposes of $227 million and $212 million as of December 29, 2013, and December 30, 2012, respectively. The potential tax benefit of all carryforwards has been fully reserved with a valuation allowance and therefore there is no net tax asset on the consolidated balance sheets related to this asset at December 29, 2013, or at December 30, 2012. The Company’s NOLs have a carryforward period of 20 years with expiration dates ranging from 2019 to 2033. As the balance sheet reflects no benefit of such NOLs, the Company anticipates that no federal tax liability, other than alternative minimum tax, would be recorded when U.S. taxable income is generated and such carryforwards are utilized.

The Company regularly completes internal evaluations as to whether ordinary transfers of the Company’s common stock between shareholders have resulted in an ownership change as defined in Section 382 of the Internal Revenue Code. Based on available information, the Company has determined that no such ownership change has occurred as of the end of December 29, 2013. If such ownership change had occurred, utilization of the Company’s NOLs would be subject to annual limitation provisions per the Internal Revenue Code and similar state laws.

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10. Commitments and Contingencies

Leases

The Company leases certain facilities and machinery and equipment primarily under operating lease arrangements, which generally provide renewal options. Future minimum rental payments under noncancellable operating leases as of December 29, 2013, follow:

Fiscal Year	Minimum Lease Payments
2014	1,231
2015	997
2016	938
2017	859
2018	847
Thereafter	1,879
Total lease payments	$6,751

Rent expense was $1.3 million, $1.1 million, $0.6 million, and $1.2 million for fiscal years 2013 and 2012, the six-month transition period 2011, and fiscal year 2011, respectively.

Litigation-Product Liability

The Company has been named, along with multiple other defendants, in asbestos-related lawsuits associated with business operations previously acquired by the Company, but which are no longer owned. During the Company's ownership, none of the businesses produced or sold asbestos-containing products. For such claims, the Company is either contractually indemnified against liability, or contractually obligated to defend and indemnify the purchaser of these former Magnetek business operations. With respect to these claims, the Company is uninsured, but management believes that it has no such liability and the Company aggressively seeks dismissal from these proceedings. Management does not believe the asbestos proceedings, individually or in the aggregate, will have a material adverse effect on its financial position or results of operations. Given the nature of the above issues, uncertainty of the ultimate outcome, and inability to estimate the potential loss, no amounts have been reserved for these matters.

Litigation—Patent Infringement and Related Proceedings

In August 2008, the Company filed a complaint in the Circuit Court of Cook County, Illinois, County Department, Law Division, against Kirkland & Ellis, LLP (“K&E”). The lawsuit involved a claim for breach of professional responsibility arising out of K&E’s representation of Magnetek in the patent infringement action, Ole K. Nilssen v. Magnetek, Inc. The Company alleged that, as a result of K&E’s negligent breach of professional duty in failing to discover or investigate the existence of prior art and prior misconduct which would have made Nilssen’s patent claim unenforceable or invalidated his patent, the Company suffered an arbitration award and judgment in the amount of $23.4 million, which judgment was ultimately settled by the payment to Nilssen of $18.75 million. The Company sought damages in the amount of $18.75 million. Following a December 2011 mediation, on January 9, 2012, the Company entered into a settlement agreement with K&E. Under the terms of the settlement agreement all outstanding claims were settled and released with prejudice in consideration of K&E making a $5 million settlement payment to Magnetek, which the Company received in January 2012. The federal proceeding and the Illinois Supreme Court proceeding were subsequently dismissed, also in January 2012. The Company entered into the settlement agreement to

eliminate the uncertainties, burden and expense of further litigation. The Company recorded the settlement payment as a gain in discontinued operations in the first quarter of fiscal 2012, as the initial patent infringement claim related to a business the Company divested in 2003.

As previously reported by the Company, Universal Lighting Technologies, Inc. (“ULT”) and Nilssen entered into a consent judgment in April 2008, for dismissal, on collateral estoppel grounds, of the patent infringement lawsuit filed by Nilssen against ULT. The Company had provided the defense in the lawsuit pursuant to an indemnification claim from ULT subject to the terms of the sale agreement under which ULT purchased Magnetek’s lighting business in 2003. In September 2009, Nilssen and ULT entered into a settlement agreement relating to attorney’s fees. Under the settlement agreement, Nilssen

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paid to the Company an amount of $0.75 million as attorney's fees as well as a nominal amount for costs. However, if a motion by Nilssen was successful such that ULT ceased to be the "prevailing party" and was no longer entitled to attorney's fees, then the Company would have been obligated to refund the $0.75 million attorney's fees settlement amount. In November 2011, the court ordered Nilssen's motion be denied and, as a result, Nilssen's potential claim to a refund of the attorney's fees settlement amount was extinguished. As a result, the Company recorded a gain of $0.75 million in discontinued operations in the six-month transition period ended January 1, 2012.

Litigation-Other

In November 2007, a lawsuit was filed by Antonio Canova in Italy, in the Court of Arezzo, Labor Law Section, against the Company and Power-One Italy, S.p.A. Mr. Canova is a former Executive Vice President of the Company and was Deputy Chairman and Managing Director of the Company's former Italian subsidiary, Magnetek, S.p.A. Mr. Canova asserted claims for damages in the amount of 3.5 million Euros (approximately US$4.8 million) allegedly incurred in connection with the termination of his employment at the time of the sale of the Company's power electronics business to Power-One, Inc. ("Power One") in October 2006. The claims against the Company relate to a change of control agreement and restricted stock grant. On March 8, 2012, the Court of Arezzo ruled in the Company's favor, dismissing Mr. Canova's claims against the Company as invalid. Mr. Canova appealed the ruling in September 2012.

In October 2010, the Company received a request for indemnification from Power-One for an Italian tax matter arising out of the sale of the Company's power electronics business to Power-One in October 2006. With a reservation of rights, the Company affirmed its obligation to indemnify Power-One for certain pre-closing taxes. The sale included an Italian company, Magnetek, S.p.A., and its wholly owned subsidiary, Magnetek Electronics (Shenzhen) Co. Ltd. (the "Power-One China Subsidiary"). The tax authority in Arezzo, Italy, issued a notice of audit report in September 2010 wherein it asserted that the Power-One China Subsidiary had its administrative headquarters in Italy with fiscal residence in Italy and, therefore, was subject to taxation in Italy. In November 2010, the tax authority issued a notice of tax assessment for the period of July 2003 to June 2004, alleging that taxes of approximately 1.9 million Euros (approximately US$2.6 million) were due in Italy on taxable income earned by the Power-One China Subsidiary during this period. In addition, the assessment alleged potential penalties calculated at 120% of the tax amount claimed together with interest in the amount of approximately 2.6 million Euros (or approximately US$3.6 million) for the alleged failure of the Power-One China Subsidiary to file its Italian tax return. The Power-One China Subsidiary filed its response with the provincial tax commission of Arezzo, Italy in January 2011. The tax authority in Arezzo, Italy issued a tax inspection report in January 2011 for the periods July 2002 to June 2003 and July 2004 to December 2006 claiming that the Power-One China Subsidiary failed to file Italian tax returns for the reported periods. A hearing before the Tax Court was held on July 5, 2012 on the tax assessment for the period of July 2003 to June 2004. On September 20, 2012, the Tax Court ruled in favor of the Power-One China Subsidiary dismissing the tax assessment for the period of July 2003 to June 2004. On February 22, 2013, the tax authority filed an appeal of the Tax Court's September 2012 ruling. On August 2, 2012, the tax authority in Arezzo, Italy issued additional notices of tax assessment for the periods July 2002 to June 2003 and July 2004 to December 2006, alleging that taxes of approximately 9.5 million Euros (approximately US$13.0 million) were due in Italy on taxable income earned by the Power-One China Subsidiary together with an allegation of potential penalties in the amount of approximately 2.8 million Euros (approximately US$3.9 million) for the alleged failure of the Power-One China Subsidiary to file its Italian tax returns. The Company believes the Italian tax claims are without merit and intends to vigorously defend against them. On October 1, 2013, the Court of Appeal of Florence issued its decision in the Canova matter rejecting all claims of the appellant Canova against Magnetek, Inc. and ordered Mr. Canova to pay a nominal amount in favor of Magnetek, Inc. toward the Company's legal expenses incurred in the appeal. Mr. Canova retains the right to appeal the decision to the Supreme Court within one year after the decision of the Court of Appeal was formally published (October 16, 2013). Any review by the Supreme Court would be limited to a review of the legal basis of the decision and no review of the merits of the case is possible.

Litigation - Environmental Matters

From time to time, Magnetek has taken action to bring certain facilities associated with previously owned businesses into compliance with applicable environmental laws and regulations. Upon the subsequent sale of certain businesses, the Company agreed to indemnify the buyers against environmental claims associated with the divested operations, subject to certain conditions and limitations. Remediation activities, including those related to the Company's indemnification obligations, did not involve material expenditures during fiscal years 2013 or 2012, transition period 2011, or fiscal year 2011.

The Company has also been identified by the United States Environmental Protection Agency and certain state agencies as a potentially responsible party for clean-up costs associated with alleged past waste disposal practices at several previously utilized, owned or leased facilities and offsite locations. Its remediation activities as a potentially responsible party were not material in fiscal years 2013 or 2012, transition period 2011, or fiscal year 2011. Although the materiality of future

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expenditures for environmental activities may be affected by the level and type of contamination, the extent and nature of clean-up activities required by governmental authorities, the nature of the Company's alleged connection to the contaminated sites, the number and financial resources of other potentially responsible parties, the availability of indemnification rights against third parties and the identification of additional contaminated sites, the Company's estimated share of liability, if any, for environmental remediation, including its indemnification obligations, is not expected to be material.

Bridgeport, Connecticut Facility

In 1986, the Company acquired the stock of Universal Manufacturing Company (“Universal”) from a predecessor of Fruit of the Loom (“FOL”), and the predecessor agreed to indemnify the Company against certain environmental liabilities arising from pre-acquisition activities at a facility in Bridgeport, Connecticut. Environmental liabilities covered by the indemnification agreement included completion of additional clean-up activities, if any, at the Bridgeport facility and defense and indemnification against liability for potential response costs related to offsite disposal locations. The Company's leasehold interest in the Bridgeport facility was assigned to the buyer in connection with the sale of the Company's transformer business in June 2001. FOL, the successor to the indemnification obligation, filed a petition for Reorganization under Chapter 11 of the Bankruptcy Code in 1999 and the Company filed a proof of claim in the proceeding for obligations related to the environmental indemnification agreement. The Company believes that FOL had substantially completed the clean-up obligations required by the indemnification agreement prior to the bankruptcy filing. In November 2001, the Company and FOL entered into an agreement involving the allocation of certain potential tax benefits and Magnetek withdrew its claims in the bankruptcy proceeding. The Company further believes that FOL's obligation to the state of Connecticut was not discharged in the reorganization proceeding.

In January 2007, the Connecticut Department of Environmental Protection (“DEP”) requested parties, including the Company, to submit reports summarizing the investigations and remediation performed to date at the site and the proposed additional investigations and remediation necessary to complete those actions at the site. DEP requested additional information from the Company relating to site investigations and remediation. The Company retained an environmental consultant to review and prepare reports on historical operations and environmental activities at the Bridgeport facility. In November 2009, the Company submitted its site summary report and proposed work plan to the DEP and in October 2010 submitted a revised work plan to the DEP. The Company and the DEP agreed to the scope of the work plan in November 2010. The Company has recorded a liability of $0.5 million related to the Bridgeport facility, representing the Company's best estimate of future site investigation costs and remediation costs which are expected to be incurred in the future. The liability is included in accrued liabilities in the consolidated balance sheet as of December 29, 2013.

FOL's inability to satisfy its remaining obligations to the state of Connecticut related to the Bridgeport facility and any offsite disposal locations or the discovery of additional environmental contamination at the Bridgeport facility could have a material adverse effect on the Company's financial position, cash flows or results of operations.

Letters of Credit

The Company had approximately $0.8 million of outstanding letters of credit as of December 29, 2013.

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11. Stock-Based Compensation Agreements

The Company has two stock option plans (the "Plans"), one of which provides for the issuance of both incentive stock options (under Section 422A of the Internal Revenue Code of 1986) and non-qualified stock options at exercise prices not less than the fair market value of the Company's common stock at the date of grant, and one of which provides only for the issuance of non-qualified stock options at exercise prices not less than the fair market value of the Company's common stock at the date of grant. One of the Plans also provides for the issuance of stock appreciation rights, restricted stock, incentive bonuses and incentive stock units. The total number of shares of the Company's common stock available for issuance of stock options and other stock rights under the Plans is approximately 158 thousand shares.

Under the provisions of the Plans, key employees and non-employee directors may be granted options to purchase shares of Magnetek common stock at a price not less than its fair market value on the date of grant. Options granted have a maximum term of 10 years. Vesting requirements are determined at the discretion of the Compensation Committee of the Company's Board of Directors, with vesting periods generally ranging from two to four years. The Company uses the Black-Scholes option pricing model to calculate the fair value of stock options. The key assumptions for the Black-Scholes valuation method include the expected life of the option, stock price volatility, a risk-free interest rate, and dividend yield. Many of these assumptions are judgmental and highly sensitive. Following is a table of the weighted average fair value of the Company's stock option grants for fiscal years 2013 and 2012, transition period 2011, and for fiscal year 2011, using the Black-Scholes valuation model, assuming no dividends, with the following assumptions:

	Fiscal Year Ended		Six Months Ended	Fiscal Year
	December 29, 2013	December 30, 2012	January 1, 2012	July 3, 2011
Expected life in years	5.8	5.3	5.6	5.7
Expected stock price volatility	70.9 %	74.9 %	73.7 %	73.3 %
Risk-free interest rate	2.0 %	0.8 %	1.2 %	1.6 %
Options granted (in thousands)	6	15	11	42
Weighted average fair value of options granted	$14.03	$6.47	$6.18	$8.00

Compensation expense related to stock option awards is recognized ratably over the vesting period.

The Company also awards restricted shares of the Company's common stock to key employees under the provisions of one of the Plans. Restrictions on the shares expire either after completion of a service period, typically three years, or upon achievement of established performance objectives, as determined by the Compensation Committee of the Company's Board of Directors. Shares are valued at the market price on the date of award. Compensation expense related to these awards is recognized ratably over the service period.

During fiscal 2013, the Company recorded $0.7 million of stock-based compensation related to all share-based awards. For fiscal year 2012, transition period 2011 and fiscal year 2011, the Company recorded $0.8 million, $0.4 million, and $0.6 million, respectively, of stock-based compensation related to share-based awards. Stock-based compensation expense is included in selling, general and administrative expense in the accompanying consolidated statements of operations. As of December 29, 2013, there was $1.0 million of total unrecognized compensation cost related to all stock option and restricted share grants, to be expensed ratably over a weighted-average remaining period of 1.8 years.

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A summary of certain information with respect to outstanding stock options under the Plans follows (options in thousands):

	Options	Weighted-Average Exercise Price	Aggregate Intrinsic Value ($000's)
Options outstanding, June 27, 2010	232	$51.60	$—
Granted	42	$12.60	
Exercised	—	—	
Canceled	(96)	58.90	
Options outstanding, July 3, 2011	178	$38.50	$270
Granted	11	$9.82	
Exercised	—	—	
Canceled	(10)	107.81	
Options outstanding, January 1, 2012	179	$32.67	$1
Granted	15	$10.41	
Exercised	—	$—	
Canceled	(20)	$65.26	
Options outstanding, December 30, 2012	174	$26.88	$18
Granted	6	$22.23	
Exercised	(8)	$12.06	
Canceled	(25)	$22.67	
Options outstanding, December 29, 2013	147	$28.22	$624
Exercisable options, July 3, 2011	114	$50.90	$23
Exercisable options, January 1, 2012	112	$43.42	$—
Exercisable options, December 30, 2012	115	$34.91	$9
Exercisable options, December 29, 2013	132	$29.87	$486

The following table provides information regarding exercisable and outstanding options as of December 29, 2013 (options in thousands):

	Exercisable			Outstanding		
Range of exercise price per share	Options exercisable	Weighted average exercise price per share	Weighted average remaining contractual life (years)	Options outstanding	Weighted average exercise price per share	Weighted average remaining contractual life (years)
8.48 - $10.00	4	$8.48	8.0	8	$8.48	8.0
10.01 - $15.00	32	11.43	7.0	38	11.27	7.3
15.01 - $20.00	7	17.79	7.5	7	17.79	7.5
20.01 - $30.00	47	22.77	4.6	52	22.71	5.2
30.01 - $80.00	42	55.74	2.1	42	55.74	2.1
Total	132	$29.87	4.7	147	$28.22	5.1

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The following table provides information regarding vested and unvested restricted stock activity for fiscal year 2011, for the six-month transition period 2011, and for fiscal years 2012 and 2013 (shares in thousands):

	Shares	Weighted average grant date fair value	Fair value of vested shares at vesting date
Unvested at June 27, 2010	64	$15.30	
Granted	50	$11.80	
Vested	—	—	$—
Forfeited	(23)	14.40	
Unvested at July 3, 2011	91	$13.60	
Granted	21	$13.00	
Vested	—	—	
Forfeited	—	—	
Unvested at January 1, 2012	112	$13.48	
Granted	46	$16.66	
Vested	(42)	$14.85	$437
Forfeited	(11)	$13.38	
Unvested at December 30, 2012	105	$14.35	
Granted	66	$12.60	
Vested	(37)	$12.28	$618
Forfeited	(3)	$11.50	
Unvested at December 29, 2013	131	$14.11	

12. Employee Benefit Plans

The Company maintains a defined benefit pension plan (the “pension plan”) for the benefit of eligible employees, former employees, and retirees in the U.S. The pension plan has been frozen since 2003, and since that time, participant accounts have not been credited with any additional years of service or additional compensation, but rather only with interest on accrued balances. The pension plan is managed in compliance with all provisions of the Employee Retirement Income Security Act of 1974, as amended ("ERISA"), the Investment Advisers Act of 1940, and other applicable laws. The Company funds the pension plan in accordance with applicable employee benefit and tax laws, primarily the Pension Protection Act of 2006, as amended ("PPA"). The primary purpose of the pension plan is to provide a source of retirement income for plan participants and beneficiaries.

Net pension expense for the Company’s pension plan follows:

	Fiscal Year Ended		Six Months Ended	Fiscal Year Ended
	December 29, 2013	December 30, 2012	January 1, 2012	July 3, 2011
Interest cost	$7,854	$8,655	$4,919	$9,686
Expected return on plan assets	(10,246)	(9,741)	(5,394)	(10,041)
Recognized net actuarial loss	8,757	8,022	3,181	6,855
Net pension expense	$6,365	$6,936	$2,706	$6,500

Net pension expense for fiscal 2014 is estimated at $3.7 million. During that time, it is expected that $7.2 million of amounts included in accumulated other comprehensive loss will be recognized in net periodic benefit cost. The expected long-term rate of return on pension plan assets in determining fiscal 2014 pension expense is 7.75%.

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Pension benefit obligations at year-end, the fair value of pension plan assets, and the pension plan funded status are as follows:

	December 29, 2013	December 30, 2012
Change in Benefit Obligation:		
Benefit obligation at beginning of period	$230,257	$217,452
Interest cost	7,854	8,655
Actuarial loss (gain)	(17,762)	16,922
Benefits paid	(11,285)	(12,772)
Benefit obligation at end of period	$209,064	$230,257
Change in Plan Assets:		
Fair value of plan assets at beginning of period	$127,917	$119,344
Actual return on plan assets	19,115	9,774
Employer contributions	24,856	11,571
Benefits paid	(11,285)	(12,772)
Fair value of plan assets at end of period	$160,603	$127,917
Funded status	$(48,461)	$(102,340)
Unrecognized net actuarial loss	169,070	204,459
Net amount recognized	$120,609	$102,119
Amounts Recognized in Statement of Financial Position:		
Pension benefit obligations, net	$(48,461)	$(102,340)
Accumulated other comprehensive loss	169,070	204,459
Net amount recognized	$120,609	$102,119

The pension plan has been in a net under-funded position for the past several years, and as a result, the Company recognized an additional minimum pension liability on its balance sheet in accordance with ASC 715. The pension plan's unrecognized losses of $169.1 million and $204.5 million (excluding tax benefits of $17 million) at December 29, 2013, and December 30, 2012, respectively, have been recorded as a reduction to equity in accumulated other comprehensive loss on the Company's consolidated balance sheets.

During fiscal years 2013 and 2012, the Company made contributions totaling $24.9 million and $11.6 million to the pension plan. The Company previously made required contributions to the pension plan of $1.9 million in transition period 2011, and $8.4 million in fiscal 2011. Based upon current actuarial projections and pension funding regulations, future minimum required contributions to the pension plan are estimated at $43.2 million, of which approximately $15.3 million is scheduled to be contributed during fiscal 2014. The net present value of the future required minimum contributions, discounted at 4.45%, is estimated at $38.0 million. Required contributions after fiscal 2014 are subject to change and will depend on future interest rate levels, values in equity and fixed income markets, and the level and timing of interim contributions we may make to the pension plan.

Weighted average assumptions used to determine benefit cost and benefit obligation for the pension plan follow:

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	Fiscal Year Ended		Six Months Ended	Fiscal Year Ended
	December 29, 2013	December 30, 2012	January 1, 2012	July 3, 2011
Discount rate used to determine benefit obligation	4.45%	3.50%	4.05%	5.15%
Discount rate used to determine benefit cost	3.50%	4.05%	5.15%	5.10%
Expected return on plan assets	7.75%	8.25%	8.25%	8.50%
Measurement date for pension benefit obligations	December 29, 2013	December 30, 2012	January 1, 2012	July 3, 2011

The Company's expected rate of return on plan assets is determined in part by reviewing past actual investment returns of plan assets and historical returns of the Company's asset allocation targets. In addition, management reviews assessments of the current market environment based on a variety of data sources by asset class, including correlations between economic growth, volatility, risk, return rates, interest rates, and inflation, applied to a number of different time periods, seeking time periods that are most representative of current markets. In reviewing these assessments, management relies in part on input
from the Company's independent investment manager and actuaries, who provide asset-liability modeling and other advice services which simulate how pension assets and liabilities will respond under different investment and interest rate scenarios. These models incorporate the Company's specific liability and cash flow information as well as other factors that influence the pension plan liability and corresponding assets. In addition, management periodically evaluates actual returns against appropriate benchmarks to determine if actual return rates were commensurate with expectations. Based on the Company's analysis of past actual return rates, current and expected asset allocations, and future expectations of asset performance, the long-term expected rate of return on assets was reduced to 7.75% for cost recognition purposes for fiscal 2013 from the expected return rate of 8.25% that was used in fiscal year 2012.

The Company has adopted an investment policy which is periodically reviewed and updated. The primary objective of the investment policy is to maximize the funded status of the pension plan based on a long-term investment horizon. The Company's long-term strategic investment objectives take into consideration a number of factors, including the funded status of the plan, the plan's projected liquidity needs, the demographics of the plan's participants, and a consideration of the probability and duration of investment losses weighted against the potential for long-term appreciation of assets.

The Company's investment policy also establishes asset allocation targets (guidelines) for each primary asset class. The asset allocation targets per the Company's most recently adopted investment policy statement are as follows:

Asset Class	Target Allocation
Equity	45% to 65%
Fixed income	15% to 30%
Alternative investments	20% to 40%
Cash	0% to 5%

Rapid unanticipated market shifts or changes in economic conditions may cause the asset mix to fall outside the target allocations. Generally these divergences should be of a short-term nature, and rebalancing may be necessary. Investments are diversified within asset classes with the intent of minimizing risk of large losses to the pension plan while maintaining liquidity sufficient to fund current benefit payments.

The U.S equity holdings portion of the portfolio consists primarily of equity securities or mutual funds of companies listed on registered exchanges or actively traded in the over-the-counter markets. International equity holdings consist

primarily of equity securities of non-U.S. issuers purchased in foreign markets, on U.S. or foreign exchanges, or the over-the-counter markets. The strategy for equity holdings is to provide opportunities to earn higher rates of return than with fixed income investments, while minimizing concentrations of risk by investing in a diversified mix of companies and industries worldwide, with varying market capitalization levels, growth and value profiles, fund types, and fund managers.

Fixed income holdings include core fixed income securities rated investment grade or better, such as bonds and debentures issued by domestic and foreign private and governmental issuers, as well as high-yield fixed income securities rated below investment grade. The fixed income investment strategy includes longer term maturities which match longer duration pension liabilities, and also includes the higher yield alternatives which are shorter in duration and allow for higher potential

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returns. The emerging market debt portion of the portfolio consists primarily of debt securities rated below investment grade of government and corporate issuers in emerging market countries and of entities organized to restructure outstanding debt of such issuers. The primary strategy for investing in emerging market debt is to provide opportunities to earn higher returns than core fixed income.

Limited partnership holdings consist primarily of investments in hedge funds and private investment funds. The portfolio may be allocated across several hedge fund styles and strategies, and may include equity securities, debt securities, asset-backed securities, exchange-traded funds, and derivatives. Investments in limited partnerships provide opportunities to earn above market returns.

The fair values of pension plan assets as of December 29, 2013, follows:

Pension Plan Assets	Balance as of December 29, 2013	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash and cash equivalents	$3	$3	$—	$—
Equity holdings:				
U.S. large cap	21,273	21,273	—	—
U.S. small cap	7,216	7,216	—	—
U.S. blended cap	27,794	27,794	—	—
International equity	34,503	34,503	—	—
Total equity holdings	90,786	90,786	—	—
Fixed income holdings:				
Core fixed income	13,654	—	13,654	—
Diversified short term debt	9,732	—	9,732	—
Emerging market debt	7,942	—	7,942	—
High yield debt	2,517	—	2,517	—
Total fixed income holdings	33,845	—	33,845	—
Multi asset class holdings	15,032	—	15,032	—
Limited partnership holdings	20,937	—	20,937	—
Total pension plan assets	$160,603	$90,789	$69,814	$—

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The fair values of pension plan assets as of December 30, 2012, follows:

Pension Plan Assets	Balance as of December 30, 2012	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash and cash equivalents	$—	$—	$—	$—
Equity holdings:				
U.S. large cap	43,759	43,759	—	—
U.S. small cap	4,087	4,087	—	—
International equity	25,185	25,185	—	—
Total equity holdings	73,031	73,031	—	—
Fixed income holdings:				
Core fixed income	19,618	—	19,618	—
Emerging market debt	5,130	—	5,130	—
Total fixed income holdings	24,748	—	24,748	—
Limited partnership holdings	30,138	—	30,138	—
Total pension plan assets	$127,917	$73,031	$54,886	$—

Pension plan assets do not include any shares of Company common stock as of December 29, 2013, or at December 30, 2012.

The Company uses the market approach in determining the fair value of pension assets, which uses observable prices and other information generated by market transactions involving identical or comparable assets. Cash is valued at cost, which approximates fair value.

The valuation of level 1 assets reflects quoted closing market prices from the exchanges where the securities are actively traded.

Level 2 assets are valued using observable inputs for similar assets in active markets, or identical assets in inactive markets. Debt securities categorized as level 2 assets are generally valued based on independent broker/dealer bids, or by comparison to other debt securities having similar durations, yields, and credit ratings.

Level 3 assets are fund investments in private companies, and are typically valued using entity-specific inputs, including discounted cash flow analysis, earnings multiple approaches, recent transactions, volatilities, and other factors.

The fair value of the Company's pension plan investments in limited partnership holdings has been estimated using the net asset value per share of the investment as a practical expedient. Investments in limited partnerships were categorized as level 3 investments at January 1, 2012, due to lock-up provisions which prohibited the sale of the Company's interest in these investments for specified periods of time. These lockup provisions have since expired, and the investments in limited partnerships can now be redeemed at net asset value in the near term (within three to six months). As a result, the investments in limited partnerships were reclassified from level 3 assets at January 1, 2012, to level 2 assets at December 30, 2012.

The following table presents a reconciliation of the fair value measurements using significant unobservable inputs (Level 3) as of December 29, 2013, and December 30, 2012:

	December 29, 2013	December 30, 2012
Balance, beginning of period	$—	$28,911
Depreciation in the fair market value of plan assets	—	—
Reclassification of assets to level 2	—	(28,911)
Balance, end of period	$—	$—

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Expected future benefit payments under the pension plan by fiscal year are as follows:

Fiscal Year	Benefit Payment
2014	$13,510
2015	13,199
2016	13,525
2017	13,405
2018	13,410
2019-2023	68,024

In addition to the pension plan, the Company maintains a defined contribution savings plan ("401k plan") for eligible employees. Contributions made by the Company to the 401k plan during fiscal 2013 were $444. Contributions made by the Company to the 401k plan during fiscal 2012, transition period 2011, and fiscal 2011 were $449, $232, and $200, respectively.

13. Warranties

The Company offers warranties for certain products that it manufactures, with the warranty term generally ranging from one to two years. Warranty reserves are established for costs expected to be incurred after the sale and delivery of products under warranty, based mainly on known product failures and historical experience, and are included in accrued liabilities in the accompanying consolidated balance sheets.

Changes in the warranty reserve for fiscal years 2013 and 2012 follow:

	December 29, 2013	December 30, 2012
Balance at beginning of period	$370	$689
Amounts charged to (included in) earnings, net	603	(255)
Use of reserve for warranty obligations	(594)	(64)
Balance at end of period	$379	$370

14. Supplemental Cash Flow Information

Changes in operating assets and liabilities of continuing operations follow:

	Fiscal Year Ended		Six Months Ended	Fiscal Year Ended
Fiscal period ended	December 29, 2013	December 30, 2012	January 1, 2012	July 3, 2011
(Increase) decrease in accounts receivable	$733	$906	$1,498	$(1,801)
(Increase) decrease in inventories	1,546	(1,163)	624	(4,044)
(Increase) decrease in prepaids and other current assets	(104)	222	(402)	54
(Increase) decrease in other assets	747	226	343	460
Increase (decrease) in accounts payable	(1,559)	(1,339)	2,290	2,196
Increase (decrease) in accrued liabilities	(1,199)	(305)	(1,253)	3,875
Increase (decrease) in operating assets and liabilities	$164	$(1,453)	$3,100	$740
Cash paid for interest and paid (refunded) for income taxes :				
Interest	$—	$—	$—	$—

Income taxes	$57	$210	$76	$(276)

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15. Accumulated Other Comprehensive Loss

Accumulated other comprehensive loss consisted of the following:

	December 29, 2013	December 30, 2012
Unrecognized pension plan liabilities, net of $17,000 income tax benefit	$(152,070)	$(187,459)
Foreign currency translation adjustments	587	871
Accumulated other comprehensive loss	$(151,483)	$(186,588)

Changes in the components of accumulated other comprehensive income (loss) for the twelve months ended December 29, 2013, were as follows:

	Foreign Currency	Defined Benefit Pension Plan	Total
Balance, beginning of period	$871	$(187,459)	$(186,588)
Other comprehensive income (loss) before reclassifications	(284)	—	(284)
Amounts reclassified from accumulated other comprehensive income (loss)	—	35,389	35,389
Balance, end of period	$587	$(152,070)	$(151,483)

The amount reclassified out of accumulated other comprehensive income (loss) reported in the table above is comprised entirely of actuarial losses related to the Company's defined benefit pension plan, and is included in the computation of periodic pension expense (see Note 12 of Notes to Condensed Consolidated Financial Statements). There is no tax effect on any of the current year activity included in the table above.

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16. Business Segment and Geographic Information

The Company currently operates within a single business segment, digital power control systems, and sells its products primarily to large original equipment manufacturers. The Company performs ongoing credit evaluations of its customers' financial conditions and generally requires no collateral. The Company does not have any single customer whose purchases represented 10% or more of the Company’s total revenue in fiscal year 2013.

Information with respect to the Company's foreign subsidiaries follows:

For the fiscal period	Fiscal Year Ended		Six Months Ended	Fiscal Year Ended
	December 29, 2013	December 30, 2012	January 1, 2012	July 3, 2011
Sales	$6,694	$7,164	$3,930	$6,593
Income from operations	368	447	305	341
Identifiable assets	7,882	6,553	5,665	5,200
Capital expenditures	0.036	—	—	—
Depreciation and amortization	31	26	23	53

Sales by foreign subsidiaries include sales of products to customers within the U.S.

Export sales from the United States were $4,625 during fiscal 2013, $6,698 during fiscal 2012, $3,327 during transition period 2011, and $5,624 in fiscal year 2011.

17. Quarterly Results (unaudited)

The supplementary financial information presented below provides quarterly financial data for fiscal year 2013 and for fiscal year 2012.

Fiscal 2013 quarter ended	March 31, 2013	June 30, 2013	September 29, 2013	December 29, 2013
Net sales	$25,059	$27,006	$26,011	$25,240
Gross profit	8,142	9,343	9,175	8,665
Income (loss) from operations	806	1,473	1,545	951
Income (loss) from continuing operations before income taxes	806	1,473	1,545	951
Provision for income taxes	261	280	262	213
Income (loss) from continuing operations	545	1,193	1,283	738
Income (loss) from discontinued operations	(73)	(28)	(161)	(365)
Net income (loss)	$472	$1,165	$1,122	$373
Earnings per common share - basic:				
Income (loss) from continuing operations	$0.17	$0.37	$0.40	$0.23
Income (loss) from discontinued operations	$(0.02)	$(0.01)	$(0.05)	$(0.11)
Net income (loss)	$0.15	$0.36	$0.35	$0.12
Earnings per common share - diluted:				
Income (loss) from continuing operations	$0.16	$0.36	$0.38	$0.22
Income (loss) from discontinued operations	$(0.02)	$(0.01)	$(0.04)	$(0.11)
Net income (loss)	$0.14	$0.35	$0.34	$0.11

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Fiscal 2012 quarter ended	April 1, 2012	July 1, 2012	September 30, 2012	December 30, 2012
Net sales	$28,725	$29,001	$26,863	$29,685
Gross profit	10,641	10,155	9,670	9,378
Income (loss) from operations	2,451	2,540	1,891	1,140
Income (loss) from continuing operations before income taxes	2,451	2,540	1,891	1,140
Provision for income taxes	276	267	231	322
Income (loss) from continuing operations	2,175	2,273	1,660	818
Income (loss) from discontinued operations	4,706	946	(159)	204
Net income (loss)	$6,881	$3,219	$1,501	$1,022
Earnings per common share - basic:				
Income (loss) from continuing operations	$0.69	$0.72	$0.52	$0.26
Income (loss) from discontinued operations	$1.49	$0.30	$(0.05)	$0.06
Net income (loss)	$2.18	$1.02	$0.47	$0.32
Earnings per common share - diluted:				
Income (loss) from continuing operations	$0.68	$0.70	$0.51	$0.25
Income (loss) from discontinued operations	$1.46	$0.29	$(0.05)	$0.06
Net income (loss)	$2.14	$0.99	$0.46	$0.31

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ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Magnetek had no disagreements with its independent accountants in fiscal year 2013 with respect to accounting and financial disclosure, and has not changed its independent accountants during the three most recent fiscal periods.

ITEM 9A. CONTROLS AND PROCEDURES

(a) Evaluation of Disclosure Controls and Procedures

Our management, under the supervision of and with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures, as such term is defined in Rules 13a-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), as of the end of the period covered by
this Annual Report on Form 10-K. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of December 29, 2013.

(b) Management’s Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles.

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

Our management assessed the effectiveness of our internal control over financial reporting as of December 29, 2013, the end of our 2013 fiscal year. Our management’s assessment was based on the criteria set forth in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Based on the assessment, our management has concluded that our internal control over financial reporting was effective as of December 29, 2013, the end of our fiscal year. This Annual Report does not include an attestation report of the Company’s registered public accounting firm regarding internal control over financial reporting. Management’s report was not subject to attestation by the Company’s registered public accounting firm pursuant to rules of the Securities and Exchange Commission that permit the Company to provide only management’s report in this Annual Report.

Because of inherent limitations, internal control over financial reporting, no matter how well designed, may not prevent or detect misstatements. Therefore, even effective internal control over financial reporting can only provide reasonable assurance with respect to the reliability of financial reporting and the preparation and presentation of

financial statements. Also, projections of any evaluation about the effectiveness of internal control over financial reporting to future periods are subject to the risk that controls may become inadequate due to changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

(c) Changes in Controls and Procedures

No change in internal control over financial reporting occurred during the period ended December 29, 2013, that has materially affected, or is reasonably likely to materially affect, such internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

No other information is required to be reported for matters not disclosed on Form 8-K during the fiscal year ended December 29, 2013.

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PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information called for by this Item 10 is hereby incorporated by reference to the sections of the Company's 2014 Proxy Statement entitled "Proposal No. 1 – Election of Directors," "Section 16(a) Beneficial Ownership Reporting Compliance," "Corporate Governance Principles," "Standing Committees of the Board" and by reference to Part I of this Annual Report on Form 10-K under the heading "Supplemental Information-Executive Officers of the Company."

Supplemental Information - Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics ("Code of Ethics") for all of our directors and employees that contains portions specifically applicable to executives and officers of the Company, including the Chief Executive Officer, the Chief Financial Officer, the Controller and employees performing financial functions for the Company. The Code of Ethics is posted on Magnetek's website at www.magnetek.com. A copy of the Code of Ethics is available, without charge, to any shareholder who sends a written request to our Corporate Secretary at N49 W13650 Campbell Drive, Menomonee Falls, Wisconsin, 53051. We intend to satisfy the disclosure requirements of Form 8-K regarding any amendment to, or waiver of, a provision of the Code of Ethics by posting such information on our website, at the web address and location specified above.

ITEM 11. EXECUTIVE COMPENSATION

The information called for by this Item 11 is hereby incorporated by reference to the section of the Company's 2014 Proxy Statement entitled "Compensation Discussion and Analysis" and the tables, narrative and notes relating to Executive and Director compensation, "Summary Compensation Table," "All Other Compensation Table," "Grants of Plan-Based Awards in Fiscal Year Table," "Outstanding Equity Awards at Fiscal Year-End Table," "Option Exercises and Stock Vested for Fiscal Year Table," "Pension Benefits for Fiscal Year Table," "Employment, Severance and Change in Control Agreements and Other Arrangements Table," "Director Compensation for Fiscal Year Table," "Compensation Committee Interlocks and Insider Participation" and "Compensation Committee Report."

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information called for by this Item 12 is hereby incorporated by reference to the sections of the Company's 2014 Proxy Statement entitled "Equity Compensation Plan Information Table" and "Beneficial Ownership of Magnetek, Inc. Common Stock by Directors, Officers and Certain Other Owners."

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this Item 13 is hereby incorporated by reference to the sections of the Company's 2014 Proxy Statement entitled "Proposal 1 – Election of Directors," "Relationships and Related Transactions," and "Corporate Governance Principles."

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information called for by this Item 14 is hereby incorporated by reference to the section of the Company's 2014 Proxy Statement entitled "Proposal No. 2 – Ratification of the Appointment of Independent Registered Public

Accounting Firm."

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PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) Documents filed as part of this report:

1. Financial statements - see Part II, Item 8

2. Financial statement Schedule II - Valuation and Qualifying Accounts

3. Exhibits - see exhibit index below

The following exhibits are filed as part of this Annual Report Form 10-K, or are incorporated herein by reference. Where an exhibit is incorporated by reference, the number which precedes the description of the exhibit indicates the documents to which the cross-reference is made.

Exhibit No.	Note	Description of Exhibit
3.1(a)	(1)	Restated Certificate of Incorporation of the Company, effective as of March 12, 2012.
3.1(b)	(2)	Certificate of Elimination
3.2	(3)	Magnetek, Inc. Amended and Restated By-Laws.
10.1	(6)	Agreement for the Sale of Magnetek, Inc. Power Electronics Group, dated as of September 28, 2006, by and between the Company and Power-One, Inc.
10.2	(7)	Asset Purchase Agreement dated February 4, 2008 by and among Magnetek, Inc., Enrange LLC, W. Christopher Dulin, William Gibson and David Ashburn.
10.3	(8)	Settlement Agreement and Release, dated as of April 27, 2007, by and between the Company and Samsung Electro-Mechanics Co., Ltd.
10.4	(9)	Settlement Agreement, dated as of May 24, 2007, by and among the Company, Magnetek Controls, Inc., Magnetek National Electric Coil, Inc., Federal-Mogul Corporation, Federal-Mogul Products, Inc., and certain other parties thereto.
10.5	(10)	Settlement Agreement, dated as of June 12, 2008, by and among Magnetek, Inc., Ole K. Nilssen and Geo Foundation, Ltd.
10.6	(11)	Lease of Menomonee Falls, Wisconsin facility, dated as of July 23, 1999.
10.7	(12)	Industrial Building Lease (Net) dated as of November 26, 2006, and Amendment of Industrial Building Lease (Net) dated as of April 5, 2007, by and between the Company and W.C. Bradley Co.
10.8(a)	(13)	Revolving Credit Agreement dated as of November 6, 2007, by and between the Company and Associated Bank, N.A.
10.8(b)	(14)	First Amendment to Credit Agreement dated as of December 15, 2008 by and between the Company and Associated Bank, N.A.
10.8(c)	(15)	Second Amendment to Credit Agreement dated effective as of February 19, 2010 by and between the Company and Associated Bank, N.A.
10.8(d)	(16)	Third Amendment to Credit Agreement dated effective as of December 9, 2010, by and between the Company and Associated Bank, N.A.
10.8(e)	(17)	Fourth Amendment to Credit Agreement dated effective as of December 15, 2011, by and between the Company and Associated Bank, N.A.
10.8(f)	(18)	Fifth Amendment to Credit Agreement dated as of June 7, 2013, by and between the Company and Associated Bank, N.A.
10.8(g)	(19)	Sixth Amendment to Credit Agreement dated as of December 19, 2013, by and between the Company and Associated Bank, N.A.

10.9*	(20)	Change of Control Agreement, dated as of December 11, 2002, by and between Peter McCormick and the Company.
10.10*	(4)	Change of Control Agreement, dated as of July 29, 2003, by and between Marty Schwenner and the Company.
10.11*	(21)	Form of Change of Control Agreement for named executive officers Peter M. McCormick and Marty J. Schwenner effective as of December 21, 2010.
10.12*	(5)	Form of Retention Agreement for named executive officer Hungsun S. Hui effective as of February 24, 2009.

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10.13*	(5)	Form of Retention Agreement for named executive officer Scott S. Cramer effective as of March 1, 2010.
10.14*	(21)	Form of Retention Agreement for named executive officer Michael J. Stauber effective as of February 28, 2011.
10.15*	.	Reserved.
10.16(a)*	(23)	Second Amended and Restated 2004 Stock Incentive Plan of Magnetek, Inc. (the “2004 Plan”).
10.16(b)*	(24)	First Amendment to the 2004 Plan.
10.16(c)*	(25)	Form of Restricted Stock Award Agreement Pursuant to the 2004 Plan.
10.16(d)*	(26)	Form of Non-Qualified Stock Option Agreement Pursuant to the 2004 Plan.
10.16(e)*	(26)	Form of Non-Qualified Stock Option Agreement (Performance Based) Pursuant to the 2004 Plan.
10.16(f)*	(26)	Form of Non-Qualified Stock Option Agreement (Retention Based) Pursuant to the 2004 Plan.
10.16(g)*	(26)	Form of Restricted Stock Award Agreement (Performance Based) Pursuant to the 2004 Plan.
10.16(h)*	(26)	Form of Restricted Stock Award Agreement (Retention Based) Pursuant to the 2004 Plan.
10.16(i)*	(27)	Standard Terms and Conditions Relating to Non-Qualified Options for the 2004 Plan.
10.17*	(28)	Amended and Restated 2010 Non-Employee Director Stock Option Plan of Magnetek, Inc.
10.18*	(24)	Magnetek, Inc. Director Compensation and Deferral Investment Plan.
10.19	(29)	Security Agreement dated September 14, 2012 between Magnetek, Inc. and the Pension Benefit Guaranty Corporation.
21.1	**	Subsidiaries of the Registrant as of December 29, 2013.
23.1	**	Consent of Independent Registered Public Accounting Firm.
31.1	**	Certification Pursuant to 15 U.S.C. Section 7241.
31.2	**	Certification Pursuant to 15 U.S.C. Section 7241.
32.1	**	Certifications Pursuant to 18 U.S.C. Section 1350.

*	Indicates a management contract or compensatory plan or arrangement
**	Filed with this Form 10-K.
(1)	Previously filed with Form 10-K for Transition Period ended January 1, 2012, and incorporated herein by this reference.
(2)	Previously filed with Form 8 K filed May 14, 2013, and incorporated herein by this reference.
(3)	Previously filed with Form 8-K filed May 6, 2013, and incorporated herein by this reference.
(4)	Previously filed with Form 10-Q for quarter ended September 30, 2003, and incorporated herein by this reference.
(5)	Previously filed with Form 8-K filed February 9, 2009, and incorporated herein by this reference.
(6)	Previously filed with Form 10-K for Fiscal Year ended July 2, 2006, and incorporated herein by this reference.
(7)	Previously filed with Form 8-K filed February 5, 2008, and incorporated herein by this reference.
(8)	Previously filed with Form 8-K filed May 1, 2007, and incorporated herein by this reference.
(9)	Previously filed with Form 8-K filed June 4, 2007, and incorporated herein by this reference.
(10)	Previously filed with Form 8-K filed June 13, 2008, and incorporated herein by this reference.
(11)	Previously filed with Form 10-K for Fiscal Year ended June 27, 1999, and incorporated herein by this reference.
(12)	Previously filed with Form 8-K filed August 23, 2007, and incorporated herein by this reference
(13)	Previously filed with Form 8-K filed November 7, 2007, and incorporated herein by this reference.
(14)	Previously filed with Form 8-K filed December 18, 2008, and incorporated herein by this reference.
(15)	Previously filed with Form 8-K filed February 22, 2010, and incorporated herein by this reference.
(16)	Previously filed with Form 8-K filed December 13, 2010, and incorporated herein by this reference.
(17)	Previously filed with Form 8-K filed December 19, 2011, and incorporated herein by this reference.
(18)	Previously filed with Form 8-K filed June 7, 2013, and incorporated herein by reference.
(19)	Previously filed with Form 8-K filed December 20, 2013 and incorporated herein by reference.

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(20)	Previously filed with Form 10-Q for quarter ended December 31, 2002, and incorporated herein by this reference.
(21)	Previously filed with Form 10-Q for quarter ended April 3, 2011, and incorporated herein by this reference.
(22)	Previously filed with Form 8-K filed March 3, 2010, and incorporated herein by this reference.
(23)	Previously filed with Company's Proxy Statement dated September 16, 2009, for the 2009 Annual Meeting of the Shareholders, and incorporated herein by this reference.
(24)	Previously filed with Company's Proxy Statement dated September 19, 2011, and incorporated herein by this reference.
(25)	Previously filed with Form 10-Q for quarter ended December 27, 2009, and incorporated herein by this reference.
(26)	Previously filed with Form 10-Q for quarter ended October 3, 2010, and incorporated herein by this reference.
(27)	Previously filed with Form 10-K for Fiscal Year ended June 27, 2010, and incorporated herein by this reference.
(28)	Previously filed with Company's Proxy Statement dated September 20, 2010, for the 2010 Annual Meeting of the Shareholders, and incorporated herein by this reference.
(29)	Previously filed with Form 8-K filed September 19, 2012 and incorporated herein by this reference.
(30)	Previously filed with Form 8-K filed June 7, 2013, and incorporated herein by reference.

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Chief Executive Officer and Chief Financial Officer Certifications

The certifications of Magnetek's Chief Executive Officer and Chief Financial Officer required under Section 302 and 906 of the Sarbanes-Oxley Act of 2002 have been filed with the Securities and Exchange Commission as Exhibits 31.1, 31.2, and 32.1 to the Company's Annual Report on Form 10-K for the fiscal year ended December 29, 2013.

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 in the Village of Menomonee Falls, State of Wisconsin, on the 21st day of March, 2014.

MAGNETEK, INC.

By:	/s/ MARTY J. SCHWENNER Marty J. Schwenner	Vice President and Chief Financial Officer (Principal Financial Officer)	March 21, 2014

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

Signature	Title	Date
/s/ MITCHELL I. QUAIN Mitchell I. Quain	Chairman of the Board of Directors	March 21, 2014
/s/ DAVID A. BLOSS, SR. David A. Bloss, Sr.	Director	March 21, 2014
/s/ ALAN B. LEVINE Alan B. Levine	Director	March 21, 2014
/s/ DAVID P. REILAND David P. Reiland	Director	March 21, 2014
/s/ PETER M. MCCORMICK Peter M. McCormick	Director, President and Chief Executive Officer	March 21, 2014
/s/ MARTY J. SCHWENNER Marty J. Schwenner	Vice President and Chief Financial Officer (Principal Financial Officer)	March 21, 2014
/s/ MICHAEL J. STAUBER Michael J. Stauber	Vice President and Corporate Controller (Principal Accounting Officer)	March 21, 2014

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SCHEDULE II

MAGNETEK, INC.
VALUATION AND QUALIFYING ACCOUNTS
PERIODS ENDED JULY 3, 2011, JANUARY 1, 2012, DECEMBER 30, 2012, AND DECEMBER 29, 2013
(amounts in thousands)

	Balance at beginning of year	Additions charged (recoveries added) to earnings	Deductions from allowance	Other	Balance at end of year
July 3, 2011					
Allowance for doubtful accounts	$249	$29	$(24)	$1	$255
January 1, 2012					
Allowance for doubtful accounts	$255	$(6)	$(42)	$(1)	$206
December 30, 2012					
Allowance for doubtful accounts	$206	$13	$—	$—	$219
December 29, 2013					
Allowance for doubtful accounts	$219	$13	$(16)	$(1)	$215

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
Magnetek, Inc.

We have audited the consolidated financial statements of Magnetek, Inc. as of, and for the years ended December 29, 2013 and December 30, 2012, the six months ended January 1, 2012, and the year ended July 3, 2011, and have issued our report thereon dated March 21, 2014 (included elsewhere in this Annual Report on Form 10-K). Our audits also included the financial statement schedule listed in Item 15(a) of this Annual Report on Form 10-K. This schedule is the responsibility of the Company's management. Our responsibility is to express an opinion based on our audits. In our opinion, the financial statement schedule referred to above, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

/s/ Ernst & Young LLP
Milwaukee, Wisconsin

March 21, 2014