CYTOGEN CORP Form 10-K March 16, 2007

# 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 <u>December 31, 2006</u> OR

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

For the transition period from \_\_\_\_\_\_ to \_\_\_\_\_ to \_\_\_\_\_ Commission File Number 000-14879

(Exact Name of Registrant as Specified in Its Charter)

Delaware 22-2322400

(State or Other Jurisdiction of (I.R.S. Employer Identification No.)

Incorporation or Organization)

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:

Title of Class Name of Exchange on which Registered

Common Stock, \$0.01 par value per share

The NASDAQ

Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: Preferred Stock Purchase Rights, \$0.01 par value per share

Indicate by check mark whether the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes "No x

Indicate by check mark whether the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes "No x

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.

Yesx 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 a large accelerated filer, an accelerated filer, or a non-accelerated filer.

Large Accelerated Filer "

Accelerated Filer x

Non- Accelerated Filer "

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes "No x

The aggregate market value of the registrant's voting shares of Common Stock held by non-affiliates of the registrant on June 30, 2006, based on \$2.50 per share, the last reported sale price on the NASDAQ Global Market on that date, was \$56,119,227.

The number of shares of Common Stock, \$.01 par value, of the registrant outstanding as of March 9, 2007 was 29,605,631 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 2007 Annual Meeting of Stockholders are incorporated by reference into Part III hereof.

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This Annual Report contains forward-looking statements, which can be identified by the use of forward-looking terminology such as, "believe," "expect," "may," "plan," "estimate," "intend," "will," "should," "potential" or "anticipate" or the negative thereof, or other variations thereof, or comparable terminology, or by discussions of strategy. No assurance can be given that the future results covered by such forward-looking statements will be achieved. The matters set forth in Item 1A. Risk Factors constitute cautionary statements identifying important factors with respect to such forward-looking statements, including certain risks and uncertainties that could cause actual results, events or developments to differ materially from those indicated in such forward-looking statements. All information in this Annual Report on Form 10-K is as of March 16, 2007. We undertake no obligation to update this information to reflect events after the date of this report.

CAPHOSOL®, QUADRAMET® (samarium Sm-153 lexidronam injection) and PROSTASCINT® (capromab pendetide) are registered United States trademarks of Cytogen Corporation. Other trademarks and trade names used in this Annual Report are the property of their respective owners.

We are sponsoring or supporting certain clinical investigations to explore potential new indications for the use of QUADRAMET and PROSTASCINT. This Annual Report contains discussions that include investigational clinical applications that differ from those reported in the package inserts for QUADRAMET and PROSTASCINT and have not been reviewed or approved by FDA. QUADRAMET is indicated for the relief of pain in patients with confirmed osteoblastic metastatic bone lesions that enhance on a radionuclide bone scan. 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.

SOLTAMOX<sup>TM</sup> (tamoxifen citrate, oral solution 10mg/5mL) is indicated for the treatment of metastatic breast cancer and to reduce the incidence of breast cancer in women who are at high risk for the disease. As with other versions of tamoxifen, the product label for SOLTAMOX includes a black box warning with information on the potential risk of adverse events. The boxed warning states, in part, that: "Serious and life threatening events associated with tamoxifen in the risk reduction setting (women at high risk for cancer and women with ductal carcinoma in situ) include uterine malignancies, stroke and pulmonary embolism."

A copy of the full prescribing information for CAPHOSOL, QUADRAMET, PROSTASCINT and SOLTAMOX in the United States may be obtained from us by calling us toll free at 800-833-3533 or by visiting our website at <a href="https://www.cytogen.com">www.cytogen.com</a>. Our website is not part of this Annual Report on Form 10-K.

We maintain www.cytogen.com to provide information to the general public and our stockholders on our products, as well as general information on Cytogen and its management, strategy, career opportunities, financial results and press releases. Copies of our most recent Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, and other reports filed with the

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Securities and Exchange Commission, or the SEC, can be obtained, free of charge as soon as reasonably practicable after such material is electronically filed with, or furnished to the SEC, from our Investor Relations Department by calling 609-750-8213, through the Investor Relations page on our website at www.cytogen.com or directly from the SEC's website at <a href="https://www.sec.gov">www.sec.gov</a>. Our website and the information contained therein or connected thereto are not intended to be incorporated into this Annual Report on Form 10-K.

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.

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#### PART I

Item 1. Business

#### Overview

Cytogen is a specialty pharmaceutical company dedicated to advancing the treatment and care of cancer patients by building, developing, and commercializing a portfolio of oncology products for underserved markets where there are unmet needs. Our product portfolio includes four oncology products approved by the United States Food and Drug Administration ("FDA"), CAPHOSOL®, QUADRAMET®, PROSTASCINT®, and SOLTAMOX,™which are marketed solely by our specialized sales force to the U.S. oncology market. We introduced our fourth product, CAPHOSOL, in the first quarter of 2007. CAPHOSOL is an advanced electrolyte solution for the treatment of oral mucositis and dry mouth that was approved as a prescription medical device. QUADRAMET is approved for the treatment of pain in patients whose cancer has spread to the bone. SOLTAMOX, which we introduced in the second half of 2006, is the first liquid hormonal therapy approved in the U.S. for the treatment of breast cancer in adjuvant and metastatic settings. PROSTASCINT is a prostate-specific membrane antigen (PSMA) targeting monoclonal antibody-based agent to image the extent and spread of prostate cancer. Currently, our clinical development initiatives are focused on new indications for QUADRAMET and PROSTASCINT, as well our product candidate, CYT-500, a radiolabeled antibody in Phase 1 development for the treatment of prostate cancer.

In 2003, we realigned our corporate direction to focus on building a successful oncology franchise with a specialized commercial infrastructure equipped to deliver sustainable value. To that end, we have established a growing commercial presence in the U.S., which targets both medical and radiation oncology. We believe marketing proprietary specialty oncology products directly, as opposed to receiving royalties on sales by licensees, will enable us to build a growth-oriented oncology business. Because there is a limited number of leading cancer clinics across the U.S., we believe our highly trained and focused sales team can effectively market a complementary product offering to a broad market segment. Our sales and marketing infrastructure has played a critical role in our ability to add new commercial-stage products to our portfolio. Further, we believe the commercial arm of our business is highly scalable and can readily support new product opportunities through modest capital investments.

## Strategy and Approach

Our strategy focuses on growing our business organically and through in-licensing initiatives. It revolves around three key priorities:

• Expanding our near- and long-term revenues. We have successfully implemented an active in-licensing program to broaden our revenue base with product opportunities that are complementary to our commercial presence in oncology. In April 2006, we acquired the commercial rights to SOLTAMOX from Savient Pharmaceuticals, Inc. ("Savient") and in October 2006, we acquired the commercial rights to CAPHOSOL from InPharma A/S ("InPharma"). These two products are new revenue sources for

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2007. We are also pursuing clinical-stage candidates in complementary therapeutic areas with promising regulatory pathways.

- Maximizing the market potential of our approved products through data-driven initiatives. A robust, data-driven strategy is underway to enhance the market opportunities for our products within their currently approved indications. We are supporting numerous post-marketing studies for QUADRAMET to optimize its potential as a safe, effective, non-narcotic option for the palliation of pain from cancers that have spread to the bone. We are also advancing initiatives to position PROSTASCINT as an important tool for managing the care of prostate cancer. Recent progress includes: (i) the publication of new data in the American Cancer Society's peer-reviewed journal, Cancer, demonstrating repeated dosing of QUADRAMET to be a safe and effective treatment option for patients with recurrent painful bone metastases; (ii) the expanded inclusion of PROSTASCINT within the National Comprehensive Cancer Network's ("NCCN") clinical practice guidelines to include patients with recurrent disease; and (iii) the publication of seven-year survival data in the American Brachytherapy Society's peer-reviewed journal, Brachytherapy, demonstrating the potential for PROSTASCINT fusion imaging to help determine patient-specific treatment regimens for prostate cancer patients undergoing brachytherapy.
- Building long-term sustainability. We are focused on maintaining a balanced specialty portfolio through three key imperatives: (i) evaluating new indications for our marketed products; (ii) accessing product candidates complementary to our commercial presence; and (iii) monetizing assets that are no longer a strategic fit and realigning our investment on projects that are in line with our business objectives. Our 2006 progress includes the presentation of promising Phase 1 data for Quadramet in combination with bortezomib for relapsed multiple myeloma and the approval of an investigational new drug application to evaluate CYT-500 as a therapy for prostate cancer. In addition, in April 2006, we monetized our interest in a preclinical-stage joint venture, PSMA Development Company LLC ("PDC") for a cash payment of \$13.2 million and potential future milestone payments totaling up to \$52 million. We are also pursuing strategic opportunities to optimize the extensive intellectual property and technology associated with our AxCell BioSciences subsidiary.

## **Marketed Products**

#### **CAPHOSOL**

Overview

CAPHOSOL is an advanced electrolyte solution indicated in the U.S. as an adjunct to standard oral care in treating oral mucositis caused by radiation or high dose chemotherapy. It is also indicated for dryness of the mouth or dryness of the throat regardless of the cause or whether the conditions are temporary or permanent. CAPHOSOL is approved in the U.S. as a prescription medical device.

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We acquired the exclusive commercial rights for CAPHOSOL in North America from InPharma in October 2006 in exchange for aggregate up-front payments totaling \$6.0 million which includes \$1 million payable in 2007, a \$400,000 payment contingent upon certain conditions, future royalties on product sales, and sales-based milestone payments. We are also obligated to pay a finder's fee based on a percentage of milestone payments made to InPharma. We also obtained options to acquire the rights to CAPHOSOL for the European and Asian markets, which we only intend to exercise in connection with obtaining a commercial partner for those areas. We will be required to obtain consents from certain licensors but not InPharma, if we sublicense the rights to market CAPHOSOL in Europe and Asia to other parties. In the event we exercise the options to license marketing rights for CAPHOSOL for the European and Asian markets, we would be obligated to pay additional fees, including sales-based milestone payments for the respective territories.

#### Oral mucositis

Oral mucositis is commonly described as one of the most significant and debilitating acute complications associated with radiation therapy and chemotherapy. It is estimated to affect more than 400,000 cancer patients each year occurring in about 40% of patients receiving conventional chemotherapy, 75% to 85% of bone marrow transplant recipients, and nearly all patients undergoing radiation therapy for head and neck cancers. Oral mucositis usually begins seven to ten days after initiation of cytotoxic therapy, and remains present for approximately two weeks after cessation of that therapy.

Oral mucositis is an oral mucosal change that manifests first by thinning of oral tissues leading to redness or inflammation of the skin or mucous membranes. As these tissues continue to thin, ulceration eventually occurs. In severe cases, oral mucositis can complicate the management of cancer by leading to interruption or stopping of treatment, which can negatively impact treatment outcomes.

While there are a number of agents available for oral mucositis, we believe the current market is significantly underserved thereby presenting us with a promising opportunity to substantially expand our revenue base.

#### CAPHOSOL for oral mucositis

CAPHOSOL lubricates the mucosa and helps maintain the integrity of the oral cavity through its mineralizing potential. We believe the distinguishing feature of CAPHOSOL is its high concentrations of calcium and phosphate ions, which are hypothesized to exert their beneficial effects by diffusing into intracellular spaces in the epithelium and permeating the mucosal lesion in mucositis. Calcium ions may play a crucial role in several aspects of the inflammatory process, the blood clotting cascade, and tissue repair. Phosphate ions may be a valuable supplemental source of phosphates for damaged mucosal surfaces.

In two single-arm studies evaluating patients receiving hematopoietic stem cell transplantation (HSCT) and head and neck radiation therapy, the CAPHOSOL-based oral health management system was well tolerated and was associated with an improvement in oral mucositis as compared with previous controlled studies. These favorable results were the basis for a prospective, randomized, double-blind, placebo-controlled trial demonstrating that

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CAPHOSOL is a significant adjunct in the management of mucositis associated with high-dose chemotherapy and radiation therapy. The trial evaluated 95 patients undergoing HSCT with the duration and severity of mucositis and requirements for opioid medications prospectively evaluated. Data demonstrated significant decreases in days of mucositis (3.72 vs. 7.20 days, P=0.001), maximum (peak) level of mucositis using the National Institute of Dental and Craniofacial Research (NIDCR) scale (median level of 1.0 vs. 3.0, P=0.004), duration of pain (2.86 vs. 7.67 days, P=0.0001), dose of morphine (30.46 mg vs. 127.96 mg), and days of morphine (1.26 vs. 4.02 days, P=0.0001) for patients receiving CAPHOSOL as compared to those administered a placebo, respectively. A total of 40% vs. 19% of patients had no mucositis in the CAPHOSOL and the control arms, respectively. The lead investigator for the study was Athena Papas, DMD, PhD, Department of Oral Medicine, Tufts University School of Medicine, Boston MA and results were published in the April 2003 issue of the peer-reviewed journal *Bone Marrow Transplantation* (Papas et al. Bone Marrow Transplant. 2003 April:31(8):705-12).

## Dry mouth

Saliva is the principle protective mechanism for oral tissues. Any absence of saliva or alteration in its composition leaves the mouth susceptible to infection or deterioration. Xerostomia or dry mouth occurs when the salivary glands do not produce enough saliva. It is a serious oral health problem that, when left untreated, leads to disease in the oral cavity and places patients at risk for oral infections. Common complaints with dry mouth include difficulty in speaking, chewing, and tasting and swallowing foods. Dry mouth may be caused by a variety of factors, including cancer treatment with chemotherapy and/or radiation, Sjögren syndrome and other autoimmune disorders, diabetes, renal dialysis, solid organ and bone marrow transplant, psychiatric disorders, and use of more than 400 pharmaceutical products known to adversely affect salivary output.

## CAPHOSOL for dry mouth

Saliva is an important part of the mucosal immune system. Caphosol lubricates the oral cavity and its high concentrations of calcium and phosphate ions can help to maintain the integrity of the teeth.

Our products, including CAPHOSOL, are subject to significant regulation by governmental agencies, including the FDA, as is more fully described below under the section entitled "Government Regulation." We cannot assure you that we will be able to successfully market CAPHOSOL for oral mucositis and/or dry mouth.

#### **OUADRAMET**

## Overview

QUADRAMET is an oncology product that pairs the targeting ability of a small molecule, bone-seeking phosphonate (ethylenediaminetetramethylenephosphonic acid, or EDTMP) with the therapeutic potential of radiation (samarium Sm-153). QUADRAMET is indicated for the relief of pain in patients with confirmed osteoblastic metastatic bone lesions that enhance on a radionuclide bone scan. We market QUADRAMET to medical and radiation oncologists in the U.S.

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#### Bone metastases

It is estimated that each year more than 100,000 patients in the U.S. develop bone metastases from spread of their primary cancer. Bone is the third most common site of metastatic disease after liver and lung, and the spread of cancer to bone is associated with considerable morbidity. This includes bone pain and fracture, spinal cord compression, and hypercalcemia. The incidence of bone metastasis is expected to increase over the next decade as patient survival improves due to advances in anticancer therapy. This will make the treatment of this problem more important in the overall management of the surviving cancer patient. The majority of skeletal metastases arise from primary tumors of the thyroid, kidney, lung, prostate, and breast, with the latter two accounting for about 80% of metastatic bone disease. While all bones can be affected, the most common site of disease spread is the spine with the subsequent development of spinal cord compression. In advanced breast cancer, a majority of skeletal events will occur every three to four months resulting in significant morbidity and impaired quality of life.

## QUADRAMET for painful bone metastases

Skeletal invasion by prostate, breast, multiple myeloma, and other cancers often create an imbalance between the normal process of bone destruction and formation. QUADRAMET selectively targets such sites of imbalance, thereby delivering radioactivity directly to areas of the skeleton that have been invaded by metastatic tumor. QUADRAMET has demonstrated a range of characteristics that may be advantageous for the treatment of pain arising from metastatic bone disease. In clinical trials, QUADRAMET demonstrated significant reductions in pain scores accompanied by reductions in opioid analgesic use as compared to placebo. Patients who respond to treatment with QUADRAMET may experience pain relief within the first week lasting a median of 16 weeks, with maximal relief generally occurring at three to four weeks after injection. Patients who experience a reduction in pain may be encouraged to decrease their use of opioid analgesics.

Despite a favorable safety and efficacy profile, the routine use of QUADRAMET for the palliation of disseminated painful bone metastases has commonly been reserved for those patients with end-stage disease when other treatment options have been exhausted. We believe this practice may have evolved as a result of experiences with earlier generation radiopharmaceuticals, such as strontium-89, which unlike QUADRAMET are associated with prolonged myelosuppression. In December 2006, the American Cancer Society's journal, *Cancer*, published new data from a multi-center Phase 4 study evaluating the safety and efficacy of repeated doses of QUADRAMET in patients with metastatic bone pain. This study is the first prospective clinical trial specifically evaluating the common clinical scenario of patients who initially respond to QUADRAMET and subsequently become candidates for re-treatment upon the recurrence of symptoms. More than 200 patients, including 55 patients who received repeated dosing of QUADRAMET participated in the multi-center study. The results demonstrated that repeated QUADRAMET dosing is a safe and effective treatment option in patients with painful bone metastases. The article, "Safety and efficacy of repeat administration of Samarium Sm-153 lexidoronam to patients with metastatic bone pain," by A. Oliver Sartor, the lead author and a nationally renowned prostate cancer specialist with Dana-Farber Cancer Institute's Lank Center for Genitourinary Oncology, appeared in the February 1, 2007 edition of *Cancer 2007*; 109: 637-43.

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Because we believe QUADRAMET is underutilized as a pain therapy for patients whose cancer has spread to the bone, we are advancing numerous clinical and commercial initiatives to better support QUADRAMET and expand its market potential within its approved label for pain palliation. In connection with our reacquisition of the commercial rights to QUADRAMET in 2003, we conducted detailed market research that formed the foundation of our product growth strategy. The key components of this strategy are summarized below.

- Distinguishing the physical properties of QUADRAMET from earlier generation agents within its class. We believe the limited use of QUADRAMET for the palliation of disseminated painful bone metastases has evolved due to the myelosuppression associated with earlier generation radiopharmaceuticals, such as strontium-89. While to date, there are no head-to-head clinical trials comparing QUADRAMET and strontium-89, we believe, there are several key differentiating features that distinguish QUADRAMET from strontium-89. First, QUADRAMET's physical half life is 1.9 days, as compared to 50.5 days for strontium-89. A shorter half life results in a much faster time to deliver the total dose of radiation, as well as a shorter exposure to radioactivity. In addition, particle emissions from strontium-89 are significantly higher in energy compared to QUADRAMET and higher-energy particles are associated with larger volumes of marrow exposed to radiation. These key differences have been highlighted in recent peer-reviewed publications that our field force can utilize when they present QUADRAMET to health care providers.
- Empowering and marketing to key prescribing audiences. We have broadened our commercial focus and are now introducing QUADRAMET to both medical and radiation oncologists, as we believe the effective treatment of bone metastases requires a cooperative effort between the two specialties. We have retrained and refocused our sales force with new resources that highlight QUADRAMET's attributes for treating painful bone metastases, such as its rapid onset and duration of relief.
- Broadening palliative use within label beyond prostate cancer to include breast, lung, and multiple myeloma. Historically, the vast majority of QUADRAMET's use has been for bone metastases secondary to prostate cancer; however, bone metastases are also a frequent complication of a number of other cancers, including breast, lung, and multiple myeloma. We have extended our therapeutic focus beyond prostate cancer specialists to include other cancers with a high propensity for painful bone metastases. In addition, our 2006 acquisitions of SOLTAMOX for breast cancer and CAPHOSOL for oral mucositis and dry mouth, two common side effects of cancer therapy, offer expanded access to new therapeutic areas for QUADRAMET.
- Generating data to support the role of QUADRAMET in contemporary oncology settings with other commonly used cancer therapeutics. We are supporting numerous clinical development initiatives evaluating QUADRAMET in combination with chemotherapies and biologics for prostate cancer, breast cancer, multiple myeloma, and osteosarcoma. These trials are designed with two key objectives. First, to broaden QUADRAMET's market potential within its currently approved treatment setting for pain palliation by evaluating the safety and tolerability of administering

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QUADRAMET in combination with other cancer regimens. Second, to support our longer-term strategy for maximizing the QUADRAMET brand by progressing QUADRAMET beyond its currently approved treatment setting as a potential therapeutic for cancer that has spread to the bone as discussed below.

## Market expansion for QUADRAMET

We believe that QUADRAMET's targeted delivery of radiotherapy may also have an important therapeutic effect beyond palliation of pain. Phase 1 clinical data suggest there may be synergistic effects between QUADRAMET and other cancer therapies for prostate cancer, breast cancer, multiple myeloma, and osteosarcoma.

#### Prostate cancer

In February 2007, we reported the presentation of interim data from a Phase 1 study evaluating QUADRAMET in combination with docetaxel (Taxotere®) for the treatment of hormone-refractory prostate cancer. Data from 18 patients were presented at the Prostate Cancer Symposium, a multidisciplinary meeting co-sponsored by the American Society of Clinical Oncology, the American Society for Therapeutic Radiology and Oncology, the Prostate Cancer Foundation, and the Society of Urologic Oncology. This trial continues to accrue patients in a Phase 1 extension to explore the optimal dosing schedule for a Phase 2 clinical study to be initiated in 2007.

#### Breast cancer

During 2007, we plan on expanding our combination strategy for QUADRAMET to include breast cancer through the initiation of a Phase 1 trial evaluating QUADRAMET in combination with albumin-bound paclitaxel (Abraxane®) and a Phase 2 trial evaluating QUADRAMET in connection with hormonal therapies.

#### Multiple myeloma

In December 2006, we reported the presentation of interim data from a Phase 1 dose escalation study evaluating QUADRAMET® in combination with bortezomib (Velcade®) in patients with relapsed multiple myeloma. Data from 20 patients administered a total of 35 treatment cycles were presented at the Annual Meeting of the American Society of Hematology. A treatment cycle is 8 weeks in duration and consists of four administrations of bortezomib (on Days 1, 4, 8 and 11) and a single administration of QUADRAMET (on Day 3). Results indicated the combination of QUADRAMET and bortezomib was well-tolerated at the doses studied and we are preparing for the initiation of a follow-up Phase 2 study in 2007.

#### Osteosarcoma

Following the presentation of encouraging data at the Connective Tissue Oncology Society (CTOS) annual meeting in November 2006, we are currently designing a Phase 2 protocol to evaluate QUADRAMET for the treatment of osteosarcoma. We expect to initiate this study during 2007.

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In addition to the aforementioned Company-sponsored clinical development initiatives in prostate cancer, breast cancer, multiple myeloma, and osteosarcoma, we continue to explore investigator-sponsored studies and studies with cooperative groups to advance our QUADRAMET combination strategy.

In July 2006, we reported that the National Cancer Institutes's (NCI) Radiation Treatment Oncology Group (RTOG) initiated a randomized phase III trial to evaluate either QUADRAMET or strontium-89 chloride in conjunction with zoledronic acid (Zometa®) in the treatment of osteoblastic metastases arising from lung, breast, and prostate cancer. The study is designed to determine if the addition of a radiopharmaceutical to bisphosphonates for patients with asymptomatic or stable symptomatic bone metastasis will delay the time to development of malignant skeletal related events (SREs), defined as a pathological bone fracture, spinal cord compression, surgery to bone, or radiation to bone. The study is expected to involve approximately 350 patients.

In March 2007, we reported that the NCI, part of the National Institutes of Health (NIH), initiated a randomized Phase 2 study to evaluate QUADRAMET in combination with the NIH's targeted therapeutic vaccine, PSA-TRICOM, for patients with progressive hormone-refractory prostate cancer who have failed docetaxel-based regimens. The primary objective of the study is to determine if there is an improvement in four-month progression-free survival for the combination regimen versus QUADRAMET therapy alone. The study is expected to enroll 68 patients. Currently, there is no standard of care for treating prostate cancer patients who have progressive disease following docetaxel-based therapy.

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.

## **PROSTASCINT**

#### Overview

Our PROSTASCINT molecular imaging agent is the first, and currently the only, commercial product targeting PSMA. PSMA is abundantly expressed on the surface of prostate cancer cells. In contrast to other prostate-related antigens such as PSA, prostatic acid phosphatase, and prostate secretory protein, PSMA is a type II integral membrane glycoprotein that is not secreted. PSMA expression is increased in high-grade cancers, metastatic disease, and hormone-refractory prostate cancer. PSMA is also present at high levels on the newly formed blood vessels, or neovasculature, needed for the growth and survival of many solid tumors. This unique expression pattern makes PSMA an excellent antigenic target for monoclonal antibody diagnostic and therapeutic options.

PROSTASCINT consists of our proprietary murine monoclonal antibody 7E11-C5.3 ("7E11") directed against PSMA and the radioisotope indium-111. A radioisotope is an element which, because of nuclear instability, undergoes radioactive decay and emits gamma 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.

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 enhancing system sensitivity. System enhancements allow improved image quality or reduced scan time, which reduces the risks associated with patient motion. Equipment vendors have introduced advanced single photon emission computed tomography (SPECT) reconstruction algorithms, as well as three dimensional iterative reconstruction techniques that 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, PROSTASCINT may now be co-registered with an anatomic image obtained with either computed tomography (CT) or magnetic resonance (MR) imaging (PROSTASCINT fusion 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.

#### Prostate cancer

Prostate cancer is the most common type of cancer found in American men, other than skin cancer. In 2007, the American Cancer Society estimates that there will be about 219,000 new cases of prostate cancer diagnosed in the United States and that about 27,000 men will die from the disease. It is estimated that there are more than 2 million American men currently living with prostate cancer. Prostate-specific antigen (PSA) is a protein produced by the cells of the prostate gland. Tests to determine the amount of PSA in the blood, along with a digital rectal exam, is used to help initially detect prostate cancer and is also used to monitor patients with a history of prostate cancer to see if the cancer has come back, or recurred; however, PSA levels cannot directly identify the extent or location of disease.

## PROSTASCINT for prostate cancer

When deciding on a course of therapy for newly diagnosed prostate cancer, physicians must determine the extent of disease in the patient. When disease has not spread beyond the

prostate gland, patients are most likely to benefit from local treatment options, such as surgical removal of the prostate gland. Patients diagnosed with distant disease that has spread beyond the prostate gland have a poorer chance of five-year survival than those with disease confined to the gland and are more likely to benefit from systemic therapy. 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. PROSTASCINT is a non-invasive way to help determine if the cancer is confined to the prostate or if it has spread to other areas of the body.

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 CT or 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 PSMA and, therefore, may identify disease not readily detectable with conventional procedures, such as CT or MR imaging alone.

In June 2006, data from a series of studies evaluating PROSTASCINT fusion imaging and advancements in image processing methods were presented at the Society of Nuclear Medicine's annual meeting. The data demonstrated new potential for PROSTASCINT fusion imaging to help determine patient-specific treatment regimens and improve outcomes for prostate cancer patients.

In January 2007, we reported that the National Comprehensive Cancer Network (NCCN) included PROSTASCINT in its updated clinical practice guidelines for recurrent prostate cancer. We believe the expanded inclusion in the NCCN's guidelines further reinforces the value of PROSTASCINT for evaluation of prostate cancer in patients suspected of having locally recurrent disease. NCCN is a non-profit alliance of 20 of the world's top cancer centers. The NCCN's Clinical Guidelines in Oncology are a benchmark for clinical policy in the oncology community. These guidelines are updated continually and are based upon evaluation of scientific data integrated with expert judgment by multidisciplinary panels of expert physicians from NCCN member institutions. We believe the expanded NCCN guidelines reflect the growing awareness of the advancements in imaging processing and the value of PROSTASCINT fusion imaging.

In February 2007, the American Brachytherapy Society's peer-reviewed journal, *Brachytherapy* published the results of a seven-year survival study that suggest PROSTASCINT may help predict which patients are less likely to benefit from brachytherapy for prostate cancer. The study, "Biochemical disease free survival rates following definitive low dose rate prostate brachytherapy with dose escalation to biologic target volumes identified with SPECT/CT Capromab Pendetide," by Ellis et al. (Brachytherapy Volume 6, Issue 1, January-March 2007, Pages 16-25) evaluated the use of PROSTASCINT fusion imaging to define brachytherapy treatment regimens for 239 newly-diagnosed prostate cancer patients. PROSTASCINT fusion imaging was used to assess local and distant disease and to alter the radiation dose to areas of suspected high tumor burden. In a multivariate analysis, uptake of PROSTASCINT outside of the prostate gland was found to be a significant and independent predictor of biochemical disease

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free survival (bDFS). Using the American Society for Therapeutic Radiation and Oncology (ASTRO) standard criteria to monitor PSA response for reporting disease free survival, the cure rate was 90.6% for patients whose fused PROSTASCINT scan showed local disease (n=217) versus 66.1% (n=22) for patients with distant disease (p=0.0005). We believe this publication further reinforces PROSTASCINT's emerging potential as a valuable tool in managing the care of prostate cancer patients.

## Validation of PSMA prognostic value

In May 2006, Cytogen announced the presentation of clinical data demonstrating that a high level of PSMA in prostate tissue is a strong predictor of prostate cancer recurrence. The data was presented at the 101st American Urological Association (AUA) Annual Meeting held May 20-25, 2006, in Atlanta, GA.

In the study, independent investigators from Ulm, Germany, and Boston, MA, analyzed PSMA expression by tissue microarray in 96 patients with either localized or metastatic prostate cancer who had undergone radical prostatectomy, or surgical removal of the prostate, as monotherapy. One third of the patients had disease confined to the prostate gland with no spread to lymph nodes (LN), 33% had only one positive LN, and the remaining third had more than one positive LN. Following therapy, patients were monitored for a maximum of 12.6 years with an average follow-up of 2.7 years.

Significant up-regulation of PSMA expression was noted in patients with metastatic disease as compared to those with localized prostate cancer and in localized disease compared to benign prostate tissue (p<0.05). High PSMA levels were associated with a significant increase in disease recurrence following therapy (p<0.001) in univariate statistical analyses. Other significant parameters for predicting disease recurrence included LN positivity, extraprostatic extension of disease, seminal vesicle invasion by disease, and Gleason score 8-10. Using multivariate statistical analyses, the best model to predict disease recurrence included high PSMA expression (p<0.01) and extraprostatic extension (p=0.02) after adjusting for Gleason score and seminal vesicle invasion.

This new study validates and extends upon data previously published demonstrating that over-expression of PSMA in primary prostate cancer not only correlates with other adverse traditional prognostic factors, but can independently predict both a higher incidence and shorter time to disease recurrence. There is a tremendous need for better prognostic markers in prostate cancer to assist in the identification of patients with aggressive forms of the disease who can potentially benefit from earlier and more intensive forms of treatment. The findings presented at AUA further support our belief in the importance of PSMA as an independent prostate cancer marker and important diagnostic and therapeutic target.

#### Market Expansion for PROSTASCINT

We believe the major developments in imaging resolution, emerging clinical data, and the increasing level of recognition of the value of PROSTASCINT fusion imaging support an important near- and long-term market opportunity for PROSTASCINT. We are focused on capitalizing on this opportunity by generating awareness and expanded usage for

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PROSTASCINT fusion imaging through a number of clinical and commercial initiatives. Key highlights from our strategy are summarized below.

- Positioning PROSTASCINT fusion imaging as the standard of care for prostate cancer imaging. PROSTASCINT fusion imaging combines anatomic and functional information to provide a complete pathology picture in a single exam. This can help physicians eliminate guesswork and enable them to better plan and individualize patient treatment. PROSTASCINT fusion imaging can be accomplished through software or hardware solutions. Of the approximately 400 sites able to perform PROSTASCINT imaging, there are approximately 150 sites currently proficient in PROSTASCINT fusion imaging. We are focused on growing the number of these sites by increasing awareness of the significant advancements that have taken place and the value of PROSTASCINT fusion imaging to expand the number of sites.
- Generating awareness of the prognostic value of the PSMA antigen. There is a growing body of clinical data demonstrating that over-expression of PSMA in prostate cancer patients correlates with other adverse prognostic factors and can independently predict disease recurrence. We are focused on generating awareness of PSMA as an important prognostic marker for prostate cancer and positioning

PROSTASCINT as an important tool for identifying patients who may benefit from more intensive treatment regimens.

- Leveraging the presentation and publication of outcomes data. In 2006, outcomes data from recent and ongoing clinical trials of PROSTASCINT were reported at major medical meetings and in the peer-reviewed publication, Brachytherapy. These data continue to support the potential of PROSTASCINT fusion imaging as an important tool to define patients with local or metastatic disease, help clarify treatment decisions, and prevent or limit treatment-related side effects.
- Advancing image-guided therapy applications. The 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. The potential of this application is described in the previously discussed 2007 publication reporting seven-year biochemical outcomes after image-guided brachytherapy using PROSTASCINT fusion imaging. The publication, "Biochemical disease free survival rates following definitive low dose rate prostate brachytherapy with dose escalation to biologic target volumes identified with SPECT/CT Capromab Pendetide," by Ellis et al. appeared in the American Brachytherapy Society's peer-reviewed journal, *Brachytherapy* (Brachytherapy Volume 6, Issue 1, January-March 2007, Pages 16-25.)
- Evaluating the potential for imaging other PSMA-expressing cancers. PSMA was originally thought to be strictly expressed in prostate tissue, but studies have

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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 may demonstrate recognition of tumor-associated neovasculature by the PROSTASCINT monoclonal antibody. Detection of other malignancies such as non-Hodgkin's lymphoma, neurofibromatosis, and meningioma has 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.

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

#### **SOLTAMOX**

#### Overview

In the second half of 2006, we introduced SOLTAMOX in the U.S. SOLTAMOX, a cytostatic estrogen receptor antagonist, is the first oral liquid hormonal therapy approved in the U.S. SOLTAMOX is indicated for the treatment of breast cancer in adjuvant and metastatic settings and to reduce the risk of breast cancer in women with ductal carcinoma *in situ* (DCIS) or with high risk of breast cancer. We market SOLTAMOX to the U.S. oncology market through our specialty sales and marketing team.

We acquired the exclusive U.S. marketing rights for SOLTAMOX in April 2006 from Savient. We also entered into a supply agreement with Rosemont Pharmaceuticals Ltd ("Rosemont"), a former subsidiary of Savient, for the manufacture and supply of SOLTAMOX. Such agreements were subsequently assigned by Savient to Rosemont. Under the terms of the transaction we paid Savient an up-front licensing fee of \$2.0 million, are obligated to pay royalties on net sales and may pay additional contingent sales-based payments of up to \$4.0 million to Rosemont.

SOLTAMOX, a liquid formulation of tamoxifen developed by Savient, received U.S. regulatory approval in October 2005.

## Breast cancer

Breast cancer is the most common non-skin cancer in women and the second leading cause of death in women after lung cancer. According to the American Cancer Society, it is estimated that in 2007 about 178,480 new cases of invasive breast cancer will be diagnosed

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among women in the United States. At this time there are slightly over 2 million breast cancer survivors in the United States. In addition to invasive breast cancer, carcinoma in situ (CIS) will account for about 62,030 new cases in 2007. CIS is noninvasive and is the earliest form of breast cancer. Breast cancer also occurs in men. An estimated 2,030 cases of invasive breast cancer will be diagnosed in men in 2007. Breast cancer is the second leading cause of cancer death in women, exceeded only by lung cancer. In 2007, about 40,460 women and 450 men will die from breast cancer in the United States. Estrogen is known to promote the growth of approximately two-thirds of breast cancers that contain estrogen or progesterone receptors. Breast cancer treatment often involves agents designed to block the effect of estrogen or lower estrogen levels. Tamoxifen, the most commonly used anti-estrogen drug, has been shown to reduce the risk of cancer recurrence and improve overall survival in all age groups.

## SOLTAMOX for breast cancer

Tamoxifen interferes with the activity of the estrogen hormone. Estrogen promotes the growth of breast cancer cells and tamoxifen works against these effects. It has been used for more than 20 years to treat patients with advanced breast cancer. Clinical trials have documented the benefits of adjuvant tamoxifen in women with early-stage breast cancer. Adjuvant tamoxifen therapy reduces the risk of a systemic recurrence and results in a significant increase in overall survival for women with hormone-receptor-positive breast cancer. The standard recommendation for women with hormone receptor-positive breast cancer is five years of tamoxifen. Soltamox is bioequivalent in rate and extent of absorption to tamoxifen citrate tablets and it is the only liquid formulation available in the U.S.

Because many patients prefer different formulations of pharmaceutical products, we believe that providing patients with a preferred delivery option can drive adherence to therapy and improve treatment outcome. While tamoxifen citrate tablets are a standard of care for certain breast cancer settings, they are associated with compliance and persistency issues. Recently published data show that although overall adherence to tamoxifen tablets is better than that seen with other chronic medications, adherence rates dropped to 50% after four years of therapy. In 2003, the Journal of Clinical Oncology published a study evaluating the adherence and predictors of non-adherence in women starting tamoxifen as adjuvant breast cancer therapy. The study "Nonadherence to Adjuvant Tamoxifen Therapy in Women with Primary Breast Cancer" by Partridge, et al., evaluated 2,378 patients initiating tamoxifen from 1990 to 1996 and concluded that nearly 25% of tamoxifen patients may be at risk for inadequate clinical response because of poor adherence. While this level of adherence is high compared with other medications, further efforts are necessary to identify and prevent suboptimal adherence.

We believe that providing an alternative oral liquid dosing form of tamoxifen is an important option for patients that may allow more women to benefit from hormonal treatment for estrogen receptor positive breast cancer.

As with other versions of tamoxifen, the SOLTAMOX product label also includes a black box warning with information on the potential risk of adverse events. The boxed warning states, in part, that: "Serious and life threatening events associated with tamoxifen in the risk reduction setting (women at high risk for cancer and women with ductal carcinoma *in situ*) include uterine malignancies, stroke, and pulmonary embolism. The benefits of SOLTAMOX outweigh its risks in women already diagnosed with breast cancer."

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Our products, including SOLTAMOX, 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 successfully compete in the taxomifen market.

## **Research and Development**

Our total research and development expenses, including our investment in PDC, a preclinical joint venture with Progenics that we sold in April 2006, for the years ended December 31, 2006, 2005, and 2004 were \$7.4 million, \$9.3 million, and \$6.2 million, respectively. These expenses included \$120,000, \$3.2 million, and \$2.9 million related to our equity in the loss of PDC, for the years ended December 31, 2006, 2005, and 2004, respectively. We are no longer responsible for funding PDC.

Our ongoing clinical development initiatives consist of expanding the market potential for our existing products along with development of new product candidates. Our research and development strategy is mindful of risk management and over the past three years we have monetized or discontinued the vast majority of our investment in research and preclinical stage programs. Our current clinical development strategy is to focus on clinical-stage opportunities that are complementary to our commercial presence and have an identifiable pathway to approval.

Our proprietary research and development activities in 2006 were primarily focused on clinical expansion studies for QUADRAMET and PROSTASCINT and preparation for the Phase 1 study for CYT-500, our radiolabeled monoclonal antibody that we are developing for the treatment of prostate cancer.

#### CYT-500

In February 2007, we announced the initiation of the first human clinical study of CYT-500, our proprietary radiolabeled monoclonal antibody targeted to PSMA. The Phase 1 clinical trial will investigate the safety and tolerability of CYT-500 and determine the optimal antibody mass and therapeutic dose for further studies. The clinical trial is being conducted at Memorial Sloan-Kettering Cancer Center under a Cytogen sponsored Investigational New Drug ("IND") application, which was approved by the United States Food and Drug Administration in May 2006, and is expected to enroll up to 36 patients.

CYT-500 employs the same 7E11 monoclonal antibody as our molecular imaging agent PROSTASCINT; however, it is linked to lutetium 177 (Lu-177), a particle emitting therapeutic radionuclide, as opposed to an imaging radionuclide. We designed this novel product candidate to enable targeted delivery of high doses of radiation to PSMA-expressing cells.

Preclinical pharmacokinetic and biodistribution studies of CYT-500 demonstrated that the compound is stable in serum, accumulates at the tumor site and clears from normal organs and tissues. Acute and expanded toxicology studies and safety pharmacology studies with unlabeled doses up to 20 times the anticipated human dose did not reveal significant adverse reactions. The preclinical data were presented in November 2005 at the American Association

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for Cancer Research-National Cancer Institute-European Organization for Research and Treatment of Cancer International Conference on Molecular Targets and Cancer Therapeutics.

We believe there is a strong rationale for development of CYT-500 for several factors, including:

- Radiotherapy has been successfully developed and used to treat hematological disorders. Prostate cancer mirrors a hematological disorder in the sense that most of the disease is in the skeleton in the bone marrow.
- •PSMA is a validated target and our proprietary 7E11 antibody is a confirmed effective PSMA-targeting agent that has been injected into more than 60,000 patients as a component of PROSTASCINT.
- The 7E11 antibody is conjugated with a bifunctional chelating agent that forms highly stable and kinetically inert complexes, which we believe lends to the optimal attachment of a therapeutic radioisotope.
- In terms of repetitive dosing, the clinical protocol in the approved IND allows for repeated administrations of the agent.

## Discontinued research and development programs

Since 2004, we have been realigning our research and development investment to focus on clinical-stage opportunities.

In April 2006, we sold our interest in PDC to Progenics for a cash payment of \$13.2 million, potential future regulatory and sales-based milestone payments totaling up to \$52.0 million, and royalties on any future PDC product sales. PDC was formed in 1999 to develop *in vivo* immunotherapeutic products utilizing PSMA.

In July 2004, we initiated the closure of the facility for our AxCell Biosciences subsidiary. Currently, our business development initiatives include an active out-licensing program to capitalize on the proprietary technology associated with AxCell. These technologies are discussed in further detail in the Technology section below.

## **Technology**

Our strategy includes pursuing strategic opportunities to optimize the value of our intellectual property and associated proprietary technologies. For example, in April 2006, we sold our interest in PDC for a cash payment of \$13.2 million, and potential future milestone and royalty payments. This provided us with additional capital to grow our business and enabled us to substantially reduce our research and development investment in early-stage projects. In addition, we have several technology platforms that are available for out-licensing. These platforms are focused within the areas that are described below.

Prostate-Specific Membrane Antigen or PSMA

PSMA is protein that is highly expressed on the surface of prostate cancer cells and the neovasculature of solid tumors. In 1987, Dr. Julius S. Horosziewicz identified the PSMA protein

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using a monoclonal antibody. The antibody technology developed by Dr. Horosziewicz was assigned to Cytogen. Researchers at the Sloan-Kettering Institute for Cancer Research identified and sequenced the gene encoding PSMA. We have the exclusive worldwide license to these technologies, which are the foundation of our proprietary PSMA-targeting monoclonal antibody, 7E11.

Our PSMA-targeting platform has been successfully applied through the commercialization of our product PROSTASCINT, the first and only commercial monoclonal antibody-based agent targeting PSMA to image the extent and spread of prostate cancer. We are also developing a third-generation radiolabeled antibody to treat prostate cancer, CYT-500. CYT-500 combines our proprietary PSMA-targeting monoclonal antibody with a high-affinity chelator and a beta-emitting isotope.

PSMA has also been found to be present at high levels in the new blood vessels, or neovasculature, formed in association with most solid tumors, including breast, lung and colorectal 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 PSMA, technologies targeting this antigen may yield novel products for the treatment and diagnosis of cancer. If PSMA-targeting 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 August 2000, we executed a sublicense agreement with Northwest Biotherapeutics Inc. (NWBT) pursuant to which we granted NWBT the right 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. Following encouraging results from a Phase 1/2 trial to evaluate the safety and efficacy of using PSMA with NWBT's proprietary dendritic cell immunotherapy, DCVax®, NWBT advanced DCVax-Prostate to the initiation of Phase 3 clinical trials. In November 2002, NWBT suspended all clinical trial activity for its DCVax product candidates and withdrew its Investigative New Drug Application (IND) for DCVax- Prostate, which resulted in a termination of the license agreement with us. As a result, we regained the rights to *ex vivo* prostate cancer immunotherapy using PSMA in December 2002. In January 2005, NWBT announced that it received clearance from the FDA to begin assessment of DCVax-Prostate in a Phase 3 clinical trial. We are awaiting clarification from NWBT on the status of this PSMA-based program following termination of the license agreement with us.

## AxCell Biosciences Subsidiary

In 1993, we licensed from the University of North Carolina at Chapel Hill (UNC-CH) exclusive worldwide rights to novel reagents and technology for identifying targeting peptides that were developed under sponsored research funded by Cytogen. This process utilizes random peptide libraries (Genetic Diversity Library, GDL<sup>TM</sup>) 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 in many regards 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 much 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

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libraries to discover specific binding molecules that would represent attractive alternatives to monoclonal antibodies for diagnostic and therapeutic products.

In 1996, Cytogen entered into a research and licensing agreement with Elan Corporation, plc, which marked the Company's 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 subsequently 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.

In November 2006, we were issued United States patent number 7,135,457 covering oral drug delivery agents - random peptide compositions that bind to gastro-intestinal tract (GIT) transport receptors. The patent specifically covers compositions of Cytogen's oral delivery agents that are capable of facilitating transport of an active agent through a human or animal GIT, and derivatives and analogs thereof, and nucleotide sequences coding for said proteins and derivatives. The oral delivery agents have use in facilitating transport of active agents from the lumenal side of the GIT into the systemic blood system, and/or in targeting active agents to the GIT.

By binding (covalently or noncovalently) one of Cytogen's delivery agents to an orally administered drug or by coating the surface of nanoparticles or liposomes with the delivery agent, the drug can be targeted to specific receptor sites or transport pathways which are known to operate in the human gastrointestinal tract, thus facilitating its systemic absorption into the bloodstream.

The binding of Cytogen's delivery agents to these receptors has been confirmed in preclinical models, and successful *in vivo* delivery of both insulin and leuprolide in animal models have been demonstrated. Based on these results, we are seeking partnerships for oral drug delivery.

A subsidiary of Cytogen, 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-CH 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<sup>TM</sup>) 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

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comprehensive network (ProChart<sup>TM</sup>) 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 network 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.

AxCell initially partnered with a leading global provider of bioinformatics software solutions to make the ProChart database available to subscribing medical and scientific researchers around the world on a commercial basis. However, due to the fact that AxCell identified protein-protein interactions through a high throughput, *in vitro* system, prospective customers were reluctant to make a significant subscription commitment in the absence of *in vivo* validation for the AxCell data. The absence of such validation, combined with a reevaluation of the subscription database business model, resulted in a realignment of the AxCell business plan in 2002 to focus on applying its extensive 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." PNAS 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).

We believe the application of our ProChart database technology may accelerate research and drug development by:

- Discovering novel signal transduction pathways and their relevant protein-protein interactions, such as rapidly identifying qualified drug targets and identifying potential unwanted side effects.
- Identifying structure and activity relationship (SAR) information regarding domain and ligand interactions that can facilitate small molecule drug design.
  - Providing high throughput screening reagents (eg, cloned domains and ligands).

In view of recent biological validation and progress through both internal data mining efforts and external research collaborations along with the oral drug delivery technology, Cytogen is currently exploring strategic transactions for AxCell.

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## **Strategic Agreements**

We frequently enter into alliances with other companies to, among other things, increase our financial resources, manage 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.

## InPharma AS

In October 2006, we entered into a license agreement with InPharma granting us exclusive rights to CAPHOSOL in North America. Under the terms of the agreement, we are obligated to pay InPharma aggregate up-front fees totaling \$6.0 million, of which \$4.6 million was paid in the fourth quarter of 2006, \$400,000 will be paid into an escrow account and \$1.0 million is payable in the second quarter of 2007. In addition, we are obligated to pay InPharma royalties on net sales and sales-based milestone payments up to an aggregate of \$49.0 million, of which payments totaling \$35 million are, based upon annual sales levels first exceeding \$30 million. We are also obligated to pay a finder's fee based on a percentage of milestone payments made to InPharma.

We also obtained options to acquire the rights to CAPHOSOL for the European and Asia markets that we only intent to exercise in connection with obtaining a commercial partner for those areas. We will be required to obtain consents from certain licensors but not InPharma, if we sublicense the rights to market CAPHOSOL in Europe and Asia to other parties. In the event we exercise the options to license the marketing rights for CAPHOSOL for the European and Asian markets, we would be obligated to pay additional fees, including sales-based milestone payments for the respective territories.

#### Rosemont Pharmaceuticals Limited

In April 2006, we entered into a distribution agreement with Savient granting us exclusive marketing rights for SOLTAMOX in the United States. In addition, we entered into a supply agreement with Savient and Rosemont for the manufacture and supply of SOLTAMOX. Such agreements were subsequently assigned by Savient to Rosemont. Under the terms of the final transaction, we paid Savient an up-front licensing fee of \$2.0 million and may pay additional contingent sales-based payments of up to a total of \$4.0 million to Rosemont. We are also required to pay Rosemont royalties on net sales of SOLTAMOX. Each of the distribution and supply agreements terminates upon the later the expiry of the last-to-expire patent covering SOLTAMOX in the United States or ten years from the date of launch of the SOLTAMOX in the United States. Thereafter, such agreements will be automatically renewed for an additional year. The manufacturing agreement is terminable by Rosemont or us on one year notice prior to the end of the then current term. In the event the tamoxifen prescriptions for an agreed upon period of time are less than the pre-established minimum, the agreement may be terminated if we are unable to reach an agreement with Rosemont to amend the terms of the contract to account for such impact.

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Bristol-Myers Squibb Medical Imaging, Inc.

Effective January 1, 2004, we entered into a manufacturing and supply agreement with Bristol-Myers Squibb Medical Imaging, Inc. ("BMSMI"), under which BMSMI manufactures, distributes and provides order processing and customer service for us for QUADRAMET. Under the terms of the agreement, we are obligated to pay at least \$4.9 million annually, subject to future annual price adjustment, through 2008, unless we or BMSMI terminates on two years prior written notice. This agreement will automatically renew for five successive one-year periods unless we or BMSMI terminates on two years prior written notice. We also pay BMSMI a variable amount per month for each QUADRAMET order placed to cover the costs of customer service which is included in selling, general and administrative expenses.

#### Laureate Pharma, L.P.

In September 2006, we entered into a non-exclusive manufacturing agreement with Laureate Pharma, L.P. ("Laureate") under which Laureate manufactures PROSTASCINT and its primary raw materials for us in Laureate's Princeton, New Jersey facility. The agreement will terminate, unless terminated earlier pursuant to its terms, upon Laureate's completion of the specified production campaign for PROSTASCINT and shipment of the resulting products from Laureate's facility.

In September 2005, we entered into a non-exclusive manufacturing agreement with Laureate for the scale-up for the cGMP manufacturing of CYT-500. Our agreement with Laureate terminated on December 31, 2006. We believe that such agreement provided us with a sufficient supply to satisfy our requirements for Phase 1 clinical trials of CYT-500.

## Holopack Verpackungstechnik GmbH

In February 2007, we entered into a non-exclusive manufacturing agreement with Holopack Verpackungstechnik GmbH for the manufacture of CAPHOSOL. The agreement has a term of two years and automatically renews for an additional year. The agreement is terminable by Holopack or us on three months notice prior to the end of each term period.

## The Dow Chemical Company

We acquired an exclusive license from The Dow Chemical Company ("Dow") for QUADRAMET for the treatment of osteoblastic bone metastases in certain territories. The agreement requires us to pay Dow royalties based on a percentage of net sales of QUADRAMET, or a guaranteed contractual minimum payment, whichever is greater, and future payments upon achievement of certain milestones.

In May 2005, we entered into a license agreement with Dow to create a targeted oncology product designed to treat prostate and other cancers. The agreement applies proprietary MeO-DOTA bifunctional chelant technology from Dow to radiolabel our PSMA antibody with a therapeutic radionuclide. Under the agreement, proprietary chelation technology and other capabilities, provided through ChelaMed<sup>SM</sup> radiopharmaceutical services from Dow, will be used to attach a therapeutic radioisotope to the 7E11 monoclonal antibody utilized in our PROSTASCINT molecular imaging agent. As a result of the agreement, we are obligated to pay a minimal license fee and aggregate future milestone payments of \$1.9 million for each licensed

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product, if approved, and royalties based on sales of related products, if any. Unless terminated earlier, the Dow agreement terminates at the later of (a) the tenth anniversary of the date of first commercial sale for each licensed product or (b) the expiration of the last to expire valid claim that would be infringed by the sale of the licensed product. We may terminate the license agreement with Dow on 90 days written notice.

Oncology Therapeutics Network, J.V.

In June 2006, we entered into a purchase and supply agreement with Oncology Therapeutics Network, JV. ("OTN") appointing OTN as the exclusive distributor of SOLTAMOX in the United States. In August 2006, the agreement was amended to revise certain terms, including changing the role of OTN to the exclusive warehousing agent and non-exclusive distributor of SOLTAMOX. Under the terms of the amended agreement, OTN will purchase SOLTAMOX from us for its own wholesaler channels and, along with third-party logistics providers, distribute SOLTAMOX to our other customers through its warehousing and distribution facilities. In January 2007, we further amended our agreement with OTN to also include CAPHOSOL.

#### **Product Contribution to Revenues**

For the years ended December 31, 2006, 2005, and 2004, PROSTASCINT and QUADRAMET accounted for, substantially all of our product revenues. For the years ended December 31, 2006, 2005 and 2004, revenues related to PROSTASCINT accounted for approximately 53%, 46% and 49%, respectively, of our total revenues; and revenues related to QUADRAMET accounted for approximately 47%, 52% and 50%, respectively, of our total revenues. During the second half of 2006, we introduced SOLTAMOX in the U.S., and during the first quarter of 2007, we introduced CAPHOSOL in the U.S. In accordance with U.S. generally accepted accounting principles (GAAP), we will recognize revenues for SOLTAMOX and CAPHOSOL in our consolidated statement of operations when we have sufficient information to estimate expected product returns for these introduced products.

#### **Concentration of Sales**

During the year ended December 31, 2006, we received 64% of our total revenues from three customers, as follows: 41% from Cardinal Health (formerly Syncor International Corporation); 14% from Mallinckrodt Inc.; and 9% from GE Healthcare (formerly Amersham Health).

During the year ended December 31, 2005, we received 67% of our total revenues from three customers, as follows: 47% from Cardinal Health (formerly Syncor International Corporation); 11% from Mallinckrodt Inc., and 9% 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,

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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.

## Competition Related to CAPHOSOL

Currently, there is limited consensus standard of care for oral mucositis supported by clinical data and to date, there has only been one commercially available prescription pharmaceutical product approved by the FDA for oral mucositis, the intravenous growth factor palifermin. Ice chips, local painkillers and narcotics are also used to reduce the patient's pain and doctors routinely prescribe mouthwashes containing traditional antibacterial and antifungal drugs for the treatment of oral mucositis, although most clinical trials have shown that they have suboptimal efficacy. There are also a number of oral rinses that have been approved as medical devices by FDA for dry mouth; however, CAPHOSOL is the only approved calcium phosphate oral rinse that is indicated for both oral mucositis and dry mouth that is supported by significant efficacy data from a randomized placebo-controlled study.

We believe there are a number of key differentiating factors that give CAPHOSOL a competitive advantage including its high concentrations of calcium and phosphate ions, its intellectual property, and the efficacy data which support its beneficial effects for relieving oral mucositis.

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## 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.

QUADRAMET primarily competes with strontium-89 chloride in the radiopharmaceutical pain palliation market. Strontium-89 chloride is manufactured and marketed as a branded product by GE Healthcare and as a generic version by Bio-Nucleonics Pharma, Inc. GE Healthcare manufactures strontium-89 chloride 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).

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.

## Competition Related to SOLTAMOX

The current competitive treatments for SOLTAMOX include the tablet form of tamoxifen citrate, a generic drug, and a class of drugs known as aromatase inhibitors.

## Competition Related to PROSTASCINT

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

#### **Manufacturing and Supply of Raw Materials**

We do not manufacture any of our products. We have contracted with third-party manufacturers to supply the raw materials and finished products to meet our needs. Our third-party manufacturers meet the FDA's current Good Manufacturing Practices or cGMP, regulations, and guidelines. cGMP regulations require that all manufacturers of pharmaceuticals for sale in the U.S. achieve and maintain compliance with regulations governing the manufacturing, processing, packaging, storing and testing of drugs intended for human use.

Holopack is the sole manufacturer of CAPHOSOL under a manufacturing supply agreement. The agreement has a term of two years and automatically renews for an additional year. Such agreement is terminable by Holopack or us on three months notice prior to the end of each term period.

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. Our manufacturing and supply agreement with BMSMI, under which BMSMI manufactures, distributes and provides order processing and customer service for us for QUADRAMET, runs through 2008, unless we

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or BMSMI terminates on two years prior written notice. This agreement will automatically renew for five successive one-year periods unless we or BMSMI terminates on two years prior written notice.

Laureate is the sole manufacturer of PROSTASCINT, the PSMA targeting antibody, 7E11, which is a component of PROSTASCINT, as well as our clinical compound, CYT-500. In September 2006, we entered into a non-exclusive manufacturing agreement with Laureate under which Laureate manufactures PROSTASCINT and its primary raw materials for us in Laureate's Princeton, New Jersey facility. The agreement will terminate, unless terminated earlier pursuant to its terms, upon Laureate's completion of the specified production campaign for PROSTASCINT and shipment of the resulting products from Laureate's facility. In September 2005, we entered into a non-exclusive manufacturing agreement with Laureate for the scale-up for the cGMP manufacturing of CYT-500. Our agreement with Laureate terminated on December 31, 2006. We believe that such agreement provided us with a sufficient supply to satisfy our requirements for Phase 1 clinical trials of CYT-500.

Rosemont is the sole manufacturer of SOLTAMOX under a supply agreement. The supply agreement terminates upon the later the expiry of the last-to-expire patent covering SOLTAMOX in the United States or ten years from the date of launch of the SOLTAMOX in the United States. Thereafter, such agreements will be automatically renewed for an additional year. The manufacturing agreement is terminable by Rosemont or us on one year notice prior to the end of the then current term.

Alternative sources for our manufacturing needs may not be readily available, and any alternate manufacturers and suppliers would have to be identified and qualified, subject to all applicable regulatory guidelines. If our manufacturers cannot obtain and/or manufacture sufficient quantities of the components for our products at commercially reasonable terms, or in a timely manner, it could result in our inability to manufacture our products at a timely and cost-effective basis.

#### **Intellectual Property**

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

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

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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. We cannot assure you, 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.
- 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.

Intellectual Property Position Related to CAPHOSOL

Under our agreement with InPharma, we are the licensee of two issued U.S. patents. The patents licensed to us under this agreement are U.S. Pat. Nos. 5,993,785 and 6,387,352, each of which expires on September 18, 2017. We have the right to prosecute and maintain the patents included in our license agreement with InPharma.

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## Intellectual Property Position Related to QUADRAMET

In May 1993, we obtained an exclusive license from Dow 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. An additional patent, U.S. Pat. No. 5,714,604, which expires on February 3, 2015, includes claims directed to the methods for QUADRAMET's 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, 2006, 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.

#### Intellectual Property Position 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, 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 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, 2006, 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

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conjugates such as PROSTASCINT, and methods for preparing such conjugates. The foregoing patents, which will expire in 2010 (or expired in 2004, as noted), 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. Pat. 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.

## Intellectual Property Position Related to SOLTAMOX

Under our exclusive license with Rosemont, we are the licensee of an issued United States patent covering SOLTAMOX. This patent, U.S. Pat. No. 6,127,425 which includes claims directed to the SOLTAMOX product and manufacturing process, expires in June 2018.

## Intellectual Property Position Related to PSMA

In 1993, we entered into an option and license agreement with the Sloan-Kettering Institute for Cancer Research (SKICR), and began a development program 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, are the responsibility of SKICR, but are 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.

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Intellectual Property Position Related to AxCell Biosciences

In November 2006, we were issued United States patent number 7,135,457 covering our oral drug delivery agents – random peptide compositions that bind to gastro-intestinal tract (GIT) transport receptors. The patent specifically covers compositions of our oral delivery agents that are capable of facilitating transport of an active agent through a human or animal gastro-intestinal tract (GIT), and derivatives and analogs thereof, and nucleotide sequences coding for said proteins and derivatives. The oral delivery agents have use in facilitating transport of active agents from the lumenal side of the GIT into the systemic blood system, and/or in targeting active agents to the GIT.

The patents and patent applications we have licensed from University of North Carolina at Chapel Hill (UNC) related to novel reagents and technology for identifying targeting peptides 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.

## **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 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

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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 us. 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.
- •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. We cannot assure you 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 1, a product is tested in a small number of healthy subjects or patients primarily for safety at one or more dosages. Phase 2 evaluates, in addition to safety, the efficacy of the product against particular diseases in a patient population that is generally somewhat larger than Phase 1. Clinical trials of certain diagnostic and cancer therapeutic agents may combine Phase 1 and Phase 2 into a single Phase 1/2 study. In Phase 3, 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

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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.

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

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

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. We cannot assure you 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

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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 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

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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 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

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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, we cannot assure you 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

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\$10,000 per claim, civil monetary penalties and exclusion from participation in the Medicare and Medicaid programs.

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

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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. We cannot assure you, however, as to whether or when governmental approvals, other than those already obtained, will be obtained or as to the terms or scope of those approvals.

## **Health Care Reimbursement**

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 were 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

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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 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.

## **Employees**

As of March 1, 2007, we employed 95 persons, 94 of whom are employed full-time. Of such 95 persons, 59 were employed in sales and marketing, 8 in medical affairs, 3 in regulatory, and 25 in administration and management. We believe that we have been successful in attracting skilled and experienced employees. None of our employees are covered by a collective

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bargaining agreement. All of our employees have executed confidentiality agreements. We consider relations with our employees to be excellent.

Item 1A. Risk Factors

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 \$15.1 million, \$26.3 million and \$20.5 million for the years ended December 31, 2006, 2005 and 2004, respectively. We had an accumulated deficit of \$427.7 million as of December 31, 2006.

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 address our trend of operating losses. Such steps include, among other things:

- Ÿ undergoing steps to realign and implement our focus as a product-driven biopharmaceutical company;
  - Ÿ establishing and maintaining our in-house specialty sales force;

Héacquiring North American and Latin American marketing rights to QUADRAMET from Berlex Laboratories in August 2003; and

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

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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 revenues in the near future. For the year ended December 31, 2006, revenues from QUADRAMET and PROSTASCINT accounted for approximately 47% and 53%, respectively, of our product revenues. For the year ended December 31, 2005, revenues from QUADRAMET and PROSTASCINT accounted for approximately 53% and 47%, respectively, of our product revenues. For the year ended December 31, 2004, revenues from QUADRAMET and PROSTASCINT each accounted for approximately 50% of our product 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.

We will depend on the market acceptance of SOLTAMOX and CAPHOSOL for future revenues.

On April 21, 2006, we and Savient entered into a distribution agreement granting us exclusive marketing rights for SOLTAMOX in the United States. We introduced SOLTAMOX to the U.S. oncology market in the second half of 2006. We have recognized only \$30,000 of SOLTAMOX sales through December 31, 2006.

On October 11, 2006, we entered into a license agreement with InPharma granting us exclusive marketing rights for CAPHOSOL in North America. We introduced CAPHOSOL during the first quarter of 2007.

Our future growth and success will depend on market acceptance of SOLTAMOX and CAPHOSOL by healthcare providers, third-party payors and patients. Market acceptance will depend, in part, on our ability to demonstrate to these parties the effectiveness of these products. Sales of these products will also depend on the availability of favorable coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid as well as private health insurance plans. If SOLTAMOX or CAPHOSOL does not achieve 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 our products to a small number of radiopharmacy networks. During the year ended December 31, 2006, we received 64% of our total revenues from three customers, as follows: 41% from Cardinal Health (formerly Syncor International Corporation); 14% from Mallinckrodt Inc.; and 9% from GE Healthcare (formerly Amersham Health). During the year ended December 31, 2005, we received 67% of our total revenues from three customers, as follows: 47% from Cardinal Health (formerly Syncor International Corporation); 11% from Mallinckrodt Inc.; and 9% from GE Healthcare (formerly Amersham Health). During the year ended December 31, 2004, we received 68% of our total revenues from three customers, as

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follows: 46% from Cardinal Health (formerly Syncor International Corporation); 12% from Mallinckrodt Inc.; and 10% from GE Healthcare (formerly Amersham Health).

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. We cannot assure you 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:

Ÿ 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. We introduced ONCOSCINT® CR/OV in December 1992, PROSTASCINT in October 1996, QUADRAMET in March 1997, BRACHYSEED<sup>TM</sup> in February 2001 and NMP22

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BLADDERCHEK® in November 2002. Revenues for PROSTASCINT grew from \$55,000 in 1996 to \$9.1 million in 2006. Royalties and sales of QUADRAMET grew from \$3.3 million in 1997 to \$8.1 million in 2006. 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:

Ÿ a license agreement with Dow relating to the QUADRAMET technology;

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

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

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

¥ license agreement with Dow relating to Dow's proprietary MeO-DOTA bifunctional chelant technology for use with our CYT-500 program;

**Y** distribution agreement and a manufacture and supply agreement with Rosemont related to the supply and marketing of SOLTAMOX;

- $\ddot{Y}$  a purchase and supply agreement with OTN for the distribution of SOLTAMOX;
- $\ddot{Y}$  a license agreement with InPharma AS for the marketing of CAPHOSOL; and
- $\ddot{Y}$  a manufacturing agreement with Holopack for the manufacturing and supply of CAPHOSOL.

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.

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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 agreements described above 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.

In addition to the agreements described above, we currently depend on the following agreements for our present and future operating results:

Agreement with Dr. Horosziewicz regarding PROSTASCINT. In 1989, we entered into an agreement with Dr. Julius S. Horosziewicz. Under this agreement, we were assigned certain rights to the patent claiming the 7E11 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.

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 will terminate on the date of expiration of the last to expire of the licensed patents unless it is terminated earlier.

Our business depends upon our patents and proprietary rights and the enforcement of these rights. Our failure to obtain and maintain patent protection may increase competition and reduce demand for our technology.

As a result of the substantial length of time and expense associated with developing products and bringing them to the marketplace in the biotechnology and agricultural industries, obtaining and maintaining patent and trade secret protection for technologies, products and processes is of vital importance. Our success will depend in part on several factors, including, without limitation:

 $\ddot{Y}$  our ability to obtain patent protection for our technologies and processes;

Ÿ our ability to preserve our trade secrets; and

Wur ability to operate without infringing the proprietary rights of other parties both in the United States and in foreign countries.

Although we believe that our technology is unique and will not violate or infringe upon the proprietary rights of any third party, we cannot assure you that these claims will not be made or if made, could be successfully defended against. If we do not obtain and maintain patent protection, we may face increased competition in the United States and internationally, which would have a material adverse effect on our business.

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Since patent applications in the United States are maintained in secrecy until patents are issued, and since publication of discoveries in the scientific and patent literature tend to lag behind actual discoveries by several months, we cannot be certain that we were the first creator of the inventions covered by our pending patent applications or that we were the first to file patent applications for these inventions.

In addition, among other things, we cannot assure you that:

Ÿ our patent applications will result in the issuance of patents;

Yny patents issued or licensed to us will be free from challenge and that if challenged, would be held to be valid;

In y patents issued or licensed to us will provide commercially significant protection for our technology, products and processes;

Wither companies will not independently develop substantially equivalent proprietary information which is not covered by our patent rights;

Ÿ other companies will not obtain access to our know-how;

Ÿ other companies will not be granted patents that may prevent the commercialization of our technology; or

We will not require licensing and the payment of significant fees or royalties to third parties for the use of their intellectual property in order to enable us to conduct our business.

Our competitors may allege that we are infringing upon their intellectual property rights, forcing us to incur substantial costs and expenses in resulting litigation, the outcome of which would be uncertain.

Patent law is still evolving relative to the scope and enforceability of claims in the fields in which we operate. We are like most biotechnology companies in that our patent protection is highly uncertain and involves complex legal and technical questions for which legal principles are not yet firmly established. In addition, if issued, our patents may not contain claims sufficiently broad to protect us against third parties with similar technologies or products, or provide us with any competitive advantage.

The U.S. Patent and Trademark Office, or PTO, and the courts have not established a consistent policy regarding the breadth of claims allowed in biotechnology patents. The allowance of broader claims may increase the incidence and cost of patent interference proceedings and the risk of infringement litigation. On the other hand, the allowance of narrower claims may limit the value of our proprietary rights.

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The laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the United States, and many companies have encountered significant problems and costs in protecting their proprietary rights in these foreign countries.

We could become involved in infringement actions to enforce and/or protect our patents. Regardless of the outcome, patent litigation is expensive and time consuming and would distract our management from other activities. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we could because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of any patent litigation could limit our ability to continue our operations.

If our technology infringes the intellectual property of our competitors or other third parties, we may be required to pay license fees or damages.

If any relevant claims of third-party patents that are adverse to us are upheld as valid and enforceable, we could be prevented from commercializing our technology or could be required to obtain licenses from the owners of such patents. We cannot assure you that such licenses would be available or, if available, would be on acceptable terms. Some licenses may be non-exclusive and, therefore, our competitors may have access to the same technology licensed to us. In addition, if any parties successfully claim that the creation or use of our technology infringes upon their intellectual property rights, we may be forced to pay damages, including treble damages.

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, Inc. Although we entered into an agreement with Laureate in September 2006 which provides for Laureate's manufacture of 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 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.

We have an agreement with Bristol-Myers Squibb Medical Imaging, Inc., or BMSMI, to manufacture QUADRAMET for us. Both primary components of QUADRAMET, particularly samarium-153 and EDTMP, are provided to BMSMI by outside suppliers. Due to radioactive

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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.

We have a supply agreement with Rosemont to manufacture SOLTAMOX for us. The supply agreement with Rosemont will terminate upon the expiration of the last to expire patent covering SOLTAMOX in the United States, which is currently June 2018. Our failure to maintain a long term supply agreement for SOLTAMOX on commercially reasonable terms will have a material adverse effect on our business, financial condition and results of operations.

We have a manufacturing agreement with Holopack to manufacture CAPHOSOL for us. The agreement has a term of two years and automatically renews for an additional year. Such agreement is terminable by Holopack or us on three months notice prior to the end of each term period. Our failure to maintain a long term supply agreement for CAPHOSOL on commercially reasonable terms will have a material adverse effect on our business, financial condition and results of operations.

We, along with our contract manufacturers and our 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 April 2006, we entered into a distribution agreement with Savient and Rosemont granting us exclusive marketing rights for SOLTAMOX in the United States. We introduced SOLTAMOX in the United States in the second half of 2006.

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In October 2006, we entered into a license agreement with InPharma granting us exclusive rights to CAPHOSOL in North America. We introduced CAPHOSOL in the United States in the first quarter of 2007.

In May 2006, the FDA cleared an Investigational New Drug application for CYT-500, our lead therapeutic candidate targeting PSMA. In February 2007, we announced the initiation of the first U.S. Phase 1 clinical trial of CYT-500 in patients with hormone-refractory prostate cancer. CYT-500 uses the same monoclonal antibody from our PROSTASCINT molecular imaging agent, but is linked through a higher affinity linker than is used for PROSTASCINT to a therapeutic as opposed to an imaging radionuclide. This PSMA technology is still in the early stages of development. We cannot assure you that we will be able to commercialize this product in the future.

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.

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;

- Ÿ to ensure that our products are safe and effective;
- Ÿ to obtain regulatory approval for the use and sale of our products;
- Ÿ to manufacture our products in sufficient quantities and at a reasonable cost;
  - Ÿ to develop a sufficient market for our products; and
- Ÿ 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.

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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.

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.

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

Ÿ	pharmaceutical companies;
Ÿ	biotechnology companies;
Ÿ	diagnostic companies;
Ÿ	medical device companies;
Ÿ	radiopharmaceutical distributors;
Ÿ	academic and research institutions; and
Ÿ	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).

Competitive imaging modalities to PROSTASCINT include CT, 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.

Currently, there is limited consensus standard of care for oral mucositis supported by clinical data and to date, there has only been one commercially available prescription pharmaceutical product approved by the FDA for oral mucositis, the intravenous growth factor palifermin. Ice chips, local painkillers and narcotics are also used to reduce the patient's pain and doctors routinely prescribe mouthwashes containing traditional antibacterial and antifungal drugs for the treatment of oral mucositis, although most clinical trials have shown that they have suboptimal efficacy. There are also a number of oral rinses that have been approved as medical devices by FDA for dry mouth; however, CAPHOSOL is the only approved calcium phsophate oral rinse that is indicated for both oral mucositis and dry mouth.

The current competitive treatments for SOLTAMOX include the tablet form of tamoxifen citrate, a generic drug, and a class of drugs known as aromatase inhibitors.

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.

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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 CAPHOSOL, QUADRAMET, PROSTASCINT and SOLTAMOX. 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. If our internal sales force is unable to successfully market CAPHOSOL, QUADRAMET, PROSTASCINT and SOLTAMOX, our business and financial condition may be adversely affected. If we are unable to establish and maintain significant sales, marketing and distribution efforts within the United States, either internally or through arrangements with third parties, our business may be significantly and adversely affected. In locations outside of the United States, we have not established a selling presence. To the extent that our sales force, from time to time, markets and sells additional products, we cannot be certain that adequate resources or sales capacity will be available to effectively accomplish these tasks.

Failure of 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

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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.

Our business is subject to various government regulations and, if we are unable to obtain regulatory approval, we may not be able to continue our operations.

At present, the U.S. federal government regulation of biotechnology is divided among three agencies:

Ÿ the USDA regulates the import, field testing and interstate movement of specific types of genetic engineering that may be used in the creation of transgenic plants;

The EPA regulates activity related to the invention of plant pesticides and herbicides, which may include certain kinds of transgenic plants; and

Ÿ the FDA regulates foods derived from new plant varieties.

The FDA requires that transgenic plants meet the same standards for safety that are required for all other plants and foods in general. Except in the case of additives that significantly alter a food's structure, the FDA does not require any additional standards or specific approval for genetically engineered foods, but expects transgenic plant developers to consult the FDA before introducing a new food into the marketplace.

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Use of our technology, if developed for human health applications, will also be subject to FDA regulation. The FDA must approve any drug or biologic product before it can be marketed in the United States. In addition, prior to being sold outside of the U.S., any products resulting from the application of our human health technology must be approved by the regulatory agencies of foreign governments. Prior to filing a new drug application or biologics license application with the FDA, we would have to perform extensive clinical trials, and prior to beginning any clinical trial, we need to perform extensive preclinical testing which could take several years and may require substantial expenditures.

We believe that our current activities, which to date have been confined to research and development efforts, do not require licensing or approval by any governmental regulatory agency. However, federal, state and foreign regulations relating to crop protection products and human health applications developed through biotechnology are subject to public concerns and political circumstances, and, as a result, regulations have changed and may change substantially in the future. Accordingly, we may become subject to governmental regulations or approvals or become subject to licensing requirements in connection with our research and development efforts. We may also be required to obtain such licensing or approval from the governmental regulatory agencies described above, or from state agencies, prior to the commercialization of our genetically transformed plants and human health technology. In addition, our marketing partners who utilize our technology or sell products grown with our technology may be subject to government regulations. If unfavorable governmental regulations are imposed on our technology or if we fail to obtain licenses or approvals in a timely manner, we may not be able to continue our operations.

Preclinical studies and clinical trials of our human health applications may be unsuccessful, which could delay or prevent regulatory approval.

Preclinical studies may reveal that our human health technology is ineffective or harmful, and/or clinical trials may be unsuccessful in demonstrating efficacy and safety of our human health technology, which would significantly limit the possibility of obtaining regulatory approval for any drug or biologic product manufactured with our technology. The FDA requires submission of extensive preclinical, clinical and manufacturing data to assess the efficacy and safety of potential products. Furthermore, the success of preliminary studies does not ensure commercial success, and later-stage clinical trials may fail to confirm the results of the preliminary studies.

Even if we receive regulatory approval, consumers may not accept products containing our technology, which will prevent us from being profitable since we have no other source of revenue.

We cannot guarantee that consumers will accept products containing our technology. Recently, there has been consumer concern and consumer advocate activism with respect to genetically engineered consumer products. The adverse consequences from heightened consumer concern in this regard could affect the markets for products developed with our technology and could also result in increased government regulation in response to that concern. If the public or potential customers perceive our technology to be genetic modification or genetic engineering, agricultural products grown with our technology may not gain market acceptance.

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Increasing political and social turmoil, such as terrorist and military actions, increase the difficulty for us and our strategic partners to forecast accurately and plan future business activities.

Recent political and social turmoil, including the conflict in Iraq and the current crisis in the Middle East, can be expected to put further pressure on economic conditions in the United States and worldwide. These political, social and economic conditions may make it difficult for us to plan future business activities.

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.

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 addition, while we currently maintain directors and officers liability insurance in the amount of \$25.0 million and an additional \$5.0 million of personal liability coverage for directors and officers, 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.

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Our security measures may not adequately protect our unpatented technology and, if we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology may be adversely affected.

Our success depends upon know-how, unpatentable trade secrets, and the skills, knowledge and experience of our scientific and technical personnel. As a result, we require all employees to agree to a confidentiality provision that prohibits the disclosure of confidential information to anyone outside of our company, during the term of employment and thereafter. We also require all employees to disclose and assign to us the rights to their ideas, developments, discoveries and inventions. We also attempt to enter into similar agreements with our consultants, advisors and research collaborators. We cannot assure you that adequate protection for our trade secrets, know-how or other proprietary information against unauthorized use or disclosure will be available.

We occasionally provide information to research collaborators in academic institutions and request the collaborators to conduct certain tests. We cannot assure you that the academic institutions will not assert intellectual property rights in the results of the tests conducted by the research collaborators, or that the academic institutions will grant licenses under such intellectual property rights to us on acceptable terms, if at all. If the assertion of intellectual property rights by an academic institution is substantiated, and the academic institution does not grant intellectual property rights to us, these events could limit our ability to commercialize our technology.

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

Our cash and cash equivalents were \$32.5 million at December 31, 2006. We expect that our existing capital resources along with the receipt of the \$4.0 million settlement from Advanced Magnetics, Inc. in the first quarter of 2007 should be adequate to fund our operations and commitments into 2008.

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:

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

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- Ÿ costs of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights;
  - Ÿ competing technological and market developments; and
  - Ÿ expansion of strategic alliances for the sale, marketing and distribution of our products.

Our business or operations may change in a manner that would consume available resources more rapidly than anticipated. We expect that we will have additional requirements for debt or equity capital, irrespective of whether and when we reach profitability, for further product development costs, product and technology acquisition costs and working capital. To the extent that our currently available funds and revenues are insufficient to meet current or planned operating requirements, we will be required to obtain additional funds through equity or debt financing, strategic alliances with corporate partners and others, or through other sources. These financial sources may not be available when we need them or they may be available, but on terms that are not commercially acceptable to us. If adequate funds are not available, we may be required to delay, 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, 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.

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Our stockholders may experience substantial dilution as a result of the exercise of outstanding options and warrants to purchase our common stock.

As of December 31, 2006, stock options and warrants to purchase 8,893,212 shares of our common stock were outstanding. In addition, as of December 31, 2006, we have 343,900 nonvested shares outstanding and have reserved an additional 1,949,494 shares of our common stock for future issuance of options granted pursuant to our 2006 Equity Compensation Plan, 2004 Stock Incentive Plan, 2004 Non-Employee Director Stock Incentive Plan and 2005 Employee Stock Purchase Plan. The exercise of these options and warrants and vesting of nonvested shares will result in dilution to our existing stockholders and could have a material adverse effect on our stock price.

The following table summarizes information about outstanding warrants to purchase our common stock at December 31, 2006:

<b>Exercise Price</b>	<b>Outstanding Warrants</b>	<b>Aggregate Exercise Price</b>
\$ 3.32	3,546,107	\$ 11,773,075
\$ 4.25	1,118,868	\$ 4,755,189
\$ 6.00	776,096	\$ 4,656,576
\$ 6.91	315,790	\$ 2,182,108
\$ 10.97	250,000	\$ 2,742,500
\$ 12.80	1,272,332	\$ 16,285,850

The warrants exercisable at \$10.97 per share and \$12.80 per share become automatically exercised, in full, if our common stock trades for 30 consecutive trading days at 130% of the respective exercise prices.

A significant portion of our total outstanding shares of common stock may be sold in the market in the near future, which could cause the market price of our common stock to drop significantly.

As of December 31, 2006, we had 29,605,631 shares of our common stock issued and outstanding, all of which are either eligible to be sold under SEC Rule 144 or are in the public float. In addition, we have registered shares of our Common Stock underlying warrants previously issued on numerous Form S-3 registration statements, and we have also registered shares of our common stock underlying options granted or to be granted under our stock option plans. Consequently, sales of substantial amounts of our common stock in the public market, or the perception that such sales could occur, may have a material adverse effect on our stock price.

Our common stock has a limited trading market, which could limit your ability to resell your shares of common stock at or above your purchase price.

Our common stock is quoted on the NASDAQ Global Market and currently has a limited trading market. The NASDAQ Global Market requires us to meet minimum financial requirements in order to maintain our listing. Currently, we believe that we meet the continued listing requirements of the NASDAQ Global Market. We cannot assure you that an active trading market will develop or, if developed, will be maintained. As a result, our stockholders

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may find it difficult to dispose of shares of our common stock and, as a result, may suffer a loss of all or a substantial portion of their investment.

Our common stock may be subject to the "penny stock" regulations which may affect the ability of our stockholders to sell their shares.

The NASDAQ Global Market requires us to meet minimum financial requirements in order to maintain our listing. Currently, we believe we meet the continued listing requirements of the NASDAQ Global Market. If we do not continue to meet the continued listing requirements, we could be delisted. If we are delisted from the NASDAQ Global Market, our common stock likely will become a "penny stock." In general, regulations of the SEC define a "penny stock" to be an equity security that is not listed on a national securities exchange or the NASDAQ Stock Market and that has a market price of less than \$5.00 per share or with an exercise price of less than \$5.00 per share, subject to certain exceptions. If our common stock becomes a penny stock, additional sales practice requirements would be imposed on broker-dealers that sell such securities to persons other than certain qualified investors. For transactions involving a penny stock, unless exempt, a broker-dealer must make a special suitability determination for the purchaser and receive the purchaser's written consent to the transaction prior to the sale. In addition, the rules on penny stocks require delivery, prior to and after any penny stock transaction, of disclosures required by the SEC.

If our common stock were subject to the rules on penny stocks, the market liquidity for our common stock could be severely and adversely affected. Accordingly, the ability of holders of our common stock to sell their shares in the secondary market may also be adversely affected.

The liquidity of our common stock could be adversely affected if we are delisted from the NASDAQ Global Market.

In the event that we are unable to maintain compliance with all relevant NASDAQ Listing Standards, our securities may be subject to delisting from the NASDAQ Global 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, and the minimum bid price for such shares. The minimum bid requirement is \$1.00 per share. On March 14, 2007, the closing sale price of our common stock as reported by NASDAQ was \$2.05.

If faced with delisting, we may submit an application to transfer the listing of our common stock to the NASDAQ Capital 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

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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.

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 common stock appreciates and they sell their shares.

We have never paid or declared any cash dividends on our common stock and we 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 investment unless the value of our common stock appreciates and they sell their shares.

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

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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

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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 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, or 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.

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We believe that our operations materially comply with applicable regulatory requirements. We cannot assure you of the outcome of any inquiry audit or investigation 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.

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.

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We have been and, in the future, may 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:

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

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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. 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.

Item 1B.	Unresolved Staff Comments					
Not applicable.						
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## 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. In February 2007, we exercised the two year option to renew our lease and extended the lease term through October 24, 2009. We intend to remain headquartered in Princeton, New Jersey for the foreseeable future.

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

# Item 3. Legal Proceedings

In January 2006, we filed a complaint against Advanced Magnetics in the Massachusetts Superior Court for breach of contract, fraud, unjust enrichment, and breach of the implied covenant of good faith and fair dealing in connection with the parties' 2000 license agreement. The complaint sought damages along with a request for specific performance requiring Advanced Magnetics to take all reasonable steps to secure FDA approval of COMBIDEX® (ferumoxtran - 10) in compliance with the terms of the licensing agreement. In February 2006, Advanced Magnetics filed an answer to our complaint and asserted various counterclaims, including tortuous interference, defamation, consumer fraud and abuse of process.

In February 2007, we settled our lawsuit against Advanced Magnetics, Inc., as well as Advanced Magnetics' counterclaims against Cytogen, by mutual agreement. Under the settlement agreement, Advanced Magnetics paid us \$4 million and will release 50,000 shares of Cytogen common stock currently being held in escrow. In addition, both parties agreed to early termination of the 10-year license and marketing agreement and supply agreement established in August 2000, as amended, for two imaging agents being developed by Advanced Magnetics, COMBIDEX and ferumoxytol, previously Code 7228. The license and marketing agreement and supply agreement would have expired in August 2010.

Item 4.	Submission of Matters to a Vote of Security Holders
Not applicable.	
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#### **PART II**

# Item Market for the Company's Common Equity, Related Stockholder Matters and Company Purchases ofEquity Securities

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

2006	High	Low
First Quarter	\$ 3.62	\$ 2.75
Second Quarter	\$ 3.73	\$ 2.42
Third Quarter	\$ 2.58	\$ 1.91
Fourth Quarter	\$ 6.87	\$ 2.15
2005		
First Quarter	\$ 15.72	\$ 5.44
Second Quarter	\$ 5.95	\$ 3.46
Third Quarter	\$ 5.47	\$ 3.68
Fourth Quarter	\$ 4.09	\$ 2.71

As of March 7, 2007, there were 2,185 holders of record 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.

## **Stock Performance Graph**

The following graph compares the cumulative total stockholder return on our common stock with the cumulative total return the NASDAQ Composite Index, the NASDAQ Biotechnology Index and the NASDAQ Pharmaceutical Index for a five-year period ended December 31, 2006.

Company/Index Name	12/01	12/02	12/03	12/04	12/05	12/06
CYTOGEN Corporation	100.00	10.80	36.15	38.27	9.10	7.74
NASDAQ Composite Index	100.00	68.85	101.86	112.16	115.32	127.52
NASDAQ Biotechnology Index	100.00	62.08	90.27	99.08	111.81	110.06
NASDAQ Pharmaceutical Index	100.00	64.40	92.31	100.78	113.36	115.84

The Perfomance Graph and related information shall not be deemed "soliciting material" or to be "filed" with the Securities and Exchange Commission, nor shall such information be incorporated by reference into any future filing under the Securities Act of 1933 or Securities Exchange Act of 1934, each as amended, except to the extent that we specifically incorporate it by reference into such filing.

## 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, 2006. 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.

	2006			Year Ended Decem 2005 2004			nber 31, 2003		2002	
Statements of Operations Data:	(All amounts in thousands, except per share data)									
Revenues: Product revenues	\$	17,296 \$	15 757	\$	14 490	\$	9,823	\$	10.626	
	Ф	17,290 \$	15,757	Э	14,480	Э		Э	10,626	
Royalties License and contract		11	189	_	139	-	1,105 2,914		1,842 463	
License and contract		11	109		139		2,914		403	
Total revenues		17,307	15,946		14,619		13,842		12,931	
Operating Expenses:										
Cost of product related revenue		10,150	9,523		9,223		6,268		4,748	
Selling, general and administrative		30,166	25,895		20,318		11,867		11,272	
Research and development		7,301	6,162		3,292		2,342		7,580	
Equity in loss of joint venture		120	3,175		2,896		3,452		2,886	
Impairment of intangible assets <sup>(1)</sup>			_	_		-	115		1,729	
Total operating expenses		47,737	44,755		35,729		24,044		28,215	
Operating loss		(30,430)	(28,809)		(21,110)		(10,202)		(15,284)	
Loss on investment			_	_		-	_	_	(516)	
Other income (expense), net		1,415	598		263		(44)		101	
Gain on sale of equity interest in joint venture		12,873	_	_		-	_	_	_	
Decrease in value of warrant liabilitites		1,039	1,666		_	-	_	-	_	
Loss before income taxes		(15,103)	(26,545)		(20,847)		(10,246)		(15,699)	
Income tax benefit		(13,103)	(256)		(307)		(888)		(13,0))	
meome an ochem			(230)		(307)		(000)			
Net loss	\$	(15,103) \$	(26,289)	\$	(20,540)	\$	(9,358)	\$	(15,699)	
	\$	(0.64) \$	(1.54)		(1.40)		(0.92)		(1.85)	
Weighted-average common shares										
outstanding, basic and diluted		23,494	17,117		14,654		10,205		8,466	
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#### December 31,

Consolidated Balance Sheet Data:	2006		2005 2004 (in thousands		2003		2002		
Cash, cash equivalents and short-term									
investments	\$ 32,507	\$	30,337	\$	35,825	\$	30,215	\$	14,725
Total assets	54,353		44,790		50,413		43,695		19,894
Warrant									
liabilities	6,464		1,869		_	_	_	_	
Other long-term									
liabilities	59		46		47		2,454		2,614
Accumulated									
deficit	(427,670)	)	(412,567)	) (	386,278)		(365,738)		(356,380)
Stockholders'									
equity	37,662		37,578		40,030		36,040		10,588

<sup>(1)</sup> 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.

# 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 negative of those terms. These forward-looking statements include statements regarding growth and market penetration for CAPHOSOL, QUADRAMET, PROSTASCINT and SOLTAMOX, increased expenses resulting from our sales force and marketing expansion, including sales and marketing expenses for CAPHOSOL, PROSTASCINT, QUADRAMET and SOLTAMOX, 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, our ability to launch a new product, 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

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cooperation of our marketing and other collaborative and strategic partners, our ability to protect our intellectual property, and the other risks identified under Item 1A "Risk Factors" in this 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

We are a specialty pharmaceutical company dedicated to advancing the treatment and care of cancer patients by building, developing, and commercializing a portfolio of oncology products for underserved markets where there are unmet needs. Our product portfolio includes four oncology products approved by the FDA, CAPHOSOL, QUADRAMET, PROSTASCINT, and SOLTAMOX, which are marketed solely by our specialized sales force to the U.S. oncology market. We introduced our fourth product, CAPHOSOL, in the first quarter of 2007. CAPHOSOL is an electrolyte solution for the treatment of oral mucositis and dry mouth that was approved as a prescription medical device. QUADRAMET is approved for the treatment of pain in patients whose cancer has spread to the bone. SOLTAMOX, which we introduced in the second half of 2006, is the first liquid hormonal therapy approved in the U.S. for the treatment of breast cancer in adjuvant and metastatic settings. PROSTASCINT is a PSMA-targeting monoclonal antibody-based agent to image the extent and spread of prostate cancer. Currently, our clinical development initiatives are focused on new indications for QUADRAMET and PROSTASCINT, as well our product candidate, CYT-500, a radiolabeled antibody in Phase 1 development for the treatment of prostate cancer.

#### Significant Events in 2006

Cytogen Announces that FDA Clears IND for CYT-500, a Monoclonal Antibody for the Treatment of Metastatic Hormone-Refractory Prostate Cancer

On May 8, 2006, we announced that the U.S. Food and Drug Administration cleared an Investigational New Drug application for CYT-500, our lead therapeutic candidate targeting PSMA. We expect to begin the first U.S. Phase 1 clinical trial of CYT-500 in patients with hormone-refractory prostate cancer, subject to Institutional Review Board (IRB) approval at the planned clinical site. CYT-500 uses the same monoclonal antibody from our PROSTASCINT molecular imaging agent, but is linked through a higher affinity linker than is used for PROSTASCINT to a therapeutic as opposed to an imaging radionuclide. This novel product candidate is designed to enable targeted delivery of a cytotoxic agent to PSMA-expressing cells.

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We retain full and exclusive development rights to CYT-500. In February 2007, we announced the initiation of the first human clinical study of CYT-500.

Cytogen Sells Ownership in PSMA Development Joint Venture to Progenics

On April 20, 2006, we entered into a Membership Interest Purchase Agreement with Progenics providing for the sale to Progenics of our 50% ownership interest in PDC, our joint venture with Progenics for the development of *in vivo* cancer immunotherapies based on PSMA. In addition, we entered into an Amended and Restated PSMA/PSMP License Agreement with Progenics and PDC pursuant to which we licensed PDC certain rights in PSMA technology. Under the terms of such agreements, we sold our 50% interest in PDC for a cash payment of \$13.2 million, potential future milestone payments totaling up to \$52.0 million payable upon regulatory approval and commercialization of PDC products, and royalties on future PDC product sales, if any. We are no longer responsible for funding PDC.

Cytogen and Rosemont Execute Marketing Agreement for SOLTAMOX

On April 21, 2006, we entered into a distribution agreement with Savient granting us exclusive marketing rights for SOLTAMOX in the United States. SOLTAMOX, a cytostatic estrogen receptor antagonist, is the first oral liquid hormonal therapy approved in the U.S. It is indicated for the treatment of breast cancer in adjuvant and metastatic settings and to reduce the risk of breast cancer in women with ductal carcinoma in situ (DCIS) or with high risk of breast cancer. In addition, we entered into a supply agreement with Savient and Rosemont, previously a wholly-owned subsidiary of Savient, for the manufacture and supply of SOLTAMOX. Cytogen's agreements with Savient were subsequently assigned by Savient to Rosemont. Under the terms of the final transaction, we paid Savient an up-front licensing fee of \$2.0 million and may pay additional contingent sales-based payments of up to a total of \$4.0 million to Rosemont. We are also required to pay Rosemont royalties on net sales of SOLTAMOX. We introduced SOLTAMOX to the U.S. oncology market in the second half of 2006.

Cytogen Enters into Purchase and Supply Agreement with Oncology Therapeutics Network

On June 20, 2006, we entered into a purchase and supply agreement with Oncology Therapeutics Network appointing OTN as the exclusive distributor of SOLTAMOX in the United States. In August 2006, the agreement was amended to revise certain terms, including changing the role of OTN to the exclusive warehousing agent and non-exclusive distributor of SOLTAMOX. Under the terms of the amended agreement, OTN will purchase SOLTAMOX from us for its own wholesaler channels and, along with third party logistics providers, distribute SOLTAMOX to our other customers through its warehousing and distribution facilities. In January 2007, the agreement was further amended for OTN to also distribute CAPHOSOL.

Cytogen and InPharma Execute License Agreement for CAPHOSOL

On October 11, 2006, we entered into a license agreement with InPharma granting us exclusive rights for CAPHOSOL in North America. Approved as a prescription medical device, CAPHOSOL is a topical oral agent indicated in the United States as an adjunct to standard oral

care in treating oral mucositis caused by radiation or high dose chemotherapy. CAPHOSOL is also indicated for dryness of the mouth or dryness of the throat regardless of the cause or whether the conditions are temporary or permanent. Under the terms of the agreement, we are obligated to pay InPharma \$6.0 million in aggregate up-front fees, of which \$4.6 million was paid upon the execution of the agreement, \$400,000 will be paid into an escrow account, and \$1.0 million will be paid after six months. In addition, InPharma is eligible to receive royalties and sales-based milestone payments. In addition, we are obligated to pay a finder's fee based on a percentage of milestone payments made to InPharma. The transaction also provides us with options to acquire the rights to CAPHOSOL for the European and Asian markets that we only intend to exercise in connection with obtaining a commercial partner for those areas. We will be required to obtain consents from certain licensors but not InPharma, if we sublicense the rights to market CAPHOSOL in Europe and Asia to other parties. In the event we exercise the options to license marketing rights for CAPHOSOL for the European and Asia markets, we would be obligated to pay additional fees, including sales-based milestone payments for the respective territories. We introduced CAPHOSOL in the U.S. in the first quarter of 2007.

# Sale of Common Stock and Warrants

On November 10, 2006, we sold to certain institutional investors 7,092,203 shares of our common stock and 3,546,107 warrants to purchase shares of our common stock. The warrants have an exercise price of \$3.32 per share and are exercisable beginning six months and ending five years after their issuance. In exchange for \$2.82, the purchasers received one share of common stock and warrants to purchase .5 shares of common stock. The offering provided net proceeds of approximately \$18.4 million to us. The placement agents in this transaction received a fee equal to 7% of the aggregate gross proceeds. In connection with this sale, we entered into a Registration Rights Agreement with the investors pursuant to which the common stock and shares of common stock underlying the warrants were registered under the Securities Act of 1933.

#### RESULTS OF OPERATIONS

# Year Ended December 31, 2006 as Compared to December 31, 2005

#### **Revenues**

	2006 (All amou	2005 n thousand data	ds, ex	crease/(De \$ cept perce	%
PROSTASCINT	\$ 9,125	\$ 7,407	\$	1,718	23%
QUADRAMET	8,141	8,350		(209)	(3%)
Other product revenue	30			30	n/a
License and contract	11	189		(178)	(94%)
	\$ 17,307	\$ 15,946	\$	1,361	9%
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Total revenues for the year ended December 31, 2006 were \$17.3 million compared to \$15.9 million for the same period in 2005. Product revenues accounted for substantially all of total revenues in 2006 and 99% of total revenues in 2005. 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, and if we fail to successfully market SOLTAMOX and CAPHOSOL, we may not be able to generate sufficient revenue to become profitable.

**PROSTASCINT.** PROSTASCINT sales were \$9.1 million for the year ended December 31, 2006, compared to \$7.4 million for the same period of 2005. Sales of PROSTASCINT accounted for 53% and 47% of product revenues for 2006 and 2005, respectively. The increase from the prior year period was due to the implementation of a 9% price increase for PROSTASCINT on September 1, 2006 and increased demand associated with our focused marketing programs. We believe recent developments in imaging resolution, emerging clinical data, and an increasing level of recognition of the value of PROSTASCINT fusion imaging support an important near- and long-term market opportunity for PROSTASCINT. We are focusing on multiple key areas to position PROSTASCINT for future growth and market penetration, including: (i) positioning PROSTASCINT fusion imaging as the standard of care for prostate cancer imaging; (ii) generating awareness of the prognostic value of the PSMA antigen; (iii) leveraging the publication and presentation of outcomes data; (iv) advancing image-guided applications including brachytherapy, intensity modulated radiation therapy, surgery, and cryotherapy; and (v) evaluating the potential for imaging other PSMA-expressing cancers. 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 \$8.1 million for the year ended December 31, 2006, compared to \$8.4 million for the same period of 2005. QUADRAMET sales accounted for 47% and 53% of product revenues for 2006 and 2005, respectively. QUADRAMET year-over-year sales were essentially flat with the exception of a change in the timing of scheduled maintenance shutdowns for one of our raw material suppliers that negatively impacted product availability during the fourth quarter of 2006. Currently, we market QUADRAMET only in the United States and have no rights to market QUADRAMET in Europe. We are focusing on multiple key initiatives to position QUADRAMET for future growth and market penetration, including: (i) distinguishing the physical properties of QUADRAMET from first-generation agents within its class; (ii) empowering and marketing to key prescribing audiences; (iii) broadening palliative use within label beyond prostate cancer to include breast, lung and multiple myeloma; (iv) evaluating the role of QUADRAMET in combination with other commonly used oncology agents; and (v) expanding clinical development to demonstrate the potential tumoricidal versus palliative attributes of QUADRAMET. 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.

*Other Product Revenue.* For the year ended December 31, 2006, other product revenue was comprised of \$30,000 of SOLTAMOX sales. We introduced SOLTAMOX in the second half of 2006 and began supplying the distribution channels to support initial patient demand. In

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2006, approximately \$1.1 million of SOLTAMOX supply was shipped to wholesalers; however, in accordance with U.S. Generally Accepted Accounting Principles, we will only recognize revenues for SOLTAMOX in our consolidated statement of operations when we have sufficient information to estimate expected product returns or when the product return privilege expires. We cannot provide any assurance that we will be able to successfully market SOLTAMOX or that SOLTAMOX will achieve greater market penetration on a timely basis or result in significant revenues for us.

*License and Contract Revenue.* License and contract revenues were \$11,000 and \$189,000 for the years ended December 31, 2006 and 2005, respectively. The 2005 revenue includes \$185,000 of contract revenue for limited services provided by us to PDC, our former joint venture with Progenics Pharmaceuticals, Inc. We did not provide any research services to the joint venture in 2006.

# **Operating Expenses**

					Ι	ncrease/(De	ecrease)
		2006		2005		\$	%
	(Al	l amount	s in	thousands	s, exc	cept percen	tage data)
Cost of product revenues	\$	10,150	\$	9,523	\$	627	7%
Selling, general and administrative		30,166		25,895		4,271	16%
Research and development		7,301		6,162		1,139	18%
Equity in loss of joint venture		120		3,175		(3,055)	(96%)
	\$	47,737	\$	44,755	\$	2,982	7%

Total operating expenses for the year ended December 31, 2006 were \$47.7 million compared to \$44.8 million for the same period of 2005.

Cost of Product Revenues. Cost of product revenues for the year ended December 31, 2006 was \$10.2 million compared to \$9.5 million for the same period of 2005 and primarily reflects manufacturing costs for PROSTASCINT and QUADRAMET, royalties on our sales of products and amortization of the up-front payments to acquire the marketing rights to QUADRAMET in 2003, SOLTAMOX in April 2006 and CAPHOSOL in October 2006. The increase from the prior year period was due primarily to higher product revenue and the amortization expenses for SOLTAMOX and CAPHOSOL in 2006.

Selling, General and Administrative. Selling, general and administrative expenses for the year ended December 31, 2006 were \$30.2 million compared to \$25.9 million for the same period of 2005. The increase in selling, general and administrative expenses is primarily attributable to \$2.1 million of launch costs associated with SOLTAMOX, which we introduced in the second half of 2006, the pre-launch costs of \$752,000 for CAPHOSOL and the recognition of \$1.6 million of share-based compensation in 2006 for options and nonvested shares granted to employees, partially offset by the \$750,000 of pre-launch costs in 2005 for Combidex.

**Research and Development.** Research and development expenses for the year ended December 31, 2006 were \$7.3 million compared to \$6.2 million for the same period of 2005.

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The increase in 2006 from the prior year period is primarily driven by costs associated with the clinical development initiatives for both QUADRAMET and PROSTASCINT and the pre-clinical development program for CYT-500. The 2006 expenses also include the recognition of \$252,000 of share-based compensation in 2006 for options and nonvested shares granted to employees. The 2005 expenses included a charge of \$500,000 related to the issuance of shares of our common stock in August 2005 to the stockholders and debtholders of Prostagen Inc. made pursuant to the terms of an addendum to our Stock Exchange Agreement dated June 15, 1999.

*Equity in Loss of Joint Venture.* Our share of the loss of the PSMA Development Company LLC (PDC), our former joint venture with Progenics, was \$120,000 for the year ended December 31, 2006 compared to \$3.2 million in the same period of 2005. Such amounts represented 50% of the joint venture's net losses. We equally shared ownership and costs of the joint venture with Progenics and accounted for the joint venture using the equity method of accounting until April 20, 2006 when we sold our ownership interest in PDC to Progenics. Following the sale of our interest in the joint venture in April 2006, we have no further obligations to the joint venture.

Interest Income/Expense. Interest income for the year ended December 31, 2006 was \$1.5 million compared to \$712,000 for the same period of 2005. The increase from the prior year period was due to higher average yield on a higher average cash balances in 2006. Interest expense for the year ended December 31, 2006 was \$36,000 compared to \$114,000 for the same period of 2005. Interest expense includes finance charges on insurance premiums which were financed and purchases of various equipment that are accounted for as capital leases. Interest expense in 2005 also includes interest on outstanding debt which was paid off in August 2005.

Gain on Sale of Equity Interest in Joint Venture. On April 20, 2006, we entered into a Membership Interest Purchase Agreement with Progenics providing for the sale to Progenics of our 50% ownership interest in PDC, our joint venture with Progenics for the development of *in vivo* cancer immunotherapies based on PSMA. In addition, we entered into an Amended and Restated PSMA/PSMP License Agreement with Progenics and PDC pursuant to which we licensed PDC certain rights in PSMA technology. Under the terms of such agreements, we sold our 50% interest in PDC for a cash payment of \$13.2 million, potential future milestone payments totaling up to \$52.0 million payable upon regulatory approval and commercialization of PDC products, and royalties on future PDC product sales, if any. As a result of the transaction, for the year ended December 31, 2006, we recorded \$12.9 million in gain on sale of equity interest in the joint venture, which represents the net proceeds after transaction costs less the carrying value of our investment in the joint venture at the time of sale.

Decrease in Warrant Liabilities. In connection with the sale of our common stock and warrants in 2005 and 2006, we recorded the warrants as a liability at their fair value at the dates of issuance using the Black-Scholes option-pricing model and will remeasure them at each reporting date until they are exercised or expire. Changes in the fair value of the warrants are reported in the statements of operations as non-operating income or expense. For the year ended December 31, 2006, we reported a gain of \$1.0 million related to the decrease in fair value of these warrants since their issuance dates or December 31, 2005, whichever is later, compared to a \$1.7 million gain recorded in the same period of 2005 related to the decrease in fair value of

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these warrants since their issuance dates. The market price for our common stock has been and may continue to be volatile. Consequently, future fluctuations in the price of our common stock may cause significant increases or decreases in the fair value of these warrants.

*Income Tax Benefit.* During 2005, we sold a portion of our New Jersey state net operating loss carryforwards, which resulted in the recognition of \$256,000 in income tax benefits. We did not sell any New Jersey state net operating loss carryforwards in 2006.

*Net Loss.* Net loss for the year ended December 31, 2006 was \$15.1 million compared to \$26.3 million for the same period of 2005. The basic and diluted net loss per share for 2006 was \$0.64 based on 23.5 million weighted-average common shares outstanding, compared to a basic and diluted net loss per share of \$1.54 based on 17.1 million weighted-average common shares outstanding for the same period in 2005.

#### RESULTS OF OPERATIONS

#### Year Ended December 31, 2005 as Compared to December 31, 2004

#### Revenues

					Iı	ncrease/(I	Decrease)	
		2005		2004		\$	<b>%</b>	
	(All amounts in thousands, except percentage data)							
PROSTASCINT	\$	7,407	\$	7,186	\$	221	3%	
QUADRAMET		8,350		7,293		1,057	14%	
NMP22 BLADDERCHEK (ceased December 2004)				1		(1)	(100%)	
License and contract		189		139		50	36%	
	\$	15,946	\$	14,619	\$	1,327	9%	

Total revenues for the year ended December 31, 2005 were \$15.9 million compared to \$14.6 million for the same period in 2004. Product revenues accounted for 99% of total revenues in each of 2005 and 2004. 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.

**PROSTASCINT.** PROSTASCINT sales were \$7.4 million for the year ended December 31, 2005, an increase of \$221,000 from \$7.2 million for the same period of 2004. Sales of PROSTASCINT accounted for 47% and 50% of product revenues for 2005 and 2004, respectively. 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: (i) improving image quality through fusion technology; (ii) validating the antigen targeted by PROSTASCINT as an independent prognostic factor; (iii) the publication and presentation of

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outcomes data; (iv) development of image-guided applications including brachytherapy, intensity modulated radiation therapy, surgery, and cryotherapy; and (v) expanding clinical development to demonstrate the potential for PROSTASCINT to monitor response to cytotoxic therapies and image other cancers. 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 \$8.4 million for the year ended December 31, 2005, an increase of \$1.1 million from \$7.3 million for the same period of 2004. QUADRAMET sales accounted for 53% and 50% of product revenues for 2005 and 2004, respectively. We believe that such increase in QUADRAMET sales was due to increased demand associated with our focused marketing programs. We have the right to market QUADRAMET in North America and Latin America. Currently, we market QUADRAMET only in the United States. We believe that the future growth and market penetration of QUADRAMET is dependent upon, among other things: (i) distinguishing the physical properties of QUADRAMET from first-generation agents within its class; (ii) empowering and marketing to key prescribing audiences; (iii) broadening palliative use within label beyond prostate cancer to include breast, lung and multiple myeloma; (iv) evaluating the role of QUADRAMET in combination with other commonly used oncology agents; and (v) expanding clinical development to demonstrate the potential tumoricidal versus palliative attributes of QUADRAMET. 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*. There were no NMP22 BLADDERCHEK sales during 2005 compared to \$1,000 in 2004. Effective December 31, 2004, we stopped selling NMP22 BLADDERCHEK.

*License and Contract Revenues.* License and contract revenues were \$189,000 and \$139,000 for the years ended December 31, 2005 and 2004, respectively. We recognized \$185,000 of contract revenues in 2005, compared to \$106,000 in 2004, for limited services provided by us to the PSMA Development Company LLC, our joint venture with Progenics Pharmaceuticals, Inc.

#### **Operating Expenses**

					]	Increase/(De	ecrease)
		2005		2004		\$	<b>%</b>
		(All amou	ınts	in thousa	nds,	except per	centage
	data)						
Cost of product revenues	\$	9,523	\$	9,223	\$	300	3%
Selling, general and administrative		25,895		20,318		5,577	27%
Research and development		6,162		3,292		2,870	87%
Equity in loss of joint venture		3,175		2,896		279	(10%)
	\$	44,755	\$	35,729	\$	9,026	25%

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Total operating expenses for the year ended December 31, 2005 were \$44.8 million compared to \$35.7 million for the same period of 2004.

Cost of Product Revenues. Cost of product revenues for the year ended December 31, 2005 was \$9.5 million compared to \$9.2 million for the same period of 2004 and primarily reflects manufacturing costs for PROSTASCINT and QUADRAMET, royalties on our sales of products and amortization of the up-front payment to Berlex Laboratories to reacquire the marketing rights to QUADRAMET in 2003. The increase from the prior year was due primarily to contractual increases in 2005 related to our agreement with BMSMI, and higher royalties to Berlex on our sales of QUADRAMET as a result of increased product sales.

Selling, General and Administrative. Selling, general and administrative expenses for the year ended December 31, 2005 were \$25.9 million compared to \$20.3 million for the same period of 2004. The increase from the prior year was due primarily to the expansion of our sales force and the implementation of other marketing initiatives for our planned and existing products. The selling, general and administrative expenses in 2004 also include increased legal and professional fees as well as a payment related to the settlement, in September 2004, of a patent infringement suit filed by Immunomedics, Inc. against us and C.R. Bard Inc. in February 2000. As of March 1, 2006, we employed 50 people in sales and marketing.

Research and Development. Research and development expenses for the year ended December 31, 2005 were \$6.2 million compared to \$3.3 million for the same period of 2004. The increase from the prior year period is primarily driven by new clinical development initiatives for both QUADRAMET and PROSTASCINT, and the pre-clinical development costs associated with our radiolabeled therapeutic program to attach the therapeutic radionuclide lutetium-177 as a payload to the 7E11 monoclonal antibody utilized in PROSTASCINT. The increase is partially offset by savings from the closure of our AxCell BioSciences facility in the fourth quarter of 2004. The 2005 and 2004 expenses also included a charge of \$500,000 and \$497,000, respectively, related to the issuance of shares of our common stock in August 2005 and November 2004, respectively, to the stockholders and debtholders of Prostagen Inc. made pursuant to the terms of an addendum to our Stock Exchange Agreement dated June 15, 1999, related to the progress of certain PSMA development programs.

In 2005 and 2004, we incurred \$50,000 and \$621,000, respectively, in expenses relating to AxCell's operations. In September 2002, we significantly reduced AxCell's workforce to reduce the cash expenditures relating to AxCell in order to leverage our oncology franchise. Further, in July 2004, as part of our continuing efforts to reduce non-strategic expenses, we initiated the closure of AxCell's facilities. Research projects through academic, governmental and corporate collaborators to be supported and additional applications for the intellectual property and technology at AxCell are being pursued.

*Equity in Loss of Joint Venture.* Our share of the loss of the PSMA Development Company LLC, our joint venture with Progenics Pharmaceuticals, Inc., was \$3.2 million in 2005 compared to \$2.9 million for the same period of 2004, and represented 50% of the joint venture's operating losses. The increase over the prior year period reflects our share of the \$2.0 million up-front fee incurred by the joint venture in the second quarter of 2005 to license proprietary

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antibody-drug conjugate technology from Seattle Genetics, Inc. for use with the joint venture's antibodies targeting PSMA. We equally shared ownership and costs of the joint venture with Progenics and accounted for the joint venture using the equity method of accounting.

Interest Income/Expense. Interest income for the year ended December 31, 2005 was \$712,000 compared to \$448,000 for the same period of 2004. The increase from the prior year period was due to higher average yields partially offset by lower average cash balances in 2005. Interest expense for the year ended December 31, 2005 was \$114,000 compared to \$185,000 for the same period of 2004. Interest expense includes interest on outstanding debt which was paid off in August 2005 and finance charges on insurance premiums which were financed and purchases of various equipment that are accounted for as capital leases.

Decrease in Value of Warrant Liability. In connection with the sale of our common stock and warrants that provided us with net proceeds of approximately \$13.9 million in July and August 2005, we recorded the warrants as a liability at their fair value at the dates of issuance using the Black-Scholes option-pricing model and will remeasure them at each reporting date until they are exercised or expire. Changes in the fair value of the warrants are reported in the statements of operations as non-operating income or expense. For the year ended December 31, 2005, we reported a gain of \$1.7 million related to the decrease in fair value of these warrants from issuance dates. The market price for our common stock has been and may continue to be volatile. Consequently, future fluctuations in the price of our common stock may cause significant increases or decreases in the fair value of these warrants.

*Income Tax Benefit.* During 2005, we sold a portion of our New Jersey state net operating loss carryforwards, which resulted in the recognition of \$256,000 in income tax benefits. In 2004, we recognized \$307,000 in such income tax benefits.

*Net Loss.* Net loss for the year ended December 31, 2005 was \$26.3 million compared to \$20.5 million for the same period of 2004. The basic and diluted net loss per share for 2005 was \$1.54 based on 17.1 million weighted-average common shares outstanding, compared to a basic and diluted net loss per share of \$1.40 based on 14.7 million weighted-average common shares outstanding for the same period in 2004.

#### **COMMITMENTS**

We have entered into various contractual and commercial commitments. The following table summarizes our obligations with respect to these commitments as of December 31, 2006:

Contractual Obligation	ss than year	1 to 3 years (All	4 to 5 years (All amounts in thousar		More than 5 years	Total
Capital lease obligations	\$ 64	\$ 59	\$	_	\$ _	\$ 123
Facility leases	338	620		_	_	958
Research and development	131	150		150	481	912
Marketing and other obligations	2,490	33		_	_	2,523
Manufacturing contracts <sup>(1)</sup>	5,378	4,859		_	_	10,237
Minimum royalty payments <sup>(2)</sup>	1,000	2,000		2,000	1,833	6,833
Total	\$ 9,401	\$ 7,721	\$	2,150	\$ 2,314	\$ 21,586

<sup>(1)</sup> Effective January 1, 2004, we entered into a new manufacturing and supply agreement with BMSMI for QUADRAMET whereby BMSMI manufactures, distributes and provides order processing and customer services for us relating to QUADRAMET. Under the terms of our agreement, we are obligated to pay at least \$4.9 million annually, subject to future annual price adjustment, through 2008, unless terminated by BMSMI or us on a two year prior written notice. This agreement will automatically renew for five successive one-year periods unless terminated by BMSMI or us on a two-year prior written notice. Accordingly, we have not included commitments beyond December 31, 2008.

In addition to the above, we are obligated to make certain royalty payments based on sales of the related product and certain milestone payments if our collaborative partners achieve specific development milestones or commercial milestones. We are also obligated to pay a finder's fee based upon a percentage of milestone payments made to InPharma in connection with the licensing of CAPHOSOL. We did not include in the table above any payments that do

<sup>(2)</sup> We acquired an exclusive license from Dow for QUADRAMET for the treatment of osteoblastic bone metastases in certain territories. The agreement requires us to pay Dow royalties based on a percentage of net sales of QUADRAMET, or a guaranteed contractual minimum payment, whichever is greater, and future payments upon achievement of certain milestones. Future annual minimum royalties due to Dow are \$1.0 million per year in 2007 through 2012 and \$833,000 in 2013.

not represent fixed or minimum payments but are instead payable only upon the achievement of a milestone, if the achievement of that milestone is uncertain or the obligation amount is not determinable.

# LIQUIDITY AND CAPITAL RESOURCES

#### **Condensed Statement of Cash Flows:**

		2006
	(All amo	unts in thousands)
Net loss	\$	(15,103)
Adjustments to reconcile net loss to net cash used in operating activities		(7,750)
Net cash used in operating activities		(22,853)
Net cash provided by investing activities		6,116
Net cash provided by financing activities		18,907
Net increase in cash and cash equivalents	\$	2,170

Our cash and cash equivalents were \$32.5 million as of December 31, 2006, compared to \$30.3 million as of December 31, 2005. The increase in cash and cash equivalents from the December 31, 2005 balance was primarily due to the sale of our 50% interest in PDC for a cash payment of \$13.2 million in April 2006 and the termination of our funding obligations related to the joint venture, and the November 2006 sale of common stock and warrants which provided net proceeds of \$18.4 million, partially offset by net cash paid for the acquisition of the product rights to SOLTAMOX and CAPHOSOL and increased operating expenditures in 2006, including costs to launch SOLTAMOX and to promote and support our oncology products, new clinical development initiatives for both QUADRAMET and PROSTASCINT and pre-clinical development programs associated with the 7E11 antibody. During 2006 and 2005, net cash used for operating activities was \$22.9 million and \$29.5 million, respectively. The decrease is primarily due to the increase in and timing of payments for accounts payable and accrued liabilities.

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

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

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payments by us in either cash or stock in addition to the costs associated with developing and marketing a product or technology. However, we believe that, if successful, such strategies may increase long-term revenues. We cannot assure you of the success of such strategies or that resulting funds will be sufficient to meet cash requirements until product revenues are sufficient to cover operating expenses, if ever. To fund these strategic and operating activities, we may sell equity, debt or other securities as market conditions permit or enter into credit facilities.

We have incurred negative cash flows from operations since our inception, and have expended, and expect to continue to expend in the future, substantial funds to implement our planned product development efforts, including acquisition of products and complementary technologies, research and development, clinical studies and regulatory activities, and to further our marketing and sales programs. We expect that our existing capital resources at December 31, 2006, along with the receipt of the \$4.0 million settlement from Advanced Magnetics, Inc. in the first quarter of 2007 should be adequate to fund our operations and commitments at least into 2008. We cannot assure you that our business or operations will not change in a manner that would consume available resources more rapidly than anticipated. We expect that we will have additional requirements for debt or equity capital, irrespective of whether and when we reach profitability, for further product development costs, product and technology acquisition costs, and working capital.

Our future capital requirements and the adequacy of available funds will depend on numerous factors, including: (i) the successful commercialization of our products; (ii) the costs associated with the acquisition of complementary products and technologies; (iii) progress in our product development efforts and the magnitude and scope of such efforts; (iv) progress with clinical trials; (v) progress with regulatory affairs activities; (vi) the cost of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights; (vii) competing technological and market developments; and (viii) the expansion of strategic alliances for the sales, marketing, manufacturing and distribution of our products. To the extent that the currently available funds and revenues are insufficient to meet current or planned operating requirements, we will be required to obtain additional funds through equity or debt financing, strategic alliances with corporate partners and others, or through other sources. We cannot assure you that the financial sources described above will be available when needed or at terms commercially acceptable to us. If adequate funds are not available, we may be required to delay, further scale back or eliminate certain aspects of our operations or attempt to obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to certain of our technologies, product candidates, products or potential markets. If adequate funds are not available, our business, financial condition and results of operations will be materially and adversely affected.

#### **Other Liquidity Events**

On April 20, 2006, we entered into a Membership Interest Purchase Agreement with Progenics providing for the sale to Progenics of our 50% ownership interest in PDC. In addition, we entered into an Amended and Restated PSMA/PSMP License Agreement with Progenics and PDC pursuant to which we licensed PDC certain rights in PSMA technology. Under the terms of such agreements, we sold our 50% interest in PDC for a cash payment of \$13.2 million, potential future milestone payments totaling up to \$52.0 million payable upon regulatory approval and

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commercialization of PDC products, and royalties on future PDC product sales, if any. Following the sale of our interest in the joint venture in April 2006, we have no further obligations to the joint venture.

On April 21, 2006, we entered into a distribution agreement with Savient granting us exclusive marketing rights for SOLTAMOX in the United States. SOLTAMOX, a cytostatic estrogen receptor antagonist, is the first oral liquid hormonal therapy approved in the U.S. It is indicated for the treatment of breast cancer in adjuvant and metastatic settings and to reduce the risk of breast cancer in women with ductal carcinoma in situ (DCIS) or with high risk of breast cancer. In addition, we entered into a supply agreement with Savient and Rosemont for the manufacture and supply of SOLTAMOX. Our agreements with Savient were subsequently assigned to Rosemont by Savient. Under the terms of the final transaction, we paid Savient an up-front licensing fee of \$2.0 million and may pay additional contingent sales-based payments of up to a total of \$4.0 million to Rosemont. We introduced SOLTAMOX to the U.S. oncology market in the second half of 2006. We are also required to pay Rosemont royalties on net sales of SOLTAMOX. Beginning in 2007, we are obligated to pay Rosemont quarterly minimum royalties based on an agreed upon percentage of total tamoxifen prescriptions in the United States. Unless terminated earlier, each of the distribution and supply agreements will terminate upon the expiration of the last to expire patent covering SOLTAMOX in the United States, which is currently June 2018. In the event the tamoxifen prescriptions for an agreed upon period of time are less than the pre-established minimum, the agreement may be terminated if we are unable to reach an agreement with Rosemont to amend the terms of the contract to account for such impact.

On October 11, 2006, we entered into a license agreement with InPharma granting us exclusive rights for CAPHOSOL in North America and options to license the marketing rights for CAPHOSOL in Europe and Asia. Approved as a prescription medical device, CAPHOSOL is a topical oral agent indicated in the United States as an adjunct to standard oral care in treating oral mucositis caused by radiation or high dose chemotherapy. CAPHOSOL is also indicated for dryness of the mouth or dryness of the throat regardless of the cause or whether the conditions are temporary or permanent. Under the terms of the Agreement, we are obligated to pay InPharma \$6.0 million in aggregate up-front fees, of which \$4.6 million was paid upon the execution of the agreement, \$400,000 will be paid into an escrow account and \$1.0 million will be paid after six months. In addition, we are obligated to pay InPharma royalties based on a percentage of net sales and future payments of up to an aggregate of \$49.0 million based upon the achievement of certain sales-based milestones of which payments totaling \$35 million are based upon annual sales levels first reaching levels in excess of \$30 million. In addition, we are obligated to pay a finder's fee based upon a percentage of milestone payments made to InPharma.

In the event we exercise the options to license marketing rights for CAPHOSOL in Europe and Asia, we are obligated to pay InPharma additional fees and payments, including sales-based milestone payments for the respective territories. We also shall pay InPharma a portion of any up-front license fees and milestone payments, but not royalties, received by us in consideration of the grant by us to other parties of the right to market CAPHOSOL in Europe and Asia, to the extent such up-front license fees and milestone payments are in excess of the respective amounts paid by us to InPharma for such rights.

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On November 10, 2006, we sold to certain institutional investors 7,092,203 shares of our common stock and 3,546,107 warrants to purchase shares of our common stock. The warrants have an exercise price of \$3.32 per share and are exercisable beginning six months and ending five years after their issuance. The warrant agreement contains a cash settlement feature, which is available to the warrant holders at their option, upon an acquisition in certain circumstances. In exchange for \$2.82, the purchasers received one share of common stock and warrants to purchase .5 shares of common stock. The offering provided us with net proceeds of approximately \$18.4 million. The placement agents received compensation consisting of a fee equal to 7% of the aggregate gross proceeds. In connection with this sale, we entered into a Registration Rights Agreement with the investors under which, we were obligated to file a registration statement with the SEC for the resale of Cytogen shares sold to the investors and shares issuable upon exercise of the warrants within a specified time period. We are also required to use commercially reasonable efforts to cause the registration to be declared effective by the SEC and to remain continuously effective until such time when all of the registered shares are sold or three years from closing date, whichever is earlier. In the event we fail to keep the registration statement effective, we are obligated to pay the investors liquidation damages equal to 1% of the purchase price paid by the investors (\$20 million) for each thirty-day period that the registration statement is not effective, up to 10%. On December 28, 2006, the SEC declared the registration statement effective. We concluded that the contingent obligation was not probable, and therefore no contingent liability was recorded as of December 31, 2006.

In September 2006, we entered into a non-exclusive manufacturing agreement with Laureate pursuant to which Laureate shall manufacture PROSTASCINT and its primary raw materials for Cytogen in Laureate's Princeton, New Jersey facility. The agreement will terminate, unless terminated earlier pursuant to its terms, upon Laureate's completion of the specified production campaign for PROSTASCINT and shipment of the resulting products from Laureate's facility. Under the terms of the agreement, we anticipate paying at least an aggregate of \$3.9 million through the end of the term of contract, of which \$500,000 was incurred and paid in 2006.

Effective January 1, 2004, we entered into a manufacturing and supply agreement with BMSMI whereby BMSMI manufactures, distributes and provides order processing and customer services for us relating to QUADRAMET. Under the terms of the new agreement, we are obligated to pay at least \$4.9 million annually, subject to future annual price adjustment, through 2008, unless terminated by BMSMI or us on two years prior written notice. During the year ended December 31, 2006, we incurred \$4.5 million of manufacturing costs for QUADRAMET. This agreement will automatically renew for five successive one-year periods unless terminated by BMSMI or us on a two year prior written notice. We also pay BMSMI a variable amount per month for each QUADRAMET order placed to cover the costs of customer service.

We acquired an exclusive license from Dow for QUADRAMET for the treatment of osteoblastic bone metastases in certain territories. The agreement requires us to pay Dow royalties based on a percentage of net sales of QUADRAMET, or a guaranteed contractual minimum payment, whichever is greater, and future payments upon achievement of certain milestones. For the year ended December 31, 2006, we incurred \$1.0 million in royalty expense.

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Future annual minimum royalties due to Dow are \$1.0 million per year in 2007 through 2012 and \$833,000 in 2013.

On May 6, 2005, we entered into a license agreement with Dow to create a targeted oncology product designed to treat prostate and other cancers. The agreement applies proprietary MeO-DOTA bifunctional chelant technology from Dow to radiolabel our PSMA antibody with a therapeutic radionuclide. Under the agreement, proprietary chelation technology and other capabilities, provided through ChelaMed<sup>SM</sup> radiopharmaceutical services from Dow, will be used to attach a therapeutic radioisotope to the 7E11 monoclonal antibody utilized in our PROSTASCINT molecular imaging agent. As a result of the agreement, we are obligated to pay a minimal license fee and aggregate future milestone payments of \$1.9 million for each licensed product, if approved, and royalties based on sales of related products, if any. Unless terminated earlier, the Dow agreement terminates at the later of (a) the tenth anniversary of the date of first commercial sale for each licensed product or (b) the expiration of the last to expire valid claim that would be infringed by the sale of the licensed product. We may terminate the license agreement with Dow on 90 days written notice.

# CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Financial Reporting Release No. 60 requires all companies to include a discussion of critical accounting policies or methods used in the preparation of financial statements. Note 1 to our Consolidated Financial Statements in our Annual Report on Form 10-K for the year ended December 31, 2006 includes a summary of our significant accounting policies and methods used in the preparation of our Consolidated Financial Statements. The following is a brief discussion of the more significant accounting policies and methods used by us. The preparation of our Consolidated Financial Statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Our actual results could differ materially from those estimates.

# **Revenue Recognition**

We generate revenue from product sales and license and contract revenues. We recognize revenue in accordance with the SEC's Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements" as amended by Staff Accounting Bulletin No. 104 (together, "SAB 101"), and FASB Statement No. 48 "Revenue Recognition When Right of Return Exists" ("SFAS 48"). SAB 101 states that revenue should not be recognized until it is realized or realizable and earned. Revenue is realized or realizable and earned when all of the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the seller's price to the buyer is fixed or determinable; and (4) collectibility is reasonably assured. SFAS 48 states that revenue from sales transactions where the buyer has the right to return the product shall be recognized at the time of sale only if (1) the seller's price to the buyer is substantially fixed or determinable at the date of sale, (2) the buyer has paid the seller, or the buyer is obligated to pay the seller and the obligation is not contingent on resale of the product, (3) the buyer's obligation to the seller would not be changed in the event of theft or physical destruction or damage of the product, (4) the

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buyer acquiring the product for resale has economic substance apart from that provided by the seller, (5) the seller does not have significant obligations for future performance to directly bring about resale of the product by the buyer, and (6) the amount of future returns can be reasonably estimated.

# **Product Sales**

We recognize revenues for product sales at the time title and risk of loss are transferred to the customer, and the other criteria of SAB 101 and SFAS 48 are satisfied, which is generally at the time products are shipped to customers. At the time gross revenue is recognized from product sales, an adjustment, or decrease, to revenue for estimated rebates, discounts and returns is also recorded. This revenue reserve is determined on a product-by-product basis. The rebate or discount reserve is recorded in accordance with Emerging Issues Task Force (EITF) Issue No. 01-9, "Accounting for Consideration Given by a Vendor to a Customer" ("EITF 01-9"), which states that cash consideration given by a vendor to a customer is presumed to be a reduction of the selling prices of the vendor's products or services and, therefore, should be characterized as a reduction of revenue when recognized in the vendor's income statement. At the time product is shipped, an adjustment is recorded for estimated rebates and discounts based on the contractual terms with customers. Revenue reserves including return allowances are established by management as its best estimate at the time of sale based on each product's historical experience adjusted to reflect known changes in the factors that impact such reserves.

In the case of new product like SOLTAMOX which we introduced in the second half of 2006, product shipments made to wholesalers do not meet the revenue recognition criteria of SFAS 48 and SAB 101. Since we cannot reliably estimate expected returns for this new product, we will defer recognition of revenue until the right of return no longer exists or until we develop sufficient historical experience to estimate sales returns. In 2006, approximately \$1.1 million of SOLTAMOX was shipped to wholesalers. For these product shipments, we invoice the wholesalers, record the payment received as "Customer Liability", and classify the inventory shipped to wholesalers as "Inventory at Wholesalers" at the Company's cost of goods for such inventory. We recognize revenue for SOLTAMOX when such product is sold through to the end-users, on a first-in first-out (FIFO) basis. Additionally, royalty amount due based on unit shipments to wholesalers is deferred and recognized as royalty expense as those units are sold through and recognized as revenue. We have the right to offset royalties paid for product that are later returned against subsequent royalty obligations. Costs related to shipments of SOLTAMOX, for which we do not have the ability to recover if and when products are returned, are expensed as incurred.

When available, we may use the following information to estimate the prescription based sales for SOLTAMOX and to estimate gross to net sales adjustments: (1) the estimated prescription based sales, (2) our analysis of third-party information, including information obtained from certain wholesalers with respect to their inventory levels and sell-through to customers and third-party market research data, and (3) our internal product sales information. Our estimates will be subject to the inherent limitations of estimates that rely on third-party data, as certain third-party information is itself in the form of estimates, and has other limitations. Our

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sales and revenue recognition for SOLTAMOX will reflect our estimates of actual product sold through to the end user.

# Provisions for Estimated Reductions to Gross Sales

At the time product sales are made, we reduce gross sales through accruals for product returns, rebates and volume discounts. We account for these reductions in accordance with EITF 01-9 and SFAS 48, as applicable.

#### Returns

Quadramet is a radioactive product that is indicated for the relief of pain due to metastatic bone disease arising from various types of cancer. Due to its rapid rate of radioactive decay, QUADRAMET has a shelf life of only about 72 hours. For this reason, QUADRAMET is ordered for a specific patient on a pre-scheduled visit, and, as such, our customers are unable to maintain stock inventories of this product. In addition, because the product is ordered for pre-scheduled visits for specific patients, product returns are very low. Our methodology to estimate sales returns is based on historical experience that demonstrates that the vast majority of the returns occur within one month of when product was shipped. At the time of sale, we estimate the quantity and value of QUADRAMET that may ultimately be returned. We generally have the exact number of returns related to prior month sales in the current month, so the provision for returns is trued up to actual quickly.

We do not allow product returns for PROSTASCINT.

Returns from new product, like SOLTAMOX, are more difficult to assess. Since we have no historical return experience with SOLTAMOX, we cannot reliably estimate expected returns of this new product. Therefore, we will defer recognition of revenue until the right of return no longer exists or until we have developed sufficient historical experience to estimate sales returns. We may use information from external sources to estimate our return provisions.

# **Volume Discounts**

We provide volume discounts to certain customers based on sales levels of given products during each calendar month. We recognize revenue net of these volume discounts at the end of each month. There are no volume discounts based on cumulative sales over more than a one month period. Accordingly, there is no current need to estimate volume discounts.

## Rebates

From time to time, we may offer rebates to our customers. We establish a rebate accrual based on the specific terms in each agreement, in an amount equal to our reasonable estimate of the expected rebate claims attributable to the sales in the current period and adjust the accrual each reporting period to reflect the actual experience. If the amount of future rebates cannot be reasonably estimated, a liability will be recognized for the maximum potential amount of the rebates.

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License and contract revenues include milestone payments and fees under collaborative agreements with third parties, revenues from research services, and revenues from other miscellaneous sources. We defer non-refundable up-front license fees and recognize them over the estimated performance period of the related agreement, when we have continuing involvement. Since the term of the performance periods is subject to management's estimates, future revenues to be recognized could be affected by changes in such estimates.

#### **Accounts Receivable**

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

#### **Inventories**

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

# **Carrying Value of Fixed and Intangible Assets**

Our fixed assets and certain of our acquired rights to market our products have been recorded at cost and are being amortized on a straight-line basis over the estimated useful life of those assets. We also acquired an option to purchase marketing rights to CAPHOSOL in Europe which was recorded as other assets and will transfer the costs to the appropriate asset account if exercised. If indicators of impairment exist, we assess the recoverability of the affected long-lived assets by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows. Regarding the option to purchase marketing rights to CAPHOSOL in Europe, we also assess our intent and ability to exercise the option, the option expiry date and market and product competitiveness. If impairment is indicated, we measure the amount of such impairment by comparing the carrying value of the assets to the present value of the expected future cash flows associated with the use of the asset. Adverse changes regarding future cash flows to be received from long-lived assets could indicate that an impairment exists, and would require the write down of the carrying value of the impaired asset at that time.

#### **Warrant Liabilities**

We follow Emerging Issues Task Force (EITF) No. 00-19, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock" which provides guidance for distinguishing between permanent equity, temporary equity and assets and liabilities. Under EITF 00-19, to qualify as permanent equity, the equity derivative must permit us to settle in unregistered shares. We do not have that ability under the securities purchase agreement for the warrants issued in July and August 2005 and, as EITF 00-19 considers the ability to keep a registration statement effective as beyond our control, the warrants cannot be classified as permanent equity and are instead classified as a liability in the accompanying consolidated balance sheets. Our warrants issued in November 2006 which permit net cash settlement at the option of the warrant holders also require classification as a liability in accordance with EITF 00-19.

We record the warrant liability at its fair value using the Black-Scholes option-pricing model and remeasure it at each reporting date until the warrants are exercised or expire. Changes in the fair value of the warrants are reported in the consolidated statements of operations as non-operating income or expense. The fair value of the warrants is subject to significant fluctuation based on changes in our stock price, expected volatility, expected life, the risk-free interest rate and dividend yield. The market price for our common stock has been and may continue to be volatile. Consequently, future fluctuations in the price of our common stock may cause significant increases or decreases in the fair value of the warrants issued.

We follow EITF No. 00-19-2 "Accounting for Registration Payment Arrangement" which specifies that registration payment arrangements should play no part in determining the initial classification and subsequent accounting for the securities they related to. The Staff position requires the contingent obligation in a registration payment arrangement to be separately analyzed under FASB Statement No. 5, "Accounting for Contingencies" and FASB Interpretation No. 14, "Reasonable Estimation of the Amount of a Loss". Consequently, if payment in a registration payment arrangement in connection with the warrants issued in November 2006 is probable and can be reasonably estimated, a liability will be recorded.

# **Share-Based Compensation**

We account for share-based compensation in accordance with SFAS No. 123(R), "Share-Based Payment." Under the fair value recognition provision of this statement, the share-based compensation, which is generally based on the fair value of the awards calculated using the Black-Scholes option pricing model on the date of grant, is recognized on a straight-line basis over the requisite service period, generally the vesting period, for grants on or after January 1, 2006. For nonvested shares, we use the fair value of the underlying common stock on the date of grant. Determining the fair value of share-based awards at the grant date requires judgment, including estimating expected dividend yield, expected forfeiture rates, expected volatility, the expected term and expected risk-free interest rates. If we were to use different estimates or a different valuation model, our share-based compensation expense and our results of operations could be materially impacted.

#### **New Accounting Pronouncements**

Accounting for Registration Payment Arrangements

On December 21, 2006, the FASB issued FASB Staff Position No. EITF 00-19-2, "Accounting for Registration Payment Arrangements" ("EITF 00-19-2"), which addresses an issuer's accounting for registration payment arrangements. EITF 00-19-2 specifies that the contingent obligation to make future payments or otherwise transfer consideration under a registration payment arrangement, whether issued as a separate agreement or included as a provision of a financial instrument or other agreement, should be separately recognized and measured in accordance with FASB Statement No. 5, Accounting for Contingencies. EITF 00-19-2 further clarifies that a financial instrument subject to a registration payment arrangement should be accounted for in accordance with other applicable accounting literature without regard to the contingent obligation to transfer consideration pursuant to the registration arrangement. EITF 00-19-2 is effective immediately for new and modified registration payment arrangements. Early adoption of EITF 00-19-2 for the interim or annual period for which the financials statements have not been issued is permitted. We adopted EITF 00-19-2 at the beginning of the fourth quarter 2006. The adoption of EITF 00-19-2 did not have any impact on our consolidated financial statements in the year ended December 31, 2006.

#### **Evaluation of Misstatements**

On September 13, 2006, the staff of the SEC issued Staff Accounting Bulletin No. 108, "Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements" ("SAB 108"), which provides interpretive guidance on how the effects of prior year misstatements should be considered in evaluating a current year misstatement. The cumulative effect from the initial adoption of SAB 108 may be reported as a cumulative effect adjustment to the beginning of year retained earnings with disclosure of the nature and amount of each individual error. We applied the provisions of SAB 108 in the fourth quarter of 2006. The adoption of SAB 108 did not have a material impact on our consolidated financial statements.

#### Fair Value Measurements

On September 15, 2006, the FASB issued SFAS No. 157, "Fair Value Measurements" ("SFAS 157"). SFAS 157 defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements. SFAS 157 is effective as of the beginning of the first fiscal year beginning after November 15, 2007. We are required to adopt this statement in the first quarter of 2008. Management is currently evaluating the requirements of SFAS 157 and has not yet determined the impact this standard will have on its consolidated financial statements.

#### **Income Taxes**

In June 2006, the FASB issued FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes" ("FIN 48"). FIN 48 is applicable for fiscal years beginning after December 15,

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2006. This Interpretation clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with FASB Statement No. 109, "Accounting for Income Taxes." This Interpretation prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. This Interpretation also provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. We are currently evaluating the impact of the adoption of FIN 48 upon our financial statements and related disclosures. We do not expect that the adoption will have a material effect on our results of operations or financial condition.

#### Sales Tax

In March 2006, the FASB's Emerging Issues Task Force released Issue 06-3, "How Sales Taxes Collected From Customers and Remitted to Governmental Authorities Should Be Presented in the Income Statement" ("EITF 06-3"). A consensus was reached that entities may adopt a policy of presenting sales taxes in the income statement on either a gross or net basis. If taxes are significant, an entity should disclose its policy of presenting taxes and the amount of taxes if reflected on a gross basis in the income statement. The guidance is effective for periods beginning after December 15, 2006. We present sales net of sales taxes in our consolidated statements of operations and do not anticipate changing our policy as a result of EITF 06-3.

# **Abnormal Inventory Costs**

In November 2004, the FASB issued SFAS No. 151, "Inventory Costs, an amendment of ARB No. 43, Chapter 4" ("SFAS No. 151"), to clarify that abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage) should be recognized as current period charges, and that fixed production overheads should be allocated to inventory based on the normal capacity of production facilities. This statement is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. Accordingly, we adopted SFAS No. 151 in our fiscal year beginning January 1, 2006. The adoption of this standard did not have any impact on our consolidated statement of operations in the year ended December 31, 2006.

# Item 7A. Quantitative and Qualitative Disclosures About Market Risk

We do not have operations subject to risks of foreign currency fluctuations, nor do we use derivative financial instruments in our operations. Our exposure to market risk is principally confined to interest rate sensitivity. Our cash equivalents and short-term investments are conservative in nature, with a focus on preservation of capital. Due to the short-term nature of our investments and our investment policies and procedures, we have determined that the risks associated with interest rate fluctuations related to these financial instruments are not material to our business.

We are exposed to certain risks arising from changes in the price of our common stock, primarily due to the potential effect of changes in fair value of the warrant liability related to the warrants issued in 2005 and 2006. The warrant liability is measured at fair value using the Black-Scholes option-pricing model at each reporting date and is subject to significant increases

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or decreases in value and a corresponding loss or gain in the statement of operations due to the effects of changes in the price of common stock at period end and the related calculation of volatility.

# Item 8. Financial Statements and Supplementary Data

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

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

Not applicable.

Item 9A.

#### **Controls and Procedures**

(a) Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2006. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Securities Exchange Act of 1934 is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applied its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our chief executive officer and chief financial officer concluded that, as of December 31, 2006, our disclosure controls and procedures were effective.

#### (b) Internal Controls Over Financial Reporting

(1) Management's Annual Report on Internal Control Over Financial Reporting Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) of the Exchange Act. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based upon the framework in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway

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Commission. Based on that evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2006.

(2) Attestation Report of the Independent Registered Public Accounting Firm

KPMG LLP, the Company's independent registered public accounting firm has issued its report on our assessment and effectiveness of the Company's internal control over financial reporting. This report appears on page 94 of this Annual Report on Form 10-K.

(3) Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) under the Exchange Act) occurred during the fiscal quarter ended as of December 31, 2006 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

#### **Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders Cytogen Corporation:

We have audited management's assessment, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting, that Cytogen Corporation maintained effective internal control over financial reporting as of December 31, 2006, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Cytogen Corporation's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, management's assessment that Cytogen Corporation maintained effective internal control over financial reporting as of December 31, 2006, is fairly stated, in all material respects, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Also, in our

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opinion, Cytogen Corporation maintained, in all material respects, effective internal control over financial reporting as of December 31, 2006, based on the criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Cytogen Corporation and subsidiaries as of December 31, 2006 and 2005, and the related consolidated statements of operations, stockholders' equity and comprehensive loss, and cash flows for each of the years in the three-year period ended December 31, 2006, and our report dated March 15, 2007 expressed an unqualified opinion on those consolidated financial statements.

/s/ KPMG LLP

Princeton, New Jersey March 15, 2007

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Item 9B. Other Information

Not applicable.

#### **PART III**

# Item 10. Directors, Executive Officers and Corporate Governance

The information relating to our directors, nominees for election as directors and executive officers under the headings "Election of Directors", "Executive Officers and Key Employees" and "Section 16(a) Beneficial Ownership Reporting Compliance" in our definitive proxy statement for the 2007 Annual Meeting of Stockholders is incorporated herein by reference to such proxy statement.

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

# Item 11. Executive Compensation

The discussion under the heading "Executive Compensation" in our definitive proxy statement for the 2007 Annual Meeting of Stockholders is incorporated herein by reference to such proxy statement.

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

The discussion under the heading "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters" in our definitive proxy statement for the 2007 Annual Meeting of Stockholders is incorporated herein by reference to such proxy statement.

# Item 13. Certain Relationships and Related Transactions, and Director Independence

The discussion under the heading "Certain Relationships and Related Transactions and Director Independence" in our definitive proxy statement for the 2007 Annual Meeting of Stockholders is incorporated herein by reference to such proxy statement.

#### **Item 14.**

# **Principal Accountant Fees and Services**

The discussion under the heading "Independent Auditors' Fees and Services" in our definitive proxy statement for the 2007 Annual Meeting of Stockholders is incorporated herein by reference to such proxy statement.

#### **PART IV**

#### **Item 15.**

#### **Exhibits and Financial Statement Schedules.**

- (a) Documents filed as a part of the Report:
- (1) and (2) The response to this portion of Item 15 is submitted as a separate section of this Annual Report on Form 10-K, beginning on page F-1.
- (3) Exhibits –

# Exhibit

No.

- 3.1.1 Restated Certificate of Incorporation of Cytogen Corporation, as amended. Filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 1996, filed with the Commission on August 2, 1996, and incorporated herein by reference.
- 3.1.2 Certificate of Amendment to the Restated Certificate of Incorporation of Cytogen Corporation, as amended. Filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2000, filed with the Commission on August 11, 2000, and incorporated herein by reference.
- 3.1.3 Certificate of Amendment to the Restated Certificate of Incorporation, as amended, as filed with the Secretary of State of the State of Delaware on October 25, 2002. Filed as an exhibit to the Company's Current Report on Form 8-K, dated October 25, 2002, filed with the Commission on October 25, 2002, and incorporated herein by reference.
- 3.1.4 Certificate of Designations of Series C Junior Participating Preferred Stock of Cytogen Corporation. Filed as an exhibit to the Company's Registration Statement on Form S-8 (Reg. No. 333-59718), filed with the Commission on April 27, 2001, and incorporated herein by reference.
- 3.1.5 Certificate of Amendment to the Restated Certificate of Incorporation dated June 15, 2005. Filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2005, filed with the Commission on August 9, 2005, and incorporated herein by reference.

# **Exhibit**

No.

- 3.2 By-Laws of Cytogen Corporation, as amended and restated. Filed as an exhibit to the Company's Current Report on Form 8-K, filed with the Commission on October 19, 2006, and incorporated herein by reference.
- 4.1.1 Amended and Restated Rights Agreement, dated as of October 19, 1998 between Cytogen Corporation and Chase Mellon Shareholder Services, L.L.C., as rights agent. The Amended and Restated Rights Agreement includes the Form of Certificate of Designations of Series C Junior Participating Preferred Stock as Exhibit A, the form of Right Certificate as Exhibit B and the Summary of Rights as Exhibit C. Filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 1998, filed with the Commission on November 13, 1998, and incorporated herein by reference.
- 4.1.2 Agreement for Substitution and Amendment of Rights Agreement by and between Cytogen Corporation and American Stock Transfer & Trust Company dated September 1, 2004. Filed as an exhibit to the Company's Current Report on Form 8-K, dated September 1, 2004, filed with the Commission on September 2, 2004, and incorporated herein by reference.
- 10.1.1 Lease Agreement, dated as of March 16, 1987, by and between Peregrine Investment Partners I, as lessor, and Cytogen Corporation, as lessee. Filed as an exhibit to the Company's Annual Report on Form 10-K for the year ended January 2, 1988, filed with the Commission on April 1, 1988, and incorporated herein by reference.
- 10.1.2 Amendment, dated as of October 16, 1987, to Lease Agreement between Peregrine Investment Partners I and Cytogen Corporation. Filed as an exhibit to the Company's Registration Statement on Form S-8 (Reg. No. 33-30595), filed with the Commission on August 18, 1989, and incorporated herein by reference.
- 10.2 1989 Employee Stock Option Plan. Filed as an exhibit to Company's Registration Statement on Form S-8 (Reg. No. 33-30595), filed with the Commission on August 18, 1989, and incorporated herein by reference. +
- 10.3.1 1988 Stock Option Plan for Non-Employee Directors. Filed as an exhibit to the Company's Registration Statement on Form S-8 (Reg. No. 33-30595), filed with the Commission on August 18, 1989, and incorporated herein by reference. +
- Amendment No. 2 to the Cytogen Corporation 1988 Stock Option Plan for Non-Employee Directors dated May 22, 1996. Filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 1996, filed with the Commission on August 2, 1996, and incorporated herein by reference. +

Exhibit No.	
10.4	1989 Stock Option Policy for Outside Consultants. Filed as an exhibit to Amendment No. 1 to the Company's Registration Statement on Form S-1 (Reg. No. 33-31280), and incorporated herein by reference. +
10.5.1	License Agreement dated March 31, 1993 between Cytogen Corporation and The Dow Chemical Company. Filed as an exhibit to Amendment No. 1 to the Company's Quarterly Report on Form 10-Q for the quarter ended July 3, 1993, filed with the Commission on October 13, 1993, and incorporated herein by reference.*
10.5.2	Amendment of the License Agreement between Cytogen Corporation and The Dow Chemical Company dated September 5, 1995. Filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 1996, filed with the Commission on May 9, 1996, and incorporated herein by reference.*
10.5.3	Second Amendment to the License Agreement between Cytogen Corporation and The Dow Chemical Company dated May 20, 1996. Filed as an exhibit to Amendment No. 1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 1996, filed with the Commission on August 2, 1996, and incorporated herein by reference.*
10.6	1992 Cytogen Corporation Employee Stock Option Plan II, as amended. Filed as an exhibit to the Company's Registration Statement on Form S-4 (Reg. No. 33-88612), filed with the Commission on January 19, 1995, and incorporated herein by reference. +
10.7	License Agreement, dated March 10, 1993, between Cytogen Corporation and The University of North Carolina at Chapel Hill, as amended. Filed as an exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 1994, filed with the Commission on March 17, 1995, and incorporated herein by reference.*
10.8	Option and License Agreement, dated July 1, 1993, between Cytogen Corporation and Sloan-Kettering Institute for Cancer Research. Filed as an exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 1994, filed with the Commission on March 17, 1995, and incorporated herein by reference.*
10.9	Horosziewicz-Cytogen Agreement, dated April 20, 1989, between Cytogen Corporation and Julius S. Horosziewicz, M.D., DMSe. Filed as an exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 1995, filed with the Commission on March 28, 1996, and incorporated herein by reference.*
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Exhibit No.	
10.10	Severance Agreement effective as of March 26, 1996 between Cytogen Corporation and John D. Rodwell, Ph.D. Filed as an exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 1996, filed with the Commission on March 24, 1997, and incorporated herein by reference. +
10.11	License Agreement between Targon Corporation and Elan Corporation, plc dated July 21, 1997. Filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 1997, filed with the Commission on August 6, 1997, and incorporated herein by reference.*
10.12	Convertible Promissory Note dated as of August 12, 1998 between Cytogen Corporation and Elan International Services, Ltd. Filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 1998, filed with the Commission on August 14, 1998, and incorporated herein by reference.
10.13	Employment agreement effective as of August 20, 1998 between Cytogen Corporation and H. Joseph Reiser. Filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 1998, filed with the Commission on November 13, 1998, and incorporated herein by reference. +
10.14	License Agreement by and between Berlex Laboratories, Inc. and Cytogen Corporation dated as of October 28, 1998. Filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 1998, filed with the Commission on November 13, 1998, and incorporated herein by reference.
10.15	Manufacturing Space Agreement between Bard BioPharma L.P. and Cytogen Corporation dated as of January 7, 1999. Filed as an exhibit to Amendment No. 1 to the Company's Registration Statement on form S-1 (Reg. No. 333-67947), filed with the Commission on January 27, 1999, and incorporated herein by reference.
10.16.1	Limited Liability Company Agreement of PSMA Development Company LLC by and among Cytogen Corporation, Progenics Pharmaceuticals, Inc. and the PSMA Development Company LLC dated June 15, 1999. Filed as an exhibit to the Company's Registration Statement on Form S-3 (Reg. No. 333-83215), filed with the Commission on July 20, 1999, and incorporated herein by reference.
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Exhibit No.	
10.16.2	Amendment No. 1 to Limited Liability Company Agreement of PSMA Development Company LLC by and among Cytogen Corporation, Progenics Pharmaceuticals, Inc. and PSMA Development Company LLC dated as of March 22, 2002. Filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2002, filed with the Commission on May 14, 2002, and incorporated herein by reference.
10.17.1	Stock Exchange Agreement among Cytogen Corporation and the Stockholders and Debtholders of Prostagen, Inc. Filed as an exhibit to the Company's Registration Statement on Form S-3 (Reg. No. 333-83215) dated July 19, 1999, as amended, filed with the Commission on July 20, 1999, and incorporated herein by reference.
10.17.2	Addendum to Stock Exchange Agreement among Cytogen Corporation and the Shareholders and Debtholders of Prostagen, Inc. dated as of May 14, 2002, and amended as of August 13, 2002. Filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, filed with the Commission on August 14, 2002, and incorporated herein by reference.
10.17.3	Addendum No. 2 to Stock Exchange Agreement among Cytogen Corporation and the Stockholders and Debtholders of Prostagen, Inc. Filed as an exhibit to the Company's Current Report on Form 8-K dated November 19, 2004, filed with the Commission on November 22, 2004, and incorporated herein by reference.
10.18	Strategic Alliance Agreement between AxCell Biosciences Corporation and InforMax, Inc. dated as of September 15, 1999. Filed as an exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 1999, filed with the Commission on March 28, 2000, and incorporated herein by reference.*
10.19	AxCell Biosciences Corporation Stock Option Plan. Filed as an exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 1999, filed with the Commission on March 28, 2000, and incorporated herein by reference. +
10.20	Master Loan and Security Agreement No. S7600 among Cytogen Corporation, AxCell Biosciences Corporation and Finova Capital Corporation dated December 30, 1999. Filed as an exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 1999, filed with the Commission on March 28, 2000, and incorporated herein by reference.
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Exhibit No.	
10.21	Written Compensatory Agreement by and between Cytogen Corporation and H. Joseph Reiser dated August 24, 1998, as revised on July 11, 2000. Filed as an exhibit to the Company's Registration Statement on Form S-8 (Reg. No. 333-48454), filed with the Commission on October 23, 2000, and incorporated herein by reference. +
10.22	Written Compensatory Agreement by and between Cytogen Corporation and Lawrence Hoffman dated July 10, 2000. Filed as an exhibit to the Company's Registration Statement on Form S-8 (Reg. No. 333-48454), filed with the Commission on October 23, 2000, and incorporated herein by reference. +
10.23	License and Marketing Agreement by and between Cytogen Corporation and Advanced Magnetics, Inc. dated August 25, 2000. Filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2000, filed with the Commission on November 14, 2000, and incorporated herein by reference.*
10.24	Development and Manufacturing Agreement by and between Cytogen Corporation and DSM Biologics Company B.V. dated July 12, 2000. Filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2000, filed with the Commission on November 14, 2000, and incorporated herein by reference.*
10.25	Product Manufacturing and Supply Agreement by and between Cytogen Corporation and Draximage Inc. dated December 5, 2000. Filed as an exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 2000, filed with the Commission on March 30, 2001, and incorporated herein by reference. *
10.26	License and Distribution Agreement by and between Cytogen Corporation and Draximage Inc. dated December 5, 2000. Filed as an exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 2000, filed with the Commission on March 30, 2001, and incorporated herein by reference. *
10.27	Cytogen Corporation Stock Payment Program Bonus Plan. Filed as an exhibit to the Company's Registration Statement on Form S-8 (Reg. No. 333-58384), filed with the Commission on April 6, 2001, and incorporated herein by reference. +
10.28	MFS Fund Distributors, Inc. 401(K) Profit Sharing Plan and Trust. Filed as an exhibit to the Company's Registration Statement on Form S-8 (Reg. No. 333-59718), filed with the Commission on April 27, 2001, and incorporated herein by reference. +
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Exhibit No.	
10.29	Adoption Agreement for MFS Fund Distributors, Inc. Non-Standardized 401(K) Profit Sharing Plan and Trust, with amendments. Filed as an exhibit to the Company's Registration Statement on Form S-8 (Reg. No. 333-59718), filed with the Commission on April 27, 2001, and incorporated herein by reference.
10.30	Cytogen Corporation Performance Bonus Plan with Stock Payment Program. Filed as an exhibit to Company's Registration Statement on Form S-8 (Reg. No. 333-75304), filed with the Commission on December 17, 2001, and incorporated herein by reference. +
10.31	Share Purchase Agreement by and between Cytogen Corporation and the State of Wisconsin Investment Board dated as of January 18, 2002. Filed as an exhibit to the Company's Current Report on Form 8-K, dated January 18, 2002, filed with the Commission on January 24, 2002, and incorporated herein by reference.
10.32	Form of Executive Change of Control Severance Agreement by and between Cytogen Corporation and each of its Executive Officers. Filed as an exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 2001, filed with the Commission on March 28, 2002, and incorporated herein by reference. +
10.33.1	Office Space Lease by and between Yardley Associates, L.P. and AxCell Biosciences Corporation dated as of July 23, 1999. Filed as an exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 2001, filed with the Commission on March 28, 2002, and incorporated herein by reference.
10.33.2	First Amendment to the Lease Agreement by and between 826 Newtown Associates, L.P. and AxCell Biosciences Corporation dated as of March 16, 2001. Filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2001, filed with the Commission on May 14, 2001, and incorporated herein by reference.
10.34.1	Sublease Agreement by and between Cytogen Corporation and Hale and Dorr LLP dated as of May 23, 2002. Filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, filed with the Commission on August 14, 2002, and incorporated herein by reference.
10.34.2	First Amendment to Sublease Agreement by and between Cytogen Corporation and Hale and Dorr LLP dated February 10, 2004. Filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2004, filed with the Commission on May 7, 2004, and incorporated herein by reference.
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Exhibit No.	
10.35	Cytogen Corporation Amended and Restated 1995 Stock Option Plan. Filed as an exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 2002, filed with the Commission on March 31, 2003, and incorporated herein by reference. +
10.36	Amended and Restated 1999 Stock Option Plan for Non-Employee Directors. Filed as an exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 2002, filed with the Commission on March 31, 2003, and incorporated herein by reference. +
10.37	Distribution Agreement by and between Cytogen Corporation and Matritech Inc. dated October 18, 2002. Filed as an exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 2002, filed with the Commission on March 31, 2003, and incorporated herein by reference. *
10.38	Written Compensatory Agreement by and between Cytogen Corporation and Michael D. Becker dated December 17, 2002. Filed as an exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 2002, filed with the Commission on March 31, 2003, and incorporated herein by reference. +
10.39	Contract Manufacturing Agreement by and between Cytogen Corporation and Laureate Pharma, L.P. dated January 15, 2003. Filed as an exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 2002, filed with the Commission on March 31, 2003, and incorporated herein by reference. *
10.40	Quality Agreement by and between Cytogen Corporation and Laureate Pharma, L.P. dated January 15, 2003. Filed as an exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 2002, filed with the Commission on March 31, 2003, and incorporated herein by reference. *
10.41	Securities Purchase Agreement by and among Cytogen Corporation and certain purchasers of the Company's common stock dated June 6, 2003. Filed as an exhibit to the Company's Current Report on Form 8-K dated June 6, 2003, filed with the Commission on June 9, 2003, and incorporated herein by reference.
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Exhibit No.	
10.42	Form of Common Stock Purchase Warrant issued by the Company in favor of certain purchasers of the Company's common stock dated June 6, 2003. Filed as an exhibit to the Company's Current Report on Form 8-K dated June 6, 2003, filed with the Commission on June 9, 2003, and incorporated herein by reference.
10.43	Registration Rights Agreement by and among the Company and certain purchasers of the Company's common stock dated June 6, 2003. Filed as an exhibit to the Company's Current Report on Form 8-K dated June 6, 2003, filed with the Commission on June 9, 2003, and incorporated herein by reference.
10.44	Securities Purchase Agreement by and among Cytogen Corporation and certain purchasers of the Company's common stock dated July 10, 2003. Filed as an exhibit to the Company's Current Report on Form 8-K dated July 10, 2003, filed with the Commission on July 11, 2003, and incorporated herein by reference.
10.45	Form of Common Stock Purchase Warrant issued by Cytogen Corporation in favor of certain purchasers of the Company's common stock dated July 10, 2003. Filed as an exhibit to the Company's Current Report on Form 8-K dated July 10, 2003, filed with the Commission on July 11, 2003, and incorporated herein by reference.
10.46	Registration Rights Agreement by and among Cytogen Corporation and certain purchasers of the Company's common stock dated July 10, 2003. Filed as an exhibit to the Company's Current Report on Form 8-K dated July 10, 2003, filed with the Commission on July 11, 2003, and incorporated herein by reference.
10.47	Share Purchase Agreement by and among Cytogen Corporation and certain purchasers of the Company's common stock dated November 6, 2003. Filed as an exhibit to the Company's Current Report on Form 8-K dated November 6, 2003, filed with the Commission on November 7, 2003, and incorporated herein by reference.
10.48	Manufacturing and Supply Agreement by and among Cytogen Corporation, Berlex Laboratories, Inc. and DuPont Pharmaceuticals Company dated November 13, 1998 and effective as of January 1, 1999. Filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2003, filed with the Commission on November 12, 2003, and incorporated herein by reference. **
10.49	Termination Agreement between Cytogen Corporation and Berlex Laboratories, Inc., dated June 16, 2003. Filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2003, filed with the Commission on November 12, 2003, and incorporated herein by reference. **
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Exhibit No.	
10.50	Assignment Agreement between Cytogen Corporation and Berlex Laboratories, Inc., dated August 1, 2003. Filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2003, filed with the Commission on November 12, 2003, and incorporated herein by reference. **
10.51	Placement Agency Agreement by and among Cytogen Corporation, CIBC World Markets Corp., JMP Securities LLC and ThinkEquity Partners LLC dated April 14, 2004. Filed as an exhibit to the Company's Current Report on Form 8-K dated April 14, 2004, filed with the Commission on April 15, 2004, and incorporated herein by reference.
10.52	Manufacturing and Supply Agreement by and between Cytogen Corporation and Bristol-Myers Squibb Medical Imaging, Inc. effective as of January 1, 2004. Filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2004, filed with the Commission on May 7, 2004, and incorporated herein by reference. **
10.53	Cytogen Corporation 2004 Stock Incentive Plan. Filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004, filed with the Commission on August 9, 2004, and incorporated herein by reference. +
10.54	Cytogen Corporation 2004 Non-Employee Director Stock Incentive Plan. Filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004, filed with the Commission on August 9, 2004, and incorporated herein by reference. +
10.55	Manufacturing Agreement dated September 10, 2004 by and between Cytogen Corporation and Laureate Pharma, L.P. Filed as an exhibit to the Company's Current Report on Form 8-K dated September 10, 2004, filed with the Commission on September 14, 2004, and incorporated herein by reference.**
10.56	Warrant Agreement, dated June 10, 2003, between Cytogen Corporation and Howard Soule, Ph.D. Filed as an exhibit to the Company's Registration Statement on Form S-8 (Reg. No. 333-121320), filed with the Commission on December 16, 2004, and incorporated herein by reference. +
10.57	Cytogen Corporation Employee Stock Purchase Plan, amended as of February 2005. Filed as an exhibit to the Company's Current Report on Form 8-K dated February 8, 2005, filed with the Commission on February 10, 2005, and incorporated herein by reference. +
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Exhibit No.	
10.58	Form of Securities Purchase Agreement by and among the Company and the Purchasers dated July 19, 2005. Filed as an exhibit to the Company's Current Report on Form 8-K, filed with the Commission on July 20, 2005, and incorporated herein by reference.
10.59	Form of Common Stock Purchase Warrant issued by the Company in favor of each Purchaser dated July 19, 2005. Filed as an exhibit to the Company's Current Report on Form 8-K, filed with the Commission on July 20, 2005, and incorporated herein by reference.
10.60	Cytogen Corporation 2005 Employee Stock Purchase Plan. Filed as an exhibit to the Company's Current Report on Form 8-K, filed with the Commission on September 27, 2005, and incorporated herein by reference. +
10.61	Form of Securities Purchase Agreement by and among the Company and the Purchasers dated December 13, 2005. Filed as an exhibit to the Company's Current Report on Form 8-K, filed with the Commission on December 14, 2005, and incorporated herein by reference.
10.62	Form of Common Stock Purchase Warrant issued by the Company in favor of each Purchaser dated December 13, 2005. Filed as an exhibit to the Company's Current Report on Form 8-K, filed with the Commission on December 14, 2005, and incorporated herein by reference.
10.63	Engagement Agreement dated December 13, 2005 between Cytogen Corporation and Rodman & Renshaw, LLC. Filed as an exhibit to the Company's Current Report on Form 8-K/A, filed with the Commission on December 14, 2005, and incorporated herein by reference.
10.64	Cytogen Corporation 2006 Equity Compensation Plan. Filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2006, filed with the Commission on May 10, 2006, and incorporated herein by reference. +
10.65	Membership Interest Purchase Agreement dated as of April 20, 2006 between the Company and Progenics Pharmaceutical, Inc. Filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2006, filed with the Commission on May 10, 2006, and incorporated herein by reference.
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Exhibit No.	
10.66	Amended and Restated PSMA/PSMP License Agreement dated April 20, 2006 among the Company, Progenics Pharmaceuticals, Inc. and PSMA Development Company LLC.** Filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2006, filed with the Commission on May 10, 2006, and incorporated herein by reference.
10.67	Exclusive Distribution Agreement dated as of April 21, 2006 between the Company and Savient Pharmaceuticals, Inc. ** Filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2006, filed with the Commission on May 10, 2006, and incorporated herein by reference.
10.68	Manufacture and Supply Agreement dated April 21, 2006 between the Company, Savient Pharmaceuticals, Inc. and Rosemont Pharmaceuticals Limited.** Filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2006, filed with the Commission on May 10, 2006, and incorporated herein by reference.
10.69	Product Purchase and Supply Agreement dated as of June 20, 2006 between the Company and Oncology Therapeutics Network, J.V. Filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2006, filed with the Commission on August 9, 2006, and incorporated herein by reference.
10.70	Manufacturing Agreement dated September 29, 2006 by and between the Company and Laureate Pharma, Inc. ** Filed as an exhibit to the Company's Quarterly Report on Form 10-Q, filed with the Commission on November 9, 2006, and incorporated herein by reference.
10.71	Product License and Assignment Agreement dated as of October 11, 2006 by and among the Company, InPharma AS, and InPharma, Inc. ** Filed as an exhibit to the Company's Quarterly Report on Form 10-Q, filed with the Commission on November 9, 2006, and incorporated herein by reference.
10.72	Securities Purchase Agreement dated as of November 1, 2006, among the Company and certain Purchasers. Filed as an exhibit to the Company's Current Report on Form 8-K, filed with the Commission on November 9, 2006, and incorporated herein by reference.
10.73	Form of Common Stock Purchase Warrant issued by the Company in favor of certain Purchasers. Filed as an exhibit to the Company's Current Report on Form 8-K, filed with the Commission on November 9, 2006, and incorporated herein by reference.
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Exhibit No.	
10.74	Form of Registration Rights Agreement among the Company and certain Purchasers. Filed as an exhibit to the Company's Current Report on Form 8-K, filed with the Commission on November 9, 2006, and incorporated herein by reference.
<u>10.75</u>	Settlement and Release Agreement dated February 15, 2007 between the Company and Advanced Magnetics, Inc. Filed herewith.
<u>10.76</u>	Contract Manufacturing Agreement dated as of January 8, 2007 between the Company and Holopack Verpackungstechnik GmbH. Filed herewith. **
<u>21</u>	Subsidiaries of Cytogen Corporation. Filed herewith.
23.1	Consent of KPMG LLP. Filed herewith
<u>23.2</u>	Consent of PricewaterhouseCoopers LLP. Filed herewith
31.1	Certification of President and Chief Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act 2002. Filed herewith.
31.2	Certification of Senior Vice President, Finance and Chief Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act 2002. Filed herewith.
<u>32.1</u>	Certification of President and Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. Filed herewith.
32.2	Certification of Senior Vice President, Finance and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. Filed herewith.

<sup>+</sup> Management contract or compensatory plan or arrangement.

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

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

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(b) Exhibits:

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

(c) Financial Statement Schedules:

None.

# **SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on the 16th day of March, 2007.

# CYTOGEN CORPORATION

By: /s/ MICHAEL D. BECKER

Michael D. Becker,

President and Chief Executive Officer

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#### SIGNATURES AND POWER OF ATTORNEY

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

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

	Signature	Title	Date
By:	/s/ MICHAEL D. BECKER Michael D. Becker	President and Chief Executive Officer (Principal Executive Officer and Director)	March 16, 2007
Ву:	/s/ KEVIN J. BRATTON Kevin J. Bratton	Senior Vice President, Finance, and Chief Financial Officer (Principal Financial and Accounting Officer)	March 16, 2007
By:	/s/ JOHN E. BAGALAY, JR. John E. Bagalay, Jr.	Director	March 16, 2007
By:	/s/ ALLEN BLOOM Allen Bloom	Director	March 16, 2007
Ву:	/s/ STEPHEN K. CARTER Stephen K. Carter	Director	March16, 2007
Ву:	/s/ JAMES A. GRIGSBY James A. Grigsby	Director and Chairman of the Board	March 16, 2007
By:	/s/ ROBERT F. HENDRICKSON Robert F. Hendrickson	Director	March 16, 2007
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By:	/s/ DENNIS H. LANGER Dennis H. Langer	Director	March 16, 2007
By:	/s/ KEVIN G. LOKAY Kevin G. Lokay	Director	March 16, 2007
By:	/s/ JOSEPH A. MOLLICA Joseph A. Mollica	Director	March 16, 2007
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# Form 10-K Item 15(a)(1) and (2)

# CYTOGEN CORPORATION AND SUBSIDIARIES

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2006, 2005 and 2004	F-7
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#### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders Cytogen Corporation:

We have audited the accompanying consolidated balance sheets of Cytogen Corporation and subsidiaries as of December 31, 2006 and 2005, and the related consolidated statements of operations, stockholders' equity and comprehensive loss, and cash flows for each of the years in the three-year period ended December 31, 2006. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We did not audit the financial statements of PSMA Development Company LLC (a development stage enterprise), a 50% owned unconsolidated investee company. The Company's equity interest in the loss of PSMA Development Company LLC was \$3.2 million and \$2.9 million for the years ended December 31, 2005 and 2004, respectively. The Company's investment in PSMA Development Company LLC was \$379,000 as of December 31, 2005. The 2005 and 2004 financial statements of PSMA Development Company LLC were audited by other auditors whose report has been furnished to us, and our opinion, insofar as it relates to the 2005 and 2004 amounts included for PSMA Development Company LLC, is based solely on the report of the other auditors. The report of the other auditors on the 2005 and 2004 financial statements of PSMA Development Company LLC contains an explanatory paragraph that states that PSMA Development Company LLC has suffered recurring losses from operations and does not have a work plan or budget for 2006, all of which raise substantial doubt about its ability to continue as a going concern, and that its financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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

In our opinion, based on our audits and the report of the other auditors, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Cytogen Corporation and subsidiaries as of December 31, 2006 and 2005, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2006, in conformity with U.S. generally accepted accounting principles.

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As discussed in notes 1 and 13 to the consolidated financial statements, the Company adopted the provisions of Statement of Financial Accounting Standards No. 123R, "Share-Based Payment" effective January 1, 2006.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Cytogen Corporation's internal control over financial reporting as of December 31, 2006, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated March 15, 2007 expressed an unqualified opinion on management's assessment of, and the effective operation of, internal control over financial reporting.

/s/ KPMG LLP

Princeton, New Jersey March 15, 2007

## **Report of Independent Registered Public Accounting Firm**

To the Management Committee and Members of PSMA Development Company LLC:

In our opinion, the balance sheet and the related statements of operations, of Members' (deficit) equity and of cash flows (not presented herein) present fairly, in all material respects, the financial position of PSMA Development Company LLC (the "Company") (a development stage enterprise) at December 31, 2005, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2005, and, cumulatively, for the period from June 15, 1999 (date of inception) to December 31, 2005 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management; our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

The financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations and does not have a work plan or budget for 2006, all of which raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ PricewaterhouseCoopers LLP

New York, New York March 15, 2006

# CYTOGEN CORPORATION AND SUBSIDIARIES

# CONSOLIDATED BALANCE SHEETS (All amounts in thousands, except share and per share data)

	Decem 2006	ber	31, 2005
ASSETS:			
Current assets:			
Cash and cash equivalents	\$ 32,507	\$	30,337
Restricted cash	1,100		
Accounts receivable, net	2,113		1,743
Inventories	2,538		3,582
Inventories at wholesalers	93		
Prepaid expenses	1,571		906
Other current assets	63		354
Total current assets	39,985		36,922
Property and equipment, less accumulated depreciation and amortization of \$1,409 and \$981 at December 31, 2006 and 2005, respectively	691		886
Product license fees, less accumulated amortization of \$2,577 and \$1,673, at December			
31, 2006 and 2005, respectively	11,612		6,327
Other assets	2,065		655
	\$ 54,353	\$	44,790
LIABILITIES AND STOCKHOLDERS' EQUITY:			
Current liabilities:			
Current portion of long-term liabilities	\$ 64	\$	26
Accounts payable and accrued liabilities	10,104		5,271
Total current liabilities	10,168		5,297
Warrant liabilities	6,464		1,869
Other long-term liabilities	59		46
Total liabilities	16,691		7,212
Commitments and contingencies (Note 19)	,		,
Stockholders' equity:			
Preferred stock, \$.01 par value, 5,400,000 shares authorized – Series C Junior			
Participating Preferred Stock, \$.01 par value, 200,000 shares authorized, none issued and			
outstanding	_	_	_
Common stock, \$.01 par value, 50,000,000 shares authorized, 29,605,631 and			
22,473,762 shares issued and outstanding at December 31, 2006 and 2005, respectively	296		225
Additional paid-in capital	465,016		450,502
Unearned compensation	_	_	(610)
Accumulated other comprehensive income	20		28
Accumulated deficit	(427,670)		(412,567)
Total stockholders' equity	37,662		37,578
	\$ 54,353	\$	44,790

The accompanying notes are an integral part of these statements.

# CYTOGEN CORPORATION AND SUBSIDIARIES

# **CONSOLIDATED STATEMENTS OF OPERATIONS** (All amounts in thousands, except per share data)

Year Ended December 31,

	2006		2005		2004
REVENUES:	2000		2005		2004
Product revenue:					
PROSTASCINT	\$ 9,125	\$	7,407	\$	7,186
QUADRAMET	8,141		8,350		7,293
Others	30		_	-	1
Total product revenue	17,296		15,757		14,480
License and contract revenue	11		189		139
Total revenues	17,307		15,946		14,619
OPERATING EXPENSES:					
Cost of product revenue	10,150		9,523		9,223
Selling, general and administrative	30,166		25,895		20,318
Research and development	7,301		6,162		3,292
Equity in loss of joint venture	120		3,175		2,896
Total operating expenses	47,737		44,755		35,729
Operating loss	(30,430)		(28,809)		(21,110)
Interest income	1,451		712		448
Interest expense	(36)		(114)		(185)
Gain on sale of equity interest in joint venture	12,873			-	
Decrease in value of warrant liabilities	1,039		1,666		_
Loss before income taxes	(15,103)		(26,545)		(20,847)
Income tax benefit	_	_	(256)		(307)
Net loss	\$ (15,103)	\$	(26,289)	\$	(20,540)
Basic and diluted net loss per share	\$ (0.64)	\$	(1.54)	\$	(1.40)
Weighted-average common shares outstanding	23,494		17,117		14,654

The accompanying notes are an integral part of these statements.

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

	Common S Share	Stock Amount	Additional Paid-in Capital (				Total ckholders' Equity
Balance, December 31, 2003	12,857,488	\$ 129	\$ 401,649	\$ _\$	-\$ (30	65,738) \$	36,040
Sale of shares of common stock including exercise of stock options	2,580,755	26	23,992	_	_	_	24,018
Issuance of shares of common stock and amendment of options related to compensation	873	_	_ 15	_	_	_	15
Issuance of shares of common stock in connection with Prostagen	50,000	_	_ 497	_	_	_	497
Net loss and comprehensive loss	<u> </u>	_			— (2	20,540)	(20,540)
Balance, December 31, 2004	15,489,116	155	426,153	_	— (38	86,278)	40,030
Sale of shares of common stock including exercise of stock options and warrants	6,887,847	69	23,129	_	_	_	23,198
Issuance of shares of common stock related to compensation	4,000	_	- 19	_	_	_	19
Issuance of shares of common stock related to Prostagen Unearned compensation	92,799	1	499	_	_	_	500
related to non-vested stock grants Reversal of unearned	_	_	_ 869	(869)	_	_	_
compensation related to non-vested stock grants Amortization of unearned compensation	_	-	– (167 <sub>)</sub>	) 167 — 92	_	_ _	92

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Comprehensive loss:							
Net loss	_	_	_	_		(26,289)	(26,289)
Unrealized gain on							
marketable securities		_			28		28
Total comprehensive							
loss	_	_		_	_		(26,261)
Balance, December 31,							
2005	22,473,762	225	450,502	(610)	28	(412,567)	37,578
Sale of shares of							
common stock	7,131,869	71	13,247	<u>—</u>	_	<u>—</u>	13,318
Share-based							
compensation expense	_		1,877	_		_	1,877
Reversal of unearned							
compensation related to							
non-vested stock grants	_	_	(610)	610	_	<u> </u>	_
Comprehensive loss:							
Net loss	_	_	_	_	_	(15,103)	(15,103)
Unrealized loss on							
marketable securities	_				(8)		(8)
Total comprehensive							
loss	_	_	_	_	_	_	(15,111)
Balance, December 31,							
2006	29,605,631 \$	296 \$	465,016 \$	<b>—</b> \$	20 \$	(427,670) \$	37,662

The accompanying notes are an integral part of these statements.

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

Year Ended December 31,

	2006	2005	2004
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	\$ (15,103) \$	(26,289) \$	(20,540)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,366	1,018	984
Decrease in value of warrant liabilities	(1,039)	(1,666)	_
Share-based compensation expense	1,877	111	15
Share-based milestone obligation	_	500	497
Increase (decrease) in provision for doubtful accounts	2	(72)	
Amortization of premiums on investments, net	_	52	132
Gain on sale of equity interest in joint venture	(12,873)	_	
Asset impairment			67
Deferred rent	(19)	12	15
Gain on disposition of assets			(2)
Changes in assets and liabilities:			
Accounts receivables	(372)	(265)	39
Inventories	1,044	51	(1,736)
Other assets	(1,588)	(139)	25
Liability related to joint venture	_	(396)	396
Accounts payable and accrued liabilities	3,852	(2,385)	2,435
Net cash used in operating activities	(22,853)	(29,468)	(17,673)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchases of product rights	(6,845)	<u></u>	
Purchases of property and equipment	(171)	(405)	(695)
Net proceeds from sale of property and equipment	(171)	(403)	187
Proceeds from sale of equity interest in joint venture	13,132	<u> </u>	10 <i>7</i>
Maturities of short-term investments		22,727	16,700
Purchases of short-term investments	<u></u>		(23,026)
Taronases of short term investments			(23,020)
Net cash provided by (used in) investing activities	6,116	22,322	(6,834)
The sum provided by (used in) investing activities	0,110	,e	(0,00.)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of common stock	13,318	23,198	24,018
Proceeds from issuance of warrants	5,634	3,535	_
Payments of long-term liabilities	(45)	(2,296)	(95)
	10.00=	0.4.45-	22.022
Net cash provided by financing activities	18,907	24,437	23,923
Net increase (decrease) in cash and cash equivalents	2,170	17,291	(584)
Cash and cash equivalents, beginning of year	30,337	13,046	13,630

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Cash and cash equivalents, end of year	\$ 32,507 \$	30,337 \$	13,046
Supplemental disclosure of non-cash information:			
Unrealized holding gain (loss) on marketable securities	\$ (8) \$	28 \$	_
Capital lease of equipment	96	25	73
Supplemental disclosure of cash information:			
Cash paid for interest	\$ 32 \$	395 \$	185
Cash received for taxes		256	307

The accompanying notes are an integral part of these statements.

# CYTOGEN CORPORATION AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

# 1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

#### **Business**

Cytogen Corporation (the "Company") is a specialty pharmaceutical company dedicated to advancing the treatment and care of cancer patients by building, developing, and commercializing a portfolio of oncology products for underserved markets where there are unmet needs. The Company's product portfolio includes four oncology products approved by the United States Food and Drug Administration ("FDA"), CAPHOSOL®, QUADRAMET®, PROSTASCINT®, and SOLTAMOX, which are marketed solely by the Company's specialized sales force to the U.S. oncology market. The Company introduced its fourth product, CAPHOSOL, in the first quarter of 2007. CAPHOSOL is an electrolyte solution for the treatment of oral mucositis and dry mouth that was approved as a prescription medical device. QUADRAMET is approved for the treatment of pain in patients whose cancer has spread to the bone. PROSTASCINT is a PSMA-targeting monoclonal antibody-based agent to image the extent and spread of prostate cancer. SOLTAMOX, which the Company introduced in the second half of 2006, is the first liquid hormonal therapy approved in the U.S. for the treatment of breast cancer in adjuvant and metastatic settings. Currently, the Company's clinical development initiatives are focused on new indications for QUADRAMET and PROSTASCINT, as well the product candidate, CYT-500, a radiolabeled antibody in Phase 1 development for the treatment of prostate cancer.

On April 21, 2006, the Company and Savient Pharmaceuticals, Inc. ("Savient") entered into a distribution agreement granting the Company exclusive marketing rights for SOLTAMOX in the United States. SOLTAMOX, a cytostatic estrogen receptor antagonist, is indicated for the treatment of breast cancer in adjuvant and metastatic settings and to reduce the risk of breast cancer in women with ductal carcinoma in situ (DCIS) or with high risk of breast cancer. In addition, the Company entered into a supply agreement with Savient and Rosemont Pharmaceuticals Limited, previously a wholly-owned subsidiary of Savient ("Rosemont"), for the manufacture and supply of SOLTAMOX.

On October 11, 2006, the Company and InPharma AS ("InPharma") entered into a license agreement granting the Company exclusive rights for CAPHOSOL in North America. Approved as a prescription medical device, CAPHOSOL is a topical oral agent indicated in the United States as an adjunct to standard oral care in treating oral mucositis caused by radiation or high dose chemotherapy. CAPHOSOL is also indicated for dryness of the mouth or dryness of the throat regardless of the cause or whether the conditions are temporary or permanent.

Cytogen has a history of operating losses since its inception. The Company currently relies on two products, PROSTASCINT and QUADRAMET, for substantially all of its revenues. In addition, the Company has, from time to time, stopped selling certain products, such as NMP22 BLADDERCHEK, BRACHYSEED and ONCOSCINT, that the Company previously

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believed would generate significant revenues. The Company's products are subject to significant regulatory review by the FDA and other federal and state agencies, which requires significant time and expenditures in seeking, maintaining and expanding product approvals. In addition, the Company relies on collaborative partners to a significant degree, among other things, to manufacture its products, to secure raw materials, and to provide licensing rights to their proprietary technologies for the Company to sell and market to others. The Company is also subject to revenue and credit concentration risks as a small number of its customers account for a high percentage of total revenues and corresponding receivables. The loss of one of these customers or changes in their buying patterns could result in reduced sales, thereby adversely affecting the operating results.

The Company has incurred negative cash flows from operations since its inception, and has expended, and expects to continue to expend, substantial funds to implement its planned product development efforts, including acquisition of products and complementary technologies, research and development, clinical studies and regulatory activities, and to further the Company's marketing and sales programs including new product launches. The Company expects its existing capital resources at December 31, 2006, along with the receipt of the \$4.0 million settlement from Advanced Magnetics, Inc. in the first quarter of 2007, should be adequate to fund operations and commitments at least into 2008. The Company cannot assure you that its business or operations will not change in a manner that would consume available resources more rapidly than anticipated. The Company expects that it will have additional requirements for debt or equity capital, irrespective of whether and when profitability is reached, for further product development costs, product and technology acquisition costs, and working capital.

#### **Basis of Consolidation**

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

#### **Use of Estimates**

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

# **Cash and Cash Equivalents**

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

#### **Restricted Cash**

In connection with the Company's license agreement with InPharma executed in October 2006, the Company pledged \$1.1 million as collateral to secure a letter of credit for \$1.0 million in favor of InPharma to guarantee Cytogen's payment of \$1.0 million on April 11, 2007 (see

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Note 19). Drawing under this letter of credit may not be made prior to April 12, 2007 and only if Cytogen fails to fulfill its payment obligation. The cash collateral is restricted from use until the expiration of the letter of credit on April 17, 2007.

#### **Accounts Receivable**

The Company's accounts receivable balances are net of an estimated allowance for uncollectible accounts. The Company continuously monitors collections and payments from its customers and maintains an allowance for uncollectible accounts based upon its historical experience and any specific customer collection issues that the Company has identified. While the Company believes its reserve estimate to be appropriate, the Company may find it necessary to adjust its allowance for uncollectible accounts if the future bad debt expense exceeds its estimated reserve. The Company is subject to concentration risks as a limited number of its customers provide a high percent of total revenues, and corresponding receivables. The Company does not have any off-balance sheet credit exposure related to its customers.

At December 31, 2006 and 2005, accounts receivable were net of an allowance for doubtful accounts of \$6,000 and \$4,000, respectively. Expense charged to the provisions for doubtful accounts during 2006 was \$2,000, compared to an expense reversal of \$72,000 recorded in 2005 which was a result of a decrease in the allowance for doubtful accounts. No such expense was charged in 2004. The Company wrote off \$7,000 of uncollectible accounts in 2004 and none in 2006 or 2005.

#### **Inventories**

The Company's inventories include PROSTASCINT and SOLTAMOX with the majority of the inventories related to PROSTASCINT. Inventories are stated at the lower of cost or market, as determined using the first-in, first-out method, which most closely reflects the physical flow of our inventories. The Company's products and raw materials are subject to expiration dating. The Company regularly reviews quantities on hand to determine the need to write-down inventory for excess and obsolete inventories based primarily on our estimated forecast of product sales. The Company's estimate of future product demand may prove to be inaccurate, in which case the Company may have understated or overstated its reserve for excess and obsolete inventories.

		Decem	ber 31,	
		2006	2	2005
	(	All amounts	in thous	ands)
Raw materials	\$	325	\$	291
Work-in process		1,296		2,625
Finished goods		917		666
	\$	2,538	\$	3,582

#### **Other Current Assets**

At December 31, 2006 and 2005, other current assets include \$6,000 and \$68,000, respectively, of receivables from employees for advances related to travel, tuition and sales incentive payments.

# **Property and Equipment**

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

	Decem	ber 31,	
	2006	,	2005
	(All amounts	in thous	ands)
Leasehold improvements	\$ 175	\$	168
Equipment and furniture	1,925		1,699
	2,100		1,867
Less: Accumulated depreciation and amortization	(1,409)		(981)
	\$ 691	\$	886

Depreciation and amortization expense for property and equipment was \$462,000, \$331,000 and \$288,000 in 2006, 2005 and 2004, respectively.

## **Fair Value of Financial Instruments**

The Company's financial instruments consist primarily of cash and cash equivalents, restricted cash, accounts receivable, accounts payable, accrued expenses and long-term debt. Management believes the carrying value of these assets and accounts payable and accrued expenses are representative of their fair value because of the short-term nature of these instruments. The fair value of long-term debt is estimated by discounting the future cash flows of each instrument at rates currently offered to the Company for similar debt instruments of comparable maturities by the Company's bankers. The resulting fair value of long-term debt approximates its carrying amount. The warrant liabilities are measured at fair value using the Black-Scholes option-pricing model at each reporting date (see Notes 11 and 12).

#### **Impairment of Long-Lived Assets**

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

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management measures the amount of such impairment by comparing the carrying value of the assets to the present value of the expected future cash flows associated with the use of the asset.

In July 2004, as part of the Company's continuing effort to reduce non-strategic expenses, the Company initiated the closure of its AxCell Biosciences facilities. In connection with such closure, the Company recorded a charge of \$100,000 for equipment impairment to write down the carrying value of the assets to fair value based on prices of similar assets and similar conditions. This charge is included in selling, general and administrative expenses for 2004 in the accompanying consolidated statement of operations.

# Costs Associated with Exit or Disposal Activities

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

As part of the Company's continuing effort to reduce non-strategic expenses, the Company restructured AxCell in September 2002 by reducing 75% of AxCell's workforce, initiated the closure of AxCell facilities in July 2004, and terminated early an operating lease in December 2004. The Company accounted for the AxCell restructuring and subsequent facility closure pursuant to SFAS No. 146. In 2002, the Company established a liability of \$350,000 for future payments on leased facilities that were no longer being used in operations. In December 2004, in connection with the lease termination, the Company was obligated to pay a termination fee of \$130,000, which was subsequently paid in January 2005. The then remaining liability for future lease payments of \$163,000 was eliminated in 2004 resulting in a gain of \$33,000 which is recorded in selling, general and administrative expense in the accompanying consolidated statement of operations.

# **Product License Fees**

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Product license fees consisted of the following:

	Decem	ber 3	31,
	2006		2005
	(All am	ounts	s in
	thous	ands	)
QUADRAMET license fee, net (see Note 6)	\$ 5,631	\$	6,327
SOLTAMOX license fee, net (see Note 17)	1,890		_
CAPHOSOL license fee, net (see Note 19)	4,091		
	\$ 11,612	\$	6,327

# **QUADRAMET** License Fee

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

		December 31,		
	200	)6	20	005
	(All a	amounts in	thousa	ınds)
QUADRAMET license fee	\$	8,000	\$	8,000
Less: Accumulated				
amortization		(2,369)		(1,673)
	\$	5,631	\$	6,327

During 2006, 2005 and 2004, Cytogen recorded \$696,000, \$697,000 and \$696,000, respectively, of such amortization as cost of product revenues in the accompanying consolidated statements of operations. Estimated amortization expense is \$696,000 for each of the next fiscal years through 2014 and \$63,000 in 2015.

#### **SOLTAMOX** License Fee

In February and April 2006, Cytogen paid an aggregate total of \$2.0 million to Savient Pharmaceuticals, Inc. representing an up-front licensing fee granting exclusive marketing rights for SOLTAMOX in the United States which was capitalized as a SOLTAMOX license fee and is being amortized on a straight-line basis over approximately 12 years, the estimated performance period of the agreement. The balance is comprised as follows:

		mber 31,
	2	2006
	(All a	mounts in
	tho	usands)
SOLTAMOX license fee	\$	2,000
Less: Accumulated amortization		(110)
	\$	1,890

During 2006, the Company recorded \$110,000 of such amortization as cost of product revenues in the accompanying consolidated statements of operations. Estimated amortization expense is \$164,000 for each of the next fiscal years through 2017 and \$86,000 in 2018.

# **CAPHOSOL** License Fee

In October 2006, Cytogen acquired from InPharma the exclusive marketing rights to CAPHOSOL in North America and an option to acquire the marketing rights to CAPHOSOL in Europe and Asia. Based on the relative fair value of the assets acquired, the Company allocated the license and option fees and related transaction costs as follows: \$4.2 million to CAPHOSOL

marketing rights in North America which excludes a \$400,000 payment contingent upon certain conditions, \$1.7 million to the option to license the product rights in Europe and \$162,000 to the option to license the product rights in Asia (see "Other Assets" below and Note 19). The allocated license fee for North America was capitalized as CAPHOSOL license fee in the accompanying consolidated balance sheet and is being amortized on a straight-line basis over approximately eleven years, which is the estimated performance period of the agreement. The balance is comprised as follows:

	December 31,
	2006
	(All amounts in
	thousands)
CAPHOSOL license fee	\$ 4,189
Less: Accumulated amortization	(98)
	\$ 4,091

During 2006, the Company recorded \$98,000 of such amortization as cost of product revenues in the accompanying consolidated statements of operations. Estimated amortization expense is \$381,000 for each of the next fiscal year through 2016 and \$281,000 in 2017.

#### **Other Assets**

Other assets consisted of the following:

	Decembe	er 31,
	2006	2005
	(All amou	nts in
	thousan	ids)
Investment in PSMA Development Company LLC (Note 4)	\$ \$	379
CAPHOSOL option fee for Europe	1,656	_
Deferred royalty expense	105	_
Other	304	276
	\$ 2,065 \$	655

In October 2006, the Company acquired from InPharma an option to purchase marketing rights to CAPHOSOL in Europe (see "CAPHOSOL License Fee" above and Note 19). The allocated option fee of \$1.7 million for Europe is recorded as other assets and will be transferred to the appropriate asset account if exercised. The Company periodically evaluates the option value for impairment by assessing, among other things, its intent and ability to exercise the option, the option expiry date and the market and product competitiveness.

In 2006, the Company introduced SOLTAMOX to the U.S. oncology market and began supplying the distribution channels to support the initial patient demand. Approximately \$1.1 million of SOLTAMOX supply was shipped to wholesalers, however, these shipments have not been recognized as revenues because the Company does not have sufficient information to estimate expected product returns. Accordingly, royalties owed based on SOLTAMOX shipments to wholesalers are deferred, since the Company has the right to offset royalties paid

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for products that are later returned against subsequent royalty obligations. At December 31, 2006, the deferred royalty expense of \$105,000 is classified as other assets in the accompanying consolidated balance sheet and will be recognized as royalty expense as SOLTAMOX sales are recognized as revenue.

Other assets in 2006 and 2005 each include \$48,000 of restricted cash which is used as collateral for a letter of credit required by a facility lease as a security deposit. The letter of credit is automatically renewed annually but not beyond the term of the lease.

Other assets in 2006 and 2005 also include \$20,000 and \$28,000, respectively, of marketable securities that relate to the 275,350 shares of Northwest Biotherapeutics, Inc. common stock which the Company received in connection with the acquisition of Prostagen, Inc. in 1999. The Company has classified this investment as available-for-sale securities in accordance with Statement of Financial Accounting Standards ("SFAS") No. 115, "Accounting for Certain Investments in Debt and Equity Securities." Available-for-sale securities are carried at fair value, based on quoted market prices, with unrealized gains or losses reported as a separate component of stockholders' equity. As of December 31, 2006, the Company had an unrealized gain of \$20,000 related to this investment compared to an unrealized gain of \$28,000 at December 31, 2005. There is no assurance, however, that the Company can sell these securities within a reasonable amount of time without negatively affecting the price of the stock because of low daily trading volume.

# **Warrant Liabilities**

Emerging Issues Task Force ("EITF") No. 00-19, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock" addresses accounting for equity derivative contracts indexed to, and potentially settled in a company's own stock, or equity derivatives, by providing guidance for distinguishing between permanent equity, temporary equity and assets and liabilities. Under EITF 00-19, to qualify as permanent equity, the equity derivative must permit the issuer to settle in unregistered shares. EITF 00-19 considers the ability to keep a registration statement effective as beyond a company's control and warrants that cannot be classified as permanent equity are instead classified as a liability. In addition, warrants that permit net cash settlement at the option of the holder are also classified as a liability.

Equity derivatives not qualifying for permanent equity accounting are recorded at their fair value using the Black-Scholes option-pricing model and are remeasured at each reporting date until the warrants are exercised or expire. Changes in the fair value of the warrants will be reported in the consolidated statements of operations as non-operating income or expense. The fair value of the warrants as calculated using the Black-Scholes option-pricing model is subject to significant fluctuation based on changes in the Company's stock price, expected volatility, expected life, the risk-free interest rate and dividend yield.

EITF No. 00-19-2 "Accounting for Registration Payment Arrangements" specifies that registration payment arrangements should play no part in determining the initial classification and subsequent accounting for the securities they related to. The Staff position requires the

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contingent obligation in a registration payment arrangement to be separately analyzed under FASB Statement No. 5, "Accounting for Contingencies" and FASB Interpretation No. 14, "Reasonable Estimation of the Amount of a Loss". If payment in a registration payment arrangement is probable and can be reasonably estimated, a liability should be recorded.

# **Revenue Recognition**

The Company generates revenue from product sales and license and contract revenues. The Company recognizes revenue in accordance with the SEC's Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements" as amended by Staff Accounting Bulletin No. 104 (together, "SAB 101"), and FASB Statement No. 48 "Revenue Recognition When Right of Return Exists" ("SFAS 48"). SAB 101 states that revenue should not be recognized until it is realized or realizable and earned. Revenue is realized or realizable and earned when all of the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the seller's price to the buyer is fixed or determinable; and (4) collectibility is reasonably assured. SFAS 48 states that revenue from sales transactions where the buyer has the right to return the product shall be recognized at the time of sale only if (1) the seller's price to the buyer is substantially fixed or determinable at the date of sale, (2) the buyer has paid the seller, or the buyer is obligated to pay the seller and the obligation is not contingent on resale of the product, (3) the buyer's obligation to the seller would not be changed in the event of theft or physical destruction or damage of the product, (4) the buyer acquiring the product for resale has economic substance apart from that provided by the seller, (5) the seller does not have significant obligations for future performance to directly bring about resale of the product by the buyer, and (6) the amount of future returns can be reasonably estimated.

#### **Product Sales**

The Company recognizes revenues for product sales at the time title and risk of loss are transferred to the customer, and the other criteria of SAB 101 and SFAS 48 are satisfied, which is generally at the time products are shipped to customers. At the time gross revenue is recognized from product sales, an adjustment, or decrease, to revenue for estimated rebates, discounts and returns is also recorded. This revenue reserve is determined on a product-by-product basis. The rebate or discount reserve is recorded in accordance with Emerging Issues Task Force (EITF) Issue No. 01-9, "Accounting for Consideration Given by a Vendor to a Customer", which states that cash consideration given by a vendor to a customer is presumed to be a reduction of the selling prices of the vendor's products or services and, therefore, should be characterized as a reduction of revenue when recognized in the vendor's income statement. At the time product is shipped, an adjustment is recorded for estimated rebates and discounts based on the contractual terms with customers. Revenue reserves including return allowances are established by management as its best estimate at the time of sale based on each product's historical experience adjusted to reflect known changes in the factors that impact such reserves.

In the case of a new product like SOLTAMOX, which the Company introduced in the second half of 2006, product shipments made to wholesalers do not meet the revenue recognition criteria of SFAS 48 and SAB 101. Because the Company cannot reliably estimate expected

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returns for this new product, the Company will defer recognition of revenue until the right of return no longer exists or until the Company develops sufficient historical experience to estimate sales returns. In 2006, approximately \$1.1 million of SOLTAMOX was shipped to wholesalers. For these product shipments, the Company invoices the wholesalers, records the payment received as "Customer Liability", and classifies the inventory shipped to wholesalers as "Inventory at Wholesalers", \$93,000 at December 31, 2006, at the Company's cost of goods for such inventory. The Company recognizes revenue for SOLTAMOX when such product is sold through to the end users, on a first-in first-out (FIFO) basis. Additionally, royalty amount due based on unit shipments to wholesalers is deferred and recognized as royalty expense as those units are sold through and recognized as revenue. The Company has the right to offset royalties paid for product that are later returned against subsequent royalty obligations. Expenses related to shipments of SOLTAMOX, for which the Company does not have the ability to recover if and when the products are returned, are expensed as incurred.

When available, the Company may use the following information to estimate the prescription-based sales for SOLTAMOX and to estimate gross-to-net sales adjustments: (1) the estimated prescription-based sales, (2) the Company's analysis of third-party information, including information obtained from certain wholesalers with respect to their inventory levels and sell-through to customers and third-party market research data, and (3) the Company's internal product sales information. The Company's estimates will be subject to the inherent limitations of estimates that rely on third-party data, as certain third-party information is itself in the form of estimates, and reflect other limitations. The Company's sales and revenue recognition for SOLTAMOX will reflect the Company's estimates of actual product sold through to the end user.

License and contract revenues include milestone payments and fees under collaborative agreements with third parties, revenues from research services, and revenues from other miscellaneous sources. The Company defers non-refundable up-front license fees and recognizes them over the estimated performance period of the related agreement, when the Company has continuing involvement. Since the term of the performance periods is subject to management's estimates, future revenues to be recognized could be affected by changes in such estimates.

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

# **Research and Development**

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

## **Advertising Costs**

Advertising costs are charged to expense as incurred. In 2006, 2005 and 2004, the advertising costs were \$2.1 million, \$710,000 and \$710,000, respectively, and are included in selling, general and administrative in the Company's consolidated statements of operations.

#### **Patent Costs**

Patent costs are charged to expense as incurred.

# **Rent Expense**

Rental expenses for the Company's corporate offices are recognized over the term of the lease. The Company recognizes rent starting when possession of the facility is taken from the landlord. When a lease contains a predetermined fixed escalation of the minimum rent, the Company recognizes the related rent expense on a straight-line basis and records the difference between the recognized rental expense and the amounts payable under the lease as deferred lease credits. Tenant leasehold improvement allowances are reflected in Accounts Payable and Accrued Liabilities in the consolidated balance sheet and are amortized as a reduction to rent expense in the statement of operations over the term of the lease.

#### **Income Taxes**

The Company accounts for income taxes under the asset and liability method in accordance with SFAS No. 109, "Accounting for Income Taxes." Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

### **Net Loss Per Share**

Basic net loss per common share is calculated by dividing the Company's net loss by the weighted-average common shares outstanding during each period. Diluted net loss per common share is the same as basic net loss per share for each of the three years ended December 31, 2006, 2005 and 2004, because the inclusion of common stock equivalents, which consist of nonvested shares, warrants and options to purchase shares of the Company's common stock, would be antidilutive due to the Company's losses (see Notes 12 and 13).

# **Variable Interest Entities**

Financial Accounting Standards Board ("FASB") Interpretation No. 46 ("FIN 46R"), "Consolidation of Variable Interest Entities" ("VIEs"), addresses how a business enterprise

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should evaluate whether it has a controlling financial interest in an entity through means other than voting rights and accordingly should consolidate the entity. The Company was required to apply FIN 46R to variable interests in VIEs created after December 31, 2003. For variable interests in VIEs created before January 1, 2004, FIN 46R applied beginning on March 31, 2004.

In June 1999, Cytogen entered into a joint venture with Progenics Pharmaceuticals Inc. ("Progenics") to form the PSMA Development Company LLC (the "Joint Venture"). The Company sold its 50% ownership interest in the Joint Venture to Progenics in April 2006. Cytogen accounted for the Joint Venture using the equity method of accounting. The Company was not required to consolidate the Joint Venture under the requirements of FIN 46R.

# **Share-Based Compensation**

Effective January 1, 2006, the Company adopted SFAS No. 123(R), "Share-Based Payment," using the modified prospective transition method. Under this method, compensation expense is reflected in the financial statements beginning January 1, 2006 with no restatement to the prior periods. As such, compensation expense, which is measured based on the fair value of the instrument on the grant date, is recognized for awards that are granted, modified, repurchased or cancelled on or after January 1, 2006 as well as for the portion of awards previously granted that have not vested as of January 1, 2006. The Company has adopted the straight-line expense attribution method for all options granted after January 1, 2006. Compensation costs associated with awards granted prior to the adoption of SFAS 123(R) are recognized using the accelerated attribution method in accordance with FASB Interpretation No. 28, "Accounting for Stock Appreciation Rights and Other Variable Stock Option or Award Plan ("FIN 28"), consistent with the Company's prior policy. Prior to the adoption of SFAS 123(R), the Company accounted for its stock-based employee compensation expense under the recognition and measurement principles of Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25"), and related interpretations.

#### **Other Comprehensive Income**

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

#### **Recent Accounting Pronouncements**

Accounting for Registration Payment Arrangements

On December 21, 2006, the FASB issued FASB Staff Position No. EITF 00-19-2, "Accounting for Registration Payment Arrangements" ("EITF 00-19-2"), which addresses an issuer's accounting for registration payment arrangements. EITF 00-19-2 specifies that the contingent obligation to make future payments or otherwise transfer consideration under a registration payment arrangement, whether issued as a separate agreement or included as a provision of a financial instrument or other agreement, should be separately recognized and

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measured in accordance with FASB Statement No. 5, Accounting for Contingencies. EITF 00-19-2 further clarifies that a financial instrument subject to a registration payment arrangement should be accounted for in accordance with other applicable accounting literature without regard to the contingent obligation to transfer consideration pursuant to the registration arrangement. EITF 00-19-2 is effective immediately for new and modified registration payment arrangements. Early adoption of EITF 00-19-2 for the interim or annual period for which the financials statements have not been issued is permitted. The Company elected to adopt EITF 00-19-2 at the beginning of the fourth quarter 2006. The adoption of EITF 00-19-2 did not have any impact on the Company's consolidated financial statements in the year ended December 31, 2006.

## Evaluation of Misstatements

On September 13, 2006, the staff of the SEC issued Staff Accounting Bulletin No. 108, "Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements" ("SAB 108"), which provides interpretive guidance on how the effects of prior year misstatements should be considered in evaluating a current year misstatement. The cumulative effect from the initial adoption of SAB 108 may be reported as a cumulative effect adjustment to the beginning of year retained earnings with disclosure of the nature and amount of each individual error. The Company applied the provisions of SAB 108 in the fourth quarter of 2006. The adoption of SAB 108 did not have a material impact on the Company's consolidated financial statements.

#### Fair Value Measurements

On September 15, 2006, the FASB issued SFAS No. 157, "Fair Value Measurements" ("SFAS 157"). SFAS 157 defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements. SFAS 157 is effective as of the beginning of the first fiscal year beginning after November 15, 2007. The Company will be required to adopt this statement in the first quarter of 2008. Management is currently evaluating the requirements of SFAS 157 and has not yet determined the impact this standard will have on its consolidated financial statements.

## Income Taxes

In June 2006, the FASB issued FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes" ("FIN 48"). FIN 48 is applicable for fiscal years beginning after December 15, 2006. This Interpretation clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with FASB Statement No. 109, "Accounting for Income Taxes." This Interpretation prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. This Interpretation also provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. The Company is currently evaluating the impact of the adoption of FIN 48 upon its financial statements and related disclosures. The Company does not expect that the adoption will have a material effect on its results of operations or financial condition.

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Sales Tax

In March 2006, the FASB's Emerging Issues Task Force released Issue 06-3, "How Sales Taxes Collected From Customers and Remitted to Governmental Authorities Should Be Presented in the Income Statement" ("EITF 06-3"). A consensus was reached that entities may adopt a policy of presenting sales taxes in the income statement on either a gross or net basis. If taxes are significant, an entity should disclose its policy of presenting sales taxes and the amount of sales taxes if reflected on a gross basis in the income statement. The guidance is effective for periods beginning after December 15, 2006. The Company presents sales net of sales taxes in its consolidated statements of operations and does not anticipate changing its policy as a result of EITF 06-3.

# Abnormal Inventory Costs

In November 2004, the FASB issued SFAS No. 151, "Inventory Costs, an amendment of ARB No. 43, Chapter 4" ("SFAS No. 151"), to clarify that abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage) should be recognized as current period charges, and that fixed production overheads should be allocated to inventory based on the normal capacity of production facilities. This statement is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. Accordingly, the Company adopted SFAS No. 151 in its fiscal year beginning January 1, 2006. The adoption of this standard did not have any impact on the Company in the year ended December 31, 2006.

#### Reclassification

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

# 2. ADVANCED MAGNETICS, INC.

In August 2000, the Company and Advanced Magnetics, Inc., a developer of superparamagnetic iron oxide nanoparticles used in pharmaceutical products, entered into marketing, license and supply agreements (the "AVM Agreements"). Under the AVM Agreements, Cytogen acquired certain rights in the United States to Advanced Magnetics' product candidates: COMBIDEX®, an investigational functional molecular imaging agent for all applications; and ferumoxytol (formerly referred to as Code 7228) for oncology applications only. Advanced Magnetics will be responsible for all costs associated with the clinical development of, and if approved by the FDA, the supply and manufacture of COMBIDEX and ferumoxytol and will receive product transfer payments and royalties based upon product sales or certain minimum payments from Cytogen, whichever is greater. The Company had no funding obligation regarding research and development for Advanced Magnetics and the Company did not earn any compensation nor incur any costs for the research and development activities related to COMBIDEX in 2006, 2005 and 2004.

In January 2006, the Company filed a complaint against Advanced Magnetics in the Massachusetts Superior Court for breach of contract, fraud, unjust enrichment, and breach of the implied covenant of good faith and fair dealing in connection with the parties' 2000 license

agreement. The complaint sought damages along with a request for specific performance requiring Advanced Magnetics to take all reasonable steps to secure FDA approval of Combidex in compliance with the terms of the licensing agreement. In February 2006, Advanced Magnetics filed an answer to the Company's complaint and asserted various counterclaims, including tortuous interference, defamation, consumer fraud and abuse of process. In February 2007, the Company settled its lawsuit against Advanced Magnetics, as well as Advanced Magnetics' counterclaims against Cytogen, by mutual agreement. Under the terms of the settlement agreement, Advanced Magnetics paid \$4.0 million to the Company and will release 50,000 shares of Cytogen common stock currently being held in escrow. In addition, both parties agreed to early termination of the licensing agreement.

# 3. ACQUISITION OF PROSTAGEN, INC.

Pursuant to a Stock Exchange Agreement (the "Prostagen Agreement") related to the Company's acquisition of Prostagen Inc. ("Prostagen") in June 1999, the Company agreed to issue up to an additional \$4.0 million worth of Cytogen Common Stock to the shareholders and debtholders of Prostagen (the "Prostagen Partners"), if certain milestones are achieved in the dendritic cell therapy and PSMA development programs. In May 2002, the Company entered into an Addendum to the Prostagen Agreement (the "Addendum"), which clarifies the future milestone payments to be made under the Prostagen Agreement, as well as the timing of such payments. Pursuant to the Addendum, the Company may be obligated to pay two additional milestone payments of \$1.0 million each, upon certain clinical achievements regarding the PSMA development programs. In November 2004, the Company entered into Addendum No. 2 to the Prostagen Agreement (the "Second Addendum"), which further clarifies the future milestone payments to be made under the Prostagen Agreement. Pursuant to the Second Addendum, the Company issued 92,799 shares and 50,000 shares of Common Stock to the Prostagen Partners in 2005 and 2004, respectively. As a result, the Company recorded charges to research and development expense of \$500,000 and \$497,000 in 2005 and 2004, respectively. The Company may be obligated to pay an additional milestone payment of \$1.0 million payable in shares of Cytogen common stock, upon certain clinical achievements regarding the PSMA development programs.

# 4. PSMA DEVELOPMENT COMPANY LLC

In June 1999, Cytogen entered into a joint venture with Progenics to form the PSMA Development Company LLC (the "Joint Venture"), a development stage enterprise. The Joint Venture was developing antibody-based and vaccine immunotherapeutic products utilizing Cytogen's proprietary PSMA technology. The Joint Venture was owned equally by Cytogen and Progenics until April 20, 2006 (see below). Cytogen accounted for the Joint Venture using the equity method of accounting. Cytogen had recognized 50% of the Joint Venture's operating results in its consolidated statements of operations until April 20, 2006, when the Company entered into a Membership Interest Purchase Agreement with Progenics to sell the Company's 50% ownership interest in the Joint Venture. In addition, the Company entered into an Amended and Restated PSMA/PSMP License Agreement with Progenics and the Joint Venture pursuant to which the Company licensed the Joint Venture certain rights in PSMA technology. Under the terms of such agreements, the Company sold its 50% interest in the Joint Venture for a cash

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payment of \$13.2 million, potential future milestone payments totaling up to \$52 million payable upon regulatory approval and commercialization of the Joint Venture products, and royalties on future product sales of the Joint Venture, if any. Cytogen has no continuing involvement and no further obligations to provide any products, services, or financial support to the Joint Venture. This transaction was a sale of an asset in which the consideration was fully received and for which the earning process is complete. As a result, the Company recorded \$12.9 million in gain on sale of equity interest in the Joint Venture in the second quarter of 2006, which represents the net proceeds after transaction costs less the carrying value of the Company's investment in the Joint Venture at the time of sale.

For the years ended December 31, 2006, 2005 and 2004, Cytogen recognized \$120,000, \$3.2 million and \$2.9 million, respectively, in losses of the Joint Venture. In 2005 and 2004, each Member contributed capital of \$4.0 million and \$2.0 million, respectively, to the Joint Venture. No capital contribution was made in 2006. As of December 31, 2005, the carrying value of the Company's investment in the Joint Venture was \$379,000, which represents Cytogen's investment in the Joint Venture, less its cumulative share of losses, which net investment is recorded in other assets (see Note 1). Selected financial statement information of the Joint Venture, is as follows (all amounts in thousands):

#### **Balance Sheet Data:**

A CODE	Dec	ember 31, 2005
ASSETS:	¢	072
Cash	\$	873
Prepaid expenses		9
Accounts receivable from Progenics Pharmaceuticals, Inc., a related party	ф	194
	\$	1,076
A A DAY AND A COLUMN TO CO		
LIABILITIES AND MEMBERS' EQUITY:		
Accounts payable to Cytogen Corporation, a related party	\$	3
Accounts payable and accrued		
expenses		332
Total liabilities		335
Capital contributions		31,198
Deficit accumulated during the development stage		(30,457)
Total members' equity		741
Total liabilities and members'		
equity	\$	1,076
F - 24		

#### **Income Statement Data:**

	Jan 20 A <sub>I</sub>	From nuary 1, 106 to oril 20, 2006	Year Ended ecember 31, 2005	Ι	Year Ended December 31, 2004	J (in	For the Period From June 15, 1999 nception) April 20, 2006
Interest income	\$	6	\$ 9	\$	7	\$	256
Total expenses		246	6,358		5,799		30,953
Net loss	\$	(240)	\$ (6,349)	\$	(5,792)	\$	(30,697)

Prior to the sale of its interest in the Joint Venture in April 2006, the Company provided limited research and development services to the Joint Venture. During 2005 and 2004, the Company recorded revenue related to the Joint Venture of \$185,000 and \$106,000, respectively, and incurred costs of \$151,000 and \$88,000, respectively. The Company did not provide any research and development services to the Joint Venture in 2006.

## 5. THE DOW CHEMICAL COMPANY

In 1993, Cytogen acquired an exclusive license from The Dow Chemical Company for QUADRAMET for the treatment of osteoblastic bone metastases in the United States. This license was amended in 1995 to expand the territory to include Canada and Latin America and again in 1996 to expand the field to include all osteoblastic diseases. The agreement requires the Company to pay Dow royalties based on a percentage of net sales of QUADRAMET, or a guaranteed annual minimum payment, whichever is greater, and future payments upon the achievement of certain milestones. The Company recorded \$1.0 million in royalty expense for each of 2006, 2005 and 2004. Future annual minimum royalties due to Dow are \$1.0 million per year in 2007 through 2012 and \$833,000 in 2013.

In May 2005, the Company entered into a license agreement with Dow to create a targeted oncology product designed to treat prostate and other cancers. The agreement applies proprietary MeO-DOTA bifunctional chelant technology from Dow to radiolabel Cytogen's PSMA antibody with a therapeutic radionuclide. Under the agreement, proprietary chelation technology and other capabilities, provided through ChelaMedSM radiopharmaceutical services from Dow, will be used to attach a therapeutic radioisotope to the same murine monoclonal antibody utilized in Cytogen's PROSTASCINT molecular imaging agent which is called 7E11-C5.3 ("7E11"). The 7E11 antibody was excluded from the PSMA technology licensed to the Joint Venture. As a result of the agreement, Cytogen is obligated to pay a minimal license fee and aggregate future milestone payments of \$1.9 million for each licensed product, if approved, and royalties based on sales of related products, if any. Unless terminated earlier, the Dow agreement terminates on the later of (a) the tenth anniversary of the date of first commercial sale for each licensed product or (b) the expiration of the last to expire valid claim that would be infringed by the sale of the licensed product. The Company may terminate the license agreement with Dow on 90 days written notice.

#### 6. BERLEX LABORATORIES INC.

On August 1, 2003, the Company reacquired marketing rights to QUADRAMET in North America and Latin America from Berlex Laboratories Inc. ("Berlex") in exchange for an up-front payment of \$8.0 million and royalties based on future sales of QUADRAMET. As a result of the agreement, the Company began recording product revenue from the sales of QUADRAMET. The up-front license payment of \$8.0 million was capitalized in 2003 as the QUADRAMET license fee in the accompanying consolidated balance sheet and is being amortized on a straight-line basis over approximately twelve years, which is the estimated performance period of the agreement (see Note 1). Cytogen also recorded \$1.3 million, \$1.4 million and \$1.2 million of royalty expenses to Berlex based on its sales of QUADRAMET in 2006, 2005 and 2004, respectively, as cost of product revenues.

## 7. BRISTOL-MYERS SQUIBB MEDICAL IMAGING, INC.

Effective January 1, 2004, the Company entered into a manufacturing and supply agreement with Bristol-Myers Squibb Medical Imaging, Inc. ("BMSMI"), whereby BMSMI will manufacture, distribute and provide order processing and customer service for Cytogen relating to QUADRAMET. Under the terms of the agreement, Cytogen is obligated to pay at least \$4.9 million annually, subject to future annual price adjustment, through 2008, unless terminated by BMSMI or Cytogen on two years prior written notice. This agreement will automatically renew for five successive one-year periods unless terminated by BMSMI or Cytogen on two years prior written notice. During 2006, 2005 and 2004, the Company incurred \$4.5 million, \$4.3 million and \$4.2 million, respectively, of manufacturing costs for QUADRAMET, of which \$4.3 million, \$4.2 million and \$4.1 million, respectively, are included in cost of product revenue and the remaining expenses for each respective period are charged to research and development expenses for clinical supplies. The Company also pays BMSMI a variable amount per month for each QUADRAMET order placed to cover the costs of customer service which is included in selling, general and administrative expenses.

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

### 8. LAUREATE PHARMA, L.P.

In September 2004, the Company entered into a non-exclusive manufacturing agreement with Laureate Pharma, L.P. pursuant to which Laureate manufactured PROSTASCINT and its primary raw materials for Cytogen in Laureate's Princeton, New Jersey facility. Laureate is the sole manufacturer of PROSTASCINT and its antibodies. The agreement terminated in the third quarter of 2006, upon Laureate's completion of the specified production campaign for POSTASCINT and shipment of the resulting products from Laureate's facility. Under the terms

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of the agreement, the Company incurred \$35,000 and \$1.8 million for the years ended December 31, 2006 and 2005, respectively, all of which were recorded as inventory when purchased.

In September 2006, the Company entered into a non-exclusive manufacturing agreement with Laureate pursuant to which Laureate shall manufacture PROSTASCINT and its primary raw materials for Cytogen in Laureate's Princeton, New Jersey facility. The agreement will terminate, unless terminated earlier pursuant to its terms, upon Laureate's completion of the specified production campaign for PROSTASCINT and shipment of the resulting products from Laureate's facility. Under the terms of the agreement, the Company anticipates it will pay at least an aggregate of \$3.9 million through the end of the term of contract, of which \$500,000 was incurred and paid in 2006 and recorded as inventory when purchased.

# 9. REVENUES FROM MAJOR CUSTOMERS

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

	Year Ended December 31,				
	2006	2005	2004		
Cardinal Health (formerly Syncor International Corporation)	41%	47%	46%		
Mallinckrodt Inc.	14%	11%	12%		
GE Healthcare (formerly Amersham Health)	9%	9%	10%		

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

As of December 31, 2006 and 2005, the receivables from the above-mentioned major customers accounted for 56% and 60%, respectively, of gross accounts receivable.

### 10. ACCOUNTS PAYABLE AND ACCRUED LIABILITIES

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

	Detellibei			1 31,		
	2006			2005		
	(A	ll amounts	in thou	sands)		
Accounts payable	\$	2,199	\$	1,288		
Accrued payroll, sales commission and related expenses		1,766		656		
Accrued royalty expense		909		764		
Accrued professional and legal						
expenses		806		451		
Accrued research contracts and						
materials		467		734		
Accrued manufacturing						
costs		170		453		
Accrued marketing						
expenses		1,545		307		
Liability to InPharma (see Note						
19)		1,000				
Insurance liability		338		261		
Other accruals		904		357		
	\$	10,104	\$	5,271		

### 11. LONG-TERM LIABILITIES

Components of long-term liabilities were as follows:

		December 31,		
	2	2006		2005
	(A)	ll amounts	in thou	sands)
Capital lease obligations	\$	123	\$	72
Warrant liabilities		6,464		1,869
		6,587		1,941
Less: Current portion of long-term liabilities		(64)		(26)
	\$	6,523	\$	1,915

In August 1998, Cytogen received \$2.0 million from Elan Corporation, plc ("Elan") in exchange for a convertible promissory note. The note bore annual interest of 7%, compounded semi-annually, however, such interest was not payable in cash but was added to the principal for the first 24 months; thereafter, interest was payable in cash. The Company recorded \$98,000 and \$160,000 in interest expense on this note for 2005 and 2004, respectively. In August 2005, the Company made a payment of \$2.3 million to satisfy its obligations on the \$2.0 million promissory note and \$280,000 unpaid accrued interest.

The Company leases certain equipment under capital lease obligations, which will expire on various dates through 2009. The leased equipment in the gross amount of \$202,000 and \$108,000 at December 31, 2006 and 2005, respectively, are included in the Property and

December 31.

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Equipment in the accompanying consolidated balance sheet with the related accumulated depreciation of \$118,000 and \$51,000 at December 31, 2006 and 2005, respectively. Depreciation of assets held under capital leases is included with depreciation expense. Payments to be made under capital lease obligations (including total interest of \$19,000) are \$75,000 in 2007, \$55,000 in 2008 and \$12,000 in 2009. The Company has the option to purchase the leased equipment at its fair value or for a dollar, depending on the term of each respective lease.

In July and August 2005, the Company sold 3,104,380 shares of its common stock and 776,096 warrants to purchase shares of its common stock having an exercise price of \$6.00 per share (see Note 12). These warrants are exercisable beginning six months and ending ten years after their issuance. The shares of common stock underlying the warrants were registered under the Company's existing shelf registration statement. The Company is required to maintain the effectiveness of the registration statement as long as any warrants are outstanding.

Under EITF 00-19, to qualify as permanent equity, the equity derivative must permit the issuer to settle in unregistered shares. The Company does not have that ability under the securities purchase agreement for the warrants issued in July and August 2005 and, as EITF 00-19 considers the ability to keep a registration statement effective as beyond the Company's control, the warrants cannot be classified as permanent equity and are instead classified as a liability in the accompanying consolidated balance sheets. Upon issuance of the warrants in July and August 2005, the Company recorded the warrant liability at its initial fair value of \$3.5 million using the Black-Scholes option-pricing model with the following assumptions:

					De	ecember	D	ecember
	Jı	ıly 20,	A	ugust 2,		31,		31,
		2005		2005		2005		2006
Dividend yield		0%		0%		0%		0%
Expected volatility		105.27%		105.03%		105.86%		104.00%
Expected life		10.0 years		10.0 years		9.6 years		8.6 years
Risk-free interest rate		4.25%		4.41%		4.40%		4.77%
Company Common Stock Price	\$	4.92	\$	5.04	\$	2.74	\$	2.33

In November 2006, the Company sold to certain institutional investors 7,092,203 shares of its common stock and 3,546,107 warrants to purchase shares of its common stock with an exercise price of \$3.32 per share (see Note 12). These warrants are exercisable beginning six months and ending five years after their issuance. The warrant agreement contains a cash settlement feature, which is available to the warrant holders at their option, upon an acquisition in certain circumstances. As a result, the warrants cannot be classified as permanent equity and are instead classified as a liability at their fair value in the accompanying consolidated balance sheet. Upon issuance of the warrants in November 2006, the Company recorded the warrant liability at its initial fair value of \$5.6 million using the Black-Scholes option-pricing model with the following assumptions:

	nber 10, 006	Dec	cember 31, 2006
Dividend yield	0%		0%
Expected volatility	81.11%		80.15%
Expected life	5.0 years		4.9 years
Risk-free interest rate	4.61%		4.74%
Company Common Stock Price	\$ 2.53	\$	2.33

Equity derivatives not qualifying for permanent equity accounting are recorded at fair value and are remeasured at each reporting date until the warrants are exercised or expire. Changes in the fair value of the warrants issued in 2005 and 2006 as described above will be reported in the consolidated statements of operations as non-operating income or expense. At December 31, 2006, the aggregate fair value of these warrants decreased to \$6.5 million, using the Black-Scholes option pricing model with the respective assumptions in the preceding tables, from their initial fair value or the fair value at December 31, 2005, as applicable, resulting in a gain of \$1.0 million for the year ended December 31, 2006. At December 31, 2005, the fair value of the warrants decreased to \$1.9 million, from their initial fair value, resulting in a gain of \$1.7 million for the year ended December 31, 2005.

## 12. PREFERRED STOCK, COMMON STOCK AND WARRANTS

On November 10, 2006, the Company sold to certain institutional investors 7,092,203 shares of its common stock and 3,546,107 warrants to purchase shares of its common stock, through a private placement offering. The warrants have an exercise price of \$3.32 per share and are exercisable beginning six months and ending five years after their issuance. The warrant agreement contains a cash settlement feature, which is available to the warrant holders at their option, upon an acquisition in certain circumstances (see Note 11). In exchange for \$2.82, the purchasers received one share of common stock and warrants to purchase .5 shares of common stock. The offering provided net proceeds of approximately \$18.4 million to the Company. The placement agents in this transaction received a fee equal to 7% of the aggregate gross proceeds. In connection with this sale, the Company entered into a Registration Rights Agreement with the investors under which, the Company was obligated to file a registration statement with the SEC for the resale of Cytogen shares sold to the investors and shares issuable upon exercise of the warrants within a specified time period. The Company is also required to use commercially reasonable efforts to cause the registration to be declared effective by the SEC and to remain continuously effective until such time when all of the registered shares are sold or three years from closing date, whichever is earlier. In the event the Company fails to keep the registration statement effective, the Company is obligated to pay the investors liquidation damages equal to 1% of the purchase price paid by the investors (\$20 million) for each thirty-day period that the registration statement is not effective, up to 10%. On December 28, 2006, the SEC declared the registration statement effective. The Company concluded that the contingent obligation was not probable, and therefore no contingent liability was recorded as of December 31, 2006.

In December 2005, the Company sold 3,729,556 shares of its common stock and 932,390 warrants to purchase shares of its common stock, through a registered direct offering. The warrants have an exercise price of \$4.25 per share and are exercisable beginning six months and ending five years after their issuance. In exchange for \$3.56, the purchasers received one share

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of common stock and warrants to purchase .25 shares of common stock. The offering provided net proceeds of approximately \$12.5 million to the Company. The placement agent in this transaction received compensation consisting of (i) a cash fee equal to 5% of the aggregate gross proceeds and (ii) warrants to purchase 186,478 shares of Cytogen common stock having an exercise price of \$4.25 per share and exercisable beginning six months and ending five years after their issuance (see Note 13).

In July and August 2005, the Company sold 3,104,380 shares of its common stock and 776,096 warrants to purchase shares of its common stock having an exercise price of \$6.00 per share, through a registered direct offering. In exchange for \$4.50, the purchasers received one share of common stock and warrants to purchase .25 shares of common stock. These warrants are exercisable beginning six months and ending ten years after their issuance. The transaction provided net proceeds of approximately \$13.9 million to the Company (see Note 11).

In June 2005, the Company stockholders approved an amendment to the Company's Certificate of Incorporation to increase the total authorized shares of common stock of the Company from 25,000,000 to 50,000,000 shares.

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

In 2005 and 2004, the Company issued to certain members of Cytogen's Board of Directors an aggregate total of 4,000 and 873 shares, respectively, of its common stock as compensation for their services as directors of the Company. No shares were issued as compensation in 2006.

See Note 3 for information regarding Cytogen common stock issued to the Prostagen Partners, and Notes 13 and 14 for information regarding Cytogen common stock issued to employees under the stock option and employee stock purchase plans and 401(k) plan, respectively.

As of December 31, 2006 and 2005, including warrants to purchase Cytogen common stock issued to non-employees (see Note 13), the Company has outstanding warrants to purchase 7,279,193 and 3,803,086 shares, respectively, of Cytogen common stock at exercise prices ranging from \$3.32 to \$12.80 per share in 2006, and at exercise prices ranging from \$4.25 to \$12.80 per share in 2005. The warrants outstanding as of December 31, 2006 expire at various times through August 2015. During 2006, 70,000 warrants to purchase shares of the Company's common stock, with an exercise price of \$5.65 per share expired. 30,000 warrants with an exercise price of \$5.65 per share were exercised during 2005. At December 31, 2006, warrants to purchase 3,733,086 shares of Cytogen's common stock with exercise prices ranging from \$4.25 to \$12.80 per share are exercisable. Some warrants may become automatically exercised, in full, subject to certain conditions.

The following table summarizes information about outstanding warrants to purchase Cytogen common stock at December 31, 2006:

Exercise Price	<b>Outstanding Warrants</b>	<b>Aggregate Exercise Price</b>
\$ 3.32	3,546,107	\$ 11,773,075
\$ 4.25	1,118,868	\$ 4,755,189
\$ 6.00	776,096	\$ 4,656,576
\$ 6.91	315,790	\$ 2,182,108
\$ 10.97	250,000	\$ 2,742,500
\$ 12.80	1,272,332	\$ 16,285,850

The warrants exercisable at \$10.97 per share and \$12.80 per share become automatically exercised, in full, if the Company's common stock trades for 30 consecutive trading days at 130% of the respective exercise prices.

The Board of Directors of the Company 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.

The Company has 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 the Company without some mechanism to secure a fair price for all of the Company's stockholders if an acquisition was completed. These rights will be exercisable if a person or group acquires beneficial ownership of 20% or more of Cytogen common stock and can be made exercisable by action of the Company's 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 Cytogen common stock. Each right will entitle the holder to buy one one-thousandth of a share of a new series of Cytogen's junior participating preferred stock for \$20. If any person or group becomes the beneficial owner of 20% or more of Cytogen 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, the Company is 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.

## 13. SHARE-BASED COMPENSATION

The Company has various share-based compensation plans that provide for the issuance of common stock and incentive and non-qualified stock options to purchase the Company's common stock to employees, non-employee directors and outside consultants. These plans are administered by the Compensation Committee of the Board of Directors (the "Compensation Committee"). From time to time, the Company may issue warrants to purchase Cytogen common stock to non-employees, which are outside of the approved share-based compensation plans, in exchange for goods or services. The grants, terms and conditions of the warrants must

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be approved by the Board of Directors. The Company utilizes newly issued common shares to satisfy option exercises or upon satisfaction of service requirement for nonvested shares.

### Cytogen Stock Options

Currently, the Company has three plans which allow for the issuance of stock options and other awards: the 2006 Equity Compensation Plan (the "2006 Plan"); the 2004 Stock Incentive Plan (the "2004 Plan"); and the 2004 Non-Employee Director Stock Incentive Plan (the "2004 Director Plan"). An aggregate of 1,500,000, 1,200,000 and 375,000 shares of Cytogen common stock have been reserved for issuance upon the exercise of options or stock awards (as applicable) under the 2006 Plan, 2004 Plan and 2004 Director Plan, respectively. As of December 31, 2006, the number of remaining options or stock authorized and available for grant is approximately 1,489,160. The Company also has certain other option plans, for which there are options outstanding but no new options can be granted under those plans. Options shall become exercisable in accordance with such terms and conditions as may be determined by the Compensation Committee. Generally, options granted to employees will vest 40%, 30% and 30% one year, two years and three years after the date of grant, respectively. Options granted to officers will generally vest annually one third each year over a three-year period from the date of grant.

On June 13, 2006, the Company's stockholders approved the 2006 Plan at the 2006 Annual Meeting of Stockholders. The 2006 Plan provides for the grant of incentive stock options, nonqualified stock options, stock units, stock awards, stock appreciation rights and other stock-based awards to the Company's employees and non-employee directors. Performance-based awards, which will vest upon the achievement of objective performance goals, may also be granted under the 2006 Plan. As long as Cytogen common stock is traded on the Nasdaq National Market, the exercise price of Cytogen stock options under the 2006 Plan will be equal to the last reported sales price for Cytogen common stock on the date of grant, unless a higher exercise price is specified by the Compensation Committee. Except for certain circumstances, the options will generally expire upon the earlier of ten years after the date of grant or within a certain period of time after termination of services as determined by the Compensation Committee.

The 2004 Plan provides for the grant of incentive stock options, non-qualified stock options or nonvested shares (see below) to the Company's employees, officers, consultants and advisors. Performance options, which will vest upon the achievement of certain milestones, may also be granted under the 2004 Plan. The exercise price of Cytogen stock options is equal to the average of high and low trading prices for Cytogen common stock on the date of grant, unless a higher exercise price is specified by the Compensation Committee. Except for certain circumstances, the options will generally expire upon the earlier of ten years after the date of grant or 90 days after termination of employment.

The 2004 Director Plan provides for the grant of non-qualified stock options and shares of Cytogen common stock, in certain circumstances, to members of the Company's Board of Directors who are not employees of the Company. According to the 2004 Director Plan, each re-elected Director shall automatically receive options to purchase shares of Cytogen common stock

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on the day following each Annual Meeting of Stockholders. Each new Director who is appointed after the date of the most recent Annual Meeting of Stockholders will receive a certain number of options, pro-rated for the number of months remaining until the next Annual Meeting. The exercise price of Cytogen stock options is equal to the average of high and low trading prices for Cytogen common stock on the date of grant. All options will become exercisable on the first anniversary of the date of grant, unless options are granted to a Director who has served on the Company's Board of Directors for at least three years and retires or resigns after reaching 55 years of age. In such case, the options may be exercised in full regardless of the time lapse since the date of grant and for these options eligible for this accelerated vesting, the share-based compensation expense is recognized entirely on the date of grant in accordance with SFAS 123(R). Prior to the adoption of SFAS 123(R), the Company recorded the compensation expense related to all such awards over the vesting period. In 2006, \$76,000 of compensation expense was recognized for previous awards that would have been recognized in 2005 had the treatment required by SFAS 123(R) been applied to awards granted prior the adoption of SFAS 123(R). Except for certain circumstances, the options will generally expire upon the earlier of ten years after the date of grant or 90 days after termination date.

A summary of option activities related to Cytogen stock options other than performance options, for the year ended December 31, 2006 is as follows:

	Number of W Cytogen	Veig	ghted-Avera <b>ð</b> Exercise	eighted-Averag Remaining	Aggregate
<b>Cytogen Options Other than Performance</b>	Stock		Price Per	Contractual	Intrinsic
Options	Options		Share	Life	Value
Balance at December 31, 2005	980,796	\$	10.04		
Granted	703,350		3.23		
Exercised					
Forfeited	(155,480)		4.89		
Expired	(68,147)		13.64		
Balance at December 31, 2006	1,460,519	\$	7.14	8.12	\$ 4,000
Exercisable and expected to vest at December 31,					
2006	1,337,924	\$	7.36	8.10	\$ 3,000
Exercisable at December 31, 2006	629,266	\$	11.23	6.79	\$ 

At December 31, 2006, the weighted-average exercise price of exercisable options was higher than the market price of the Company's underlying common share, and as a result, the aggregate intrinsic value was zero.

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A summary of option activities related to performance options for the year ended December 31, 2006 is as follows:

	Number of V						
Dayformana Ontions	Cytogen Stock Options		Exercise Price Per Share	Remaining Contractual Life	Aggregate Intrinsic Value		
Performance Options	-	Φ		Lile	value		
Balance at December 31, 2005	150,000	Ф	3.54				
Granted							
Exercised							
Forfeited and Expired							
•							
Balance at December 31, 2006	150,000	\$	3.54	5.97			
Exercisable and expected to vest at December 31,							
2006	50,000	\$	3.54	5.97			
Exercisable at December 31, 2006	50,000	\$	3.54	5.97			

In 2002, options to purchase 150,000 shares of Cytogen common stock were granted to a key employee. These options have three separate and equal tranches which vest upon the achievement of certain milestones established by the Company's Board of Directors. In June 2006, the Board of Directors determined that one of the performance milestones had been met, and as a result, approved the vesting of 50,000 performance options. During the year ended December 31, 2006, the Company recorded \$152,000 in selling, general and administrative expenses, which represent the grant date fair value of the vested options based on the Black-Scholes option pricing model. The remaining 100,000 performance options are not deemed probable of becoming exercisable at December 31, 2006.

At December 31, 2006, the weighted-average exercise price of outstanding, exercisable and expected to vest, and exercisable options each was higher than the market price of the Company's underlying common share, and as a result, the aggregate intrinsic value was zero.

### Nonvested Shares

Under the 2004 Plan, the Company may issue nonvested shares to employees, officers, consultants and advisors. The maximum number of shares authorized for grant under the 2004 Incentive Plan is 200,000. Generally, the nonvested shares will vest in installments over three to six year periods. The Company may also issue stock awards to its employees and non-employee directors under the 2006 Plan.

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A summary of the Cytogen's nonvested share activities for the year ended December 31, 2006 is as follows:

	Number	Weighted-Average				
Nonvested Shares	of Nonvested Shares		ighted-Average Grant Date Fair Value	Remaining Vesting Term	1	Aggregate Intrinsic Value
Balance at December 31, 2005	136,200	\$		Term		varue
Granted	246,800		3.00			
Vested						
Forfeited	(39,100)	)	4.82			
Balance at December 31, 2006	343,900	\$	3.65	2.56	\$	801,000
Vested and expected to vest at December 31, 2006	300,156	\$	3.58	2.56	\$	699,000
Vested at December 31, 2006						

### Employee Stock Purchase Plan

In September 2005, the Board of Directors of the Company adopted the 2005 Employee Stock Purchase Plan (the "2005 ESPP"). The 2005 ESPP, which was approved by the Company's stockholders on June 13, 2006, is effective October 1, 2005, and replaces the Company's existing employee stock purchase plan which had no remaining shares available for future issuance. Under the 2005 ESPP, eligible employees may elect to purchase shares of Cytogen common stock at 85% of the lower of fair value as of the first or last trading day of each participation period. Under the 2005 ESPP, officers of the Company who purchase shares may not transfer such shares for a period of 12 months after the purchase date. The initial offering period was a nine-month period beginning on October 1, 2005 and ending on June 30, 2006. Subsequent purchase periods will be three-month periods beginning on the first day in July, October, January and April. The Company has reserved 500,000 shares of common stock for future issuance under the 2005 ESPP. The 2005 ESPP plan is compensatory under SFAS 123(R). In the year ended December 31, 2006, employees purchased 39,666 shares of common stock for aggregate proceeds to the Company of \$82,000. At December 31, 2006, 460,334 shares remain available for purchase under the 2005 ESPP.

### Warrants and Options Issued to Non-Employees

From time to time, the Company may issue warrants and options to purchase Cytogen common stock to non-employees, excluding directors, in exchange for goods or services. Warrants are issued outside of any approved compensation plans. Terms of warrants and options vary among various arrangements, with vesting period generally up to one year and may require exercise if certain conditions are met. Contractual term ranges up to ten years.

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A summary of the Cytogen warrants and options issued to non-employees for the year ended December 31, 2006 is as follows:

	Number of							
	Cytogen V	Cytogen Weighted-Average						
Warrants and Options to Non-Employees	Warrants And Options		Exercise Price Per Share	Remaining Contractual Life	Aggregate Intrinsic Value			
Balance at December 31, 2005	359,978	\$	6.96					
Granted								
Exercised								
Forfeited								
Expired	(70,000)	\$	5.65					
Balance at December 31, 2006	289,978	\$	7.27	3.09				
Exercisable and expected to vest at December 31,								
2006	289,978	\$	7.27	3.09				
Exercisable at December 31, 2006	289,978	\$	7.27	3.09				

At December 31, 2006, the weighted-average exercise price of outstanding, exercisable and expected to vest, and exercisable warrants each was higher than the market price of the Company's underlying common share, and as a result, the aggregate intrinsic value was zero.

### AxCell BioSciences Stock Options

AxCell BioSciences, a non-publicly traded subsidiary of Cytogen Corporation, also has a stock option plan that provides for the issuance of incentive and non-qualified stock options to purchase AxCell common stock ("AxCell Stock Options") to employees, for which 2,000,000 shares of AxCell common stock have been reserved. AxCell Stock Options are granted with a term of 10 years and generally become exercisable in installments over periods of up to five years.

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A summary of AxCell stock option activities for the year ended December 31, 2006 is as follows:

AxCell Stock Options	Number of AxCell Stock Options	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term
Balance at December 31, 2005	69,405	\$ 4.34	6.10
Granted			
Exercised			
Forfeited			
Expired	(19,405)	3.60	
Balance at December 31, 2006	50,000	\$ 4.63	5.33
Exercisable and expected to vest at December 31, 2006	50,000	\$ 4.63	5.33
Exercisable at December 31, 2006	50,000	\$ 4.63	5.33

AxCell is not a publicly traded subsidiary. While there was not a readily available market price for AxCell's underlying common share at December 31, 2006, the Company estimated that its fair value was less than the exercise price, and as a result, the aggregate intrinsic value was zero.

### Adoption of SFAS No. 123(R)

Effective January 1, 2006, the Company adopted SFAS No. 123(R) which requires companies to measure and recognize compensation expense for all share-based payments at fair value. Prior to the adoption of SFAS 123(R), the Company accounted for its stock-based employee compensation expense under the recognition and measurement principles of APB 25, and related interpretations. Under APB 25, compensation costs related to stock options granted with exercise prices equal to or greater than the fair value of the underlying shares at the date of grant under those plans were not recognized in the consolidated statements of operations. Compensation costs related to nonvested shares and stock options granted with exercise prices below fair value of the underlying shares at the date of grant were recognized in the consolidated statements of operations over the requisite service period, generally the vesting periods of the awards. Compensation costs associated with those awards granted prior to the adoption of SFAS 123(R) were recognized using the accelerated attribution method in accordance with FIN 28 and forfeitures were recorded as incurred. The following table illustrates the effect on net loss and net loss per share as if the fair value method under SFAS 123 had been applied for the years ended December 31, 2005 and 2004 (all amounts in thousands, except per share data):

		Year Ended I 2005	Decemb	oer 31, 2004
	(All	amounts in to		ds, except
Net loss, as reported	\$	(26,289)	\$	(20,540)
Add: Stock-based employee compensation expense included in				
reported net loss		111		15
Deduct: Total stock-based employee compensation expense				
determined under fair value-based method for all awards		(1,894)		(2,152)
Pro forma net loss	\$	(28,072)	\$	(22,677)
Basic and diluted net loss per share, as reported	\$	(1.54)	\$	(1.40)
Pro forma basic and diluted net loss per share	\$	(1.64)	\$	(1.55)

The Company adopted SFAS No. 123(R) using the modified prospective transition method, which requires that share-based compensation cost be based on the grant-date fair value estimated in accordance with the provisions of SFAS 123(R) and is recognized for all awards granted, modified or settled after the effective date as well as awards granted to employees prior to the effective date that remain unvested as of the effective date. In 2006, the Company recorded \$1.9 million of share-based compensation expense, of which \$1.6 million was included in selling, general and administrative expenses and \$252,000 was recorded in research and development expenses. No compensation costs were capitalized in 2006. In 2005 and 2004, the Company recorded a charge of \$111,000 and \$15,000, respectively, for share-based compensation. There were no modification to the share-based awards in 2006, 2005 and 2004.

The adoption of SFAS 123(R) resulted in higher net loss for the year ended December 31, 2006 of \$1.6 million or \$0.07 per basic and diluted share, than if the Company had continued to account for the share-based compensation under APB 25. At December 31, 2006, unrecognized compensation expense, which includes the impact of estimated forfeitures, related to unvested awards granted under the Company's share-based compensation plans is approximately \$2.3 million and remains to be recognized over a weighted average period of 1.3 years. The Company recognizes share-based compensation on a straight-line basis over the requisite service period for grants on or after January 1, 2006, however, the cumulative amount of compensation expense recognized at any point in time for an award cannot be less than the portion of the grant date fair value of the award that is vested at that date. Unrecognized compensation expense related to grants made prior to adoption of SFAS 123(R) are recognized using the accelerated amortization method. Prior periods were not restated to reflect the impact of adopting the new standard. No cumulative effect adjustment was recorded for the accounting change related to recording actual forfeitures as incurred under APB 25 to estimating forfeitures in accordance with SFAS 123(R) as the amount was de minimus.

The Company's share-based compensation costs are generally based on the fair value of the option awards calculated using the Black-Scholes option pricing model on the date of grant.

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The weighted-average fair value per share of the options granted under the Cytogen stock option plans during 2006, 2005 and 2004 is estimated at \$2.59, \$3.67 and \$8.74 per share, respectively, on the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions for 2006, 2005 and 2004:

Valuation Assumptions	2006	2005	2004
Dividend yield	0%	0%	0%
Expected volatility	95.64%	96.27%	109.66%
Risk-free interest			
rate	4.88%	3.97%	3.78%
Expected life	6.4 yrs	4.6 yrs	4.6 yrs

The compensation costs for nonvested share awards are based on the fair value of Cytogen common stock on the date of grant. The weighted-average grant date fair value per share of nonvested share awards granted during 2006 and 2005 was \$3.00 and \$5.15, respectively.

The weighted-average fair value per share ascribed to the shares purchased under the employee stock purchase plan during 2006, 2005 and 2004 is estimated at \$0.57, \$3.35 and \$3.81 per share, respectively, on the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions for 2006, 2005 and 2004:

Valuation Assumptions	2006	2005	2004
Dividend yield	0%	0%	0%
Expected volatility	43.97%	112.23%	52.63%
Risk-free interest			
rate	4.91%	2.71%	1.26%
Expected life	2 months	3 months	3 months

The weighted-average fair value per share of the warrants granted to non-employees in exchange for services during 2005 is estimated at \$2.30 per share on the date of grant using the Black-Scholes option pricing model with the weighted-average assumptions of 0% for dividend yield, 93.3% for expected volatility, 4.43% for risk-free interest rate and 5 years for expected life. The Company recognized the compensation charge for the associated warrants of \$430,000 as transaction costs and netted them against the proceeds received from the 2005 financing transaction (see Note 12). No warrants were granted to non employees in exchange for services during 2006 and 2004.

Because the Company has never declared cash dividends and has no intention to declare cash dividends in the near future, an expected dividend yield of zero is used. The Company calculates expected volatility for stock-based awards using historical volatility, measured over a period equal to the expected term of the award, which it believes is a reasonable estimate of future volatility. The Company bases the risk-free interest rate on the implied yield available on U.S. Treasury zero-coupon issues with the remaining term equal to the expected term used.

In 2005 and 2004, the Company determined the expected term of an award by analyzing historical exercise experience and post-vesting employment termination behavior from its history of grants and exercises. In 2006, the Company calculates the expected life using the simplified method as described in the SEC's Staff Accounting Bulletin No. 107 ("SAB 107") for "plain

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vanilla" options meeting certain criteria. The simplified method is based on the vesting period and the contractual term for each grant or each vesting-tranche of awards with graded vesting. The mid-point between the vesting date and the expiration date is used as the expected term under this method. As options granted to the Board of Director members do not meet the criteria of "plain vanilla" options, the Company determines the expected term for these options by analyzing the historical exercise experience and post-vesting termination behaviors. The Company believes the result is a reasonable estimate of the length of time that the options are expected to be outstanding.

In addition, under SFAS 123(R), the Company is required to estimate expected forfeitures of options and stock grants over the requisite service period and adjust shared-based compensation accordingly. The estimate of forfeitures will be adjusted over the requisite service period to the extent that actual forfeitures differ, or are expected to differ, from such estimates. The cumulative effect of changes in estimated forfeitures will be recognized in the period of change and will also impact the amount of stock compensation expense to be recognized in future periods. Under the provisions of SFAS 123(R), the Company will record additional expense if the actual forfeiture rate is lower than what had been estimated and the Company will record a recovery of prior expense if the actual forfeiture rate is higher than what had been estimated.

There was no vesting of nonvested shares in 2006, 2005 and 2004. There were no option exercises in 2006. Total intrinsic value was \$2,000 and \$46,000 for options exercised in 2005 and 2004, respectively. Cash received from the option exercises in 2005 and 2004 was \$7,000 and \$25,000, respectively.

### 14. RETIREMENT SAVINGS PLAN

The Company maintains a defined contribution 401(k) plan for its employees. The contribution is determined by the Board of Directors and is based upon a percentage of gross wages of eligible employees. The plan provides for vesting over four years, with credit given for prior service. The Company also makes contributions in cash or its common stock, at the Company's discretion, under the 401(k) plan in amounts which match up to 50% of the salary deferred by the participants up to 6% of total salary. Total expense related to the 401(k) contributions was \$223,000, \$164,000 and \$136,000 for 2006, 2005 and 2004, respectively. All contributions were made in cash.

### 15. INCOME TAXES

As of December 31, 2006, Cytogen had federal and state net operating loss carryforwards of approximately \$304.7 million and \$244.4 million, respectively. The components of the federal net operating loss carryforward that will expire in the next five years are as follows: \$15.7 million in 2007, \$10.9 million in 2008, \$3.8 million in 2009, \$11.9 million in 2010 and \$24.8 million in 2011. The components of the state net operating loss carryforward that will expire in the next five years are as follows: \$13.9 million in 2007, \$31.9 million in 2008, \$16.9 million in 2009, \$20.4 million in 2010 and \$19.4 million in 2011. The Company also had federal and state research and development tax credit carryforwards of approximately \$4.6 million and

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\$441,000, respectively. These net operating loss and credit carryforwards have begun to expire and will continue to expire through 2026.

The Tax Reform Act of 1986 contains provisions that limit the utilization of net operating loss and tax credit carryforwards if there has been an "ownership change". Such an "ownership change", as described in Section 382 and 383 of the Internal Revenue Code, may limit the Company's utilization of its net operating loss and tax credit carryforwards. Additionally, various states have similar limitations on utilization of certain state net operating loss and credit carryforwards that may limit the Company's ability to realize the benefits of these carryforwards.

Deferred income taxes reflect the net tax effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amount used for income tax purposes. Based on the Company's loss before income taxes during 2006, 2005 and 2004, the Company would have been expected to record a tax benefit using the statutory tax rate. During 2006, there was a decrease in the valuation allowance of \$1.1 million due primarily to the expiration of federal and state net operating loss carryforwards in 2006. During 2005 and 2004, there were increases of \$4.3 million and \$3.1 million, respectively, in the valuation allowance, due to the Company's loss history, and uncertainty regarding the realization of deferred tax assets. These increases to the valuation allowance reduced the actual benefit to \$256,000 and \$307,000 in 2005 and 2004, respectively, which amounts are related to the sales of New Jersey state operating loss carryforwards as discussed below. The Company did not sell any New Jersey state net operating loss carryforwards in 2006. Deferred tax assets have been fully reserved as of December 31, 2006 and 2005.

	2006 (All amounts :	2005		
Deferred tax assets:			-Suiius)	
Net operating loss carryforwards	\$ 117,533	\$	111,341	
Capitalized research and development expenses	1,461		8,220	
Research and development credit	5,023		5,606	
Acquisition of in-process technology	613		722	
Other, net	7,040		6,873	
Total deferred tax assets	131,670		132,762	
Valuation allowance	(131,670)		(132,762)	
Net deferred tax assets	\$ <u> </u>	\$		

During 2005 and 2004, the Company sold New Jersey state operating loss carryforwards, resulting in the recognition of \$256,000 and \$307,000 of income tax benefit, respectively.

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The effective income tax rate for the Company's continuing operations differs from the statutory tax rate as follows:

	2006	2005	2004
Federal statutory income tax rate	34.0%	34.0%	34.0%
Increase in valuation allowance	(29.4%)	(29.9%)	(39.0%)
Sale of New Jersey net operating loss carryforwards	%	1.0%	1.5%
Other	(4.6%)	(4.1%)	5.0%
Effective income tax			
rate	<u> </u>	1.0%	1.5%

### COMMITMENTS AND CONTINGENCIES

The Company leases its facilities and certain equipment under non-cancelable operating leases that expire in October 2009. Rent expense on these leases was \$320,000, \$351,000 and \$510,000 in 2006, 2005 and 2004, respectively. Minimum future obligations under the operating leases are \$958,000 as of December 31, 2006 and will be paid as follows: \$338,000 in 2007, \$338,000 in 2008 and \$282,000 in 2009.

The Company is obligated to make minimum future payments under contracts for research and development, marketing, investor relations, consulting and other supporting services that expire at various times. As of December 31, 2006, the minimum future payments under these contracts are \$4.0 million and will be paid as follows: \$3.1 million in 2007, \$106,000 in 2008, \$76,000 in 2009, \$75,000 each year from 2010 to 2017, and \$31,000 in 2018. In addition, under the BMSMI agreement, the Company is obligated to pay at least \$4.9 million annually, subject to future annual price adjustment, through 2008. The Company may terminate this agreement on two years prior written notice (see Note 7). The Company is also obligated to pay milestone payments upon achievement of certain milestones and royalties on revenues from commercial product sales including certain guaranteed minimum payments. Such obligations include payments to Dow (see Note 5), Berlex Laboratories (see Note 6), Rosemont (see Note 17) and InPharma (see Note 19).

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

In the ordinary course of business, the Company enters into agreements with third parties that include indemnification provisions which, in its judgment, are normal and customary for companies in its industry sector. These agreements are typically with business partners, clinical sites, and suppliers. Pursuant to these agreements, the Company generally agrees to indemnify, hold harmless and reimburse the indemnified parties for losses suffered or incurred by the indemnified parties with respect to the Company's products or product candidates, use of such

products or other actions taken or omitted by the Company. The maximum potential amount of future payments the Company could be required to make under these indemnification provisions is unlimited. The Company has not incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. The current estimated liabilities relating to this provision are minimal. Accordingly, the Company has no liabilities recorded for these provisions as of December 31, 2006 and 2005.

### 17. SAVIENT PHARMACEUTICALS, INC.

On April 21, 2006, the Company and Savient entered into a distribution agreement granting the Company exclusive marketing rights for SOLTAMOX in the United States. SOLTAMOX, a cytostatic estrogen receptor antagonist, is the first oral liquid hormonal therapy approved in the U.S. It is indicated for the treatment of breast cancer in adjuvant and metastatic settings and to reduce the risk of breast cancer in women with ductal carcinoma in situ (DCIS) or with high risk of breast cancer. The Company introduced SOLTAMOX to the U.S. oncology market in the second half of 2006.

In addition, the Company entered into a supply agreement with Savient and Rosemont previously a wholly-owned subsidiary of Savient, for the manufacture and supply of SOLTAMOX. Cytogen's agreements with Savient were subsequently assigned to Rosemont by Savient. Under the terms of the final transaction, the Company paid Savient an up-front licensing fee of \$2.0 million and may pay additional contingent sales-based payments of up to a total of \$4.0 million to Savient and Rosemont. The Company is also required to pay Rosemont royalties on net sales of SOLTAMOX. Such royalty expense was \$111,000 in 2006. Beginning in 2007, Cytogen is obligated to pay Rosemont quarterly minimum royalties based on an agreed upon percentage of total tamoxifen prescriptions in the United States. Unless terminated earlier, the distribution and supply agreements will each terminate upon the expiration of the last to expire patent covering SOLTAMOX in the United States, which is currently June 2018. The manufacturing agreement is terminable by Rosemont or the Company on one year notice prior to the end of the then current term. In the event the tamoxifen prescriptions for an agreed upon period of time are less than the pre-established minimum, the agreement may be terminated if the parties are unable to reach an agreement to amend the terms of the contract to account for such impact.

The up-front license payment of \$2.0 million was capitalized as SOLTAMOX license fee in the accompanying consolidated balance sheet and is being amortized on a straight-line basis over approximately twelve years which is the estimated performance period of the agreement. The amortization expense for 2006 was \$110,000 and is recorded as cost of product revenue (see Note 1).

## 18. ONCOLOGY THERAPEUTICS NETWORK, J.V.

On June 20, 2006, the Company entered into a purchase and supply agreement with Oncology Therapeutics Network, J.V. ("OTN") appointing OTN as the exclusive distributor of SOLTAMOX in the United States. In August 2006 and January 2007, the agreement was amended to revise certain terms, including changing the role of OTN to the exclusive

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warehousing agent and non-exclusive distributor of SOLTAMOX and CAPHOSOL ("Products"). Under the terms of the amended agreements, OTN will purchase Products from the Company for its own wholesaler channels and, along with third party logistics providers, distribute the Products to the Company's other customers through its warehousing and distribution facilities. The Company was obligated to pay OTN a minimal set up fee upon execution of the agreement which was recorded as selling, general and administrative expense in the second quarter of 2006. In addition, the Company also pays OTN management fees based upon a percentage of the value of Products shipped during the period. In 2006, the management fees totaled \$67,000 and are included in cost of product revenues. This agreement has a three-year term and will automatically renew for successive one-year periods unless terminated by OTN or Cytogen on a 90 days written notice prior to the end of the applicable term. Either party also may terminate the agreement, without cause, on 180 days written notice.

In 2006, the Company received a payment from OTN for the purchase of SOLTAMOX, of which \$50,000 is subject to be refunded to OTN if the product is returned to the Company. Such amount is recorded as "Customer Liability" in Accounts Payable and Accrued Liabilities in the accompanying consolidated balance sheet at December 31, 2006.

### 19. INPHARMA AS

On October 11, 2006, the Company and InPharma entered into a license agreement granting the Company exclusive rights for CAPHOSOL in North America and options to license the marketing rights for CAPHOSOL in Europe and Asia. Approved as a prescription medical device, CAPHOSOL is a topical oral agent indicated in the United States as an adjunct to standard oral care in treating oral mucositis caused by radiation or high dose chemotherapy. CAPHOSOL is also indicated for dryness of the mouth (hyposalivation) or dryness of the throat (xerostomia) regardless of the cause or whether the conditions are temporary or permanent. Under the terms of the Agreement, the Company is obligated to pay InPharma \$6.0 million in aggregate up-front fees, of which \$4.6 million was paid upon the execution of the agreement, \$400,000 will be paid into an escrow account and to be released over time provided there are no indemnification claims by the Company, and \$1.0 million will be paid upon the six-month anniversary of the execution of the agreement. In addition, the Company is obligated to pay InPharma royalties based on a percentage of net sales and future payments of up to an aggregate of \$49.0 million based upon the achievement of certain sales-based milestones of which payments totaling \$35 million are based upon annual sales levels first reaching levels in excess of \$30 million. The Company is also obligated to pay a finder's fee based upon a percentage of milestone payments paid to InPharma.

In the event the Company exercises the options to license marketing rights for CAPHOSOL in Europe and Asia, the Company is obligated to pay InPharma additional fees and payments, including sales-based milestone payments for the respective territories. The Company is required to obtain consents from certain licensors but not InPharma, if the Company sublicenses the rights to market CAPHOSOL in Europe and Asia to other parties. The Company shall pay InPharma a portion of any up-front license fees and milestone payments, but not royalties, received by Cytogen in consideration of the grant by Cytogen to other parties of the right to market CAPHOSOL in Europe and Asia, to the extent such up-front license fees

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and milestone payments are in excess of the respective amounts paid by Cytogen to InPharma for such rights.

Based on the relative fair value of the assets acquired, the Company allocated the up-front fees and related transaction costs as follows: \$4.2 million to CAPHOSOL marketing rights in North America which excludes the \$400,000 contingent payment, \$1.7 million to the option to license the product rights in Europe and \$162,000 to the option to license the product rights in Asia. The allocated license fee for North America was capitalized as CAPHOSOL license fee in the accompanying consolidated balance sheet and is being amortized on a straight-line basis over approximately eleven years, which is the estimated performance period of the agreement. The amortization expense in 2006 was \$98,000 and is recorded as cost of product revenue. The allocated option fee for Europe is recorded as other assets and will be transferred to the appropriate asset account if exercised. The Company periodically evaluates the option value for impairment by assessing, among other things, its intent and ability to exercise the option, the option expiry date and the market and product competitiveness. The allocated option fee for Asia is charged to research and development expense in the accompanying consolidated statement of operations, because the product was not approved in Asia at the time of purchase and there was no future alternative uses for the asset. In 2006, there was no royalty expense, since CAPHOSOL was not introduced to the market until the first quarter of 2007.

### 20. LITIGATION AND RELATED MATTERS

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

In December 2005, Trapezoid Healthcare Communications LLC filed a complaint against the Company in the Superior Court of New Jersey, Law Division, Mercer County, seeking approximately \$426,000 in damages arising from the Company's alleged failure to pay Trapezoid for marketing services allegedly provided to the Company. On May 22, 2006, the Company settled this matter for \$365,000, without any admission of fault or liability. The Company had previously established a reserve for the full amount of this claim in 2005.

In January 2006, the Company filed a complaint against Advanced Magnetics in the Massachusetts Superior Court for breach of contract, fraud, unjust enrichment, and breach of the implied covenant of good faith and fair dealing in connection with the parties' 2000 license agreement. The complaint sought damages along with a request for specific performance requiring Advanced Magnetics to take all reasonable steps to secure FDA approval of COMBIDEX in compliance with the terms of the licensing agreement. In February 2006, Advanced Magnetics filed an answer to the Company's complaint and asserted various counterclaims, including tortuous interference, defamation, consumer fraud and abuse of process. In February 2007, the Company settled its lawsuit against Advanced Magnetics, as well as

Advanced Magnetics' counterclaims against Cytogen, by mutual agreement. Under the terms of the settlement agreement, Advanced Magnetics paid \$4 million to the Company and will release 50,000 shares of Cytogen common stock currently being held in escrow. In addition, both parties agreed to early termination of the licensing agreement.

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

March 31,

2006

**Three Months Ended** 

Sept. 30,

2006

Dec. 31,

2006

June 30,

2006

## 21. CONSOLIDATED QUARTERLY FINANCIAL DATA - UNAUDITED

The following tables provide quarterly data for the years ended December 31, 2006 and 2005.

		2000		2000		2000		2000
		(amounts	in tl	housands	exc	ept per sh	are	data)
Total revenues	\$	•	\$		\$	4,172		4,521
Total operating								
expenses		11,768		11,038		10,408		14,523
Operating loss		(7,326)		(6,866)		(6,236)		(10,002)
Gain on sale of equity interest in joint venture		_	_	12,873		_	_	_
Other (expense)/income,								
net		(340)		1,199		498		1,097
Income (loss) before income taxes		(7,666)		7,206		(5,738)		(8,905)
Income tax benefit		_	_	_	_	_	-	_
Net loss	\$	(7,666)		7,206	\$	(5,738)		(8,905)
Basic and diluted net income (loss) per share	\$	(0.34)	\$	0.32	\$	(0.26)	\$	(0.34)
Weighted-average common shares outstanding, basic and								
diluted		22,474		22,474		22,494		26,468
Product related gross								
margin <sup>(1)</sup>	\$	2,078	\$	1,616	\$	1,538	\$	1,914
			т	huaa Mar	.tha	Ended		
	M	anah 21		hree Mor			Т	Nog 31
		arch 31, 2005	Jı	ıne 30,		ept. 30,	Ι	Dec. 31,
		arch 31, 2005	Jı				Ι	Dec. 31, 2005
		2005	Ju	ine 30, 2005	S	ept. 30, 2005		2005
Total revenues		2005 (amounts	Ju in tl	ine 30, 2005 housands	S	ept. 30, 2005 ept per sh	are	2005 data)
Total revenues Total operating		2005	Ju	ine 30, 2005	S	ept. 30, 2005	are	2005
Total operating		2005 (amounts	Ju in tl	ine 30, 2005 housands	S	ept. 30, 2005 ept per sh	are	2005 data)
Total operating expenses		2005 (amounts 3,994	Ju in tl	une 30, 2005 housands 4,156	S	ept. 30, 2005 ept per sh 3,551	are	2005 data) 4,245
Total operating		2005 (amounts 3,994 10,688	Ju in tl	nne 30, 2005 housands 4,156 12,009	S	ept. 30, 2005 ept per sh 3,551 11,549	are	2005 data) 4,245 10,509
Total operating expenses Operating loss		2005 (amounts 3,994 10,688 (6,694)	Ju in tl	nne 30, 2005 housands 4,156 12,009 (7,853)	S	ept. 30, 2005 ept per sh 3,551 11,549 (7,998)	are	2005 data) 4,245 10,509 (6,264)
Total operating expenses Operating loss Other income, net		2005 (amounts 3,994 10,688 (6,694)	Ju in tl	nne 30, 2005 housands 4,156 12,009 (7,853)	S	ept. 30, 2005 ept per sh 3,551 11,549 (7,998)	are	2005 data) 4,245 10,509 (6,264)
Total operating expenses Operating loss Other income, net Loss before income		2005 (amounts 3,994 10,688 (6,694) 101	Ju in tl	nne 30, 2005 housands 4,156 12,009 (7,853) 112	S	ept. 30, 2005 ept per sh 3,551 11,549 (7,998) 877	are	2005 data) 4,245 10,509 (6,264) 1,174
Total operating expenses Operating loss Other income, net Loss before income taxes		2005 (amounts 3,994 10,688 (6,694) 101	Ju in tl \$	nne 30, 2005 housands 4,156 12,009 (7,853) 112	exc \$	ept. 30, 2005 ept per sh 3,551 11,549 (7,998) 877	are \$	2005 data) 4,245 10,509 (6,264) 1,174 (5,090)
Total operating expenses Operating loss Other income, net Loss before income taxes Income tax benefit	\$	2005 (amounts 3,994  10,688 (6,694) 101 (6,593)	Juin tl	nne 30, 2005 housands 4,156 12,009 (7,853) 112 (7,741)	exc \$	ept. 30, 2005 ept per sh 3,551 11,549 (7,998) 877 (7,121)	are \$ - \$	2005 data) 4,245 10,509 (6,264) 1,174 (5,090) (256)
Total operating expenses Operating loss Other income, net Loss before income taxes Income tax benefit Net loss	\$	2005 (amounts 3,994 10,688 (6,694) 101 (6,593) (6,593)	Juin tl	nne 30, 2005 housands 4,156 12,009 (7,853) 112 (7,741)	exc \$	ept. 30, 2005 ept per sh 3,551 11,549 (7,998) 877 (7,121)	are \$ - \$	2005 data) 4,245 10,509 (6,264) 1,174 (5,090) (256) (4,834)

Weighted-average common shares outstanding, basic and diluted Product related gross \$ margin<sup>(1)</sup>

(1) Reflects reclassifications of certain costs related to QUADRAMET clinical supplies from cost of product revenue to research and development expenses.

1,539 \$

1,854 \$

1,156 \$

1,685