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Poniard Pharmaceuticals

Annual Report 2008



May 8, 2009

Dear Shareholders:

2008 was a year of solid progress and achievement for Poniard as we continued to execute on our strategy of building a U.S. oncology company. We focused on the late-stage development of our lead product, picoplatin, a new generation, highly differentiated platinum chemotherapy designed to overcome drug resistance with a lower incidence and severity of neurotoxicity and nephrotoxicity compared to existing platinum-based therapies.

We are pleased to report that, during the year, we continued enrolling patients in our pivotal Phase 3 SPEAR (Study of Picoplatin Efficacy After Relapse) trial of picoplatin in small cell lung cancer (SCLC) and, in March 2009, we reached our enrollment goal for this trial. This was a significant accomplishment for Poniard and is a clear reflection of our ability to execute on our business plan. We achieved several other important milestones in 2008, including completing enrollment in our Phase 2 trial of picoplatin in metastatic colorectal cancer (CRC), and we presented updated data throughout the year from our Phase 2 trial of picoplatin in castration-resistant prostate cancer (CRPC). We also announced results from our Phase 1 trial of an oral formulation of picoplatin demonstrating positive bioavailability. Finally, we appointed four new members to our Clinical Advisory Board to help guide our expanding clinical development strategy for picoplatin. These esteemed physicians bring extensive experience and comprehensive understanding of cancer treatment for a wide variety of tumor types.

Preparing for the commercialization of picoplatin, we announced agreements with W. C. Heraeus GmbH for the manufacture of picoplatin's active pharmaceutical ingredient and Baxter Oncology GmbH for the manufacture and supply of injectable picoplatin drug product.

Picoplatin is designed to overcome at least three distinct mechanisms of platinum resistance. This provides a compelling opportunity where resistance mechanisms limit clinical benefit of existing platinum-based chemotherapies. We believe that picoplatin represents a pipeline in a product, as is exemplified by its potential use in the first-line as a preferred neuropathy-sparing platinum and second-line, to overcome platinum resistance in tumors. Both of these treatment settings with picoplatin suggest a strong rationale to bring this product to the market. The company is focused on commercializing this product in 2010, initially for the treatment of platinum-refractory or progressive SCLC. Our clinical programs and commercial focus are supported by a cash position that we anticipate will fund our operations into the first quarter of 2010.

Small Cell Lung Cancer Program: Overcoming Platinum Resistance

In 2008, we presented final picoplatin data from our second Phase 2 trial of picoplatin in SCLC at the 1st IASLC-ESMO European Lung Cancer Conference. This study demonstrated a survival benefit in patients with recurrent SCLC who have failed prior platinum-containing first-line chemotherapy or who have progressed within six months of first-line therapy. The median overall survival rate was 27 weeks. This data compares favorably with current medical treatments, which often include palliative best supportive care (BSC), with reported median overall survival of 14 weeks. An international Phase 3 SPEAR (Study of Picoplatin Efficacy After Relapse) trial is ongoing to compare picoplatin with BSC to BSC alone. This trial is being conducted under a Special Protocol Assessment with the U.S. Food and Drug Administration (FDA) and Fast Track designation has been granted by the FDA. We believe that picoplatin has a high probability of technical success given that the primary endpoint for SPEAR is overall

survival and comparable survival data was observed in two independent multi-centered Phase 2 trials. In addition, platinum-based therapy is the backbone of multiple treatment regimens for various cancers and the underlying mechanism of action is well understood. Picoplatin has been administered in over 1,100 cancer patients with signals of efficacy in multiple cancers and settings. It has demonstrated an improved and manageable safety profile with a low incidence and less severe neurotoxicity and nephrotoxicity compared to existing platinum-based drugs. The approval of picoplatin for patients with early relapse or refractory SCLC following traditional platinum-based chemotherapy would be unprecedented, presenting a new market opportunity with the potential of moving into other lines of therapy and tumor types.

Colorectal Cancer Program: Reducing Neurotoxicity

In 2008, we completed enrollment of our randomized, controlled Phase 2 trial of picoplatin in metastatic CRC and presented efficacy and safety data at several major medical conferences. The Phase 2 results to date have shown that picoplatin, given once every four weeks in combination with 5-fluorouracil and leucovorin (FOLPI), is associated with less frequent and less severe neurotoxicity than the FOLFOX (5-fluorouracil, leucovorin and oxaliplatin) regimen. Results also continue to indicate that both the FOLPI and FOLFOX regimens have similar anti-tumor activity as first-line treatments for metastatic CRC, supporting the potential use of picoplatin as a neuropathy-sparing alternative to oxaliplatin. Although 61% of US metastatic CRC patients received oxaliplatin-containing regimen for first-line treatment, oxaliplatin is associated with significant side effects, including long-term neurotoxicities that can limit its use and result in discontinuation of therapy.

Prostate Cancer Program: First Potential Platinum-Based Product

In 2008, we continued to present updated safety and efficacy results from our ongoing Phase 2 clinical trial of picoplatin in combination with docetaxel and prednisone in patients with CRPC. There is no platinum-based chemotherapy approved for use in the treatment of prostate cancer. Positive efficacy results to date have shown that reductions in prostate specific antigen (PSA) levels of at least 50 percent for at least 4 weeks were achieved in 78 percent of evaluable patients who received the picoplatin combination, which compares favorably with PSA response of 45 percent from published data of docetaxel and prednisone in the same treatment setting. In addition, an interim analysis has revealed that the median time to PSA progression was at least 8.5 months with the picoplatin combination. In this Phase 2 study, patients were treated with picoplatin therapy for up to 10 cycles and received a cumulative picoplatin dose of up to 1200 mg. Safety results continue to demonstrate that picoplatin can be safely administered with full doses of docetaxel and prednisone, the standard treatment for metastatic CRPC, supporting continued studies of this combination for future prostate clinical trials.

In addition, the results we have observed in prostate cancer may be broadly applicable and support trials in other solid tumors treated with a platinum in combination with a taxane – such as ovarian, non-small cell lung or bladder cancer.

Oral Picoplatin Program: Use in Potential New Indications

We are developing picoplatin as an oral agent that contains the same active pharmaceutical ingredient as intravenous picoplatin. The oral formulation is designed to potentially be used in new indications, new dosing schedules and in combinations with other orally administered cancer treatments or radiation therapy. In 2008, we announced results from our Phase 1 clinical trial of the oral formulation of picoplatin in patients with solid tumors. Results indicated that picoplatin achieves linear and dose-dependent plasma exposure when given orally, indicating sufficient bioavailability to support further clinical development of an oral formulation of the drug.

Corporate Developments: Strategic Realignment and Strengthening of Management Team

During 2008, we secured a \$27.6 million amended loan facility, resulting in additional net cash proceeds of approximately \$20.0 million. In addition, we discontinued our in-house preclinical research operations at the end of March 2009 to allow us to concentrate our resources on advancing picoplatin and attain our goal of commercializing it in 2010. With this realignment, we extended our estimated cash runway into the first quarter of next year.

In the past 18 months, we also made strategic hires to strengthen our management team. We appointed Robert De Jager, M.D., as our chief medical officer, Janet R. Rea, M.S.P.H., as vice president, regulatory affairs and quality, and Greg Weaver as chief financial officer and senior vice president. All have extensive biopharmaceutical experience and will be essential to our continued progress.

Looking to the Future

We are proud of the achievements we made in 2008. Looking forward, our strategic intent is to build a U.S. oncology company that leverages our strengths of managing global clinical drug development programs and NDA filings, while taking full advantage of commercialization opportunities to grow shareholder value. Our near term priority is focused on the continued clinical development of picoplatin for multiple indications, combinations and formulations. During the second half of 2009, we expect to:

- Report data from the Phase 3 SPEAR trial in the second half of 2009. Based on two independent Phase 2 studies, we expect that the overall survival data from the Phase 3 SPEAR trial will show a statistically significant survival advantage compared to patients who receive best supportive care alone.
- Initiate submission of an NDA with the FDA for picoplatin as a second-line treatment for SCLC, targeting approval and commercialization in 2010. Providing a new treatment option for the many SCLC patients who do not achieve clinical benefit from current first-line therapies would be a significant accomplishment for this aggressive tumor type, for which there are very few FDA-approved therapies.
- Present additional efficacy and safety data from our ongoing Phase 2 trials of picoplatin in colorectal and prostate cancers at ASCO and other medical conferences.

I would like to express my appreciation to our management team and employees for their dedication and efforts over the past year, and to our board of directors for strategic counsel and continued support.

We appreciate your support and look forward to keeping you apprised of our progress.

Sincerely,



Jerry McMahon, Ph.D.
Chairman and Chief Executive Officer

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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

for the fiscal year ended December 31, 2008

or

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

For the transition period from _____ to _____

Commission File No. 0-16614

PONIARD PHARMACEUTICALS, INC.

(Exact name of Registrant as specified in its charter)

Washington

(State or other jurisdiction of
incorporation or organization)

7000 Shoreline Court, Suite 270,
South San Francisco, CA

(Address of principal executive offices)

91-1261311

(IRS Employer Identification No.)

94080

(Zip Code)

(650) 583-3774

Registrant's telephone number, including area code:

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

Title of Class

Name of each exchange on which registered

Common Stock, \$.02 par value

The Nasdaq Stock Market LLC

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

\$2.4375 Convertible Exchangeable Preferred Stock, Series 1, \$.02 par value

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

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer
(Do not check if a smaller
reporting company)

Smaller reporting company

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was approximately \$98.0 million as of June 30, 2008, based on a per share closing price of \$4.24 on the Nasdaq Global Market on that date.

As of March 6, 2009, 34,687,724 shares of the registrant's common stock, \$.02 par value per share, were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement for the Annual Meeting of Shareholders to be held on June 24, 2009 are incorporated by reference into Part III of this report.

PART I

IMPORTANT INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

This Form 10-K contains forward-looking statements within the meaning of the Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and in reliance upon the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are those that predict or describe future events or trends and that do not relate solely to historical matters. In some cases, you can identify forward-looking statements by terminology such as “may,” “will,” “could,” “should,” “expect,” “plan,” “intend,” “anticipate,” “believe,” “estimate,” “predict,” “potential,” “propose,” “continue,” “assume” or other similar expressions, or the negatives of those expressions. These statements reflect our current views with respect to future events and are based on assumptions and are subject to risks and uncertainties that are difficult to predict. We have identified some of the factors that could cause future events to differ from our current expectations under the headings “Risk Factors” in Item 1A below and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in Item 7 below. Given these risks and uncertainties, you should not place undue reliance on our forward-looking statements, which speak only as of the date of this report.

You should read this Form 10-K and the documents that we incorporate by reference completely and with the understanding that our actual results, performance and achievements may be materially different from any future results, performance or achievements expressed or implied by our forward-looking statements. We undertake no obligation to update publicly any forward-looking statements to reflect new information, events or circumstances after the date of this report, or to reflect the occurrence of unanticipated events.

Unless otherwise indicated, all common stock-related amounts in this report have been adjusted to reflect our one-for-six reverse stock split effective September 22, 2006.

Item 1. BUSINESS

The Company

Poniard is a biopharmaceutical company focused on the development and commercialization of cancer therapy products. Our lead product candidate is picoplatin, a new generation platinum-based cancer therapy with the potential to become a platform product addressing multiple indications, combinations and formulations. An intravenous chemotherapeutic agent, picoplatin is designed to overcome platinum resistance in the treatment of solid tumors and has the potential for an improved safety profile compared to other currently marketed platinum-based agents. In August 2006, we completed patient enrollment in a Phase II clinical study of picoplatin in small cell lung cancer. Based on positive interim median overall survival data from that ongoing Phase II study, we initiated a pivotal Phase III SPEAR (Study of Picoplatin Efficacy After Relapse) trial of picoplatin in small cell lung cancer and enrolled the first patient in April 2007. We also are conducting separate Phase II studies of picoplatin in the first-line treatment of patients with metastatic colorectal cancer and hormone-refractory prostate cancer (also known as “castration resistant prostate cancer”). The Phase II prostate and colorectal cancer trials have both completed enrollment. Additionally, a Phase I study of an oral formulation of picoplatin is ongoing.

We have financed our operations to date primarily through the sale of equity securities, technology licensing, collaborative agreements and debt instruments. In September, 2008, we borrowed approximately \$20.0 million of additional net cash proceeds under an amended and restated loan facility with GE Healthcare Financial Services and Silicon Valley Bank. On April 30, 2007, we completed a public offering of 11.8 million shares of our common stock at an offering price of \$6.33 per share. Net proceeds of the offering, after payment of underwriters’ discounts and commissions and

offering expenses, were approximately \$70.0 million. Additionally, in April 2006, we received \$62.0 million in net proceeds from an equity financing, pursuant to which we issued 15.5 million shares of common stock at a purchase price of \$4.20 per share. Investors in the 2006 financing also received warrants to purchase an aggregate of 4.6 million shares of common stock at a purchase price of \$4.62 per share. As a result of the 2006 and 2007 financings, entities affiliated with MPM Capital Management, or MPM, beneficially owned an aggregate of approximately 21.9% of our common stock outstanding on December 31, 2008. Entities affiliated with Bay City Capital Management IV LLC, or Bay City Management, beneficially owned an aggregate of approximately 15.7% of our common stock outstanding on December 31, 2008. Nicholas J. Simon, a representative of MPM, and Fred B. Craves and Carl S. Goldfischer, managing directors of Bay City Capital LLC, an affiliate of Bay City Management, serve on our board of directors. We are using the proceeds from the loan and the financings for the continued clinical development of picoplatin, including our ongoing clinical trials of intravenous picoplatin in small cell lung cancer, metastatic colorectal cancer and hormone-refractory prostate cancer and of oral picoplatin in advanced solid tumors, for the commercialization of our picoplatin product candidate, and for general corporate purposes, including working capital.

Since our inception in 1984, we have dedicated substantially all of our resources to research and development. We have not generated any significant revenue from product sales to date and have operated at a loss in each year of our existence. We had a net loss of \$48.6 million for the year ended December 31, 2008, a net loss of \$32.8 million for the year ended December 31, 2007, and a net loss of \$23.3 million for the year ended December 31, 2006. We do not anticipate that our picoplatin product candidate will be commercially available before 2010, if at all. We expect to incur additional operating losses in the future as we complete our clinical trials and seek to commercialize picoplatin. Clinical studies are inherently uncertain, and our ongoing and potential future trials of picoplatin may not confirm the results achieved in earlier clinical and preclinical studies. If picoplatin is not shown to be safe and effective, we will not receive the required regulatory approvals for commercial sale of such product. To the extent that we are successful in obtaining approvals for the commercial sale of picoplatin, we will need to secure one or more corporate partners for the manufacture, marketing and/or sale of such product. We may not be able to secure such corporate partners or enter into partnering arrangements in a timely manner or on terms acceptable to us.

Our consolidated financial statements have been prepared assuming that we will continue as a going concern, which contemplates realization of assets and the satisfaction of liabilities in the normal course of business for a reasonable period following the date of these financial statements. As of December 31, 2008, we had net working capital of \$54.9 million, an accumulated deficit of \$362.3 million and total shareholders' equity of \$47.6 million. Cash, cash equivalents and investment securities, net of restricted cash of \$0.3 million, totaled \$72.8 million at December 31, 2008.

Our current loan facility with GE Healthcare Financial Services and Silicon Valley Bank, the terms of which are described below under the heading, "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources," requires us to maintain a minimum amount of unrestricted cash during the term of the loan equal to the lesser of (i) \$17.9 million or (ii) the outstanding aggregate principal balance of the term loans plus \$4 million. Taking into account the minimum unrestricted cash we are required to maintain during 2009 and our projected operating results, we believe that our current cash, cash equivalent and investment securities balances will provide adequate resources to fund operations at least into the first quarter of 2010. However, given the uncertainties of outcomes of our ongoing clinical trials, there is no assurance that we can achieve our projected operating results. Thereafter, unless we raise additional funds, we will be in default of the minimum unrestricted cash requirement and potentially other provisions of the loan facility. The occurrence of an event of default would increase the applicable rate of interest by 5% and could result in the acceleration of our payment obligations under the loan agreement. We have no assurance that, especially in light of the current distressed economic environment, that the lenders will

be willing to waive or renegotiate the terms of the loan agreement to address or avoid financial or other loan defaults.

If an event of default were to occur, we might not have sufficient funds to repay the loan or to fund our continuing operations. In such case, we would need to delay, scale back or eliminate some or all of our picoplatin trials and commercialization efforts; reduce our workforce, license our picoplatin product candidates for development and commercialization by third parties; attempt to sell the company, cease operations or declare bankruptcy. Provisions of the loan agreement would limit our ability to dispose of certain assets, engage in certain mergers, incur certain indebtedness, make certain distributions and engage in certain investment activities without the prior consent of the lenders. These factors, among others, raise substantial doubt about the Company's ability to continue as a going concern. Management is developing plans to address the Company's liquidity needs, including raising additional capital through the public or private sale of equity or debt securities or through the establishment of credit or other funding facilities; and entering into strategic collaborations, which may include joint ventures or partnerships for product development and commercialization, merger, sale of assets or other similar transactions and taking other actions to limit our expenditures. There can be no assurance that the Company can obtain financing or otherwise raise additional funds, if at all, on terms acceptable to the Company or to its lenders.

Our Picoplatin Development Program

Overview of Cancer and its Treatment

Cancer is a disease characterized by the uncontrolled growth and spread of abnormal cells. Cancer cells often originate from one tissue site and invade, spread and damage other tissues and organs, leading to death. Cancer is the second highest cause of death in the United States, exceeded only by heart disease. In the United States, cancer accounts for one of every four deaths. In 2008, approximately 565,650 Americans were expected to die of cancer, more than 1,500 people a day. The National Cancer Institute estimated that 1,437,180 new cancer cases would be diagnosed in 2008 (American Cancer Society: Cancer Facts & Figures 2008).

In recent years, the diagnosis and treatment of human cancers have greatly improved. However, there is still a substantial need to improve the early diagnosis of cancer, the staging of cancer and the treatment of cancer. It is anticipated that chemotherapeutics and targeted anti-cancer agents will be used both as single agents and in combination to provide benefit to cancer patients. Often patients are treated with multiple agents in combination and in varying sequences depending on the particular cancer type and severity of disease. The oncologist will often assess clinical benefit of a particular therapeutic combination by determining the impact of treatment on tumor size or spread compared to tolerability features. In this regard, chemotherapeutics have continued to have significant impact on cancer treatment, especially when combined with agents that show different anti-cancer properties and different tolerability features. We believe that new treatment combinations that incorporate recently approved targeted agents with chemotherapeutics exhibiting improved safety features, including acceptable risk to benefit ratios for specific patient populations, will be supported by physicians and their patients.

Current treatments for cancer include surgery, external-beam radiation, chemotherapy, targeted pharmaceuticals, hormone therapy, cytokines, interferons, antibodies and antibody-based radiotherapeutics. There has been substantial success in the combined use of both traditional chemotherapeutics, which generally destroy cells, and in targeted agents, which generally are combined with more conventional chemotherapeutics for maximum effect. Occasionally, chemotherapeutics or targeted agents are used as stand-alone agents in the treatment of human cancers.

There is considerable need for new cancer treatments, as well as treatments that improve upon existing therapies. In recent years, many new classes of agents providing modest increases in patient

survival have been approved for use. We anticipate that the use of multiple agents, either in combination or in sequence, will continue to provide benefits to cancer patients. In addition, we believe that individualized therapies will become more prominent as enhanced tumor diagnostics and agents with different mechanisms of anti-cancer effect are approved and become available to the practicing oncologist. We also expect that early diagnosis and cancer prevention will provide for interventions that will allow patients to live longer and have a better quality of life.

Picoplatin and Platinum-Based Chemotherapeutics

Over the past two decades, platinum-based drugs have become a critical part of cancer treatment, administered primarily in combination with other agents, including with recently approved targeted cancer agents. Platinum-based agents, such as cisplatin, carboplatin and oxaliplatin, are currently used to treat a variety of tumors, including testicular, ovarian, colorectal and lung cancers. The mechanism that underlies the use of platinum-based agents relies upon the targeting of tumor DNA where the platinum compound binds. Cells that undergo active cell division are prevented from completing the cell cycle by the presence of the platinum drug that is chemically bound to the DNA. The inability to proceed through normal cell division ultimately causes cell death. In some cases, treatment of cancer patients with platinum compounds leads to reduction in tumor mass due to a higher rate of tumor cell death compared with tumor cell replication.

All platinum-based agents exhibit toxicity to the blood forming cells in the bone marrow, or myelosuppression, as a major adverse effect. The degree and characteristics of myelosuppression vary by platinum compound, dose and regimen. In addition, some current platinum agents show different degrees of other adverse side effects, including kidney toxicity, hearing loss, nausea, vomiting and peripheral nerve damage. As in the case of myelosuppression, these side effects vary with dose, agent, combination therapy and regimen.

For most cancers that are treated with platinum-containing regimens, patients whose cancer initially responds to platinum-containing chemotherapy, but subsequently progresses six months or more after chemotherapy, are described as having “platinum-sensitive” disease. Patients whose cancer initially responds to platinum-containing chemotherapy and then relapses and progresses within six months after completing chemotherapy are said to have “platinum-resistant” disease. Patients whose cancer does not respond or whose disease progresses during platinum-containing chemotherapy are said to have “platinum-refractory” cancer. As described below, in the case of small cell lung cancer, the distinction between platinum-sensitive and platinum-resistant disease is generally drawn based on whether progression occurs before or after 90 days of completing first-line platinum-containing chemotherapy. We believe that patients would benefit from a platinum-based agent that can be used initially to prevent or delay the development of the platinum-refractory or -resistant disease and that is effective in the treatment of disease that becomes refractory or resistant to currently used platinum-based therapies.

In April 2004, we acquired the rights to develop, manufacture and commercialize picoplatin. In September 2006, we renegotiated the financial terms of our April 2004 license agreement and obtained exclusive worldwide rights to picoplatin. Picoplatin is a new generation platinum-based cancer therapeutic designed to overcome platinum-resistance and has the potential for an improved safety profile compared to other platinum-based therapies. It has shown signs of efficacy in preclinical and clinical studies of platinum-sensitive, -resistant and -refractory disease. We believe that picoplatin has the potential to become a platform product addressing multiple indications, combinations and presentations. Clinical evidence of activity has been observed for picoplatin in a variety of tumor types, including small cell and non-small cell lung, colorectal, ovarian, prostate and head and neck cancers. In addition, evaluation of several hundred cancer patients has suggested that picoplatin has a manageable toxicity profile and may result in less severe and less frequent side effects than have been observed with other currently marketed platinum-based agents.

Our Picoplatin Clinical Studies

We currently are evaluating picoplatin in an ongoing Phase III clinical trial in the second-line treatment of small cell lung cancer and in separate Phase II clinical trials in the first-line treatment of metastatic colorectal and hormone-refractory prostate cancers. In addition, we have undertaken a Phase I clinical trial of an oral formulation of picoplatin. These programs are described below and in the section of this report entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Research and Development.” It is important to keep in mind that clinical studies are inherently uncertain, and later trials may not confirm the results achieved in earlier clinical and preclinical studies and may not be supported by the results obtained in subsequent trials. You should refer to the section of this report entitled “Risk Factors” for a discussion of some of the factors that could materially affect our picoplatin clinical development program.

Small Cell Lung Cancer

Small Cell Lung Cancer and its Treatment. Small cell lung cancer accounts for approximately 20% of all lung cancer cases and is the most aggressive and fastest growing type of lung cancer. Small cell lung cancer is strongly related to smoking, with 99% of tumors occurring in smokers or persons exposed to second-hand smoke (American Lung Association, 2007). According to IntrinsiQ, the leading provider of United States oncology market data, 52,619 small cell lung cancer patients were treated in the United States in 2007. Small cell lung cancer metastasizes rapidly to other sites within the body and is most often discovered after it has spread extensively. At the time of diagnosis, approximately two-thirds of small cell lung cancer patients have metastases beyond the chest region. Few patients are cured. Radiation therapy plus chemotherapy is the standard of care for cancer confined to one side of the chest that can be treated with a single area of radiation therapy (limited-stage disease). Surgery is used for the few patients whose limited-stage disease is treated early. Combination chemotherapy is the standard treatment for patients with disease involving both sides of the chest and/or obvious spread of the cancer beyond the chest region (extensive-stage disease).

Platinum-based therapy is the chemotherapy used in the first line-treatment of small cell lung cancer. According to IntrinsiQ, more than 80% of patients with small cell lung cancer in the United States were treated with either carboplatin or cisplatin plus etoposide as first-line chemotherapy in 2007. Despite a response rate of 40% to 90% to first-line therapy, long-term survival is rare because patients develop resistance to chemotherapy and their disease relapses.

The prognosis for patients who receive second-line therapy after disease relapse is poor, and the expected mean survival after relapse is two to four months. There is no standard second-line chemotherapy for small cell lung cancer, especially for patients with platinum-resistant disease. Intravenous topotecan is approved by the FDA for the treatment of sensitive small cell lung cancer after failure of first-line chemotherapy. In clinical studies submitted to support approval, platinum-sensitive lung cancer was defined as disease responding to chemotherapy but subsequently progressing at least 60 days (in the Phase III study) or at least 90 days (in the Phase II studies) after chemotherapy.

Based on clinical and preclinical data to date, we believe that picoplatin has potential activity in small cell lung cancer patients who have failed first-line platinum-containing therapy. A Phase II study conducted by a prior licensee during 2001 and 2002 to assess the activity and tolerability of picoplatin when given intravenously as a second-line therapy to patients with small cell lung cancer demonstrated that 4 of 13 patients (30.8%) had a partial response (a decrease in the size of the tumor or the extent of cancer in the body) or stable disease (no increase or decrease in extent or severity of the cancer). Two of 13 patients (15.4%) with platinum-resistant small cell lung cancer had a partial response, and two additional patients (15.4%) had stable disease. The median survival of all 13 treated patients was approximately 27 weeks. Our Phase II confirmatory small cell lung cancer study showed median overall survival of 27 weeks in 77 evaluable patients.

Phase II and Phase III Clinical Trials. In October 2004, we filed an investigational new drug application, or IND, with the United States Food and Drug Administration, or FDA, to conduct a Phase II clinical trial of intravenous picoplatin versus intravenous topotecan for injection (Hycamtin®) in patients with small cell lung cancer. Intravenous topotecan is an anti-tumor drug currently approved by the FDA as a treatment for patients with sensitive small cell lung cancer after failure of first-line chemotherapy. In clinical studies submitted to support approval of intravenous topotecan, sensitive disease was defined as responding to chemotherapy but subsequently progressing at least 60 days (in the Phase III study) or at least 90 days (in the Phase II study) after chemotherapy. Our Phase II trial was initiated in June 2005 in the United States and Canada, and the first patient was treated in July 2005. The objective for patient enrollment was approximately 75 patients with platinum-resistant or-refractory small cell lung cancer, defined as subjects who either (1) initially responded to first-line platinum-containing chemotherapy and then relapsed or progressed within 90 days after completion of first-line chemotherapy (resistant disease); or (2) failed to respond to or progressed during first-line platinum-containing chemotherapy (refractory disease). The clinical endpoints of the study included safety, objective tumor response rate (tumor shrinkage), time to tumor progression and overall survival.

We amended our Phase II clinical trial protocol in January 2006 from a two-arm study of picoplatin versus intravenous topotecan to a single-arm study of picoplatin. We discontinued the intravenous topotecan arm of the study because patients and investigators often were unwilling to accept this study arm. The rationale for the amendment was that the dose and schedule of intravenous topotecan approved by the FDA for use in patients with platinum-sensitive small cell lung cancer have minimal, if any, efficacy in patients with platinum-resistant or -refractory small cell lung cancer and unacceptable toxicity, thus presenting a situation in which an ineffective but toxic treatment regimen was to be used as one arm of the randomized Phase II trial. We also amended the protocol because we no longer intended to use intravenous topotecan as the comparator treatment for our Phase III trial and wanted data in more patients treated with picoplatin to help us make a decision on whether to embark upon a large Phase III trial.

We discussed the design of our Phase III trial with the FDA in April 2006 and modified our ongoing Phase II trial to support our plans for the Phase III trial. We expanded our small cell lung cancer study to include additional clinical sites in Eastern Europe, India and South America, where we believed the greater availability of patients could enable us to more rapidly increase patient enrollment. In May 2006, we amended our Phase II protocol to provide for enrollment of a subset of patients with platinum-sensitive disease who relapsed within 91 to 180 days of completing first-line platinum-containing chemotherapy. We completed enrollment of our Phase II small cell lung cancer trial in August 2006. In November 2006, we announced positive interim overall survival results from the study, indicating a median overall survival of 27 weeks in 71 evaluable patients. This data served as the basis for our decision to initiate our pivotal Phase III SPEAR (Study of Picoplatin Efficacy after Relapse) trial. In June and September 2007, we announced additional data from our Phase II trial, including longer follow-up on more patients, which confirmed the interim results with median overall survival of 27 weeks in 77 evaluable patients.

We initiated our pivotal Phase III SPEAR trial and enrolled the first patient in April 2007. The Phase III trial is being undertaken pursuant to a Special Protocol Assessment, or SPA, with the FDA. The SPA is a written agreement between us and the FDA on the objectives, design and endpoints to be used as a basis of filing for approval of picoplatin and the data analysis plan necessary to support full regulatory approval of picoplatin. The Phase III trial is an international, multi-center, open-label, controlled study to compare the efficacy and safety of picoplatin plus best supportive care with best supportive care alone as a second-line therapy. We are blinded to any analysis of the aggregate data until the database is locked at the end the study when the data base is considered complete. The study is designed to enroll approximately 400 patients with small cell lung cancer whose disease is non-responsive (refractory) to first-line platinum-containing (cisplatin or carboplatin) chemotherapy or

whose disease responded initially to first-line platinum-containing therapy but then progressed within six months after treatment was completed. Patients are being randomized in a 2:1 ratio to receive picoplatin plus best supportive care or best supportive care alone. Best supportive care includes all medical, radiation and surgical interventions that small cell lung cancer patients should receive to relieve the symptoms and treat the complications caused by small cell lung cancer, but excludes treatment with systemic therapies intended to kill cancer cells.

The primary endpoint of our Phase III SPEAR study is improved overall survival, as measured in time from randomization to death. Secondary endpoints include overall response rates, disease control and progression-free survival. We currently anticipate in 2009 completing patient enrollment, commencing the preparation of a New Drug Application, or NDA, and requesting permission to submit the NDA in a rolling manner. As described below, the rolling submission process enables companies that have been granted Fast Track designation to submit sections of the NDA for FDA review as they become available, rather than the normal process of submitting the NDA to the FDA all at once. The actual timing for completion of patient enrollment and the commencement of the rolling NDA process will depend on the rate of patient enrollment, survival times of all patients in the trial, as well as other factors, such as patient performance status and extent of disease. We presently anticipate completing the rolling NDA submission and, subject to FDA approval, initiating the commercialization of picoplatin during 2010. FDA approval of picoplatin will depend on a variety of factors, including whether the FDA determines that the data from our completed Phase III clinical trial are sufficient to support approval. Additionally, the timing of the completion of the rolling NDA submission and any commercialization of picoplatin will be affected by our ability to obtain a corporate partner or otherwise obtain additional funding to support these activities.

The FDA has designated picoplatin as an orphan drug for the treatment of small cell lung cancer under the provisions of the Orphan Drug Act, as amended. To qualify for orphan drug status, a proposed drug must be intended for use in the treatment of a condition that affects fewer than 200,000 people in the United States. Orphan drug status entitles us to exclusive marketing rights for picoplatin in the United States for seven years following marketing approval, if any, and qualifies us for research grants to support clinical studies, tax credits for certain research expenses and an exemption from certain application user fees.

In August 2007, the FDA also granted picoplatin Fast Track designation for the second-line treatment of small cell lung cancer. The FDA's Fast Track programs are designed to facilitate the development and expedite the review of drugs that are intended to treat a serious or life-threatening condition and that demonstrate the potential to address unmet medical needs. Fast Track designation provides for priority interactions with the FDA to improve the efficiency of clinical development and support the expeditious review of promising drug candidates, including a rolling NDA submission. The rolling submission process permits us to submit sections of the NDA as they become available, allowing the review process to begin before the complete dossier has been submitted.

The European Commission, in 2007, designated picoplatin as an orphan medicinal product for the treatment of small cell lung cancer in the European Union. To qualify for this designation, a proposed drug must be intended for the treatment of life-threatening or serious conditions that are rare and affect not more than five in 10,000 persons in the European Union. Orphan medicinal product designation entitles us to certain incentives, such as eligibility protocol assistance and possible exemptions or reductions of certain regulatory fees during development or at the time of application for marketing approval in the European Union. If such approval is received, picoplatin would qualify for ten years of marketing exclusivity in the European Union.

Metastatic Colorectal Cancer

Colorectal Cancer and its Treatment. According to the American Cancer Society, colon cancer is the third most common cancer among American men and women and the second and third leading cause of cancer death in the United States for men and women, respectively. An estimated 148,810 new cases of colon and rectal cancer were diagnosed in 2008, with an estimated 49,960 deaths in 2008, accounting for approximately 9% of all cancer deaths in the United States (American Cancer Society, Cancer Facts and Figures 2008). A FOLFOX-based regimen is the standard of care in the United States for treatment of advanced colorectal cancer and adjuvant (post surgical) treatment of colon cancer in patients who have their primary tumors surgically removed. According to IntrinsiQ, 41.8% of colorectal cancer patients in the United States received oxaliplatin-containing treatment regimes in 2008. However, approximately 82% of the patients previously untreated for advanced colorectal cancer who receive this treatment develop neuropathy, and approximately 19% of patients develop severe neuropathy, according to the oxaliplatin package insert. Neuropathy is a peripheral nerve function problem that can result in numbness, tingling and pricking sensations, sensitivity to touch, pain, and muscle weakness or wasting. The National Comprehensive Cancer Network Guidelines for Physicians recommends discontinuation of oxaliplatin after three months of therapy, or sooner if severe neuropathy develops, with other drugs maintained until time of tumor progression. Picoplatin has been tested in more than 750 patients in Phase I and Phase II safety and efficacy studies. In contrast to oxaliplatin, picoplatin was generally well-tolerated, with approximately 16% of patients treated with picoplatin as a single agent developing mild or moderate neuropathy and 1% of the patients developing severe neuropathy.

Phase I/II Clinical Trial. In May 2006, we treated the first patient in our ongoing Phase I/II study of intravenous picoplatin in the first-line treatment of patients with metastatic colorectal cancer. The trial is being conducted in Eastern Europe, and enrollment was completed in May 2008. The Phase I component of the trial was designed to determine an appropriate dose of picoplatin, either once every two weeks or once every four weeks, in combination with the chemotherapy agents 5-fluorouracil and leucovorin for further testing in the Phase II component of the trial. Based on interim Phase I safety data, which was presented at the ASCO Annual Meeting in June 2008, the therapy was generally well-tolerated. No severe neuropathy (grade 3 or grade 4) was observed. Twenty-three percent of the patients treated had mild (grade 1 or grade 2) neuropathy. The most frequent dose limiting toxicity was to the blood forming cells in the bone marrow, or myelosuppression. The maximum tolerated dose was established in the every-four-week schedule at 150 mg/m². The maximum tolerated dose for the every-two-week regimen was not reached. We initiated a Phase II trial in November 2007 to generate proof-of-concept data to demonstrate that picoplatin can be used as a first-line chemotherapeutic agent with a favorable toxicity profile compared to oxaliplatin (Eloxatin®). Enrollment in the Phase II trial was completed in May 2008. One hundred and one patients were randomized 1:1 to receive either 5-fluorouracil and leucovorin plus oxaliplatin, also known as the FOLFOX regimen, or picoplatin (150mg/m²) given once every four weeks with 5-fluorouracil and leucovorin, which we refer to as the FOLPI regimen. Endpoints of the Phase I/II study include safety, objective tumor response rate (tumor shrinkage), time to tumor progression, progression-free survival and overall survival. Interim Phase II data presented at ASCO Gastrointestinal Satellite Symposia in January 2009 showed that 65 percent of evaluable FOLFOX-treated patients showed evidence of neurotoxicity compared with 28 percent of patients treated with FOLPI. Ten percent of FOLFOX-treated patients exhibited severe (Grade 3/4) neuropathy compared with no FOLPI-treated patients. Anti-tumor activity was similar in the FOLPI and FOLFOX groups. Of patients in the FOLPI arm, 76 percent achieved disease control (complete response, partial response and stable disease), including one patient with a complete response and seven patients with a partial response, as did 76 percent of patients in the FOLFOX arm, including seven patients with a partial response.

Hormone-Refractory Prostate Cancer

Hormone-Refractory Prostate Cancer and its Treatment. Prostate cancer has the highest number of new cases among men in the United States and is the second leading cause of death in American men. The American Cancer Society estimated that, in 2008, there would be approximately 186,320 new cases of prostate cancer in the United States and that approximately 28,660 men would die from this disease. Ten to twenty percent of men with prostate cancer present with metastatic disease, and all patients with metastatic prostate cancer become resistant to hormone treatment. According to a June 2006 report by Decision Resources, a biopharmaceutical industry market research firm, the incidence of diagnosed cases of metastatic hormone-refractory prostate cancer in major pharmaceutical markets is projected to grow 2.2% per year.

Many patients diagnosed with prostate cancer initially receive surgery or radiation therapy, and some of these patients are cured. For many, however, the disease recurs. At this point the recurrent disease is treated with hormone therapy, and most patients initially respond well. The average duration of response is only 10 to 12 months, however, and the tumor cells eventually become resistant to the hormones, or hormone-refractory, and the tumor again progresses. Hormone-refractory prostate cancer is also known as “castration-resistant prostate cancer.” Increasingly, chemotherapy is being used as a first-line treatment for hormone-refractory prostate cancer, but few effective drugs have been identified. Docetaxel in combination with prednisone was approved by the FDA in 2004 for the treatment of patients with metastatic (stage IV) hormone-refractory prostate cancer. According to IntrinsiQ, 88.5% of U.S. patients received a docetaxel-containing regimen for first-line treatment of stage IV hormone-refractory prostate cancer in 2008. Docetaxel or mitoxantrone, each as a single agent, were the two most commonly prescribed second-line treatment therapies for hormone-refractory prostate cancer in the United States in 2008. We believe that the combination of picoplatin and docetaxel has the potential to be more effective as a first-line treatment than either docetaxel or picoplatin alone.

Phase I/II Clinical Trial. In May 2006, the first patient was treated in our ongoing Phase I/II study of intravenous picoplatin in the treatment of patients with prostate cancer that was not responsive to hormone treatments and had not previously been treated with chemotherapy. The trial is being conducted in Eastern Europe, and enrollment was completed in December 2007. The Phase I component of the trial was designed to evaluate increasing doses of picoplatin in combination with 60 or 75 mg/m² of the chemotherapy agent docetaxel (Taxotere®) administered every three weeks with 5 mg prednisone twice daily, to establish a dose of picoplatin for further testing in the Phase II component of the trial. Interim Phase I safety data, which was presented at the ASCO Gastrourinary Satellite Symposium in February 2008 showed that the picoplatin and docetaxel combination was generally well-tolerated, with only mild neuropathy in three of 33 patients (9%), with a prostate specific antigen (PSA) response rate of 65 percent (20 of 31 evaluable patients). Myelosuppression was the dose limiting toxicity. We initiated the 30 patient Phase II component of the trial in July 2007 and completed patient enrollment in December 2007. The Phase II trial is a proof-of-concept trial designed to demonstrate that picoplatin improves efficacy when combined with the labeled dosage of docetaxel and prednisone in the first-line setting. This single-arm study examined 120 mg/m² picoplatin in combination with 75 mg/m² docetaxel administered once every three weeks with 5 mg prednisone twice daily. Endpoints of the study include safety, reduction in PSA, objective tumor response rate (tumor shrinkage), time to tumor progression, progression-free survival and overall survival. Initial Phase II data was presented at the 20th EORTC-NCI-AACR Symposium in October 2008, where we reported that reductions of PSA of at least 50 percent were achieved in 78 percent of evaluable patients. Normalized PSA levels were achieved in 26 percent of patients. In contrast to picoplatin monotherapy, thrombocytopenia was less severe and less frequent in combination with docetaxel. To date, no neurotoxicity has been observed in this study. Additional efficacy and safety data was presented at the ASCO Genitourinary Cancers Symposium in February 2009, where we reported (i) that we achieved reductions of PSA levels of at least 50 percent in 78 percent of 27 evaluable patients who were

administered picoplatin in combination with docetaxel and prednisone, (ii) that the median time to PSA progression to date is 8.5 months with picoplatin administered in combination with docetaxel and prednisone and (iii) that picoplatin can be safely administered with full-dose docetaxel. Neutropenia was the main hematologic toxicity. Thrombocytopenia was less severe and less frequent with picoplatin administered in combination with docetaxel compared with picoplatin administered alone.

Oral Picoplatin

Phase I Clinical Trial. In April 2007 we initiated a Phase I randomized, open-label, dose-ranging study of the safety (adverse effects), tolerability, pharmacokinetics (how the body processes the drug) and clinical pharmacology (how the drug works in the body) of picoplatin administered orally compared with picoplatin administered intravenously in patients with advanced solid tumor malignancies. This ongoing trial is being conducted at clinical sites in the United States. We believe that oral picoplatin has significant potential for use in combination with radiation therapies, oral chemotherapies and targeted therapies, including in a refractory setting following relapse from first-line therapies. In preclinical studies, picoplatin has been shown to have up to 40% oral bioavailability. In April 2008, we presented interim results from our ongoing Phase I clinical trial of oral picoplatin, which indicated oral bioavailability of 20% to 44% in patients with advanced cancer. Bioavailability refers to the fraction of an administered dose of an unchanged drug that reaches systemic circulation. In November 2008, we announced that picoplatin achieved linear and dose-dependent plasma exposure when administered orally. The results demonstrated that exposure to orally administered picoplatin was linear at doses below 200 mg, and that maximum exposure to orally administered picoplatin was achieved at doses of 200 mg or greater, thereby indicating sufficient bioavailability to support further clinical studies.

Picoplatin Source of Supply

We have entered into separate agreements with W.C. Heraeus GmbH, or Heraeus, for the manufacture of picoplatin active pharmaceutical ingredient, or API, for use in our clinical studies and for commercial purposes. We similarly have entered into separate agreements with Baxter Oncology GmbH, or Baxter, for the bulk production and distribution of finished picoplatin drug product for clinical and commercial use.

Clinical Supply. Heraeus is our sole supplier of API and Baxter is our sole supplier of finished drug product for our clinical trials. Manufacturing services are provided on a purchase order, fixed-fee basis. The API clinical supply agreement continues in effect until it is terminated by one or both of the parties in accordance with its terms. Unless earlier terminated, the finished drug product clinical supply agreement runs for an initial term ending December 31, 2009, and is subject to renewal for two additional one-year terms, at our option. The agreements generally provide that they may be terminated:

- by mutual agreement of the parties;
- by either party, if there is a material breach by the other party that remains uncured;
- by either party, in the event of solvency or bankruptcy of the other party;
- in the case of the API clinical supply agreement:
 - by either party, if the other party or any its personnel performing services is debarred;
 - by us, if there is a change of control of Heraeus; and
- in the case of the finished drug product clinical supply agreement:
 - by us at any time with one year's advance notice; and

- By Baxter, with 24 months prior written notice if we enter into a partnership or transfer rights to picoplatin involving a direct competitor of Baxter.

Commercial Supply. We entered into a picoplatin API commercial supply agreement with Heraeus in March 2008 and a finished drug product commercial supply agreement with Baxter in November 2008. Under these agreements, Heraeus and Baxter will produce picoplatin API and finished drug product, respectively, for commercial use. Manufacturing services are provided on a purchase order, fixed-fee basis, subject to certain purchase price adjustments and minimum quantity requirements. The API commercial supply agreement continues for an initial term ending December 31, 2013, and the finished drug product commercial supply agreement continues for an initial term ending November 22, 2013, in each case subject to extension. The agreements generally may be terminated upon the same terms and conditions as the clinical supply agreements described above.

We have no assurance that our current suppliers will be able to continue to manufacture sufficient picoplatin API and/or finished drug product on a timely or cost-effective basis at all times in the future. We believe that there are other contract manufacturers with the capacity to manufacture picoplatin API and finished drug product. If we are required to seek out alternative manufacturers, we may incur significant additional costs and suffer delays in, or be prevented from, subject to FDA approval, initiating commercial sales of picoplatin. We believe that we currently have adequate supplies of picoplatin API and finished drug product to complete our current clinical trials.

Patents and Proprietary Rights

Our policy is to aggressively protect our proprietary technologies. We have filed applications for United States and foreign patents on many aspects of our technologies.

We hold an exclusive worldwide license granted from Genzyme Corporation (successor to AnorMED, Inc.) for the development and commercial sale of picoplatin. Under the license agreement, as amended, Genzyme retains the right to prosecute its patent applications and maintain all licensed patents, with us reimbursing such expenses. We have the right to sue any third party infringers of the picoplatin patents. If we do not file suit, Genzyme, in its sole discretion, has the right to sue the infringer at its expense.

The parties executed the license agreement in April 2004, at which time we paid a one-time upfront milestone payment of \$1.0 million in common stock and \$1.0 million in cash. The original license agreement excluded Japan from the licensed territory and provided for \$13.0 million in development and commercialization milestones, payable in cash or a combination of cash and common stock, and a royalty rate of up to 15% of product net sales after regulatory approval. The parties amended the license agreement on September 18, 2006, modifying several key financial terms and expanded the licensed territory to include Japan, thereby providing us worldwide rights. In consideration of the amendment, we paid Genzyme \$5.0 million in cash on October 12, 2006 and paid Genzyme an additional \$5.0 million in cash on March 30, 2007. The amendment eliminated all development milestone payments to Genzyme. We remain obligated to pay a total of \$5.0 million in commercialization milestones upon the attainment of certain levels of annual net sales of picoplatin after regulatory approval. The amendment also reduced the royalty payable to Genzyme to a maximum of 9% of annual net product sales and eliminated sharing of sublicense revenues with Genzyme. The license agreement may be terminated by either party for breach, or if the other party files a petition in bankruptcy or insolvency or for reorganization or is dissolved, liquidated or makes assignment for the benefit of creditors. We can terminate the license at any time upon prior written notice to Genzyme. If not earlier terminated, the license agreement will continue in effect, in each country in the territory in which the licensed product is sold or manufactured, until the earlier of (i) expiration of the last valid claim of a pending or issued patent covering the licensed product in that country or (ii) a specified number of years after first commercial sale of the licensed product in that country.

Our picoplatin portfolio includes United States and foreign patents and applications licensed from Genzyme, which cover the picoplatin product. With respect to picoplatin, we expect to rely primarily on US patent number 5,665,771 (expiring February 7, 2016), which is licensed to us by Genzyme, and additional licensed patents expiring in 2016 covering picoplatin in the European Union and other countries. The FDA designated picoplatin as an orphan drug for the treatment of small cell lung cancer under the provisions of the Orphan Drug Act, which entitles us to exclusive marketing rights for picoplatin in the United States for seven years following market approval. In addition, the European Commission has designated picoplatin as an orphan medicinal product for the treatment of small cell lung cancer in the European Union, which entitles us to exclusive marketing rights for picoplatin in the European Union for ten years following market approval.

A number of additional potential avenues exist which may further extend our picoplatin patent protection and exclusivity. In the United States, these include The Drug Price and Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act, which, among other things, generally provides for patent term extension for up to five years for an issued patent covering a drug product which has undergone regulatory review before marketing. In addition, since picoplatin has not been previously approved for marketing in the United States, picoplatin may qualify for new chemical entity data exclusivity, under which the FDA bans for a period of time submissions of applications from competitors based on published data or Abbreviated New Drug Applications for a drug containing the same active agent. Certain patent term restoration procedures and marketing exclusivity rights also may be available for qualifying drug products in the European Union or individual foreign countries. We intend to evaluate the availability of these mechanisms for extending the patent term and marketing exclusivity for picoplatin on an individual regional or country basis. We cannot be certain that we will be successful in any efforts to extend the term of any patent relating to picoplatin or that picoplatin will be granted additional marketing exclusivity rights in the United States or abroad.

Risks associated with the protection of our patents and other proprietary technologies are described under the heading “Risk Factors” in Item 1A below. Pending or future patent applications by us or our collaborators will not necessarily result in issued patents. Moreover, the current patents that we own or license may not provide substantial protection or commercial benefit. In addition to patent protection, we rely upon trade secrets, unpatented proprietary know-how and continuing technological innovation to develop and maintain our competitive position. Third parties could acquire or independently develop the same or similar technology or our issued patents or those licensed by us could be circumvented, invalidated or rendered obsolete by new technology. Third parties also could gain access to or disclose our proprietary technology, and we may be unable to meaningfully protect our rights in such unpatented proprietary technology.

Under United States law, although a patent has a statutory presumption of validity, the issuance of a patent is not conclusive as to its validity or as to the enforceable scope of its claims. Accordingly, the patents owned or licensed by us could be invalidated, infringed or designed around by third parties. Also, third parties could obtain patents that we would need to license or design around.

Competition

The competition for development of cancer therapies is substantial. There is intense competition from biotechnology and pharmaceutical companies, as well as academic research institutions, clinical reference laboratories and government agencies that are pursuing research and development activities similar to ours in the United States and abroad. Our initial focus for picoplatin is small cell lung cancer, the most aggressive and deadly form of lung cancer. Although platinum therapies are the preferred treatment, no FDA-approved therapies are available for patients with platinum-refractory or -resistant disease. If approved, picoplatin will be competing with existing treatment regimens, as well as emerging therapies for small cell lung cancer, and other platinum-based therapeutics. Large

pharmaceutical/biotechnology companies, including Abbott, Amgen, AstraZeneca, Baxter Healthcare, Bristol-Myers Squibb Company, Celgene Corporation, Dainippon Sumitomo Pharma Co. Ltd., Eli Lilly and Company, Genentech, Inc., GlaxoSmithKline PLC, Merck & Co., Nippon Kayaku Co. Ltd., Novartis AG, Pfizer Inc., OSI Pharmaceuticals, Sanofi-Aventis Group, Shionogi & Co. Ltd. and SK Pharma, are marketing and/or developing therapeutics in late-stage clinical trials for the treatment of small cell lung cancer or platinum agents for the treatment of cancer. Multiple biotechnology companies are engaged in clinical trials for the treatment of small cell lung cancer and other platinum-based therapeutics, including Abraxis BioScience Inc., Access Pharmaceuticals Inc., Antigenics, Inc., Ascenta Therapeutics, Gemin X, GPC Biotech AG (whose merger with Agennix was announced in February 2009), ImmunoGen, Inc., Ipsen Group, Keryx Biopharmaceuticals Inc., Meabco A/S, MolMed S.p.A., Onyx Pharmaceuticals Inc., PharmaMar (Zeltia Group), Proacta, Inc., Regulon, Inc., Schering-Plough, Simcere Pharmaceuticals, Sunesis Pharmaceuticals Inc., Theradex, Transave Inc., Vertex Pharmaceuticals and Vion Pharmaceuticals Inc. As we expand the utility of picoplatin into other oncology indications, such as hormone-refractory prostate cancer and colorectal cancer, we will be facing additional competition from major pharmaceutical companies, biotechnology companies, research institutions and government agencies. We cannot assure you that we will be able to effectively compete with these or future third-party product development programs.

Many of our existing or potential competitors have, or have access to, substantially greater financial, research and development, marketing and production resources than we do, and may be better equipped than we are, to develop, manufacture and market competing products. Further, our competitors may have, or may develop and introduce, new products that would render our picoplatin or any other proposed product candidates less competitive, uneconomical or obsolete.

Our ability to commercialize picoplatin and to compete effectively will depend in large part on:

- our ability to meet all necessary regulatory requirements and to advance picoplatin through the FDA approval process;
- the perception by physicians and other members of the health care community of the safety, efficacy and benefits of picoplatin compared to those of competing products or therapies;
- our ability to acquire picoplatin API and finished drug product on a commercial scale;
- timing of market introduction;
- the effectiveness of our sales and marketing efforts;
- the willingness of physicians to adopt new or modified treatment regimens using picoplatin;
- our ability to secure reimbursement for picoplatin;
- the price of picoplatin relative to competing products; and
- our ability to develop a commercial scale infrastructure, either on our own or with a collaborator, which would include the development of a distribution network and other operational and financial systems necessary to support our increased scale.

We believe that competition among products approved for sale will be based, among other things, on product safety, efficacy, reliability, availability, third-party reimbursement, price and patent position. Our competitiveness also will depend on our ability to advance our product candidates, license additional technology, maintain a proprietary position in our technologies and products, obtain required government and other approvals on a timely basis, attract and retain key personnel and enter into corporate relationships that enable us and our collaborators to develop effective products that can be manufactured cost-effectively and marketed successfully.

Government Regulation and Product Testing

The FDA and comparable regulatory health authorities in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, manufacture, marketing and distribution of drugs. These health authorities and other federal, state, local and foreign entities regulate research and development activities and the testing, manufacture, quality control, safety, storage, record-keeping, approval, advertising and promotion of picoplatin and any other future drug candidates. Product development and approval within these regulatory frameworks take a number of years to accomplish, if at all, and involve the expenditure of substantial resources.

U.S. Government Regulation

In the United States, drugs and biologics are subject to regulation by the FDA under the Federal Food, Drug and Cosmetic Act of 1976, as amended, and implementing regulations. The process required by the FDA before picoplatin and any other future drug candidates may be marketed in the United States generally involves the following:

- completion of extensive preclinical laboratory tests, *in vivo* preclinical studies and formulation studies;
- submission to the FDA of an Investigational New Drug Application, or IND, which must become effective before clinical trials can commence;
- performance of properly designed and well-controlled clinical trials to establish the safety and efficacy of the product candidate for each proposed indication;
- submission of a New Drug Application, or an NDA, to the FDA; and
- FDA review and approval of the NDA prior to any commercial sale or shipment of the drug.

In addition to obtaining FDA approval for each product, each domestic drug manufacturing establishment must be registered with and inspected by the FDA. Domestic manufacturing establishments are subject to biennial inspections by the FDA and must comply with current Good Manufacturing Practice, or cGMP, regulations, which are enforced by the FDA through its facilities inspection program for biologics, drugs and devices. To supply products for use in the United States, foreign manufacturing establishments must also comply with cGMP regulations and are subject to periodic inspection by the FDA or by corresponding regulatory health authorities in such countries under reciprocal agreements with the FDA.

Preclinical studies include laboratory evaluation of product chemistry and formulation, as well as animal studies, to assess the potential safety and efficacy of the proposed product. Laboratories that comply with the FDA regulations regarding Good Laboratory Practice must conduct preclinical safety tests. The results of the preclinical studies are submitted to the FDA as part of an IND and are reviewed by the FDA prior to commencement of clinical trials. Unless the FDA provides comments to an IND, the IND will become effective 30 days following its receipt by the FDA. Submission of an IND does not assure FDA authorization to commence clinical trials.

Clinical trials involve the administration of the investigational new drug to healthy volunteers or to patients under the supervision of a qualified principal investigator. Clinical trials are conducted in accordance with the FDA's Protection of Human Subjects regulations and Good Clinical Practices under protocols that detail the objectives of the study, the parameters to be used to monitor safety, and the efficacy criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND. Further, each clinical study must be conducted under the auspices of an independent Institutional Review Board, or IRB, at the institution where the study will be conducted. The IRB will consider, among other things, ethical factors, the safety of human subjects and the possible liability of the institution.

Clinical trials are typically conducted in three sequential phases, but the phases may overlap. In Phase I, the drug is tested for:

- safety (adverse effects);
- dosage tolerance;
- pharmacokinetics (how the body processes the drug) and
- clinical pharmacology (how the drug works in the body).

In Phase II, a limited patient population is studied to:

- determine the efficacy of the drug for specific, targeted indications;
- determine the dosage tolerance and optimal dosage; and
- identify possible adverse effects and safety risks.

If a compound is found to have potential activity in a disease or condition and to have an acceptable safety profile in Phase II clinical trials, Phase III clinical trials are undertaken to further evaluate clinical activity and to further test for safety within an expanded patient population at geographically dispersed clinical study sites. Often, Phase IV (post-marketing) studies are required by the FDA in order to gain more data on safety and efficacy of a drug after it has transitioned into general medical practice. With respect to picoplatin or any proposed products subject to clinical trials, there can be no assurance that Phase I, Phase II or Phase III studies will be completed successfully within any specific time period, if at all. Clinical studies are inherently uncertain, and our current picoplatin and any future clinical trials may not confirm the results achieved in earlier clinical or preclinical trials. If picoplatin is not shown to be safe and effective, we will not be able to obtain the required regulatory approvals for commercial sale of that product. Furthermore, we or the FDA may suspend clinical trials at any time if it is determined that the subjects or patients are being exposed to an unacceptable health risk.

The results of the pharmaceutical development, preclinical studies and clinical trials are submitted to the FDA in the form of an NDA for approval of the marketing and commercial shipment of the drug. The testing and approval processes are likely to require substantial cost, time and effort, and there is no assurance that approval will be granted on a timely basis, or at all. The FDA may deny an NDA if applicable regulatory criteria are not satisfied, may require additional testing or information, or may require post-market testing and surveillance to monitor the safety of the product. If regulatory approval is granted, such approval may entail limitations on the indicated uses for which the product may be marketed. The FDA may withdraw product approvals if compliance with regulatory standards is not maintained or if problems occur following initial marketing. Among the conditions for NDA approval is the requirement that the prospective manufacturers' quality control and manufacturing procedures conform to cGMP regulations. In complying with standards set forth in these regulations, manufacturers must continue to expend time, money and effort in the areas of production and quality control to ensure full technical compliance.

Foreign Regulation

In addition to regulation in the United States, we are subject to a variety of foreign regulations governing clinical trials and will be subject to foreign regulations with respect to commercial sales and distribution of picoplatin and any proposed future products. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by comparable regulatory health authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that

required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement also vary greatly from country to country.

Under the European Union regulatory systems, marketing authorizations may be submitted either under a centralized or mutual recognition procedure. For oncology products, a centralized procedure is required. It provides for the grant of a single marketing authorization that is valid for all European Union member states. The mutual recognition procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the application and assessment report, each member state must decide whether to recognize approval.

Our Employees

As of March 6, 2009, we had 59 full-time employees and 5 part-time employees. Of these full-time employees, 15 hold PhD degrees, 3 hold M.D. degrees, and one holds a J.D. degree. Of the total full-time employees, 39 employees were engaged in research and development activities and 20 were employed in general administration. We consider our relations with employees to be good. None of our employees is covered by a collective bargaining agreement.

Our Executive Officers

Information with respect to the Company's executive officers is set forth below:

<u>Name</u>	<u>Age</u>	<u>Position with the Company</u>
Gerald McMahon, PhD	54	Chairman and Chief Executive Officer
Ronald A. Martell	47	President and Chief Operating Officer
Robert L. De Jager, M.D.	67	Chief Medical Officer
Gregory L. Weaver	52	Chief Financial Officer and Senior Vice President, Finance

Business Experience

Gerald McMahon, Ph.D., was appointed Chief Executive Officer of the Company in May 2004 and Chairman of the Board of Directors in June 2004. Dr. McMahon served as our President from June 2005 to May 2007. Previously, he was President of SUGEN, Inc., a biopharmaceutical company focused on the discovery and development of novel targeted small-molecule drugs. At SUGEN, Dr. McMahon played a key role in the discovery and development of several innovative cancer products, including Sutent®, a multi-targeted protein kinase inhibitor for the treatment of advanced cancers marketed by Pfizer Inc. SUGEN was acquired by Pharmacia Corp. in 1999, which subsequently was acquired by Pfizer in 2003. Prior to his role at SUGEN, which he joined in 1993, Dr. McMahon held several research and development management positions at Sandoz Pharmaceuticals (now Novartis), where his responsibilities included the establishment of external collaborations and the development of corporate alliances within the United States and Europe. Dr. McMahon has contributed to more than 100 scientific publications and was a Staff Scientist and Principal Investigator at the Massachusetts Institute of Technology and Tufts University School of Medicine early in his career. He holds a B.S. in Biology and a PhD in Biochemistry from Rensselaer Polytechnic Institute.

Ronald A. Martell was appointed President and Chief Operating Officer in May 2007. He initially joined the Company's board of directors in June 2006. Mr. Martell served as Senior Vice President, Commercial Operation of ImClone Systems Incorporated from January 2004 to August 2006. While at ImClone, Mr. Martell was responsible for overseeing the company's sales, marketing, and project and alliance management. Mr. Martell joined ImClone in November 1998 as Vice President, Marketing. From 1988 to 1998, he served in a variety of positions at Genentech, Inc., most recently as Group Manager, Oncology Products.

Robert L. De Jager, M.D. was appointed Chief Medical Officer in February 2008. Prior to joining the Company, Dr. De Jager served as Senior Vice President, Clinical Development and Chief Medical Officer of Kosan Biosciences Incorporated, a publicly held life biotechnology company, from November 2006 until November 2007. From November 2004 to May 2006, he served as Chief Medical Officer and Vice President, Clinical Research and Development at Conforma Therapeutics Corporation, a biotechnology company acquired by Biogen Idec Inc., and Senior Director, Oncology Research & Development of Biogen Idec from May 2006 to November 2006. From 2001 to November 2004, Dr. De Jager served as Vice President, Research & Development, Oncology and Internal Medicine at Daiichi Pharmaceutical Corporation and previously served as its Executive Director, Research and Development, Oncology and Senior Director, Research and Development, Oncology. Prior to joining Daiichi Pharmaceutical Corporation, Dr. De Jager served in various positions at Rgene Therapeutics, Inc., PerImmune, Inc. (formerly Akzo-Organon Teknika/Biotechnology Research Institute), and Sanofi Research. Dr. De Jager has been a principal investigator and served on committees of many cancer organizations, including the European Organization for Research and Treatment of Cancer (EORTC), the Southeastern Cancer Study Group and the Eastern Cooperative Oncology Group. He earned his M.D. degree and his B.S. degree in premedical sciences from the Free University of Brussels in Belgium, and did postdoctoral training at Lenox Hill Hospital (internship), the Mayo Clinic (residency in internal medicine) and Memorial Sloan-Kettering Cancer Center (fellowship in medical oncology and clinical pharmacology).

Gregory L. Weaver was appointed Chief Financial Officer and Senior Vice President, Finance in February 2009. Prior to joining Poniard, Mr. Weaver served as Chief Financial Officer of Talyst Inc., a privately-held pharmacy automation information technology company, from April 2007 to December 2008. Prior to that, he served as Senior Vice President and Chief Financial Officer of Sirna Therapeutics, a public RNAi therapeutics company from February 2006 until sale of the company to Merck, Inc. in December 2006. From April 2002 to September 2005, Mr. Weaver was Chief Financial Officer of Natestch Pharmaceuticals, a public drug delivery company. From April 1999 to April 2002, Mr. Weaver was Chief Financial Officer of Ilex Oncology, Inc., a public cancer drug development company, and from 1996 to 1998, he was Chief Financial Officer of Prism Technologies, a private medical device manufacturer. In addition, Mr. Weaver held increasingly senior positions with Fidelity Capital in Boston and Arthur Andersen LLP. Mr. Weaver has served as a director and the chairman of the audit committee of Celsion Corp., a public oncology drug development company, since 2005, and as a director and the chairman of the audit committee of SCOLR Pharmaceuticals, a public drug delivery company, since 2007. Mr. Weaver is a certified public accountant and received his M.B.A. in finance from Boston College and his B.S. in accounting from Trinity University.

Corporate Background

We are a Washington corporation that was originally incorporated as NeoRx Corporation in 1984. We changed our name to Poniard Pharmaceuticals, Inc. in June 2006 and relocated our corporate headquarters from Seattle, WA to South San Francisco, CA in September 2006. Our principal executive office and mailing address is 7000 Shoreline Court, Suite 270, South San Francisco, California 94080, and our telephone number is (650) 583-3774.

WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and current reports, as well as registration and proxy statements and other information, with the SEC. These documents may be read and copied at the SEC's public reference rooms in Washington, DC, New York, NY and Chicago, IL. Please call the SEC at 1-800-SEC-0330 for further information on the public reference rooms. Our SEC filings also are available to the public at the Internet web site maintained by the SEC at www.sec.gov. Our reports filed with the SEC after January 1, 2003, also are available on our web site, www.poniard.com. The information contained in our web site does not constitute part of, nor is it incorporated by reference into, this report. We will provide paper copies of our SEC filings free of charge upon request.

Item 1A. RISK FACTORS

Investing in our common stock or other securities involves a high degree of risk. You should carefully read the risks and uncertainties described below and all information contained in this report before you decide to purchase our common stock. If any of the possible adverse events described below actually occurs, we may be unable to conduct our business as currently planned and our financial and operating results could be harmed. In addition, the trading price of our common stock could decline due to the occurrence of any of these risks and you may lose all or part of your investment. Please see “Important Information Regarding Forward-Looking Statements” at the beginning of this report.

Risks Related to Our Business

We have a history of operating losses, we expect to continue to incur losses, and we may never become profitable.

We have not been profitable since our formation in 1984. As of December 31, 2008, we had an accumulated deficit of \$362.3 million. Our net loss for the year ended December 31, 2008 was \$48.6 million. We had net losses of \$32.8 million for the year ended December 31, 2007 and \$23.3 million for the year ended December 31, 2006. These losses resulted principally from costs incurred in our research and development programs and from our general and administrative activities. To date, we have been engaged only in research and development activities and have not generated any significant revenue from product sales. We do not anticipate that our picoplatin product candidate will be commercially available before 2010, if at all. We expect to incur additional operating losses in the future. These losses may increase significantly as we expand our clinical trials and increase our research and development activities and seek to commercialize picoplatin or any future product candidates.

Our ability to achieve long-term profitability is dependent upon achieving successful results in clinical trials and obtaining regulatory approvals for our picoplatin product candidate and successfully commercializing our products alone or with third parties.

We will need to raise additional capital to develop and commercialize our product candidates and fund operations, and our future access to capital is uncertain and additional financing may have dilutive or adverse effects on our shareholders.

Considering our projected operating results, we believe that our current cash, cash equivalent and investment securities balances will provide adequate resources to fund operations at least into the first quarter of 2010. However, given the uncertainties of outcomes of the Company’s ongoing clinical trials, there is no assurance that the Company can achieve its projected operating results. Thereafter, unless we raise additional funds, we will be in default of the minimum unrestricted cash requirement and potentially other provisions of the amended and restated loan agreement with GE Healthcare Financial Services and Silicon Valley Bank, as described in the risk factor below. Our consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States, assuming that we will continue as a going concern and do not include any adjustments that might result from the outcome of this uncertainty. The report of our independent registered public accountants issued in connection with our annual report on Form 10-K for the year ended December 31, 2008 contains a statement expressing substantial doubt regarding our ability to continue as a going concern.

It is expensive to develop cancer therapy products and conduct clinical trials for these products. We have not generated revenue from the commercialization of any product, and we expect to continue to incur substantial net operating losses and negative cash flows from operations for the foreseeable future. We will require substantial additional funding to develop and commercialize picoplatin and to fund our future operations.

Management is continuously exploring financing alternatives, including:

- raising additional capital through the public or private sale of equity or debt securities or through the establishment of credit or other funding facilities; and
- entering into strategic collaborations, which may include joint ventures or partnerships for product development and commercialization, merger, sale of assets or other similar transactions.

We may not be able to obtain the required additional capital or enter into relationships with corporate partners on a timely basis, on favorable terms, or at all. Conditions in the capital markets in general, and in the life science capital market specifically, may affect our potential financing sources and opportunities for strategic partnering. Uncertainty about current global conditions and the current financial turmoil affecting capital and credit markets may make it particularly difficult for us to obtain capital market financing or credit on favorable terms, if at all, or to attract potential strategic partners.

If we raise additional funds by issuing common stock or securities convertible into or exercisable for common stock, our shareholders may experience substantial dilution, and new investors could have rights superior to current security holders. If we are unable to obtain sufficient additional cash when needed, we may be forced to reduce expenses through the delay, reduction or curtailment of our picoplatin development and commercialization activities or through other cost-savings measures, including the sale of our company or sale of our assets.

The amount of additional financing we will require in the future will depend on a number of factors, including:

- the costs of performing our obligations under our loan facility with GE Healthcare Financial Services and Silicon Valley Bank, including the cost of interest and other payment obligations and penalties and the cost of complying with the covenants and restrictions under the amended and restated loan agreement.
- the scope and timing of our picoplatin clinical program and commercialization efforts, including the progress and costs of our ongoing Phase III trial of picoplatin in small cell lung cancer, our ongoing Phase II trials in colorectal and prostate cancers, as well as our ongoing Phase I trial of picoplatin (oral formulation) in solid tumors;
- our ability to obtain clinical supplies of picoplatin active pharmaceutical ingredient, or API, and finished drug product in a timely and cost effective manner;
- actions taken by the FDA and other regulatory authorities;
- the timing and amount of any milestone or other payments we might receive from or be obligated to pay to potential strategic partners;
- our degree of success in commercializing picoplatin;
- the emergence of competing technologies and products, and other adverse market developments;
- the acquisition or in-licensing of other products or intellectual property;
- the costs of any research collaborations or strategic partnerships established; and
- the costs of preparing, filing, prosecuting, maintaining and enforcing patent claims and other intellectual property rights.

Restrictions imposed under the terms of our current loan facility may limit our ability to utilize capital for operations and may limit our ability to raise capital through the sale of assets or a merger not approved by the lenders.

On September 2, 2008, we entered into an amended and restated loan and security agreement, with GE Healthcare Financial Services and Silicon Valley Bank in the principal amount of \$27.6 million. The loan agreement, the terms of which are described in detail under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources,” contains restrictions on our ability, without the prior consent of the lenders, to:

- dispose of certain assets,
- engage in certain mergers and acquisition transactions,
- incur indebtedness,
- create liens on assets,
- make investments,
- pay dividends, and
- repurchase stock.

The loan agreement also contains covenants requiring us to maintain a minimum amount of unrestricted cash during the term of the loan equal to the lesser of (i) \$17.9 million or (ii) the outstanding aggregate principal balance of the term loans plus \$4 million. This minimum unrestricted cash requirement may limit our ability to utilize a portion of our cash in 2009 to pay for operating costs and to pursue our clinical and commercial strategies.

The loan agreement contains events of default that include:

- nonpayment of principal, interest or fees,
- breaches of covenants,
- material adverse changes,
- bankruptcy and insolvency events,
- cross defaults to any other indebtedness,
- material judgments,
- inaccuracy of representations and warranties, and
- events constituting a change of control.

The loan agreement limits our ability to dispose of certain assets, engage in certain mergers, incur certain indebtedness, make certain distributions or engage in certain investment activities without the prior consent of the lenders. Additionally, the minimum unrestricted cash requirement under the loan agreement prohibits us from utilizing a significant portion of our cash (\$17.9 million in 2009) to pay for operating costs and to pursue our clinical and commercial strategies. We have no assurance that, especially in light of the distressed economic environment, that the lenders will be willing to waive or renegotiate the terms of the loan agreement to address or avoid financial or other loan defaults.

Presently, taking into account the minimum unrestricted cash requirement under the loan agreement and our projected operating results, we believe that our current cash, cash equivalent and investment securities balances will provide adequate resources to fund operations at least into the first quarter of 2010. However, given the uncertainties of outcomes of the Company’s ongoing clinical trials,

there is no assurance that the Company can achieve its projected operating results. Thereafter, unless we raise additional funds, we will be in default of the minimum unrestricted cash requirement and potentially other provisions of the loan agreement. The occurrence of an event of default would increase the applicable rate of interest by 5% and could result in the acceleration of our payment obligations under the loan agreement. If an event of default were to occur, we might not have sufficient funds to repay the loan or to fund our continuing operations. In such case, we would need to delay, scale back or eliminate some or all of our picoplatin trials and commercialization efforts; reduce our workforce, license our picoplatin product candidates for development and commercialization by third parties; attempt to sell the company, cease operations or declare bankruptcy. We have no assurance that we can obtain financing or otherwise raise additional funds, if at all, on terms acceptable to us or to our lenders.

Our potential products must undergo rigorous clinical testing and regulatory approvals, which are costly and time consuming, and may subject us to unanticipated delays or prevent us from marketing any products.

The manufacture and marketing of our picoplatin product candidate and our research and development activities are subject to regulation for safety, efficacy and quality by the FDA in the United States and by comparable regulatory authorities in foreign countries.

The process of obtaining FDA and other required regulatory approvals, including any foreign approvals, is expensive, often takes many years and can vary substantially depending on the type, complexity and novelty of the products involved. We will not be able to commercialize picoplatin until we obtain regulatory approvals, and consequently any delay in obtaining, or our inability to obtain, regulatory approvals could materially adversely affect our business. We have had only limited experience in filing and pursuing applications necessary to gain regulatory approvals. This may impede our ability to obtain timely approvals from the FDA or foreign regulatory agencies.

If we violate regulatory requirements at any stage, whether before or after marketing approval is obtained, we may be fined, forced to remove a product from the market or experience other adverse consequences, including delay of the approval of our marketing applications, which would materially harm our business and financial results. Additionally, we may not be able to obtain the labeling claims necessary or desirable for product promotion and could be required to conduct post-marketing studies on the safety or effectiveness of our products. If we or other parties identify serious side effects after any of our products are on the market, or if manufacturing or regulatory problems occur, regulatory approval may be withdrawn and reformulation of our products, additional clinical trials, changes in labeling of our products, and/or additional marketing applications may be required.

The requirements governing the conduct of clinical trials and manufacturing and marketing of our proposed products outside the United States vary widely from country to country. Foreign approvals may take longer to obtain than FDA approvals and can involve additional testing. Foreign regulatory approval processes include all of the risks associated with the FDA approval processes. Also, approval of a product by the FDA does not ensure approval of the same product by the health authorities of other countries.

We may take longer to complete our clinical trials than we project, or we may be unable to complete them at all.

In April 2007, we initiated an international, multi-center randomized Phase III SPEAR (Study of Picoplatin Efficacy After Relapse) pivotal trial of picoplatin in small cell lung cancer. The Phase III trial, which is being conducted pursuant to an SPA with the FDA, is designed to compare the efficacy and safety of picoplatin plus best supportive care with best supportive care alone as a second-line therapy. The study is designed to enroll approximately 400 patients with small cell lung cancer whose

disease did not respond to a first-line platinum-containing (cisplatin or carboplatin) chemotherapy regimen or whose disease responded initially to first-line platinum-containing therapy, but then progressed within six months after completion of treatment. Patients are being randomized on a 2:1 ratio to receive picoplatin plus best supportive care or best supportive care alone. The primary endpoint of the study is improved overall survival, as measured in time from randomization to death. Secondary endpoints include response rates, disease control, duration of response and progression-free survival.

We currently anticipate completing patient enrollment and commencing the rolling submission of an NDA with the FDA in 2009. The rolling submission process enables companies that have been granted Fast Track designation to submit sections of the NDA for FDA review as they become available. The actual timing for completion of patient enrollment and the commencement of the rolling NDA process, however, will depend on the rate of patient enrollment, survival times of all patients in the trial, as well as other factors, such as patient performance status and extent of disease. We currently anticipate completing the rolling NDA submission and, subject to FDA approval, initiating the commercialization of picoplatin during 2010. FDA approval of picoplatin will depend on a variety of factors, including whether the FDA determines that the data from our completed Phase III clinical trial is sufficient to support approval. Additionally, the timing of the completion of the rolling NDA submission and any commercialization of picoplatin will be affected by our ability to obtain a corporate partner or otherwise obtain additional funding to support these activities.

We also are conducting separate Phase I/II studies of picoplatin in the first-line treatment of patients with metastatic colorectal cancer and hormone-refractory prostate cancer (also known as “castration-resistant prostate cancer”). The Phase I/II colorectal cancer study is designed to determine the safety and efficacy of picoplatin substituted for oxaliplatin in the FOLFOX regimen (combination of chemotherapy agents 5-fluorouracil, leucovorin and oxaliplatin) to treat patients newly diagnosed with metastatic colorectal cancer. Our Phase I/II prostate cancer study is designed to determine the safety and efficacy of picoplatin when combined with the chemotherapy agent docetaxel and prednisone in the treatment of patients with hormone-refractory prostate cancer. Endpoints of these studies include safety, response, time to progression, progression-free survival and overall survival. The Phase I/II prostate and colorectal cancer trials both have completed enrollment. We also are conducting an ongoing Phase I study of an oral formulation of picoplatin in advanced solid tumors.

The actual times for initiation and completion of our current or any future picoplatin clinical trials depend upon numerous factors, including:

- our ability to obtain adequate additional funding or enter into strategic partnerships;
- approvals and other actions by the FDA and other regulatory agencies and the timing thereof;
- our ability to open clinical sites;
- our ability to recruit and enroll qualified patients into our studies;
- our ability to obtain sufficient, reliable and affordable supplies of the picoplatin API and finished drug product;
- the extent of competing trials at the clinical institutions where we conduct our trials;
- reaching agreement on acceptable terms with prospective clinical research organizations, or CROs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining institutional review board, or IRB, approval to conduct a clinical trial at a prospective site;

- our ability to assure that clinical trials are conducted in accordance with regulatory requirements or our clinical protocols;
- results of inspections of the clinical trial operations or trial sites by the FDA or other regulatory authorities, including the risk of the imposition of a clinical hold;
- unforeseen safety and efficacy issues;
- the extent of scheduling conflicts with participating clinicians and clinical institutions; and
- the identified endpoints of the studies, the extent of patient disease and patient performance status.

We may not initiate, advance or complete our picoplatin clinical studies as projected or achieve successful results.

We rely on academic institutions and CROs to conduct, supervise or monitor some or all aspects of clinical trials involving picoplatin. Further, to the extent that we now or in the future participate in collaborative arrangements in connection with the development and commercialization of our proposed products, we will have less control over the timing, planning and other aspects of our clinical trials. If we fail to initiate, advance or complete, or experience delays in or are forced to curtail our current or any future clinical trials, our stock price and our ability to conduct our business could be materially negatively affected.

If testing of a particular product does not yield positive results, we will be unable to commercialize that product.

Our research and development programs are designed to test the safety and efficacy of our proposed products in humans through extensive preclinical and clinical testing. We may experience numerous unforeseen events during, or as a result of, the testing process that could delay or prevent commercialization of picoplatin, including the following:

- the safety and efficacy results obtained in early human clinical trials may not be indicative of results obtained in later clinical trials;
- the results of preclinical studies may be inconclusive, or they may not be indicative of results that will be obtained in human clinical trials;
- after reviewing test results, we or any potential collaborators may abandon projects that we previously believed were promising;
- we, our potential collaborators or regulators may suspend or terminate clinical trials if the participating subjects or patients are being exposed to unacceptable health risks; and
- the effects of our potential products may not be the desired effects or may include undesirable side effects or other characteristics that preclude regulatory approval or limit their commercial use if approved.

Clinical testing is very expensive, can take many years, and the outcome is uncertain. The data that we may collect from our picoplatin clinical trials may not be sufficient to support regulatory approval of our proposed picoplatin product. The clinical trials of picoplatin may not be initiated or completed as planned and the FDA or foreign regulatory agencies may not ultimately approve any of our product candidates for commercial sale. Our failure to adequately demonstrate the safety and efficacy of picoplatin would delay or prevent regulatory approvals, which would prevent us from marketing the product.

Success in early clinical trials may not be indicative of results obtained in later trials.

Results of early preclinical and clinical trials are based on a limited number of patients and may, upon review, be revised or negated by authorities or by later stage clinical results. Historically, the results from preclinical testing and early clinical trials often have not been predictive of results obtained in later clinical trials. A number of new drugs and therapeutics have shown promising results in initial clinical trials, but subsequently failed to establish sufficient safety and effectiveness data to obtain necessary regulatory approvals. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval.

If we cannot negotiate and maintain licenses or collaborative arrangements with third parties, our development, manufacturing, sales and marketing activities may not be cost-effective or successful.

Our success will depend in significant part on our ability to attract and maintain collaborative partners and strategic relationships to support the development, manufacture, sale, marketing and distribution of picoplatin.

We have entered into an exclusive worldwide license, as amended, with Genzyme Corporation (successor to AnorMED, Inc.) for the development and commercial sale of picoplatin. Under that license, we are solely responsible for the development and commercialization of picoplatin. Genzyme retains the right, at our cost, to prosecute its patent applications and maintain all licensed patents. The parties executed the license agreement in April 2004, at which time we paid a one-time upfront payment of \$1.0 million in common stock and \$1.0 million in cash. The original agreement excluded Japan from the licensed territory and provided for \$13.0 million in development and commercialization milestones, payable in cash or a combination of cash and common stock, and a royalty rate of up to 15% on product net sales after regulatory approval. The parties amended the license agreement on September 18, 2006, modifying several key financial terms and expanding the licensed territory to include Japan, thereby providing us worldwide rights. In consideration of the amendment, we paid Genzyme \$5.0 million in cash on October 12, 2006 and an additional \$5.0 million in cash on March 30, 2007. The amendment eliminated all development milestone payments to Genzyme. Genzyme remains entitled to receive up to \$5.0 million in commercialization milestones upon the attainment of certain levels of annual net sales of picoplatin after regulatory approval. The amendment also reduced the royalty payable to Genzyme to a maximum of 9% of annual net product sales and eliminated sharing of sublicense revenues with Genzyme. We began dosing patients in the second quarter of 2007 in our single pivotal Phase III SPEAR trial under our approved SPA. We currently anticipate completing patient enrollment and commencing the rolling submission of an NDA with the FDA in 2009. We have targeted 2010 for completion of the NDA submission and, subject to FDA approval, initiation of commercial sales. However, we cannot currently predict the actual timing for completion of patient enrollment, the length of time to regulatory approval, if any, or the extent of annual sales, if any, of picoplatin and, therefore, cannot predict when or if the milestone and royalty payments under our license agreement with Genzyme may be triggered.

The license agreement may be terminated by either party for breach, or if the other party files a petition in bankruptcy or insolvency or for reorganization or is dissolved, liquidated or makes assignment for the benefit of creditors. We can terminate the license at any time upon prior written notice to Genzyme. If not earlier terminated, the license agreement will continue in effect, in each country in the territory in which the licensed product is sold or manufactured, until the earlier of (i) expiration of the last valid claim of a pending or issued patent covering the licensed product in that country or (ii) a specified number of years after first commercial sale of the licensed product in that country. If Genzyme were to breach its obligations under the license, or if the license expires or is terminated and we cannot renew, replace, extend or preserve our rights under the license agreement, we would be unable to move forward with our picoplatin clinical studies and commercialization efforts.

On August 4, 2005, we entered into a research funding and option agreement with The Scripps Research Institute, or TSRI. Under the agreement, as amended, we provided TSRI an aggregate of

\$2.5 million over a 30-month period to fund research relating to synthesis and evaluation of novel small molecule, multi-targeted protein kinase inhibitors as therapeutic agents, including the treatment of cancer. We paid TSRI total funding payments of approximately \$0.1 million in 2005, \$1.0 million in 2006 and \$1.4 million in 2007, all of which were charged to R&D expense. The amended agreement expired December 31, 2007. In connection with our option under the amended agreement to negotiate a worldwide exclusive license (including the rights to sublicense) to develop and commercialize any compounds arising from the collaboration, we executed a follow-on agreement to license compounds that were discovered by TSRI, including classes of protein kinase inhibitors for the treatment of human diseases, including cancer. Kinases regulate signaling networks and thereby control cellular properties such as proliferation, invasion, survival and differentiation. We have no assurance that the research funded under this arrangement, or any compounds arising from the collaboration, will be successful or ultimately will give rise to any viable product candidates.

We are dependent on third-party suppliers for the timely delivery of materials and services and may experience future interruptions in supply.

For our picoplatin product candidate to be successful, we need sufficient, reliable and affordable supplies of the picoplatin API and finished drug product. Sources of these supplies may be limited, and third-party suppliers may be unable to manufacture picoplatin API and finished drug product in amounts and at prices necessary for successful commercialization. Moreover, third-party manufacturers must continuously adhere to current Good Manufacturing Practice, or cGMP, regulations enforced by the FDA through its facilities inspection program. If the facilities of these manufacturers cannot pass a Pre-Approval Inspection, the FDA will not approve the NDA for our proposed products. In complying with cGMP and foreign regulatory requirements, any of our third-party manufacturers will be obligated to expend time, money and effort in production, record-keeping and quality control to assure that our products meet applicable specifications and other requirements. If any of our third-party manufacturers or suppliers fails to comply with these requirements, we may be subject to regulatory action.

We have limited experience in drug formulation or manufacturing, and we lack the resources and capability to manufacture picoplatin on a clinical or commercial scale. As a result, we rely on third parties to manufacture picoplatin API and finished drug product for our clinical trials and for our planned commercialization activities. The finished drug product has been demonstrated to be stable for up to 30 months from the date of manufacture, and we believe that we currently have adequate supplies of picoplatin API and finished drug product to complete our current clinical trials.

We currently have separate agreements with one supplier each of picoplatin API and finished drug product for clinical and commercial use. Manufacturing services are provided on a purchase order, fixed-fee basis pursuant to separate clinical and commercial API and finished drug product supply agreements. Our API clinical supply agreement continues in effect until it is terminated by mutual agreement of the parties or by either party in accordance with its terms. Our finished drug product clinical supply agreement runs for an initial term ending December 31, 2009, and is subject to renewal for two additional one-year terms, at our option. Our commercial API and finished drug supply agreements have initial terms ending in late 2013. Additional information about these agreements, including the termination rights of the parties, can be found in the discussion entitled "Picoplatin Source of Supply" in Section 1 above.

We have no assurance that our current suppliers will be able to continue to manufacture sufficient picoplatin API and finished drug product on a timely or cost-effective basis at all times in the future. The recent tightening of global credit may increase the risk of disruptions or delays of performance by our third party manufacturers and other contractors. We believe that there are other contract manufacturers with the capacity to manufacture picoplatin API and finished drug product. However, if we are required to seek out alternative manufacturers, we may incur significant additional costs and suffer delays in, or be prevented from, subject to FDA approval, initiating commercial sales of picoplatin.

We also rely on third-party contractors to perform for us, or assist us with, the set-up, conduct, support and management of our clinical studies. Because these contractors provide specialized services, their activities and quality of performance may be outside our direct control. If these contractors do not perform their contractual duties or obligations, do not meet expected deadlines, or need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical trial protocols or for any other reasons, we may need to enter into new arrangements with alternative third parties. If any of these circumstances were to occur, our clinical trials may be extended, delayed or terminated or may need to be repeated, we may not be able to obtain regulatory approval for or commercialize picoplatin or the product candidate being tested in such trials, and we may be subject to regulatory action.

We currently have no sales and marketing staff or distribution organization. If we are unable to develop sales, marketing and distribution capabilities on our own or through collaborations with corporate partners, we may not be successful in commercializing our future products.

We have limited experience in selling, marketing or distributing therapeutic drug products. To the extent we are successful in obtaining approval for the commercial sale of picoplatin, we will need to secure one or more corporate partners to conduct these activities. We may not be able to enter into partnering arrangements in a timely manner, on terms acceptable to us, or at all. To the extent that we enter into co-promotion or other licensing arrangements, our net product revenues are likely to be lower than if we directly marketed and sold our products, and any revenues we receive would depend upon the efforts of third parties, which efforts may not be successful. If we are not able to secure adequate partnering arrangements, we would have to hire additional employees or consultants with expertise in sales, marketing and distribution. Employees with relevant skills may not be available to us. Additionally, any increase in the number of employees would increase our expense level and could have a material adverse effect on our financial position. If we are not successful in commercializing picoplatin, either on our own or through collaborations with one or more parties, our future product revenue would suffer and we would incur significant additional losses.

We face substantial competition in the development of cancer therapies and may not be able to compete successfully, and our potential products may be rendered obsolete by rapid technological change.

The competition for development of cancer therapies is substantial. There is intense competition from biotechnology and pharmaceutical companies, as well as academic research institutions, clinical reference laboratories and government agencies that are pursuing research and development activities similar to ours in the United States and abroad. Our initial focus for picoplatin is small cell lung cancer, the most aggressive and deadly form of lung cancer. Although platinum therapies are the preferred treatment, no FDA-approved therapies are available for patients with platinum-refractory or -resistant disease. If approved, picoplatin will be competing with existing treatment regimens, as well as emerging therapies for small cell lung cancer and other platinum-based therapeutics. Large pharmaceutical/biotechnology companies, including Abbott, Amgen, AstraZeneca, Baxter Healthcare, Bristol-Myers Squibb Company, Celgene Corporation, Dainippon Sumitomo Pharma Co. Ltd., Eli Lilly and Company, Genentech, Inc., GlaxoSmithKline PLC, Merck & Co., Nippon Kayaku Co. Ltd., Novartis AG, Pfizer Inc., OSI Pharmaceuticals, Sanofi-Aventis Group, Shionogi & Co. Ltd. and SK Pharma, are marketing and/or developing therapeutics in late-stage clinical trials for the treatment of small cell lung cancer or platinum agents for the treatment of cancer. Multiple biotechnology companies are engaged in clinical trials for the treatment of small cell lung cancer and other platinum-based therapeutics, including Abraxis BioScience Inc., Access Pharmaceuticals Inc., Antigenics, Inc., Ascenta Therapeutics, Gemin X, GPC Biotech AG (whose merger with Agennix was announced in February 2009), ImmunoGen, Inc., Ipsen Group, Keryx Biopharmaceuticals Inc., Meabco A/S, MolMed S.p.A., Onyx Pharmaceuticals Inc., PharmaMar (Zeltia Group), Proacta, Inc., Regulon, Inc., Schering-Plough, Simcere Pharmaceuticals, Sunesis Pharmaceuticals Inc., Theradex, Transave Inc.,

Vertex Pharmaceuticals and Vion Pharmaceuticals Inc. As we expand the utility of picoplatin into other oncology indications such as prostate and colon cancers, we will be facing additional competition from major pharmaceutical companies, biotechnology companies, research institutions and government agencies. We cannot assure you that we will be able to effectively compete with these or future third party product development programs.

Many of our existing or potential competitors have, or have access to, substantially greater financial, research and development, marketing and production resources than we do and may be better equipped than we are to develop, manufacture and market competing products. Further, our competitors may have, or may develop and introduce, new products that would render our picoplatin product candidates less competitive, uneconomical or obsolete.

Even if any of our drug candidates receives regulatory approval, our drug candidates will still be subject to extensive post-marketing regulation.

If we or our collaborators receive regulatory approval for our drug candidates, we will also be subject to ongoing FDA obligations and continued regulatory review, such as cGMP regulations and continued adverse event reporting requirements. We may also be subject to additional FDA post-marketing obligations, all of which may result in significant expense and limit our ability to commercialize such drugs.

If any of our drug candidates receive U.S. regulatory approval, the FDA may still impose significant restrictions on the indicated uses for which such drugs may be marketed or impose ongoing requirements for potentially costly post-approval studies. In addition, regulatory agencies subject a drug, its manufacturer and the manufacturer's facilities to continual review and inspections. The subsequent discovery of previously unknown problems with a drug, including adverse events of unanticipated severity or frequency, or problems with the facility where the drug is manufactured, may result in restrictions on the marketing of that drug, up to and including withdrawal of the drug from the market. Failure to comply with applicable regulatory requirements may result in:

- issuance of warning letters by the FDA;
- imposition of fines and other civil penalties;
- criminal prosecution;
- injunction, suspension or revocation of marketing approvals;
- suspension of any ongoing clinical trials;
- suspension of manufacturing;
- delays in commercialization;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or our collaborators;
- bans on the import or export of the drugs to or from the United States;
- restrictions on operations, including costly new manufacturing requirements; and
- product recalls or seizures.

The FDA's policies may change and additional government regulations may be enacted that could prevent or delay regulatory approval of picoplatin or further restrict or regulate post-approval activities. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to maintain regulatory compliance, we might not be permitted to market picoplatin and our business could suffer.

If we are unable to protect our proprietary rights, we may not be able to compete effectively, or operate profitably.

Our success is dependent in part on obtaining, maintaining and enforcing our patents and other proprietary rights and our ability to avoid infringing the proprietary rights of others. The United States Patent and Trademark Office, or the USPTO, may not issue patents from the patent applications owned by or licensed to us. If issued, the patents may not give us an advantage over competitors with similar technologies. The issuance of a patent is not conclusive as to its validity or enforceability and it is uncertain how much protection, if any, will be given to our patents if we attempt to enforce them and they are challenged in court or in other proceedings, such as oppositions, which may be brought in foreign jurisdictions to challenge the validity of a patent. A third party may challenge the validity or enforceability of a patent after its issuance by the USPTO. It is possible that a competitor may successfully challenge our patents or that a challenge will result in limiting their coverage. Moreover, the cost of litigation to uphold the validity of patents and to prevent infringement can be substantial. If the outcome of litigation is adverse to us, third parties may be able to use our patented invention without payment to us. Moreover, it is possible that competitors may infringe our patents or successfully avoid them through design innovation. We may need to file lawsuits to stop these activities. These lawsuits can be expensive and would consume time and other resources, even if we were successful in stopping the violation of our patent rights. In addition, there is a risk that a court would decide that our patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of our patents was upheld, a court would refuse to stop the other party on the ground that its activities do not infringe our patents. The protection afforded by issued patents is limited in duration. With respect to picoplatin, in the United States we expect to rely primarily on US Patent Number 5,665,771 (expiring February 7, 2016), which is licensed to us by Genzyme, and additional licensed patents expiring in 2016 covering picoplatin in Europe and other countries. The FDA has designated picoplatin as an orphan drug for the treatment of small cell lung cancer under the provisions of the Orphan Drug Act, which entitles us to exclusive marketing rights for picoplatin in the United States for seven years following market approval. If approved, we may also be able to extend the term of a U.S. patent covering picoplatin under the Hatch-Waxman Act, which Act permits the extension of the term of a United States Patent on a new drug for up to a maximum of five years. In addition, the European Commission has designated picoplatin as an orphan medicinal product for the treatment of small cell lung cancer in the European Union, which entitles us to exclusive marketing rights for picoplatin in the European Union for ten years following market approval in the European Union. Additional potential avenues exist which may supplement patent protection and exclusivity for picoplatin in Europe.

Under our license agreement with Genzyme, Genzyme retains the right to prosecute its patent applications and maintain all licensed patents, with us reimbursing such expenses. We have the right to sue any third party infringers of the picoplatin patents. If we do not file suit, Genzyme, in its sole discretion, has the right to sue the infringer at its expense. U.S. Patent 5,665,771 is co-owned by Genzyme and a third party, which has exclusively licensed its rights to the patent to Genzyme (as successor to AnorMED, Inc.).

In addition to the intellectual property rights described above, we rely on unpatented technology, trade secrets and confidential information. Therefore, others may independently develop substantially equivalent information and techniques or otherwise gain access to or disclose our technology. We may not be able to effectively protect our rights in unpatented technology, trade secrets and confidential information. We require each of our employees, consultants and advisors to execute a confidentiality agreement at the commencement of an employment or consulting relationship with us. However, these agreements may not provide effective protection of our information or, in the event of unauthorized use or disclosure, may not provide adequate remedies.

The use of our technologies could potentially conflict with the rights of others.

Our competitors or others may have or may acquire patent rights that they could enforce against us. In such case, we may be required to alter our products, pay licensing fees or cease activities. If our products conflict with patent rights of others, third parties could bring legal actions against us claiming damages and seeking to enjoin manufacturing and marketing of the affected products. If these legal actions are successful, in addition to any potential liability for damages, we could be required to obtain a license in order to continue to manufacture or market the affected products. We may not prevail in any legal action and a required license under the patent may not be available on acceptable terms.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights.

The cost to us of any litigation or other proceedings relating to intellectual property rights, even if resolved in our favor, could be substantial. Some of our competitors may be better able to sustain the costs of complex patent litigation because they have substantially greater resources. If there is litigation against us, we may not be able to continue our operations. If third parties file patent applications, or are issued patents claiming technology also claimed by us in pending applications, we may be required to participate in interference proceedings in the USPTO to determine priority of invention. We may be required to participate in interference proceedings involving our issued patents and pending applications. We may be required to cease using the technology or license rights from prevailing third parties as a result of an unfavorable outcome in an interference proceeding. A prevailing party in that case may not offer us a license on commercially acceptable terms.

Product liability claims in excess of the amount of our insurance would adversely affect our financial condition.

The testing, manufacture, marketing and sale of picoplatin and any other proposed cancer therapy products, including past clinical and manufacturing activities in connection with our terminated skeletal targeted radiotherapy, or STR, development program, may subject us to product liability claims. We are insured against such risks up to a \$10.0 million annual aggregate limit in connection with clinical trials of our products under development and intend to obtain product liability coverage in the future. However, insurance coverage may not be available to us at an acceptable cost. We may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise. Regardless of merit or eventual outcome, product liability claims may result in decreased demand for a product, injury to our reputation, withdrawal of clinical trial volunteers and loss of revenues. As a result, regardless of whether we are insured, a product liability claim or product recall may result in losses that could be material.

Our past use of radioactive and other hazardous materials exposes us to the risk of material environmental liabilities, and we may incur significant additional costs to comply with environmental laws in the future.

Our past research and development and manufacturing processes, as well as the manufacturing processes that may have been used by our collaborators, involved the controlled use of hazardous and radioactive materials. As a result, we are subject to foreign, federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain materials and wastes in connection with our use of these materials. Although we believe that our safety procedures for handling and disposing of such materials complied with the standards prescribed by such laws and regulations, we may be required to incur significant costs to comply with environmental and health and safety regulations in the future. We terminated our STR manufacturing operations in Denton, Texas in May 2005. We recorded costs associated with the closure of the Denton facility of \$0.5 million in 2005 and \$0.3 million in 2006. We completed the sale of the Denton facility on October 1, 2007. Our current insurance does not cover liability for the clean-up of hazardous waste materials or other environmental risks.

Even if we bring products to market, changes in health care reimbursement could adversely affect our ability to effectively price our products or obtain adequate reimbursement for sales of our products.

Potential sales of our products may be affected by the availability of reimbursement from governments or other third parties, such as insurance companies. It is difficult to predict the reimbursement status of newly approved, novel medical products. In addition, third-party payers are increasingly challenging the prices charged for medical products and services. If we succeed in bringing picoplatin to market, we cannot be certain that it will be considered cost-effective and that reimbursement to the consumer will be available or will be sufficient to allow us to competitively or profitably sell this product.

The levels of revenues and profitability of biotechnology companies may be affected by the continuing efforts of government and third-party payers to contain or reduce the costs of health care through various means. For example, in certain foreign markets, pricing or profitability of prescription pharmaceuticals is subject to governmental control. In the United States, there have been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental controls. It is uncertain what legislative proposals will be adopted or what actions federal, state or private payers for health care goods and services may take in response to any health care reform proposals or legislation. Even in the absence of statutory change, market forces are changing the health care sector. We cannot predict the effect health care reforms may have on the development, testing, commercialization and marketability of our picoplatin cancer therapy products. Further, to the extent that such proposals or reforms have a material adverse effect on the business, financial condition and profitability of other companies that are prospective collaborators, our ability to commercialize picoplatin may be adversely affected.

The loss of key employees could adversely affect our operations.

Caroline M. Loewy resigned as our chief financial officer effective November 28, 2008. We did not experience any material disruptions as a consequence of Ms. Loewy's resignation. Gerald McMahon, our chief executive officer, and Ronald A. Martell, our president and chief operating officer, assumed Ms. Loewy's responsibilities while we conducted a search for a new chief financial officer. Gregory L. Weaver was appointed as our chief financial officer effective February 18, 2009.

On November 21, 2008, we terminated David A. Karlin, M.D., our senior vice president of clinical development and regulatory affairs. The termination was based on our determination that we no longer required the services of Dr. Karlin, and we did not experience any material disruptions as a consequence of Dr. Karlin's termination. Dr. Karlin's responsibilities have been assumed by Robert De Jager, our chief medical officer.

As of March 6, 2009, we had a total workforce of 59 full-time employees and 5 part-time employees. In September 2006, we moved our corporate headquarters to newly leased facilities in South San Francisco. We intend to maintain clinical development and support activities and facilities in Seattle and do not have plans to relocate any of our 44 employees currently in Seattle. Our success depends, to a significant extent, on the continued contributions of our principal management and scientific personnel participating in our picoplatin development and commercialization efforts. We have limited or no redundancy of personnel in key development areas, including finance, legal, clinical operations, regulatory affairs, product development, quality control and assurance. The loss of the services of one or more of our employees could delay our picoplatin product development or commercialization activities. We do not maintain key-person life insurance on any of our officers, employees or consultants.

Competition for qualified employees among companies in the biotechnology and biopharmaceutical industry is intense. Our future success depends upon our ability to attract, retain and motivate highly skilled employees and consultants. In order to successfully commercialize picoplatin, we may in the

future be required to substantially expand our workforce, particularly in the areas of business development, sales and marketing. These activities would require the addition of new personnel and the development of additional expertise by existing personnel.

We have change of control agreements and severance agreements with all of our officers and consulting agreements with several of our scientific advisors. Our agreements with our officers provide for “at will” employment, which means that each officer may terminate his or her service with us at any time. In addition, our scientific advisors may terminate their services to us at any time.

Our operations might be interrupted by the occurrence of a natural disaster or other catastrophic event.

Our principal executive offices are in South San Francisco, California and we maintain clinical development and support activities in Seattle, Washington. We depend on our facilities and on our collaborators, contractors and vendors for the continued operation of our business. Natural disasters or other catastrophic events, including terrorist attacks, power interruptions, wildfires and other fires, actions of animal rights activists, earthquakes and wars could disrupt our operations or those of our collaborators, contractors and vendors. Even though we believe we carry commercially reasonable business interruption and liability insurance, and our contractors may carry liability insurance that protect us in certain events, we might suffer losses as a result of business interruptions that exceed the coverage available under our and our contractors’ insurance policies or for which we or our contractors do not have coverage. Any natural disaster or catastrophic event could have a significant negative impact on our operations and financial results. Moreover, any such event could delay our picoplatin clinical program and commercialization efforts.

Risks Relating to Our Securities

Our common stock may be delisted from The Nasdaq Global Market if we are unable to maintain compliance with Nasdaq Global Market continued listing requirements.

Our common stock listing was upgraded to The Nasdaq Global Market on October 1, 2007. Prior to that time, our common stock was listed on the Nasdaq Capital Market. In order to continue to be included in the Nasdaq Global Market, we must meet the Nasdaq Global Market continued listing standards, including maintaining a closing bid price of \$1.00 per share (the Minimum Bid Price Requirement). Our common stock has in the past, and may in the future, fall below the Minimum Bid Price Requirement, or we may in the future fail to meet other requirements for continued listing on the Nasdaq Global Market. If we are unable to cure any events of noncompliance in a timely or effective manner, our common stock could be delisted from The Nasdaq Global Market.

If our common stock were threatened with delisting from The Nasdaq Global Market, we may, depending on the circumstances, seek to extend the period for regaining compliance with Nasdaq listing requirements by moving our common stock to the Nasdaq Capital Market. Failing that, we may seek quotation on a regional stock exchange, if available. Any such change in listing could reduce the market liquidity for our common stock. If our common stock is not eligible for quotation on another market or exchange, trading of our common stock could be conducted in the over-the-counter market on an electronic bulletin board established for unlisted securities such as the Pink Sheets or the OTC Bulletin Board. As a result, an investor would find it more difficult to dispose of, or obtain accurate quotations for the price of, our common stock.

If our common stock were to be delisted from The Nasdaq Stock Market, and our trading price remained below \$5.00 per share, trading in our common stock might also become subject to the requirements of certain rules promulgated under the Securities Exchange Act of 1934, as amended, or the Exchange Act, which require additional disclosure by broker-dealers in connection with any trade involving a stock defined as a “penny stock” (generally, any equity security not listed on a national

securities exchange or quoted on Nasdaq that has a market price of less than \$5.00 per share, subject to certain exceptions). Many brokerage firms are reluctant to recommend low-priced stocks to their clients. Moreover, various regulations and policies restrict the ability of shareholders to borrow against or “margin” low-priced stocks, and declines in the stock price below certain levels may trigger unexpected margin calls. Additionally, because brokers’ commissions on low-priced stocks generally represent a higher percentage of the stock price than commissions on higher priced stocks, the current price of the common stock can result in an individual shareholder paying transaction costs that represent a higher percentage of total share value than would be the case if our share price were higher. This factor may also limit the willingness of institutions to purchase our common stock. Finally, the additional burdens imposed upon broker-dealers by these requirements could discourage broker-dealers from facilitating trades in our common stock, which could severely limit the market liquidity of the stock and the ability of investors to trade our common stock.

Our stock price is volatile and, as a result, you could lose some or all of your investment.

There has been a history of significant volatility in the market prices of securities of biotechnology companies, including our common stock. In 2008, the reported high and low closing sale prices of our common stock were \$6.18 and \$1.40. During 2007 the reported high and low closing sale prices of our common stock were \$8.89 and \$4.09. The reported high and low closing sale prices during the period from January 3, 2006 through September 22, 2006 (the last trading day preceding the effectiveness of our one-for-six reverse stock split) were \$1.57 and \$0.50. The reported high and low closing sale prices during the period from September 25, 2006 through December 31, 2006 (after the effective date of our reverse stock split) were \$7.74 and \$3.00. Our stock price has been and may continue to be affected by this type of market volatility, as well as our own performance. Our business and the relative price of our common stock may be influenced by a large variety of factors, including:

- announcements by us or our competitors concerning acquisitions, strategic alliances, technological innovations, new commercial products or changes in product development strategies;
- the availability of critical materials used in developing our proposed picoplatin product;
- our ability to conduct our picoplatin clinical development program on a timely and cost-effective basis and the progress and results of our clinical trials and those of our competitors;
- developments concerning potential agreements with collaborators;
- the expense and time associated with, and the extent of our ultimate success in, securing regulatory approvals;
- our available cash or other sources of funding; and
- future sales of significant amounts of our common stock by us or our shareholders.

In addition, potential public concern about the safety and efficacy of our proposed picoplatin product and any other products we develop, comments by securities analysts, our ability to maintain the listing of our common stock on the Nasdaq system, and conditions in the capital markets in general and in the life science capital market specifically, may have a significant effect on the market price of our common stock. The realization of any of the risks described in this report, as well as other factors, could have a material adverse impact on the market price of our common stock and may result in a loss of some or all of your investment in our securities.

In the past, securities class action litigation often has been brought against companies following periods of volatility in their stock prices. We may in the future be the target of similar litigation. Securities litigation could result in substantial costs and divert our management’s time and resources, which could cause our business to suffer.

Certain investors beneficially own significant blocks of our common stock; these large shareholders may take actions that are contrary to your interests, including selling their stock.

A small number of our shareholders hold a significant amount of our outstanding stock. As of December 31, 2008, entities affiliated with Bay City Management beneficially owned an aggregate of approximately 15.7% of our outstanding common stock. Two of our directors, Fred B. Craves and Carl S. Goldfischer, are managing directors of Bay City Capital LLC, an affiliate of Bay City Management, and possess capital and carry interests in the Bay City Management entities holding our shares. Entities affiliated with MPM owned an aggregate of approximately 21.9% of our outstanding common stock as of December 31, 2008. Nicholas J. Simon III, a director of our company, is a general partner of certain of the MPM entities that hold those shares. As of December 31, 2008, entities affiliated with Deerfield Capital, L.P. and OrbiMed Capital LLC beneficially owned an aggregate of approximately 9.0% and approximately 6.9% of our outstanding common stock, respectively. These shareholders may support competing transactions and have interests that are different from yours. Sales of a large number of shares of our stock by one or more of these large shareholders or other shareholders within a short period of time could adversely affect our stock price.

Any future equity or debt issuances by us may have dilutive or adverse effects on our existing shareholders.

We have financed our operations, and we expect to continue to finance our operations, primarily by issuing and selling our common stock or securities convertible into or exercisable for shares of our common stock. In light of our need for additional financing, we may issue additional shares of common stock or convertible securities that could dilute your ownership in our company and may include terms that give new investors rights that are superior to yours. Moreover, any issuances by us of equity securities may be at or below the prevailing market price of our common stock and in any event may have a dilutive impact on your ownership interest, which could cause the market price of our common stock to decline.

We may also raise additional funds through the incurrence of debt, and the holders of any debt we may issue would have rights superior to your rights in the event we are not successful and are forced to seek the protection of bankruptcy laws.

Certain provisions in our articles of incorporation and Washington state law could discourage a change of control.

Our articles of incorporation authorize our board of directors to issue up to 200,000,000 shares of common stock and up to 2,998,425 shares of preferred stock. With respect to preferred stock, our board has the authority to determine the price, rights, preferences, privileges and restrictions, including voting rights, of those shares without any further vote or action by our shareholders.

Washington law imposes restrictions on certain transactions between a corporation and significant shareholders. Chapter 23B.19 of the Washington Business Corporation Act prohibits a target corporation, with some exceptions, from engaging in particular significant business transactions with an acquiring person, which is defined as a person or group of persons that beneficially owns 10% or more of the voting securities of the target corporation, for a period of five years after the date the acquiring person first became a 10% beneficial owner of voting securities of the target corporation, unless (i) the business transaction or the acquisition of shares is approved by a majority of the members of the target corporation's board of directors prior to the time the acquiring person first became a 10% beneficial owner of the target corporation's voting securities or (ii) at or after the acquiring first person became a 10% beneficial owner of the target corporation, the business transaction is approved by a majority of the members of the target corporation's board of directors and at least $\frac{2}{3}$ of the outstanding voting

shares of the target corporation (excluding shares held by the acquiring person). Prohibited business transactions include, among other things:

- a merger or consolidation with, disposition of assets to, or issuance or redemption of stock to or from the acquiring person;
- termination of 5% or more of the employees of the target corporation; or
- receipt by the acquiring person of any disproportionate benefit as a shareholder.

After the five-year period, a significant business transaction may occur if it complies with “fair price” provisions specified in the statute. A corporation may not opt out of this statute. This provision may have an anti-takeover effect with respect to transactions that our board does not approve in advance.

The provisions of our articles of incorporation and Washington law discussed above may have the effect of delaying, deterring or preventing a change of control of the company, even if this change would be beneficial to our shareholders. These provisions also may discourage bids for our common stock at a premium over market price and may adversely affect the market price of, and the voting and other rights of the holders of, our common stock. In addition, these provisions could make it more difficult to replace or remove our current directors and management in the event our shareholders believe this would be in the best interests of the corporation and our shareholders.

Item 1B. UNRESOLVED STAFF COMMENTS

Not Applicable.

Item 2. PROPERTIES

In September 2006, we relocated our corporate headquarters to 7000 Shoreline Court in South San Francisco, CA, where we lease 17,000 square feet of office and laboratory space under a lease that expires in July 2011. The lease may be renewed for one three-year term, effective upon notice by us of our intent to renew nine months prior to the expiration of the current term.

We also currently occupy approximately 21,000 square feet of office space located at 300 Elliott Avenue West in Seattle, WA, under an amended lease that expires December 31, 2010. The lease may be renewed for one five-year term, effective upon notice by us of our intent to renew six months prior to the expiration of the current term. Through May 2006, we occupied approximately 2,900 square feet in a building and a parking area adjacent to 410 West Harrison Street, Seattle, WA. The lease on this space expired on May 31, 2006.

We believe that the South San Francisco and Seattle facilities are in good condition and are adequate for their present uses.

Item 3. LEGAL PROCEEDINGS

Not Applicable.

Item 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

Not Applicable.

PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our common stock has been listed on The Nasdaq Global Market since October 1, 2007. Prior to that time, our common stock was listed on the Nasdaq Capital Market. The following table sets forth, for the periods indicated, the high and low sales prices for our common stock as reported on The Nasdaq Global Market or The Nasdaq Capital Market, as the case may be.

	<u>High</u>	<u>Low</u>
2008		
First Quarter	\$6.39	\$3.27
Second Quarter	5.29	3.31
Third Quarter	4.91	3.50
Fourth Quarter	4.38	1.05
2007		
First Quarter	\$6.44	\$4.65
Second Quarter	8.95	5.45
Third Quarter	7.42	5.26
Fourth Quarter	6.24	4.02

The closing sale price of our common stock on The Nasdaq Global Market was \$1.91 on March 6, 2009.

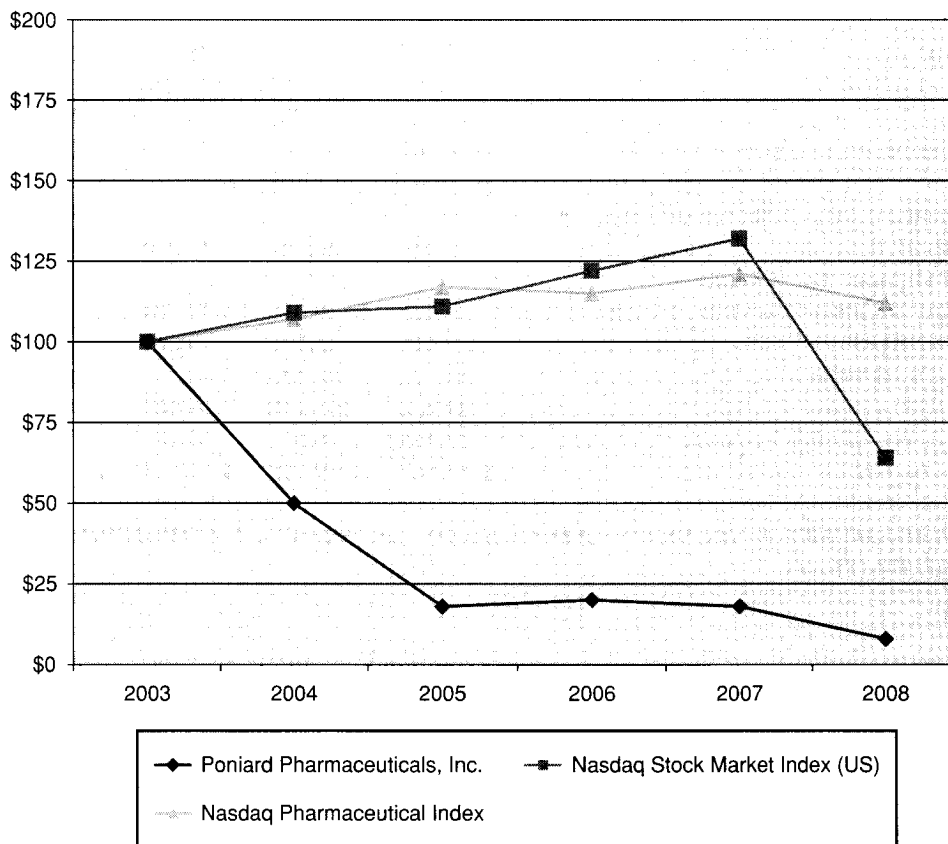
There were approximately 801 shareholders of record on March 6, 2009. This figure does not include the number of shareholders whose shares are held on record by a broker or clearing agency, but includes such a brokerage house or clearing agency as one holder of record.

See Part III, Item 12, for information regarding securities authorized for issuance under our incentive compensation plans.

Stock Price Performance Graph

The graph below compares the cumulative total shareholder return on our common stock with the cumulative shareholder return of the Nasdaq Stock Market Index (US) and the Nasdaq Pharmaceuticals Stocks Index. Stock price performance shown below is historical and not necessarily indicative of future price performance.

Comparison of Five-Year Cumulative Total Return Among Poniard Pharmaceuticals, Inc., Nasdaq Stock Market (US) and Nasdaq Pharmaceuticals Stocks Index(1)



	2003	2004	2005	2006	2007	2008
Poniard Pharmaceuticals, Inc.	\$100	\$ 50	\$ 18	\$ 20	\$ 18	\$ 8
Nasdaq Stock Market Index (US)	100	109	111	122	132	64
Nasdaq Pharmaceutical Index	100	107	117	115	121	112

(1) Assumes \$100 invested on December 31, 2003, in our common stock, the Nasdaq Stock Market Index and the Nasdaq Pharmaceutical Stocks Index, an index of approximately 217 companies with common stock quoted on the Nasdaq National Market. The Primary Standard Industrial Classification Code Number (SIC) of these companies is #2835—Pharmaceutical Companies. Total return performance for the Nasdaq Stock Market Index and the Nasdaq Pharmaceutical Stocks Index is weighted based on the market capitalization of the firms included in each index and assumes that dividends are reinvested. The Nasdaq Stock Market Index and the Nasdaq Pharmaceutical Stocks Index are produced and published by the Center for Research in Securities Pricing at the University of Chicago.

Item 6. SELECTED FINANCIAL DATA

The following table shows selected financial data. It is important to read this selected financial data along with the “Financial Statements and Supplementary Data,” as well as the “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

	Years Ended December 31,				
	2008	2007	2006	2005	2004
	(in thousands, except per share data)				
Consolidated Statement of Operations Data: . . .					
Revenues	\$ —	\$ —	\$ —	\$ 15	\$ 1,015
Operating expenses	49,157	35,353	21,234	21,075	20,502
Loss from operations	(49,157)	(35,353)	(21,234)	(21,060)	(19,487)
Net loss	(48,565)	(32,782)	(23,294)	(20,997)	(19,371)
Net loss applicable to common shareholders . . .	(49,065)	(33,282)	(23,794)	(21,497)	(19,871)
Net loss per common share-basic and diluted . .	\$ (1.41)	\$ (1.08)	\$ (1.37)	\$ (3.83)	\$ (3.96)
Weighted average common shares outstanding - basic and diluted	34,686	30,762	17,376	5,611	5,024
Consolidated Balance Sheet Data:					
Cash, cash equivalents and restricted cash	\$ 44,425	\$ 29,616	\$ 44,284	\$ 4,523	\$ 16,254
Investment securities	28,611	63,286	9,562	—	1,499
Working capital (deficit)	54,873	84,383	42,299	(1,880)	15,689
Total assets	84,232	105,140	69,067	10,114	27,436
Notes payable, net of current portion	17,445	6,561	9,975	—	3,905
Shareholders’ equity	\$ 47,647	\$ 89,105	\$ 46,891	\$ 3,173	\$ 20,828

Item 7. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Introduction

The following discussion of results of operations and liquidity and capital resources contains forward-looking statements that involve risks and uncertainties. As described under the heading “Important Information Regarding Forward-Looking Statements” at the beginning of this report, our actual results may differ materially from the results discussed in these forward-looking statements. Factors that might cause or contribute to such differences include those discussed below and in the section above entitled “Risk Factors.”

Unless otherwise indicated, all common stock related amounts have been adjusted to reflect our one-for-six reverse stock split effective September 22, 2006.

Critical Accounting Policies

Basis of Revenue Recognition: To date, we do not have any significant ongoing revenue sources.

Impairment of Long-Lived and Intangible Assets: As of December 31, 2008, we had net property and equipment of approximately \$1.1 million and a net intangible asset of approximately \$8.8 million, which represents capitalized payments for our picoplatin license. In accounting for these long-lived and intangible assets, we estimate the expected useful lives of the assets, the expected residual values of the assets, and the potential for impairment based on events or circumstances, such as changes in our business strategy and plans, a significant decrease in market value, a significant change in asset condition or a significant adverse change in regulatory climate. Specifically, the value of the picoplatin intangible asset could be impaired as a result of negative results of clinical trials or as a result of adverse decisions or rulings of regulatory bodies, such as the FDA. Application of the test for

impairment requires significant judgment, taking into account potentially unfavorable factors, such as those mentioned above, that could adversely affect the carrying value of the asset.

In June 2005, we recognized an asset impairment loss of \$3.3 million on certain facilities and equipment resulting from the termination of our STR program. The loss on the equipment at the Seattle facility was determined based on estimates of potential sales values of used equipment and other selling costs. In December 2006, we recognized an additional impairment loss of \$0.4 million on the STR manufacturing facility in Denton, Texas, based on our evaluation of market data for this property, and classified this asset as a long-term asset held for sale. On October 1, 2007, we sold the Denton facility, which resulted in net sales proceeds of \$2.7 million, with a net gain of \$0.1 million.

Long-Term Debt: On September 2, 2008, we entered into an Amended and Restated Loan and Security Agreement (loan agreement), with GE Healthcare Financial Services (formerly known as Merrill Lynch Capital) and Silicon Valley Bank. The loan agreement amends and restates in its entirety the earlier Loan and Security Agreement dated as of October 25, 2006 (original loan), with Merrill Lynch Capital and Silicon Valley Bank, pursuant to which we obtained a \$15.0 million capital loan that was to mature on April 1, 2010. The loan agreement provides for a senior secured term loan facility (loan facility) to be made available as follows: (i) an initial term loan advance in the amount of \$17.6 million, which was comprised of (a) the outstanding principal balance of \$7.6 million remaining on the original loan and (b) an additional cash advance of approximately \$10.0 million (cash portion), which was fully funded on September 2, 2008; and (ii) a second term loan advance in the amount of \$10.0 million, which was fully funded on September 30, 2008. The advances under the loan facility are repayable over 42 months, commencing on October 1, 2008. Interest on the advances is fixed at 7.80% per annum. Final loan payments in the amounts of \$1.1 million and \$0.9 million are due upon maturity or earlier repayment of the initial term loan advance and the second term loan advance, respectively. Additionally, as a condition to the amendment and restatement of the original loan, we agreed to modification of the final payment obligations under the original loan, pursuant to which we paid \$0.6 million to Silicon Valley Bank on September 2, 2008, the effective date of the loan facility, and will pay \$0.7 million to GE Healthcare Financial Services on the earlier of March 31, 2010 or the date of repayment of the loan facility. All final payment amounts will be accreted to the note payable balance over the term of the loan facility using the effective interest rate method and reflected as additional interest expense. All interest payable under the loan agreement and the full amount of the final payments must be paid upon any prepayment of a term loan advance. The loan facility is secured by a first lien on all of our non-intellectual property assets. In connection with the loan agreement, we issued to the lenders ten-year warrants to purchase an aggregate of 219,920 shares of our common stock at an exercise price of \$4.297 per share. The portion of the loan proceeds allocable to the warrants is approximately \$0.8 million based on the relative fair value of the warrants, which we recorded as additional discount to notes payable. We classify the portion of the loan that is due for payment in 2010 and thereafter as a long-term payable.

Stock Compensation: Beginning January 1, 2006, we account for share-based compensation arrangements in accordance with the provisions of Statement of Financial Accounting Standards No. 123R, "Share-Based Payments," which requires the measurement and recognition of compensation expense for all share-based payment awards to employees and directors based on estimated fair values. We use the Black-Scholes option valuation model to estimate the fair value of our stock options at the date of grant. The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options which have no vesting restrictions and are fully transferable. Our employee stock options, however, have characteristics significantly different from those of traded options. For example, employee stock options are generally subject to vesting restrictions and are generally not transferable. In addition, option valuation models require the input of highly subjective assumptions, including the expected stock price volatility, the expected life of an option and the number of awards ultimately expected to vest. Changes in subjective input assumptions can materially affect the fair value

estimates of an option. Furthermore, the estimated fair value of an option does not necessarily represent the value that will ultimately be realized by an employee. We use historical data, and other related information as appropriate, to estimate the expected price volatility, the expected option life and the expected forfeiture rate. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of a grant. If actual results are not consistent with our assumptions and judgments used in estimating the key assumptions, we may be required to increase or decrease compensation expense, which could be material to our results of operations.

Results of Operations

Years Ended December 31, 2008, 2007 and 2006

Revenues

We had no revenue for the years ended December 31, 2008, 2007 and 2006.

Research and Development

Research and development expenses increased 49% to \$34.7 million in 2008 and increased 75% to \$23.4 million in 2007. Our research and development expenses are summarized as follows:

	2008	2007	2006	Annual Percentage Change	
				2008-2007	2007-2006
	(\$ in thousands)				
Research	\$ 3,551	\$ 3,401	\$ 1,427	4%	138%
Contract manufacturing	4,248	4,149	2,321	2%	79%
Clinical	25,334	14,503	9,382	75%	55%
Share-based compensation	1,581	1,320	226	20%	484%
Total	<u>\$34,714</u>	<u>\$23,373</u>	<u>\$13,356</u>	49%	75%

Research expenses include, among other things, personnel, occupancy and external laboratory expenses associated with the discovery and identification of new therapeutic agents for the treatment of cancer. Research expenses also include research activities associated with our product candidate, picoplatin, including formulation and *in vitro* and *in vivo* studies. Research expenses increased 4% to \$3.6 million in 2008 primarily due to higher personnel and laboratory supply costs, offset by reduced outside laboratory costs. Research expenses increased 138% to \$3.4 million in 2007, largely as a result of higher personnel, collaborative research fees, laboratory supplies and occupancy costs.

Contract manufacturing expenses include personnel and occupancy expenses and external contract manufacturing costs for the scale up and manufacturing of drug product for use in our clinical trials, in addition to drug product stability and toxicology studies. Contract manufacturing costs increased 2% to \$4.2 million in 2008, due to slightly higher personnel costs. Contract manufacturing costs increased 79% to \$4.1 million in 2007, primarily due to higher personnel costs and increased drug product production.

Clinical expenses include personnel expenses, travel, occupancy costs and external clinical trial costs, including clinical research organization charges, principal investigator fees, clinical site expenses and regulatory activities associated with conducting human clinical trials. Clinical expenses also include quality control and assurance activities, such as storage and shipment services for our drug product candidates. Clinical costs increased 75% to \$25.3 million in 2008, due to primarily to expanded external clinical trial costs associated with our picoplatin trials and increased personnel costs. Clinical costs increased 55% to \$14.5 million in 2007, principally due to increased external costs related to the initiation of our Phase III trial of picoplatin in small cell lung cancer.

Share-based compensation expenses reflect the non-cash charge relating to the adoption of FAS 123R on January 1, 2006, under which the fair value of all employee share-based payments is charged to expense over the vesting period of the stock option. Share-based compensation expense increased 20% to \$1.6 million in 2008, primarily as a result of a higher number of stock option grants reflecting higher staffing levels. Share-based compensation expense increased 484% to \$1.3 million in 2007, primarily due to the recognition of expense for option grants that were awarded in 2006 and approved by shareholders in 2007.

Our major research and development program during the fiscal years ended December 31, 2008, 2007 and 2006 was picoplatin. Picoplatin is a new generation platinum-based chemotherapeutic designed to overcome platinum resistance in the treatment of solid tumors. We completed patient enrollment in our Phase II clinical study of picoplatin in small cell lung cancer in August 2006 and, based on positive median overall survival data from that ongoing study, we initiated a Phase III pivotal trial of picoplatin in small cell lung cancer in April 2007. In May 2006, we treated our first patients in separate Phase I/II studies evaluating picoplatin as a first-line treatment of advanced colorectal cancer and hormone-refractory prostate cancer. We initiated the Phase II component of our prostate cancer study in July 2007 and completed enrollment in December 2007. We initiated enrollment in the Phase II component of our colorectal cancer study in November 2007 and completed enrollment in May 2008. We also initiated a Phase I study of an oral formulation of picoplatin in advanced solid tumors in April 2007.

As of December 31, 2008, we have incurred external costs of approximately \$54.8 million in connection with our entire picoplatin clinical program. Total estimated future costs of our picoplatin Phase II and Phase III trials in small cell lung cancer are in the ranges of \$0.1 million to \$0.2 million and \$35.0 million to \$40.0 million, respectively, through 2010, including the cost of drug supply. Total estimated future costs of our picoplatin Phase II trial in colorectal cancer and our Phase II trial in hormone-refractory prostate cancer are in the ranges of \$5.5 million to \$8.0 million and \$3.0 million to \$5.0 million, respectively, through 2010, including the cost of drug supply. Total estimated future costs of our Phase I trial in oral picoplatin are in the range of \$0.2 million to \$0.4 million through 2010, including the cost of drug supply. These costs could be substantially higher if we have to repeat, revise or expand the scope of any of our trials. Material cash inflows relating to our picoplatin development will not commence unless and until we complete required clinical trials and obtain FDA marketing approvals, and then only if picoplatin finds acceptance in the marketplace. To date, we have not received any revenues from product sales of picoplatin.

Recap of Development and Clinical Program Costs. Our development administration overhead costs, consisting of rent, utilities, consulting fees, patent costs and other various overhead costs, are included in total research and development expense for each period, but are not allocated among our various projects. Our total research and development costs include the costs of various research efforts directed toward the identification and evaluation of future product candidates. These other research

projects are preclinical and not considered major projects. Our total research and development costs are summarized below:

	2008	2007	2006	Annual Percentage Change	
				2008-2007	2007-2006
	(\$ in thousands)				
Picoplatin	\$25,143	\$15,391	\$ 9,058	63%	70%
Discontinued programs (1)	—	—	68	—	—
Other unallocated costs and overhead	7,990	6,662	4,004	20%	66%
Share-based compensation	1,581	1,320	226	20%	484%
Total research and development costs	<u>\$34,714</u>	<u>\$23,373</u>	<u>\$13,356</u>	49%	75%

(1) The \$68,000 represents costs related to the winding down of our STR program that was discontinued in 2005.

Our external costs for picoplatin in 2008 and 2007 reflect costs associated with our various picoplatin clinical studies and the manufacture of drug product to support our clinical trials. We expect our external costs for picoplatin to increase slightly in 2009 as we prepare for submission of our rolling NDA application, offset by lower costs for clinical trials upon completion.

The risks and uncertainties associated with completing the development of picoplatin on schedule, or at all, include the following, as well as the other risks and uncertainties described in this report:

- we may not have adequate funds to complete the development of picoplatin;
- picoplatin may not be shown to be safe and efficacious in clinical trials; and
- we may be unable to obtain regulatory approvals of the drug or may be unable to obtain such approvals on a timely basis.

If we fail to obtain marketing approvals for picoplatin, are unable to secure adequate commercial supplies of picoplatin active pharmaceutical ingredient and finished drug product, or do not complete development and obtain United States and foreign regulatory approvals on a timely basis, our operations, financial position and liquidity could be severely impaired, including as follows:

- we would not earn any sales revenue from picoplatin, which would increase the likelihood that we would need to obtain additional financing for our other research and development efforts; and
- our reputation among investors might be harmed, which could make it more difficult for us to obtain equity capital on attractive terms, or at all.

Because of the many risks and uncertainties relating to completion of clinical trials, receipt of marketing approvals and acceptance in the marketplace, we cannot predict the period in which material cash inflows from our picoplatin program will commence, if ever.

General and Administrative

	2008	2007	2006	Annual Percentage Change	
				2008-2007	2007-2006
	(\$ in thousands)				
General and administrative	\$ 8,901	\$ 7,936	\$6,290	12%	26%
Share-based compensation	5,542	4,149	1,258	34%	230%
Total	<u>\$14,443</u>	<u>\$12,085</u>	<u>\$7,548</u>	20%	60%

General and administrative expenses increased 20% to approximately \$14.4 million in 2008 and increased 60% to approximately \$12.1 million in 2007. General and administrative expenses, excluding share-based compensation expense, increased 12% in 2008 and increased 26% in 2007. In 2008, the increase was primarily attributable to personnel costs, resulting from increased headcount, and consulting. The increase in 2007 was primarily due to personnel costs. Share-based compensation expense in 2008, 2007 and 2006 reflects non-cash charges related to the adoption of FAS 123R, under which the fair value of all employee share-based payments is charged to expense over the vesting period of the stock option. Share-based compensation expense increased 34% in 2008 and increased 230% in 2007. In 2008, the increase was largely due to a higher number of stock option grants reflecting higher staffing levels. The increase in 2007 was primarily due to the recognition of expense for option grants that were awarded in 2006 and approved by shareholders in 2007.

Other Income and Expense

	2008	2007	2006	Annual Percentage Change	
				2008-2007	2007-2006
	(\$ in thousands)				
Other income (expense), net	\$592	\$2,571	\$(2,060)	(77)%	225%

Other income and expense decreased 77% to approximately \$0.6 million in 2008 and increased 225% to approximately \$2.6 million in 2007. The decrease in 2008 was primarily due to decreased average yields from our investment securities portfolio and increased interest costs resulting from additional borrowings in 2008 under our bank loan. The increase in 2007 was primarily due to increases in our investment securities portfolio resulting from our 2007 and 2006 financings and to decreased interest expense during 2007 under our bank note payable.

Liquidity and Capital Resources

	December 31,		
	2008	2007	2006
	(\$ in thousands)		
Cash, cash equivalents and investment securities	\$72,755	\$92,621	\$53,710
Working capital	54,873	84,383	42,299
Shareholders' equity	47,647	89,105	46,891

	Years Ended December 31,		
	2008	2007	2006
	(\$ in thousands)		
Cash provided by (used in):			
Operating activities	\$(33,487)	\$(24,653)	\$(17,274)
Investing activities	34,282	(55,542)	(14,837)
Financing activities	14,014	65,382	72,736

We have historically experienced recurring operating losses and negative cash flows from operations. As of December 31, 2008, we had net working capital of \$54.9 million, an accumulated deficit of \$362.3 million and total shareholders' equity of \$47.6 million.

We have financed our operations to date primarily through the sale of equity securities, debt instruments, technology licensing and collaborative agreements. We invest excess cash in investment securities that will be used to fund future operating costs. Cash used for operating activities for the year ended December 31, 2008 totaled \$33.5 million. There were no revenues and other income sources for the year ended December 31, 2008. We may not be able to obtain capital or enter into

relationships with corporate partners on a timely basis, on favorable terms, or at all. Conditions in the capital markets in general, and in the life science capital market specifically, may affect our potential financing sources and opportunities for strategic partnering. Our consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States, assuming that we will continue as a going concern and do not include any adjustments that might result from the outcome of this uncertainty. Cash, cash equivalents and investment securities, net of restricted cash of \$0.3 million, totaled \$72.8 million at December 31, 2008. The report of our independent registered public accountants issued in connection with our annual report on Form 10-K for the year ended December 31, 2008 contains a statement expressing substantial doubt regarding our ability to continue as a going concern.

On September 2, 2008, we entered into an amended and restated loan and security agreement (loan agreement) with GE Healthcare Financial Services Inc. and Silicon Valley Bank, establishing a \$27.6 million senior secured loan facility. The loan agreement amends and restates our earlier loan and security agreement with Silicon Valley Bank and Merrill Lynch Capital dated as of October 25, 2006, pursuant to which we obtained a \$15.0 million capital loan that was to mature on April 1, 2010 (original loan). Funds under the loan facility were made available as follows: (i) an initial term loan advance in the amount of \$17.6 million, which was comprised of (a) the outstanding principal balance of \$7.6 million remaining on the original loan and (b) an additional cash advance of approximately \$10.0 million, which was fully funded on September 2, 2008; and (ii) a second term loan advance in the amount of \$10.0 million, which was fully funded on September 30, 2008. The advances under the loan facility are repayable over 42 months, commencing on October 1, 2008. Interest on the advances is fixed at 7.80% per annum. Final payments in the amounts of \$1.1 million and \$0.9 million are due upon maturity or earlier repayment of the initial term loan advance and the second term loan advance, respectively. Additionally, as a condition to the amendment and restatement of the original loan, we agreed to modification of the final payment obligations under the original loan pursuant to which we paid \$0.6 million to Silicon Valley Bank on September 2, 2008, the effective date of the loan facility, and will pay \$0.7 million to GE Healthcare Financial Services on the earlier of March 31, 2010 or the date of repayment of the loan facility. The loan facility is secured by a first lien on all of our non-intellectual property assets.

The loan agreement contains restrictions on our ability to, among other things, dispose of certain assets, engage in certain mergers and acquisition transactions, incur indebtedness, create liens on assets, make investments, pay dividends and repurchase stock. The loan agreement also contains covenants requiring us to maintain a minimum amount of unrestricted cash during the term of the loan equal to the lesser of (i) \$17.9 million or (ii) the outstanding aggregate principal balance of the term loans plus \$4.0 million. The loan agreement contains events of default that include nonpayment of principal, interest or fees, breaches of covenants, material adverse changes, bankruptcy and insolvency events, cross defaults to any other indebtedness, material judgments, inaccuracy of representations and warranties and events constituting a change of control. The occurrence of an event of default would increase the applicable rate of interest by 5% and could result in the acceleration of our payment obligations under the loan agreement. In connection with the loan agreement, we issued to the lenders ten-year warrants to purchase an aggregate of 219,920 shares of common stock at an exercise price of \$4.297 per share. At December 31, 2008, the outstanding principal amount under the loan facility was \$25.3 million.

Taking into account the minimum unrestricted cash requirement under the loan agreement and our projected operating results, we believe that our current cash, cash equivalent and investment securities balances will provide adequate resources to fund operations at least into the first quarter of 2010. However, given the uncertainties of outcomes of the Company's ongoing clinical trials, there is no assurance that the Company can achieve its projected operating results. Thereafter, unless we raise additional funds, we will be in default of the minimum unrestricted cash requirement and potentially

other provisions of the loan agreement. The occurrence of an event of default would increase the applicable rate of interest by 5% and could result in the acceleration of our payment obligations under the loan agreement. We have no assurance that, especially in light of the current distressed economic environment, the lenders will be willing to waive or renegotiate the terms of the loan agreement to address or avoid financial or other defaults.

If an event of default were to occur, we might not have sufficient funds to repay the loan or to fund our continuing operations. In such case, we would need to delay, scale back or eliminate some or all of our picoplatin trials and commercialization efforts; reduce our workforce, license our picoplatin product candidates for development and commercialization by third parties; attempt to sell the company, cease operations or declare bankruptcy. Provisions of the loan agreement would limit our ability to dispose of certain assets, engage in certain mergers, incur certain indebtedness, make certain distributions and engage in certain investment activities without the prior consent of the lenders. We have no assurance that we can obtain financing or otherwise raise additional funds, if at all, on terms acceptable to us or to our lenders.

We have entered into clinical supply agreements with Heraeus and Baxter, pursuant to which they produce picoplatin API and finished drug product, respectively, for our clinical trials. Manufacturing services under these clinical supply agreements are provided on a purchase order, fixed-fee basis. Our API clinical supply agreement continues in effect until it is terminated by mutual agreement of the parties or by either party in accordance with its terms. Our finished drug product clinical supply agreement runs for an initial term ending December 31, 2009, and is subject to renewal for two additional one-year terms, at our option. The total aggregate cost of clinical supplies of picoplatin API and finished drug product for the year ended December 31, 2008 was \$2.6 million. We believe that we presently have adequate supplies of picoplatin API and finished drug product to complete our current clinical trials.

We also have entered into a picoplatin API commercial supply agreement with Heraeus in March 2008 and a finished drug product commercial supply agreement with Baxter in November 2008. Under these agreements, Heraeus and Baxter will produce picoplatin API and finished drug product, respectively, for commercial use. Manufacturing services are provided on a purchase order, fixed-fee basis, subject to certain purchase price adjustments and minimum quantity requirements. The costs to Heraeus for the purchase and set-up of dedicated equipment, estimated to be approximately \$1.3 million, will be repaid by us in the form of a surcharge on an agreed upon amount of the picoplatin API ordered and delivered on or before December 31, 2013. If we order and take delivery of less than the agreed upon amount of picoplatin API through December 31, 2013, we will be obligated to pay the balance of the dedicated equipment cost as of that date. The API commercial supply agreement continues for an initial term ending December 31, 2013, and the finished drug product commercial supply agreement continues for an initial term ending November 22, 2013, in each case subject to extension.

On April 30, 2007, we completed a public offering of 11.8 million shares of our common stock at a price of \$6.33 per share. Net proceeds of the offering were \$70.0 million. On April 26, 2006, we completed an equity financing, pursuant to which we issued to a group of institutional and other accredited investors an aggregate of 15.5 million shares of common stock at a cash purchase price of \$4.20 per share. Investors in the 2006 equity financing also received five-year warrants to purchase an aggregate of 4.6 million shares of common stock at an exercise price of \$4.62 per share. We received \$62.0 million in net proceeds from the 2006 equity financing, which, along with the net proceeds received from our April 2007 public offering, we intend to use to fund our ongoing picoplatin clinical trials and commercialization efforts and for general corporate purposes, including working capital.

In connection with our 2006 equity financing, we entered into a letter agreement with Texas State Bank, pursuant to which we agreed to accelerate the maturity date of our promissory note with the

Bank to June 5, 2006. The Texas State Bank note, which was secured by our radiopharmaceutical manufacturing plant and other STR assets located in Denton, Texas, had an adjustable interest rate equal to the bank prime rate reported in the Wall Street Journal (8.00% at May 23, 2006). We paid off the outstanding balance of the note, \$2.7 million, on May 23, 2006. On October 1, 2007, we sold the Denton property, which resulted in net sales proceeds of \$2.7 million, with a net gain of \$0.1 million.

We completed the relocation of our corporate headquarters to South San Francisco in September 2006. We intend to maintain our current clinical and development and support activities in Seattle. The addition of 17,045 square feet of office and laboratory space leased in the South San Francisco facility resulted in a substantial increase in our rent and operating costs. The initial term under the lease agreement dated July 10, 2006 is 60 months. We may, upon written notice delivered at least nine months prior to expiration of the initial lease term, extend the lease for an additional three years, with rent payable at the then market rate. Monthly base rent during the first seven months of the lease averaged \$21,000 during the construction of tenant improvements. Base rental payments under this lease are subject to annual adjustment based on the Consumer Price Index in the San Francisco metropolitan market (CPI-SFMM) and a one-time adjustment for reimbursement for tenant improvements. Monthly base rent was increased by \$1,400 to \$46,600 following the adjustment for the 2007 CPI-SFMM and an additional \$1,400 to \$48,000 following the adjustment for the 2008 CPI-SFMM. In December 2007, the Company received approximately \$251,000 as a tenant reimbursement that resulted in a further \$5,400 increase in monthly base rent to \$53,400. Additional rental payments under this lease are paid based on the Company's share of operating expenses of the project in which the leased facilities are located.

During the year ended December 31, 2008, we paid total rent (base rent and additional rent based on our share of facility common operating expenses) of \$1.5 million under the operating leases for our South San Francisco headquarters facility and our Seattle facility. Of this amount, \$1.2 million represents total aggregate minimum lease payments under these leases.

In April 2004, we acquired the worldwide exclusive rights, excluding Japan, to develop, manufacture and commercialize picoplatin from AnorMED, Inc. AnorMED was acquired by Genzyme Corporation in November 2006. Under the terms of the original agreement, we paid a one-time upfront payment of \$1.0 million in common stock and \$1.0 million in cash. The original agreement provided for development and commercialization milestone payments of up to \$13.0 million, payable in cash or a combination of cash and common stock, and a royalty rate of up to 15% of net product sales after regulatory approval. The parties executed an amendment to the license agreement on September 18, 2006, modifying several key financial terms and expanding the licensed territory to include Japan, thereby providing us worldwide rights. In consideration of the amendment, we paid Genzyme \$5.0 million in cash on October 12, 2006 and \$5.0 million in cash on March 30, 2007. The amendment eliminated \$8.0 million in development milestone payments to Genzyme. If we are successful in our efforts to commercialize picoplatin, we would, under our amended license agreement with Genzyme Corporation, be required to pay Genzyme up to \$5.0 million in commercialization milestones upon the attainment of certain levels of annual net sales of picoplatin after regulatory approval. Genzyme also would be entitled to royalty payments of up to 9% of annual net product sales. Finally, the amendment eliminated sharing of sublicense revenues with Genzyme.

On August 4, 2005, we entered into a research funding and option agreement with The Scripps Research Institute, or TSRI. Under the agreement, as amended, we provided TSRI an aggregate of \$2.5 million over a 30-month period to fund research relating to synthesis and evaluation of novel small molecule, multi-targeted protein kinase inhibitors as therapeutic agents, including the treatment of cancer. We paid TSRI total funding payments of approximately \$0.1 million in 2005, \$1.0 million in 2006 and \$1.4 million in 2007, all of which were charged to R&D expense. The amended agreement expired on December 31, 2007. In connection with our option under the amended agreement to negotiate a worldwide exclusive license (including the rights to sublicense) to develop and to commercialize any compounds arising from the collaboration, we executed a follow-on agreement to license compounds that were discovered by TSRI. We have no assurance that the research funded under this arrangement, or any compounds arising from the collaboration, will be successful or ultimately will give rise to any viable product candidates.

We will require substantial additional funding to develop and commercialize picoplatin and to fund our operations. Management is continuously exploring financing alternatives, including:

- raising additional capital through the public or private sale of equity or debt securities or through the establishment of credit or other funding facilities; and
- entering into strategic collaborations, which may include joint ventures or partnerships for product development and commercialization, merger, sale of assets or other similar transactions.

If we are unable to obtain sufficient additional cash when needed, we may be forced to reduce expenses through the delay, reduction or curtailment of our picoplatin development and commercialization activities or through other cost-savings measures, including the sale of our company or sale of our assets.

Our actual capital requirements will depend upon numerous factors, including:

- the costs of performing our obligations under our loan facility with GE Healthcare Financial Services and Silicon Valley Bank, including the cost of interest and other payment obligations and penalties and the cost of complying with the covenants and restrictions under the amended and restated loan agreement;
- the scope and timing of our picoplatin clinical program and commercialization efforts, including the progress and costs of our ongoing Phase III trial of picoplatin in small cell lung cancer, our ongoing Phase II trials in colorectal and prostate cancers, as well as our ongoing Phase I trial of picoplatin (oral formulation) in solid tumors;
- our ability to obtain clinical supplies of picoplatin active pharmaceutical ingredient, or API, and finished drug product in a timely and cost effective manner;
- actions taken by the FDA and other regulatory authorities;
- the timing and amount of any milestone or other payments we might receive from or be obligated to pay to potential strategic partners;
- our degree of success in commercializing picoplatin;
- the emergence of competing technologies and products, and other adverse market developments;
- the acquisition or in-licensing of other products or intellectual property;
- the costs of any research collaborations or strategic partnerships established; and
- the costs of preparing, filing, prosecuting, maintaining and enforcing patent claims and other intellectual property rights,

During 2006, we experienced significant changes to our capital structure which resulted in an ownership change, as defined under Section 382 of the IRC. Consequently, the amount of net operating loss carryforwards and research and experimentation credit carryforwards available to be used in future years are limited under IRC Sections 382 and 383. This limitation resulted in the loss of approximately \$93.3 million of our net operating loss carryforwards and \$9.1 million of our research and development credit carryforwards. At December 31, 2008, we had net operating loss carryforwards of approximately \$109.6 million for federal taxes (net of the impact of the above referenced change in ownership under IRC Section 382) and approximately \$14.7 million for state taxes, which expire from 2009 through 2028 and from 2015 through 2018, respectively.

Contractual Obligations and Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenue or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors.

At December 31, 2008, we had the following contractual obligations (in thousands):

	Payments due by period				
	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
<i>Contractual Obligations</i>					
Long-term debt obligations:					
Note payable(2) (3)	\$31,651	\$ 9,626	\$18,057	\$3,968	\$—
Operating lease obligations:					
Seattle premises	1,104	557	547	—	—
South San Francisco premises(1)	1,670	651	1,019	—	—
	2,774	1,208	1,566	—	—
Capital lease obligations:					
Equipment capital lease(4)	77	37	40	—	—
Total	<u>\$34,502</u>	<u>\$10,871</u>	<u>\$19,663</u>	<u>\$3,968</u>	<u>\$—</u>

- (1) Lease executed in July 2006. See discussion above for details.
- (2) Amounts include interest payments.
- (3) Amount in "Total" column includes total principal payment of \$25,293 as reflected on the Consolidated Balance Sheet for the year ended December 31, 2008.
- (4) Amount in "Total" column includes total principal payment of \$70 as reflected on the Consolidated Balance Sheet for the year ended December 31, 2008.

New Accounting Pronouncements

See Item 8, Note 2 to our Consolidated Financial Statements, New Accounting Pronouncements, for a discussion of new accounting standards.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

The Company's exposure to market rate risk for changes in interest rates relates primarily to the debt securities included in its investment portfolio. The Company does not invest in any derivative financial instruments. The Company invests in money market funds, debt instruments of the U.S.

Government and its agencies and high-quality corporate issuers. Investments in both fixed rate and floating rate interest earning instruments carry a degree of interest rate risk. The fair market value of fixed rate securities may be adversely impacted due to a rise in interest rates, while floating rate securities may produce less income than expected if interest rates decrease. Due in part to these factors, the Company's future investment income may fall short of expectations due to changes in interest rates or the Company may experience losses in principal if forced to sell securities that have declined in market value due to changes in interest rates. At December 31, 2008, the Company owned government debt instruments totaling \$5.0 million and owned corporate debt securities totaling \$23.6 million. The Company's exposure to losses as a result of interest rate changes is managed through investing primarily in securities with relatively short maturities of two years or less and in securities with variable interest rates. The Company owned corporate debt securities totaling \$1.1 million at December 31, 2008 with maturities greater than one year.

The Company's only material outstanding debt is its loan obligation to GE Healthcare Financial Services and Silicon Valley Bank. The outstanding balance of this loan was \$25.3 million on December 31, 2008. The loan, which matures on March 1, 2012, bears interest at a fixed rate of 7.80%. The occurrence of an event of default under the loan, as described above, would increase the applicable rate of interest by 5% during the continuance of the event of default and could result in acceleration of the Company's payment obligations under the loan agreement. As described elsewhere in this report, unless the Company raises additional capital or obtains a waiver or renegotiates the loan agreement, there is a likelihood that it will be in default of the minimum unrestricted cash requirement and potentially other requirements under the loan.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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All financial schedules are omitted since the required information is not applicable or has been presented in the consolidated financial statements and the notes thereto.

Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders
Poniard Pharmaceuticals, Inc.:

We have audited the accompanying consolidated balance sheets of Poniard Pharmaceuticals, Inc. and subsidiary as of December 31, 2008 and 2007, and the related consolidated statements of operations, shareholders' equity and comprehensive loss, and cash flows for each of the years in the three-year period ended December 31, 2008. We also have audited Poniard Pharmaceuticals, Inc. and subsidiary's internal control over financial reporting as of December 31, 2008, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Poniard Pharmaceuticals, Inc.'s management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on these consolidated financial statements and an opinion on the effectiveness of the Company's internal control over financial reporting based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the consolidated financial statements included 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. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

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, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Poniard Pharmaceuticals, Inc. and subsidiary as of December 31, 2008 and 2007, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2008, in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, Poniard Pharmaceuticals, Inc.

maintained, in all material respects, effective internal control over financial reporting as of December 31, 2008, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations and negative cash flows. Furthermore, the Company's long-term debt agreement contains certain covenants that require the Company to maintain a certain level of unrestricted cash and cash equivalents, and contains certain subjective acceleration clauses related to material adverse changes 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 consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ KPMG LLP

Seattle, Washington

March 16, 2009

PONIARD PHARMACEUTICALS, INC. AND SUBSIDIARY
CONSOLIDATED BALANCE SHEETS
(in thousands, except share data)

	As of December 31,	
	2008	2007
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 44,144	\$ 29,335
Cash—restricted	281	281
Investment securities	28,611	63,286
Prepaid expenses and other current assets	977	955
Total current assets	74,013	93,857
Facilities and equipment, net of depreciation of \$1,319 and \$954	1,123	1,121
Other assets	289	141
Licensed products, net	8,807	10,021
Total assets	\$ 84,232	\$ 105,140
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 604	\$ 677
Accrued liabilities	10,618	4,550
Current maturities of note payable and capital lease obligations	7,918	4,247
Total current liabilities	19,140	9,474
Long-term liabilities:		
Note payable and capital lease obligations, net of current portion and discount of \$2,980 and \$1,018	17,445	6,561
Total long-term liabilities	17,445	6,561
Shareholders' equity:		
Preferred stock, \$.02 par value, 2,998,425 shares authorized:		
Convertible preferred stock, Series 1, 205,340 shares issued and outstanding (entitled in liquidation to \$5,175, respectively)	4	4
Common stock, \$.02 par value, 200,000,000 shares authorized:		
34,687,724 and 34,662,689 shares issued and outstanding	694	693
Additional paid-in capital	409,244	401,225
Accumulated deficit, including other comprehensive income (loss) of \$(354) and \$59	(362,295)	(312,817)
Total shareholders' equity	47,647	89,105
Total liabilities and shareholders' equity	\$ 84,232	\$ 105,140

See notes to the consolidated financial statements.

PONIARD PHARMACEUTICALS, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share amounts)

	Years Ended December 31,		
	2008	2007	2006
Revenues	\$ —	\$ —	\$ —
Operating expenses:			
Research and development	34,714	23,373	13,356
General and administrative	14,443	12,085	7,548
Gain on sale of real estate and equipment	—	(105)	(73)
Asset impairment loss	—	—	403
Total operating expenses	<u>49,157</u>	<u>35,353</u>	<u>21,234</u>
Loss from operations	(49,157)	(35,353)	(21,234)
Other income (expense), net	592	2,571	(2,060)
Net loss	(48,565)	(32,782)	(23,294)
Preferred stock dividends	(500)	(500)	(500)
Net loss applicable to common shares	<u>\$(49,065)</u>	<u>\$(33,282)</u>	<u>\$(23,794)</u>
Net loss per share applicable to common shares - basic and diluted . . .	<u>\$ (1.41)</u>	<u>\$ (1.08)</u>	<u>\$ (1.37)</u>
Weighted average common shares outstanding - basic and diluted	<u>34,686</u>	<u>30,762</u>	<u>17,376</u>

See notes to the consolidated financial statements.

PONIARD PHARMACEUTICALS, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Years Ended December 31,		
	2008	2007	2006
Cash flows from operating activities:			
Net loss	\$(48,565)	\$ (32,782)	\$(23,294)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,603	1,526	605
Amortization of discount on notes payable	790	775	3,604
Amortization of discount on investment securities	(411)	(1,167)	—
Gain on disposal of real estate and equipment	—	(105)	(27)
Asset impairment loss	—	—	403
Increase in restricted cash to secure operating lease	—	—	(136)
Stock options and warrants issued for services	119	55	13
Stock-based employee compensation	7,004	5,414	1,471
Change in operating assets and liabilities:			
Prepaid expenses and other assets	(22)	(301)	(199)
Accounts payable	(73)	(98)	(220)
Accrued liabilities	6,068	2,030	506
Net cash used in operating activities	(33,487)	(24,653)	(17,274)
Cash flows from investing activities:			
Proceeds from sales and maturities of investment securities	80,950	51,560	—
Purchases of investment securities	(46,277)	(104,058)	(9,562)
Facilities and equipment purchases	(391)	(773)	(385)
Purchase of licensed product	—	(5,000)	(5,000)
Proceeds from sales of equipment and facilities	—	2,729	110
Net cash provided by (used in) investing activities	34,282	(55,542)	(14,837)
Cash flows from financing activities:			
Net proceeds from bank note payable	19,997	—	15,000
Proceeds from bridge note payable	—	—	3,460
Repayment of principal on notes payable	(5,345)	(3,905)	(4,584)
Payment of debt issuance costs	(200)	—	(144)
Proceeds from stock options and warrants exercised	91	22	19
Repayment of capital lease obligation	(29)	(36)	—
Net proceeds from issuance of common stock and warrants	—	69,946	58,485
Decrease (increase) in restricted cash	—	(145)	1,000
Payment of preferred dividends	(500)	(500)	(500)
Net cash provided by financing activities	14,014	65,382	72,736
Net increase (decrease) in cash and cash equivalents	14,809	(14,813)	40,625
Cash and cash equivalents:			
Beginning of period	29,335	44,148	3,523
End of period	\$ 44,144	\$ 29,335	\$ 44,148
Supplemental disclosure of non-cash financing activities:			
Accrual of preferred dividend	\$ 500	\$ 500	\$ 500
Increase in capital leases	—	134	—
Increase in licensed products with increase in current obligations payable	—	—	5,000
Debt discount capitalized in shareholders' equity	806	—	4,000
Conversion of bridge loan plus interest accrued thereon into common stock	—	—	3,524
Supplemental disclosure of cash paid during the period for:			
Interest	\$ 1,001	\$ 974	\$ 209

See notes to the consolidated financial statements.

PONIARD PHARMACEUTICALS, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
AND COMPREHENSIVE LOSS

(in thousands)

	Preferred Stock, Series 1		Preferred Stock, Series B		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive (Loss)/Income	Shareholders' Equity
	Shares	Par Value	Shares	Par Value	Shares	Par Value				
Balance, December 31, 2005	205	\$ 4	2	\$—	5,720	\$114	\$258,855	\$(255,800)	\$ —	\$ 3,173
Exercise of stock options and warrants	—	—	—	—	6	—	19	—	—	19
Common stock issued, net of offering costs of \$3,953	—	—	—	—	14,652	293	58,192	—	—	58,485
Conversion of bridge loan and interest accrued thereon into common stock	—	—	—	—	839	17	3,507	—	—	3,524
Conversion of preferred shares into common stock	—	—	(2)	—	1,591	32	(32)	—	—	—
Share-based employee compensation expense	—	—	—	—	—	—	1,572	—	—	1,572
Modification of outstanding employee options	—	—	—	—	—	—	(101)	—	—	(101)
Warrants issued and recognition of beneficial conversion feature in connection with issuance of debt	—	—	—	—	—	—	4,000	—	—	4,000
Stock options and warrants issued for services	—	—	—	—	—	—	13	—	—	13
Comprehensive loss:										
Net loss	—	—	—	—	—	—	—	(23,294)	—	(23,294)
Unrealized gain on investment securities	—	—	—	—	—	—	—	—	—	—
Total comprehensive loss	—	—	—	—	—	—	—	—	—	(23,294)
Preferred stock dividends	—	—	—	—	—	—	—	(500)	—	(500)
Balance, December 31, 2006	205	4	—	—	22,808	456	326,025	(279,594)	—	46,891
Exercise of stock options and warrants	—	—	—	—	6	—	22	—	—	22
Common stock issued, net of offering costs of \$5,054	—	—	—	—	11,849	237	69,709	—	—	69,946
Share-based employee compensation expense	—	—	—	—	—	—	5,414	—	—	5,414
Stock options and warrants issued for services	—	—	—	—	—	—	55	—	—	55
Comprehensive loss:										
Net loss	—	—	—	—	—	—	—	(32,782)	—	(32,782)
Unrealized gain on investment securities	—	—	—	—	—	—	—	—	59	59
Total comprehensive loss	—	—	—	—	—	—	—	—	—	(32,723)
Preferred stock dividends	—	—	—	—	—	—	—	(500)	—	(500)
Balance, December 31, 2007	205	4	—	—	34,663	693	401,225	(312,876)	59	89,105
Exercise of stock options and warrants	—	—	—	—	25	1	90	—	—	91
Warrants issued in connection with issuance of debt	—	—	—	—	—	—	806	—	—	806
Share-based employee compensation expense	—	—	—	—	—	—	7,004	—	—	7,004
Stock options and warrants issued for services	—	—	—	—	—	—	119	—	—	119
Comprehensive loss:										
Net loss	—	—	—	—	—	—	—	(48,565)	—	(48,565)
Unrealized loss on investment securities	—	—	—	—	—	—	—	—	(413)	(413)
Total comprehensive loss	—	—	—	—	—	—	—	—	—	(48,978)
Preferred stock dividends	—	—	—	—	—	—	—	(500)	—	(500)
Balance, December 31, 2008	205	\$ 4	—	\$—	34,688	\$694	\$409,244	\$(361,941)	\$(354)	\$ 47,647

See notes to the consolidated financial statements.

PONIARD PHARMACEUTICALS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1. Business Overview and Summary of Significant Accounting Policies

Overview

Poniard Pharmaceuticals, Inc. is a biopharmaceutical company focused on the development and commercialization of innovative oncology products to impact the lives of people with cancer. The consolidated financial statements include the accounts of Poniard Pharmaceuticals, Inc. and its wholly owned subsidiary, NeoRx Manufacturing Group, Inc. (the Company).

All inter-company balances and transactions have been eliminated.

Unless otherwise indicated, all common stock related amounts have been adjusted to reflect the Company's one-for-six reverse stock split effective September 22, 2006.

Liquidity Matters

The accompanying audited consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates realization of assets and the satisfaction of liabilities in the normal course of business for a reasonable period following the date of these financial statements. The Company has historically suffered recurring operating losses and negative cash flows from operations. As of December 31, 2008, the Company had net working capital of \$54,873,000, an accumulated deficit of \$362,295,000 and total shareholders' equity of \$47,647,000. The Company's total cash, cash equivalents and investment securities, net of restricted cash of \$281,000, was \$72,755,000 at December 31, 2008.

Furthermore, the loan facility with GE Healthcare Financial Services and Silicon Valley Bank, described in Note 6 below, requires that the Company maintain a minimum amount of unrestricted cash during the term of the loan equal to the lesser of (i) \$17,940,000 or (ii) the outstanding aggregate principal balance of the term loans plus \$4,000,000. Taking into account this minimum unrestricted cash requirement and the Company's projected operating results, the Company believes that its current cash, cash equivalent and investment securities balances will provide adequate resources to fund operations at least into the first quarter of 2010. However, given the uncertainties of outcomes of the Company's ongoing clinical trials, there is no assurance that the Company can achieve its projected operating results. Thereafter, unless the Company raises additional funds, there is a likelihood that it will be in default of the minimum unrestricted cash requirement and potentially other provisions of the loan facility. The occurrence of an event of default would increase the applicable rate of interest by 5% and could result in the acceleration of the Company's payment obligations under the loan agreement. The Company has no assurance that, especially in light of the current distressed economic environment, the lenders will be willing to waive or renegotiate the terms of the loan agreement to address or avoid financial or other loan defaults. If an event of default were to occur, the Company might not have sufficient funds to repay the loan or to fund its continuing operations. In such case, it would need to delay, scale back or eliminate some or all of our picoplatin trials and commercialization efforts; reduce its workforce, license its picoplatin product candidates for development and commercialization by third parties; attempt to sell the company, cease operations or declare bankruptcy. Provisions of the loan agreement would limit the Company's ability to dispose of certain assets, engage in certain mergers, incur certain indebtedness, make certain distributions and engage in certain investment activities without the prior consent of the lenders.

These factors, among others, raise substantial doubt about the Company's ability to continue as a going concern. Management is developing plans to address the Company's liquidity needs, including raising additional capital through the public or private sale of equity or debt securities or through the establishment of credit or other funding facilities; and entering into strategic collaborations, which may

PONIARD PHARMACEUTICALS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

NOTE 1. Business Overview and Summary of Significant Accounting Policies (Continued)

include joint ventures or partnerships for product development and commercialization, merger, sale of assets or other similar transactions and taking other actions to limit the Company's expenditures. There can be no assurance that the Company can obtain financing or otherwise raise additional funds, if at all, on terms acceptable to the Company or to its lenders.

Significant Accounting Policies

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

Research and Development Revenues and Expenses: To date, the Company does not have any significant ongoing revenue sources. Research and development costs are expensed as incurred. It is the Company's practice to offset third-party collaborative reimbursements received as a reduction of research and development expenses. Third-party reimbursements for 2008, 2007, and 2006 were \$154,000, \$64,000, and \$52,000, respectively.

Cash Equivalents: All highly liquid investments with an original maturity of three months or less when purchased are considered to be cash equivalents. Cash equivalents represent cash invested primarily in money market funds, federal government and agency securities and corporate debt securities.

Investment Securities: The Company considers all investment securities as available-for-sale. All securities are carried at fair value. The Company does not invest in derivative financial instruments. Unrealized gains and losses on investment securities are reported as a component of comprehensive income or loss and classified as accumulated deficit—unrealized gain on investment securities in shareholders' equity. The Company monitors investment securities for other than temporary declines in fair value and charges impairment losses to income when an other than temporary decline in estimated value occurs.

Facilities and Equipment: Facilities and equipment are stated at acquired cost, less any charges for impairment. Depreciation is provided using the straight-line method over estimated useful lives of five to seven years for equipment and furniture, three years for computer equipment and software and thirty years for buildings. Leasehold improvements are amortized using the straight-line method over the shorter of the assets' estimated useful lives or the terms of the leases.

Impairment of Long-Lived and Intangible Assets: Long-lived assets, including property and equipment and intangible assets, including capitalized license payments for the Company's picoplatin product candidate, are reviewed for possible impairment whenever significant events or changes in circumstances, including changes in the Company's business strategy and plans, a significant decrease in market value, a significant change in asset condition, or a significant adverse change in regulatory climate, indicate that an impairment may have occurred. An impairment is indicated when the sum of the expected future undiscounted net cash flows identifiable to that asset or asset group is less than its carrying value. Impairment losses are determined from actual or estimated fair values, which are based on market values, net realizable values or projections of discounted net cash flows, as appropriate. The Company reviews long-lived and intangible assets annually and on an as-needed basis to determine if there have been any adverse events or circumstances that would indicate that an impairment exists. In

PONIARD PHARMACEUTICALS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

NOTE 1. Business Overview and Summary of Significant Accounting Policies (Continued)

particular, the value of the picoplatin intangible asset could be impaired as a result of negative results of clinical trials or as a result of adverse decisions or rulings of regulatory bodies, such as the FDA. As a result of these reviews, the Company recorded an impairment charge related to the restructuring activities during 2005 and an additional impairment charge in 2006. No additional impairment charges were recognized in 2007 or 2008. See Note 13 below for further details.

Debt Issuance Costs: Costs incurred in connection with the securing of long-term bank loans and other long-term debt are deferred and amortized as interest expense over the term of the related debt using a method that approximates the effective interest method.

Licensed Products: Licensed products represent an exclusive license to develop, manufacture and commercialize picoplatin, a platinum-based anti-cancer agent. Licensed products are amortized using the straight-line method over their estimated useful life of twelve years. The Company evaluates the recoverability of licensed products periodically and takes into account events or circumstances that might indicate that an impairment exists as discussed above under “*Impairment of Long-Lived and Intangible Assets.*” No impairment of licensed products was identified during 2008, 2007 or 2006. See Note 10 below for additional information.

Income Taxes: The Company computes income taxes using the asset and liability method, under which deferred income taxes are provided for the temporary differences between the financial reporting basis and the tax basis of the Company’s assets and liabilities and for operating loss and tax credit carryforwards. A valuation allowance is established when necessary to reduce deferred tax assets to the amount, if any, which is expected more likely than not to be realized.

The Company accounts for uncertain tax positions in accordance with FASB Interpretation No. 48, “Accounting for Uncertainty in Income Taxes—an Interpretation of FASB Statement No. 109” (FIN 48). FIN 48 prescribes a recognition threshold and measurement attribute for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return and also provides guidance on various related matters such as derecognition, interest and penalties, and disclosure. The Company has been in a net operating loss position since its inception and, by providing a full valuation allowance, has not recognized any tax benefits for any of its income tax. Historically, the Company has not incurred any interest or penalties associated with tax matters and no interest or penalties were recognized during the year ended December 31, 2008. The Company has adopted a policy whereby amounts related to interest and penalties associated with tax matters are classified as additional income tax expense when incurred.

Net Loss Per Common Share: Basic and diluted loss per share are based on net loss applicable to common shares, which is comprised of net loss and preferred stock dividends in all periods presented. Shares used to calculate basic loss per share are based on the weighted average number of common shares outstanding during the period. Shares used to calculate diluted loss per share are based on the potential dilution that would occur upon the exercise or conversion of securities into common stock using the treasury stock method. The computation of diluted net loss per share excludes the following options and warrants to acquire shares of common stock for the years indicated because their effect would not be dilutive.

	2008	2007	2006
Common stock options	5,893,000	4,650,000	1,660,000
Common stock warrants	6,060,000	5,947,000	5,947,000

PONIARD PHARMACEUTICALS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

NOTE 1. Business Overview and Summary of Significant Accounting Policies (Continued)

Additionally, aggregate common shares of 39,015, issuable as of December 31, 2008 upon conversion of the Company's Series 1 convertible exchangeable preferred stock, are not included in the calculation of diluted loss per share for 2008, 2007, and 2006 because the share increments would not be dilutive.

Share-Based Compensation: Effective January 1, 2006, the Company adopted the provisions of Statement of Financial Accounting Standards (SFAS) No. 123 (revised 2004), "Share-Based Payment" (SFAS 123R), which establishes accounting for equity instruments exchanged for employee services. Under the provisions of SFAS 123R, share-based compensation cost is measured at the grant date, based on the fair value of the award, and is recognized as an expense over the employee's requisite service period (generally the vesting period of the equity grant).

Concentration in the Available Sources of Supply of Materials: The Company relies on third parties to manufacture picoplatin active pharmaceutical ingredient (API) and finished drug product for its clinical trials and for its planned commercialization activities. The Company currently has separate agreements with one supplier each of picoplatin API and finished drug product for clinical and commercial use. The Company's API clinical supply agreement continues in effect until it is terminated by mutual agreement of the parties or by either party in accordance with its terms. The Company's finished drug product clinical supply agreement runs for an initial term ending December 31, 2009, and is subject to renewal for two additional one-year terms, at the Company's option. The Company's commercial API and finished drug supply agreements have initial terms ending in late 2013. The Company believes that it currently has adequate supplies of picoplatin API and finished drug product in order to complete its current clinical trials. The Company has no assurance that its current suppliers will be able to manufacture sufficient picoplatin API and/or finished drug product on a timely or cost-effective basis at all times in the future. The Company believes that there are other contract manufacturers with the capacity to manufacture picoplatin API and finished drug product.

Fair Value of Financial Instruments: Effective January 1, 2008, the Company adopted Statement of Financial Accounting Standard No. 157, "Fair Value Measurement" (SFAS 157), for all financial instruments and non-financial instruments accounted for at fair value on a recurring basis. SFAS 157 introduces a framework for measuring fair value and expands disclosure requirements about fair value measurements. In accordance with the provisions of FASB Statement of Position No. FAS 157-2, "Effective Date of FASB Statement No. 157," the Company has elected to defer implementation of SFAS 157 as it relates to its non-financial assets and non-financial liabilities that are recognized and disclosed at fair value in the financial statements on a nonrecurring basis until January 1, 2009. The adoption of SFAS 157 for financial assets and liabilities and non-financial assets and liabilities that are re-measured and reported at fair value at least annually did not have a material impact on the Company's consolidated financial statements.

Segment Reporting: The Company has one operating business segment, cancer therapeutics development.

NOTE 2. New Accounting Pronouncements

Effective January 1, 2008, the Company adopted SFAS 157 for all financial instruments and non-financial instruments accounted for at fair value on a recurring basis. In accordance with the provisions of FSP FAS 157-2, "Effective Date of FASB Statement No. 157," the Company deferred the implementation of SFAS 157 as it relates to its non-financial assets and non-financial liabilities that are recognized and disclosed at fair value in the financial statements on a nonrecurring basis until

PONIARD PHARMACEUTICALS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

NOTE 2. New Accounting Pronouncements (Continued)

January 1, 2009. The Company is currently evaluating this statement and its impact, if any, on the Company's consolidated financial statements.

In March 2008, the FASB issued SFAS No. 161, "Disclosures about Derivative Instruments and Hedging Activities" (SFAS 161). SFAS 161 requires companies with derivative instruments to disclose information that should enable financial statement users to understand how and why a company uses derivative instruments, how derivative instruments and related hedged items are accounted for under SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities," and how derivative instruments and related hedged items affect a company's financial position, financial performance and cash flows. SFAS 161 is effective for financial statements issued for fiscal years beginning after November 15, 2008, and interim periods within those fiscal years. The Company is currently evaluating this statement and its impact, if any, on the Company's consolidated financial statements.

In April 2008, the FASB issued FASB Staff Position (FSP) FAS 142-3, "Determination of the Useful Life of Intangible Assets" (FSP 142-3). FSP 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, "Goodwill and Other Intangible Assets." The intent of this FSP is to improve the consistency between the useful life of a recognized intangible asset under SFAS No. 142 and the period of expected cash flows used to measure the fair value of the asset under SFAS No. 141R, and other GAAP. FSP 142-3 is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. Early adoption is prohibited. The Company is currently evaluating this statement and its impact, if any, on the Company's consolidated financial statements.

In December 2007, the FASB issued SFAS No. 141R (revised 2007), "Business Combinations" (SFAS 141R) which replaces SFAS No. 141. SFAS 141R retains the purchase method of accounting for acquisitions, but requires a number of changes, including changes in the way assets and liabilities are recognized in the accounting for a purchase. It also changes the recognition of assets acquired and liabilities assumed arising from contingencies, requires the capitalization of in-process research and development at fair value, and requires the expensing of acquisition-related costs as incurred. SFAS 141R is effective for acquisitions occurring in fiscal years beginning after December 15, 2008. While the Company is currently evaluating this statement and its impact, if any, on the Company's consolidated financial statements, it believes that the adoption of SFAS 141R would have an impact on the accounting for any future acquisition, if one were to occur.

In November 2007, the FASB ratified the consensus opinion in EITF Issue No. 07-1, "Accounting for Collaborative Arrangements" (EITF 07-1). EITF- 07-1 prescribes the accounting for collaborations. It requires certain transactions between collaborators to be recorded in the income statement on either a gross or net basis within expenses when certain characteristics exist in the collaboration relationship. EITF 07-1 is effective for all collaborations occurring in fiscal years beginning after December 15, 2008. The Company is currently evaluating this issue and its impact, if any, on the Company's consolidated financial statements.

In June 2008, the FASB ratified the consensus opinion in EITF Issue No. 07-5, "Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock" (EITF 07-5). EITF 07-5 provides guidance for determining whether an equity-linked financial instrument or embedded feature is considered indexed to an entity's own stock. The consensus establishes a two-step approach as a framework for determining whether an instrument or embedded feature is indexed to an entity's own stock. The approach includes evaluating (1) the instrument's contingent exercise provisions,

PONIARD PHARMACEUTICALS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

NOTE 2. New Accounting Pronouncements (Continued)

if any, and (2) the instrument's settlement provisions. Entities that issue financial instruments such as warrants or options on their own shares, convertible debt, convertible preferred stock, forward contracts on their own shares, or market-based employee stock option valuation instruments will be affected by EITF Issue 07-5. EITF 07-5 is effective for financial statements issued for fiscal years beginning after December 15, 2008. The Company is currently evaluating this Issue and its impact, if any, on the Company's consolidated financial statements.

NOTE 3. Fair Value Measurements

The Company holds available-for-sale securities that are measured at fair value which is determined on a recurring basis. These securities are classified within Level 2 of the fair value hierarchy prescribed by SFAS 157 because the value of the securities is based on quoted market prices or broker/dealer quotations.

The SFAS 157 framework requires fair value to be determined based on the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. SFAS 157 establishes a fair value hierarchy which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The standard describes the following three levels of inputs that may be used to measure fair value:

- *Level 1*—Quoted prices in active markets for identical assets or liabilities.
- *Level 2*—Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- *Level 3*—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The determination of a financial instrument's level within the fair value hierarchy is based on an assessment of the lowest level of any input that is significant to the fair value measurement. The Company utilizes the market approach to measure fair value for its financial assets and liabilities. The market approach uses prices and other relevant information generated by market transactions involving identical or comparable assets or liabilities. The Company's investment securities, consisting of debt securities, are classified as available-for-sale. Unrealized holding gains or losses on these securities are included in other comprehensive income. Realized gains and losses and declines in value judged to be other-than-temporary (of which there were none for the year ended December 31, 2008) on available-for-sale securities are included in interest income.

The following table presents a summary of the Company's assets and liabilities stated at fair value on a recurring basis (in thousands):

	Fair Value Measurements as of December 31, 2008			
	<u>Total</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
Cash equivalents	\$44,144	\$44,144	\$ —	\$ —
Investment securities	<u>28,611</u>	<u>—</u>	<u>28,611</u>	<u>—</u>
Total	<u>\$72,755</u>	<u>\$44,144</u>	<u>\$28,611</u>	<u>\$ —</u>

PONIARD PHARMACEUTICALS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

NOTE 4. Investment Securities

Investment securities consisted of the following at December 31, 2008 (in thousands):

	<u>Amortized Cost</u>	<u>Gross</u>	<u>Unrealized</u>	<u>Estimated</u>
		<u>Gains</u>	<u>(Losses)</u>	<u>Fair Value</u>
Type of security:				
Corporate debt securities	\$23,967	\$26	\$(382)	\$23,611
Federal government and agency securities . .	4,998	2	—	5,000
	<u>\$28,965</u>	<u>\$28</u>	<u>\$(382)</u>	<u>\$28,611</u>
Net unrealized loss			<u>\$(354)</u>	
Maturity:				
Less than one year	\$27,912			\$27,561
Due in 1–2 years	1,053			1,050
	<u>\$28,965</u>			<u>\$28,611</u>

Investment securities consisted of the following at December 31, 2007 (in thousands):

	<u>Amortized Cost</u>	<u>Gross</u>	<u>Unrealized</u>	<u>Estimated</u>
		<u>Gains</u>	<u>(Losses)</u>	<u>Fair Value</u>
Type of security:				
Corporate debt securities	\$63,227	\$76	\$(17)	\$63,286
Net unrealized gain			<u>\$ 59</u>	
Maturity:				
Less than one year	\$63,227			\$63,286

As of December 31, 2008, the Company held a debt security issued by American General Finance Corporation (AGFC), a wholly-owned subsidiary of American International Group, Inc. (AIG), with a par value of \$1,200,000, coupon rate of 3.875%, amortized cost of approximately \$1,195,000 at December 31, 2008 and maturity date of October 1, 2009. The market value for this security as of December 31, 2008, based on Level 2 inputs as described in Note 3, was approximately \$851,000, resulting in an unrealized loss of approximately \$344,000. The Company's management has concluded that the unrealized loss on the AGFC debt security, and the other debt securities that it holds, is temporary due to (a) the relatively short duration of the decline in value of the investments; (b) the assessment of the Company's management that it is probable that all contractual amounts under the debt securities will be received and (c) the Company's intent and ability to hold the securities until at least substantially all of the cost is recovered.

PONIARD PHARMACEUTICALS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

NOTE 5. Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	As of December 31,	
	2008	2007
Clinical trials	\$ 8,266	\$2,811
Accrued expenses	689	720
Compensation	1,164	901
Severance	285	—
Other	214	118
	\$10,618	\$4,550

NOTE 6. Note Payable

On September 2, 2008, the Company entered into an Amended and Restated Loan and Security Agreement (loan agreement) with GE Healthcare Financial Services (formerly known as Merrill Lynch Capital) and Silicon Valley Bank. The loan agreement amends and restates in its entirety the earlier Loan and Security Agreement dated as of October 25, 2006 (original loan), with Merrill Lynch Capital and Silicon Valley Bank, pursuant to which the Company obtained a \$15,000,000 capital loan that was to mature on April 1, 2010.

The loan agreement provides for a senior secured term loan facility (loan facility) to be made available as follows: (i) an initial term loan advance in the amount of \$17,600,000, which is comprised of (a) the outstanding principal balance of \$7,600,000 remaining on the original loan and (b) an additional cash advance of approximately \$10,000,000 (cash portion), which was fully funded on September 2, 2008; and (ii) a second term loan advance in the amount of \$10,000,000, which was fully funded on September 30, 2008. The cash portion of the initial term loan advance and the proceeds of the second term loan advance will be used to fund the Company's clinical trials and for general corporate purposes. The advances under the loan facility are repayable over 42 months, commencing on October 1, 2008. Interest on the advances is fixed at 7.80% per annum. Principal and interest in the amount of \$6,341,000, \$4,879,000, and \$813,000 was paid on the notes for the years ended December 31, 2008, 2007 and 2006, respectively. Final loan payments in the amounts of \$1,070,000 and \$900,000 are due upon maturity or earlier repayment of the initial term loan advance and the second term loan advance, respectively. Additionally, as a condition to the amendment and restatement of the original loan, the Company agreed to modification of the final payment obligations under the original loan, pursuant to which the Company paid \$600,000 to Silicon Valley Bank on September 2, 2008, the effective date of the loan facility, and will pay \$675,000 to GE Healthcare Financial Services on the earlier of March 31, 2010 or the date of repayment of the loan facility. All final payment amounts will be accreted to the note payable balance over the term of the loan facility using the effective interest rate method and reflected as additional interest expense. All interest payable under the loan agreement and the full amount of the final payments must be paid upon any prepayment of a term loan advance. The loan facility is secured by a first lien on all of the non-intellectual property assets of the Company.

In connection with the loan agreement, the Company issued to the lenders ten-year warrants to purchase an aggregate of 219,920 shares of the Company's common stock at an exercise price of \$4.297 per share. The fair value of the warrants using the Black-Scholes option-pricing model was approximately \$928,000 based upon assumptions of expected volatility of 90%, a contractual term of ten

PONIARD PHARMACEUTICALS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

NOTE 6. Note Payable (Continued)

years, an expected dividend rate of zero and a risk-free interest rate of 3.74%. The portion of the loan proceeds allocable to the warrants is approximately \$806,000 based on the relative fair value of the warrants, which the Company recorded as additional discount to notes payable. The total of the final loan payments and the proceeds allocated to the warrants of approximately \$4,051,000 will be amortized to interest expense using an effective interest rate of 13.8%.

The loan agreement contains restrictions on the Company's ability to, among other things, dispose of certain assets, engage in certain mergers and acquisition transactions, incur indebtedness, create liens on assets, make investments, pay dividends and repurchase stock. The loan agreement also contains covenants requiring the Company to maintain a minimum amount of unrestricted cash during the term of the loan equal to the lesser of (i) \$17,940,000 or (ii) the outstanding aggregate principal balance of the term loans plus \$4,000,000. The loan agreement contains events of default that include, nonpayment of principal, interest or fees, breaches of covenants, material adverse changes, bankruptcy and insolvency events, cross defaults to any other indebtedness, material judgments, inaccuracy of representations and warranties and events constituting a change of control. The occurrence of an event of default would increase the applicable rate of interest by 5% and could result in the acceleration of the Company's payment obligations under the loan agreement. See Note 1 for a discussion of the Company's potential inability to comply with the minimum unrestricted cash requirement and other loan covenants.

In connection with the Company's 2001 purchase of the radiopharmaceutical manufacturing plant and other assets located in Denton, Texas, the Company assumed \$6,000,000 principal amount of restructured debt held by Texas State Bank, McAllen, Texas. The loan, which was paid off in May 2006, was secured by the assets acquired in the transaction. Principal and interest paid on the note during the year ended December 31, 2006 totaled \$3,980,000.

Note payable maturities as of December 31, 2008 are as follows (in thousands):

<u>Year</u>	<u>Capital Lease</u>	<u>Note Payable</u>	<u>Total</u>
2009	\$32	\$ 7,886	\$ 7,918
2010	35	8,561	8,596
2011	3	7,886	7,889
2012	—	3,940	3,940
	<u>70</u>	<u>28,273</u>	<u>28,343</u>
Less: discount	—	(2,980)	(2,980)
	<u>\$70</u>	<u>\$25,293</u>	<u>\$25,363</u>

NOTE 7. Commitments and Contingencies

The Company entered into a picoplatin API commercial supply agreement with W.C. Heraeus (Heraeus) in March 2008. Under this agreement Heraeus will produce picoplatin API to be used for preparing picoplatin finished drug product for commercial use. Manufacturing services are provided on a purchase order, fixed-fee basis, subject to certain purchase price adjustments and minimum quantity requirements. The costs to Heraeus for the purchase and set-up of dedicated equipment as required under the commercial supply agreement, estimated to be approximately \$1.3 million, will be reimbursed by the Company in the form of a surcharge on an agreed upon amount of the picoplatin API ordered

PONIARD PHARMACEUTICALS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

NOTE 7. Commitments and Contingencies (Continued)

and delivered on or before December 31, 2013. If the Company orders and takes delivery of less than the agreed upon amount of picoplatin API through December 31, 2013, it will be obligated to pay the balance of the dedicated equipment cost as of that date. At December 31, 2008, Heraeus had completed partial construction of the dedicated equipment that represented approximately \$415,000 of cost. Because the Company is not under a present obligation to pay this amount and the agreement is not under any potential circumstance of default or termination, it is not probable that a financial liability exists for this amount as of December 31, 2008.

The Company leases the office and laboratory space for its principal locations under various leasing arrangements. In July 2006, the Company entered into a five-year lease for approximately 17,000 square feet of office space and laboratory space in South San Francisco. The Company relocated its corporate headquarters to these facilities in September 2006. The lease may be renewed for one three-year term, effective upon notice by us of our intent to renew nine months prior to the expiration of the current term. Base rental payments under this lease are subject to annual adjustment based on the Consumer Price Index in the San Francisco metropolitan market (CPI-SFMM) and a one-time adjustment for reimbursement for tenant improvements. Monthly base rent was increased by \$1,400 to \$46,600 following the adjustment for the 2007 CPI-SFMM and an additional \$1,400 to \$48,000 following the adjustment for the 2008 CPI-SFMM. In December 2007, the Company received approximately \$251,000 as a tenant reimbursement that resulted in a further \$5,400 increase in monthly base rent to \$53,400. Additional rental payments under this lease are paid based on the Company's share of operating expenses of the project in which the leased facilities are located.

The Company also leases approximately 21,000 square feet of office space in Seattle, WA, under an amended lease that expires December 31, 2010. The lease may be renewed for one five-year term, effective upon notice by the Company of its intent to renew six months prior to the expiration of the current term. Monthly base rent on this property is \$45,000 and additional rent payments under this lease are paid based on the Company's share of operating expenses of the facility.

Total rent expense under non-cancelable operating leases was approximately \$1,485,000, \$1,355,000, and \$958,000 for 2008, 2007 and 2006, respectively. The Company recognizes rent expense on a straight-line basis over the term of each lease, including any periods of free rent. Minimum lease payments under non-cancelable operating leases as of December 31, 2008 were as follows (in thousands):

<u>Year</u>	
2009	\$1,245
2010	1,229
2011	377
Thereafter	<u>—</u>
Total minimum lease payments	<u>\$2,851</u>

At December 31, 2008 and 2007, the Company had restricted cash of \$281,000 in the form of certificates of deposit. The certificates of deposit serve as collateral for standby letters of credit issued by Silicon Valley Bank on behalf of the Company.

Under the covenants contained in the loan agreement with GE Healthcare Financial Services and Silicon Valley Bank, discussed in Note 6, the Company is required to maintain a minimum amount of

PONIARD PHARMACEUTICALS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

NOTE 7. Commitments and Contingencies (Continued)

unrestricted cash during the term of the loan equal to the lesser of (i) \$17,940,000 or (ii) the outstanding aggregate principal balance of the term loans plus \$4,000,000. Refer to Note 6 above for further information on the note payable and related covenants.

NOTE 8. Stock-Based Compensation

Effective January 1, 2006, the Company adopted the provisions of SFAS 123R, using the modified prospective transition method. Under the provisions of SFAS 123R, share-based compensation cost is measured at the grant date, based on the fair value of the award, and is recognized as an expense over the employee's requisite service period (generally the vesting period of the equity grant). Prior to January 1, 2006, the Company accounted for share-based compensation to employees in accordance with APB 25 and related interpretations.

Under SFAS 123R, the Company is required to select a valuation technique or option-pricing model that meets the criteria as stated in SFAS 123R, which includes a binomial model and the Black-Scholes-Merton (Black-Scholes) model. At the present time, the Company is continuing to use the Black-Scholes model. The adoption of SFAS 123R, applying the modified prospective transition method, as elected by the Company, requires the Company to value stock options prior to its adoption of SFAS 123R under the fair value method and expense these amounts over the stock options' remaining vesting period. Under this transition method, compensation expense recognized during the year ended December 31, 2006 included compensation expense for all share-based awards granted prior to, but not yet vested, as of December 31, 2005, based on the grant date fair value estimated in accordance with the original provisions of SFAS 123. The Company recorded expense for stock-based compensation, not including expense for options granted to non-employee consultants, for the periods presented as follows (in thousands):

	Years Ended December 31,		
	2008	2007	2006
Research and development expense	\$1,462	\$1,265	\$ 213
General and administrative expense	5,542	4,149	1,258
Total	\$7,004	\$5,414	\$1,471

The stock option expense for the twelve months ended December 31, 2008 includes the grant of stock options during the first quarter of 2008 to Company officers to purchase an aggregate of 460,000 shares of common stock, the grant of stock options in the third quarter of 2008 to purchase an aggregate of 60,000 shares of common stock and the grant of stock options during the fourth quarter of 2008 to purchase an aggregate of 385,000 shares of common stock. Certain options that were granted to Company officers during 2006 and 2007 vest 50% in equal monthly installments over four years from the date of grant and vest another 50% on the seven-year anniversary of the date of grant, subject to accelerated vesting of up to 25% of such portion of the options, based on the Company's achievement of annual performance goals established under its annual incentive plan, at the discretion of the equity awards subcommittee of the Company's board of directors. Based on the overall achievement of corporate goals in 2006, 2007 and 2008, the equity awards subcommittee accelerated vesting with respect to 20% of the shares subject to the seven-year vesting schedule in the second quarter of 2007 and both the first and fourth quarters of 2008, resulting in cumulative accelerated vesting of 60% of the shares subject to the seven-year vesting schedule as of December 31, 2008.

PONIARD PHARMACEUTICALS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

NOTE 8. Stock-Based Compensation (Continued)

The Company's Amended and Restated 2004 Incentive Compensation Plan (the 2004 Plan) was the only compensation plan under which options were available for grant on December 31, 2008. The Company's 1991 Stock Option Plan for Non-Employee Directors (the Directors Plan) was terminated on March 31, 2005, and no further options can be granted under that plan. The Company's 1994 Stock Option Plan (the 1994 Plan) was terminated on February 17, 2004, and no further options can be granted under that plan. Although no Company securities are available for issuance under the Directors Plan or the 1994 Plan, options granted prior to termination of those plans continue in effect in accordance with their terms.

The 2004 Plan, as amended and restated on June 14, 2007, authorizes the Company's board or a committee appointed by the board to grant options to purchase an aggregate of 5,899,800 shares of common stock. The 2004 Plan also contains an evergreen provision pursuant to which the number of shares available under the plan will automatically increase each year, beginning in 2008, according to certain limits set forth in the plan. The aggregate of 5,899,800 shares reflects an increase of 2,500,000 shares that was approved by shareholders at the Company's 2007 annual meeting of shareholders held on June 14, 2007 and an increase of 1,733,134 shares on January 1, 2008, pursuant to the operation of the evergreen provision. The 2004 Plan allows for the issuance of incentive stock options, nonqualified stock options, restricted stock and restricted stock units (RSUs) to employees, officers, directors, agents, consultants, advisors and independent contractors of the Company, subject to certain restrictions. All option grants expire ten years from the date of grant, except in the event of earlier termination of employment or service. Option grants for employees with less than one year of service generally become exercisable at a rate of 25% after one year from the grant date and then in monthly increments at a rate of 1/36th of the remaining balance over the following three years. Option grants for employees with at least one year of service and employees receiving promotions become exercisable at a rate of 1/48th per month over four years from the grant date.

During 2008 the Company awarded 91,974 RSUs under the 2004 Plan to non-officer employees as an incentive for future performance. Upon vesting, each RSU is payable with one share of the Company's common stock. The fair value of the RSUs was \$3.14 per unit, or approximately \$288,000 in total, based upon the closing market price of the Company's common stock on the award date. The RSUs vest based on the achievement of certain performance milestones during 2009 and 2010. The rate of vesting would be 20% in April 2009, 20% in June 2009 and 60% in June 2010 if the milestones are achieved. It is probable that the April 2009 milestone will be achieved and 20% of the RSUs will vest resulting in approximately \$58,000 of compensation expense.

As of December 31, 2008, there were 55,987 shares of common stock available for issuance as new awards under the 2004 Plan. As of January 1, 2009, 1,734,386 additional shares of common stock became available under the 2004 Plan due the automatic annual increase under the evergreen provision. Accordingly, as of January 1, 2009, an aggregate of 1,790,373 shares of common stock were available for issuance as new awards under the 2004 Plan.

On September 13, 2006, February 7, 2007, February 27, 2007, May 7, 2007 and May 31, 2007, the Company issued stock options to employees and consultants that were subject to shareholder approval of an increase in the number of shares authorized for issuance under the 2004 Plan at the Company's 2007 annual meeting of shareholders. As stated above, shareholders approved the increase in the number of shares authorized for issuance under the 2004 Plan to 4,166,666 shares of common stock, thereby allowing these grants to be effective and exercisable to the extent vested as of June 14, 2007.

PONIARD PHARMACEUTICALS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

NOTE 8. Stock-Based Compensation (Continued)

Under the requirements of SFAS 123R, the Company treated these stock options as having a grant date of June 14, 2007.

The Company modified certain stock options which had been granted to a member of the Company's board of directors, so that such stock options would fully vest as of August 14, 2006, the date that the director retired from the board. No other modifications were made to these stock options. The effect of this modification was a decrease in total stock compensation expense of \$101,000 for the year ended December 31, 2006.

During 2008 the Company modified certain stock options which had been granted to an officer of the Company upon his conversion to consultant status effective with his termination of employment such that any vested options would remain exercisable until the earliest of (a) thirty days after the Company receives approval from the FDA of its NDA for picoplatin, (b) twenty-four months after termination of service, and (c) the option expiration date (as defined in the 2004 Plan) for the options. As a result of this conversion, the Company incurred expense of \$50,000 for the outstanding grants during the fourth quarter of 2008.

The Company records compensation expense for employee stock options based on the estimated fair value of the options on the date of grant using the Black-Scholes option-pricing model. This fair value is amortized on a straight-line basis over the requisite service periods for the grants, which is generally the vesting period. The remaining unrecognized compensation cost related to unvested awards at December 31, 2008, was approximately \$11,566,000 and the weighted-average period of time over which this cost will be recognized is 2.8 years. The Company uses historical data, and other related information as appropriate, to estimate the expected price volatility, the expected option life and the expected forfeiture rate. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of the grant. The weighted-average fair value per share of the Company's stock options granted to employees was estimated to be \$2.20, \$5.83 and \$5.49 for the years ended December 31, 2008, 2007 and 2006, respectively, using the Black-Scholes model with the following weighted-average assumptions:

	<u>Years Ended December 31,</u>		
	<u>2008</u>	<u>2007</u>	<u>2006</u>
Expected term (in years)	4.58	6.38	6.82
Risk-free interest rate	2.26%	5.03%	5.03%
Expected stock price volatility	90%	101%	105%
Expected dividend rate	0%	0%	0%

PONIARD PHARMACEUTICALS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

NOTE 8. Stock-Based Compensation (Continued)

The Company issues previously authorized but unissued shares of common stock upon exercise of stock options. A summary of option activity as of December 31, 2008 and changes during the three years then ended are as follows (shares and intrinsic value in thousands):

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in Years	Aggregate Intrinsic Value
Outstanding at December 31, 2005	721			
Granted	1,046	\$ 6.44		
Exercised	(6)	3.17		
Forefeited/cancelled/expired	(101)	9.15		
Outstanding at December 31, 2006	<u>1,660</u>	10.50		
<i>Exercisable at December 31, 2006</i>	<i>587</i>	<i>17.55</i>		
Granted	3,283	5.93		
Exercised	(6)	3.66		
Forefeited/cancelled/expired	(287)	13.14		
Outstanding at December 31, 2007	<u>4,650</u>	7.12		
<i>Exercisable at December 31, 2007</i>	<i>1,251</i>	<i>9.66</i>		
Granted	1,599	3.27		
Exercised	(25)	3.61		
Forefeited/cancelled/expired	(331)	6.97		
Outstanding at December 31, 2008	<u>5,893</u>	6.10	<u>7.9</u>	<u>\$103</u>
<i>Exercisable at December 31, 2008</i>	<i>2,583</i>	<i>\$ 7.69</i>	<u>6.8</u>	<u>\$ —</u>

Information relating to stock options outstanding and exercisable at December 31, 2008 is as follows (shares in thousands):

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number of Shares	Weighted Average Remaining Life in Years	Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Price
\$ 1.78 - \$ 3.66	1,499	8.4	\$ 2.76	499	\$ 3.59
3.72 - 4.66	995	8.7	4.25	259	4.15
4.80 - 6.48	1,259	7.6	5.97	615	6.10
6.77 - 7.17	987	8.4	6.90	407	6.91
7.44 - 15.00	1,050	7.1	9.05	700	9.56
15.42 - 109.50	103	2.5	36.31	103	36.31
	<u>5,893</u>	7.9	6.10	<u>2,583</u>	7.69

PONIARD PHARMACEUTICALS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

NOTE 8. Stock-Based Compensation (Continued)

No income tax benefit has been recorded for stock option exercises as the Company provides a full valuation allowance because management has concluded it is more likely than not that the net deferred tax asset will not be realized.

Cash proceeds and intrinsic value related to total stock options exercised during the years ended December 31, 2008, 2007 and 2006 are provided in the following table (in thousands):

	Years Ended December 31,		
	2008	2007	2006
Proceeds from stock options exercised	\$91	\$22	\$19
Intrinsic value of stock options exercised	38	6	11

In connection with various consulting and service contracts, the Company has issued stock options to non-employees. These options are revalued quarterly using the Black-Scholes option-pricing model and the total value of the stock options is recognized as expense over the service period. Stock options to purchase 40,000, 44,998, and 3,333 shares of common stock were granted during 2008, 2007 and 2006, respectively. The Company recorded compensation expense of \$119,000, \$55,000, and \$8,000 during 2008, 2007 and 2006, respectively, due to these grants.

NOTE 9. Shareholders' Equity

Common Stock Transactions: In connection with the Company's 2007 public offering, the Company issued approximately 11,849,000 shares of common stock at a purchase price of \$6.33 per share. Net proceeds of the public offering, after payment of underwriters' discounts and commissions and offering expenses, were approximately \$69,946,000.

In connection with the 2006 equity financing, the Company issued to a group of institutional and other accredited investors an aggregate of 15,491,000 shares of common stock at a cash purchase price of \$4.20 per share. Investors in the financing also received five-year warrants to purchase an aggregate of 4,643,000 shares of common stock at an exercise price of \$4.62 per share. Concurrent with the closing of the financing, the Company issued an aggregate of 1,591,000 shares of common stock to the holders of its Series B preferred stock upon conversion of the outstanding Series B preferred shares (the Series B shares).

As part of the 2006 equity financing, on February 1, 2006, the Company received a \$3,460,000 bridge loan from investors in the 2006 equity financing. Pursuant to the bridge loan, the Company issued convertible promissory notes in the principal amount of the loan and five-year warrants to purchase approximately 412,000 shares of common stock at an exercise price of \$4.62 per share. The fair value attributable to the warrants using the Black-Scholes option-pricing model was approximately \$1,647,000 based upon assumptions of expected volatility of 114%, a contractual term of five years, an expected dividend rate of zero and a risk-free rate of interest of 4.5%. The Company recorded the warrants' fair value as a discount to the promissory notes payable. The convertibility of the promissory notes gave rise to a beneficial conversion feature, which the Company recorded as additional discount on the promissory notes of approximately \$1,813,000. The proceeds of the bridge loan were used for working capital pending closing of the 2006 equity financing on April 26, 2006. The convertible promissory notes provided for an interest rate of 8% per annum and, at the closing of the 2006 equity financing, the principal amount of the notes, together with approximately \$63,000 of accrued interest

PONIARD PHARMACEUTICALS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

NOTE 9. Shareholders' Equity (Continued)

thereon, automatically converted, at a conversion rate of \$4.20 per share, into approximately 839,000 shares of common stock. The Company has registered with the SEC the shares of common stock issued to investors in the 2006 equity financing, including the shares of common stock issuable upon exercise of the related warrants.

On September 22, 2006, the Company's shareholders approved a one-for-six reverse split of the Company's outstanding common stock, which became effective at the close of business that day. As a result of the reverse split, every six shares of Company common stock outstanding at the effective time automatically were combined into one outstanding share of Company common stock. The reverse stock split did not change the number of authorized shares of Company common stock designated in the Company's articles of incorporation, nor did it change the par value of the Company's common stock. In lieu of fractional shares, shareholders are entitled to receive an amount in cash equal to the value of their fractional shares based on \$0.57, the closing price per share of the Company's common stock on September 22, 2006.

During 2008, the Company received approximately \$91,000 in net proceeds from the issuance of approximately 25,000 shares of common stock related to the exercises of employee stock options.

During 2007, the Company received approximately \$22,000 in net proceeds from the issuance of approximately 6,000 shares of common stock related to the exercises of employee stock options.

During 2006, the Company received approximately \$19,000 in net proceeds from the issuance of approximately 6,000 shares of common stock related to the exercises of employee stock options.

Preferred Stock Transactions: During 2003, the Company issued 1,575 shares of a newly created class of Series B Convertible Preferred Stock with attached warrants to buy 105,000 shares of common stock. As described above, in connection with the 2006 equity financing, the 1,575 shares of Series B shares were converted into 1,591,000 shares of common stock in April 2006. The Series B shares received by the Company were retired and cancelled and are not reissuable. The Company had 205,340 shares of Series 1 Convertible Exchangeable Preferred Stock (Series 1 preferred stock) outstanding at December 31, 2008. Holders of the Series 1 preferred stock are entitled to receive an annual cash dividend of \$2.4375 per share if declared by the Board, payable semi-annually on June 1 and December 1. Dividends are cumulative. Each share of Series 1 preferred stock is convertible into 0.19 shares of common stock, subject to adjustment in certain events. The Series 1 preferred stock is redeemable at the option of the Company at \$25.00 per share. Holders of Series 1 preferred stock have no voting rights, except in limited circumstances. Dividends of \$500,000 were paid in each of the years 2008, 2007 and 2006, respectively.

The Company's board of directors may, without further action by the shareholders, issue preferred stock in one or more series and fix the rights and preferences thereof, including dividend rights, dividend rates, conversion rates, voting rights, terms of redemption, redemption price or prices, liquidation preferences and the number of shares constituting any series or the designations of such series.

Shareholder Rights Plan: The Company's Shareholder Rights Plan, and all preferred share purchase rights issued there under, expired on April 10, 2006.

PONIARD PHARMACEUTICALS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

NOTE 9. Shareholders' Equity (Continued)

Stock Options: At December 31, 2008, the Company's Amended and Restated 2004 Incentive Compensation Plan (the 2004 Plan) was the only compensation plan under which options were available for grant. See Note 8 for more details regarding this plan.

Restricted Stock Units: The 2004 Plan allows for the award of restricted stock units (RSUs). During 2008 the Company awarded 91,974 RSUs under the 2004 Plan to non-officer employees as an incentive for future performance. See Note 8 for additional details.

Warrants: The Company had outstanding warrants to purchase an aggregate of 6,060,000 and 5,947,000 shares of the Company's common stock as of December 31, 2008 and 2007, respectively. The weighted average exercise price of warrants outstanding was \$5.51 and \$6.09 per share for 2008 and 2007, respectively.

In connection with the 2008 loan agreement described in Note 6 above, the Company issued to the lenders ten-year warrants to purchase an aggregate of 219,920 shares of the Company's common stock at an exercise price of \$4.297 per share. The fair value of the warrants using the Black-Scholes option-pricing model was approximately \$928,000 based upon assumptions of expected volatility of 90%, a contractual term of ten years, an expected dividend rate of zero and a risk-free interest rate of 3.74%. The portion of the loan proceeds allocable to the warrants is approximately \$806,000 based on the relative fair value of the warrants, which the Company recorded as additional discount to notes payable. The total of the final loan payments and the proceeds allocated to the warrants of approximately \$4,051,000 will be amortized to interest expense using an effective interest rate of 13.8%.

In connection with the 2006 equity financing, the Company issued five-year warrants to purchase a total of approximately 4,643,000 shares of common stock at an exercise price of \$4.62 per share as follows:

- Warrants to purchase approximately 4,231,000 shares of common stock that were issued to investors and became exercisable on April 26, 2006 and, thereafter, are exercisable at any time during their term; and
- Warrants to purchase approximately 412,000 shares of common stock that were issued to investors in connection with the bridge notes that were issued as part of the 2006 equity financing and became exercisable on February 1, 2006 and, thereafter, are exercisable at any time during their term.

In payment of placement agent fees for the 2006 equity financing, the Company issued five-year warrants to purchase approximately 140,000 shares of common stock at an exercise price of \$4.62 per share. The shares of common stock issuable upon exercise of the 2006 financing warrants have been registered with the SEC.

In connection with the loan and security agreement with Silicon Valley Bank and Merrill Lynch Capital executed on October 25, 2006, the Company issued five-year warrants to purchase approximately 174,000 shares of common stock at an exercise price of \$4.30 per share. The fair value of the warrants was determined to be approximately \$611,000 using the Black-Scholes option pricing model with assumptions of expected volatility of 112%, contractual term of five years, expected dividend rate of zero and a risk-free interest rate of 4.8%. Based on this fair value, approximately \$540,000 was ascribed to the warrants and treated as a discount against the \$15,000,000 loan obtained

PONIARD PHARMACEUTICALS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

NOTE 9. Shareholders' Equity (Continued)

from Silicon Valley Bank and Merrill Lynch Capital. The warrants became exercisable upon issuance and are exercisable at any time during their term.

In connection with an agreement in 2006 for corporate communications services, the Company issued a two-year warrant to purchase approximately 2,000 shares of common stock at an exercise price of \$3.66 per share. The Company recorded an expense in the amount of approximately \$3,400 for the fair value of the warrant on the date the services were completed. Based upon the Black-Scholes option pricing model, the grant date fair value of the warrant was \$2.06 per share using assumptions of expected volatility of 105%, contractual term of two years, expected dividend rate of zero and a risk-free interest rate of 4.8%. The warrant became exercisable upon issuance and was exercisable at any time during its term. This warrant expired without any exercises or redemptions on September 13, 2008.

In connection with a 2005 financing, the Company issued five-year warrants to purchase approximately 278,000 shares of common stock at an exercise price of \$9.54 per share. The warrants became exercisable on September 3, 2005 and, thereafter, are exercisable at any time during their term. In payment of placement agent fees for the 2005 financing, the Company issued a five-year warrant to purchase approximately 42,000 shares of common stock at an exercise price of \$9.54 per share. The warrants contain provisions requiring the adjustment of the exercise price and number of shares issuable if the Company sells (other than in connection with certain permitted transactions, such as strategic collaborations and acquisitions approved by the board) shares of common stock at a price lower than the then-current exercise price of the warrants. The shares of common stock issuable upon exercise of the 2005 financing warrants have been registered with the SEC.

In connection with a 2004 financing, the Company issued five-year warrants to purchase approximately 557,000 shares of common stock, at an exercise price of \$11.58 per share. The warrants became exercisable on February 23, 2004 and, thereafter, are exercisable at any time during their term. The warrants contain provisions requiring the adjustment of the exercise price and number of shares issuable if the Company sells shares of common stock at a price lower than the then-current exercise price of the warrants. In payment of placement agent fees for the 2004 financing, the Company issued three-year warrants to purchase approximately 6,000 shares of common stock at an exercise price of \$33.24 per share. The Company recorded a charge to general and administrative expense of \$118,000 for the fair value of the warrants on February 23, 2004. Based upon the Black-Scholes option-pricing model, the fair value of the warrants was \$20.28 per share using assumptions of expected volatility of 124%, contractual terms of three years, expected dividend rate of zero, and a risk-free rate of interest of 2.2%. These warrants expired without any exercises or redemptions on February 23, 2009.

In connection with the sale of its Series B preferred stock in 2003, the purchasers of the Series B preferred stock received five-year warrants to purchase approximately 105,000 shares of common stock, at an exercise price of \$36.00 per share. The warrants became exercisable on June 3, 2004. The warrants were redeemable at the election of the Company at any time after December 3, 2005, if the volume-weighted average price of the underlying common stock for each trading day over a period of 20 consecutive trading days was equal to or greater than \$51.00 per share, subject to adjustment. The shares of common stock issuable upon exercise of the warrants were registered with the SEC. These warrants expired without any exercises or redemptions on December 3, 2008.

PONIARD PHARMACEUTICALS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

NOTE 10. Picoplatin License and Amendment

The Company has entered into an exclusive worldwide license, as amended, with Genzyme Corporation (successor to AnorMED, Inc.) for the development and commercial sale of picoplatin. Under that license, the Company is solely responsible for the development and commercialization of picoplatin. Genzyme retains the right, at the Company's cost, to prosecute its patent applications and maintain all licensed patents. The parties executed the license agreement in April 2004, at which time the Company paid a one-time up-front payment of \$1,000,000 in common stock and \$1,000,000 in cash. The original agreement excluded Japan from the licensed territory and provided for \$13,000,000 in development and commercialization milestones, payable in cash or a combination of cash and common stock, and a royalty rate of up to 15% on product net sales after regulatory approval. The parties amended the license agreement on September 18, 2006, modifying several key financial terms and expanding the licensed territory to include Japan, thereby providing the Company worldwide rights. In consideration of the amendment, the Company paid Genzyme \$5,000,000 in cash on October 12, 2006 and an additional \$5,000,000 in cash on March 30, 2007. The amendment eliminated all development milestone payments to Genzyme. Genzyme remains entitled to receive up to \$5,000,000 in commercialization milestones upon the attainment of certain levels of annual net sales of picoplatin after regulatory approval. The amendment also reduced the royalty payable to Genzyme to a maximum of 9% of annual net product sales and eliminated sharing of sublicense revenues with Genzyme.

The Company accounted for all payments made in consideration of the picoplatin license, as amended, by capitalizing them as an intangible asset. The Company's capitalization of the total \$12,000,000 of picoplatin license payments is based on the Company's reasonable expectation at the time of acquisition and through the date of the amendment that the intravenous formulation of picoplatin, as it existed at the time of the acquisition of the picoplatin license and the license amendment, would be used in research and development (R&D) projects and therefore had alternative future uses in the treatment of different cancer indications. At the time of acquisition, the Company planned to use intravenous picoplatin in a Phase II clinical trial in patients with small cell lung cancer and reasonably expected that the intravenous formulation could be used in additional, currently identifiable R&D projects in the form of clinical trials for other solid cancer indications, such as prostate and colorectal cancers.

The Company determined the original useful life of the picoplatin intangible asset in accordance with the requirements of the FASB SFAS No. 142, "Goodwill and Other Assets." The Company, at the time of acquisition of the picoplatin license, reasonably anticipated using intravenous picoplatin in clinical trials that could be conducted during the remaining term of the primary patent, which is active through 2016. The Company concluded that the twelve years remaining for the primary patent term was the appropriate useful life for the picoplatin intangible asset, in satisfaction of the expected use and legal life provisions of SFAS No. 142, and is amortizing the initial \$2,000,000 license payment over this twelve year useful life beginning April 2004. The Company concluded that no change in the twelve-year useful life of the picoplatin intangible asset occurred as a result of the 2006 license amendment and is, therefore, continuing to amortize the initial \$2,000,000 license payment over the twelve year useful life and is amortizing the license amendment payment of \$10,000,000 over the remainder of the twelve year useful life of the picoplatin intangible asset.

Licensed products consists of the picoplatin amortizable intangible asset with a gross amount of \$12,000,000 less accumulated amortization of \$3,193,000 and \$1,979,000 at December 31, 2008 and 2007, respectively. The Company recognized amortization expense of \$1,215,000 in each of the years

PONIARD PHARMACEUTICALS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

NOTE 10. Picoplatin License and Amendment (Continued)

ended December 31, 2008 and 2007. The estimated annual amortization expense for licensed products is approximately \$1,215,000 for each of the years 2009 through 2013.

NOTE 11. Federal Income Taxes

Temporary differences and carryforwards giving rise to deferred tax assets (liabilities) were as follows (in thousands):

	December 31,	
	2008	2007
Deferred Tax Assets (Liabilities):		
Net operating loss carryforwards	\$ 38,104	\$ 31,525
Research and experimentation credit carryforwards	2,030	1,444
Capitalized research and development	19,768	12,995
Stock compensation	3,362	572
Property and equipment	6	(11)
Other	1,768	704
	65,038	47,229
Net deferred tax assets		
Deferred tax assets valuation allowance	(65,038)	(47,229)
Net deferred income taxes	\$ —	\$ —

The Company has established a valuation allowance equal to the amount of its net deferred tax assets because the Company has not had taxable income since its inception and significant uncertainty exists regarding the ultimate realization of its deferred tax assets. Accordingly, no tax benefits have been recorded in the accompanying statements of operations. The valuation allowance increased by \$17,809,000 in 2008 and \$11,542,000 in 2007.

In April 2006, the Company experienced a significant change to its capital structure which resulted in an ownership change, as defined under Section 382 of the IRC. Consequently, the amount of net operating loss carryforwards and research and experimentation credit carryforwards available to be used in future years are limited under IRC Sections 382 and 383, respectively. This limitation resulted in the loss of approximately \$93,300,000 (approximately \$31,700,000 in tax benefits) of the Company's net operating loss carryforwards and \$9,100,000 of the Company's research and development credit carryforwards. Accordingly, the deferred tax asset and related valuation allowance associated to these carryforwards were reduced in 2006 by approximately \$40,800,000.

At December 31, 2008, the Company's net operating loss carryforwards consisted of approximately \$109,553,000 for federal taxes (net of the impact of the above referenced change in ownership under IRC Section 382) and approximately \$14,677,000 for state taxes, which expire from 2009 through 2028 and from 2015 through 2018, respectively. Research and experimentation credits expire from 2009 to 2028. Future changes in the Company's ownership could result in additional limitations on the Company's ability to utilize its remaining net operating loss carryforwards and research and experimentation credit carryforwards.

PONIARD PHARMACEUTICALS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

NOTE 11. Federal Income Taxes (Continued)

Approximately \$20,771,000 of the Company's net operating loss carryforwards at December 31, 2008, result from deductions associated with the exercise of non-qualified employee stock options, the realization of which would result in a credit to shareholders' equity.

On January 1, 2007, the Company adopted the provisions of FASB Interpretation 48, "Accounting for Uncertainty in Income Taxes: An Interpretation of FASB Statement No. 109" (FIN 48), supplemented by FASB Financial Staff Position FIN 48-1, "Definition of Settlement in FASB Interpretation No. 48," issued May 2, 2007. Previously, the Company had accounted for tax contingencies in accordance with SFAS No. 5, "Accounting for Contingencies." FIN 48 clarifies the accounting for uncertainty in income taxes recognized in the Company's consolidated financial statements in accordance with SFAS No. 109, "Accounting for Income Taxes" (SFAS 109). The interpretation establishes guidelines for recognition, measurement, presentation and disclosure of uncertain tax positions taken or expected to be taken in income tax returns. Due to the Company's full valuation allowance against its deferred tax assets, coupled with the Section 382 limitation on prior years' net operating loss carryforwards (as discussed above), there are no material unrecognized tax benefits as of December 31, 2008 or December 31, 2007.

Historically, the Company has not incurred any material interest or penalties associated with tax matters and no material interest or penalties were recognized during the year ended December 31, 2008. The Company has adopted a policy whereby amounts related to interest and penalties associated with tax matters are classified as income tax expense when incurred. The Company is subject to income taxes in the U.S. federal and various states jurisdictions. Tax regulations within each jurisdiction are subject to the interpretation of the related tax laws and regulations and require significant judgment to apply. Tax years that remain open for examination include 2005, 2006, 2007 and 2008. In addition, tax years from 1993 to 2004 may be subject to examination in the event that the Company utilizes the net operating loss carryforwards from those years in its current or future tax returns.

NOTE 12. Restructuring

In May and June 2005, the Company restructured its operations and reduced its workforce by approximately 50% in connection with the implementation of its plan to discontinue its skeletal targeted radiotherapy (STR) development program and refocus its resources on the development of picoplatin. The employees terminated as part of the reduction of staff were no longer with the Company at December 31, 2005 and did not provide future services to the Company. The Company incurred termination benefits charges totaling \$892,000 related to the reduction in staff in May and June 2005. Of this amount, \$250,000 remained unpaid as of December 31, 2005 and was included in accrued expenses in the consolidated balance sheet as of December 31, 2005. This amount was paid during 2006. The Company incurred additional non-employee charges totaling \$612,000 related to the discontinuation of its STR clinical trials and the closure of its radiopharmaceutical manufacturing plant and STR research facilities, primarily consisting of contract termination and decommissioning costs. The Company recorded additional charges of \$237,000 for decommissioning costs during the third and fourth quarters of 2005 due to anticipated increased waste disposal costs at its radiopharmaceutical manufacturing plant in Denton, Texas and anticipated increased STR study finalization costs. Total non-employee charges totaled \$849,000. Of this amount, \$217,000 remained unpaid as of December 31, 2005 and was included in accrued expenses in the consolidated balance sheet as of December 31, 2005. This amount was paid during 2006.

PONIARD PHARMACEUTICALS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

NOTE 12. Restructuring (Continued)

In conjunction with the Company's restructuring, in June 2005, the Company negotiated the early termination of its STR-related supply agreement with the University of Missouri Research Reactor facility group (MURR). The Company paid MURR a fee of \$368,000 in connection with such early termination. The Company also paid MURR \$190,000 in minimum purchase requirements under the agreement in 2005. These two amounts are included in the non-employee charges of \$612,000 discussed above.

The following table summarizes the change in the restructuring accrual from initial recognition through December 31, 2006, after which there were no accrued restructuring charges payable:

<u>Description</u>	<u>Initial Restructuring Charge</u>	<u>Adjustment of Restructuring Charge</u>	<u>Adjusted Restructuring Charge</u>	<u>Payment of Restructuring Obligations</u>	<u>Accrued Restructuring Charge as of Dec. 31, 2005</u>	<u>Payment of Restructuring Obligations</u>	<u>Accrued Restructuring Charge as of Dec. 31, 2006</u>
Employee termination benefits	\$ 892,000	\$ —	\$ 892,000	\$ (642,000)	\$250,000	\$(250,000)	\$—
Contract termination costs	378,000	(10,000)	368,000	(366,000)	2,000	(2,000)	—
Other termination costs	234,000	247,000	481,000	(266,000)	215,000	(215,000)	—
Sub-total	612,000	237,000	849,000	(632,000)	217,000	(217,000)	—
Total	<u>\$1,504,000</u>	<u>\$237,000</u>	<u>\$1,741,000</u>	<u>\$(1,274,000)</u>	<u>\$467,000</u>	<u>\$(467,000)</u>	<u>\$—</u>

NOTE 13. Asset Impairment Loss

In June 2005, the Company recognized an asset impairment loss of \$3,346,000 on certain facilities and equipment resulting from the Company's termination of its STR development program. The loss on the Denton manufacturing facility and related equipment was determined based on an appraisal study commissioned by the Company, as well as management reviews with the assistance of outside commercial real estate brokers. The Company used a fair value of \$3,300,000 for the Denton facility in determining the impairment loss. This valuation was the result of weighting the range of values in the appraisal study, which varied from \$3,100,000 to \$5,000,000. The loss on the equipment at the Seattle facility was determined based on estimates of potential sales values of used equipment. These impairment charges established new cost bases for the impaired assets, which are reported in Assets Held for Sale in current assets and other non-current assets on the consolidated balance sheets as of December 31, 2005 and 2006. All equipment in current Assets Held for Sale was disposed of as of December 31, 2006. Given the inherent uncertainty of the timing of the sale of the Denton facility, the Company classified this asset as non-current as of December 31, 2006.

As of December 31, 2006, the Company reduced the carrying value of Denton facility in non-current Assets Held for Sale based on a fair value of \$2,800,000 and recognized additional impairment loss of \$403,000. This valuation adjustment was based on the Company's review of listing prices and completed sales of comparable properties in the region and the interest of prospective buyers. The Company sold the Denton facility on October 1, 2007, which resulted in net sales proceeds of \$2,729,000, and a net gain of \$105,000.

PONIARD PHARMACEUTICALS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

NOTE 13. Asset Impairment Loss (Continued)

The following table summarizes activity related to the impairment charges and impaired assets' carrying values:

	<u>Equipment Seattle, WA</u>	<u>Equipment, Manufacturing Facility Denton, TX</u>	<u>Manufacturing Facility Denton, TX</u>	<u>Total</u>
Impairment Loss	\$155,000	\$ 589,000	\$ 2,602,000	\$ 3,346,000
Impaired Carrying Value as of June 30, 2005	45,000	183,000	3,027,000	3,255,000
Disposals of Assets	(44,000)	(101,000)	—	(145,000)
Post Impairment Carrying Value as of December 31, 2005	1,000	82,000	3,027,000	3,110,000
Disposals of Assets, 2006	(1,000)	(82,000)	—	(83,000)
Post Impairment Loss, 2006 . .	—	—	(403,000)	(403,000)
Post Impairment Carrying Value as of December 31, 2006	—	—	2,624,000	2,624,000
Disposals of Assets, 2007	—	—	(2,624,000)	(2,624,000)
Post Impairment Carrying Value as of December 31, 2007	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

NOTE 14. Related Party Transactions

Entities affiliated with Bay City Capital Management IV LLC (Bay City Management) beneficially owned an aggregate of approximately 15.7% of the Company's common stock outstanding on December 31, 2008. Fred B. Craves and Carl S. Goldfischer, managing directors of Bay City Capital LLC (BCC), an affiliate of Bay City Management, serve on the Company's board of directors. Entities affiliated with MPM Capital (MPM) owned an aggregate of approximately 21.9% of the Company's outstanding common stock as of December 31, 2008. Nicholas J. Simon III, a director of the Company, is a general partner of certain of the MPM entities that hold those shares. The Company has agreed, for as long as MPM owns at least 10% of the shares of common stock and warrants purchased by MPM in the 2006 equity financing, to use its best efforts to cause one person designated by MPM and one person designated by mutual agreement of MPM and BCC to be nominated and elected to the Company's board of directors. Mr. Simon serves as MPM's designee on the Company's board. MPM and BCC have not named the other designee.

NOTE 15. Employee Benefit Plan

The Company sponsors a 401(k) plan that covers substantially all employees. In its sole discretion, the Company may make contributions to the plan on a percentage of participants' contributions. The Company made contributions of approximately \$19,000, \$15,000, and \$9,000 for the years ended

PONIARD PHARMACEUTICALS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

NOTE 15. Employee Benefit Plan (Continued)

December 31, 2008, 2007 and 2006, respectively. The Company has no other post-employment or post-retirement benefit plans.

NOTE 16. Unaudited Quarterly Data

The following table presents summarized unaudited quarterly financial data (in thousands, except per share data):

	<u>First Quarter</u>	<u>Second Quarter</u>	<u>Third Quarter</u>	<u>Fourth Quarter</u>
2008				
Revenues	\$ —	\$ —	\$ —	\$ —
Operating expenses	10,519	12,874	12,407	13,357
Net loss	(9,855)	(12,531)	(12,237)	(13,942)
Net loss applicable to common shares . . .	(9,980)	(12,656)	(12,362)	(14,067)
Net loss per common share:				
Basic	(0.29)	(0.36)	(0.36)	(0.41)
Diluted	(0.29)	(0.36)	(0.36)	(0.41)
2007				
Revenues	\$ —	\$ —	\$ —	\$ —
Operating expenses	7,900	9,190	7,856	10,407
Net loss	(7,729)	(8,528)	(6,959)	(9,566)
Net loss applicable to common shares . . .	(7,854)	(8,653)	(7,084)	(9,691)
Net loss per common share:				
Basic	(0.34)	(0.28)	(0.20)	(0.28)
Diluted	(0.34)	(0.28)	(0.20)	(0.28)

Note: Net loss per common share, basic and diluted, may not add to net loss per common share for the year due to rounding.

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

Not Applicable.

Item 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of the Company's Chief Executive Officer and the Chief Financial Officer, management has evaluated the effectiveness and design of its disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this report. Based on that evaluation, the Chief Executive Officer and the Chief Financial Officer have concluded that these disclosure controls and procedures were effective as of December 31, 2008 in ensuring that information required to be disclosed in our Exchange Act reports is (1) recorded, processed, summarized and reported in a timely manner, and (2) accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Management's Annual Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting for the Company and for the assessment of the effectiveness of internal control over financial reporting. The 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 accounting principles generally accepted in the United States of America. The Company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the Company's assets; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with accounting principles generally accepted in the United States of America, and that the Company's receipts and expenditures are being made only in accordance with authorizations of the Company's management and directors; and (iii) provide reasonable assurance regarding the 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 and procedures may deteriorate.

Management conducted an evaluation of the effectiveness of the system of internal control over financial reporting based on the framework in Internal Control Integrated Framework issued by the Committee Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that the Company's internal control over financial reporting was effective as of December 31, 2008. The Company's internal control over financial reporting as of December 31, 2008 has been audited by KPMG LLP, a registered independent public accounting firm, as stated in its report set forth in Item 8, "Financial Statements and Supplementary Data," on page 51, under the caption "Report of Independent Registered Public Accounting Firm."

Changes in Internal Control Over Financial Reporting

There have been no changes in the Company's internal control over financial reporting that occurred during the Company's fourth fiscal quarter that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Item 9B. OTHER INFORMATION

Not Applicable.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

(a) *Directors.* The information required by this item is incorporated herein by reference to the sections captioned "Election of Directors" and "Board of Directors and Corporate Governance" in the Company's definitive Proxy Statement for the 2009 Annual Meeting of Shareholders to be held June 24, 2009, to be filed with the Commission not later than 120 days after December 31, 2008.

(b) *Executive Officers.* The information concerning our executive officers is set forth in Item 1 of this report under the heading "Our Executive Officers."

(c) *Compliance with Section 16(a) of the Exchange Act.* The information required by this item is incorporated herein by reference to the section captioned "Section 16(a) Beneficial Ownership Reporting Compliance" in the Company's definitive Proxy Statement for the 2009 Annual Meeting of Shareholders to be held June 24, 2009, to be filed with the Commission not later than 120 days after December 31, 2008.

(d) *Code of Ethics.* The information required by this item is incorporated herein by reference to the section captioned "Board of Directors and Corporate Governance " in the Company's definitive Proxy Statement for the 2009 Annual Meeting of Shareholders to be held June 24, 2009, to be filed with the Commission not later than 120 days after December 31, 2008.

(e) *Audit Committee.* The information required by this item is incorporated herein by reference to the section captioned "Board of Directors and Corporate Governance " in the Company's definitive Proxy Statement for the 2009 Annual Meeting of Shareholders to be held June 24, 2009, to be filed with the Commission not later than 120 days after December 31, 2008.

Item 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated herein by reference to the sections captioned "Executive Compensation" and "Board of Directors and Corporate Governance—Compensation Committee Interlocks and Insider Participation" in the Company's definitive Proxy Statement for the 2009 Annual Meeting of Shareholders to be held June 24, 2009, to be filed with the Commission not later than 120 days after December 31, 2008.

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

Equity Compensation Plan Information

The following table presents information as of December 31, 2008 with respect to our compensation plans, including individual compensation arrangements, under which equity securities of the company are authorized for issuance to employees and non-employees of the company, such as directors, lenders, consultants, and advisors:

<u>Plan Category</u>	<u>(a) Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights</u>	<u>(b) Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights</u>	<u>(c) Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a) (3))</u>
Equity Compensation Plans Approved by			
Shareholders(1)	5,893,071	\$6.10	55,987
Equity Compensation Plans Not Approved by			
Shareholders(2)	<u>6,060,128</u>	\$5.51	<u>—</u>
Total	<u>11,953,199</u>	\$5.80	<u>55,987</u>

- (1) Includes the Company's 1991 Stock Option Plan for Non-Employee Directors (Directors Plan), the 1994 Stock Option Plan (1994 Plan) and the Amended and Restated 2004 Incentive Compensation Plan (2004 Plan). The Directors Plan was terminated on March 31, 2005 and the 1994 Plan was terminated on February 17, 2004. Accordingly, no further equity derivative securities can be issued under the Directors and 1994 Plans. For a description of the 2004 Plan, see Note 8 to the notes to the consolidated financial statements in Item 8 of this report.
- (2) Reflects a warrant issued for placement agent services in connection with our 2006 equity financing and warrants issued to financial institutions participating in our term loan facility. For a description of these warrants, see Note 9 to the notes to the consolidated financial statements in Item 8 of this report.
- (3) All shares remaining available for issuance under equity compensation plans are issuable under our 2004 Plan. The 2004 Plan contains an evergreen provision, pursuant to which the number of shares available under the plan will automatically increase on the first day of each of the Company's fiscal years beginning in 2008. The number of additional shares made available each year is equal to the least of (i) 3,000,000 shares, (ii) 5% of the outstanding shares of common stock as of the end of the Company's immediately preceding fiscal year, (iii) any lesser number of shares determined by the Company's board of directors, or (iv) a number of shares that, when added to the sum of (x) the number of shares subject to outstanding awards under the 2004 Plan as of the end of the Company's immediately preceding fiscal year (other than awards not subject to vesting or forfeiture conditions) and (y) the number of shares that could be made subject to outstanding awards as of the end of the Company's immediately preceding fiscal year, does not exceed 20% of the outstanding shares of common stock on a fully diluted basis as of the end of the Company's immediately preceding fiscal year. Any additional shares made available under the evergreen provision shall continue to be available for issuance

under the 2004 Plan for subsequent years. Giving effect to the evergreen provision of the 2004 Plan, as of January 1, 2009, the aggregate number of common shares available for issuance as new awards was 1,790,373 shares.

Other information required by this item is incorporated herein by reference to the section captioned “Security Ownership of Certain Beneficial Owners and Management” in the Company’s definitive Proxy Statement for the 2009 Annual Meeting of Shareholders to be held June 24, 2009, to be filed with the Commission not later than 120 days after December 31, 2008.

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

The information required by this item is incorporated herein by reference to the sections captioned “Certain Relationships and Related Transactions with Management” and “Board of Directors and Corporate Governance” in the Company’s definitive Proxy Statement for the 2009 Annual Meeting of Shareholders to be held June 24, 2009, to be filed with the Commission not later than 120 days after December 31, 2008.

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item is incorporated herein by reference to the sections captioned “Independent Registered Public Accounting Firm” and “Ratification of Appointment of Independent Registered Public Accounting Firm” in the Company’s definitive Proxy Statement for the 2009 Annual Meeting of Shareholders to be held June 24, 2009, to be filed with the Commission not later than 120 days after December 31, 2008.

PART IV

Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

- (a) (1) Financial Statements—See Index to Financial Statements.
 - (2) Financial Statement Schedules—Financial statement schedules have been omitted since they are either not required, not applicable, or the information is otherwise included.
 - (3) Exhibits—See Exhibit Index beginning on page 88 of this Annual Report on Form 10-K.
- (b) Exhibits—See Exhibit Index beginning on page 88 of this Annual Report on Form 10-K.

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.

PONIARD PHARMACEUTICALS, INC.
(Registrant)

By: /s/ GREGORY L. WEAVER
 Gregory L. Weaver
 Chief Financial Officer and
 Senior Vice President, Finance

Date: March 16, 2009

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 as of the dates indicated:

<u>Name</u>	<u>Title</u>	<u>Date</u>
<u> /s/ GERALD MCMAHON </u> Gerald McMahon	Chairman and Chief Executive Officer	March 16, 2009
<u> /s/ RONALD A. MARTELL </u> Ronald A. Martell	Director, President and Chief Operating Officer	March 16, 2009
<u> /s/ GREGORY L. WEAVER </u> Gregory L. Weaver	Chief Financial Officer and Senior Vice President, Finance (Principal Financial Officer)	March 16, 2009
<u> /s/ FRED B. CRAVES </u> Fred B. Craves	Director	March 16, 2009
<u> /s/ E. ROLLAND DICKSON </u> E. Rolland Dickson	Director	March 16, 2009
<u> /s/ CARL S. GOLDFISCHER </u> Carl S. Goldfischer	Director	March 16, 2009

<u>Name</u>	<u>Title</u>	<u>Date</u>
<u>/s/ ROBERT M. LITTAUER</u> Robert M. Littauer	Director	March 16, 2009
<u>/s/ DAVID R. STEVENS</u> David R. Stevens	Director	March 16, 2009
<u>/s/ NICHOLAS J. SIMON III</u> Nicholas J. Simon III	Director	March 16, 2009
<u>/s/ ROBERT S. BASSO</u> Robert S. Basso	Director	March 16, 2009
<u>/s/ MICHAEL K. JACKSON</u> Michael K. Jackson	Principal Accounting Officer	March 16, 2009

EXHIBIT INDEX**

Exhibit	Description	
3.1	Amended and Restated Articles of Incorporation, as amended February 7, 2007	(N)
3.2	Restated Bylaws, as amended March 28, 2006	(V)
10.1	1991 Stock Option Plan for Non-Employee Directors, as amended(‡)	(E)
10.2	Restated 1994 Stock Option Plan(‡)	(F)
10.3	Stock Option Grant Program for Nonemployee Directors under the NeoRx Corporation 1994 Restated Stock Option Plan(‡)	(M)
10.4	2004 Incentive Compensation Plan, as amended and restated June 14, 2007(‡)	(B)
10.5	Stock Option Grant Program for Nonemployee Directors under the 2004 Incentive Compensation Plan, as amended June 14, 2007(‡)	(X)
10.6	Form of Non-Qualified Stock Option Agreement under 2004 Incentive Compensation Plan, as amended June 14, 2007(‡)	(D)
10.7	Form of Incentive Stock Option Agreement under 2004 Incentive Compensation Plan(‡)	(O)
10.8	Stock Option Agreement, dated December 19, 2000, between NeoRx Corporation and Carl S. Goldfischer(‡)	(I)
10.9	Stock Option Agreement, dated January 17, 2001, between NeoRx Corporation and Carl S. Goldfischer(‡)	(I)
10.10	License Agreement dated as of April 2, 2004, between the Company and AnorMED, Inc. Certain portions of the agreement have been omitted pursuant to a request for confidential treatment	(Q)
10.11	Amendment No. 1 to License Agreement effective as of September 18, 2006, between the Company and AnorMED, Inc. Certain portions of the agreement have been omitted pursuant to a request for confidential treatment	(Y)
10.12	Facilities Lease dated February 15, 2002, between NeoRx Corporation and Selig Real Estate Holdings Six	(A)
10.12.1	Amendment to Lease dated November 21, 2008, between the Company and Selig Holdings Company, LLC	(S)
10.13	Indemnification Agreement(‡)	(H)
10.14	Amended and Restated Key Executive Severance Agreement dated as of February 24, 2009, between the Company and Gerald McMahon(‡)	(Z)
10.15	Amended and Restated Change of Control Agreement dated as of February 24, 2009, between the Company and Gerald McMahon(‡)	(Z)
10.16	Amended and Restated Key Executive Severance Agreement dated as of February 24, 2009, between the Company and Ronald A. Martell(‡)	(Z)
10.17	Amended and Restated Change of Control Agreement dated as of February 24, 2009, between the Company and Ronald A. Martell(‡)	(Z)
10.18	Amended and Restated Key Executive Severance Agreement dated as of February 24, 2009, between the Company and Robert De Jager(‡)	(Z)
10.19	Amended and Restated Change of Control Agreement dated as of February 24, 2009, between the Company and Robert De Jager(‡)	(Z)

Exhibit	Description	
10.20	Letter Agreement dated as of January 29, 2008, between the Company and Robert L. De Jager(‡)	(T)
10.21	Amended and Restated Key Executive Severance Agreement dated as of February 18, 2009, between the Company and Gregory L. Weaver(‡)	(Z)
10.22	Amended and Restated Change of Control Agreement dated as of February 18, 2009, between the Company and Gregory L. Weaver(‡)	(Z)
10.23	Letter Agreement dated as of February 3, 2009, between the Company and Gregory L. Weaver(‡)	(Z)
10.24	Amended and Restated Key Executive Severance Agreement dated as of February 24, 2009, between the Company and Cheni Kwok(‡)	(Z)
10.25	Amended and Restated Change of Control Agreement dated as of February 24, 2009, between the Company and Cheni Kwok(‡)	(Z)
10.26	Amended and Restated Key Executive Severance Agreement dated as of February 24, 2009, between the Company and Anna Wight(‡)	(Z)
10.27	Amended and Restated Change of Control Agreement dated as of February 24, 2009, between the Company and Anna Wight(‡)	(Z)
10.28	Amended and Restated Key Executive Severance Agreement dated as of February 24, 2009, between the Company and Janet Rea(‡)	(Z)
10.29	Amended and Restated Change of Control Agreement dated as of February 24, 2009, between the Company and Janet Rea(‡)	(Z)
10.30	Amended and Restated Key Executive Severance Agreement dated as of February 24, 2009, between the Company and Michael K. Jackson(‡)	(Z)
10.31	Form of Directors' Indemnification Agreements(‡)	(K)
10.32	Lease Agreement dated as of July 10, 2006, between the Company and ARE San Francisco No. 17 LLC	(W)
10.33	Amended and Restated Loan and Security Agreement dated as of September 2, 2008, by and among the Company, GE Business Financial Services Inc. and Silicon Valley Bank	(J)
10.34	Commercial Picoplatin Active Pharmaceutical Ingredient Manufacturing Agreement between the Company and W.C. Heraeus GmbH, dated as of March 24, 2008. Certain portions of the agreement have been omitted pursuant to a request for confidential treatment.	(J)
10.35	Separation/Consulting Agreement and General Release, dated as of November 21, 2008, by and between David A. Karlin and the Company.(‡)	(S)
10.36	Commercial Supply Agreement between the Company and Baxter Oncology GmbH, dated as of November 22, 2008. Certain portions of the agreement have been omitted pursuant to a request for confidential treatment.	(Z)
23.1	Consent of KPMG LLP	(Z)
31.1	Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer	(Z)
31.2	Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer	(Z)
32.1	Section 1350 Certification of Chief Executive Officer	(Z)

Exhibit	Description	
32.2	Section 1350 Certification of Chief Financial Officer	(Z)

- (‡) Management contract or compensatory plan
- (A) Filed as an exhibit to the Company's Form 10-K for the fiscal year ended December 31, 2001, and incorporated herein by reference.
- (B) Incorporated by reference to Annex A of the Company's definitive proxy statement on Schedule 14A filed May 8, 2007.
- (C) Reserved.
- (D) Filed as an exhibit to the Company's Form 10-Q for the quarterly period ended June 30, 2007, and incorporated herein by reference.
- (E) Incorporated by reference to Exhibit A to the Company's definitive proxy statement on Schedule 14A filed April 10, 1996.
- (F) Filed as an exhibit to the Company's Form 10-K for the fiscal year ended December 31, 1995, and incorporated herein by reference.
- (G) Reserved.
- (H) Filed as an exhibit to the Company's Form 10-Q for the quarterly period ended March 31, 1996, and incorporated herein by reference.
- (I) Filed as an exhibit to the Company's Form 10-K for the fiscal year ended December 31, 2000, and incorporated herein by reference.
- (J) Filed as an exhibit to the Company's Current Report on Form 8-K filed on September 6, 2008, and incorporated herein by reference.
- (K) Filed as an exhibit to the Company's Current Reports on Form 8-K filed on April 28, 2006, June 27, 2006 and May 9, 2007, and incorporated herein by reference.
- (L) Reserved.
- (M) Filed as an exhibit to the Company's Form 10-Q for the quarterly period ended June 30, 2002, and incorporated herein by reference.
- (N) Filed as an exhibit to the Company's Current Report on Form 8-K filed on February 8, 2007, and incorporated herein by reference.
- (O) Filed as an exhibit to the Company's Form 10-Q for the quarterly period ended September 30, 2004, and incorporated herein by reference.
- (P) Reserved.
- (Q) Filed as an exhibit to the Company's Form 10-Q for the quarterly period ended March 31, 2004, and incorporated herein by reference.
- (R) Reserved.
- (S) Filed as an exhibit to the Company's Current Report on Form 8-K filed November 26, 2008, and incorporated herein by reference.
- (T) Filed as an exhibit to the Company's Current Report on Form 8-K/A filed February 11, 2008, and incorporated herein by reference.
- (U) Reserved.

- (V) Filed as an exhibit to the Company's Form 10-Q for the quarterly period ended March 31, 2006 and incorporated herein by reference.
- (W) Filed as an exhibit to the Company's Current Report Form 8-K filed on July 13, 2006 and incorporated herein by reference.
- (X) Filed as an exhibit to the Company's Form 10-Q for the quarterly period ended September 30, 2007 and incorporated herein by reference.
- (Y) Filed as an exhibit to the Company's Form 10-Q for the quarterly period ended September 30, 2006 and incorporated herein by reference.
- (Z) Filed herewith.

**** *In reviewing the agreements included as exhibits to this Annual Report on Form 10-K, please remember that they are included to provide you with information regarding their terms and are not intended to provide any other factual or disclosure information about the Company or the other parties to the agreements. The agreements contain representations and warranties of each of the parties to the applicable agreement. These representations and warranties have been made solely for the benefit of the other parties to the applicable agreements and***

- should not be treated as categorical statements of fact, but rather as a way of allocating risk to one of the parties if those statements prove to be inaccurate;***
- have been qualified by disclosures that were made to the other party in connection with the negotiation of the applicable agreement, which disclosures are not necessarily reflected in the agreement;***
- may apply standards of materiality in a way that is different from what may be viewed as material to you and other investors; and***
- were made only as of the date of the applicable agreement or such other date or dates as may be specified in the agreement and are subject to more recent developments.***

Accordingly, these representations and warranties may not describe the actual state of affairs of as of the date they were made or any other time. Additional information about the Company may be found elsewhere in this Form 10-K and the Company's other public filings which are available without charge through the SEC's website at <http://www.sec.gov>. See "Where You Can Find Other Information."

Consent of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders
Poniard Pharmaceuticals, Inc.:

We consent to the incorporation by reference in the registration statements (Nos. 333-134480, 333-123672, 333-115497, 333-113706, 333-111344, 333-45398, and 333-35442) on Form S-3 and in the registration statements (Nos. 333-143965, 333-135861, 333-126209, 333-115729, 333-89476, 333-71368, 333-41764, 333-32583, 333-43860, 333-46317, and 333-87108) on Form S-8 of Poniard Pharmaceuticals, Inc. of our report dated March 16, 2009, with respect to the consolidated balance sheets of Poniard Pharmaceuticals, Inc. and subsidiary as of December 31, 2008 and 2007, and the related consolidated statements of operations, shareholders' equity and comprehensive loss, and cash flows for each of the years in the three-year period ended December 31, 2008, and the effectiveness of internal control over financial reporting, as of December 31, 2008, which report appears in the December 31, 2008 annual report on Form 10-K of Poniard Pharmaceuticals, Inc. Our report dated March 16, 2009 contains an explanatory paragraph that states that the Company has suffered recurring losses from operations and negative cash flows. Furthermore, the Company's long-term debt agreement contains certain covenants that require the Company to maintain a certain level of unrestricted cash and cash equivalents, and contains certain subjective acceleration clauses related to material adverse changes 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 consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ KPMG LLP

Seattle, Washington
March 16, 2009

CERTIFICATION

I, Gerald McMahon, certify that:

1. I have reviewed this annual report on Form 10-K of Poniard Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
 - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 16, 2009

/s/ GERALD MCMAHON

Gerald McMahon
Chief Executive Officer

CERTIFICATION

I, Gregory L. Weaver, certify that:

1. I have reviewed this annual report on Form 10-K of Poniard Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
 - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 16, 2009

/s/ GREGORY L. WEAVER

Gregory L. Weaver
*Chief Financial Officer and
Senior Vice President, Finance*

Certification of Annual Report

I, Gregory L. Weaver, Chief Financial Officer of Poniard Pharmaceuticals, Inc. (the "Company"), certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that:

1. the Annual Report on Form 10-K for the Company for the year ended December 31, 2008 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (12 U.S.C. 78m or 78o(d)); and
2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 16, 2009

By: /s/ GREGORY L. WEAVER

Gregory L. Weaver
*Chief Financial Officer and Senior Vice
President, Finance*

Poniard Corporate Information

As of May 8, 2009

Company Officers and Management Team

Gerald McMahon, Ph.D.

Chairman and Chief Executive Officer

Ronald A. Martell

President and Chief Operating Officer

Gregory L. Weaver

Chief Financial Officer and Senior Vice
President, Finance

Robert L. De Jager, M.D.

Chief Medical Officer

Cheni Kwok, Ph.D.

Senior Vice President, Corporate Development

Anna L. Wight, J.D.

Vice President, Legal

Janet R. Rea, MSPH, RAC

Vice President, Regulatory Affairs and Quality

Directors

Gerald McMahon, Ph.D.

Chairman and Chief Executive Officer
Poniard Pharmaceuticals, Inc.

Robert S. Basso

BEST Partners LLC

Frederick B. Craves, Ph.D.

Managing Director, Bay City Capital LLC

E. Rolland Dickson, M.D., M.A.C.P.

Professor of Medicine, Mayo Medical School,
Mayo Clinic

Emeritus Mary Lowell Leary

Emeritus Medical Director of Development &
Emeritus Member

Board of Trustees, Mayo Foundation

Carl S. Goldfischer, M.D.

Managing Director, Bay City Capital LLC

Robert M. Littauer

Vice President, Chief Financial Officer and
Treasurer, Light Sciences Oncology, Inc.

Ronald A. Martell

President and Chief Operating Officer
Poniard Pharmaceuticals, Inc.

Nicholas J. Simon

Managing Director, Clarus Ventures, LLC
General Partner, MPM BioVentures III

David R. Stevens, Ph.D.

Chairman, CanCog Technologies, Inc.

CORPORATE HEADQUARTERS
Poniard Pharmaceuticals, Inc.
7000 Shoreline Court, Suite 270
South San Francisco, CA 94080
Tel: 650-583-3774

SEATTLE OFFICE
Poniard Pharmaceuticals, Inc.
300 Elliott Avenue West, Suite 500
Seattle, WA 98119
Tel: 206-281-7001

WEB SITE
www.poniard.com

SHAREHOLDER INQUIRIES
Registered shareholders who have questions regarding their stock should contact Poniard's transfer agent and registrar:

BNY Mellon Shareowner Services
480 Washington Blvd
Jersey City, NJ 07310
www.bnymellon.com/shareowner/isd
Dedicated Toll free: 866-357-2543
TDD for hearing impaired: 800-231-5469
Foreign shareholders: 201-680-6578
TDD Foreign shareholders: 201-680-6610

INDEPENDENT PUBLIC ACCOUNTANTS
KPMG LLP
Seattle, WA

CORPORATE COUNSEL
Perkins Coie LLP
Seattle, WA

INVESTOR RELATIONS
Poniard Pharmaceuticals, Inc.
Attn: Investor Relations
7000 Shoreline Court Suite 270
South San Francisco, CA 94080
Tel: 650-583-3774 ext. 6
ir@poniard.com

STOCK EXCHANGE LISTING
Poniard Common Stock trades on the Nasdaq Global Market under the symbol PARD.
Poniard does not pay cash dividends on its common stock and does not anticipate doing so in the foreseeable future.

This document contains forward-looking statements, including statements regarding the Company's results of clinical trials, drug development and commercialization strategy, financial resources and potential sources of capital. The Company's actual results may differ materially from those indicated in these forward-looking statements due to risks and uncertainties that are described in the Company's current and periodic reports filed with the Securities and Exchange Commission, including the Company's Annual Report on Form 10-K for the year ended December 31, 2008 and its Quarterly Report on Form 10-Q for the quarter ended March 31, 2009. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this document. Except as required by law, the Company undertakes no obligation to update any forward-looking statement to reflect new information, events, or circumstances after the date of this document or to reflect the occurrence of unanticipated events.

