ZIOPHARM ONCOLOGY INC
Form 10-K
March 17, 2010

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

x **ANNUAL REPORT UNDER SECTION 13 OR 15(d)**
OF THE SECURITIES EXCHANGE ACT OF 1934
For the Fiscal Year Ended December 31, 2009
OR

o **TRANSITION REPORT UNDER SECTION 13 OR 15(d)**
OF THE SECURITIES EXCHANGE ACT OF 1934

For the Transition Period from to

Commission File Number 0-32353

ZIOPHARM Oncology, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	84-1475642
(State or Other Jurisdiction of	(IRS Employer

Incorporation or Organization)	Identification No.)
1180 Avenue of the Americas, 19th Floor, New York, NY (Address of Principal Executive Offices)	10036 (Zip Code)

(646) 214-0700

(Issuer s Telephone Number, Including Area Code)

(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

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

Common Stock (Par Value $0.001 per Share)

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. o

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 past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will 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. o

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 definition of large accelerated filer, accelerate filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large Accelerated Filer o Accelerated Filer o Non- Accelerated Filer o Smaller Reporting Company x

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

The aggregate market value of the registrant s common stock held by non-affiliates was $31,745,280 as of June 30, 2009 (the last business day of the registrant s most recently completed second fiscal quarter), based upon the closing price of the registrant s common stock as reported on the NASDAQ Capital Market on that date. Shares of common stock held by each executive officer and director of the registrant and by each entity that owns 10% or more of the registrant s outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 17, 2010, there were 41,568,245 shares of the registrant s common stock, $.001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the definitive proxy statement for our 2010 annual meeting of stockholders, which is to be filed within 120 days after the end of the fiscal year ended December 31, 2009, are incorporated by reference into Part III of this Form 10-K, to the extent described in Part III.

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ZIOPHARM Oncology, Inc.
(A Development Stage Enterprise)

FORM 10-K
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2009

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PART I

Item 1. Business

General

ZIOPHARM Oncology, Inc. is a biopharmaceutical company that is seeking to develop and commercialize a diverse, risk-sensitive portfolio of in-licensed cancer drugs that address unmet medical needs through enhanced efficacy and/or safety and quality of life. Our focus is on the licensing and development of proprietary small molecule drug candidates that are related to cancer therapeutics already on the market or in development and that can be developed in intravenous (IV) and/or oral forms of administration. We believe this approach will result in lower risk and expedited drug development programs. Our strategy is also to assure a low cost of manufacturing to address changing pricing and reimbursement policies around the world. While we may complete development and commercialize our products on our own in North America, we also recognize that partnering may accelerate our development efforts or allow us to address certain market geographies with greater success. Our product candidate portfolio includes palifosfamide (Zymafos™, ZIO-201), darinaparsin (Zinapar™, ZIO-101), and indibulin (Zybulin™, ZIO-301).

Our principal focus following our financings late 2009 remains IV palifosfamide for the treatment of soft tissue sarcoma (STS). We have completed Phase I and Phase II trials for IV palifosfamide and a randomized ***P***hase II multicenter, parallel group, randomized study of pal***I***fosfamide tris plus doxorubicin versus doxorubi***C***in in subjects with unresect***A***ble or metastatic ***S***oft tissue ***S***arc***O***ma (PICASSO) is ongoing in the front- and second-line setting of soft tissue sarcoma. We reported favorable interim results from the PICASSO trial which were subsequently presented at the 2009 Connective Tissue Oncology Society s (CTOS) annual meeting after enrollment in the trial was terminated early at 67 patients. Following U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) protocol review, we expect to initiate a global registration trial in STS as early as the first half of 2010. We are also in the planning stages for an initial clinical trial for oral palifosfamide. Manufacturing scale-up of the palifosfamide active pharmaceutical ingredient and finished dosage forms are progressing in line with planned clinical trials.

We have completed Phase I and Phase II trials for the IV form of darinaparsin and reported favorable Phase II results in peripheral T-cell lymphoma (PTCL) from a study in refractory hematological malignancies at the 2009 Annual Meeting for the American Society for Clinical Oncology (ASCO). Subject to FDA review, and following an evaluation of various alternatives in light of our principal focus on palifosfamide development, we expect to initiate a planned registration and other trials for IV darinaparsin. A Phase I trial for an oral form of darinaparsin is in progress and early results were reported at ASCO in 2009.

We have completed Phase I trials of an oral form of indibulin both as a single agent and in combination. A maximum tolerated dose has not yet been established. The results of these trials have shown evidence of drug activity and, more importantly, have demonstrated a well tolerated safety profile and absence of peripheral neuropathy to date. We currently expect that a Phase I portion of a Phase I/II study in breast cancer involving a dose dense administration schedule developed preclinically by our consultant, Dr. Larry Norton, will initiate in the first half of 2010 at the Memorial Sloan Kettering Cancer Center.

More detailed descriptions of palifosfamide, darinaparsin and indibulin, and our clinical development plans for each, are set forth in this report under the caption Business Product Candidates.

Our corporate office, which houses 3 full time employees, is located at 1180 Avenue of the Americas, 19th Floor, New York, NY 10036, and our telephone number is (646) 214-0700. Our main operations are located in Boston, Massachusetts, where we currently have 12 full time employees.

Cancer Overview

Cancer is a group of diseases characterized by either the runaway growth of cells or the failure of cells to die normally. Often, cancer cells spread to distant parts of the body, where they can form new tumors. Cancer can arise in any organ of the body and, according to the American Cancer Society, strikes one of every two American men and one of every three American women at some point in their lives.

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It is reported that there are more than 100 different varieties of cancer. Carcinomas, the most common type of cancer, originate in tissues that cover a surface or line a cavity of the body. Lymphomas are cancers of the lymph system, which is a circulatory system that bathes and cleanses the body s cells. Leukemias involve blood-forming tissues and blood cells. As their name indicates, brain tumors are cancers that begin in the brain, skin cancers, including melanomas, originate in the skin, while soft tissue sarcomas arise in soft tissue. Cancers are considered metastatic if they spread via the blood or lymphatic system to other parts of the body to form secondary tumors.

Cancer is caused by a series of mutations (alterations) in genes that control cells ability to grow and divide. Some mutations are inherited; others arise from environmental factors such as smoking or exposure to chemicals, radiation, or viruses that damage cells DNA. The mutations cause cells to divide relentlessly or lose their normal ability to die.

According to Cancer Statistics 2008 (published by the American Cancer Society in Cancer Facts & Figures 2009), it was estimated that 562,340 Americans would die from cancer in 2008 more than 1,500 each day. The cost of treating cancer is significant. The National Institute of Health estimates that the overall cost of cancer in 2008 was $228.1 billion. This cost included an estimate of $93.2 billion in direct medical expenses and $134.9 billion in indirect mortality costs.

Cancer Treatments

Major treatments for cancer include surgery, radiotherapy, and chemotherapy; the latter including newer approaches generally referred to as anti-angiogenic, vascular disruption or targeted therapies. There are many different drugs that are used to treat cancer, including supportive care. While there are also hundreds of experimental treatments under investigation, we believe cancer treatment will remain a significant unmet medical need for the foreseeable future.

Radiotherapy: Also called radiation therapy, radiotherapy is the treatment of cancer and other diseases with ionizing radiation. Ionizing radiation deposits energy that injures or destroys cells in the area being treated (the target tissue) by damaging their genetic material, making it impossible for these cells to continue growing. Although radiation damages both cancer cells and normal cells, the latter are able to repair and regain proper function. Radiotherapy may be used to treat localized solid tumors such as cancers of the skin, tongue, larynx, brain, breast, or uterine cervix. It can also be used to treat leukemia and lymphoma.

Scientists are also looking for ways to increase the effectiveness of radiation therapy. Two types of investigational drugs are being studied for their effect on cells exposed to radiation. Radiosensitizers increase the damage done to tumor cells by radiation; radioprotectors protect normal tissues from the effects of radiation.

Cytotoxics: Cytotoxics are anticancer drugs that destroy cancer cells by stopping them from multiplying. Healthy cells, especially those that divide quickly, can also be harmed with the use of cytotoxics. Harm to healthy cells is what causes side effects. These cells usually repair themselves after chemotherapy and in many cases, newer agents may offer a greater therapeutic window the difference between a dose that is helpful and one that is toxic.

Cytotoxic agents act primarily by disrupting cellular pathways involved in maintaining cellular integrity including blood supply, repair, or activity that affects the production or function of DNA, RNA, or protein. Although there are many cytotoxic agents, there is a considerable overlap in their mechanisms of action. As such, the choice of a particular agent or group of agents is generally not a consequence of a prior prediction of antitumor activity by the drug, but instead the result of empirical clinical trials.

Supportive Care: The treatment of a cancer may include the use of chemotherapy, radiation therapy, biologic response modifiers, surgery, or some combination of all of these or other therapeutic options. All of these treatment options are directed at killing or eradicating the cancer that exists in a patient s body. Unfortunately, the delivery of many cancer therapies adversely affects the body s normal organs. The undesired consequence of harming an organ not involved with cancer is referred to as a complication of treatment or a side effect.

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In addition to anemia, fatigue, hair-loss, reduction in blood platelets and white and red blood cells, and bone pain, two of the most common side effects of chemotherapy are nausea and vomiting. Several drugs have been developed to help prevent and control chemotherapy-induced nausea and vomiting, including 5HT3 receptor antagonists such as ondansetron, which is a selective blocking agent of the hormone serotonin.

Product Candidates

ZIO-101, Darinaparsin, Zinapar™

General. Darinaparsin is a novel anti-mitochondrial agent (organic arsenic) covered by issued U.S. patents and U.S. and international applications. A commercially available inorganic arsenic (arsenic trioxide [Trisenox®] or ATO) has been approved for the treatment of acute promyelocytic leukemia (APL). ATO is delivered intravenously and has been studied for the treatment of various other cancers. ATO has been shown to be toxic to the heart, nerves and liver, which limits its use as a broad anti-cancer agent. Our preclinical studies demonstrate that darinaparsin is considerably less toxic than ATO, particularly with regard to cardiac toxicity. In phase I and/or phase II clinical studies with both the IV and oral capsule forms, darinaparsin has been safely administered at exposures significantly higher than are approved for IV Trisenox®, confirming preclinical findings.

In vitro testing of darinaparsin using the National Cancer Institute s human cancer cell panel detected activity against cell lines derived from multiple cancers including lung, colon, brain, melanoma, ovarian, and kidney cancer. Moderate activity was detected against breast and prostate cancer. In addition to cell lines derived from solid tumors, *in vitro* testing in both the National Cancer Institute s cancer cell panel and *in vivo* testing in a leukemia animal model demonstrated substantial activity against hematological cancers (cancers of the blood and blood-forming tissues) such as leukemia, lymphoma, myelodysplastic syndromes, and multiple myeloma. In addition, darinaparsin has potent anti-angiogenic activity as demonstrated in *in vitro* as well as *in vivo* studies.

In a murine leukemia model, darinaparsin demonstrated oral activity comparable to that achieved with systemic administration. Subsequent pharmacokinetic studies in dogs established oral bioavailability comparable to IV administration. Oral administration of an effective cancer drug would allow prolonged and potentially more effective dosing regimens.

Potential Lead Indication: Lymphoma. Three phase II intravenous studies of IV darinaparsin evaluating hematological malignancies, myeloma and liver cancer, are almost completed. Data from these trials have been reported, the most promising being in lymphomas and particularly in peripheral T-cell lymphoma.

Clinical Development Plan for Darinaparsin: IV administered darinaparsin safety, pharmacokinetics, and drug activity has been evaluated in phase I studies. In phase II study, darinaparsin is active in both Hodgkin s and non-Hodgkin s lymphoma. The Company has concluded that further study in certain non-Hodgkin s lymphoma, particularly peripheral T-cell lymphoma (PTCL), is warranted and plans to pursue a registration and other studies following FDA review and in line with priorities and capital utilization and partnering and other alternatives.

In addition, an oral darinaparsin phase I program is nearing completion in both solid tumors and hematological malignancies and has shown early evidence of activity. We expect that the toxicity profile of oral darinaparsin will be consistent with that of intravenous form. Although our initial focus for darinaparsin is to pursue further study with the IV form, we expect that advancing the oral program would likely follow subject to priorities, available resources, and partnering and other considerations.

ZIO-201, Palifosfamide, Zymafos™

General. Palifosfamide, or isophosphoramide mustard (IPM), is a proprietary active metabolite of the pro-drug ifosfamide. Ifosfamide, as well as the related drug cyclophosphamide, are alkylating agents. Cyclophosphamide is believed to be the most widely used agent in cancer therapy. Ifosfamide has been shown to be effective at high doses by itself, or in combination with other agents, in treating sarcoma and lymphoma and it is approved in the U.S. for the treatment of testicular cancer. Although ifosfamide-based treatment generally represents a standard of care for sarcoma, it is not licensed for this indication by the U.S. Food and Drug Administration.

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Our preclinical studies have shown that, in animal and laboratory models, palifosfamide evidences activity against leukemia and solid tumors. These studies also indicate that palifosfamide has a better pharmacokinetic and safety profile than ifosfamide or cyclophosphamide, offering the possibility of safer and more efficacious therapy.

In addition to IPM, other metabolites of ifosfamide are produced including acrolein, which is toxic to the kidneys and bladder. The presence of acrolein mandates the administration of a protective agent called mesna, which is inconvenient to use and expensive. Chloroacetaldehyde, another metabolite of ifosfamide, is toxic to the central nervous system, causing fuzzy brain syndrome for which there is currently no protective measure. Similar toxicity concerns pertain to high-dose cyclophosphamide, which is widely used in bone marrow and blood cell transplantation. Because palifosfamide is the active metabolite without acrolein or chloroacetaldehyde metabolites the Company believes that the administration of palifosfamide (without the administration of mesna) may avoid many of the toxicities of ifosfamide without compromising efficacy.

In addition to anticipated lower toxicity, palifosfamide may have other advantages over ifosfamide and cyclophosphamide. Palifosfamide cross-links DNA differently than the active metabolite of cyclophosphamide, resulting in a different activity profile. Moreover, in some preclinical studies, palifosfamide shows activity in cisplatin-, ifosfamide- and/or cyclophosphamide-resistant cancer cells. In xenografts of human breast cancer and in a mouse leukemia model, palifosfamide has anti-tumor activity when administered orally, which is a potential additional advantage over ifosfamide and cyclophosphamide.

Potential Lead Indication for Palifosfamide: Sarcoma. Sarcomas are cancers of the bone, cartilage, fat, muscle, blood vessels, or other connective or supportive tissue. There are more than 50 histological or tissue types of soft tissue sarcomas but with considerable homogeneity when the disease is metastatic. The prognosis for patients with soft tissue sarcoma depends on several factors, including the patient s age, size of the primary tumor, histological grade, and stage of the tumor. Factors associated with a poorer prognosis include being older than 60 years of age, having tumors larger than five centimeters, and having tumors of high-grade histology. While small, low-grade tumors are usually curable by surgery alone, the higher-grade or larger sarcomas are associated with higher local treatment failure rates and increased metastatic potential.

Intravenous palifosfamide may be a useful agent that, either alone or in combination with other agents and doxorubicin in particular, may deliver therapeutic activity with fewer side effects of the type that have been associated with ifosfamide. In the United States, ifosfamide is regularly included in combination regimens for the treatment of sarcomas, testicular cancers, head and neck cancer, certain types of non-Hodgkin s lymphomas, and other solid tumors, although it is not formally approved by FDA for the treatment of soft tissue sarcoma. Doxorubicin, approved decades ago, is the only FDA-approved treatment for sarcoma. The Company believes that palifosfamide in combination with doxorubicin may be more effective than doxorubicin alone and with a far improved safety profile over the combination of ifosfamide use with doxorubicin.

Clinical Development Plan for Palifosfamide. Following completion of Phase I study, we completed a Phase II study in advanced sarcoma with strong evidence of activity and a safety profile distinguished from ifosfamide. With few options to treat sarcoma, the primary focus is to stabilize disease while maintaining quality of life. Following expert advice regarding the current treatment setting for STS and preclinical study that established a strong synergy of doxorubicin with palifosfamide, we subsequently completed Phase I study of doxorubicin in combination with palifosfamide primarily in patients with STS. We reported favorable results and the dosage regimen for further study from these trials at ASCO s 2009 Annual Meeting. The Company then initiated a randomized Phase II trial in metastatic or unresectable STS with palifosfamide in combination with doxorubicin vs. doxorubicin alone in the front- and second-line setting. We reported a favorable interim analysis of this trial in October of 2009 after pre-specified efficacy milestones had been reached and enrollment was suspended (at 67 patients) following safety and efficacy

review by the Data Committee, sarcoma experts, and the Company s Medical Advisory Board. We presented further positive interim data from the randomized trial at the CTOS Annual Meeting in November 2009. Upon FDA and EMA protocol review, a global registration trial in STS is expected to initiate as early as the first half of 2010. Initial clinical study of an oral form of palifosfamide is in an early planning stage. Palifosfamide has received an orphan drug designation in both the United States and the European Union for the treatment of STS.

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ZIO-301, Indibulin, Zybulin™

General. Oral indibulin is a novel small molecular-weight tubulin polymerization inhibitor that we acquired from Baxter Healthcare in 2006. The microtubule component, tubulin, is currently one of the best established anti-tumor targets available for the treatment of cancer. A number of other tubulin-targeting drugs available only in IV form in the United States are currently on the market, including paclitaxel (Taxol®), *vinca alkaloids* (vincristine, vinorelbine) and the epothilone Iexempra™. The use of these drugs is associated with important toxicities, notably peripheral neuropathy. By contrast, no peripheral neurotoxicity has been observed to date with indibulin administration, either in preclinical testing or in Phase I clinical testing. In addition, its activity as an oral formulation could offer significant advantage and convenience to patients, since no oral capsule formulations of paclitaxel or related compounds have been developed thus far in the United States.

Indibulin has a different pharmacological profile from other tubulin inhibitors currently on the market as it binds to a unique site on tubulin and is active in multi-drug-resistant (MDR-1, MRP-1) and taxane-resistant tumors. Indibulin binding causes destabilization of microtubules *in vitro*, an effect similar to that of the vinca alkaloid family or colchicine, but opposite to that of paclitaxel and related drugs and different from the epothilones.

Testing of indibulin for *in vitro* growth inhibitory activity against a panel of human and rodent tumor-derived cell lines revealed that the drug candidate is active in a broad spectrum of cell lines derived from different organs. *In vivo*, indibulin is active in a number of xenograft and rodent tumor models. Its unique pharmacodynamic properties demonstrated in preclinical studies, as well as an excellent safety profile observed thus far in ongoing phase I studies, warrant further evaluation in the clinic.

Clinical Development Plan for Indibulin. The Phase I program with indibulin established safety, pharmacokinetics (PK) pharmacodynamics and biomarkers. Following preclinical synergy studies, additional evidence of activity and the expected safety profile were confirmed in subsequent Phase I trials with indibulin alone and in combination. Indibulin is well tolerated and clinical activity has been observed in patients with several histologic subtypes. Preclinical work with our consultant, Dr. Larry Norton, further explored dose dense schedules with results supporting a planned Phase I dose dense and dose escalation trial in breast cancer, which we expect to be initiated at the Memorial Sloan Kettering Cancer Center in the first half of 2010.

Competition

The development and commercialization for new products to treat cancer, including for both the targeted indications of STS for palifosfamide and PTCL for darinaparsin, is highly competitive, and considerable competition exists from major pharmaceutical, biotechnology, and specialty cancer companies. Many of our competitors have access to substantially greater financial and technical resources than we do. In addition, many of these companies have more experience in preclinical and clinical development, manufacturing, regulatory, and global commercialization. We are also competing with academic institutions, governmental agencies, and private organizations that are conducting research in the field of cancer. Competition for highly qualified employees and their retention is intense, particularly as companies adjust to the current economic environment.

Other treatments for cancer that compete with our product candidates are summarized under the caption Cancer Treatments.

License Agreements and Intellectual Property

Our goal is to obtain, maintain, and enforce patent protection for our products, formulations, processes, methods, and other proprietary technologies in order to preserve our trade secrets and to operate without infringing upon the proprietary rights of other parties, both in the United States and in other countries. Our policy is to actively seek the broadest possible intellectual property protection for our product candidates through a combination of contractual arrangements and patents, both in the United States and abroad.

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Patent and Technology License Agreement The University of Texas M. D. Anderson Cancer Center and the Texas A&M University System.

On August 24, 2004, the Company entered into a patent and technology license agreement with The Board of Regents of the University of Texas System, acting on behalf of The University of Texas M. D. Anderson Cancer Center and the Texas A&M University System (collectively, the Licensors). Under this agreement, the Company was granted an exclusive, worldwide license to rights (including rights to U.S. and foreign patent and patent applications and related improvements and know-how) for the manufacture and commercialization of two classes of organic arsenicals (water- and lipid-based) for human and animal use. The class of water-based organic arsenicals includes darinaparsin.

As partial consideration for the license rights obtained, the Company made an upfront payment in 2004 of $125 thousand and granted the Licensors 250,487 shares of the Company s common stock. In addition, the Company issued options to purchase an additional 50,222 shares outside the 2003 Stock Option Plan for $0.002 per share following the successful completion of certain clinical milestones, which vested with respect to 12,555 shares upon the filing of an Investigation New Drug application (IND) for darinaparsin in 2005 and vested with respect to another 25,111 shares upon the completion of dosing of the last patient for both Phase I clinical trials in 2007. The Company recorded $120 thousand of stock based compensation expense related to the vesting in 2007. The remaining 12,556 shares will vest upon enrollment of the first patient in a multi-center pivotal clinical trial, i.e., a human clinical trial intended to provide the substantial evidence of efficacy necessary to support the filing of an approvable New Drug Application (NDA). In addition, the Licensors are entitled to receive certain milestone payments, including $100 thousand that was paid in 2005 upon the commencement of Phase I clinical trial and $250 thousand that was paid in 2006 upon the dosing of the first patient in the Registrant-sponsored Phase II clinical trial for darinaparsin. The Company may be required to make additional payments upon achievement of certain other milestones, in varying amounts which on a cumulative basis could total up to $4.85 million. In addition, the Licensors are entitled to receive royalty payments on sales from a licensed product should such a product be approved for commercial sale and sales of a licensed product be effected in the United States, Canada, the European Union or Japan. The Licensors also will be entitled to receive a portion of any fees that the Company may receive from a possible sublicense under certain circumstances. The Company also paid the Licensors $100 thousand in 2006 and 2007 to conduct scientific research with the Company obtaining exclusive right to all resulting intellectual property rights. The sponsored research agreements governing this research and any related extensions expired in February 2008 with no payments being made in 2008 or 2009.

The license agreement also contains other provisions customary and common in similar agreements within the industry, such as the right to sublicense the Company rights under the agreement. However, if the Company sublicenses its rights prior to the commencement of a pivotal study, *i.e.*, a human clinical trial intended to provide the substantial evidence of efficacy necessary to support the filing of an approvable NDA, the Licensors will be entitled to receive a share of the payments received by the Company in exchange for the sublicense (subject to certain exceptions).

License Agreement with DEKK-Tec, Inc.

On October 15, 2004, the Company entered into a license agreement with DEKK-Tec, Inc., pursuant to which it was granted an exclusive, worldwide license for palifosfamide. As part of the signing of license agreement with DEKK-Tec, the Company expensed an upfront $50 thousand payment to DEKK-Tec in 2004.

In consideration for the license rights, DEKK-Tec is entitled to receive milestone payments upon the occurrence of certain achievements of certain milestones in varying amounts which on a cumulative basis may total $3.9 million. Of the aggregate milestone payments, most of the total amount will be creditable against future royalty payments as

referenced below. The Company expensed a $100 thousand milestone payment upon achieving Phase II milestones during the year ended December 31, 2006. Additionally, in 2004 the Company issued DEKK-Tec an option to purchase 27,616 shares of the Company s common stock for $0.02 per share. Upon the execution of the license agreement, 6,904 shares vested and were subsequently exercised in 2005 and the remaining options will vest upon certain milestone events, culminating with final FDA approval of the first NDA submitted by the Company (or by its sublicensee) for palifosfamide. None of

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the remaining options have vested as of December 31, 2009. DEKK-Tec is entitled to receive royalty payments on the sales of palifosfamide should it be approved for commercial sale. There were no payments during 2008 or 2009.

Option Agreement withh Southern Research Institute (SRI)

On December 22, 2004, the Company entered into an Option Agreement with SRI (the Option Agreement), pursuant to which the Company was granted an exclusive option to obtain an exclusive license to SRI s interest in certain intellectual property, including exclusive rights related to certain isophosphoramide mustard analogs.

Also on December 22, 2004, the Company entered into a Research Agreement with SRI pursuant to which, the Company agreed to spend a sum not to exceed $200 thousand between the execution of the agreement and December 21, 2006, including a $25 thousand payment that was made simultaneously with the execution of the agreement, to fund research and development work by SRI in the field of isophosphoramide mustard analogs. The Option Agreement was exercised on February 13, 2007. In connection with the exercise of the option, minimum annual royalty payments of $25 thousand were made in the years ended December 31, 2008 and 2007 as part of the License Agreement. No payment was made in 2009.

License Agreement withh Baxter Healthcare Corporation

On November 3, 2006, the Company entered into a definitive Asset Purchase Agreement (for indibulin) and License Agreement (to Baxter's proprietary nanosuspension technology) with affiliates of Baxter. Indibulin is a novel anti-cancer agent that binds to tubulin, one of the essential proteins for chromosomal segregation, and targets mitosis like the taxanes and vinca alkaloids. It is being developed as an oral form. Among the more well known antimitotic drugs are the taxanes (paclitaxel, docetaxel) and the vinca alkaloids (vincristine, vinblastine). The purchase included the entire indibulin intellectual property portfolio as well as existing drug substance and capsule inventories. The terms of the Asset Purchase Agreement included an upfront cash payment of approximately $1.1 million and an additional $100 thousand payment for existing inventory, both of which were expensed in 2006. In addition to the upfront costs, the Asset Purchase Agreement includes additional milestone payments that could amount to approximately $8 million in the aggregate and royalties on net sales of products covered by a valid claim of a patent for the life of the patent on a country-by-country basis. The Company expensed a $625 thousand milestone payment upon the successful U.S. IND application for indibulin in 2007. The License Agreement requires payment of a $15 thousand annual patent and license prosecution/maintenance fee through the expiration of the last to expire of the Licensed Patents which is expected to expire in 2025 and royalties on net sales of licensed products covered by a valid claim of a patent for the life of the patent on a country-by-country basis.

In October 2009, the Baxter License Agreement was amended to allow the Company to manufacturer indibulin.

Collaboration Agreement withh Harmon Hill, LLC

On April 8, 2008, the Company signed a collaboration agreement for Harmon Hill, LLC (Harmon Hill) to provide consulting and other services for the development and commercialization of oncology therapeutics by ZIOPHARM. Under the agreement the Company has agreed to pay Harmon Hill $20 thousand per month for the consulting services and has further agreed to pay Harmon Hill (a) $500 thousand upon the first patient dosing of the Specified Drug in a pivotal trial, which trial uses a dosing Regime introduced by Harmon Hill; and (b) provided that the Specified Drug receives regulatory approval from the FDA, the EMEA or another regulatory agency for the marketing of the Specified Drug, a 1% royalty of the Company s net sales will be awarded to Harmon Hill. If the Specified Drug is sublicensed to a third party, the agreement entitles Harmon Hill to a 1% award of royalties received from a sublicense.

Subject to renewal or extension by the parties, the term of the agreement was for a one year period that expired April 7, 2009. Although the Company and Harmon Hill have not entered into a formal written renewal or extension, the parties continued to operate under the terms of the agreement at December 31, 2009. The Company expensed $180 thousand and $240 thousand during 2008 and 2009, respectively, for consulting services per the aforementioned agreement. No milestones have been reached or accrued during the years ended December 31, 2009 or 2008.

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Other Intellectual Property Rights and Protection.

We depend upon the skills, knowledge, and experience of our scientific and technical personnel, as well as those of our advisors, consultants, and other contractors, none of which is patentable. To help protect proprietary know-how, which is not patentable, and for inventions for which patents may be difficult to enforce, we currently rely, and in the future will continue to rely, on trade secret protection and confidentiality agreements to protect our interests. To this end, we generally require employees, consultants, advisors and other contractors to enter into confidentiality agreements that prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business.

Governmental Regulation

The research, development, testing, manufacture, labeling, promotion, advertising, distribution, and marketing, among other things, of our products are extensively regulated by governmental authorities in the United States and other countries. In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (FDCA) and it s implementing regulations. Failure to comply with the applicable U.S. requirements may subject us to administrative or judicial sanctions, such as FDA refusal to approve pending New Drug Applications (NDAs), warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, and/or criminal prosecution.

Drug Approval Process. None of our drugs may be marketed in the U.S. until the drug has received FDA approval. The steps required before a drug may be marketed in the U.S. include:

Preclinical laboratory tests, animal studies, and formulation studies;
Submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials may begin;
Adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug for each indication;
Submission to the FDA of an NDA;
Satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current good manufacturing practices, or cGMPs ; and
FDA review and approval of the NDA.

Preclinical tests include laboratory evaluation of product chemistry, toxicity, and formulation, as well as animal studies. The conduct of the preclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND application, which must become effective before human clinical trials may begin. An IND automatically takes effect 30 days after receipt by the FDA, unless before that time the FDA raises safety concerns or questions about issues such as the design of the trials as outlined in the IND. In such a case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials may proceed. The Company cannot be certain that submission of an IND will result in the FDA allowing a clinical trial(s) to be initiated.

Clinical trials involve the administration of an investigational drug to human subjects under the supervision of qualified investigators. Clinical trials are conducted according to protocols that detail the study objectives, the parameters to be used in monitoring participants safety, and the effectiveness criteria by which the investigational drug will be evaluated. Each protocol must be submitted to the FDA as part of the IND.

Clinical trials are typically conducted in three sequential phases, but the phases may overlap. The study protocol and informed consent information for study subjects in a clinical trial must also be approved by an Institutional Review Board for each institution where the trial will be conducted. Study subjects must sign an informed consent form before participating in a clinical trial. Phase I usually involves the initial introduction of the investigational drug into people to evaluate its short-term safety, dosage tolerance, metabolism, pharmacokinetics, and pharmacologic actions and, if possible, to gain an early indication of its effectiveness. Phase II usually involves trials in a limited patient population in order to (1) evaluate dosage tolerance and appropriate

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dosage; (2) identify possible adverse effects and safety risks; and (3) evaluate preliminarily the efficacy of the drug for specific indications. Phase III trials usually continue to evaluate clinical efficacy and further test for safety by using the drug in its final form in an expanded patient population. There can be no assurance that phase I, phase II, or phase III testing will be completed successfully within any specified period of time, if at all. Furthermore, the sponsoring company or the FDA may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

The FDCA permits the FDA and the IND sponsor to agree in writing on the design and size of clinical studies intended to form the primary basis of a claim of effectiveness in an NDA application. This process is known as Special Protocol Assessment (SPA) and can be a somewhat lengthy process. An agreement may not be changed by the sponsor or FDA after the trial begins, *except* (1) with the written agreement of the sponsor and the FDA, or (2) if the director of the FDA reviewing division determines that a substantial scientific issue essential to determining the safety or effectiveness of the drug was identified after the testing began.

Assuming successful completion of the required clinical testing, the results of the preclinical studies and of the clinical studies, together with other detailed information, including information on the manufacture and composition of the drug, are submitted to the FDA in the form of an NDA requesting approval to market the product for one or more indications. The testing and approval process requires substantial time, effort, and financial resources. The FDA reviews the application and may deem it to be inadequate to support the registration, and companies cannot be sure that any approval will be granted on a timely basis, if at all. The FDA may also refer the application to the appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendations of the advisory committee.

The NDA application is the vehicle through which investigational drug sponsors formally propose that the FDA approve a new pharmaceutical agent to be marketed and sold in the U.S. The data gathered during the animal studies and human clinical trials of an IND become part of the NDA. The goals of the NDA are to provide enough information to permit FDA to reach the following key decisions:

Is the drug safe and effective in its proposed use(s), and do the benefits of the drug outweigh the risks?
Is the drug s proposed labeling (package insert) is appropriate, and what it should contain?
Are the methods used in manufacturing the drug and the controls used to maintain the drug s quality adequate to preserve the drug s identity, strength, quality, and purity?

The FDA has various programs, including Exploratory INDs (also referred to as phase 0), orphan drug, fast track, priority review, and accelerated approval, which are intended to expedite or simplify the process for developing and reviewing drugs, and/or provide for approval on the basis surrogate endpoints, or provide financial incentives and market exclusivity. Generally, drugs that may be eligible for one or more of these programs are those for serious or life-threatening conditions, those with the potential to address unmet medical needs, and those that provide meaningful benefit over existing treatments. A company cannot be certain that any of its investigational drugs will qualify for any of these programs, or that, if a drug does qualify, the review time will be reduced.

Section 505(b)(2) of the FDCA allows the FDA to approve a follow-on drug on the basis of data in the scientific literature or a prior FDA approval of an NDA for a related drug. Specifically, a 505(b)(2) application is one for which one or more of the investigations relied upon by the applicant for approval were not conducted by or for the applicant, and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. A 505(b)(2) application may be submitted for a new drug product when some part of the data necessary for approval are derived from studies not conducted by or for the applicant and to which the applicant has not obtained a right of reference. For a new drug, these data are likely to be derived from published studies rather than the FDA s previous finding of safety and effectiveness of a drug. For changes to a previously

approved drug product, an application may rely on the FDA s finding of safety and effectiveness of the previously approved product, coupled with the information needed to support the change from the approved product. The additional information could be new studies

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conducted by the applicant or published data. This use of Section 505(b)(2), described in the regulations at 21 CFR 314.54, was intended to encourage innovation without creating duplicate work, and reflects the principle that it is wasteful and unnecessary to carry out studies to demonstrate what is already known about a drug. This procedure potentially makes it easier for generic drug manufacturers to obtain rapid approval of new forms of drugs based on proprietary data of the original drug manufacturer.

Before approving an NDA, the FDA usually will inspect the facility or the facilities at which the drug is manufactured and will not approve the product unless cGMP compliance is satisfactory. If the FDA evaluates the NDA and the manufacturing facilities and deems them to be acceptable, the FDA may issue an approval letter, or in many cases, a complete response letter followed subsequently by an approval letter. The complete response letter contains the conditions that must be met in order to secure final approval of the NDA. When and if those conditions have met with the FDA s satisfaction, the FDA will issue an approval letter. The approval letter authorizes commercial marketing of the drug for specific indications. As a condition of NDA approval, the FDA may require post-marketing testing and surveillance to monitor the drug s safety or efficacy, or impose other conditions.

After approval, certain changes to the approved drug product, such as adding new indications, initiating certain manufacturing changes, or making certain additional labeling claims, are subject to further FDA review and approval. Before a company can market a drug product for any additional indication(s), it must obtain additional approval from FDA. Obtaining approval for a new indication generally requires that additional clinical studies be conducted. A company cannot be sure that any additional approval for new indications for any product candidate will be approved on a timely basis, or at all.

Post-Approval Requirements. Often times, even after a drug has been approved by the FDA for sale, the FDA may require that certain post-approval requirements be satisfied, including the conduct of additional clinical studies. If such post-approval conditions are not satisfied, the FDA may withdraw its approval of the drug. In addition, holders of an approved NDA are required to: (1) report certain adverse reactions to the FDA; (2) comply with certain requirements concerning advertising and promotional labeling for their products; and (3) continue to have quality control and manufacturing procedures conform to cGMP. The FDA periodically inspects the sponsor s records relating to safety reporting and/or manufacturing facilities; this latter effort includes assessment of cGMP compliance. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. We intend to use third- party manufacturers to produce our products in clinical and commercial quantities, and future FDA inspections may identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved NDA, including withdrawal of the product from the market.

Employees

As of the date of this report, the Company has 15 full time and 2 part time employees.

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Item 1A. Risk Factors

An investment in our common stock is very risky. In addition to the other information in this Annual Report on Form 10-K, you should consider carefully the following risk factors in evaluating us and our business. If any of the events described in the following risk factors were to occur, our business, financial condition, results of operation and future growth prospects would likely be materially and adversely affected. In that event, the trading price of our common stock could decline and you could lose all or a part of your investment in our common stock. Therefore, we urge you to carefully review this entire 10-K and consider the risk factors discussed below. Moreover, the risks described below are not the only ones that we face. Additional risks not presently known to us or that we currently deem immaterial may also affect our business, financial condition, operating results or prospects.

Risks Related to Our Business

We will require additional financial resources in order to continue on-going development of our product candidates; if we are unable to obtain these additional resources, we may be forced to delay or discontinue clinical testing of our product candidates.

We believe based on information as of the date of this filing that we have sufficient capital to continue in our ongoing randomized Phase II trial for palifosfamide and with the initiation and enrollment of a registration trial expected to initiate as early as the first half of 2010, to collect the IV darinaparsin data necessary for the design of a registration and other trials with darinaparsin while continuing the oral Phase I trials to completion, and to initiate a Phase I portion of a Phase I/II trial with indibulin. We continue to seek additional financial resources to fund the further development of palifosfamide, darinaparsin and indibulin. If we are unable to obtain sufficient additional capital, one or more of these programs could be placed on hold. Because we are currently devoting a significant portion of our resources to the development of palifosfamide, further progress with the development of darinaparsin and indibulin may be significantly delayed and may depend on the success of our ongoing clinical trial involving palifosfamide.

Currently, we have no committed sources of additional capital. We do not know whether additional financing will be available on terms favorable or acceptable to us when needed, if at all. Our business is highly cash-intensive and our ability to continue operations after our current cash resources are exhausted depends on our ability to obtain additional financing and achieve profitable operations, as to which no assurances can be given. If adequate additional funds are not available when required, or if unsuccessful in entering into partnership agreements for the further development of our products, we will be required to delay, reduce or eliminate planned preclinical and clinical trials and terminate the approval process for our product candidates from the FDA or other regulatory authorities. In addition, we could be forced to discontinue product development, reduce or forego sales and marketing efforts, forego attractive business opportunities or pursue merger or divestiture strategies. In the event we are unable to continue as a going concern, we may be forced to cease operations altogether.

We need to raise additional capital to fund our operations. The manner in which we raise any additional funds may affect the value of your investment in our common stock.

As of December 31, 2009, we had incurred approximately $91.1 million of cumulative net losses and had

approximately $48.8 million of cash and cash equivalents. Given our current plans for development of our product candidates, we anticipate that our cash resources will be sufficient to fund our operations very early into 2012. However, changes may occur that would consume our existing capital prior to that time, including the scope and progress of our research and development efforts and changes in governmental regulation. Specifically, we currently anticipate commencing a registration trial for IV palifosfamide as early as the first half of 2010. However, we are still evaluating the protocol design for this trial, including with respect to overall trial size, clinical endpoints and our ability to receive Special Protocol Assessment. We also continue to evaluate the appropriate number of and locations for trial sites. We have estimated the sufficiency of our cash resources based on our current expectations for the trial design. However, the final trial design may ultimately vary from our current expectations, which could materially impact the schedule and cost of the trial and, in turn, alter our use of capital and our forecast of the period of time through which our financial resources will be adequate to support our operations. In addition to the amount and timing of expenses related

We need to raise additional capital to fund our operations. The manner inwhich we raise any additional funds may a

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to the planned IV palifosfamide registration trial, our actual cash requirements may vary materially from our current expectations for a number of other factors that may include, but are not limited to, changes in the focus and direction of our development programs, competitive and technical advances, costs associated with the development of our product candidates, our ability to secure partnering arrangements, and costs of filing, prosecuting, defending and enforcing our intellectual property rights.

Recently, capital markets have experienced a period of unprecedented instability that we expect may severely hinder our ability to raise capital within the time periods needed or on terms we consider acceptable, if at all. Moreover, if we fail to advance one or more of our current product candidates to later-stage clinical trials, successfully commercialize one or more of our product candidates, or acquire new product candidates for development, we may have difficulty attracting investors that might otherwise be a source of additional financing.

In the current economic environment, our need for additional capital and limited capital resources may force us to accept financing terms that could be significantly more dilutive than if we were raising capital when the capital markets were more stable. To the extent that we raise additional capital by issuing equity securities, our stockholders may experience dilution. In addition, we may grant future investors rights superior to those of our existing stockholders. If we raise additional funds through collaborations and licensing arrangements, it may be necessary to relinquish some rights to our technologies, product candidates or products, or grant licenses on terms that are not favorable to us. If we raise additional funds by incurring debt, we could incur significant interest expense and become subject to covenants in the related transaction documentation that could affect the manner in which we conduct our business.

We may not be able to commercialize any products, generate significant revenues, or attain profitability.

We have never generated revenue and have incurred significant net losses in each year since our inception. For the twelve months ended December 31, 2009, we had a net loss of $7.6 million and we had incurred approximately $91.1 million of cumulative net losses since our inception in 2003. We expect to continue to incur significant operating expenditures. Although we have taken near-term cost cutting measures aimed at preserving capital while we pursue sources of potential additional financing, further development of our product candidates will likely require substantial increases in our expenses as we:

Continue to undertake clinical trials for product candidates;
Scale-up the formulation and manufacturing of our product candidates;
Seek regulatory approvals for product candidates;
Implement additional internal systems and infrastructure; and
Hire additional personnel.

To date, none of our product candidates have been approved for commercial sale in any country. The process to develop, obtain regulatory approval for, and commercialize potential drug candidates is long, complex, and costly. Unless and until we receive approval from the FDA and/or other regulatory authorities for our product candidates, we cannot sell our drugs and will not have product revenues. Even if we obtain regulatory approval for one or more of our product candidates, if we are unable to successfully commercialize our products, we may not be able to generate sufficient revenues to achieve or maintain profitability, or to continue our business without raising significant additional capital, which may not be available. Our failure to achieve or maintain profitability could negatively impact the trading price of our common stock.

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We have a limited operating history upon which to base an investment decision.

We are a development-stage company that was incorporated in September 2003. To date, we have not demonstrated an ability to perform the functions necessary for the successful commercialization of any product candidates. The successful commercialization of any product candidates will require us to perform a variety of functions, including:

Continuing to undertake preclinical development and clinical trials;
Participating in regulatory approval processes;
Formulating and manufacturing products; and
Conducting sales and marketing activities.

Our operations have been limited to organizing and staffing our Company, acquiring, developing, and securing our proprietary product candidates, and undertaking preclinical and clinical trials of our product candidates: darinaparsin, palifosfamide, and indibulin. These operations provide a limited basis for you to assess our ability to commercialize our product candidates and the advisability of investing in our securities.

The success of our growth strategy depends upon our ability to identify, select, and acquire additional pharmaceutical product candidates for development and commercialization. Because we currently neither have nor intend to establish internal research capabilities, we are dependent upon pharmaceutical and biotechnology companies and academic and other researchers to sell or license us their product candidates.

Proposing, negotiating, and implementing an economically viable product acquisition or license is a lengthy and complex process. We compete for partnering arrangements and license agreements with pharmaceutical, biopharmaceutical, and biotechnology companies, many of which have significantly more experience than we do, and have significantly more financial resources. Our competitors may have stronger relationships with certain third parties including academic research institutions, with whom we are interested in collaborating and may have, therefore, a competitive advantage in entering into partnering arrangements with those third parties. We may not be able to acquire rights to additional product candidates on terms that we find acceptable, or at all.

We expect that any product candidate to which we acquire rights will require significant additional development and other efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All drug product candidates are subject to the risks of failure inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe or effective for approval by regulatory authorities. Even if our product candidates are approved, they may not be economically manufactured or produced, or be successfully commercialized.

We actively evaluate additional product candidates to acquire for development. Such additional product candidates, if any, could significantly increase our capital requirements and place further strain on the time of our existing personnel, which may delay or otherwise adversely affect the development of our existing product candidates. We must manage our development efforts and clinical trials effectively, and hire, train and integrate additional management, administrative, and sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our Company.

The success of our growth strategy depends upon our ability to identify,select, and acquire additional pharmaceutic

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We may not be able to successfully manage our growth.

In the future, if we are able to advance our product candidates to the point of, and thereafter through, clinical trials, we will need to expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide for these capabilities. Any future growth will place a significant strain on our management and on our administrative, operational, and financial resources. Therefore, our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To manage this growth, we must expand our facilities, augment our operational, financial and management systems, and hire and train additional qualified personnel. If we are unable to manage our growth effectively, our business may be harmed.

Our business will subject us to the risk of liability claims associated with the use of hazardous materials and chemicals.

Our contract research and development activities may involve the controlled use of hazardous materials and chemicals. Although we believe that our safety procedures for using, storing, handling and disposing of these materials comply with federal, state and local laws and regulations, we cannot completely eliminate the risk of accidental injury or contamination from these materials. In the event of such an accident, we could be held liable for any resulting damages and any liability could have a materially adverse effect on our business, financial condition, and results of operations. In addition, the federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous or radioactive materials and waste products may require our contractors to incur substantial compliance costs that could materially adversely affect our business, financial condition, and results of operations.

We rely on key executive officers and scientific and medical advisors, and their knowledge of our business and technical expertise would be difficult to replace.

We are highly dependent on Dr. Jonathan Lewis, our Chief Executive Officer and Chief Medical Officer, Richard Bagley, our President, Chief Operating Officer and Chief Financial Officer, and our principal scientific, regulatory, and medical advisors. Dr. Lewis and Mr. Bagley s employment are governed by written employment agreements that provide for terms that expire in January 2011 and July 2011, respectively. Dr. Lewis and Mr. Bagley may terminate their employment with us at any time, subject, however, to certain non-compete and non-solicitation covenants. The loss of the technical knowledge and management and industry expertise of Dr. Lewis and Mr. Bagley, or any of our other key personnel, could result in delays in product development, loss of customers and sales, and diversion of management resources, which could adversely affect our operating results. We do not carry key person life insurance policies on any of our officers or key employees.

If we are unable to hire additional qualified personnel, our ability to grow our business may be harmed.

We will need to hire additional qualified personnel with expertise in preclinical and clinical research and testing, government regulation, formulation and manufacturing, and eventually, sales and marketing. We compete for qualified individuals with numerous biopharmaceutical companies, universities, and other research institutions. Competition for such individuals is intense and we cannot be certain that our search for such personnel will be successful. Attracting and retaining qualified personnel will be critical to our success. If we are unable to hire

additional qualified personnel, our ability to grow our business may be harmed.

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We may incur substantial liabilities and may be required to limit commercialization of our products in response to product liability lawsuits.

The testing and marketing of medical products entail an inherent risk of product liability. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products, if approved. Even a successful defense would require significant financial and management resources. Regardless of the merit or eventual outcome, liability claims may result in:

Decreased demand for our product candidates;
Injury to our reputation;
Withdrawal of clinical trial participants;
Withdrawal of prior governmental approvals;
Costs of related litigation;
Substantial monetary awards to patients;
Product recalls;
Loss of revenue; and
The inability to commercialize our product candidates.

We currently carry clinical trial insurance and product liability insurance. However, our inability to renew our policies or to obtain sufficient insurance at an acceptable cost could prevent or inhibit the commercialization of pharmaceutical products that we develop, alone or with collaborators.

Risks Related to the Clinical Testing, Regulatory Approval and Manufacturing of Our Product Candidates

If we are unable to obtain the necessary U.S. or worldwide regulatory approvals to commercialize any product candidate, our business will suffer.

We may not be able to obtain the approvals necessary to commercialize our product candidates, or any product candidate that we may acquire or develop in the future for commercial sale. We will need FDA approval to commercialize our product candidates in the U.S. and approvals from regulatory authorities in foreign jurisdictions equivalent to the FDA to commercialize our product candidates in those jurisdictions. In order to obtain FDA approval of any product candidate, we must submit to the FDA a New Drug Application, demonstrating that the product candidate is safe for humans and effective for its intended use. This demonstration requires significant research and animal tests, which are referred to as preclinical studies, as well as human tests, which are referred to as clinical trials. Satisfaction of the FDA s regulatory requirements typically takes many years, depending upon the type, complexity, and novelty of the product candidate, and will require substantial resources for research, development, and testing. We cannot predict whether our research, development, and clinical approaches will result in drugs that the FDA will consider safe for humans and effective for their intended uses. The FDA has substantial discretion in the drug approval process and may require us to conduct additional preclinical and clinical testing or to perform post-marketing studies. The approval process may also be delayed by changes in government regulation, future legislation, or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals may:

Delay commercialization of, and our ability to derive product revenues from, our product candidates;
Impose costly procedures on us; and
Diminish any competitive advantages that we may otherwise enjoy.

If we are unable to obtain the necessary U.S. or worldwide regulatoryapprovals to commercialize any product candi

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Even if we comply with all FDA requests, the FDA may ultimately reject one or more of our NDAs. We cannot be sure that we will ever obtain regulatory clearance for any of our product candidates. Failure to obtain FDA approval for our product candidates will severely undermine our business by leaving us without a saleable product, and therefore without any potential revenue source, until another product candidate can be developed. There is no guarantee that we will ever be able to develop or acquire another product candidate or that we will obtain FDA approval if we are able to do so.

In foreign jurisdictions, we similarly must receive approval from applicable regulatory authorities before we can commercialize any drugs. Foreign regulatory approval processes generally include all of the risks associated with the FDA approval procedures described above.

Our product candidates are in various stages of clinical trials, which are very expensive and time-consuming. We cannot be certain when we will be able to file an NDA with the FDA and any failure or delay in completing clinical trials for our product candidates could harm our business.

Our product candidates are in various stages of development and require extensive clinical testing. Notwithstanding our current clinical trial plans for each of our existing product candidates, we may not be able to commence additional trials or see results from these trials within our anticipated timelines. As such, we cannot predict with any certainty if or when we might submit an NDA for regulatory approval of our product candidates or whether such an NDA will be accepted. Because we do not anticipate generating revenues unless and until we submit one or more NDAs and thereafter obtain requisite FDA approvals, the timing of our NDA submissions and FDA determinations regarding approval thereof, will directly affect if and when we are able to generate revenues.

Clinical trials are very expensive, time-consuming, and difficult to design and implement.

Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process itself is also time consuming. We estimate that clinical trials of our product candidates will take at least several years to complete. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. The commencement and completion of clinical trials may be delayed by several factors, including:

Unforeseen safety issues;
Determination of dosing issues;
Lack of effectiveness during clinical trials;
Slower than expected rates of patient recruitment;
Inability to monitor patients adequately during or after treatment; and
Inability or unwillingness of medical investigators to follow our clinical protocols.

We have received Orphan Drug status for palifosfamide in both the United States and Europe and we are hopeful that we may be able to obtain Fast Track and/or Orphan Drug status from the FDA for our product candidates. Fast Track allows the FDA to facilitate development and expedite review of drugs that treat serious and life-threatening conditions so that an approved product can reach the market expeditiously. Fast Track status does not apply to a product alone, but applies to a combination of a product and the specific indications for which it is being studied. Therefore, it is a drug s development program for a specific indication that receives Fast Track designation. Orphan Drug status promotes the development of products that demonstrate the promise for the diagnosis and treatment of one

disease or condition and affords certain financial and market protection benefits to successful applicants. However, there is no guarantee that any of our product candidates, other than palifosfamide, will be granted Orphan Drug status or will be granted Fast Track status by the FDA or that, even if such product candidate is granted such status, the product candidate s clinical development and regulatory approval process will not be delayed or will be successful.

Clinical trials are very expensive, time-consuming, and difficult to design andimplement. 36

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In addition, we or the FDA may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA finds deficiencies in our IND submission or in the conduct of these trials. Therefore, we cannot predict with any certainty the schedule for future clinical trials.

The results of our clinical trials may not support our product candidate claims.

Even if our clinical trials are completed as planned, we cannot be certain that their results will support approval of our product candidates. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be certain that the results of later clinical trials will replicate the results of prior clinical trials and preclinical testing. The clinical trial process may fail to demonstrate that our product candidates are safe for humans and effective for the indicated uses. This failure would cause us to abandon a product candidate and may delay development of other product candidates. Any delay in, or termination of, our clinical trials will delay the filing of our NDAs with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues. In addition, our clinical trials involve small patient populations. Because of the small sample size, the results of these clinical trials may not be indicative of future results.

Because we are dependent upon clinical research institutions and other contractors for clinical testing and for research and development activities, the results of our clinical trials and such research activities are, to a certain extent, beyond our control.

We materially rely upon independent investigators and collaborators, such as universities and medical institutions, to conduct our preclinical and clinical trials under agreements with us. These collaborators are not our employees and we cannot control the amount or timing of resources that they devote to our programs. These investigators may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking such programs ourselves. If outside collaborators fail to devote sufficient time and resources to our drug development programs, or if their performance is substandard, the approval of our FDA applications, if any, and our introduction of new drugs, if any, will be delayed. These collaborators may also have relationships with other commercial entities, some of whom may compete with us. If our collaborators assist our competitors to our detriment, our competitive position would be harmed.

Our reliance on third parties to formulate and manufacture our product candidates exposes us to a number of risks that may delay the development, regulatory approval and commercialization of our products or result in higher product costs.

We do not have experience in drug formulation or manufacturing and do not intend to establish our own manufacturing facilities. We lack the resources and expertise to formulate or manufacture our own product candidates. We currently are contracting for the manufacture of our product candidates. We intend to contract with one or more manufacturers to manufacture, supply, store, and distribute drug supplies for our clinical trials. If a product candidate we develop or acquire in the future receives FDA approval, we will rely on one or more third-party contractors to manufacture our drugs. Our anticipated future reliance on a limited number of third-party manufacturers exposes us to the following risks:

We may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA must approve any replacement contractor. This approval would require new testing and compliance inspections. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of FDA approval, if any.

Our third-party manufacturers might be unable to formulate and manufacture our drugs in the volume and of the quality required to meet our clinical needs and commercial needs, if any.

Our future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store, and distribute our products.

Our reliance on third parties to formulate and manufacture our productcandidates exposes us to a number of risks t

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Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Administration the DEA), and corresponding state agencies to ensure strict compliance with good manufacturing practices and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers compliance with these regulations and standards.

If any third-party manufacturer makes improvements in the manufacturing process for our products, we may not own, or may have to share, the intellectual property rights to the innovation.

Each of these risks could delay our clinical trials, the approval, if any, of our product candidates by the FDA or the commercialization of our product candidates or result in higher costs or deprive us of potential product revenues.

Risks Related to Our Ability to Commercialize Our Product Candidates

If we are unable either to create sales, marketing and distribution capabilities or enter into agreements with third parties to perform these functions, we will be unable to commercialize our product candidates successfully.

We currently have no marketing, sales, or distribution capabilities. If and when we become reasonably certain that we will be able to commercialize our current or future products, we anticipate allocating resources to the marketing, sales and distribution of our proposed products in North America; however, we cannot assure that we will be able to market, sell, and distribute our products successfully. Our future success also may depend, in part, on our ability to enter into and maintain collaborative relationships for such capabilities and to encourage the collaborator s strategic interest in the products under development, and such collaborator s ability to successfully market and sell any such products. Although we intend to pursue certain collaborative arrangements regarding the sale and marketing of our products, there are no assurances that we will be able to establish or maintain collaborative arrangements or, if we are able to do so, whether we would be able to conduct our own sales efforts. There can also be no assurance that we will be able to establish or maintain relationships with third-party collaborators or develop in-house sales and distribution capabilities. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful. In addition, there can also be no assurance that we will be able to market and sell our products in the United States or overseas.

If we are not able to partner with a third party and are not successful in recruiting sales and marketing personnel or in building a sales and marketing infrastructure, we will have difficulty commercializing our product candidates, which would harm our business. If we rely on pharmaceutical or biotechnology companies with established distribution systems to market our products, we will need to establish and maintain partnership arrangements, and we may not be able to enter into these arrangements on acceptable terms or at all. To the extent that we enter into co-promotion or other arrangements, any revenues we receive will depend upon the efforts of third parties that may not be successful and that will be only partially in our control.

If we cannot compete successfully for market share against other drug companies, we may not achieve sufficient product revenues and our business will suffer.

The market for our product candidates is characterized by intense competition and rapid technological advances. If a

product candidate receives FDA approval, it will compete with a number of existing and future drugs and therapies developed, manufactured and marketed by others. Existing or future competing products may provide greater therapeutic convenience or clinical or other benefits for a specific indication than our products, or may offer comparable performance at a lower cost. If our products fail to capture and maintain market share, we may not achieve sufficient product revenues and our business will suffer.

If we cannot compete successfully for market share against other drugcompanies, we may not achieve sufficient pr

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We will compete against fully integrated pharmaceutical companies and smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. Many of these competitors have products already approved or in development. In addition, many of these competitors, either alone or together with their collaborative partners, operate larger research and development programs or have substantially greater financial resources than we do, as well as significantly greater experience in:

Developing drugs;
Undertaking preclinical testing and human clinical trials;
Obtaining FDA and other regulatory approvals of drugs;
Formulating and manufacturing drugs; and
Launching, marketing, and selling drugs.

If physicians and patients do not accept and use our product candidates, our ability to generate revenue from sales of our products will be materially impaired.

Even if the FDA approves our product candidates, physicians and patients may not accept and use them. Acceptance and use of our products will depend upon a number of factors including:

Perceptions by members of the health care community, including physicians, about the safety and effectiveness of our drugs;
Pharmacological benefit and cost-effectiveness of our products relative to competing products;
Availability of reimbursement for our products from government or other healthcare payors;
Effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any; and
The price at which we sell our products.

Because we expect sales of our current product candidates, if approved, to generate substantially all of our product revenues for the foreseeable future, the failure of a drug to find market acceptance would harm our business and could require us to seek additional financing in order to fund the development of future product candidates.

Our ability to generate product revenues will be diminished if our drugs sell for inadequate prices or patients are unable to obtain adequate levels of reimbursement.

Our ability to commercialize our drugs, alone or with collaborators, will depend in part on the extent to which reimbursement will be available from:

Government and health administration authorities;
Private health maintenance organizations and health insurers; and
Other healthcare payers.

Government and other healthcare payers increasingly attempt to contain healthcare costs by limiting both coverage and the level of reimbursement for drugs. As a result, we cannot provide any assurances that third-party payors will provide adequate coverage of and reimbursement for any of our product candidates. If we are unable to obtain adequate coverage of and payment levels for our product candidates from third-party payors, physicians may limit how much or under what circumstances they will prescribe or administer them and patients may decline to purchase them. This in turn could affect our ability to successfully commercialize our products and impact our profitability and future success.

Our ability to generate product revenues will be diminished if our drugs sellfor inadequate prices or patients are una

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In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory policies and proposals in recent years to change the healthcare system in ways that could impact our ability to sell our products profitably. On December 8, 2003, President Bush signed into law the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), which contains, among other changes to the law, a wide variety of changes that have and will impact Medicare reimbursement of pharmaceuticals to physicians and hospitals.

There also likely will continue to be legislative and regulatory proposals that could bring about significant changes in the healthcare industry. We cannot predict what form those changes might take or the impact on our business of any legislation or regulations that may be adopted in the future. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

In addition, in many foreign countries, particularly the countries of the European Union, the pricing of prescription drugs is subject to government control. We may face competition for our product candidates from lower-priced products in foreign countries that have placed price controls on pharmaceutical products. In addition, there may be importation of foreign products that compete with our own products, which could negatively impact our profitability.

Risks Related to Our Intellectual Property

If we fail to adequately protect or enforce our intellectual property rights or secure rights to patents of others, the value of our intellectual property rights would diminish.

Our success, competitive position, and future revenues will depend in part on our ability and the abilities of our licensors to obtain and maintain patent protection for our products, methods, processes and other technologies, to preserve our trade secrets, to prevent third parties from infringing on our proprietary rights, and to operate without infringing the proprietary rights of third parties.

To date, we have exclusive rights to certain U.S. and foreign intellectual property. We anticipate filing additional patent applications both in the U.S. and in other countries, as appropriate. However, we cannot predict:

The degree and range of protection any patents will afford us against competitors, including whether third parties will find ways to invalidate or otherwise circumvent our patents;

If and when patents will be issued;

Whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications; or

Whether we will need to initiate litigation or administrative proceedings that may be costly whether we win or lose.

Our success also depends upon the skills, knowledge, and experience of our scientific and technical personnel, our consultants and advisors, as well as our licensors and contractors. To help protect our proprietary know-how and our inventions for which patents may be unobtainable or difficult to obtain, we rely on trade secret protection and confidentiality agreements. To this end, it is our general policy to require our employees, consultants, advisors, and contractors to enter into agreements that prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries, and inventions important to our business. These agreements may not provide adequate protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure or the lawful development by others of such information. If any of our trade secrets, know-how or other proprietary information is disclosed, the value of our trade

secrets, know-how and other proprietary rights would be significantly impaired and our business and competitive position would suffer.

If we fail to adequately protect or enforce our intellectual property rights orsecure rights to patents of others, the valu

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Third-party claims of intellectual property infringement would require us to spend significant time and money and could prevent us from developing or commercializing our products.

In order to protect or enforce patent rights, we may initiate patent litigation against third parties. Similarly, we may be sued by others. We also may become subject to proceedings conducted in the U.S. Patent and Trademark Office, including interference proceedings to determine the priority of inventions, or reexamination proceedings. In addition, any foreign patents that are granted may become subject to opposition, nullity, or revocation proceedings in foreign jurisdictions having such proceedings opposed by third parties in foreign jurisdictions having opposition proceedings. The defense and prosecution, if necessary, of intellectual property actions are costly and divert technical and management personnel away from their normal responsibilities.

No patent can protect its holder from a claim of infringement of another patent. Therefore, our patent position cannot and does not provide any assurance that the commercialization of our products would not infringe the patent rights of another. While we know of no actual or threatened claim of infringement that would be material to us, there can be no assurance that such a claim will not be asserted.

If such a claim is asserted, there can be no assurance that the resolution of the claim would permit us to continue marketing the relevant product on commercially reasonable terms, if at all. We may not have sufficient resources to bring these actions to a successful conclusion. If we do not successfully defend any infringement actions to which we become a party or are unable to have infringed patents declared invalid or unenforceable, we may have to pay substantial monetary damages, which can be tripled if the infringement is deemed willful, or be required to discontinue or significantly delay commercialization and development of the affected products.

Any legal action against us or our collaborators claiming damages and seeking to enjoin developmental or marketing activities relating to affected products could, in addition to subjecting us to potential liability for damages, require us or our collaborators to obtain licenses to continue to develop, manufacture, or market the affected products. Such a license may not be available to us on commercially reasonable terms, if at all.

An adverse determination in a proceeding involving our owned or licensed intellectual property may allow entry of generic substitutes for our products.

Other Risks Related to Our Company

We are subject to Sarbanes-Oxley and the reporting requirements of federal securities laws, which can be expensive.

As a public reporting company, we are subject to the Sarbanes-Oxley Act of 2002, as well as to the information and reporting requirements of the Securities Exchange Act of 1934, as amended, and other federal securities laws. As a result, we incur significant legal, accounting, and other expenses that we did not incur as a private company, including costs associated with our public company reporting requirements and corporate governance requirements. As an example of public reporting company requirements, we evaluate the effectiveness of disclosure controls and procedures and of our internal control over financing reporting in order to allow management to report on such controls. Pursuant to Sarbanes-Oxley, our independent registered public accounting firm will be attesting to the effectiveness of our internal control over financial reporting, as of December 31, 2010, in our Annual Report on Form 10-K for the fiscal year ending December 31, 2010. While management has not currently identified any material

weaknesses in our internal control over financial reporting, there can be no assurance that we will not identify identified any material weaknesses during the current year or that our systems will be deemed effective when our independent registered public accounting firm reviews the systems during 2010 and tests transactions. In addition, any updates to our finance and accounting systems, procedures and controls, which may be required as a result of our ongoing analysis of internal controls, or results of testing by our independent auditor, may require significant time and expense.

As a company with limited capital and human resources, our management has identified that there is a potential for a lack of segregation of duties due to the limited number of employees within our company s financial and administrative functions. Management believes that, based on the employees involved and the increased monitoring control procedures in place, risks associated with such lack of segregation are not significant and that the potential benefits of adding employees to segregate duties more clearly do not justify the

We are subject to Sarbanes-Oxley and the reporting requirements of federalsecurities laws, which can be expensive

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associated added expense. However, our management is working to continuously monitor and improve internal controls and has set in place controls to mitigate the potential segregation of duties risk. In the event significant deficiencies or material weaknesses are indentified in our internal control over financial reporting that we cannot remediate in a timely manner, investors and others may lose confidence in the reliability of our financial statements and the trading price of our common stock and ability to obtain any necessary equity or debt financing could suffer. In addition, in the event that our independent registered public accounting firm is unable to rely on our internal controls over financial reporting in connection with its audit of our financial statements, and in the further event that it is unable to devise alternative procedures in order to satisfy itself as to the material accuracy of our financial statements and related disclosures, we may be unable to file our periodic reports with the Securities and Exchange Commission. This would likely have an adverse affect on the trading price of our common stock and our ability to secure any necessary additional equity or debt financing, and could result in the delisting of our common stock from the NASDAQ Capital Market, which would severely limit the liquidity of our common stock.

There is not now, and there may not ever be an active market for shares of our common stock.

In general, there has been limited trading activity in shares of the Company s common stock. The small trading volume may make it more difficult for our stockholders to sell their shares as and when they choose. Furthermore, small trading volumes generally depress market prices. As a result, you may not always be able to resell shares of our common stock publicly at the time and prices that you feel are fair or appropriate.

Our common stock could be delisted from The NASDAQ Capital Market, which could negatively impact the price of our common stock and our ability to access the capital markets.

Our common stock is listed on The NASDAQ Capital Market. The listing standards of The NASDAQ Capital Market provide, among other things, that a company may be delisted if the bid price of its stock drops below $1.00 for a period of 30 consecutive trading days. In addition, our total stockholders equity at December 31, 2009 was approximately $28.1 million. If our stockholders equity is less than $2.5 million, we will fail to comply with The NASDAQ Capital Market s listing standards if shares of our common stock fail to have an aggregate market value of at least $35 million for 30 consecutive trading days. If we fail to comply with these or other listing standards applicable to us, our common stock may be delisted from The NASDAQ Capital Market. The delisting of our common stock would significantly affect the ability of investors to trade our securities and would significantly negatively affect the value and liquidity of our common stock. In addition, the delisting of our common stock could materially adversely affect our ability to raise capital on terms acceptable to us or at all. Delisting from The NASDAQ Capital Market could also have other negative results, including the potential loss of confidence by suppliers and employees, the loss of institutional investor interest and fewer business development opportunities.

Anti-takeover provisions in our charter documents and under Delaware law may make an acquisition of us, which may be beneficial to our stockholders, more difficult.

Provisions of our amended and restated certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us, even if doing so would benefit our stockholders. These provisions authorize the issuance of blank check preferred stock that could be issued by our board of directors to increase the number of outstanding shares and hinder a takeover attempt, and limit who may call a special meeting of

stockholders. In addition, Section 203 of the Delaware General Corporation Law, which prohibits business combinations between us and one or more significant stockholders unless specified conditions are met, may discourage, delay or prevent a third party from acquiring us.

Because we do not expect to pay dividends, you will not realize any income from an investment in our common stock unless and until you sell your shares at profit.

We have never paid dividends on our capital stock and we do not anticipate that we will pay any dividends for the foreseeable future. Accordingly, any return on an investment in our Company will be realized, if at all, only when you sell shares of our common stock.

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Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our corporate office is located at 1180 Avenue of the Americas, 19th Floor, New York, NY 10036. The New York office space is subject to a five-year lease agreement that expires in June 2010. Under the terms of the lease, we lease approximately 2,580 square feet and are required to make monthly rental payments of approximately $11 thousand through the remainder of the term of the lease. We also maintain business and development operations in Boston, Massachusetts in an office facility that occupies approximately 12,000 square feet. The Boston office space consists of two floors which are leased pursuant to two separate lease agreements. The second floor, 4,872 square feet, is under a three-year lease that expires April 2010 and we are required to make monthly rental payments of approximately $11 thousand through the remainder of the lease term. The third floor, 6,750 square feet, is under a five-year lease that expires August 2012 and we are required to make monthly rental payments that range from approximately $15 thousand during the current year of the lease to approximately $16 thousand during the last year of the lease (see Note 7 to the financial statements, Commitments and Contingencies).

Item 3. Legal Proceedings

We are not currently involved in any material legal proceedings.

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

No matters were submitted to a vote of our security holders during the fourth quarter of the fiscal year ended December 31, 2009.

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PART II

Item 5. Market for Common Equity and Related Stockholders Matters

Market for Common Stock

Our common stock trades on the NASDAQ Capital Market under the symbol ZIOP. The following table sets forth the high and low sale prices for our common stock during each quarter within the two most recently completed fiscal years as reported by the NASDAQ Capital Market.

	2009		2008	
Quarter Ended	High	Low	High	Low
March 31	$ 0.95	$ 0.51	$ 3.65	$ 2.38
June 30	$ 2.14	$ 0.50	$ 3.39	$ 1.80
September 30	$ 2.74	$ 1.25	$ 2.19	$ 1.07
December 31	$ 4.10	$ 2.35	$ 1.78	$ 0.56

Record Holders

As of March 4, 2010, we had approximately 212 holders of record of our common stock, one of which was Cede & Co., a nominee for Depository Trust Company, or DTC. Shares of common stock that are held by financial institutions as nominees for beneficial owners are deposited into participant accounts at DTC, and are considered to be held of record by Cede & Co. as one stockholder. As of March 4, 2010, we had approximately 3,100 beneficial holders of our common stock.

Dividends

We have never declared or paid a cash dividend on our common stock and do not anticipate paying any cash dividends in the foreseeable future.

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

During 2009, we purchased 103,823 restricted shares from employees to cover withholding taxes due from the employees at the time the shares vested. The following table provides information about these purchases of restricted shares for the year ended December 31, 2009:

Period

	Total Number of Shares Purchased	Average Price Paid per Share ($)	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares that May Yet Be Purchased Under the Plans or Programs
January 1 to 31, 2009		$		
February 1 to 28, 2009		$		
March 1 to 31, 2009		$		
April 1 to 30, 2009		$		
May 1 to 31, 2009		$		
June 1 to 30, 2009		$		
July 1 to 31, 2009		$		
August 1 to 31, 2009		$		
September 1 to 30, 2009		$		
October 1 to 31, 2009		$		
November 1 to 30, 2009		$		
December 1 to 31, 2009	103,823	$ 3.66		
Total	103,823			

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Item 6. Selected Financial Data

Smaller reporting companies are not required to provide disclosure pursuant to this Item.

Item 7. Management Discussion and Analysis of Financial Condition and Results of Operation

The following Management's Discussion and Analysis of Financial Condition and Results of Operations , as well as disclosures included elsewhere in this Form 10-K, include forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. This Act provides a safe harbor for forward-looking statements to encourage companies to provide prospective information about themselves so long as they identify these statements as forward-looking and provide meaningful cautionary statements identifying important factors that could cause actual results to differ from the projected results. All statements other than statements of historical fact we make in this Form 10-K are forward-looking. In particular, the statements herein regarding future sales and operating results; our ability to raise capital or finance our operations; Company and industry growth and trends; growth of the markets in which the Company participates; international events; product performance; the generation, protection and acquisition of intellectual property, and litigation related to such intellectual property; new product introductions; development of new products, technologies and markets; the acquisition of or investment in other entities; the construction of new or refurbishment of existing facilities by the Company; and statements preceded by, followed by or that include the words intends , estimates , plans , believes , expects , anticipates , should , could or similar expressi forward-looking statements. Forward-looking statements reflect our current expectations and are inherently uncertain. Our actual results may differ significantly from our expectations. We assume no obligation to update this forward-looking information. The section entitled Risk Factors describes some, but not all, of the factors that could cause these differences.

The following discussion and analysis should be read in conjunction with our historical financial statements and the notes to those financial statements which are included in Item 8 of Part II of this Form 10-K.

Business Overview:

ZIOPHARM Oncology, Inc. is a biopharmaceutical company that is seeking to develop and commercialize a diverse, risk-sensitive portfolio of in-licensed cancer drugs that can address unmet medical needs through enhanced efficacy and/or safety and quality of life. Our principal focus is on the licensing and development of proprietary small molecule drug candidates that are related to cancer therapeutics already on the market or in development and that can be administered by intravenous and/or oral capsule dosing. We believe this strategy will result in lower risk and expedited drug development programs with product candidates having a low cost of manufacturing to address changing reimbursement requirements around the world. While we may endeavor to commercialize our products on our own in North America, we recognize that favorable clinical trial results can be better addressed by partnering with companies with the requisite financial resources. With partnering, we could also negotiate the right to complete development and marketing in certain geographies, especially for certain limited (niche) indications. Although we are currently in phase I and/or II studies for three product candidates identified as darinaparsin (Zinapar™, ZIO-101), palifosfamide (Zymafos™, ZIO-201), and indibulin (Zybulin™, ZIO-301), our current focus has been and remains on palifosfamide development and more specifically on completing the ongoing randomized phase II trial with palifosfamide to support a registration trial for palifosfamide in combination with doxorubicin in the front- and second-line setting of soft tissue sarcoma. We anticipate the initiation of such a registration trial as early as the first half of 2010.

ZIO-101 or darinaparsin (Zinapar™) is an anti-mitochondrial (organic arsenic) compound covered by issued patents and pending patent applications in the U.S. and in foreign countries. A form of commercially available inorganic arsenic (arsenic trioxide [Trisenox®] or ATO) has been approved in the United States and the European Union and Japan for the treatment of acute promyelocytic leukemia, a precancerous condition. In the United States, ATO is on the compendia listing for the therapy of multiple myeloma, and has been studied for the treatment of various other cancers. Nevertheless, ATO has been shown to be toxic to the heart, liver, and brain, which limits its use as an anti-cancer agent. ATO carries a black box warning for ECG abnormalities since arsenic trioxide has been shown to cause QT interval prolongation and complete atrioventricular block. QT prolongation can lead to a *torsade de pointes* -type ventricular arrhythmia, which can be fatal. Inorganic arsenic has also been shown to cause cancer of the skin and lung in humans. The toxicity of arsenic

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is generally correlated to its accumulation in organs and tissues. Our preclinical and clinical studies to date have demonstrated that darinaparsin is considerably less toxic than ATO, particularly with regard to cardiac toxicity. *In vitro* testing of darinaparsin using the National Cancer Institute s human cancer cell panel demonstrated activity against a series of tumor cell lines including lung, colon, brain, melanoma, ovarian, and kidney cancer. Moderate activity was shown against breast and prostate cancer tumor cell lines. In addition to solid tumors, *in vitro* testing in both the National Cancer Institute s cancer cell panel and *in vivo* testing in a leukemia animal model demonstrated substantial activity against hematological cancers (cancers of the blood and blood-forming tissues) such as leukemia, lymphoma, myelodysplastic syndromes, and multiple myeloma. Results indicate significant activity against the HuT 78 cutaneous T-cell lymphoma, the NK-G2MI natural killer-cell NHL, KARPAS-299 T-cell NHL, SU-DHL-8 B-cell NHL, SU-DHL-10 B-cell NHL and SU-DHL-16 B-cell NHL cell lines. Preclinical studies have also established anti-angiogenic properties of darinaparsin and provided support for the development of an oral capsule form of the drug, and established synergy of darinaparsin in combination with other approved anti-cancer agents.

Phase I testing of the intravenous (IV) form of darinaparsin in solid tumors and hematological cancers has been completed. We reported clinical activity and, importantly, a safety profile from these studies as predicted by preclinical results. We subsequently completed Phase II studies in advanced myeloma and primary liver cancer and are nearing completion of a Phase II study in certain other hematological cancers. In addition, we are completing two Phase I studies with an oral capsule form of darinaparsin. At the May 2009 annual meeting of the American Society of Clinical Oncology, we reported favorable results from the trial with IV-administered darinaparsin in lymphoma, particularly peripheral T-cell lymphoma. In the ongoing Phase I trials, also reported at the ASCO annual meeting, preliminary data primarily in solid tumors indicate the oral form is active and well tolerated. We are completing data collection from the IV Phase II trial to address a registration and other trials with the U.S. Food and Drug Administration. The oral Phase I program will be progressed to establish a dose for further clinical testing.

ZIO-201 or palifosfamide (Zymafos™), comprises the active metabolite of ifosfamide, a compound chemically related to cyclophosphamide. Patent applications covering proprietary forms of palifosfamide for pharmaceutical composition and method of use have been filed in the U.S. and internationally and in the U.S. we recently received a Notice of patent allowance. Like cyclophosphamide, ifosfamide and bendamustine, palifosfamide is a DNA alkylating agent, a form of cancer therapy to treat a wide range of solid tumors and hematological malignancies. We believe that cyclophosphamide is the most widely used alkylating agent in cancer therapy, with significant use in the treatment of breast cancer and non-Hodgkin s lymphoma. Bendamustine has been recently approved and successfully launched by Cephalon in the U.S. and Europe to treat certain hematological malignancies. Ifosfamide has been shown to be effective in the treatment of sarcoma and lymphoma, either by itself or in combination with other anticancer agents. Ifosfamide is approved by the FDA as a treatment for testicular cancer while ifosfamide-based treatment is a standard of care for sarcoma, although it is not licensed for this indication by the FDA. Preclinical studies have shown that palifosfamide has activity against leukemia and solid tumors. These studies also indicate that palifosfamide may have a better safety profile than ifosfamide or cyclophosphamide because it does not appear to produce known toxic metabolites of ifosfamide, such as acrolein and chloroacetaldehyde. Acrolein, which is toxic to the kidneys and bladder, can mandate the administration of a protective agent called mesna, which is inconvenient and expensive. Chloroacetaldehyde is toxic to the central nervous system, causing fuzzy brain syndrome for which there is currently no protective measure. Similar toxicity concerns pertain to high-dose cyclophosphamide, which is widely used in bone marrow and blood cell transplantation. Palifosfamide has evidenced activity against ifosfamide- and/or cyclophosphamide-resistant cancer cell lines. Also in preclinical cancer models, palifosfamide was shown to be orally active and

encouraging results have been obtained with palifosfamide in combination with doxorubicin, an agent approved to treat sarcoma.

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Following completion of Phase I study, we completed Phase II testing of the intravenous form of palifosfamide as a single agent to treat advanced sarcoma. In both Phase I and Phase II testing, palifosfamide has been administered without the uroprotectant mesna, and the toxicities associated with acrolein and chloroacetaldehyde have not been observed. We reported clinical activity of palifosfamide when used alone in the Phase II study addressing advanced sarcoma. Following review of preclinical combination studies, clinical data, and discussion with sarcoma experts, we initiated a Phase I dose escalation study of palifosfamide in combination with doxorubicin primarily in patients with soft tissue sarcoma. We reported favorable results and safety profile from this study at ASCO s 2009 annual meeting. In light of reported favorable Phase II clinical activity data and with the combination of palifosfamide with doxorubicin well tolerated in the Phase I trial and evidencing activity, we initiated a Phase II randomized controlled trial in the second half of 2008 to compare doxorubicin plus palifosfamide to doxorubicin alone in patients with front and second-line metastatic or unresectable soft tissue sarcoma. The study has generated positive top line interim data in 2009. Upon reaching a pre-specified efficacy milestone and following safety and efficacy data review by the Data Committee, sarcoma experts, and our Medical Advisory Board, we elected to suspend enrollment in the trial in October 2009. We subsequently presented further positive interim data from the trial at the 15th Annual Connective Tissue Oncology Society meeting held in November 2009. We currently plan to initiate a registration trial following regulatory review of the palifosfamide program to date. We are also developing an oral capsule form of palifosfamide to be studied clinically following receipt of further data from the IV trials and subject to obtaining sufficient additional sources of funding, either from potential partnering arrangements or from other sources. To date we have no such partnering arrangements or other sources of such financing in place. We are also considering additional Phase II trials in other solid tumors as funding becomes available. Orphan Drug Designation for palifosfamide has been obtained in both the United States and the European Union for the treatment of soft tissue sarcomas.

ZIO-301 or indibulin (Zybulin™), is a novel, orally available small molecular-weight inhibitor of tubulin polymerization that we acquired from Baxter Healthcare in 2006 and is the subject of numerous patents worldwide, including the United States, the European Union and Japan. The microtubule component, tubulin, is one of the more well established drug targets in cancer. Microtubule inhibitors interfere with the dynamics of tubulin polymerization, resulting in inhibition of chromosome segregation during mitosis and consequently inhibition of cell division. A number of marketed IV anticancer drugs target tubulin, such as the taxane family members, paclitaxel (Taxol®), docetaxel (Taxotere®), the *Vinca alkaloid* family members, vincristine and vinorelbine, and the new class of epothilones with Ixempra™ marketed. This class of agents is typically the mainstay of therapy in a wide variety of indications. In spite of their effectiveness, the use of these drugs is associated with significant toxicities, notably peripheral neurotoxicity.

Preclinical studies with indibulin demonstrate significant and broad antitumor activity, including activity against taxane-refractory cell lines. The cytotoxic activity of indibulin was demonstrated in several rodent and human tumor cell lines derived from prostate, brain, breast, pancreas, lung, ovary, and cervical tumor tissues and in rodent tumor and human tumor xenograft models. In addition, indibulin was effective against multidrug resistant tumor cell lines (breast, lung, and leukemia) both *in vitro* and *in vivo*. Indibulin is potentially safer than other tubulin inhibitors. No neurotoxicity has been observed at therapeutic doses in rodents and in the Phase I trials. Indibulin has also demonstrated synergy with approved anti-cancer agents in preclinical studies. The availability of an oral capsule formulation of indibulin creates significant commercial opportunity because no oral capsule formulations of the taxane family are currently on the market in the United States.

Indibulin, as a single agent, has completed Phase I trials in patients with advanced solid tumors. We have reported clinical activity at well-tolerated doses using a continuous dosing scheme without the development of clinically relevant peripheral neuropathy. Following encouraging results obtained with indibulin in combination with erlotinib, and 5-FU in preclinical models, two Phase I combination studies were initiated with Tarceva™ and Xeloda™, respectively. Favorable activity and safety profile of oral indibulin with oral Xeloda™ were reported at ASCO s annual meeting in May 2009.

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Preclinical work with our consultant, Dr. Larry Norton, to explore dose scheduling for the clinical setting have been completed, with results supporting the our current plan to initiate the Phase I portion of a Phase I/II breast cancer trial using a mathematical dose schedule / frequency established preclinically.

Subject to the sufficiency of our financial resources, we intend to continue with clinical development of IV palifosfamide for soft tissue sarcoma in a registration trial and, with additional funding, to initiate a clinical study with the oral form following FDA approval and/or additional indications beyond STS; with IV darinaparsin, to obtain additional funding for PTCL registration and other trials and with the further development of the oral form; and with oral indibulin, to complete the Phase I breast cancer trial and subsequently, with additional funding, other trials. However, the successful development of our product candidates is highly uncertain. Product development costs and timelines can vary significantly for each product candidate, are difficult to accurately predict, and will require us to obtain additional funding, either alone or in connection with partnering arrangements. Various statutes and regulations also govern or influence the manufacturing, safety, labeling, storage, record keeping and marketing of each product. The lengthy process of seeking approval and the subsequent compliance with applicable statutes and regulations require the expenditure of substantial resources. Any failure by us to obtain, or any delay in obtaining, regulatory approvals could materially, adversely affect our business. To date, we have not received approval for the sale of any drug candidates in any market and, therefore, have not generated any revenues from our drug candidates.

Development Plan

Our development plan for the next twelve months remains focused on the following endeavors:

completing the randomized Phase II trial for IV palifosfamide;
initiating a registration trial for IV palifosfamide;
collecting data for the darinaparsin Phase II trial in hematological malignancies;
establishing a registration pathway and seeking additional financial resources to fund on-going development of darinaparsin; and
conducting the Phase I portion of an oral indibulin study in breast cancer.

We expect our material expenditures during this time to be predominately for palifosfamide clinical trial expense, employment expense (we currently have 15 full time employees) and other expenses associated with clinical trials.

We continue to use senior advisors, consultants, clinical research organizations, and other third parties to perform certain aspects of product development, manufacturing, clinical, and preclinical development, and regulatory, safety and quality assurance functions.

Given our current plans to use internal financial resources to develop palifosfamide and pursue the clinical work discussed above, but with the intention of partnering or otherwise raising additional resources to support further development activities for all three product candidates, we expect to incur the following expenses during the next twelve months: Approximately $3.4 million on preclinical and regulatory expenses; approximately $10.3 million on clinical expenses; approximately $3.0 million on manufacturing expenses; approximately $1.2 million on facilities, rent, and other facilities-related expenses; and approximately $4.8 million on general corporate and administrative expenses. With our current cash position, previous adjustments in staffing and ongoing aggressive cash management strategy, we believe that we currently have sufficient capital that will support our current operations very early into 2012. Our forecast of the period of time through which our financial resources will be adequate to support our operations, the costs to complete development of products and the cost to commercialize our future products are forward-looking statements and involve risks and uncertainties, and actual results could vary materially and negatively as a result of a number of factors, including the factors discussed in the Risk Factors section of this report. We have

based these estimates on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we currently expect. Specifically, we currently anticipate commencing a registration trial for IV palifosfamide as early as the first half of 2010. However, we are still in the evaluative phase regarding the protocol design for this trial, including with respect to overall trial size, clinical endpoints and our ability

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to receive Special Protocol Assessment. We also continue to evaluate the appropriate number of and locations for trial sites. We have estimated the sufficiency of our cash resources based on our current expectations for the trial design. However, the final trial design may ultimately vary from our current expectations, which could materially impact the schedule and cost of the trial and, in turn, alter our use of capital and our forecast of the period of time through which our financial resources will be adequate to support our operations. In addition to the amount and timing of expenses related to the planned IV palifosfamide registration trial, our actual cash requirements may vary materially from our current expectations for a number of other factors that may include, but are not limited to, changes in the focus and direction of our development programs, competitive and technical advances, costs associated with the development of our product candidates, our ability to secure partnering arrangements, and costs of filing, prosecuting, defending and enforcing our intellectual property rights.

Product Candidate Development and Clinical Trials

Intravenous darinaparsin, an organic arsenic, has been tested in patients with advanced myeloma, other hematological malignancies, and liver cancer. At the May 2009 ASCO Annual Meeting, we reported positive results in patients with lymphoma, particularly PTCL, which has led to the planning of a pivotal trial in PTCL subject to the availability of sufficient financial resources. The Phase I trials with an oral form of darinaparsin are ongoing in solid tumors and have been expanded to include non-Hodgkin s lymphoma patients. The Company is actively seeking partners and other sources of funding for continuing the development program of the IV form in a pivotal trial for PTCL and for continuing additional studies for both IV and oral administration. Technology transfer and scale-up for the commercial manufacture of the active pharmaceutical ingredient and final product specification will continue as the development program and resources allow.

Intravenous palifosfamide, the proprietary stabilized form of isophosphoramide mustard, is being developed presently to treat soft tissue sarcoma. A Phase II trial in advanced sarcoma has been completed with favorable activity and with the expected safety profile. Favorable activity and safety data from a Phase I trial of IV palifosfamide in combination with doxorubicin were reported at the 2009 ASCO Annual Meeting. The Company has initiated a randomized Phase II trial designed to compare palifosfamide in combination with doxorubicin to doxorubicin alone in the front or second-line treatment of metastatic or unresectable soft tissue sarcoma and recently announced favorable interim efficacy data, thereby ending further enrollment, and presented the results at the November 2009 CTOS Annual Meeting. The Company expects to review its data with the FDA and EMA and, subject to the results of such reviews, plans to initiate a global registration trial as early as the first half of 2010. An oral formulation has also been developed preclinically and we plan to initiate a Phase I trial following further IV study results and subject to obtaining additional sources of financing from partnering or other arrangements. Other trials are under consideration pending further funding. Orphan Drug Designation has been obtained for both the United States and the European Union for the treatment of soft tissue sarcomas. Technology transfer and scale-up for the commercial manufacture of the active pharmaceutical ingredient and final product specification will continue as resources allow.

Indibulin, a novel anti-cancer agent that targets mitosis by inhibiting tubulin polymerization, is administered as an oral capsule formulation. Indibulin has completed Phase I trials with favorable results of activity and safety profile reported for all trials. Phase I trials of indibulin in combination with Tarceva™ and also with Xeloda™ have been conducted. At the 2009 ASCO Annual Meeting, the Company presented favorable preliminary activity and safety data of oral indibulin with oral Xeloda™. Preclinical studies under the direction of Dr. Larry Norton to support clinical study of dose dense dosing are completed and were also reported at 2009 ASCO Annual Meeting. The Company intends to initiate the Phase I portion of a Phase I/II study in breast cancer with a schedule identified preclinically to determine maximum tolerated dose in the Phase I portion prior to formal Phase II testing.

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Results of Operations for the Fiscal Year Ended December 31, 2009 versus December 31, 2008

Revenues. We had no revenues for the years ended December 31, 2009 and 2008.

Research and Development Expenses. Research and development expenses during the years ended December 31, 2009 and 2008 were as follows:

	Year Ended December 31,			
($ in Thousands)	2009	2008	Change	
Research and development	$ 4,556	$ 17,245	$ (12,689)	-74 %

Research and development expenses decreased by $12.7 million from the year ended December 31, 2008 to the year ended December 31, 2009. The decrease is primarily attributable to reduced activity related to clinical trials amounting to $10.4 million, decreased headcount amounting to $1.8 million and other reductions amounting to $413 thousand. These reductions and savings resulted from the cost cutting initiatives we implemented starting in 2008 leading into 2009.

General and Administrative Expenses. General and administrative expenses during the years ended December 31, 2009 and 2008 were as follows:

	Year Ended December 31,			
($ in Thousands)	2009	2008	Change	
General and administrative	$ 7,567	$ 8,374	$ (807)	-10 %

General and administrative expenses decreased by $807 thousand from the year ended December 31, 2008 to the year ended December 31, 2009. The decrease is primarily attributable to cost cutting initiatives. These initiatives include reduced headcount amounting to a savings of $857 thousand, reduced legal, patent and license activities amounting to a savings of $336 thousand and other reductions amounting to a savings of $176 thousand. These savings were partially offset by an increase in stock compensation expense of $562 thousand attributable to increased stock option awards during 2009.

Other Income (Expense). Other income (expense) during the years ended December 31, 2009 and 2008 were as follows:

	Year Ended December 31,			
($ in Thousands)	2009	2008	Change	
Other income (expense), net	$ 13	$ 388	$ (375)	-97 %
Change in fair value of warrants	4,461		$ 4,461	-100 %
Total	$ 4,474	$ 388	$ 4,086	

The increase in other income (expense) from the year ended December 31, 2008 to the year ended December 31, 2009 was due primarily to liability-classified warrants being marked to market in 2009. (see Note 8 to the financial statements, Warrants, for a discussion on the reclassification of certain warrants from stockholders equity to liabilities

on January 1, 2009). Additionally, interest income decreased due to lower cash balances on hand during 2009.

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Results of Operations for the Fiscal Year Ended December 31, 2008 versus December 31, 2007

Revenues. We had no revenues for the years ended December 31, 2008 and 2007.

Research and Development Expenses. Research and development expenses during the years ended December 31, 2008 and 2007 were as follows:

	Year Ended December 31,			
($ in Thousands)	2008	2007	Change	
Research and development	$ 17,245	$ 18,992	$ (1,747)	-9 %

The decrease in research and development expenses from the year ended December 31, 2007 to the year ended December 31, 2008 is primarily attributable to a decrease of approximately $1.2 million in clinical research and development expenses due to the company prioritizing the clinical trial direction along with cost management. The decrease in research and development is also attributable to a decrease of approximately $777 thousand in manufacturing related costs. These decreases were offset by approximately $217 thousand due to increased payroll and related expenses in 2008.

General and Administrative Expenses. General and administrative expenses during the years ended December 31, 2008 and 2007 were as follows:

	Year Ended December 31,			
($ in Thousands)	2008	2007	Change	
General and administrative	$ 8,374	$ 9,578	$ (1,204)	-13 %

The decrease is primarily attributable to a decrease of approximately $660 thousand in investor relations and financial consulting costs, a decrease of approximately $304 thousand in payroll, stock compensation, and related expenses, a decrease of approximately $319 thousand in patent and related expenses, and a decrease of approximately $188 thousand in recruiting expenses. These decreases were slightly offset by an increase of approximately $260 thousand in legal fees.

Other Income (Expense). Other income (expense) during the years ended December 31, 2008 and 2007 were as follows:

	Year Ended December 31,			
($ in Thousands)	2008	2007	Change	
Other income (expense), net	$ 388	$ 1,962	$ (1,574)	-80 %

Other income during the years ended December 31, 2008 and 2007 was comprised of interest income. The decrease is due to a lower average cash balance and the drop in the return from our investments, primarily in U.S. treasuries and money market funds as compared to the previous period.

Liquidity and Capital Resources

We have incurred losses since our inception in September 2003 and as of December 31, 2009 we had an accumulated deficit of $91.1 million. We have financed our operations to date principally through the sale of our securities, including private placements of common stock and warrants and an underwritten sale of common stock and warrants, as well as interest earned on investments. Working capital as of December 31, 2009 was $46.1 million, consisting of $49.2 million in current assets and $3.1 million in current liabilities. Working capital as of December 31, 2008 was $5.9 million, consisting of $11.7 million in current assets and $5.8 million in current liabilities. Our cash and cash equivalents are held in interest-bearing cash accounts. Cash in excess of immediate requirements is invested in U.S. treasuries and demand deposit accounts in accordance with our investment policy, primarily to achieve liquidity and capital preservation.

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The following table summarizes our net increase (decrease) in cash and cash equivalents for the years ended December 31, 2009, 2008 and 2007 and the period from September 9, 2003 (date of inception) through December 31, 2009:

	Year Ended December 31,			Period from September 9, 2003 (Date of Inception) through December 31, 2009
($ in Thousands)	2009	2008	2007	
Net cash provided by (used in):				
Operating activities	$(12,294)	$(23,519)	$(21,650)	$(84,364)
Investing activities	(11)	(131)	817	(1,639)
Financing activities	49,765		29,006	134,842
Net increase (decrease) in cash and cash equivalents	$37,460	$(23,650)	$8,173	$48,839

Net cash used in operating activities was $12.3 million for the year ended December 31, 2009 compared to $23.5 million for the year ended December 31, 2008. The $11.2 million decrease was primarily due to a reduction in spending resulting in a $13.1 million decrease in the net loss, excluding the gain from changes in the fair value of warrants, partially offset by payments made to decrease accounts payable and accrual balances during 2009.

Net cash used in investing activities was $11 thousand for the year ended December 31, 2009 compared to $131 thousand for the year ended December 31, 2008. The decrease was primarily due to a reduction in spending for purchases of property and equipment.

Net cash provided by financing activities was $49.8 million for the year ended December 31, 2009 compared to $0 for the year ended December 31, 2008. The increase is attributable to the private placement of securities completed on September 15, 2009 and the underwritten securities offering completed on December 9, 2009 (see Note 2 to the financial statements, Financing).

Operating Capital and Capital Expenditure Requirements

As of December 31, 2009, we had $48.8 million in cash. We believe that our existing cash will be sufficient to fund our operations very early into 2012. We expect that we will need additional financing to support our long-term plans for clinical trials and new product development. We expect to finance our cash needs through the sale of equity securities, strategic collaborations and/or debt financings, or through other sources that may be dilutive to existing stockholders. There can be no assurance that we will be able to obtain funding from any of these sources or, if obtained, what the terms of such funding(s) may be, or that any amount that the Company is able to obtain will be adequate to support the Company s working capital requirements until it achieves profitable operations. Currently, we have no committed sources of additional capital. Recently, capital markets have experienced a period of unprecedented instability that we expect may severely hinder our ability to raise capital within the time periods needed

or on terms we consider acceptable, if at all. If we are unable to raise additional funds when needed, we may not be able to market our products as planned or continue development and regulatory approval of our products, or we could be required to delay, scale back or eliminate some or all our research and development programs.

The Company anticipates that losses will continue for the foreseeable future. At December 31, 2009, the Company s accumulated deficit was approximately $91.1 million. Our actual cash requirements may vary materially from those planned because of a number of factors including:

Changes in the focus and direction of our development programs;

Competitive and technical advances;

Internal costs associated with the development of palifosfamide and indibulin and our ability to secure further financing for darinaparsin development from a partner, and

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Costs of filing, prosecuting, defending and enforcing any patent claims and any other intellectual property rights, or other developments.

Contractual Obligations

The following table summarizes our outstanding obligations as of December 31, 2009 and the effect those obligations are expected to have on our liquidity and cash flows in future periods:

($ in Thousands)	Total	Less than 1 Year	2 3 Years	4 5 Years	More than 5 Years
Operating Leases	$ 603	$ 287	$ 316	$	$

Our commitments for operating leases relate to the lease for our corporate headquarters in New York, NY and our operations center in Boston, Massachusetts (see Note 7 to the financial statements, Commitments and Contingencies).

Critical Accounting Policies and Significant Estimates

Our management's discussion and analysis of our financial condition and results of operations is based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported expenses during the reporting periods. We evaluate our estimates and judgments on an ongoing basis. Actual results may differ materially from these estimates under different assumptions or conditions.

We believe the following are our more significant estimates and judgments used in the preparation of our financial statements:

Clinical trial expenses;
Fair value measurements;
Stock-based compensation; and
Income taxes.

Clinical Trial Expenses

Clinical trial expenses include expenses associated with Clinical Research Organizations (CRO). The invoicing from CROs for services rendered can lag several months. We accrue the cost of services rendered in connection with CRO activities based on our estimate of site management, monitoring costs, and project management costs. We maintain regular communication with our CROs to gauge the reasonableness of our estimates. Differences between actual clinical trial expenses and estimated clinical trial expenses recorded have not been material and are adjusted for in the period in which they become known.

Fair Value Measurements

We have warrant liabilities that are measured using fair value. Accounting standards define fair value, establish a framework for measuring fair value under generally accepted accounting principles and enhance disclosures about fair value measurements. Fair value is defined as 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. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The standard describes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value which are the following:

Level 1 Quoted prices in active markets for identical assets or liabilities.

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Level 2 Inputs other than Level 1 that are observable, either directly or indirectly, 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.

Stock-Based Compensation and Warrants

We make certain assumptions in order to value and expense our share-based compensation awards. In connection with valuing stock options and warrants we use the Black-Scholes model, which requires us to estimate certain subjective assumptions. The key assumptions we make are: the expected volatility of our stock; the expected term of the award; and the expected forfeiture rate. In connection with our restricted stock programs, we make assumptions principally related to the forfeiture rate.

We review our valuation assumptions periodically and, as a result, we may change our valuation assumptions used to value share-based awards granted in future periods. Such changes may lead to a significant change in the expense we recognize in connection with share-based payments.

Income Taxes

In preparing our financial statements, we estimate our income tax liability in each of the jurisdictions in which we operate by estimating our actual current tax expense together with assessing temporary differences resulting from differing treatment of items for tax and financial reporting purposes. These differences result in deferred tax assets and liabilities, which are included in our balance sheets. Significant management judgment is required in assessing the realizability of our deferred tax assets. In performing this assessment, we consider whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. In making this determination, under the applicable financial accounting standards, we are allowed to consider the scheduled reversal of deferred tax liabilities, projected future taxable income, and the effects of tax planning strategies. Our estimates of future taxable income include, among other items, our estimates of future income tax deductions related to the exercise of stock options. In the event that actual results differ from our estimates, we adjust our estimates in future periods and we may need to establish a valuation allowance, which could materially impact our financial position and results of operations.

We account for uncertain tax positions using a more-likely-than-not threshold for recognizing and resolving uncertain tax positions. The evaluation of uncertain tax positions is based on factors that include, but are not limited to, changes in tax law, the measurement of tax positions taken or expected to be taken in tax returns, the effective settlement of matters subject to audit, new audit activity and changes in facts or circumstances related to a tax position. We evaluate uncertain tax positions on an annual basis and adjust the level of the liability to reflect any subsequent changes in the relevant facts surrounding the uncertain positions. Our liabilities for uncertain tax positions can be relieved only if the contingency becomes legally extinguished through either payment to the taxing authority or the expiration of the statute of limitations, the recognition of the benefits associated with the position meet the more-likely-than-not threshold or the liability becomes effectively settled through the examination process. We consider matters to be effectively settled once the taxing authority has completed all of its required or expected examination procedures, including all appeals and administrative reviews; we have no plans to appeal or litigate any aspect of the tax position; and we believe that it is highly unlikely that the taxing authority would examine or re-examine the related tax position. We also accrue for potential interest and penalties, related to unrecognized tax benefits in income tax expense.

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Recent Accounting Pronouncements

In January 2010, the FASB issued Accounting Standards Update (ASU) No. 2010-06 *Fair Value Measurements and Disclosures* (Topic 820) which improves disclosures about fair value measurements. More specifically, ASU 2010-06 updates Topic 820-10 to require disclosure of transfers in and out of levels 1 and 2 and the reason for the transfers. Additionally, it requires separate reporting of purchases, sales, issuances and settlements for level 3. This update is effective for periods beginning after December 15, 2009. The adoption of this standard will not have an impact on our financial position or results of operations.

Off-Balance Sheet Arrangements

We currently do not have any special purpose entities or off-balance sheet financing arrangements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Our exposure to market risk is limited to our cash. The goals of our investment policy are preservation of capital, fulfillment of liquidity needs and fiduciary control of cash and investments. We also seek to maximize income from our investments without assuming significant risk. To achieve our goals, we maintain our cash in interest-bearing cash accounts. As all of our investments are cash deposits in a global bank, it is subject to minimal interest rate risk.

Effect of Currency Exchange Rates and Exchange Rate Risk Management

We conduct clinical studies outside of the United States primarily in Western Europe. These business operations are not material at this time and therefore, any currency fluctuations will not have a material impact on our financial position, results of operations or cash flows.

Item 8. Financial Statements and Supplementary Data

The information required by this Item 8 is contained on pages F-1 through F-33 of this annual report on Form 10-K and is incorporated herein by reference.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosures

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we have evaluated the effectiveness of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) or 15d-15(e) promulgated under the Securities Exchange Act of 1934, as amended (the Exchange Act), as of December 31, 2009. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that as of such date, our disclosure controls and procedures were effective.

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Management s Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting for the Company. Internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) is a process to provide reasonable assurance regarding the reliability of our financial reporting for external purposes in accordance with accounting principles generally accepted in the United States of America. Internal control over financial reporting includes maintaining records that in reasonable detail accurately and fairly reflect our transactions; providing reasonable assurance that transactions are recorded as necessary for preparation of our financial statements; providing reasonable assurance that receipts and expenditures of company assets are made in accordance with management authorization; and providing reasonable assurance that unauthorized acquisition, use or disposition of company assets that could have a material effect on our financial statements would be prevented or detected on a timely basis. Because of its inherent limitations, internal control over financial reporting is not intended to provide absolute assurance that a misstatement of our financial statements would be prevented or detected.

Management conducted an evaluation of the effectiveness, as of December 31, 2009, of our internal control over financial reporting based on the framework in *Internal Control Integrated Framework* issued by the Committee of 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, 2009.

This annual report does not include an attestation report of the Company s registered public accounting firm regarding internal controls over financial reporting. Management s report was not subject to attestation by the Company s registered public accounting firm pursuant to the temporary rules of the Securities and Exchange Commission that permit the Company to only provide management s report in this annual report.

Changes in Internal Controls Over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2009 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

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PART III

Item 10. Directors, Executive Officers and Corporate Governance

Information in response to this Item is incorporated herein by reference to our definitive proxy statement to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this form 10-K.

Our Board of Directors adopted a Code of Business Conduct and Ethics to be applicable to all officers, directors and employees. The Code of Business Conduct and Ethics is intended to be designed to deter wrong-doing and promote honest and ethical behavior, full, fair, timely, accurate and understandable disclosure, and compliance with applicable laws. The Code of Ethics is available on our website at *www.ziopharm.com* and a copy may be obtained without charge upon written request to the Company s President at the Company s headquarters address.

Item 11. Executive Compensation

Information in response to this Item is incorporated herein by reference to our definitive proxy statement to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this form 10-K.

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

Securities Authorized for Issuance Under Equity Compensation Plans

The Company s 2003 Stock Option Plan (the 2003 Plan), which is currently the Company s only equity compensation plan, has been approved by the Company's stockholders. The following table sets forth certain information as of December 31, 2009 with respect to the 2003 Plan:

Plan Category	Number of Securities to Be Issued Upon Exercise of Outstanding Options (A)	Weighted-Average Exercise Price of Outstanding Options (B)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column

			(A)) (C)
Equity compensation plans approved by stockholders:			
2003 Stock Option Plan	3,533,436	$ 2.82	368,817
Total:	3,533,436	$ 2.82	368,817
Equity compensation plans not approved by stockholders:			
2000 individual option grant[1]	1,250	$ 20.00	
Total:	1,250	$ 20.00	

(1) Represents a stock option that is scheduled to expire on December 20, 2010.

Additional information in response to this Item is incorporated herein by reference to our definitive proxy statement to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this form 10-K.

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

Information in response to this Item is incorporated herein by reference to our definitive proxy statement to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this form 10-K.

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Item 14. Principal Accountant Fees and Services

Information in response to this Item is incorporated herein by reference to our definitive proxy statement to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this form 10-K.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(1) Financial Statements:

The Financial Statements required to be filed by Item 8 of this Annual Report on Form 10-K, and filed in this Item 15, are as follows:

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Audited Financial Statements of ZIOPHARM Oncology, Inc.:	
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Balance Sheets as of December 31, 2009 and 2008	F-3
Statements of Operations for the Years Ended December 31, 2009, 2008, and 2007, and for the Period from September 9, 2003 (Date of Inception) through December 31, 2009	F-4
Statements of Changes in Convertible Preferred Stock and Stockholders Equity (Deficit) for the Period from September 9, 2003 (Date of Inception) through December 31, 2009	F-5 8
Statements of Cash Flows for the Years Ended December 31, 2009, 2008, and 2007, and for the Period from September 9, 2003 (Date of Inception) through December 31, 2009	F-9
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(2) Financial Statement Schedules:

Schedules are omitted because they are not applicable, or are not required, or because the information is included in the financial statements and notes thereto.

(3) Exhibits:

The exhibits which are filed or furnished with this report or which are incorporated herein by reference are set forth in the Exhibit Index beginning on page A-1, which is incorporated herein by reference.

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SIGNATURES

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

ZIOPHARM ONCOLOGY, INC.
By:

/s/ Jonathan Lewis

Date: March 17, 2010

Jonathan Lewis
Chief Executive Officer
(Principal Executive Officer)
By:

/s/ Richard Bagley

Date: March 17, 2010

Richard Bagley
President, Chief Financial Officer, Treasurer and
Chief Operating Officer
(Principal Financial and Accounting Officer)

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

Signature	Title	Date
/s/ Jonathan Lewis Jonathan Lewis	Director and Chief Executive Officer (Principal Executive Officer)	March 17, 2010
/s/ Richard Bagley Richard Bagley	Director, President, Chief Financial Officer, Treasurer and Chief Operating Officer (Principal Accounting and Financial Officer)	March 17, 2010
/s/ Murray Brennan Murray Brennan	Director	March 17, 2010
/s/ James Cannon James Cannon	Director	March 17, 2010
/s/ Timothy McInerney Timothy McInerney	Director	March 17, 2010
/s/ Wyche Fowler, Jr. Wyche Fowler, Jr.	Director	March 17, 2010
/s/ Gary S. Fragin Gary S. Fragin	Director	March 17, 2010
/s/ Michael Weiser Michael Weiser	Director	March 17, 2010

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ZIOPHARM Oncology, Inc.
(A Development Stage Enterprise)

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
ZIOPHARM Oncology, Inc.
Boston, Massachusetts

We have audited the balance sheets of ZIOPHARM Oncology, Inc. (a development stage company) as of December 31, 2009 and 2008 and the related statements of operations, changes in convertible preferred stock and stockholders equity (deficit) and cash flows for each of the years in the three-year period ended December 31, 2009 and for the period from September 9, 2003 (date of inception) through December 31, 2009. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, audits of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company s internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of ZIOPHARM Oncology, Inc. as of December 31, 2009 and 2008 and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2009 and from September 9, 2003 (date of inception) through December 31, 2009 in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 3 to the financial statements, the Company changed the manner in which it accounts for certain warrants effective January 1, 2009.

Caturano and Company, P.C.

Boston, Massachusetts
March 17, 2010

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ZIOPHARM Oncology, Inc.
(A Development Stage Enterprise)

BALANCE SHEETS
(In Thousands, Except Share and per Share Data)

	December 31, 2009	December 31, 2008
ASSETS		
Current assets:		
Cash and cash equivalents	$48,839	$11,379
Prepaid expenses and other current assets	354	327
Total current assets	49,193	11,706
Property and equipment, net	255	489
Deposits	46	87
Other non current assets	242	291
Total assets	$49,736	$12,573
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$1,789	$2,639
Accrued expenses	1,261	3,137
Deferred rent current portion	45	
Total current liabilities	3,095	5,776
Deferred rent	66	58
Warrant liabilities	18,471	
Total liabilities	21,632	5,834
Commitments and contingencies (note 7)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 30,000,000 shares authorized and no shares issued and outstanding		
Common stock, $0.001 par value; 250,000,000 shares authorized; 41,583,528 and 21,860,464 shares issued and outstanding at December 31, 2009 and 2008, respectively	42	22
Additional paid-in capital common stock	96,133	71,274
Additional paid-in capital warrants issued	23,073	20,504
Deficit accumulated during the development stage	(91,144)	(85,061)
Total stockholders' equity	28,104	6,739
Total liabilities and stockholders' equity	$49,736	$12,573

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

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ZIOPHARM Oncology, Inc.
(A Development Stage Enterprise)

STATEMENTS OF OPERATIONS
(In Thousands, Except Share and per Share Data)

	For the Year Ended December 31,			Period from September 9, 2003 (Date of Inception) through December 31,
	2009	2008	2007	2009
Research contract revenue	$	$	$	$
Operating expenses:				
Research and development, including costs of research contracts	4,556	17,245	18,992	58,906
General and administrative	7,567	8,374	9,578	42,175
Total operating expenses	12,123	25,619	28,570	101,081
Loss from operations	(12,123)	(25,619)	(28,570)	(101,081)
Other income (expense), net	13	388	1,962	3,910
Change in fair value of warrants	4,461			6,027
Net loss	$(7,649)	$(25,231)	$(26,608)	$(91,144)
Basic and diluted net loss per share	$(0.33)	$(1.19)	$(1.41)	
Weighted average common shares outstanding used to compute basic and diluted net loss per share	23,108,039	21,232,663	18,832,351	

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

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ZIOPHARM Oncology, Inc.
(A Development Stage Enterprise)

STATEMENTS OF CHANGES IN CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (DEFICIT)
For the Period September 9, 2003 (Date of Inception) to December 31, 2009
(In Thousands, Except Share and per Share Data)

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

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ZIOPHARM Oncology, Inc.
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STATEMENTS OF CHANGES IN CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (DEFICIT) (Cont.)
For the Period September 9, 2003 (Date of Inception) to December 31, 2009
(In Thousands, Except Share and per Share Data)

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

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ZIOPHARM Oncology, Inc.
(A Development Stage Enterprise)

STATEMENTS OF CHANGES IN CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (DEFICIT) (Cont.)
For the Period September 9, 2003 (date of inception) to December 31, 2009
(In Thousands, Except Share and per Share Data)

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STATEMENTS OF CHANGES IN CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (DEFICIT) (Cont.)
For the Period September 9, 2003 (date of inception) to December 31, 2009
(In Thousands, Except Share and per Share Data)

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

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ZIOPHARM Oncology, Inc.
(A Development Stage Enterprise)

STATEMENTS OF CASH FLOWS
(In Thousands)

	For the Year Ended December 31,			Period From September 9, 2003 (Date of Inception) Through December 31,
	2009	2008	2007	2009
Cash flows from operating activities:				
Net loss	$(7,649)	$(25,231)	$(26,608)	$(91,144)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	330	388	433	1,460
Stock-based compensation	2,181	1,600	1,439	8,904
Change in fair value of warrants	(4,461)			(6,027)
Loss on disposal of fixed assets			9	9
Change in operating assets and liabilities:				
(Increase) decrease in:				
Prepaid expenses and other current assets	(27)	172	(36)	(354)
Other noncurrent assets	49	66	(179)	(242)
Deposits	41	8	(86)	(46)
Increase (decrease) in:				
Accounts payable	(850)	(270)	2,133	1,789
Accrued expenses	(1,876)	(259)	1,235	1,261
Deferred rent	(32)	7	10	26
Net cash used in operating activities	(12,294)	(23,519)	(21,650)	(84,364)
Cash flows from investing activities:				
Purchases of property and equipment	(11)	(132)	(738)	(1,640)
Proceeds from sale of property and equipment		1		1
(Increase) decrease in short-term investments			1,555	
Net cash provided by (used in) investing activities	(11)	(131)	817	(1,639)
Cash flows from financing activities:				
Stockholders' capital contribution				500
Proceeds from exercise of stock options	73		35	139
Payments to employees for repurchase of restricted common stock	(380)			(380)
Proceeds from exercise of warrants	279			279

Proceeds from issuance of common stock and warrants, net	49,793		28,971	117,544
Proceeds from issuance of preferred stock, net				16,760
Net cash provided by financing activities	49,765		29,006	134,842
Net increase (decrease) in cash and cash equivalents	37,460	(23,650)	8,173	48,839
Cash and cash equivalents, beginning of period	11,379	35,029	26,856	
Cash and cash equivalents, end of period	$48,839	$11,379	$35,029	$ 48,839
Supplementary disclosure of cash flow information:				
Cash paid for interest	$	$	$	$
Cash paid for income taxes	$	$	$	$
Supplementary disclosure of noncash investing and financing activities:				
Warrants issued to placement agents and investors	$27,068	$	$5,433	$ 47,276
Preferred stock conversion to common stock	$	$	$	$ 16,760
Warrants converted to common shares	$	$	$	$ 18

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

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ZIOPHARM Oncology, Inc.
(A Development Stage Enterprise)

NOTES TO FINANCIAL STATEMENTS

1. Organization

ZIOPHARM Oncology, Inc. (ZIOPHARM or the Company) is a biopharmaceutical company that seeks to acquire, develop and commercialize, on its own or with other commercial partners, products for the treatment of important unmet medical needs in cancer.

The Company has had limited operations to date and its activities have consisted primarily of raising capital and conducting research and development. Accordingly, the Company is considered to be in the development stage at December 31, 2009. The Company's fiscal year ends on December 31.

The Company has operated at a loss since its inception in 2003 and has no revenues. The Company anticipates that losses will continue for the foreseeable future. At December 31, 2009, the Company s accumulated deficit was approximately $91.1 million. The Company currently believes that it has sufficient capital to fund development and commercialization activities, principally for palifosfamide, very early into 2012. The Company s ability to continue operations after its current cash resources are exhausted depends on its ability to obtain additional financing and achieve profitable operations, as to which no assurances can be given. Cash requirements may vary materially from those now planned because of changes in the focus and direction of its research and development programs, competitive and technical advances, patent developments or other developments. Additional financing will be required to continue operations after the Company exhausts its current cash resources and to continue its long-term plans for clinical trials and new product development. There can be no assurance that any such financing can be realized by the Company, or if realized, what the terms thereof may be, or that any amount that the Company is able to raise will be adequate to support the Company s working capital requirements until it achieves profitable operations. The Company s failure to raise capital as and when needed would have a negative impact on its financial condition and its ability to pursue its business strategies. If adequate additional funds are not available when required, or if unsuccessful in entering into partnership agreements for the further development of its products, the Company will be required to delay, reduce or eliminate planned preclinical and clinical trials and terminate the approval process for its product candidates from the FDA or other regulatory authorities. In addition, the Company could be forced to discontinue product development, reduce or forego sales and marketing efforts, forego attractive business opportunities, pursue merger or divestiture strategies, cease operations or declare bankruptcy. There can be no assurances that forecasted results will be achieved or that additional financing will be obtained. The financial statements do not include any adjustments relating to the recoverability and classification of asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

2. Financings

On December 4, 2009, the Company entered into an underwriting agreement (the Underwriting Agreement) in which JMP Securities LLC and Rodman & Renshaw, LLC agreed to serve as co-lead managers (together, the Underwriters) in connection with a public offering and sale by the Company of 15,484,000 units at a price to the public of $3.10 per

unit for gross proceeds of $48.0 million. The Company paid $2.8 million in commissions and offering expenses and expects to use the remaining net proceeds of $45.2 million for general corporate purposes, which include ongoing research and development activities. Each unit sold in the Offering consisted of one share of our common stock and an investor warrant to purchase 0.5 of a share of common stock. The shares of common stock and investor warrants were immediately separable. The closing of the transaction occurred on December 9, 2009.

In connection with this public offering, the Company issued warrants to purchase an aggregate of 8,206,520 shares of common stock (including the investor warrants and 464,520 warrants issued to the Underwriters). The investor warrants are exercisable immediately and the underwriter warrants exercisable six months after the date of issuance. The warrants have an exercise price of $4.02 per share and have a

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ZIOPHARM Oncology, Inc.
(A Development Stage Enterprise)

NOTES TO FINANCIAL STATEMENTS

2. Financings (continued)

five year term. The fair value of the warrants was estimated at $22.9 million using a Black-Scholes model with the following assumptions: expected volatility of 105%, risk free interest rate of 2.14%, expected life of five years and no dividends.

The Company assessed whether the warrants require accounting as derivatives. The Company determined that the warrants were (1) not indexed to the Company s own stock and (2) not classified in stockholders equity in accordance with Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC)Topic 815, *Derivatives and Hedging*. As such, the Company has concluded the warrants did not meet the scope exception for determining whether the instruments require accounting as derivatives and should be classified as liabilities (see Note 8 to the financial statements, Warrants).

On September 9, 2009, the Company entered into a securities purchase agreement (the 2009 Private Placement) with certain investors pursuant to which it sold a total of 2,772,337 units, each unit consisting of one share of common stock and a warrant to purchase one share of common stock for a purchase price of $1.825 per unit. The closing of the transaction occurred on September 15, 2009. In connection with the 2009 Private Placement, the Company raised approximately $5.1 million in gross proceeds. After paying $455 thousand in placement agent fees and offering expenses, the net proceeds were $4.6 million.

In connection with the 2009 Private Placement, the Company issued warrants to purchase an aggregate of 2,910,954 shares of common stock (including 138,617 warrants issued to the placement agents) which are exercisable immediately. The warrants have an exercise price of $2.04 per share and have a five year term. The fair value of the warrants was estimated at $4.2 million using a Black-Scholes model with the following assumptions: expected volatility of 105%, risk free interest rate of 2.41%, expected life of five years and no dividends. The fair value of the warrants was recorded in the equity section of the balance sheet.

The Company assessed whether the warrants require accounting as derivatives. The Company determined that the warrants were both (1) indexed to the Company s own stock and (2) classified in stockholders equity in accordance with ASC Topic 815, *Derivatives and Hedging*. As such, the Company has concluded the warrants meet the scope exception for determining whether the instruments require accounting as derivatives and should be classified in stockholders equity.

In connection with the 2009 Private Placement, the Company entered into a registration rights agreement with each of the investors. The registration rights agreement provides that the Company file a resale registration statement covering all of the shares issued in the 2009 Private Placement and the shares issuable upon exercise of the warrants issued in the 2009 Private Placement, up to the maximum number of shares able to be registered pursuant to applicable Securities and Exchange Commission (SEC) regulations, within 30 days of the closing of the 2009 Private Placement. The Company filed the registration statement with the SEC on September 28, 2009 (File No. 333-162160). Under the

terms of the registration rights agreement, the Company is obligated to maintain the effectiveness of the resale registration statement until all securities therein are sold or are otherwise can be sold pursuant to Rule 144, without any restrictions. A cash penalty at the rate of 1% of the purchase price per month, capped at a maximum of 10% of the purchase price (or $506 thousand), will be triggered for any filing or effectiveness failures or if, at any time after six months following the closing of the 2009 Private Placement, the Company ceases to be current in periodic reports with the SEC.

In December 2006, the FASB issued an accounting standard, which addresses an issuer's accounting for registration payment arrangements. The accounting standard specifies that the contingent obligation to make future payments or otherwise transfer consideration under a registration payment arrangement, whether issued as a separate agreement or included as a provision of a financial instrument or other agreement, should be separately recognized and measured in accordance with FASB guidance in Accounting for Contingencies. The accounting standard further clarifies that a financial instrument subject to a registration payment arrangement should be accounted for in accordance with US GAAP without regard to the contingent obligation to transfer

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ZIOPHARM Oncology, Inc.
(A Development Stage Enterprise)

NOTES TO FINANCIAL STATEMENTS

2. Financings (continued)

consideration pursuant to the registration payment arrangement. The Company applied the recognition and measurement provisions of the accounting standard to the registration rights associated with the registration rights agreement. As result, the Company believes that the contingent obligation to make future payments is not probable and as such has recorded no liability associated with these registration rights.

On February 23, 2007, pursuant to subscription agreements between the Company and certain institutional and other accredited investors, the Company completed the sale of an aggregate of 5,910,049 shares of the Company s common stock at a price of $5.225 per share in a private placement (the 2007 Offering). In addition to these shares sold in the 2007 Offering, the Company also issued to each investor a five-year warrant to purchase, at an exercise price of $5.75 per share, an additional number of shares of common stock equal to 20 percent of the shares purchased by such investor in the 2007 Offering. In the aggregate, these warrants entitle investors to purchase an additional 1,182,015 shares of common stock. The Company estimated the fair value of these warrants at $4.7 million using the Black-Scholes model, using an assumed risk-free rate of 4.71% and an expected life of 5 years, volatility of 93%, and a dividend yield of 0%. The total gross proceeds resulting from the 2007 Offering was approximately $30.9 million, before deducting selling commissions and expenses.

The Company assessed whether the warrants require accounting as derivatives. The Company determined that the warrants were both (1) indexed to the Company s own stock and (2) classified in stockholders equity in accordance with ASC Topic 815, *Derivatives and Hedging*. As such, the Company has concluded the warrants meet the scope exception for determining whether the instruments require accounting as derivatives and should be classified in stockholders equity.

The Company engaged Paramount BioCapital, Inc. (Paramount), Oppenheimer & Co. Inc., and Griffin Securities, Inc. (together, the 2007 Placement Agents) as placement agents in connection with the 2007 Offering. In consideration for their services, the Company paid the 2007 Placement Agents aggregate cash commissions of $1.6 million (of which $1.0 million was paid to Paramount; see Note 6 to the financial statements, Related Party Transactions) and issued 5-year warrants to the 2007 Placement Agents and their designees to purchase an aggregate of 156,058 shares of the Company s common stock at an exercise price of $5.75 per share. In connection with the 2007 Offering, the Company also made cash payments of $222 thousand and issued 5-year warrants to purchase 21,244 shares of the Company's common stock, at an exercise price of $5.75 per share, to a financial consultant pursuant to the non-circumvention provision of a prior agency agreement. The Company estimated the fair value of these 177,302 warrants at $709 thousand using the Black-Scholes model, using an assumed risk-free rate of 4.71% and an expected life of 5 years, volatility of 93%, and a dividend yield of 0%.

The Company assessed whether the warrants require accounting as derivatives. The Company determined that the warrants were both (1) indexed to the Company s own stock and (2) classified in stockholders equity in accordance with ASC Topic 815, *Derivatives and Hedging*. As such, the Company has concluded the warrants met the scope

exception for determining whether the instruments require accounting as derivatives and should be classified in stockholders equity.

Pursuant to the 2007 Offering, the Company agreed to use its best efforts to (i) file a registration statement covering the resale of the shares sold in the 2007 Offering and the common stock issuable upon exercise of the investor warrants and placement agent warrants issued in the 2007 Offering within 45 days following the closing date of the 2007 Offering, and (ii) use reasonable commercial efforts to cause the registration statement to be effective within 120 days after such final closing date.

With respect to each investor in the 2007 Offering, the Company also agreed to use reasonable commercial efforts to cause the registration statement to remain effective until the earliest of (i) the date on which the investor may sell all of the shares and shares issuable upon exercise of the warrants then held by the investor pursuant to Rule 144(k) of the Securities Act of 1933 without regard to volume restrictions; and (ii) such time

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ZIOPHARM Oncology, Inc.
(A Development Stage Enterprise)

NOTES TO FINANCIAL STATEMENTS

2. Financings (continued)

as all of the securities held by the investor and registered under the registration statement have been sold pursuant to a registration statement, or in a transaction exempt from the registration and prospectus delivery requirements of the Securities Act of 1933 under Section 4(1) thereof so that all transfer restrictions and restrictive legends are removed upon the consummation of such sale. The 2007 Placement Agents have been afforded equivalent registration rights as the investors in the 2007 Offering with respect to the shares issuable upon exercise of the placement agent warrants. Effective January 1, 2007, the Company adopted a new accounting standard which requires that instruments subject to registration payments are accounted for without regard to the contingent obligation to make registration payments. As a result, the Company has determined that no contingent loss exists based on its history of timely annual, quarterly and registration filings. The Company intends to continue the timely compliance with all SEC filing requirements, which will keep the Company current and the shares registered. On March 1, 2007, the Company filed a registration statement on Form S-3 with the Securities and Exchange Commission. The registration statement was declared effective on March 26, 2007, rendering the resale of the shares issued in the 2007 Offering registered under the Securities Exchange Act of 1933 and no penalty was recorded.

On May 3, 2006, pursuant to subscription agreements, the Company and certain institutional and other accredited investors, the Company completed the sale of an aggregate of 7,991,256 shares of the Company s common stock at a price of $4.63 per share in a private placement (the 2006 Offering). In addition to the shares, the Company also issued to each investor a five-year warrant to purchase, at an exercise price of $5.56 per share, an additional number of shares of common stock equal to 30 percent of the shares purchased by such investor in the 2006 Offering. In the aggregate, these Warrants entitle investors to purchase an additional 2,397,392 shares of common stock. The Company estimated the fair value of these warrants at $9.6 million using the Black-Scholes model, using an assumed risk-free rate of 5.01% and an expected life of 5 years, volatility of 100%, and a dividend yield of 0%. The total gross proceeds resulting from the 2006 Offering was approximately $37 million, before deducting selling commissions and expenses.

The Company assessed whether the warrants require accounting as derivatives. The Company determined that the warrants were both (1) indexed to the Company s own stock and (2) classified in stockholders equity in accordance with ASC Topic 815, *Derivatives and Hedging*. As such, the Company has concluded the warrants meet the scope exception for determining whether the instruments require accounting as derivatives and should be classified in stockholders equity.

The Company engaged Paramount BioCapital, Inc. and Griffin Securities, Inc. (together, the 2006 Placement Agents) as co-placement agents in connection with the 2006 Offering. In consideration for their services, the Company paid the 2006 Placement Agents and certain selected dealers engaged by the 2006 Placement Agents and their designees aggregate cash commissions of $2.6 million (of which $1.7 million was paid to Paramount; see Note 6 to the Financial Statements, Related Party Transactions) and issued 7-year warrants to the 2006 Placement Agents and their designees to purchase an aggregate of 799,126 shares of the Company s common stock (10 percent of the shares sold in the 2006 Offering) at an exercise price of $5.09 per share. The Company estimated the fair value of these warrants at $3.5

million using the Black-Scholes model, using an assumed risk-free rate of 5.01% and an expected life of 7 years, volatility of 100% and a dividend yield of 0%. The Company made reimbursements of $100 thousand to the 2006 Placement Agents for their expenses incurred in connection with the 2006 Offering.

Pursuant to the 2006 Offering, the Company agreed to use its best efforts to (i) file a registration statement covering the resale of the shares issued in the 2006 Offering and the common stock issuable upon exercise of the warrants issued in the 2006 Offering (including the placement agent warrants) within 30 days following the closing date of the 2006 Offering, and (ii) use its reasonable commercial efforts to cause the registration statement to be effective within 120 days after such final closing date.

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ZIOPHARM Oncology, Inc.
(A Development Stage Enterprise)

NOTES TO FINANCIAL STATEMENTS

2. Financings (continued)

With respect to each investor in the 2006 Offering, the Company also agreed to use its reasonable commercial efforts to cause the registration statement to remain effective until the earliest of (i) the date on which the investor may sell all of the shares issued in the 2006 Offering and shares issuable upon exercise of the warrants then held by the investor pursuant to Rule 144(k) of the Securities Act of 1933 without regard to volume restrictions; and (ii) such time as all of the securities held by the investor and registered under the registration statement have been sold pursuant to a registration statement, or in a transaction exempt from the registration and prospectus delivery requirements of the Securities Act of 1933 under Section 4(1) thereof so that all transfer restrictions and restrictive legends are removed upon the consummation of such sale. The 2006 Placement Agents have been afforded equivalent registration rights as the investors in the 2006 Offering with respect to the shares issuable upon exercise of the placement agent warrants. Warrants issued in the 2006 Offering are classified as equity. On May 19, 2006, the Company filed a registration statement on Form S-3 with the Securities and Exchange Commission. The registration statement was declared effective on May 30, 2006, rendering the resale of the shares issued in the 2006 Offering registered under the Securities Exchange Act of 1933 and no penalties were recorded.

On August, 3, 2005, the Company entered into an Agreement and Plan of Merger dated as of August 3, 2005 (the Merger Agreement) with EasyWeb, Inc., a Delaware corporation (EasyWeb), and ZIO Acquisition Corp., a Delaware corporation and wholly-owned subsidiary of EasyWeb (ZIO Acquisition). EasyWeb was a company that was incorporated in September 1998 and had been in the business of designing, marketing, selling and maintaining customized and template turnkey sites on the Internet that are hosted by third parties. At the time of the Merger (as defined below), however, EasyWeb had no operating business and had limited assets and liabilities. Pursuant to the Merger Agreement, ZIO Acquisition merged with and into ZIOPHARM, with ZIOPHARM remaining as the surviving company and a wholly-owned subsidiary of EasyWeb (the Merger). In connection with the Merger, which was effective as of September 13, 2005, ZIO Acquisition ceased to exist and the surviving company changed its corporate name to ZIOPHARM, Inc. Based upon an Exchange Ratio, as defined in the Merger Agreement, in exchange for all of their shares of capital stock in ZIOPHARM, the ZIOPHARM stockholders received a number of shares of common stock of EasyWeb such that, upon completion of the Merger, the then-current ZIOPHARM stockholders held approximately 96.8% of the outstanding shares of common stock of EasyWeb on a fully-diluted basis. Upon completion of the Merger, EasyWeb ceased all of its remaining operations and adopted and continued implementing the business plan of ZIOPHARM. Further, effective upon the Merger, the then current officers and directors of EasyWeb resigned, and the then current officers and directors of ZIOPHARM were appointed officers and directors of EasyWeb. In conjunction with the Merger, ZIOPHARM made payments of approximately $425,000 to certain affiliates of EasyWeb in the third quarter of 2005. Subsequently, on September 14, 2005, ZIOPHARM merged into EasyWeb, and EasyWeb changed its name to ZIOPHARM Oncology, Inc.

Although EasyWeb was the legal acquirer in the transaction, ZIOPHARM became the registrant with the Securities and Exchange Commission. Under generally accepted accounting principles, the transaction was accounted for as a reverse acquisition, whereby ZIOPHARM was considered the acquirer of EasyWeb for financial reporting purposes

because ZIOPHARM s stockholders controlled more than 50% of the post-transaction combined entity, the management and the board were that of ZIOPHARM after the transaction, EasyWeb had no operating activity and limited assets and liabilities as of the transaction date, and the continuing operations of the entity are those of ZIOPHARM.

Accordingly, the equity of EasyWeb was adjusted to reflect a recapitalization of the stock and the equity of ZIOPHARM was adjusted to reflect a financing transaction with the proceeds equal to the net asset value of EasyWeb immediately prior to the Merger. The historical financial statements of ZIOPHARM became the historical financial statements of the Company. The historical stockholders equity was retroactively restated to

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ZIOPHARM Oncology, Inc.
(A Development Stage Enterprise)

NOTES TO FINANCIAL STATEMENTS

2. Financings (continued)

adjust for the exchange of shares pursuant to the Merger Agreement. All share and per share information included in the accompanying financial statements and notes give effect to the exchange, except as otherwise stated.

On June 6, 2005, the Company completed an offering (the 2005 Offering) of Series A Convertible Preferred Stock (Series A Preferred Stock). The Company issued 4,197,946 shares at $4.31 for gross proceeds of approximately $18.1 million. In connection with the 2005 Offering, the Company compensated Paramount, placement agent for the 2005 Offering, or its affiliates for its services through the payment of (a) cash commissions equal to 7% of the gross proceeds from the sale of the shares of Series A Preferred Stock, and (b) placement warrants to acquire 419,794 shares of Series A Preferred Stock (the Series A Stock Warrants), exercisable for a period of 7 years from the closing date at a per-share exercise price equal to 110% of the price per share sold in the 2005 Offering. These commissions are also payable on additional sales by the Company of securities (other than in a public offering) to investors introduced to the Company by Paramount during the twelve (12) month period subsequent to the final closing of the Offering. The Company also paid Paramount an expense allowance of $50 thousand to reimburse Paramount for its out-of-pocket expenses. Also, for a period of 36 months from the final Closing, Paramount has the right of first refusal to act as the placement agent for any private sale of the Company s securities. On September 13, 2005, the Series A Preferred Stock was converted to 4,197,946 of the company s common stock. Lastly, the Company has agreed to indemnify Paramount against certain liabilities, including liabilities under the Securities Act (see Note 6 to the financial statements, Related Party Transactions).

The Company valued the Series A Stock Warrants using the Black-Scholes model and recorded a charge of $1.7 million against additional paid-in capital. The Company has estimated the fair value of such warrants using the Black-Scholes model, using an assumed risk-free rate of 3.93% and expected life of 7 years, volatility of 134% and dividend yield of 0%. The net proceeds from the 2005 Offering were used for research and development, licensing fees and expenses, and for working capital and general corporate purposes.

3. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP).

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets

and liabilities and the 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. Although the Company regularly assesses these estimates, actual results could differ from those estimates. Changes in estimates are recorded in the period in which they become known.

The Company s most significant estimates and judgments used in the preparation of our financial statements:

Clinical trial expenses;
Fair value measurements;
Stock-based compensation; and
Income taxes.

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ZIOPHARM Oncology, Inc.
(A Development Stage Enterprise)

NOTES TO FINANCIAL STATEMENTS

3. Summary of Significant Accounting Policies (continued)

Accounting Standards Codification

In July 2009, the Company adopted a newly issued accounting standard which codified prior pronouncements and is the source of authoritative accounting principles recognized by the FASB to be applied by nongovernmental entities in preparation of financial statements in conformity with U.S. GAAP for interim and annual periods. Adoption of this new standard during the third quarter of 2009 did not have a material impact on the Company s financial position, results of operations or cash flows however, it changes the way in which U.S. GAAP is referenced.

Subsequent Events

During the second quarter of 2009, the Company adopted a new accounting standard which established general standards of accounting and disclosure of events which occur after the balance sheet date. The Company evaluated all events or transactions that occurred after the balance sheet date through the date when the Company issued these financial statements. During this period the Company did not have any material recognizable subsequent events.

Cash and Cash Equivalents

Cash equivalents consist primarily of demand deposit money market accounts. Cash equivalents are stated at cost, which approximates fair market value.

Concentrations of Credit Risk

Financial instruments which potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents. The Company maintains cash accounts in commercial banks, which may, at times, exceed federally insured limits. The Company has not experienced any losses in such accounts. The Company believes it is not exposed to any significant credit risk on cash and cash equivalents.

Property and Equipment

Property and equipment are recorded at cost. Expenditures for maintenance and repairs are charged to expense while the costs of significant improvements are capitalized. Depreciation is provided using the straight-line method over the following estimated useful lives of the related assets, which is between three and five years. Upon retirement or sale, the cost of the assets disposed of and the related accumulated depreciation are eliminated from the consolidated balance sheets and related gains or losses are reflected in the consolidated statements of operations.

Long-Lived Assets

In accordance with FASB accounting standards, the Company reviews the carrying values of its long-lived assets for possible impairment whenever events or changes in circumstances indicate that the carrying amounts of the assets may not be recoverable. Any long-lived assets held for disposal are reported at the lower of their carrying amounts or fair values less costs to sell.

Warrants

On January 1, 2009, the Company adopted a newly issued accounting standard which provides guidance in assessing whether an equity-based financial instrument is indexed to an entity s own stock for purposes of determining whether a financial instrument should be treated as a derivative. In applying the methodology the Company concluded that certain warrants issued by the Company in May 2005 have terms that do not meet the criteria to be considered indexed to the Company s own stock and therefore were re-classified from the equity section to the liability section of the Company s balance sheet as of January 1, 2009. The warrants are subject to re-measurement at each balance sheet date and any change in fair value is recognized as a component of other income (expense). Fair value is measured using the Black-Scholes valuation model. Adoption of

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ZIOPHARM Oncology, Inc.
(A Development Stage Enterprise)

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3. Summary of Significant Accounting Policies (continued)

this new standard decreased equity warrants classified in stockholders equity by $1,638 thousand, decreased deficit accumulated during the development stage by $1,566 thousand and increased warrant liabilities by $72 thousand (see Note 8 to the financial statements, Warrants, for additional disclosure).

Fair Value Measurements

Effective January 1, 2008, the Company adopted a newly issued accounting standard for fair value measurements for financial assets and liabilities and for non-financial assets and non-financial liabilities, except those that are recognized or disclosed in the financial statements at fair value on a recurring basis, and adopted in this standard for the previously exempt assets and liabilities effective January 1, 2009. The accounting standard defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles and enhances disclosures about fair value measurements. Fair value is defined as 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. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The standard describes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value which are the following:

Level 1 Quoted prices in active markets for identical assets or liabilities.

Level 2 Inputs other than Level 1 that are observable, either directly or indirectly, 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.

In April 2009, the Company adopted a newly issued accounting standard which provides guidelines for making fair value measurements more consistent including additional authoritative guidance in determining whether a market is active or inactive and whether a transaction is distressed. The adoption of these accounting standards did not have a material impact on the Company s results of operations, financial condition or cash flow.

Assets and liabilities measured at fair value on a recurring basis as of December 31, 2009 are as follows:

($ in Thousands) Description	Fair Value Measurements at Reporting Date Using			
	Balance as of December 31, 2009	Quoted Prices in Active Markets for Identical	Significant Other Observable Inputs	Significant Unobservable Inputs (Level 3)

		Assets/ Liabilities (Level 1)	(Level 2)	
Warrant liability	$ 18,471	$	$ 18,471	$

No such assets or liabilities require disclosure as of or for the year ended December 31, 2008. The warrants were valued using a Black-Scholes valuation model. See Note 8 to the financial statements, Warrants for additional disclosure on the valuation methodology and significant assumptions.

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NOTES TO FINANCIAL STATEMENTS

3. Summary of Significant Accounting Policies (continued)

Research and Development Costs

Research and development expenditures are charged to the statement of operations as incurred. Such costs include proprietary research and development activities, purchased research and development, and expenses associated with research and development contracts, whether performed by the Company or contracted with independent third parties.

Income Taxes

The provision for income taxes includes federal, state, local and foreign taxes. Income taxes are accounted for under the liability method. Deferred tax assets and liabilities are recognized for the estimated future tax consequences of temporary differences between the financial statement carrying amounts and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the year in which the temporary differences are expected to be recovered or settled. The Company evaluates the realizability of our deferred tax assets and establishes a valuation allowance when it is more likely than not that all or a portion of deferred tax assets will not be realized.

The Company accounts for uncertain tax positions using a more-likely-than-not threshold for recognizing and resolving uncertain tax positions. The evaluation of uncertain tax positions is based on factors including, but not limited to, changes in tax law, the measurement of tax positions taken or expected to be taken in tax returns, the effective settlement of matters subject to audit, new audit activity and changes in facts or circumstances related to a tax position. The Company evaluates this tax position on an annual basis. The Company also accrues for potential interest and penalties, related to unrecognized tax benefits in income tax expense. (see Note 9 to the Financial Statements, Income Taxes).

Accounting for Stock-Based Compensation

On January 1, 2006, the Company adopted the accounting standard which provides guidelines for recording stock-based compensation. The Company used the modified prospective method, which resulted in the accounting standard only being applied to the financial statements on a go-forward basis (that is, the prior period results have not been restated). Under the fair value recognition provisions of the accounting standard, stock-based compensation cost is measured at the grant date based on the value of the award using the Black-Scholes Model and is recognized as expense over the service period. Previously, the Company had followed accounting standards which resulted in accounting for employee share options at their intrinsic value in the financial statements.

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3. Summary of Significant Accounting Policies (continued)

The Company recognizes the full impact of its share-based employee payment plans in the statements of operations for each of the years ended December 31, 2009, 2008, and 2007 and did not capitalize any such costs on the balance sheets. The Company recognized $1.2 million, $1.3 million, and $1.3 million of compensation expense related to vesting of employee stock options during the year ended December 31, 2009, 2008, and 2007, respectively. In the years ended December 31, 2009, 2008, and 2007, the company recognized $990 thousand, $289 thousand and $9 thousand of compensation expense, respectively, related to vesting of restricted stock (see Note 11 to the Financial Statements, Stock Option Plan). During the year ended December 31, 2007, the Company recorded compensation expense in the amount of $120 thousand related to the vesting of non-employee options (see Note 7 to the financial statements, Commitments and Contingencies). The following table presents share-based compensation expense included in the Company s Statements of Operations:

	For the Year Ended December 31,		
(In Thousands)	2009	2008	2007
Research and development, including costs of research contracts	$512	$493	$ 666
General and administrative	1,669	1,107	773
Share based employee compensation expense before tax	2,181	1,600	1,439
Income tax benefit			
Net share based employee compensation expense	$2,181	$1,600	$ 1,439

Prior to the current accounting standards in 2006, the Company previously accounted for stock-based awards to employees using the intrinsic value method and had elected the disclosure-only alternative. All stock-based awards to nonemployees were accounted for at their fair value. The Company had recorded the fair value of each stock option issued to non-employees as determined at the date of grant using the Black-Scholes option pricing model.

The following table illustrates the effect on net loss and earnings per share if the Company had applied the fair value recognition provisions of current accounting standards to stock-based awards from September 9, 2003 (date of inception) to December 31, 2005:

(In Thousands, Except per Share Data)	September 9, 2003 (Date of Inception) to December 31, 2005

Net loss:	
As reported	$ (15,364)
Stock-based compensation expense included in reported net loss	802
Stock-based compensation expense under the fair-value based method	(1,756)
Pro forma net loss	$ (16,318)
Basic and diluted net loss per share:	
As reported	$ (3.75)
Pro forma	$ (3.98)

The fair value of each stock option is estimated at the date of grant using the Black-Scholes option pricing model. The estimated weighted-average fair value of stock options granted to employees in 2009, 2008, and 2007 was approximately $1.18, $1.20 and $2.66 per share, respectively. Assumptions regarding volatility, expected term, dividend yield and risk-free interest rate are required for the Black-Scholes model.

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NOTES TO FINANCIAL STATEMENTS

3. Summary of Significant Accounting Policies (continued)

The volatility assumption is based on the Company's historical experience. The risk-free interest rate is based on a U.S. treasury note with a maturity similar to the option award's expected life. The expected life represents the average period of time that options granted are expected to be outstanding. Because the Company does not have sufficient historical exercise data, the Company calculated using the simplified method described in SEC Staff Accounting Bulletin (SAB) No. 107 and No. 110. The assumptions for volatility, expected life, dividend yield and risk-free interest rate are presented in the table below:

	2009		2008		2007	
Weighted average risk-free interest rate	1.31	2.61%	1.52	3.49%	3.48	5.03%
Expected life in years	5		5		5	
Expected volatility	102	105%	94	99%	91	96%
Expected dividend yield	0		0		0	

Net Loss per Share

Basic net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding for the period. The Company's potential dilutive shares, which include outstanding common stock options, unvested restricted stock and warrants, have not been included in the computation of diluted net loss per share for any of the periods presented as the result would be antidilutive. Such potential common shares at December 31, 2009, 2008 and 2007 consist of the following:

	December 31,		
	2009	2008	2007
Stock options	3,534,686	2,738,089	2,797,000
Unvested restricted stock	1,467,167	586,500	70,000
Warrants	16,020,147	5,039,659	5,039,659
	21,022,000	8,364,248	7,906,659

New Accounting Pronouncements

In January 2010, the FASB issued Accounting Standards Update (ASU) No. 2010-06 *Fair Value Measurements and Disclosures* (Topic 820) which improves disclosures about fair value measurements. More specifically, ASU 2010-06 updates Topic 820-10 to require disclosure of transfers in and out of levels 1 and 2 and the reason for the transfers. Additionally, it requires separate reporting of purchases, sales, issuances and settlements for level 3. This update is effective for periods beginning after December 15, 2009. The adoption of this standard will not have an impact on our financial position or results of operations.

4. Property and Equipment, net

Property and equipment, net consist of the following:

	December 31,	
(In Thousands)	2009	2008
Office and computer equipment	$ 383	$ 375
Software	330	328
Leasehold improvements	398	284
Manufacturing equipment	12	12
	1,123	999
Less accumulated depreciation	(868)	(510)
Property and equipment, net	$ 255	$ 489

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ZIOPHARM Oncology, Inc.
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NOTES TO FINANCIAL STATEMENTS

4. Property and Equipment, net (continued)

Depreciation and amortization charged to the Statement of Operations for the years ended December 31, 2009, 2008, 2007 and from September 9, 2003 (date of inception) to December 31, 2009 (in thousands) was: $330, $388, $433 and $1,457, respectively.

5. Accrued Expenses

Accrued expenses consists of the following:

	December 31,	
(In Thousands)	2009	2008
Professional services	$ 230	$ 152
Clinical consulting services	408	1,229
NASDAQ fees	159	
Manufacturing services	120	1,512
Accrued vacation	109	42
Insurance	104	
Research and development consulting services	63	110
Payroll taxes	29	
Employee compensation	4	9
Other	35	83
Accrued expenses	$ 1,261	$ 3,137

6. Related Party Transactions

During 2005, the Company engaged Paramount to assist in placing shares of Series A Preferred Stock on a best efforts basis. Lindsay A. Rosenwald, M.D. is Chairman and Chief Executive Officer of Paramount. Dr. Rosenwald is also managing member of Horizon BioMedical Ventures, LLC (Horizon). On December 30, 2004, Horizon authorized the distribution of 2,428,911(4,848,376 pre-Merger) shares of common stock (such shares, the Horizon Distributed Shares), in equal installments of 1,214,456 (2,424,188 pre-Merger) shares of common stock to Mibars, LLC (Mibars) and to Dr. Rosenwald and his designees (the Designated Shares). The disposition of the Designated Shares will be subject to certain restrictions as agreed to among Dr. Rosenwald and Dr. Rosenwald s designees. Among other things, under certain circumstances set forth in pledge agreements between Dr. Rosenwald and his designees, Dr. Rosenwald has the right to re-acquire the Designated Shares from his designees. As a result of those rights, Dr. Rosenwald may be deemed to be an affiliate of the Company.

In connection with the December 22, 2004 Option Agreement with Southern Research Institute (SRI), the Company entered into a Finders Agreement, dated December 23, 2004, with Paramount pursuant to which the Company has agreed to compensate Paramount, for services in connection with the Company s introduction to SRI through the payment of (a) a cash fee of $60 thousand and (b) warrants to purchase 62,621 (125,000 pre-Merger) shares of the Company s common stock at a price equal to $4.75 ($2.38 pre-Merger) per share. The Company has estimated the fair value of such warrants using the Black-Scholes model, using an assumed risk-free rate of 3.93%, and expected life of 7 years, volatility of 134% and dividend yield of 0%. In December 2004, the Company expensed the $60 thousand that was payable to Paramount and recognized compensation expense in the amount of $251 thousand for the issuance of the warrants.

In connection with the Series A Preferred Stock Offering, the Company and Paramount entered into an Introduction Agreement in January 2005, pursuant to which the Company had agreed to compensate Paramount for its services in connection with the Offering through the payment of (a) cash commissions equal to 7% of the gross proceeds from the sale of the shares of Series A Preferred Stock, and (b) placement warrants

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6. Related Party Transactions (continued)

to acquire a number of shares of Series A Preferred Stock equal to 10% of the number of shares of Series A Preferred Stock issued in the Offering, exercisable for a period of 7 years from the Closing Date at a per Share exercise price equal to 110% of the price per Share sold in the Offering. These commissions are also payable on additional sales by the Company of securities (other than in a public offering) to investors introduced to the Company by Paramount during the twelve (12) month period subsequent to the final closing of the Offering. The Company also agreed to pay to Paramount a non-accountable expense allowance of $50 thousand to reimburse Paramount for its out-of-pocket expenses. Also, for a period of 36 months from the final Closing, Paramount has the right of first refusal to act as the placement agent for the private sale of the Company s securities. Lastly, the Company has agreed to indemnify Paramount against certain liabilities, including liabilities under the Securities Act.

In connection with the 2006 Offering, on May 3, 2006, the Company paid Paramount a cash commission equal to 7% of the gross proceeds from the sale of the Shares sold by Paramount in the 2006 Offering, resulting in a cash payment of approximately $1.7 million. In addition, the Company issued 7-year warrants to the 2006 Placement Agents and their designees to purchase an aggregate of 799,126 shares (10 percent of the Shares sold in the Offering) of the Company s common stock, of which 532,750 were issued to Paramount at an exercise price of $5.09 per share.

On December 18, 2006 the Company paid Paramount a cash settlement of $180 thousand in exchange for Paramount s agreement to terminate certain of its rights under the 2005 and 2004 agreements. This amount was expensed in the year ended December 31, 2006.

Mr. Timothy McInerney, who is a member of the Board of Directors of the Company, was a full-time employee of Paramount from 1992 through March 2007. In addition, Michael Weiser, a current member of the Board of Directors of the Company, and David M. Tanen, who was a member of the Board of Directors of the Company, were full-time employees of Paramount from July 1998 through November 2006, and July 1996 through August 2004, respectively. Mr. John Knox, our former Treasurer, is also a full-time Paramount employee.

In connection with the 2007 Offering, on February 23, 2007, the Company paid Paramount cash commissions equal to 6% of the gross proceeds from the sale of the shares sold by Paramount in the 2007 Offering, resulting in a cash payment of approximately $1.0 million. In addition, the Company issued 5-year warrants to the placement agents in the 2007 Offering and their designees to purchase an aggregate of 177,302 shares (3% of the shares sold in the 2007 Offering) of the Company s common stock at an exercise price of $5.75 per share, of which 97,536 were issued to Paramount.

During the year ended December 31, 2008, there were no related party transactions.

Mr. Timothy McInerney, who is a member of the Board of Directors of the Company, has been a Partner at Riverbank Capital Securities, Inc. since June 2007. In connection with the 2009 Private Placement, on September 15, 2009, the

Company paid Riverbank Capital Securities, Inc. cash commissions equal to 3.325% of the gross proceeds from the sale of the shares sold by Riverbank Capital Securities, Inc. in the 2009 Private Placement, resulting in a payment of approximately $168 thousand. In addition, the Company issued 5-year warrants to the placement agents in the 2009 Private Placement and their designees to purchase an aggregate of 138,617 shares (5% of the shares sold in the September 2009 Offering) of the Company s common stock at an exercise price of $2.04 per share, of which 65,843 were issued to Riverbank Capital Securities, Inc.

7. Commitments and Contingencies

Operating Leases

In May 2005, the Company entered into an operating lease for a new office in New York, NY consisting of 2,580 square feet. The lease expires in June 2010. In connection with this lease agreement, the Company

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7. Commitments and Contingencies (continued)

entered into a letter of credit in the amount of $60 thousand naming the Company's landlord as beneficiary. As of December 31, 2009 and 2008, the Company has classified the $60 thousand letter of credit as other non-current assets on the balance sheet.

In August 2006, the Company entered into an operating lease for new office space in New Haven, CT consisting of 2,200 square feet. The lease expired in September 2009. In connection with this lease agreement the Company provided a security deposit of $4 thousand. This lease was terminated in December 2008 in consideration of a payment of $12 thousand, equaling three months rent. As of December 31, 2008, the Company had no further obligations under this agreement.

In April 2007, the Company entered into a sublease for new office space in Charlestown, MA consisting of 4,872 square feet. The lease expires in April 2010. In connection with this lease agreement the Company provided a security deposit of $41 thousand. At December 31, 2008, the Company classified this amount in long-term deposits on the balance sheet. At December 31, 2009, the security deposit has been reclassified to prepaid expenses and other current assets on the balance sheet.

In August 2007, the Company entered into a sublease for new office space in Charlestown, MA consisting of 6,750 square feet. The lease expires in August 2012. In connection with this lease agreement the Company provided a security deposit of $46 thousand. At December 31, 2009 and 2008, the Company has classified this amount in deposits on the balance sheet.

Future minimum lease payments under operating leases as of December 31, 2009 are as follows (in thousands):

2010	$ 287
2011	188
2012	128
Total future minimum lease payments	$ 603

Total rent expense was approximately $456 thousand, $506 thousand, $593 thousand and $2.1 million for the years ended December 31, 2009, 2008, 2007 and for September 9, 2003 (date of inception) to December 31, 2009, respectively.

The Company records rent expense on a straight-line basis over the term of the lease. Accordingly, the Company has recorded a liability for deferred rent at December 31, 2009 and 2008 of $111 thousand and $58 thousand, respectively, which is recorded in deferred rent on the balance sheet.

License Agreements

Patent and Technology License Agreement The University of Texas M. D. Anderson Cancer Center and the Texas A&M University System.

On August 24, 2004, the Company entered into a patent and technology license agreement with The Board of Regents of the University of Texas System, acting on behalf of The University of Texas M. D. Anderson Cancer Center and the Texas A&M University System (collectively, the Licensors). Under this agreement, the Company was granted an exclusive, worldwide license to rights (including rights to U.S. and foreign patent and patent applications and related improvements and know-how) for the manufacture and commercialization of two classes of organic arsenicals (water- and lipid-based) for human and animal use. The class of water-based organic arsenicals includes darinaparsin.

As partial consideration for the license rights obtained, the Company made an upfront payment in 2004 of $125 thousand and granted the Licensors 250,487 shares of the Company s common stock. In addition, the Company issued options to purchase an additional 50,222 shares outside the 2003 Stock Option Plan for $0.002 per share following the successful completion of certain clinical milestones, which vested with respect

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7. Commitments and Contingencies (continued)

to 12,555 shares upon the filing of an Investigation New Drug application (IND) for darinaparsin in 2005 and vested with respect to another 25,111 shares upon the completion of dosing of the last patient for both Phase I clinical trials in 2007. The Company recorded $120 thousand of stock based compensation expense related to the vesting in 2007. The remaining 12,556 shares will vest upon enrollment of the first patient in a multi-center pivotal clinical trial i.e., a human clinical trial intended to provide the substantial evidence of efficacy necessary to support the filing of an approvable New Drug Application (NDA). In addition, the Licensors are entitled to receive certain milestone payments, including $100 thousand that was paid in 2005 upon the commencement of Phase I clinical trial and $250 thousand that was paid in 2006 upon the dosing of the first patient in the Registrant-sponsored Phase II clinical trial for darinaparsin. The Company may be required to make additional payments upon achievement of certain other milestones, in varying amounts which on a cumulative basis could total up to $4.85 million. In addition, the Licensors are entitled to receive royalty payments on sales from a licensed product should such a product be approved for commercial sale and sales of a licensed product be effected in the United States, Canada, the European Union or Japan. The Licensors also will be entitled to receive a portion of any fees that the Company may receive from a possible sublicense under certain circumstances. The Company also paid the Licensors $100 thousand in 2006 and 2007 to conduct scientific research with the Company obtaining exclusive right to all resulting intellectual property rights. The sponsored research agreements governing this research and any related extensions expired in February 2008 with no payments being made in 2008 or 2009.

The license agreement also contains other provisions customary and common in similar agreements within the industry, such as the right to sublicense the Company rights under the agreement. However, if the Company sublicenses its rights prior to the commencement of a pivotal study *i.e.*, a human clinical trial intended to provide the substantial evidence of efficacy necessary to support the filing of an approvable NDA, the Licensors will be entitled to receive a share of the payments received by the Company in exchange for the sublicense (subject to certain exceptions).

License Agreement with DEKK-Tec, Inc.

On October 15, 2004, the Company entered into a license agreement with DEKK-Tec, Inc., pursuant to which it was granted an exclusive, worldwide license for palifosfamide. As part of the signing of license agreement with DEKK-Tec, the Company expensed an upfront $50 thousand payment to DEKK-Tec in 2004.

In consideration for the license rights, DEKK-Tec is entitled to receive milestone payments upon the occurrence of certain achievements of certain milestones in varying amounts which on a cumulative basis may total $3.9 million. Of the aggregate milestone payments, most of the total amount will be creditable against future royalty payments as referenced below. The Company expensed a $100 thousand milestone payment upon achieving Phase II milestones during the year ended December 31, 2006. Additionally, in 2004 the Company issued DEKK-Tec an option to purchase 27,616 shares of the Company s common stock for $0.02 per share. Upon the execution of the license

agreement, 6,904 shares vested and were subsequently exercised in 2005 and the remaining options will vest upon certain milestone events, culminating with final FDA approval of the first NDA submitted by the Company (or by its sublicensee) for palifosfamide. None of the remaining options have vested as of December 31, 2009. DEKK-Tec is entitled to receive royalty payments on the sales of palifosfamide should it be approved for commercial sale. There were no payments during 2008 or 2009.

Option Agreement with Southern Research Institute (SRI)

On December 22, 2004, the Company entered into an Option Agreement with SRI (the Option Agreement), pursuant to which the Company was granted an exclusive option to obtain an exclusive license to SRI s interest in certain intellectual property, including exclusive rights related to certain isophosphoramide mustard analogs.

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7. Commitments and Contingencies (continued)

Also on December 22, 2004, the Company entered into a Research Agreement with SRI pursuant to which, the Company agreed to spend a sum not to exceed $200 thousand between the execution of the agreement and December 21, 2006, including a $25 thousand payment that was made simultaneously with the execution of the agreement, to fund research and development work by SRI in the field of isophosphoramide mustard analogs. The Option Agreement was exercised on February 13, 2007. In connection with the exercise of the option, minimum annual royalty payments of $25 thousand were made in the years ended December 31, 2008 and 2007 as part of the License Agreement. No payment was made in 2009.

License Agreement with Baxter Healthcare Corporation

On November 3, 2006, the Company entered into a definitive Asset Purchase Agreement (for indibulin) and License Agreement (to Baxter's proprietary nanosuspension technology) with affiliates of Baxter. Indibulin is a novel anti-cancer agent that binds to tubulin, one of the essential proteins for chromosomal segregation, and targets mitosis like the taxanes and vinca alkaloids. It is being developed as an oral form. Among the more well known antimitotic drugs are the taxanes (paclitaxel, docetaxel) and the vinca alkaloids (vincristine, vinblastine). The purchase included the entire indibulin intellectual property portfolio as well as existing drug substance and capsule inventories. The terms of the Asset Purchase Agreement included an upfront cash payment of approximately $1.1 million and an additional $100 thousand payment for existing inventory, both of which were expensed in 2006. In addition to the upfront costs, the Asset Purchase Agreement includes additional milestone payments that could amount to approximately $8 million in the aggregate and royalties on net sales of products covered by a valid claim of a patent for the life of the patent on a country-by-country basis. The Company expensed a $625 thousand milestone payment upon the successful U.S. IND application for indibulin in 2007. The License Agreement requires payment of a $15 thousand annual patent and license prosecution/maintenance fee through the expiration of the last to expire of the Licensed Patents which is expected to expire in 2025 and royalties on net sales of licensed products covered by a valid claim of a patent for the life of the patent on a country-by-country basis.

In October 2009, the Baxter License Agreement was amended to allow the Company to manufacturer indibulin.

Collaboration Agreement with Harmon Hill, LLC

On April 8, 2008, the Company signed a collaboration agreement for Harmon Hill, LLC (Harmon Hill) to provide consulting and other services for the development and commercialization of oncology therapeutics by ZIOPHARM. Under the agreement the Company has agreed to pay Harmon Hill $20 thousand per month for the consulting services and has further agreed to pay Harmon Hill (a) $500 thousand upon the first patient dosing of the Specified Drug in a pivotal trial, which trial uses a dosing Regime introduced by Harmon Hill; and (b) provided that the Specified Drug receives regulatory approval from the FDA, the EMEA or another regulatory agency for the marketing of the Specified Drug, a 1% royalty of the Company s net sales will be awarded to Harmon Hill. If the Specified Drug is

sublicensed to a third party, the agreement entitles Harmon Hill to a 1% award of royalties received from a sublicense. Subject to renewal or extension by the parties, the term of the agreement was for a one year period that expired April 7, 2009. Although the Company and Harmon Hill have not entered into a formal written renewal or extension, the parties continued to operate under the terms of the agreement at December 31, 2009. The Company expensed $180 thousand and $240 thousand during 2008 and 2009, respectively, for consulting services per the aforementioned agreement. No milestones have been reached or accrued during the years ended December 31, 2009 or 2008.

Guarantees and Indemnification Obligations

Certain officer and employees also have specific guaranteed severance agreements. In conjunction with the 2005 Offering, the Company has agreed to indemnify Paramount against certain liabilities, including liabilities under the Securities Act. The Company has not recorded any expense or liabilities related to these guarantees as of December 31, 2009 and 2008.

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8. Warrants

The Company has issued both warrants that are accounted for as liabilities and warrants that are accounted for as equity instruments.

On January 1, 2009, the Company adopted a newly issued accounting standard which provides guidance in assessing whether an equity-issued financial instrument is indexed to an entity s own stock for purposes of determining whether a financial instrument should be treated as a derivative. In applying the methodology, the Company concluded that certain warrants issued by the Company in May 2005 have terms that do not meet the criteria to be considered indexed to the Company s own stock and therefore were re-classified from the equity section to the liability section of the Balance Sheets as of January 1, 2009. Accounting standards require that the warrants be valued at each financial reporting period and the resulting gain or loss be recorded as other income (expense) in the Statements of Operations. Fair value is measured using the Black-Scholes valuation model.

In May 2005, the Company issued 419,786 warrants to placement agents for services performed in connection with the 2005 Offering, 11,083 of which were subsequently exercised. The remaining 408,703 warrants were originally valued at $1.6 million. Subject to certain exceptions, these warrants provide for anti-dilution protection should common stock or common stock equivalents be subsequently issued at a price less than the exercise price of the warrants then in effect, which was initially $4.75 per share. This provision was triggered in 2006 when stock was sold at $4.63 per share in the 2006 Offering. Accordingly, the warrants were re-priced at $4.69. The provision was triggered a second time with 2009 Private Placement when stock was sold at $1.825 per share and the warrants were subsequently re-priced at $4.25. The provision was triggered again with the Company s December 2009 public offering when stock was sold at $3.10 per share and the warrants were subsequently re-priced at $3.93. Using a Black-Scholes model, the warrants were valued at $72 thousand on January 1, 2009, when the accounting standard was adopted. The reclassification attributed to the new standard had the following cumulative effect on the Balance Sheets:

	Liabilities	Stockholders Equity	
(In Thousands)	Warrants	Warrants	Deficit Accumulated During the Development Stage
As reported on December 31, 2008	$	$ 20,504	$ (85,061)
Re-classification	72	(1,638)	1,566
Balance on January 1, 2009	$ 72	$ 18,866	$ (83,495)

Also, in connection with the December 2009 public offering, the Company issued warrants to purchase an aggregate of 8,206,520 shares of common stock (including the investor warrants and 464,520 warrants issued to the

Underwriters). The investor warrants are exercisable immediately and the underwriter warrants exercisable six months after the date of issuance. The warrants have an exercise price of $4.02 per share and have a five year term. The fair value of the warrants was estimated at $22.9 million using a Black-Scholes model with the following assumptions: expected volatility of 105%, risk free interest rate of 2.14%, expected life of five years and no dividends.

The Company assessed whether the warrants require accounting as derivatives. The Company determined that the warrants were not indexed to the Company s own stock in accordance with accounting standards codification Topic 815, *Derivatives and Hedging*. As such, the Company has concluded the warrants did not meet the scope exception for determining whether the instruments require accounting as derivatives and should be classified in liabilities.

On December 31, 2009, the liability-classified warrants were valued at $18.5 million using a Black-Scholes valuation model. The decrease in the fair value of the warrant liabilities of $4.5 million for the year ended December 31, 2009 was charged to other income (expense) in the Statements of Operations.

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ZIOPHARM Oncology, Inc.
(A Development Stage Enterprise)

NOTES TO FINANCIAL STATEMENTS

8. Warrants (continued)

The following assumptions were used at January 1, 2009 and December 31, 2009:

	January 1, 2009	December 31, 2009	
Risk-free interest rate	1.55%	1.37	2.65%
Expected life in years	3.42	2.42	4.92
Expected volatility	102%	105%	
Expected dividend yield	0	0	

Warrants accounted for as equity instruments include the following issuances:

During 2004, the Company issued warrants to purchase 62,621 shares of the Company s common stock to Paramount as compensation for services rendered in connection with our entering into an option agreement with Southern Research Institute. In connection with the warrants issued, the Company recorded a charge of $251 thousand to general and administrative expense. The Company has estimated the fair value of such options using the Black-Scholes model, using an assumed risk-free rate of 3.93%, and expected life of 7 years, volatility of 134% and dividend yield of 0%.

In 2005, the Company issued performance warrants to purchase 50,000 shares of the Company s common stock for services to be rendered to its investor relations consultant as compensation. In connection with the warrant issuance 12,500 shares are exercisable immediately and the Company recorded a charge of $45 thousand to general and administrative expense in the year ended December 31, 2005. The Company has estimated the fair value of such options using the Black-Scholes model, using an assumed risk-free rate of 4.39%, an expected life of 5 years, volatility of 109%, and dividend yield of 0%. The remaining 37,500 warrants were cancelled in the year ended December 31, 2006 due to performance objectives not being obtained at the expiration of agreement.

In connection with the 2006 Offering completed on May 3, 2006, the Company issued warrants to purchase 2,397,392 shares of common stock to investors and 799,126 warrants to purchase common stock to the 2006 Placement Agents and their designees. The Company estimated the fair value of the warrants at $9.6 million and $3.5 million, respectively, using the Black-Scholes model, using an assumed risk-free rate of 5.01% and an expected life of 5 and 7 years, volatility of 100% and a dividend yield of 0%.

On February 23, 2007, as part of the 2007 Offering, the Company issued warrants to purchase 1,182,015 shares of common stock to investors and 177,302 warrants to purchase common stock to the 2007 Placement Agents, their designees and a previously-engaged financial consultant. The Company estimated the fair value of the warrants at $4.7 million and $709 thousand respectively, using the Black-Scholes model, using an assumed risk-free rate of 4.71% and an expected life of 5 years, volatility of 93% and a dividend yield of 0%.

No warrants were issued or exercised in the year ending December 31, 2008.

In connection with the 2009 Private Placement, the Company issued warrants to purchase an aggregate of 2,910,954 shares of common stock (including 138,617 warrants issued to the placement agents) which are exercisable immediately. The warrants have an exercise price of $2.04 per share and have a five year term. The fair value of the warrants was estimated at $4,207 thousand using a Black-Scholes model with the following assumptions: expected volatility of 105%, risk free interest rate of 2.41%, expected life of five years and no dividends. The fair value of the warrants was recorded in the equity section of the balance sheet. In October 2009, 136,986 of these warrants were exercised.

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ZIOPHARM Oncology, Inc.
(A Development Stage Enterprise)

NOTES TO FINANCIAL STATEMENTS

8. Warrants (continued)

The following is a summary of warrants outstanding as of December 31, 2009.

Number of Warrants	Issued in Connection With	Exercise Price	Expiration Date
62,621	Services performed	$ 4.75	December 23, 2011
408,703	Placement warrants for services performed	$ 4.75	May 31, 2012
12,500	Services performed	$ 4.76	September 14, 2010
2,397,392	Investor warrants	$ 5.56	May 3, 2011
799,126	Placement warrants for services performed	$ 5.09	May 3, 2013
1,182,015	Investor warrants	$ 5.75	February 23, 2012
177,302	Placement warrants for services performed	$ 5.75	February 23, 2012
2,635,351	Investor warrants	$ 2.04	September 15, 2014
138,617	Placement warrants for services performed	$ 2.04	September 15, 2014
7,742,000	Investor warrants	$ 4.02	December 9, 2014
464,520	Underwriter warrants for services performed	$ 4.02	December 9, 2014
16,020,147			

9. Income Taxes

There is no provision for income taxes because the Company has incurred operating losses since inception. The reported amount of income tax expense for the years differs from the amount that would result from applying domestic federal statutory tax rates to pretax losses primarily because of the changes in the valuation allowance. Significant components of the Company's deferred tax assets at December 31, 2009 and 2008 are as follows:

	December 31,	
(In Thousands)	2009	2008
Net operating loss carryforwards	$ 7,687	$ 6,465
Start-up and organizational costs	24,193	23,199
Research and development credit carryforwards	1,869	1,665
Stock compensation	501	475
Accrued bonus		
Depreciation	112	(27)
Other	384	460
	34,746	32,237
Less valuation allowance	(34,746)	(32,237)

Net deferred tax assets	$	$

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. At December 31, 2009, the Company has aggregate net operating loss carryforwards for federal tax purposes of approximately $19.2 million available to offset future federal and state taxable income to the extent permitted under the Internal Revenue Code (IRC), expiring in varying amounts through 2029. Additionally, the Company has approximately $1.8 million of research and development credits at December 31, 2009, expiring in varying amounts through 2029, which may be available to reduce future taxes. Under the IRC Section 382, certain substantial changes in the Company s ownership may limit the amount of net operating loss carryforwards that can be utilized in any one year to offset future taxable income. As a result of a Private Placement in September 2009, a Public Offering in December 2009, and prior equity transactions, it is possible that, net operating loss carryforwards and other tax attributes may have been limited by these rules. The change-in-control provisions of IRC section 382 have not been fully investigated in relation to these transactions. The

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ZIOPHARM Oncology, Inc.
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NOTES TO FINANCIAL STATEMENTS

9. Income Taxes (continued)

net operating loss carryforwards for the year ended December 31, 2009 includes approximately $15 thousand resulting from excess tax deductions from stock options exercised in 2007. Pursuant to accounting standards, the deferred tax asset relating to excess tax benefits generated from exercises was not recognized for financial statement purposes.

The Company has provided a valuation allowance for the full amount of these net deferred tax assets, since it is more likely than not that these future benefits will not be realized. However, these deferred tax assets may be available to offset future income tax liabilities and expenses. The valuation allowance increased by $2.5 million primarily due to net operating loss carryforward, start-up and organizational costs, and the increase in research and development credits.

A reconciliation of income tax expense (benefit) at the statutory federal income tax rate and income taxes as reflected in the financial statements is as follows:

	December 31,		
(In Thousands)	2009	2008	2007
Federal income tax at statutory rates	34.0 %	34.0 %	34.0 %
State income tax, net of federal tax benefit	4.8 %	6.1 %	6.1 %
Research and development credts	2.4 %	2.5 %	2.1 %
Stock compensation	-8.2 %	-1.7 %	-1.4 %
Uncertain tax position adjustment	0.0 %	0.0 %	-5.7 %
Other	-0.7 %	-0.5 %	0.0 %
Increase in valuation allowance	-32.3 %	-40.4 %	-35.0 %
Effective tax rate	0.0 %	0.0 %	0.0 %

The Company adopted a new accounting standard relating to accounting for uncertain tax positions on January 1, 2007. The standard prescribes a recognition threshold and measurement of a tax position taken or expected to be taken in a tax return. The company did not establish any additional reserves for uncertain tax liabilities upon adoption of the standard. A summary of the company's adjustments to its uncertain tax positions in the years ended December 31, 2009, 2008 and 2007 are as follows:

(In Thousands)	
Balance at January 1, 2007 (adoption of Accounting Standard)	$ 134
Increase/Decrease for tax positions related to the current year	104
Increase/Decrease for tax positions related to prior years	
Decreases for settlements with applicable taxing authorities	
Decreases for lapses of statute of limitations	

Balance at December 31, 2007	238
Increase/Decrease for tax positions related to the current year	
Increase/Decrease for tax positions related to prior years	
Decreases for settlements with applicable taxing authorities	
Decreases for lapses of statute of limitations	
Balance at December 31, 2008	238
Increase/Decrease for tax positions related to the current year	
Increase/Decrease for tax positions related to prior years	
Decreases for settlements with applicable taxing authorities	
Decreases for lapses of statute of limitations	
Balance at December 31, 2009	$ 238

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ZIOPHARM Oncology, Inc.
(A Development Stage Enterprise)

NOTES TO FINANCIAL STATEMENTS

9. Income Taxes (continued)

The uncertain tax position adjustments in 2007 relate to Federal and State research and development tax credits. The Company has not recognized any interest and penalties in the statement of operations because of the Company s net operating losses and tax credits that are available to be carried forward. When necessary, the Company will account for interest and penalties related to uncertain tax positions as part of its provision for federal and state income taxes. The Company does not expect the amounts of unrecognized benefits will change significantly within the next twelve months.

The Company is currently open to audit under the statute of limitations by the Internal Revenue Service and state jurisdictions for the years ended December 31, 1999 through 2009.

10. Convertible Preferred Stock and Stockholders Equity

On April 26, 2006, the date of the Company s annual stockholders meeting, the shareholders approved the adoption of an Amended and Restated Certificate of Incorporation pursuant to which the Company has 280,000,000 shares of authorized capital stock, of which 250,000,000 shares are designated as common stock (par value $.001 per share), and 30,000,000 shares are designated as preferred stock (par value $.001 per share) (the Preferred Stock).

Common Stock of ZIOPHARM Oncology, Inc.

As of December 31, 2009, the Company has 41,583,528 shares of common stock issued and outstanding and no shares of Preferred Stock.

In September 2003, the Company issued 1,001,949 shares of common stock at $0.50 per share for gross proceeds of $500 thousand.

In January 2004, the Company issued 9,017,538 shares of common stock at $0.50 per share for gross proceeds of $4.5 million.

In February 2004, the Company amended its articles of incorporation to provide for the combination of the Company s common stock, par value $0.001 per share on a 1-for-4 basis.

On June 6, 2005, the Company completed the 2005 Offering (see Note 2 to the financial statements, Financings). As a result of the Merger, all shares of the Series A Preferred Stock were automatically converted into the number of shares of common stock that the holders of Series A Preferred Stock would have received if their shares of Series A Preferred Stock had been converted into common stock immediately prior to the Merger.

On May 3, 2006, pursuant to subscription agreements between the Company and certain institutional and other accredited investors, the Company completed the sale of an aggregate of 7,991,256 shares of the Company s common stock at a price of $4.63 per Share in the 2006 Offering. The total gross proceeds resulting from the 2006 Offering was approximately $37 million, before deducting selling commissions and expenses.

On February 23, 2007, pursuant to subscription agreements between the Company and certain institutional and other accredited investors, the Company completed the sale of an aggregate of 5,910,049 shares of the Company s common stock at a price of $5.225 per share in a private placement. The total gross proceeds resulting from the 2007 Offering was approximately $30.9 million, before deducting selling commissions and expenses.

On September 15, 2009, pursuant to subscription agreements between the Company and certain institutional and other accredited investors, the Company completed the sale of an aggregate of 2,772,337 shares of the Company s common stock at a price of $1.825 per share in a private placement. The total gross proceeds resulting from the September 2009 Offering was approximately $5.1 million, before deducting selling commissions and expenses (see Note 2 to the financial statements, Financings).

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ZIOPHARM Oncology, Inc.
(A Development Stage Enterprise)

NOTES TO FINANCIAL STATEMENTS

10. Convertible Preferred Stock and Stockholders Equity (continued)

On December 9, 2009, pursuant to underwriting agreement between the Company and certain brokers, the Company completed the sale of an aggregate of 15,484,000 shares of the Company s common stock at a price of $3.10 per share in a private placement. The total gross proceeds resulting from the 2009 public offering was approximately $48.0 million, before deducting selling commissions and expenses (see Note 2 to the financial statements, Financings).

Series A Convertible Preferred Stock of ZIOPHARM, Inc.

All shares of Series A Preferred Stock have been converted into shares of common stock of the Company.

Preferred Stock of ZIOPHARM Oncology, Inc.

The Company s Board of Directors are authorized to designate any series of Preferred Stock, to fix and determine the variations in relative rights, preferences, privileges and restrictions as between and among such series.

11. Stock Option Plan

The Company has adopted the 2003 Stock Option Plan (the Plan), under which the Company had reserved for the issuance of 1,252,436 shares of its common stock. The Plan was approved by the Company s stockholders on December 21, 2004. On June 4, 2009, April 25, 2007 and April 26, 2006, the dates of the Company s annual stockholders meetings, the Company s stockholders approved amendments to the Plan increasing the total shares reserved by 2,000,000, 2,000,000 and 750,000 shares, respectively, for a total of 6,002,436 shares.

As of December 31, 2009, the Company had outstanding options issued to its employees to purchase up to 2,914,262 shares of the Company s common stock, to its directors to purchase up to 615,174 shares of the Company s common stock, as well as options to consultants in connection with services rendered to purchase up to 5,250 shares of the Company s common stock. In December 2008, 5,000 options were granted to a consultant and vest ratably over a two-year period, contingent upon performance of future consulting services during that time.

Currently, stock options are granted with an exercise price equal to the closing market price of the Company s common stock on the day before the date of grant. Stock options to employees generally vest ratably over three years and have contractual terms of ten years. Stock options to directors generally vest ratably over two or three years and have contractual terms of ten years. Stock options are valued using the Black-Scholes option pricing method and compensation is recognized based on such fair value over the period of vesting on a straight-line basis. The Company has also reserved an aggregate of 45,823 additional shares for issuance under options granted outside of the 2003

Stock Option Plan. The options were granted to The University of Texas M. D. Anderson Cancer Center and DEKK-Tec, Inc. (see Note 7 to the financial statements, Commitments and Contingencies). During the year ended December 31, 2007, the Company recorded a $120 thousand stock compensation expense in connection with the Company achieving a predetermined development milestone, which triggered the vesting of 25,111 of the options granted outside of the 2003 Stock Option Plan. The 25,111 options were exercised on August 13, 2007. Proceeds from this exercise amounted to $50.22 and the intrinsic value of these options amounted to $104 thousand.

Proceeds from the 2009, 2008 and 2007 exercises amounted to $73, $0, and $36 thousand, respectively. The intrinsic value of these options amounted to $238, $0, and $32 thousand for years ended December 31, 2009, 2008, and 2007, respectively.

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ZIOPHARM Oncology, Inc.
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NOTES TO FINANCIAL STATEMENTS

11. Stock Option Plan (continued)

Transactions under the Plan for the years ending December 31, 2009, 2008, and 2007 were as follows:

(In Thousands, Except Share and per Share Data)	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding, December 31, 2006	1,913,035	$ 3.95		
Granted	1,101,250	3.63		
Exercised	(20,905)	1.70		
Cancelled	(196,380)	4.36		
Outstanding, December 31, 2007	2,797,000	3.81		
Granted	384,000	1.64		
Exercised				
Cancelled	(442,911)	4.31		
Outstanding, December 31, 2008	2,738,089	3.43		
Granted	1,324,000	1.53		
Exercised	(102,564)	0.71		
Cancelled	(424,839)	3.19		
Outstanding, December 31, 2009	3,534,686	$ 2.82	7.55	$ 2,968
Options exercisable, December 31, 2009	2,456,268	$ 3.02	6.79	$ 2,204
Options available for future grant	368,817			

At December 31, 2009, total unrecognized compensation costs related to non-vested stock options outstanding amounted to $1.7 million. The cost is expected to be recognized over a weighted-average period of 1.64 years.

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ZIOPHARM Oncology, Inc.
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NOTES TO FINANCIAL STATEMENTS

11. Stock Option Plan (continued)

Restricted Stock

In December 2009, the Company issued 347,500 shares of restricted stock to employees and 45,000 shares of restricted stock to its non-employee directors, which will vest ratably in annual installments over three and two years, respectively, commencing on the first anniversary of the grant date. In September 2009, the Company issued 828,000 shares of restricted stock to employees and 180,000 shares of restricted stock to its board of directors, all of which vest in their entireties on the one year anniversary of the grant date. In December 2008, the Company issued 396,500 shares of restricted stock to employees and 90,000 shares of restricted stock to its board of directors, all of which vested in December 2009. Also, in January 2008, the Company issued 100,000 shares of restricted stock to one employee which vest ratably over a three-year period. In 2007, the Company issued 70,000 shares of restricted stock to several employees which vested in December 2008. During the years ended December 31, 2009, 2008 and 2007, $1.0 million, $289 thousand and $9 thousand of compensation expense was recognized, respectively. In December 2009, the Company repurchased 103,823 shares of vested restricted stock from employees at $3.66 per share to pay for payroll taxes. A summary of the status of non-vested restricted stock as of December 31, 2009, 2008 and 2007 is as follows:

	Number of Shares	Weighted-Average Grant Date Fair Value
Outstanding, December 31, 2006		$
Granted	70,000	2.73
Vested		
Cancelled		
Outstanding, December 31, 2007	70,000	2.73
Granted	586,500	0.83
Vested	(45,000)	2.73
Cancelled	(25,000)	2.73
Outstanding, December 31, 2008	586,500	1.15
Granted	1,400,500	2.28
Vested	(450,333)	0.97
Cancelled	(69,500)	0.83
Outstanding, December 31, 2009	1,467,167	$ 2.30

As of December 31, 2009, there was $2.7 million of total unrecognized stock-based compensation expense related to non-vested restricted stock arrangements granted under the 2003 Plan. The expense is expected to be recognized over a weighted-average period of 1.38 years.

12. Employee Benefit Plan

The Company sponsors a qualified 401(k) Retirement Plan (the Plan) under which employees are allowed to contribute certain percentages of their pay, up to the maximum allowed under Section 401(k) of the Internal Revenue Code. The Company may make contributions to these plans at its discretion. The Company contributed approximately $35 thousand, $113 thousand and $0 to this plan during the years ended December 31, 2009, 2008 and 2007, respectively.

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Exhibit No.	Description of Document
1.1	Underwriting Agreement dated December 4, 2009 between ZIOPHARM Oncology, Inc. and JMP Securities LLC, as representative of the several underwriters named thererin (incorporated by reference to Exhibit 1.1 to the Registrant s Current Report of Form 8-K filed December 8, 2009).
2.1	Agreement and Plan of Merger among the Registrant (formerly EasyWeb, Inc.), ZIO Acquisition Corp. and ZIOPHARM, Inc., dated August 3, 2005 (incorporated by reference to Exhibit 10.1 to the Registrant s Form 8-K filed August 9, 2005).
3.1	Amended and Restated Certificate of Incorporation, as filed with the Delaware Secretary of State on April 26, 2006 (incorporated by reference to Exhibit 3.1 to the Registrant s Current Report of Form 8-K filed April 26, 2006).
3.2	Certificate of Merger dated September 13, 2005, relating to the merger of ZIO Acquisition Corp. with and into ZIOPHARM, Inc. (incorporated by reference to Exhibit 3.1 to the Registrant s Form 8-K filed September 19, 2005).
3.3	Certificate of Ownership of the Registrant (formerly EasyWeb, Inc.) dated as of September 14, 2005, relating the merger of ZIOPHARM, Inc. with and into the Registrant, and changing the Registrant s corporate name from EasyWeb, Inc. to ZIOPHARM Oncology, Inc. (incorporated by reference to Exhibit 3.2 to the Registrant s Form 8-K filed September 19, 2005).
3.4	Bylaws, as amended to date (incorporated by reference to Exhibit 3.3 to the Registrant s Form 8-K filed September 19, 2005).
4.1	Specimen common stock certificate. (incorporated by reference to Exhibit 4.1 to the Registrant s Registration Statement on Form SB-2, SEC File No. 333-129020, filed October 14, 2005).
4.2	Form of Warrant issued to placement agents in connection with ZIOPHARM, Inc. 2005 private placement (incorporated by reference to Exhibit 4.2 to the Registrant s Registration Statement on Form SB-2, SEC File No. 333-129020, filed October 14, 2005).
4.3	Schedule identifying holders of Warrants in the form filed as Exhibit 4.2 to this Report (incorporated by reference to Exhibit 4.3 to the Registrant s Registration Statement on Form SB-2, SEC File No. 333-129020, filed October 14, 2005).
4.4	Warrant for the Purchase of Shares of common stock dated December 23, 2004. (incorporated by reference to Exhibit 4.4 to the Registrant s Registration Statement on Form SB-2, SEC File No. 333-129020, filed October 14, 2005).
4.5	Option for the Purchase of common stock dated October 15, 2004 and issued to DEKK-Tec, Inc. (incorporated by reference to Exhibit 4.5 to the Registrant s Annual Report on Form 10-KSB filed March 20, 2006).
4.6	Form of Option for the Purchase of Shares of common stock dated August 30, 2004 and issued to The University of Texas M. D. Anderson Cancer Center. (incorporated by reference to Exhibit 4.6 to the Registrant s Annual Report on Form 10-KSB filed March 20, 2006).
4.7	Schedule identifying material terms of Options for the Purchase of Shares of common stock in the form filed as Exhibit 4.6 to this Report. (incorporated by reference to Exhibit 4.7 to the Registrant s Annual Report on Form 10-KSB filed March 20, 2006).
4.8	Form of common stock Purchase Warrant issued to investors in connection with the Registrant s 2006 private placement (incorporated by reference to Exhibit 4.1 to the Registrant s

	Current Report of Form 8-K filed May 3, 2006).
4.9	Form of common stock Purchase Warrant issued to placement agents in connection with the Registrant s 2006 private placement (incorporated by reference to Exhibit 4.2 to the Registrant s Current Report of Form 8-K filed May 3, 2006).

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Exhibit No.	Description of Document
4.10	Form of Warrant to Purchase Common Stock issued to investors in connection with the Registrant s February 2007 private placement (incorporated by reference to Exhibit 4.1 to the Registrant s Current Report of Form 8-K filed February 26, 2007).
4.11	Form of Warrant to Purchase Common Stock issued to placement agents in connection with the Registrant s February 2007 private placement (incorporated by reference to Exhibit 4.2 to the Registrant s Current Report of Form 8-K filed February 26, 2007).
4.12	Form of Warrant to Purchase Common Stock issued to investors in connection the Registrant s September 2009 private placement (incorporated by reference to Exhibit 4.1 to the Registrant s Current Report of Form 8-K filed September 15, 2009).
4.13	Form of Warrant to Purchase Common Stock issued to placement agents in connection with the Registrant s September 2009 private placement (incorporated by reference to Exhibit 4.2 to the Registrant s Current Report of Form 8-K filed September 15, 2009).
4.14	Form of Warrant to Purchase Common Stock issued to investors in connection with the Registrant s December 2009 public offering (incorporated by reference to Exhibit 4.1 to the Registrant s Current Report of Form 8-K filed December 8, 2009).
4.15	Form of Warrant to Purchase Common Stock issued to underwriters in connection with the Registrant s December 2009 public offering (incorporated by reference to Exhibit 4.1 to the Registrant s Current Report of Form 8-K filed December 8, 2009).
10.1	2003 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 to the Registrant s Registration Statement on Form SB-2, SEC File No. 333-129020, filed October 14, 2005).
10.2	Amendment No. 1 to 2003 Stock Incentive Plan of ZIOPHARM Oncology, Inc. (incorporated by reference to Exhibit 3.1 to the Registrant s Current Report on Form 8-K filed April 26, 2006).
10.3	Amendment No. 2 to 2003 Stock Incentive Plan of ZIOPHARM Oncology, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-QSB filed May 2, 2007).
10.4	Amendment No. 3 to 2003 Stock Incentive Plan of ZIOPHARM Oncology, Inc. (incorporated by reference to Exhibit 4.1 to the Registrant s Registration Statement on Form SB-2, SEC File No. 333-160496, filed July 9, 2009).
10.5	Employment Agreement dated as of January 8, 2008 by and between the Registrant and Dr. Jonathan Lewis. (incorporated by reference to exhibit 10.6 to the Registrant s Annual Report on Form 10-KSB filed February 21, 2008).
10.6	Employment Agreement dated as of June 25, 2008 between the Registrant and Richard E. Bagley (incorporated by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q filed July 30, 2008).
10.7	Patent and Technology License Agreement dated August 24, 2004, among ZIOPHARM, Inc. (predecessor to the Registrant), the Board of Regents of the University of Texas System on behalf of the University of Texas M.D. Anderson Cancer Center and the Texas A&M University System (incorporated by reference to Exhibit 10.5 to the Registrant s Registration Statement on Form SB-2, SEC File No. 333-129020, filed October 14, 2005).++
10.8	License Agreement dated October 15, 2004, between ZIOPHARM, Inc. (predecessor to the Registrant) and DEKK-Tec, Inc. (incorporated by reference to Exhibit 10.6 to the Registrant s Registration Statement on Form SB-2, SEC File No. 333-129020, filed October 14, 2005).++
10.9	Form of subscription agreement between the ZIOPHARM, Inc. and the investors in the Registrant s 2005 private placement (incorporated by reference to Exhibit 10.7 to the

Registrant s Registration Statement on Form SB-2, SEC File No. 333-129020, filed October 14, 2005).

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Exhibit No.	Description of Document
10.10	Form of Incentive Stock Option Agreement granted under 2003 Stock Option Plan (incorporated by reference to Exhibit 10.7 to the Registrant s Annual Report on Form 10-KSB filed March 20, 2006).
10.11	Form of Employee Non-Qualified Stock Option Agreement granted under 2003 Stock Option Plan (incorporated by reference to Exhibit 10.8 to the Registrant s Annual Report on Form 10-KSB filed March 20, 2006).
10.12	Form of Director Non-Qualified Stock Option Agreement granted under 2003 Stock Option Plan (incorporated by reference to Exhibit 10.9 to the Registrant s Annual Report on Form 10-KSB filed March 20, 2006).
10.13	Form of Subscription Agreement by and between ZIOPHARM Oncology, Inc. and investors in the ZIOPHARM Oncology, Inc. 2006 private placement (incorporated by reference to Exhibit 10.1 to the Registrant s Current Report of Form 8-K filed May 3, 2006).
10.14	Asset Purchase Agreement dated November 3, 2006 by and among Baxter Healthcare S.A., Baxter International, Inc., Baxter Oncology GmbH and ZIOPHARM Oncology, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-QSB filed November 13, 2006).++
10.15	License Agreement dated November 3, 2006 by and among Baxter Healthcare S.A., Baxter International, Inc. and ZIOPHARM Oncology, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10_QSB filed November 13, 2006).++
10.16	Amendment to License Agreement dated September 24, 2009 by and among Baxter Healthcare S.A., Baxter International, Inc. and ZIOPHARM Oncology, Inc.
10.17	Form of Securities Purchase Agreement by and between ZIOPHARM Oncology, Inc. and investors in the ZIOPHARM Oncology, Inc. February 2007 private placement (incorporated by reference to Exhibit 10.1 to the Registrant s Current Report of Form 8-K filed February 26, 2007).
10.18	Form of Registration Rights Agreement by and between ZIOPHARM Oncology, Inc. and investors in the ZIOPHARM Oncology, Inc. February 2007 private placement (incorporated by reference to Exhibit 10.2 to the Registrant s Current Report of Form 8-K filed February 26, 2007).
10.19	Form of Restricted Stock Agreement (incorporated by reference to Exhibit 10.1 to the Registrant s Current Report of Form 8-K filed December 18, 2007).
10.20	Form of Securities Purchase Agreement dated September 9, 2009 by and between ZIOPHARM Oncology, Inc. and investors in the ZIOPHARM Oncology, Inc. September 2009 private placement (incorporated by reference to Exhibit 10.1 to the Registrant s Current Report of Form 8-K filed September 15, 2009).
10.21	Form of Registration Rights Agreement dated September 9, 2009 by and between ZIOPHARM Oncology, Inc. and investors in the ZIOPHARM Oncology, Inc. September 2009 private placement (incorporated by reference to Exhibit 10.2 to the Registrant s Current Report of Form 8-K filed September 15, 2009).
23.1	Consent of Independent Registered Public Accounting Firm Caturano and Company, P.C.
31.1	Certification of Chief Executive Officer pursuant to Securities Exchange Act Rule 13a-15(e)/15d-15(e) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Securities Exchange Act Rule 13a-15(e)/15d-15(e) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	

Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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

++ Confidential treatment has been granted as to certain portions of this exhibit pursuant to Rule 406 of the Securities Act of 1933, as amended, or Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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Exhibit No.	Description of Document
23.1	Consent of Independent Registered Public Accounting Firm Caturano and Company, P.C.
31.1	Certification of Chief Executive Officer pursuant to Securities Exchange Act Rule 13a-15(e)/15d-15(e) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Securities Exchange Act Rule 13a-15(e)/15d-15(e) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.