ZIOPHARM ONCOLOGY INC

FORM 10-K
(Annual Report)

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

(Mark One)

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

For the Fiscal Year Ended December 31, 2008

OR

☐ **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 Incorporation or Organization)	(IRS Employer Identification No.)
1180 Avenue of the Americas, 19th Floor, New York, NY	**10036**
(Address of Principal Executive Offices)	(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 ☐ No ☒

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

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 ☒ No ☐

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. ☒

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 ☐	Accelerated Filer ☐
Non-Accelerated Filer ☐	Smaller Reporting Company ☒

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

The approximate aggregate market value of the registrant's common stock held by non-affiliates was $41,566,892 as of June

30, 2008 (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 12, 2009, there were 21,848,464 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 2009 annual meeting of stockholders, which is to be filed within 120 days after the end of the fiscal year ended December 31, 2008, are incorporated by reference into Part III of this Form 10-K, to the extent described in Part III.

TABLE OF CONTENTS

ZIOPHARM Oncology, Inc.

(A Development Stage Enterprise)

FORM 10-K
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2008

TABLE OF CONTENTS

Additional Information

Descriptions in this report are qualified by reference to the contents of any contract, agreement or other documents and are not necessarily complete. Reference is made to each such contract or document filed as an exhibit to this report, or previously filed by the Company pursuant to regulations of the Securities and Exchange Commission (the "SEC") (see "Item 15. Exhibits and Financial Statement Schedules").

References in this document to "us", "we", "our", "the Company", or "the registrant" refer to ZIOPHARM Oncology, Inc. On September 13, 2005, our wholly-owned subsidiary, ZIO Acquisition Corp., merged with and into ZIOPHARM, Inc. with ZIOPHARM, Inc. remaining as the surviving corporation and our wholly-owned subsidiary. This transaction is referred to throughout this report as the "Merger." On September 14, 2005, ZIOPHARM, Inc. merged with and into us, leaving us as the surviving corporation. In connection with this parent-subsidiary merger, we relinquished our prior corporate name, EasyWeb, Inc., and assumed in its place the name "ZIOPHARM Oncology, Inc." The parent-subsidiary merger and name change became effective on September 14, 2005. Unless provided otherwise, references in this document to "us", "we", "our", "the Company", or "the registrant" for periods prior to these transactions refer to ZIOPHARM, Inc. See "Business — Corporate Developments — Acquisition of ZIOPHARM, Inc."

Special Note Regarding Forward Looking Statements

This Annual Report on Form 10-K contains statements that are not historical, but are forward-looking in nature, including statements regarding the expectations, beliefs, intentions or strategies regarding the future. In particular, the discussion contained in this report under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operation" includes forward-looking statements that reflect our current views with respect to future events and financial performance. We use words such as we "expect," "anticipate," "believe," and "intend" and similar expressions to identify forward-looking statements. A number of important factors could, individually or in the aggregate, cause actual results to differ materially from those expressed or implied in any forward-looking statements. Such factors include, but are not limited to, our ability to develop successfully our product candidates, to obtain regulatory approval for such product candidates or to successfully commercialize them, our ability to obtain additional financing, our ability to develop and maintain vendor relationships, regulatory developments relating to and the general success of our products, and our ability to protect our proprietary technology. Other risks that may impact forward-looking statements contained in this Annual Report on 10-K are described under the heading "Risk Factors."

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. 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 developed in intravenous ("IV") and/or oral forms of administration. 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 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 for the remainder of the development program and for commercialization. With partnering, the Company could also negotiate the right to complete development and marketing in certain geographies, particularly for certain limited (niche) indications. Currently, we are 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 most advanced product candidate, IV palifosfamide, is currently in a phase II randomized controlled trial for the treatment of metastatic or unresectable soft tissue sarcoma as front- or second-line therapy in combination with doxorubicin (Adriamycin ™ , Doxil ™) and is presently the principal focus of our resources. We expect that clinical development of an oral capsule form of palifosfamide that we have developed preclinically will occur pending our obtaining additional working capital from financing alternatives or entering into a partnering arrangement.

Phase I studies with the oral capsule form of indibulin administered either by itself or in combination are nearing completion while additional preclinical study of different dosing schedules conducted with our consultant, Dr. Larry Norton, are nearing completion. Although we view the commercial opportunity for oral indibulin as substantial, we have prioritized our projects in what is a very challenging financial climate and expect that further clinical study of indibulin will similarly be subject to our obtaining additional financial resources or entering into partnering arrangements. Consistent with previously outlined plans, the Company intends to partner the further clinical development of darinaparsin (both IV and oral capsule) for hematological malignancies now that our exploratory phase I/II trials are almost completed. Our success in partnering darinaparsin will depend on our final data, on general market competitive conditions, and on the availability of investment capital to potential partners or other interested parties, and well as other factors outside of our control.

Our corporate office, which houses two 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 15 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.

It is reported that there are more than 100 different varieties of cancer divided into six major categories. Carcinomas, the most common type of cancer, originate in tissues that cover a surface or line a cavity of the body. Sarcoma begins in tissue that connects, supports or surrounds other tissues and organs. 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, and skin cancers, including melanomas, originate in the skin. 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 2007 (published in CA: Cancer Journal for Clinicians, vol. 57), it was estimated that 559,650 Americans would die from cancer in 2007 — 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 2006 was $206.3 billion. This cost included an estimate of $78.2 billion in direct medical expenses, $17.9 billion in indirect morbidity costs, and $110.2 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 themselves 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.

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®]); ("ATO") has been approved for the treatment of acute promyelocytic leukemia ("APL"). ATO is delivered intravenously (IV) 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 darinaparsin evaluating hematological malignancies, myeloma and liver cancer, are almost completed. Data from these trials have been reported, the most promising being in lymphomas.

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, is warranted and plans to pursue this study only upon entering into partnering arrangements or obtaining additional capital from other similar outside sources.

In addition, an oral darinaparsin phase I program is nearing completion in both solid tumors and hematological malignancies with the expected toxicity profile seen with the intravenous form and with early evidence of activity. Although the Company would, following the aforementioned partnering or other financial arrangement, recommend further study with the IV form initially, advancing the oral program based on the promise of use in solid tumors would likely follow.

The Company is actively seeking one or more partners, or other sources of funding, to progress the darinaparsin program into expanded phase II study and particularly certain sub-types of non-Hodgkin's lymphoma. If we cannot find a partner to fund the development of either one or both forms of darinaparsin, or obtain other funding that allows us to proceed on our own, we plan to complete the ongoing studies which are included in the Company's current estimate of expenses and then temporarily discontinue the development program for darinaparsin.

ZIO-201, Palifosfamide, Zymafos ™

General. Palifosfamide, or isophosphoramide mustard ("IPM"), is a proprietary active metabolite of the pro-drug ifosfamide. A number of patent applications have been filed in the U.S. and internationally. 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 the standard of care for sarcoma, it is not licensed for this indication by the U.S. Food and Drug Administration.

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. The prognosis for patients with soft tissue sarcomas 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.

Palifosfamide may be a useful agent that, either alone or in combination with other agents, 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. The Company believes that palifosfamide may be able to replace ifosfamide in any or all of these combination protocols.

Clinical Development Plan for palifosfamide. The phase I studies of IV palifosfamide (solid tumors and advanced sarcoma) have been completed. In both of these trials, palifosfamide was given without mesna and no treatment-related hemorrhagic cystitis or CNS-toxicity was reported. Bone marrow toxicity was modest and the dose-limiting toxicity was renal toxicity. One subject with mesothelioma had stable disease for more than 13 months and two patients with sarcoma had a response of stable disease or better.

A 50 patient phase II trial in advanced sarcoma is completed. Interim data from the study were reported in the fourth quarter of 2007 and updated near-final data in the fourth quarter of 2008. The trial indicated that palifosfamide was well tolerated, with renal toxicity being the most clinically relevant adverse event (a different stabilizing agent recently incorporated in the palifosfamide finished dosage form has not evidenced that renal toxicity to date). This study confirmed that IV palifosfamide is an active agent when used as a single agent in advanced sarcoma and the data therefore warranted further study toward a registration pathway.

The Company then initiated a Phase I study in which IV palifosfamide is administered in combination with doxorubicin, which is the most commonly used agent and combination for treating sarcoma, and palifosfamide evidenced considerable synergy with doxorubicin in preclinical study. With a combination dose established in that still ongoing study and with evidence of considerable activity, and an unchanged safety profile, all as reported in the fourth quarter of 2008, the Company initiated a Phase II randomized controlled trial to compare doxorubicin plus palifosfamide to doxorubicin alone in patients with front- and second-line metastatic or unresectable soft tissue sarcoma. The analysis of initial data from patients enrolled in this trial are expected to shape a Phase III trial in the same setting for initiation as early as the first half of 2010. The Company has also developed an oral capsule form of palifosfamide that tested favorably preclinically and, subject to obtaining additional financial resources or entering into partnering arrangements, is expected to be studied clinically. Importantly, 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, Indibulin, Zybulin ™

General. Indibulin is a novel small molecular-weight tubulin polymerization inhibitor that was acquired from Baxter Healthcare. 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 IV in the United States are currently on the market, including paclitaxel (Taxol®) and *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

TABLE OF CONTENTS

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 is evaluating safety, pharmacokinetics ("PK"), pharmacodynamics, biomarkers, maximum tolerated dose ("MTD"), and dose limiting toxicity ("DLT") in patients with advanced solid tumors; these trials are nearing completion and MTD has not yet been reached. Indibulin is well tolerated and clinical activity has been observed in patients with several histologic subtypes. Preclinical combination studies demonstrated synergy with erlotinib, docetaxel, and capecitabine and Phase I studies were initiated and are nearing interim conclusion in combination with erlotinib and capecitabine. Preclinical work with our consultant Dr. Larry Norton to explore dosing schedules is nearing completion with the intent of proceeding to establish a maximum tolerated dose using a schedule from preclinical study in further Phase II clinical study as further funding becomes available.

Competition

The development and commercialization for new products to treat cancer is highly competitive, and considerable competition from major pharmaceutical, biotechnology, and specialty cancer companies is anticipated. Many of our competitors have access to substantially more resources than we do, including both financial and technical. In addition, many of these companies have more experience in preclinical and clinical development, manufacturing, regulatory, and global commercialization. The Company is 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.

Patent and Technology License Agreement — 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 for human and animal use. One of these classes includes darinaparsin.

In October 2004, we received a notice of allowance for U.S. Patent Application No. 10/337969, entitled "S-dimethylarsino-thiosuccinic acid S-dimethylarsino-2-thiobenzoic acid S-(dimethylarsino) glutathione as treatments for cancer." The patent was granted on June 28, 2005 as U.S. Patent No. 6,911,471. The patent claims both therapeutic uses and pharmaceutical compositions containing a novel class of organic arsenicals, including darinaparsin, for the treatment of cancer. In February 2006, we announced a second organic arsenic patent that was issued under U.S. Patent No. 6,995,188. This patent provides further coverage of cancer treatment using organic arsenic, including darinaparsin, in combination with other agents or therapies. On July 29, 2008, an additional organic arsenic patent was issued under U.S. Patent No. 7,405,314, providing further coverage of cancer treatment using organic arsenic, including higher purity darinaparsin. Currently there are corresponding foreign applications relating to darinaparsin in various foreign countries **.**

As partial consideration for the license rights obtained by us, we paid the Licensors an upfront, nonrefundable $125,000 fee and issued 250,487 shares of our common stock to The University of Texas M. D. Anderson Cancer Center, and granted it an option to purchase an additional 50,222 shares of our common

stock for $0.002 per share. The option vested and became exercisable with respect to 25% of its shares upon the Company's filing of an Investigational New Drug ("IND") in the fiscal year ended December 31, 2005. During the year ended December 31, 2007, an additional 50% of the option vested and became exercisable upon completion of the dosing of the last patient for both the blood and solid tumor phase I trials for darinaparsin. We recorded a $120,492 stock compensation expense in connection

with vesting of 25,111 of the options granted outside of the Company's 2003 Stock Option Plan. The remainder of the option will vest and become exercisable with respect to 25% of the shares 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") for darinaparsin). As additional consideration for the license, the Licensors are entitled to receive up to an aggregate of $4.85 million in cash payments, payable in varying amounts, upon the achievement of certain milestones, including $100,000 that we paid upon the commencement of the phase I clinical trial for darinaparsin in May 2005 and $250,000 upon the dosing of the first patient in the Registrant-sponsored phase II clinical trial for darinaparsin in November 2006. The Licensors are entitled to receive royalty payments from sales of a licensed product (should such a product be approved for commercial sale), as well and a portion of any fees that we may receive from a sublicensee under certain circumstances. Finally, the license agreement provided that we enter into two separate sponsored research agreements with the Licensors, each of which required that we make annual payments of $100,000 for no less than two years following the contract's execution. We have the exclusive right to all intellectual property rights resulting from such research pursuant to the terms of the agreements. These sponsored research agreements and any related extensions expired on February 2008.

The agreement also contains other provisions that are customary and common to similar agreements within the industry, such as our right to sublicense our rights under the agreement. Nevertheless, if we sublicense our rights prior to the commencement of a 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 NDA), the Licensors will generally be entitled to receive a share of the payments we receive in exchange for the sublicense (subject to certain exceptions).

License Agreement with DEKK-Tec, Inc. On October 15, 2004, we entered into a license agreement with DEKK-Tec, Inc., pursuant to which we were granted an exclusive, worldwide license to the second of our lead product candidates, palifosfamide. The licensed patent estate includes two pending United States patent applications and numerous foreign counterparts.

As partial consideration for the license rights obtained by us, we paid DEKK-Tec an upfront, non-refundable $50,000 fee. In addition, DEKK-Tec is entitled to receive cash payments in an aggregate amount of up to $3.9 million, which are payable in varying amounts upon the occurrence of certain milestone events. The majority of these milestone payments will be creditable against future royalty payments, as referenced below. During the year ended December 31, 2006, the Company recorded a charge of $100,000 for achieving phase II milestones. We also issued DEKK-Tec an option to purchase up to 27,616 shares of our common stock for approximately $0.02 per share, of which 6,904 shares vested upon the execution of the license agreement. DEKK-Tec has since exercised the vested portion of the option in its entirety. The option will vest with respect to the remaining shares upon certain milestone events, culminating with final FDA approval of the first NDA submitted by us (or by our sublicensee) for palifosfamide. DEKK-Tec is entitled to receive royalty payments on the sales of palifosfamide should it be approved for commercial sale. The license agreement also contains other provisions customary and common in similar agreements within the industry.

Option and Research Agreements with Southern Research Institute . On December 22, 2004, we entered into an Option Agreement with Southern Research Institute ("SRI"), pursuant to which we were 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, we entered into a Research Agreement with SRI pursuant to which we agreed to spend a sum not to exceed $200,000 between the execution of the agreement and December 21, 2006, including a $25,000 payment that we 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 and the exclusively licensed patent estate includes one U.S. patent (U.S. Patent No. 6,197,760) and two foreign

patents as well as corresponding patent applications in Japan and Canada. An annual payment of $25,000 was made in 2008 and 2007 for maintenance of this option agreement.

Asset Purchase of Indibulin from Baxter Healthcare Corporation . On November 3, 2006, the Company signed a definitive Asset Purchase Agreement and License Agreement to acquire indibulin (and license rights to nanosuspension technology) from affiliates of Baxter Healthcare Corporation. The terms of the agreement include an upfront cash payment of approximately $1.125 million, which has been expensed as purchased research and development. In the year ended December 31, 2006, $15,000 was paid for annual patent and license maintenance fee, and $100,000 was paid for existing inventory. In addition to the upfront payments, there will be follow-on milestone cash payments that could amount to approximately $8 million in the aggregate and royalties on net sales typical of a product at this stage of development. During the year ended December 31, 2007, we paid $625,000 in milestone payments for the successful U.S. Investigational New Drug ("IND") application for indibulin.

Additionally, we paid $15,000 for the annual patent and license maintenance fee in the years ending December 31, 2008 and 2007. The purchase price includes the entire indibulin intellectual property portfolio as well as existing drug substance and capsule inventories.

The patent estate related to indibulin currently includes one U.S. patent (U.S. Patent No. 6,008,231) and eighteen (18) foreign patents that cover the indibulin molecule, as well as numerous corresponding pending foreign applications. In addition, there are three U.S. Patents (U.S. Patent Nos. 6,232,327, 6,693,119 and 7,452,910) and thirty-one (31) foreign patents covering methods of using indibulin as a cancer therapeutic, as well as three pending U.S. and numerous corresponding pending foreign applications.

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.

Collaboration agreement with Harmon Hill, LLC. On April 8, 2008, the Company signed a collaboration agreement for Harmon Hill, LLC to provide consulting and other services related to the Company's development and commercialization of oncology therapeutics. The initial term of the agreement is one year and may be renewed or extended. Under the agreement, the Company pays Harmon Hill $20,000 per month for the consulting services. In addition, under the agreement, (a) the Company agreed to pay Harmon Hill $500,000 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, Harmon Hill will be entitled to a royalty equal to one percent of the Company's net sales from the Specified Drug. Harmon Hill will be entitled to receive one percent of royalties received from a sublicensee in the event the Specified Drug is sublicensed. During the year ended December 31, 2008, the Company paid Harmon Hill $180,000 for consulting services per aforementioned contract. No milestones have been reached or accrued during the year ending December 31, 2008.

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 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 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 Agency'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 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 Good Manufacturing Practice ("cGMP") compliance is satisfactory. If the FDA evaluates the NDA and the manufacturing facilities as acceptable, the FDA may issue an approval letter, or in many cases, an approvable letter followed by an approval letter. Both letters usually contain a number of 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 17 full time and 3 part time employees.

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

If we do not succeed in raising additional funds on acceptable terms or if we cannot successfully enter into partnership agreements for the further development of our products, we will be unable to continue our planned preclinical and clinical trials or obtain approval for any of 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 and forego attractive business opportunities. In the event that we are unable to continue as a going concern, we may be forced to cease operations altogether or may elect or be required to seek protection from our creditors by filing a voluntary petition in bankruptcy or may be subject to an involuntary petition in bankruptcy.

We believe we have sufficient capital to continue enrolling patients in our ongoing randomized phase II trial for palifosfamide as we are currently seeking a partner to fund the development of darinaparsin and we complete our current trials with indibulin. Further work with indibulin is ongoing preclinically and will be further extended clinically if we are able to obtain sufficient additional capital. If we are unable to obtain sufficient additional capital, the program will be placed on hold. If we cannot find a partner to fund the development of darinaparsin, we intend to discontinue its development following the completion of ongoing trials. We are currently devoting a significant portion of our resources to the development of palifosfamide. Accordingly, the resources that we are devoting to the development of indibulin and darinaparsin have significantly diminished. As a result, further progress with the development of darinaparsin and indibulin, if any, may be significantly delayed and may depend on the success of our ongoing clinical trials involving palifosfamide.

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 year ended December 31, 2008, we had a net loss of $25.2 million and we had incurred approximately $85.0 million of cumulative net losses since our inception in 2003. We expect to continue to incur significant operating and capital 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 in the future as we:

- Continue to undertake preclinical development and 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.

Even if we succeed in developing and commercializing one or more of our product candidates, for which success is not assured, we may not be able to generate significant revenues. If we do generate significant revenues, we may never achieve or maintain profitability. Our failure to achieve or maintain profitability could negatively impact the trading price of our common stock.

If we are not able to successfully develop and commercialize our product candidates, we may not generate sufficient revenues

to continue our business operations.

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 continue our business without raising significant additional capital, which may not be available.

We may 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, 2008, we had incurred approximately $85.0 million of cumulative net losses and had approximately $11.4 million of cash, cash equivalents, and short-term investments. Currently and anticipating additional reductions in expense with no additional capital, we anticipate that we will have sufficient cash to fund our operations, principally related to the development of palifosfamide, late into the second quarter of 2010. However, changes may occur that would consume our existing capital prior to that time, including the progress of our research and development efforts, changes in governmental regulation, and acquisitions of additional product candidates.

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.

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. This dilution could be particularly substantial because the price of our stock is trading at historically low prices. In addition, we may grant future investors rights superior to those of our common 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 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.

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.

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.

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 early 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 early 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.

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.

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, regarding the safety and effectiveness of our drugs;
- Cost-effectiveness of our products relative to competing products;
- Availability of reimbursement for our products from government or other healthcare payers; and
- Effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

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.

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.
- 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.

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.

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.

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.

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 required to attest to the effectiveness of our internal control over financial reporting, as of December 31, 2009, in our Annual Report on Form 10-K for the fiscal year ending December 31, 2009. While management has not currently identified any material weaknesses in our internal control over financial reporting, there can be no assurance that our systems will be deemed effective when our independent registered public accounting firm reviews the systems during 2009 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 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 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. We have engaged the services of a Sarbanes-Oxley consultant to tighten our internal controls and ensure adherence to the regulations. 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 business days. In light of current market conditions, The Nasdaq Stock Market has suspended this listing requirement until April 20, 2009. Recently our stock has traded below $1.00, and if we fail to comply with the listing standards applicable to issuers listed on The NASDAQ Capital Market, our common stock may be delisted absent further suspension of the trading price requirements. 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.

Item 1B. Unresolved Staff Comments

Not applicable.

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 $11,000 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 that range from $9,947 during the current year of the lease to $10,759 during the last year of the lease. 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 $13,218 during the current year of the lease to $16,031 during the last year of the lease. The Company is presently exploring subletting a portion of its existing space to third parties but current unfavorable market conditions make this an unlikely outcome.

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, 2008.

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.

	2008		2007	
Quarter Ended	High	Low	High	Low
March 31	$ 3.65	$ 2.38	$ 5.97	$ 4.35
June 30	$ 3.39	$ 1.80	$ 6.50	$ 4.59
September 30	$ 2.19	$ 1.07	$ 5.45	$ 3.06
December 31	$ 1.78	$ 0.56	$ 3.60	$ 2.08

Record Holders

As of March 12, 2009, we had approximately 248 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.

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

We did not make any repurchases of our common stock during the fiscal year ended December 31, 2008.

Item 6. Selected Financial Data

Not applicable.

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

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 can be administered by intravenous ("IV") and/or oral capsule forms of administration. 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 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. The Company 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), with limited capital resources the Company's focus is on palifosfamide and more specifically on completing initial enrollment of 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 trial as early as the first half of 2010.

- ZIO-101 or darinaparsin 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®]; "ATO") has been approved in the United States and the European Union for the treatment of acute promyelocytic leukemia ("APL"), a precancerous condition. 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 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 inorganic arsenic, particularly with regard to cardiac toxicity. *In vitro* testing of darinaparsin using the National Cancer Institute's human cancer cell panel detected activity against a series of tumor cell lines including lung, colon, brain, melanoma, ovarian, and kidney cancer. Moderate activity was detected against breast and prostate cancer. 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. Preliminary 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 form of darinaparsin in solid tumors and hematological cancers has been completed. The Company has reported clinical activity and, importantly, a safety profile from these studies as predicted by preclinical results. The Company is nearing completion of Phase II studies in advanced myeloma, in certain other hematological cancers, and primary liver cancer. In addition, the Company is completing two Phase I studies with an oral capsule form of darinaparsin. Preliminary favorable results from the trial with IV-administered darinaparsin in hematologic cancers have been reported. Initial study results indicate efficacy and a favorable safety profile in various types of blood cancers. In the ongoing Phase I trials, preliminary reported data in solid tumors indicate the oral form is active and well tolerated. The Company is actively seeking a partner or partners, or other sources of funding, to progress both the IV and oral programs into phase II study in particular sub-types of non-Hodgkin's lymphoma. If we cannot find a partner to fund the development of either one or both forms of darinaparsin, we would intend to complete the ongoing studies which are included in the Company's current estimate of expenses and then discontinue the development program for darinaparsin.

- ZIO-201 or palifosfamide, is 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. Like cyclophosphamide and ifosfamide, palifosfamide is an alkylating agent. The Company believes 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. Ifosfamide has been shown to be effective at high doses in the treatment of sarcoma and lymphoma, either by itself or in combination with other anticancer agents. Ifosfamide is approved by the U.S. Food and Drug Administration ("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 U.S. Food and Drug Administration. 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.

Following a Phase I dose escalation study, Phase II testing of the intravenous form of palifosfamide as a single agent to treat advanced sarcoma has been completed. 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. With an earlier form of palifosfamide, that has been substituted in the clinic with a new form, kidney toxicity (Fanconi's Syndrome) and acute renal failure were reported primarily at doses significantly higher than the dose currently used in clinical trials. In clinical study to date with the new form, there have been no reports of kidney toxicity and palifosfamide has been otherwise well tolerated. The Company reported clinical activity of palifosfamide when used alone in the Phase II study addressing advanced sarcoma. Following review of the preclinical combination studies, clinical data, and discussion with sarcoma experts, the Company initiated a Phase I dose escalation study of palifosfamide in combination with doxorubicin in patients with metastatic or unresectable soft tissue sarcoma. In light of the 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 (enrollment completed, study ongoing), the Company has initiated a Phase II randomized controlled trial to compare doxorubicin plus palifosfamide to doxorubicin alone in patients with front and second-line metastatic or unresectable soft tissue sarcoma. Data from the initial patients in this trial are expected to shape a registration trial in the same setting which is expected to initiate as early as the first half of 2010. The Company is also developing an oral capsule form of palifosfamide to be studied clinically following further data from the IV trials and partnering or other sources of funding and is considering other 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.

- Indibulin is a novel, orally available small molecular-weight inhibitor of tubulin polymerization that was acquired from Baxter Healthcare 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 ^{TM} 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 ongoing 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 paclitaxel or related compounds are currently on the market in the United States.

Indibulin has completed a Phase I trial in Europe and two additional Phase I trials are nearing completion in the U.S. in patients with advanced solid tumors. The Company has reported signs of 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 have been enrolled with Tarceva® and Xeloda® and are reaching interim completion. Preclinical work with consultant Dr. Larry Norton is continuing to explore dose scheduling for the clinical setting. With the data from the phase I single agent and combination studies showing activity and with a dose limiting toxicity not yet reached, the Company has decided to continue the indibulin development program with a focus on Dr. Norton's dose scheduling findings and, with the availability of additional funding, with dose escalation to maximum tolerated dose using a schedule selected

from the preclinical work.

Although we intend to continue with clinical development of darinaparsin for lymphoma in conjunction with a partner, of palifosfamide for soft tissue sarcoma and of indibulin for solid tumors, the successful development of our product candidates is highly uncertain. Product development costs and timelines can vary significantly for each product candidate and are difficult to accurately predict. 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 is focused on completing the first 50 patients in the randomized Phase II trial for palifosfamide, partnering darinaparsin, and further establishing dose scheduling and maximum tolerated dose with indibulin. We expect our principal expenditures during those 12 months to be predominately for palifosfamide and include:

- Clinical trial expenses;
- Clinical trial expenses, including the close down and data collection expenses for darinaparsin and indibulin;
- Costs related to the manufacturing of palifosfamide for the first 50 patients in the palifosfamide randomized phase II trial;
- Rent for our facilities; and
- General corporate and working capital, including general and administrative expenses.

We intend 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.

With the planned development of palifosfamide and continued collection of indibulin data, with the intention of partnering further development of darinaparsin following completion of ongoing studies, and with other adjustments in our project and personnel expenses, including a recent workforce reduction of four positions in February 2009 and other loss of personnel, following the initial patient enrollment and assuming no additional capital from financing or partnering, we expect to incur, during the next twelve months, approximately $1.6 million on preclinical and regulatory expenses, approximately $3.1 million on clinical expenses (including clinical trials that we expect to be triggered under the license agreements relating to our product candidates), approximately $1.4 million on manufacturing costs, approximately $0.7 million on facilities, rent, and other facilities-related costs and approximately $3.7 million on general corporate and working capital.

With our current cash position, adjustments in staffing, aggressive cash management strategy and amortization of prepaid expenses, we believe that we currently have sufficient capital that will support our current operations strategy into the second quarter of 2010. 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 utilize our available capital resources sooner than we currently expect.

Product Candidate Development and Clinical Trials

Intravenous darinaparsin , organic arsenic, has been or is being tested in patients with advanced myeloma, other hematological malignancies, and liver cancer. Two separate Phase II trials have been completed with a third nearing completion. Recently reported positive results in patients with lymphoma have led to the expansion of the hematological trial focusing on non-Hodgkin's lymphoma. The Phase I trials with an oral form of darinaparsin are ongoing in solid tumors and have been also expanded to include non-Hodgkin’s lymphoma patients. The Company is in actively seeking partners and other sources of funding for continuing the development program of both the IV and oral forms in certain sub-types of non-Hodgkin’s lymphoma. If funding or partnering is not accomplished, the project will be terminated.

Intravenous palifosfamide , the proprietary form of isophosphoramide mustard, is being developed presently to treat soft tissue sarcoma. A Phase II trial in advanced sarcoma has been completed. A Phase I trial in combination with doxorubicin is fully enrolled with treatment still ongoing and with the combination well tolerated, evidencing activity, and with the dose combination established for further study. The Company has initiated a randomized controlled 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 intends to treat initial patients to develop a registration trial to initiate as early as the first half of 2010. An oral formulation has also been developed preclinically and, following further IV study results, additional funding or partnering, a phase I is expected to initiate. Other trials in solid tumors 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 a Phase I trial in Europe and two additional Phase I trials are nearing completion in the United States with preliminary results reported for all three trials. Phase I trials of indibulin in combination with Tarceva® and also with Xeloda® have been initiated and enrolled. Preclinical studies under the direction of Dr. Larry Norton to support clinical study of dose dense and metronomic dosing are well underway. Pending further results from the Norton preclinical work and available funding, the Company intends to further study indibulin with an identified schedule and to determine maximum tolerated dose prior to formal phase II testing in a selected solid tumor. If further funding is not available, the project will be placed on hold.

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. For the year ended December 31, 2008, research and development expenses decreased by $1,747,329, or 9.2%, to $17,245,306 from $18,992,635 in the year ended December 31, 2007. Decreased research and development expenses in the current year are 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 $777,000 in manufacturing related costs. These decreases were offset by approximately $217,000 due to increased payroll and related expenses in 2008.

General and administrative expenses. For the year ended December 31, 2008, general and administrative expenses decreased by $1,203,980, or 12.6%, to $8,373,878 from $9,577,858 in the year ended December 31, 2007. The decrease is primarily attributable to a decrease of approximately $660,000 in investor relations and financial consulting costs, a decrease of approximately $304,000 in payroll, stock compensation, and related expenses, a decrease of approximately $319,000 in patent and related expenses, and a decrease of approximately $188,000 in recruiting expenses. These decreases were slightly offset by an increase of approximately $260,000 in legal fees.

Other income (expense) . Other income decreased by $1,574,537, or 80.2%, to $387,710 in the year ended December 31, 2008 from $1,962,247 recorded in the year ended December 31, 2007. Other income during the year ended December 31, 2008 and 2007, respectively, 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.

Net income (loss). For the reasons described above, the net loss increased by $1,376,772, or 5.2%, to $25,231,474 in the year ended December 31, 2008 from $26,608,246 for the same period of 2007.

Results of Operations for the Fiscal Year Ended December 31, 2007 Versus December 31, 2006

Revenues. We had no revenues for years ended December 31, 2007 and 2006.

Research and development expenses. For the year ended December 31, 2007, research and development expenses increased by $8,601,333, or 82.8%, to $18,992,635 from $10,391,302 in the year ended December 31, 2006. Increased research and development expenses in 2007 were primarily attributable to an approximately $3.7 million increase in the cost of clinical trials, clinical milestone, and regulatory-related expenses, an increase of $0.5 million in preclinical related expenses, and an increase of approximately $3.4 million in manufacturing-related costs. The increase in expenses was also attributable to an increase of approximately $1.0 million in payroll and employee-related costs as a result of our increasing headcount and an approximate

increase of $0.3 million in non-cash stock compensation expense-related to grants of stock options.

General and administrative expenses. For the year ended December 31, 2007, general and administrative expenses increased by $857,568, or 9.8%, to $9,577,858 from $8,720,290 in the year ended December 31, 2006. The increase was attributable to an increase of approximately $300,000 in financial consulting costs, approximately $72,000 for investors relations services, approximately $0.5 million in legal and patent related fees, approximately $0.2 million in rent and related facility expenses, approximately $0.3 million for recruiting expenses, approximately $0.1 million for travel, meals, and other related expenses, and approximately $0.1 million for insurance, utilities, and office supply related expenses. The increase in expense was also attributed to an increase of approximately $1.0 million in payroll and employee-related costs resulting from our increasing headcount. These increases were offset by an approximate $1.7 million decrease in stock compensation expenses relating to grants of stock options recorded in the year ended December 31, 2006.

Other income (expense) . Other income increased by $707,574, or 56.4%, to $1,962,247 in the year ended December 31, 2007 from $1,254,673 recorded in the year ended December 31, 2006. Other income during the year ended December 31, 2007 and 2006, respectively, comprised interest income. The increase was due to higher cash balances, which was derived from our February 23, 2007 private placement of common stock and warrants that was made available for investing purposes. We received approximately $29.0 million in the net proceeds from this private placement.

Net income (loss). For the reasons described above, the net loss increased by $8,751,327, or 49.0%, to $26,608,246 in the year ended December 31, 2007 from $17,856,919 for the same period of 2006.

Liquidity and Capital Resources

As of December 31, 2008, we had approximately $11.4 million in cash and cash equivalents, down from $35.0 million in cash and cash equivalents as of December 31, 2007. Given the rate at we have historically used cash, the limited amount of cash for use in operations and the recent instability in the capital markets, we have taken measures to reduce our near term expenses while we seek additional financing and partnering arrangements for the development of certain drug candidates. We have reduced staffing, including a recent

workforce reduction of four positions in February 2009 and other personnel and project related expenses, and have focused our priorities, including changes in our clinical trial program and seeking a partner to continue the further development of darinaparsin. If we cannot find a partner to fund the development of either one or both forms of darinaparsin, we intend to discontinue the development of darinaparsin following the completion of ongoing trials for which associated expenses are included in the current forecast. If we are able to obtain additional financing, further studies will progress with regard to indibulin. Based on our current costs saving plan, we believe that we currently have sufficient capital to fund the development programs for palifosfamide into the second quarter of 2010 (see Development Plan). Because our business does not generate any cash flow, however, we will need to raise additional capital to continue development of the palifosfamide beyond that time or to continue development of our other product candidates. To the extent additional capital is not available when we need it, or if we cannot successfully enter into partnership agreements for the further development of our products, we may be forced to abandon some or all of our development efforts, which would have a material adverse effect on the prospects of our business. Further, our assumptions relating to the expected costs of development and commercialization and timeframe for completion are dependent on numerous factors other than available financing, including significant unforeseen delays in the clinical trial and regulatory approval process, which could be extremely costly. In addition, our estimates assume that we will be able to enroll a sufficient number of patients in each clinical trial.

The Company anticipates that losses will continue for the foreseeable future. At December 31, 2008, the Company's accumulated deficit was approximately $85.0 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;
- Costs associated the development of palifosfamide and indibulin and the further financing of darinaparsin development by a partner; and
- Costs of filing, prosecuting, defending and enforcing any patent claims and any other intellectual property rights, or other developments.

In order to continue our long-term plans for clinical trials and new product development, we will need to raise additional capital to continue to fund our research and development as well as operations after we exhaust our current cash resources. We expect to finance our cash needs through the sale of equity securities and strategic collaborations or debt financings or through other sources that may be dilutive to existing stockholders. 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. 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.

Since inception, our primary source of funding for our operations has been the private sale of our securities. During the year ended December 31, 2007, we received gross proceeds of approximately $30.9 million ($28,970,915 net of cash issuance costs) as a result of a 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, 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 engaged Paramount BioCapital, Inc., 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 $1,630,800 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 $222,000 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 the warrants issued in the 2007 offering at $4,724,169 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.

During the year ended December 31, 2006, we received gross proceeds of approximately $37 million ($34,280,121 net of cash issuance costs) as a result of the sale of an aggregate of 7,991,256 shares of common stock, at a price of $4.63 per share, in a private placement (the "2006 Offering") that was completed on May 3, 2006. In addition to these 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 engaged Paramount BioCapital, Inc. and Griffin Securities, Inc. (the "Placement Agents") as co-placement agents in connection with the 2006 Offering. In consideration for their services, the Company paid the Placement Agents and certain selected dealers engaged by the Placement Agents aggregate cash commissions of $2,589,966 and issued 7-year warrants to the Placement Agents and their designees to purchase an aggregate of 799,126 shares at an exercise price of $5.09 per share. The Company also agreed to reimburse the Placement Agents for their accountable expenses incurred in connection with the 2006 Offering.

During the year ended December 31, 2005, we received $4,815 proceeds from the exercise of stock options and gross proceeds of approximately $18.1 million ($16.8 net of issuance costs) as a result of the sale by ZIOPHARM, Inc. of Series A Convertible Preferred Stock in a private placement transaction. During the twelve months ended December 31, 2004, we received proceeds of approximately $4.5 million as a result of the sale by ZIOPHARM, Inc. of common stock in a private placement transaction.

At December 31, 2008, working capital was approximately $6.0 million, compared to working capital of approximately $29.2 million at December 31, 2007. The decrease in working capital reflects the use of funds for operations.

Capital expenditures were approximately $132,000 for the year ended December 31, 2008. We anticipate capital expenditures of approximately $14,000 for the fiscal year ended December 31, 2009.

Future minimum lease payments under operating leases as of December 31, 2008 are as follows (in thousands):

2009	$ 429
2010	287
2011	188
2012	128
Thereafter	—
Total future minimum lease payments	$1,032

Critical Accounting Policies and Significant Estimates

The preparation of financial statements requires the Company to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, the Company evaluates its estimates, including those related to accounting for stock-based compensation and research and development activities. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under difference assumptions or conditions.

Operating Expenses

Research and development expenses consist primarily of salaries and related personnel costs; fees paid to consultants and outside service providers for preclinical, clinical, and manufacturing development; legal expenses resulting from intellectual property prosecution and organizational affairs; and other expenses relating to the design, development, testing, and enhancement of our product candidates. We expense our research and development costs as they are incurred. General and administrative expenses consist primarily of salaries and related expenses for executive, finance, and other administrative personnel, recruitment expenses, professional fees and other corporate expenses, including business development and general legal activities.

Stock-based Compensation

The Company's most critical estimates consist of accounting for stock-based compensation. On January 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123(R) ("SFAS 123R") Share-Based Payment, using the modified prospective method, which results in the provision of SFAS 123R being applied only to the financial statements on a going-forward basis (that is, the prior period results have not been restated). Under the fair value recognition provisions of SFAS 123R, 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 Principles Board ("APB") Opinion No. 25, *Accounting for Stock Issued to Employees* , and related interpretations which resulted in account for employee share options at their intrinsic value in the financial statements.

The Company had previously adopted the provisions of SFAS No. 123, *Accounting for Stock-Based Compensation ("SFAS 123")* , as amended by SFAS No. 148, *Accounting for Stock-Based Compensation — Transition and Disclosure*, through disclosure only. SFAS 123 required the measurement of the fair value of stock option or warrants granted to employees to be included in the statement of operations or alternatively, disclosed in the notes to the financial statements. The Company previously accounted for stock-based awards to employees using the intrinsic value method as prescribed by Accounting Principles Board ("APB") Opinion No. 25, *Accounting for Stock Issued to Employee* , and related interpretations, and had elected the disclosure only alternative under SFAS 123. All stock-based awards to nonemployees were accounted for at their fair value in accordance with SFAS 123 and Emerging Issues Task Force ("EITF") 96-18, *Accounting for Equity Instruments that are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services* . 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. We expect to record additional non-cash compensation expense in the future, which may be significant.

Net Operating Losses and Tax Credit Carryforwards

We record income taxes using the asset and liability method. Deferred income tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and

liabilities and their respective income tax bases and operating loss and tax credit carryforwards. Our consolidated financial statements contain certain deferred tax assets, which have arisen primarily as a result of operating losses, as well as other temporary differences between financial and tax accounting. Statement of Financial Accounting Standards ("SFAS") No. 109 " *Accounting for Income Taxes* ," requires us to establish a valuation allowance if the likelihood of realization of the deferred tax assets is reduced based on an evaluation of objective verifiable evidence. Significant management judgment is required in determining our provision for income taxes, deferred tax assets and liabilities and any valuation allowance recorded against those net deferred tax assets. We evaluate the weight of all available evidence to determine whether it is more likely than not that some portion or all of the net deferred income tax assets will not be realized.

Impairment of Long-Lived Assets

Long-lived assets primarily include property and equipment. In accordance with SFAS No. 144, " *Accounting for the Impairment or Disposal of Long-Lived Assets* ," we periodically review long-lived assets for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable or that the useful lives are no longer appropriate. Each impairment test is based on a comparison of the undiscounted cash flows expected to result from the use and eventual disposition of the asset to the carrying amount of the asset. If impairment is indicated, the asset is written down to its estimated fair value based on a discounted cash flow analysis. Determining the fair value of long-lived assets includes significant judgment by management, and different judgments could yield different results.

Recent Accounting Pronouncements

In September 2006, the FASB issued SFAS No. 157, " *Fair Value Measurements*" ("SFAS 157"). This statement is effective for financial statements issued for fiscal years beginning after November 15, 2007. On February 6, 2008, the FASB announced it issued a FASB Staff Position (FSP) to allow a one-year deferral of adoption of SFAS 157 for nonfinancial assets and nonfinancial liabilities that are recognized at fair value on a nonrecurring basis. SFAS 157 provides a common fair value hierarchy for companies to follow in determining fair value measurements in the preparation of financial statements and expands disclosure requirements relating to how such fair value measurements were developed. SFAS 157 clarifies the principle that fair value should be based on the assumptions that the marketplace would use when pricing an asset or liability, rather than company specific data. This statement became effective for the Company on January 1, 2008. Adoption of this new standard did not have a material impact on the Company's financial position, results of operations or cash flows.

In February 2007, the FASB issued SFAS No. 159, " *The Fair Value Option for Financial Assets and Liabilities, Including an amendment of FASB Statement No. 115"* ("SFAS 159"). This statement permits entities to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value. SFAS 159 is effective as of the beginning of fiscal 2008. This statement became effective for the Company on January 1, 2008. Adoption of this new standard did not have a material impact on the Company's financial position, results of operations or cash flows.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), " *Business Combinations"* ("SFAS 141(R)"). SFAS 141 (R) expands the definition of a business combination and requires the fair value of the purchase price of an acquisition, including the issuance of equity securities, to be determined on the acquisition date. SFAS 141(R) also requires that all assets, liabilities, contingent considerations, and contingencies of an acquired business be recorded at fair value at the acquisition date. In addition, SFAS 141(R) requires that acquisition costs generally be expensed as incurred, restructuring costs generally be expensed in periods subsequent to the acquisition date, changes in accounting for deferred tax asset valuation allowances be expensed after the measurement period, and acquired income tax uncertainties be expensed after t he measurement period. SFAS 141(R) is effective for fiscal years beginning after December 15, 2008 with early adoption prohibited. SFAS 141(R) is effective for the Company beginning January 1, 2009 and will change accounting for business combinations on a prospective basis.

In June 2007, the Emerging Issues Task Force ("EITF") issued EITF Issue 07-03, " *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities* " ("EITF No. 07-03"). EITF No. 07-03 addresses the diversity which exists with respect to the accounting for the non-refundable portion of a payment made by a research and development entity for future research and development activities. Under EITF No. 07-03, an entity would defer and capitalize non-refundable advance payments made for research and development activities until the related goods are delivered or the related services are performed. EITF No. 07-03 did not have a material impact on our financial position, results of operations or cash flows.

In November 2007, the EITF issued EITF Issue 07-01 " *Accounting for Collaborative Arrangements* " (EITF No. 07-01).

EITF No. 07-01 requires collaborators to present the results of activities for which they act as the principal on a gross basis and report any payments received from (made to) other collaborators based on other applicable GAAP or, in the absence of other applicable GAAP, based on analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. Further,

EITF No. 07-01 clarified that the determination of whether transactions within a collaborative arrangement are part of a vendor-customer (or analogous) relationship subject to Issue 01-9, "Accounting for Consideration Given by a Vendor to a Customer". EITF No. 07-01 did not have a material impact on our financial position, results of operations or cash flows.

In May 2008, the FASB issued SFAS No. 162 " *The Hierarchy of Generally Accepted Accounting Principles* ." SFAS No. 162 identified the sources of accounting principles to be used in the preparation of financial statements of nongovernmental entities that are presented in conformity with generally accepted accounting principles (GAAP) in the United States. SFAS No. 162 01 did not have a material impact on our financial position, results of operations or cash flows.

Off-Balance Sheet Arrangements

We do not have any "off-balance sheet arrangements," as that term is defined by SEC regulation.

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 business operations 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- 9 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 required by Rule 13a-15(b) of the Exchange Act, as of the end of the period covered by this report. 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.

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, 2008, 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, 2008.

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, 2008 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

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, 2008 with respect to the 2003 Plan:

	Number of	Number of Securities Remaining Available for Future Issuance

Plan Category	Issued Upon Exercise of Outstanding Options (A)	Average Exercise Price of Outstanding Options (B)	Compensation Plans (Excluding Securities Reflected in Column (A)) (C)
Equity compensation plans approved by stockholders:			
2003 Stock Option Plan	2,378,089	$ 3.43	597,728
Total:	2,378,089	$ 3.43	597,728
Equity compensation plans not approved by stockholders:			
None	—	$ —	—
Total:	—	$ —	—

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.

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.

TABLE OF CONTENTS

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:

(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.

TABLE OF CONTENTS

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.

Date: March 23, 2009

By: /s/ Jonathan Lewis

Jonathan Lewis
Chief Executive Officer
(Principal Executive Officer)

Date: March 23, 2009

By: /s/ Richard Bagley

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

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 23, 2009
/s/ Richard Bagley Richard Bagley	Director, President, Chief Financial Officer, Treasurer and Chief Operating Officer (Principal Accounting and Financial Officer)	March 23, 2009
/s/ Murray Brennan Murray Brennan	Director	March 23, 2009
/s/ James Cannon James Cannon	Director	March 23, 2009
/s/ Timothy McInerney Timothy McInerney	Director	March 23, 2009
/s/ Wyche Fowler, Jr. Wyche Fowler, Jr.	Director	March 23, 2009
/s/ Gary S. Fragin	Director	March 23, 2009

Gary S. Fragin		
/s/ Michael Weiser	Director	March 23, 2009
Michael Weiser		

TABLE OF CONTENTS

ZIOPHARM Oncology, Inc.
(A Development Stage Enterprise)

INDEX TO FINANCIAL STATEMENTS

TABLE OF CONTENTS

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, 2008 and 2007 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, 2008 and for the period from September 9, 2003 (date of inception) through December 31, 2008. 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, 2008 and 2007 and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2008 and from September 9, 2003 (date of inception) through December 31, 2008 in conformity with accounting principles generally accepted in the United States of America.

Vitale, Caturano & Company, P.C.
Boston, Massachusetts
March 16, 2009

TABLE OF CONTENTS

ZIOPHARM ONCOLOGY, INC.
(A Development Stage Enterprise)

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

	December 31, 2008	December 31, 2007
ASSETS		
Current assets:		
Cash and cash equivalents	$ 11,379	$ 35,029
Prepaid expenses and other current assets	327	499
Total current assets	11,706	35,528
Property and equipment, net	489	746
Deposits	87	95
Other non current assets	291	357
Total assets	$ 12,573	$ 36,726
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,639	$ 2,909
Accrued expenses	3,137	3,397
Total current liabilities	5,776	6,306
Deferred rent	58	51
Total Liabilities	5,834	6,357
Commitments and contingencies (note 7)		
Stockholders' equity:		
Common stock, $.001 par value; 280,000,000 shares authorized; 21,860,464 and 21,298,964 shares issued and outstanding at December 31, 2008 and December 31, 2007, respectively	22	21
Preferred stock, $0.01 par value; 30,000,000 shares authorized and no shares issued and outstanding	—	—
Additional paid-in capital	71,274	69,674
Warrants issued	20,504	20,504
Deficit accumulated during the development stage	(85,061)	(59,829)

Total liabilities and stockholders' equity	$ 12,573	$ 36,727

The Accompanying Notes Are an Integral Part of These Financial Statements.

TABLE OF CONTENTS

ZIOPHARM ONCOLOGY, INC.
(A Development Stage Enterprise)

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

	Year Ended December 31,			Period from September 9, 2003 (Date of Inception) through December 31, 2008
	2008	2007	2006	
Research contract revenue	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development, including costs of research contracts	17,245	18,992	10,392	54,350
General and administrative	8,374	9,578	8,720	34,608
Total operating expenses	25,619	28,570	19,112	88,958
Loss from operations	(25,619)	(28,570)	(19,112)	(88,958)
Interest income	388	1,962	1,255	3,897
Net loss	$ (25,231)	$ (26,608)	$ (17,857)	$ (85,061)
Basic and diluted net loss per share	$ (1.19)	$ (1.41)	$ (1.42)	
Weighted average common shares outstanding used to compute basic and diluted net loss per share	21,232,663	18,832,351	12,571,951	

The Accompanying Notes Are an Integral Part of These Financial Statements.

TABLE OF CONTENTS

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, 2008

(In Thousands, Except Share and per Share Data)

	Convertible Preferred Stock and Warrants			Stockholders' Equity (Deficit)					
	Series A Convertible Preferred Stock		Warrants to Purchase Series A Convertible Preferred Stock	Common Stock		Additional Paid-In Capital	Warrants	Deficit Accumulated During the Development Stage	Total Stockholders' Equity/ (Deficit)
	Shares	Amount	Warrants	Shares	Amount				
Stockholders' contribution, September 9, 2003	—	$ —	$ —	250,487	$ —	$ 500	$ —	$ —	$ 500
Net loss	—	—	—	—	—	—	—	(160)	(160)
Balance at December 31, 2003	—	—	—	250,487	—	500	—	(160)	340
Issuance of common stock	—	—	—	2,254,389	2	4,498	—	—	4,500
Issuance of common stock for services	—	—	—	256,749	1	438	—	—	439
Fair value of options/warrants issued for nonemployee services	—	—	—	—	—	13	251	—	264
Net loss	—	—	—	—	—	—	—	(5,687)	(5,687)
Balance at December 31, 2004	—	—	—	2,761,625	$ 3	$ 5,449	$ 251	$ (5,847)	$ (144)

The Accompanying Notes Are an Integral Part of These Financial Statements.

TABLE OF CONTENTS

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, 2008
(In Thousands, Except Share and per Share Data)

	Convertible Preferred Stock and Warrants			Stockholders' Equity (Deficit)					
	Series A Convertible Preferred Stock		Warrants to Purchase Series A Convertible Preferred Stock	Common Stock		Additional Paid-In Capital	Warrants	Deficit Accumulated During the Development Stage	Total Stockholders' Equity/ (Deficit)
	Shares	Amount	Warrants	Shares	Amount				
Issuance of Series A convertible preferred stock (net of expenses									

warrant cost of $1,682,863)	4,197,946	15,077	—	—	—	—	—	—	15,077
Fair value of warrants to purchase Series A convertible preferred stock	—	—	1,683	—	—	—	—	—	1,683
Issuance of Common stock to EasyWeb Stockholders	—	—	—	189,922	—	—	—	—	—
Conversion of Series A convertible preferred stock @ $0.001 into $0.001 common stock on September 13, 2005 at an exchange ratio of .500974	(4,197,946)	(15,077)	(1,683)	4,197,823	4	15,073	1,683	—	—
Issuance of common stock for options	—	—	—	98,622	—	4		—	4
Fair value of options/warrants issued for nonemployee services	—	—	—	—	—	54	45	—	99
Net loss	—	—	—	—	—	—	—	(9,517)	(9,517)
Balance at December 31, 2005	—	—	—	7,247,992	7	20,580	1,979	(15,364)	7,202

The Accompanying Notes Are an Integral Part of These Financial Statements.

TABLE OF CONTENTS

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, 2008
(In Thousands, Except Share and per Share Data)

	Convertible Preferred Stock and Warrants			Stockholders' Equity (Deficit)					
	Series A Convertible Preferred Stock		Warrants to Purchase Series A Convertible Preferred Stock	Common Stock		Additional Paid-In Capital	Warrants	Deficit Accumulated During the Development Stage	Total Stockholders' Equity/ (Deficit)
	Shares	Amount	Warrants	Shares	Amount				
Issuance of common stock in private placement, net of expenses $2,719,395	—	—	—	7,991,256	8	21,180	—	—	21,188
Issuance of warrants	—	—	—	—	—	—	13,092	—	13,092
Issuance of common stock for services rendered	—	—	—	25,000	—	106	—	—	106
Stock based compensation									

Issuance of common stock due to exercise of stock options	—	—	—	5,845	—	25	—	—	25
Issuance of common stock due to exercise of stock warrants	—	—	—	2,806	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	(17,857)	(17,857)
Balance at December 31, 2006	—	—	—	15,272,899	15	44,668	15,071	(33,221)	26,533
Issuance of common stock in private placement, net of expenses $1,909,090	—	—	—	5,910,049	6	23,532	—	—	23,538
Issuance of warrants	—	—	—	—	—	—	5,433	—	5,433
Stock-based compensation for employees	—	—	—	—	—	1,318	—	—	1,318
Stock-based compensation for nonemployee	—	—	—	—	—	120	—	—	120
Issuance of common stock for stock options	—	—	—	46,016	—	36	—	—	36
Issuance of restricted stock	—	—	—	70,000	—	—	—	—	—
Net Loss	—	—	—	—	—	—	—	(26,608)	(26,608)
Balance at December 31, 2007	—	—	—	21,298,964	21	69,674	20,504	(59,829)	30,370

The Accompanying Notes Are an Integral Part of These Financial Statements.

TABLE OF CONTENTS

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, 2008
(In Thousands, Except Share and per Share Data)

	Convertible Preferred Stock and Warrants			Stockholders' Equity (Deficit)					
	Series A Convertible Preferred Stock		Warrants to Purchase Series A Convertible Preferred Stock	Common Stock		Additional Paid-In Capital	Warrants	Deficit Accumulated During the Development Stage	Total Stockholders' Equity/ (Deficit)
	Shares	Amount	Warrants	Shares	Amount				
Stock-based compensation	—	—	—	—	—	1,600	—	—	1,600
Issuance of restricted stock	—	—	—	586,500	1	(1)	—	—	—
Cancellation of restricted stock	—	—	—	(25,000)	—	—	—	—	—

Net loss	—	—	—	—	—	—	—	(25,231)	(25,231)
Balance at December 31, 2008	—	$ —	$ —	21,860,464	$ 22	$ 71,274	$ 20,504	$ (85,061)	$ 6,739

The Accompanying Notes Are an Integral Part of These Financial Statements.

TABLE OF CONTENTS

ZIOPHARM ONCOLOGY, INC.
(A Development Stage Enterprise)

STATEMENTS OF CASH FLOWS
(In Thousands)

	Year Ended December 31,			Period from September 9, 2003 (Date of Inception) through December 31, 2008
	2008	2007	2006	
Cash flows from operating activities:				
Net loss	$ (25,231)	$ (26,608)	$ (17,857)	$ (85,061)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	388	433	174	1,130
Stock-based compensation	1,600	1,439	2,883	6,723
(Gain) loss on disposal of fixed assets	0	9	(1)	9
Change in operating assets and liabilities:				
(Increase) decrease in:				
Prepaid expenses and other current assets	172	(36)	(251)	(327)
Other noncurrent assets	66	(179)	(54)	(291)
Deposits	8	(86)	(4)	(87)
Increase (decrease) in:				
Accounts payable	(270)	2,133	(60)	2,639
Accrued expenses	(259)	1,235	743	3,137
Deferred rent	7	10	6	58
Net cash used in operating activities	(23,519)	(21,650)	(14,421)	(72,070)
Cash flows from investing activities:				
Purchases of property and equipment	(132)	(738)	(354)	(1,629)
Proceeds from sale of property and equipment	1	—		1
(Increase) decrease in short-term investments	—	1,555	(1,555)	—
Net cash (used in) provided by investing activities	(131)	817	(1,909)	(1,628)
Cash flows from financing activities:				
Stockholders' capital contribution	—	—	—	500
Proceeds from exercise of stock options	—	35	25	66

warrants, net	—	28,971	34,280	67,751
Proceeds from issuance of preferred stock, net	—	—	—	16,760
Net cash provided by financing activities	—	29,006	34,305	85,077
Net increase (decrease) in cash and cash equivalents	(23,650)	8,173	17,975	11,379
Cash and cash equivalents, beginning of period	35,029	26,856	8,881	—
Cash and cash equivalents, end of period	$ 11,379	$ 35,029	$ 26,856	$ 11,379
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, in connection with private placement	$ —	$ 5,433	$ 13,093	$ 20,208
Preferred stock conversion to common stock	$ —	$ —	$ —	$ 16,760
Warrants converted to common shares	$ —	$ —	$ 18	$ 18

The Accompanying Notes Are an Integral Part of These Financial Statements.

TABLE OF CONTENTS

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, 2008, as defined by the Financial Accounting Standards Board (“FASB”) in Statement of Financial Accounting Standards (“SFAS”) No. 7, “ *Accounting and Reporting by Development Stage Enterprises* .” 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, 2008, the Company’s accumulated deficit was approximately $85.0 million. With the proceeds from its 2007 common stock offering, which was completed on February 23, 2007, the Company currently believes that it has sufficient capital to fund development and commercialization activities, principally for palifosfamide, late into the second quarter of 2010. 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. The Company is working with placement agents to obtain additional equity or debt financing. 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. 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. Financing

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 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 $1,019,250 was paid to Paramount; see Note 6 — 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

ZIOPHARM ONCOLOGY, INC.
(A Development Stage Enterprise)

NOTES TO FINANCIAL STATEMENTS

2. Financing – (continued)

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%.

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 its 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 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 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 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 FASB Staff Position No. EITF 00-19-2, *Accounting for Registration Payment Arrangements (*" FSP EITF 00-19-2"). In accordance with FSP EITF 00-19-2, the Company accounts for obligations under registration payment arrangements in accordance with SFAS No. 5, *Accounting for Contingencies* . Instruments subject to registration payments are accounted for without regard to the contingent obligation to make registration payments. In accordance with FSP EITF 00-19-2, the warrants have been classified as permanent equity. 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 (each a "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 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 — 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

ZIOPHARM ONCOLOGY, INC.
(A Development Stage Enterprise)

NOTES TO FINANCIAL STATEMENTS

2. Financing – (continued)

(10 percent of the Shares sold in the 2006 Offering) at an exercise price of $5.09 per share (the "Placement Agent Warrants"). 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 Offering, the Company agreed to use its best efforts to (i) file a registration statement covering the resale of the Shares and the common stock issuable upon exercise of the Warrants and 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.

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 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 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 May 3, 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

ZIOPHARM ONCOLOGY, INC.
(A Development Stage Enterprise)

NOTES TO FINANCIAL STATEMENTS

2. Financing – (continued)

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 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 — 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. It is management's opinion that the accompanying consolidated financial statements reflect all adjustments (which are normal and recurring) that are necessary to present fairly the Company's financial position at December 31, 2008 and 2007 and results of operations and cash flows for the years ended December 31, 2008, 2007, 2006 and the period from September 3, 2003 (date of inception) through December 31, 2008.

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

ZIOPHARM ONCOLOGY, INC.
(A Development Stage Enterprise)

NOTES TO FINANCIAL STATEMENTS

3. Summary of Significant Accounting Policies – (continued)

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.

Cash and Cash Equivalents

Cash equivalents consist of short-term, highly liquid high-grade investments with a maturity of ninety days or less when purchased. 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.

Short-Term Investments

The Company accounts for its short-term investments in accordance with SFAS No. 115, *" Accounting for Certain Investments in Debt and Equity Securities."* The Company's investments, which are carried at fair value, consist of funds comprised of certificate of deposits with maturities over ninety days. No short-term investments were on the Company's balance sheet as of December 31, 2008 and 2007.

Fair Value of Financial Instruments

The carrying amounts of cash equivalents, accounts payable and accrued expenses approximate their fair value because of their short-term nature.

Income Taxes

The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the Company's financial statements or tax returns. Deferred tax assets and liabilities are determined based upon the difference between the financial reporting basis and the tax basis of existing assets and liabilities using enacted tax rates expected to be in effect in the year(s) in which the differences are expected to reverse. A valuation allowance is provided against deferred tax assets if it is more likely than not that such assets will not be realized.

In July 2006, the Financial Accounting Standards Board issued Interpretation No. ("FIN") 48, *Accounting for Uncertainty in Income Taxes* . This Interpretation sets forth a recognition threshold and valuation method to recognize and measure an income tax position taken, or expected to be taken, in a tax return. The evaluation is based on a two-step approach. The first step requires an entity to evaluate whether the tax position would "more likely than not," based upon its technical merits, be sustained upon examination by the appropriate taxing authority. The second step requires the tax position to be measured at the largest amount of tax benefit that is greater than 50 percent likely of being realized upon ultimate settlement. In addition, previously recognized benefits from tax positions that no longer meet the new criteria would no longer be recognized. The application of this Interpretation will be considered a change in accounting principle with the cumulative effect of the change recorded to the opening balance of retained earnings in the period of adoption. This Interpretation was effective for the Company on January 1, 2007. Adoption of this new Standard did not have a material impact on our financial position, results of operations or cash flows (see Note 8 — Income Taxes).

ZIOPHARM ONCOLOGY, INC.
(A Development Stage Enterprise)

NOTES TO FINANCIAL STATEMENTS

3. Summary of Significant Accounting Policies – (continued)

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. There have been no material retirements or sale of assets since September 3, 2003 (date of inception).

Long-Lived Assets

In accordance with SFAS No. 144, " *Accounting for the Impairment or Disposal of Long-Lived Assets* ," 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.

Research and Development Costs

Costs related to research and development are charged to the Statement of Operations when 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.

Accounting for Stock-Based Compensation

On January 1, 2006, the Company adopted SFAS No. 123(R), " *Share-Based Payment* ," using the modified prospective method, which results in the provision of SFAS 123R only being applied to the financial statements on a going-forward basis (that is, the prior period results have not been restated). Under the fair value recognition provisions of SFAS 123R, 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 Principles Board ("APB") Opinion No. 25, " *Accounting for Stock Issued to Employees* ," and related interpretations which resulted in account for employee share options at their intrinsic value in the financial statements.

The adoption of SFAS 123R resulted in incremental stock-based compensation expense which caused the Company's net loss to increase by $1.6 million and $1.3 million or $0.08 and $0.07 per share, for the years ended December 31, 2008 and 2007, respectively. The adoption had no impact on cash used in operating activities or cash provided by financing activities.

In November 2005, the FASB released the final FASB Staff Position No. FAS 123(R)-3, " *Transition Election Related to Accounting for the Tax Effects of Share-Based Payment Awards* " ("FSP FAS 123(R)-3"). Effective January 1, 2006, the

Company adopted FSP FAS 123(R)-3, which provides the Company the option to use the "short-cut method" for calculating the historical pool of windfall tax benefits upon adopting SFAS 123(R).

The Company recognized the full impact of its share-based employee payment plans in the statements of operations for each of the years ended December 31, 2008, 2007, and 2006 under SFAS 123R and did not capitalize any such costs on the balance sheets. The Company recognized $1.4 million, $1.3 million, and $2.8 million of compensation expense related to vesting of stock options during the year ended December 31, 2008, 2007, and 2006, respectively. In the years ended December 31, 2008, 2007, and 2006, the company

ZIOPHARM ONCOLOGY, INC.
(A Development Stage Enterprise)

NOTES TO FINANCIAL STATEMENTS

3. Summary of Significant Accounting Policies – (continued)

recognized $289 thousand, $9 thousand, and $0 of compensation expense, respectively, related to vesting of restricted stock (see Note 10 — Stock Option Plan). The following table presents share-based compensation expense included in the Company's Statements of Operations:

	For the Year Ended December 31,		
	2008	2007	2006
	(In Thousands)		
Research and development, including costs of research contracts	$ 493	$ 545	$ 375
General and administrative	1,107	773	2,402
Share based employee compensation expense before tax	1,600	1,318	2,777
Income tax benefit	—	—	
Net share based employee compensation expense	$ 1,600	$ 1,318	$ 2,777

The Company had previously adopted the provisions of SFAS No. 123, " *Accounting for Stock-Based Compensation* " ("SFAS 123"), as amended by SFAS No. 148, " *Accounting for Stock-Based Compensation — Transition and Disclosure* ," through disclosure only. SFAS 123 required the measurement of the fair value of stock option or warrants granted to employees to be included in the statement of operations or alternatively, disclosed in the notes to the financial statements. The Company previously accounted for stock-based awards to employees using the intrinsic value method as prescribed by Accounting Principles Board ("APB") Opinion No. 25, " *Accounting for Stock Issued to Employee* ," and related interpretations, and had elected the disclosure-only alternative under SFAS 123. All stock-based awards to nonemployees were accounted for at their fair value in accordance with SFAS 123 and Emerging Issues Task Force ("EITF") 96-18, " *Accounting for Equity Instruments that are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services"* ("EITF 96-18"). 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 SFAS 123 to stock-based awards from September 9, 2003 (date of inception) to December 31, 2005:

	September 9, 2003 (Date of Inception) to December 31, 2005
	(In Thousands, Except per Share Data)
Net loss:	
As reported	$ (15,364)
Stock-based compensation expense included in reported net loss	802

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 2008, 2007, and 2006 was approximately $1.20, $2.66 and $4.10 per share, respectively. Assumptions regarding volatility, expected term, dividend yield and risk-free interest rate are required for the Black-Scholes model. The volatility assumption is based on the Company's historical experience. The risk-free interest rate is based

ZIOPHARM ONCOLOGY, INC.
(A Development Stage Enterprise)

NOTES TO FINANCIAL STATEMENTS

3. Summary of Significant Accounting Policies – (continued)

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 the Securities and Exchange Commissions 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:

	2008	2007	2006
Weighted average risk-free interest rate	1.52 – 3.49%	3.48 – 5.03%	4.53 – 5.02%
Expected life in years	5	5	5
Expected volatility	94 – 99%	91 – 96%	92 – 102%
Expected dividend yield	0	0	0

Net Loss Per Share

Consistent with SFAS No. 128, “ *Earnings Per Share* ” (“SFAS 128”) basic loss per share amounts are based on the weighted-average number of shares of common stock outstanding during the period. Diluted loss per share amounts are based on the weighted average number of shares of common stock and potentially dilutive common stock outstanding during the period. The impact of options, warrants, and non-vested restricted stock to purchase 8,364,248, 7,906,659, and 5,593,377 shares of common stock have been excluded from the calculation of diluted weighted-average share amounts as their inclusion would have been anti-dilutive for 2008, 2007, and 2006, respectively.

Recent Accounting Pronouncements

In September 2006, the FASB issued SFAS No. 157, “ *Fair Value Measurements* ” (“SFAS 157”). This statement is effective for financial statements issued for fiscal years beginning after November 15, 2007. On February 6, 2008, the FASB announced it issued a FASB Staff Position (FSP) to allow a one-year deferral of adoption of SFAS 157 for nonfinancial assets and nonfinancial liabilities that are recognized at fair value on a nonrecurring basis. SFAS 157 provides a common fair value hierarchy for companies to follow in determining fair value measurements in the preparation of financial statements and expands disclosure requirements relating to how such fair value measurements were developed. SFAS 157 clarifies the principle that fair value should be based on the assumptions that the marketplace would use when pricing an asset or liability, rather than company specific data. This statement became effective for the Company on January 1, 2008. Adoption of this new standard did not have a material impact on the Company’s financial position, results of operations or cash flows.

In February 2007, the FASB issued SFAS No. 159, “ *The Fair Value Option for Financial Assets and Liabilities, Including an Amendment of FASB Statement No. 115* ” (“SFAS 159”). This statement permits entities to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value. SFAS 159 is

effective as of the beginning of fiscal 2008. This statement became effective for the Company on January 1, 2008. Adoption of this new standard did not have a material impact on the Company's financial position, results of operations or cash flows.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), " *Business Combinations* " ("SFAS 141(R)"). SFAS 141 (R) expands the definition of a business combination and requires the fair value of the purchase price of an acquisition, including the issuance of equity securities, to be determined on the acquisition date. SFAS 141(R) also requires that all assets, liabilities, contingent considerations, and contingencies of an acquired business be recorded at fair value at the acquisition date. In addition, SFAS 141(R) requires that acquisition costs generally be expensed as incurred, restructuring costs generally be expensed in periods subsequent to the acquisition date, changes in accounting for deferred tax asset valuation allowances be

ZIOPHARM ONCOLOGY, INC.
(A Development Stage Enterprise)

NOTES TO FINANCIAL STATEMENTS

3. Summary of Significant Accounting Policies – (continued)

expensed after the measurement period, and acquired income tax uncertainties be expensed after t he measurement period. SFAS 141(R) is effective for fiscal years beginning after December 15, 2008 with early adoption prohibited. SFAS 141(R) is effective for the Company beginning January 1, 2009 and will change accounting for business combinations on a prospective basis.

In June 2007, the Emerging Issues Task Force ("EITF") issued EITF Issue 07-03, " *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities* " ("EITF No. 07-03"). EITF No. 07-03 addresses the diversity which exists with respect to the accounting for the non-refundable portion of a payment made by a research and development entity for future research and development activities. Under EITF No. 07-03, an entity would defer and capitalize non-refundable advance payments made for research and development activities until the related goods are delivered or the related services are performed. EITF No. 07-03 did not have a material impact on our financial position, results of operations or cash flows.

In November 2007, the EITF issued EITF Issue 07-01 " *Accounting for Collaborative Arrangements* " (EITF No. 07-01). EITF No. 07-01 requires collaborators to present the results of activities for which they act as the principal on a gross basis and report any payments received from (made to) other collaborators based on other applicable GAAP or, in the absence of other applicable GAAP, based on analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. Further, EITF No. 07-01 clarified that the determination of whether transactions within a collaborative arrangement are part of a vendor-customer (or analogous) relationship subject to Issue 01-9, "Accounting for Consideration Given by a Vendor to a Customer". EITF No. 07-01 did not have a material impact on our financial position, results of operations or cash flows.

In May 2008, the FASB issued SFAS No. 162 " *The Hierarchy of Generally Accepted Accounting Principles* ." SFAS No. 162 identified the sources of accounting principles to be used in the preparation of financial statements of nongovernmental entities that are presented in conformity with generally accepted accounting principles (GAAP) in the United States. SFAS No. 162 01 did not have a material impact on our financial position, results of operations or cash flows.

4. Property and Equipment, Net

Property and equipment, net consist of the following:

	December 31,	
	2008	2007
	(In Thousands)	
Office and computer equipment	$ 375	$ 475
Software	328	325
Leasehold improvements	284	225
Manufacturing equipment	12	12

Less accumulated depreciation	(510)	(291)
Property and equipment, net	$ 489	$ 746

Depreciation and amortization charged to the Statement of Operations for the years ended December 31, 2008, 2007, 2006 and from September 9, 2003 (date of inception) to December 31, 2008 (in thousands) was: $388, $433, $174 and $1,130, respectively.

During the year ended December 31, 2008, the Company retired and disposed of $169 thousand of property and equipment which was fully depreciated. There were no gains or losses on the disposal.

ZIOPHARM ONCOLOGY, INC.
(A Development Stage Enterprise)

NOTES TO FINANCIAL STATEMENTS

4. Property and Equipment, Net – (continued)

Additionally, during the year ended December 31, 2008, $1 thousand of property and equipment with accumulated depreciation of $0.6 thousand was sold for $0.7 thousand.

During the year ended December 31, 2007, the Company retired and disposed of $459 thousand of property and equipment with accumulated depreciation of $449 thousand resulting in a loss on retirement of $10 thousand.

5. Accrued Expenses

Accrued expenses consist of the following:

	December 31,	
	2008	2007
	(In Thousands)	
Manufacturing services	$ 1,512	$ 1,226
Clinical consulting services	1,229	1,507
Professional services	152	124
Research and development consulting services	110	123
Accrued vacation	42	35
Employee compensation	9	275
Other	83	107
Accrued expenses	$ 3,137	$ 3,397

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 $60,000 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

ZIOPHARM ONCOLOGY, INC.
(A Development Stage Enterprise)

NOTES TO FINANCIAL STATEMENTS

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 $1,726,644. 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.

7. Commitments and Contingencies

Operating Leases

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

amount of $60 thousand naming the Company's landlord as beneficiary. As of December 31, 2008 and 2007, 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 expires in September 2009. In connection with this lease agreement the Company provided a security deposit of $4 thousand. At December 31, 2007, the Company has classified

ZIOPHARM ONCOLOGY, INC.
(A Development Stage Enterprise)

NOTES TO FINANCIAL STATEMENTS

7. Commitments and Contingencies – (continued)

this amount in deposits on the balance sheet. This lease was terminated in December 2008 in consideration of a payment of $12 thousand, equaling three months rent. At December 31, 2008, the Company has 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 and 2007, the Company has classified this amount in deposits 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 September 2012. In connection with this lease agreement the Company provided a security deposit of $45 thousand. At December 31, 2008 and 2007, the Company has classified this amount in deposits on the balance sheet.

Future minimum lease payments under operating leases as of December 31, 2008 are as follows (in thousands):

2009	$	429
2010		287
2011		188
2012		128
Thereafter		—
Total future minimum lease payments	$	1,032

Total rent expense was approximately $506 thousand, $593 thousand, $253 thousand and $1.7 million for the years ended December 31, 2008, 2007, 2006 and for September 9, 2003 (date of inception) to December 31, 2008, 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, 2008 and 2007 of $58 thousand and $51 thousand, respectively, which is recorded in deferred rent on the accompanying 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 US 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.

In October 2004, the Company received a notice of allowance for US Patent Application No. 10/337969, entitled “S-dimethylarsino-thiosuccinic acid S-dimethylarsino-2-thiobenzoic acid S-(simethylarsino) glutathione as treatments for cancer.” The patent application claims both therapeutic uses and pharmaceutical compositions containing a novel class of organic

arsenicals, including darinaparsin, for the treatment of cancer. In February 2006, we announced that a second organic arsenic case has been issued under U.S. Patent No. 6995188. This patent provides further coverage of cancer treatment using organic arsenic, including darinaparsin, in combination with other agents or therapies. On July 29, 2008, an additional organic arsenic patent was issued under U.S. Patent No. 7,405,314, providing further coverage of cancer treatment using

ZIOPHARM ONCOLOGY, INC.
(A Development Stage Enterprise)

NOTES TO FINANCIAL STATEMENTS

7. Commitments and Contingencies – (continued)

organic arsenic, including higher purity darinaparsin. Currently there are corresponding foreign applications relating to darinaparsin in various foreign countries.

As partial consideration for the license rights obtained, the Company made an upfront payment of $125 thousand and granted the Licensors 250,487 (500,000 pre-Merger) shares of our common stock. The Company expensed the $125 thousand upfront payment and recognized research and development compensation expense of $426 thousand in connection with the issuance of the 250,487 shares of common stock in the year ended December 31, 2004. In addition, the Company issued options to purchase an additional 50,222 (100,250 pre-Merger) shares outside the 2003 Stock Option Plan for $0.002 per share following the successful completion of certain clinical milestones. Upon the filing of an Investigation New Drug Application (“IND”) for darinaparsin in 2005, 12,555 (25,063 pre-Merger) shares vested and the Company recognized compensation expense of $54 thousand. Upon the completion of dosing of the last patient for both phase I clinical trials in 2007, 25,111 (50,125 pre-Merger) shares vested and the Company recognized compensation expense of $120 thousand. The remaining 12,556 (25,062 pre-Merger) 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”) for darinaparsin). The options were subject to accounting pursuant to EITF 96-18, and therefore are valued at the date which the milestones are achieved. In addition, the Licensors are entitled to receive certain milestone payments (the “Anderson Milestones”), including $100,000 that was paid upon the commencement of phase I clinical trial for which the Company recognized the expense in the year ended December 31, 2005 and $250 thousand upon the dosing of the first patient in the Registrant-sponsored phase II clinical trial for darinaparsin which was recognized in the year ended December 31, 2006. 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 $4.9 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. For the years ended December 31, 2007 and 2006, the Company expensed $100 thousand for payments made to the Licensors to conduct scientific research. The Company has the exclusive right to all intellectual property rights resulting from such research pursuant to the terms of the license agreement. These sponsored research agreements and any related extensions expired in February 2008 with no payments being made in 2008.

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 to the second lead product candidate, palifosfamide. As part of the signing of license agreement with DEKK-Tec, the Company expensed a $50 thousand up-front payment in the year ended December 31, 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 $3,900,000. Of the aggregate milestone payments, most of the total amount will be creditable

TABLE OF CONTENTS

ZIOPHARM ONCOLOGY, INC.
(A Development Stage Enterprise)

NOTES TO FINANCIAL STATEMENTS

7. Commitments and Contingencies – (continued)

against future royalty payments, as referenced below. During the year ended December 31, 2006, the Company recorded a charge of $100 thousand for achieving phase II milestones. Additionally in 2004, the Company issued DEKK-Tec an option to purchase 27,616 shares of our common stock for $0.02 per share. The options were subject to accounting pursuant to EITF 96-18, and therefore are valued at the date which the milestones are achieved. Upon the execution of the license agreement, 6,904 shares vested and were exercised in the fiscal year ended December 31, 2005 and resulted in a recorded charge of $12 thousand to research and development expense. In regard to these options, the Company has estimated the fair value of such options using the Black-Scholes model, using an assumed risk-free rate of 3.35%, and expected life of 5 years, volatility of 134% and dividend yield of 0%. The remaining options will vest upon certain milestone events, culminating with final FDA approval of the first NDA submitted by the Company (or by our sublicensee) for palifosfamide. DEKK-Tec is entitled to receive royalty payments on the sales of palifosfamide should it be approved for commercial sale.

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 (the "SRI Option").

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 "SRI Research Program"). Under the terms of the Option Agreement, the Company's exclusive right to exercise the SRI Option will expire sixty days after the termination or expiration of the SRI Research Program and the delivery of the reports required thereunder. The option agreement was exercised on February 13, 2007 and an annual payments of $25 thousand were made in the years ended December 31, 2008 and 2007 for maintenance of this option agreement (see Note 6 — Related Party Transactions).

License Agreement with Baxter Healthcare Corporation

On November 3, 2006, the Company signed a definitive Asset Purchase Agreement (for indibulin) and License Agreement (to Baxter's proprietary nanosuspension technology) with affiliates of Baxter Healthcare Corporation. 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 available as both an oral and a proprietary nanosuspension intravenous form. Molecules that target mitosis and inhibit cell division (antimitotic agents) are a major focus of cancer research and they are among the most widely used anti-cancer drugs in oncology today. Among the more well known antimitotic drugs are the taxanes (paclitaxel, docetaxel) and the vinca alkaloids (vincristine, vinblastine). The terms of the agreement include an upfront cash payment of approximately $1.1 million, which has been expensed as purchased research and development in the year ended December 31, 2006. In addition, $15 thousand was paid for annual patent and license maintenance fee and $100 thousand was paid for existing inventory during 2006. During the year ended December 31, 2007, the Company recorded an expense of $625 thousand related to the achievement of a milestone for the successful US IND application for indibulin and also paid an additional $15 thousand for the annual patent and license maintenance fee. In 2008, the Company paid $15 thousand for the annual patent and license maintenance fee. In addition to the upfront costs, there will be additional milestone payments that could amount to approximately $8 million in the aggregate and royalties on net sales. The purchase price includes the entire indibulin intellectual property portfolio as well as existing drug substance and capsule inventories.

TABLE OF CONTENTS

7. Commitments and Contingencies – (continued)

Collaboration agreement with Harmon Hill, LLC

On April 8, 2008, the Company signed a collaboration agreement for Harmon Hill to provide consulting and other services for the development and commercialization of oncology therapeutics by ZIOPHARM. The initial term is one year and may be renewed or extended. The Company shall pay Harmon Hill $20 thousand per month for the consulting services. In addition the Company agrees 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 LLC. A 1% award of royalties received from a sublicensee will be given to Harmon Hill in any event that the Specified Drug is sublicensed. During the year ended December 31, 2008, the Company paid and expensed $180 thousand for consulting services per aforementioned contract. No milestones have been reached or accrued during the year ending December 31, 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 under FIN 45, *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others — An Interpretation of FASB Statements No. 5, 57, and 107 and Rescission of FASB Interpretation No. 34* .

8. 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, 2008 and 2007 are as follows:

	December 31,	
	2008	**2007**
	(In Thousands)	
Net operating loss carryforwards	$ 6,465	$ 5,917
Start-up and organizational costs	23,199	14,385
Research and development credit carryforwards	1,665	1,191
Stock compensation	475	393
Accrued bonus	—	10
Depreciation	(27)	12
Other	460	159
	32,237	22,067
Less valuation allowance	(32,237)	(22,067)
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, 2008, the Company has aggregate net operating loss carryforwards for federal tax purposes of approximately $16.1 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 2028. Additionally, the Company has approximately $1.6 million of research and development credits at December 31, 2008, expiring

ZIOPHARM ONCOLOGY, INC.
(A Development Stage Enterprise)

NOTES TO FINANCIAL STATEMENTS

8. Income Taxes – (continued)

in varying amounts through 2028, which may be available to reduce future taxes. Under the IRC, 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. The net operating loss carryforwards for the year ended December 31, 2008 includes approximately $15 thousand resulting from excess tax deductions from stock options exercised in 2007. Pursuant to SFAS No. 123R, 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 $3.6 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,		
	2008	2007	2006
		(In Thousands)	
Federal income tax at statutory rates	34.0%	34.0%	34.0%
State income tax, net of federal tax benefit	6.1%	6.1%	6.3%
Research and development credits	2.5%	2.1%	2.3%
Stock compensation	-1.7%	-1.4%	-4.3%
FIN 48 adjustment	0.0%	-5.7%	0.0%
Other	-0.5%	0.0%	-0.1%
Increase in valuation allowance	-40.4%	-35.0%	-38.2%
Effective tax rate	0.0%	0.0%	0.0%

The company adopted Financial Interpretation Number 48, "Accounting for Uncertain Tax Positions" on January 1, 2007. FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with FASB Statement No. 109, "Accounting for Income Taxes." FIN 48 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 FIN 48. A summary of the company's adjustments to its uncertain tax positions in the current year are as follows:

	(In Thousands)
Balance at January 1, 2007 (adoption of FIN 48)	$ 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	—

TABLE OF CONTENTS

ZIOPHARM ONCOLOGY, INC.
(A Development Stage Enterprise)

NOTES TO FINANCIAL STATEMENTS

8. Income Taxes – (continued)

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 if limitations by the Internal Revenue Service and state jurisdictions for the years ended December 31, 1999 through 2007.

9. 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, 2008, the Company has issued and outstanding 21,860,464 shares of common stock and no shares of Preferred Stock.

In September 2003, the Company issued 2,000,000 (before the split discussed below and pre-Merger) shares of common stock at $0.25 per share for gross proceeds of $500 thousand.

In January 2004, the Company issued 18,000,000 (before the split discussed below and pre-Merger) shares of common stock at $0.25 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 (unless stated otherwise all other share and per share amounts presented reflect the reverse split).

On June 6, 2005, the Company completed the 2005 Offering (see Note 2). 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.

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.

ZIOPHARM ONCOLOGY, INC.
(A Development Stage Enterprise)

NOTES TO FINANCIAL STATEMENTS

9. Convertible Preferred Stock and Stockholders' Equity – (continued)

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.

10. 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 April 25, 2007 and April 26, 2006, the date 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 and 750,000 shares, respectively, for a total of 4,002,436 shares.

As of December 31, 2008 there were 2,738,089 shares that are issuable under its 2003 Stock Option Plan upon exercise of outstanding options to purchase common stock. As of December 31, 2008, the Company had outstanding options issued to its employees to purchase up to 2,252,665 shares of the Company's common stock, to its directors to purchase up to 480,174 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. The Company had estimated the fair value of the 5,000 options issued to the consultant using the Black-Scholes model, using an assumed risk-free rate of 1.52 %, and expected life of 5 years, volatility of 99%, and dividend yield of 0%. The options issued to the consultant were valued at $3 thousand and are recorded as a pro-rata charge to compensation expense over the option's two-year vesting period which began on December 3, 2008.The Company had estimated the fair value of the remaining 250 options issued to a consultant in 2004 using the Black-Scholes model, using an assumed risk-free rate of 4.23%, and expected life of 10 years, volatility of 134%, and dividend yield of 0%. The options issued to the consultant were valued at $1 thousand and were recorded as a charge to compensation expense in December 2004.

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. 359,188 options granted, in 2006, to the Board of Directors and some members of management vested immediately. Stock options are valued using the Black-Scholes option valuation 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 — 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 2008, 2007, and 2006 exercises amounted to $0, $36 thousand, and $25 thousand respectively. The intrinsic value of these options amounted to $0, $32 thousand, and $8 thousand for years ended December 31, 2008, 2007, and 2006, respectively.

ZIOPHARM ONCOLOGY, INC.
(A Development Stage Enterprise)

10. Stock Option Plan – (continued)

Transactions under the Plan for the years ending December 31, 2008, 2007, and 2006 were as follows:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Contractual Term (Years)	Aggregate Intrinsic Value
	(In Thousands, Except Share and per Share Data)			
Outstanding, January 1, 2006	973,639	$ 2.56		
Granted	988,180	5.42		
Exercised	(5,845)	4.31		
Cancelled	(42,939)	4.50		
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	7.66	$ 134
Options exercisable, December 31, 2008	1,753,141	$ 3.63	6.91	$ 134
Options available for future grants	597,728			

At December 31, 2008, total unrecognized compensation costs related to non-vested stock options outstanding amounted to $1.6 million. The cost is expected to be recognized over a weighted-average period of 1.36 years.

Restricted Stock

In January 2008, the Company issued 100,000 shares of restricted stock to one employee which vest ratably over a three-year period. Also, 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 vest in one year. In 2007, the Company issued restricted stock to several employees which will vest entirely on December 1, 2008 and 2007, respectively. During the year ended December 31, 2008 and 2007, $289 thousand and $9 thousand of compensation expense was recognized, respectively. A summary of the status of non-vested restricted stock as of December 31, 2008 and 2007 is as follows:

	Number of Shares	Weighted-Average Grant Date Fair Value
Non-vested, 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

TABLE OF CONTENTS

ZIOPHARM ONCOLOGY, INC.
(A Development Stage Enterprise)

NOTES TO FINANCIAL STATEMENTS

10. Stock Option Plan – (continued)

As of December 31, 2008, there was $582 thousand 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 1.27 years.

11. Warrants

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 also 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 2005 Offering completed in June 2005, the Company compensated Paramount, placement agent for the Offering, or its affiliates for its services through the payment of placement warrants to acquire 419,794 (837,956 — pre-Merger) shares of Series A Preferred Stock (the "Series A Stock Warrants"), exercisable for a period of 7 years at a per-share exercise price equal to 110% of the price per share sold in the 2005 Offering. 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 estimated the fair value of the Series A Stock 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 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%. The fair value of the warrants was recorded as a permanent component of shareholders' equity.

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%. The fair value of the warrants was recorded as a permanent component of shareholder's equity.

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

TABLE OF CONTENTS

11. Warrants – (continued)

The following is a summary of warrants outstanding as of December 31, 2008.

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
5,039,659			

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 $113 thousand to this plan during the year ending December 31, 2008. No contributions were made in the years ended December 31, 2007 and 2006.

TABLE OF CONTENTS

INDEX

Exhibit No.	Description of Document
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

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 (SEC File No. 000-32353) 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 [SEC File No. 000-32353] 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 [SEC File No. 000-32353] March 20, 2006).
4.8	Form of common stock Purchase Warrant issued to investors in connection with ZIOPHARM Oncology, Inc. 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 ZIOPHARM Oncology, Inc. 2006 private placement (incorporated by reference to Exhibit 4.2 to the Registrant's Current Report of Form 8-K filed May 3, 2006).
4.10	Form of Warrant to Purchase Common Stock issued to investors in connection with ZIOPHARM Oncology, Inc. 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).

TABLE OF CONTENTS

Exhibit No.	Description of Document
4.11	Form of Warrant to Purchase Common Stock issued to placement agents in connection with ZIOPHARM Oncology, Inc. 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).
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	Employment Agreement dated January 8, 2004, between the Registrant and Dr. Jonathan Lewis (incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form SB-2 [SEC File No. 333-129020] filed October 14, 2005).
10.5	Employment Agreement Extension dated December 21, 2006, between the Registrant and Dr. Jonathan Lewis (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed December 26, 2007).
10.6	Employment Agreement dated as of January 8, 2008 by and between the Registrant and Dr. Jonathan Lewis.
10.7	Employment Agreement dated July 21, 2004, between the Registrant and Richard Bagley (incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form SB-2 [SEC File No. 333-129020] filed October 14, 2005).
10.8	Employment Agreement Extension dated June 18, 2007 by and between the Registrant and Richard Bagley (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed June 19, 2007).
10.9	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

[SEC File No. 333-129020] filed October 14, 2005).++

10.10	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).++
10.11	Form of subscription agreement between the ZIOPHARM, Inc. and the investors in ZIOPHARM, Inc.'s 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).
10.12	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 [SEC File No. 000-32353] filed March 20, 2006).
10.13	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 [SEC File No. 000-32353] filed March 20, 2006).
10.14	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 [SEC File No. 000-32353] filed March 20, 2006).
10.15	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).

TABLE OF CONTENTS

Exhibit No.	Description of Document
10.16	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).++
10.17	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).++
10.18	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).
10.19	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).
10.20	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).
23.1	Consent of Independent Registered Public Accounting Firm — Vitale, Caturano & 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.

++ 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.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

As independent registered public accountants, we hereby consent to the incorporation by reference of our report dated March 16, 2009 relating to the financial statements of ZIOPHARM Oncology, Inc. as of December 31, 2008 and 2007, and for the three year period ended December 31, 2008, and from September 9, 2003 (date of inception) through December 31, 2008, and to all references to our Firm, included in or made part of this Form 10-K, into the Company's previously filed Registration Statements on Forms S-8 (File Nos. 333-129884, 333-134280 and 333-142701) and Forms S-3 (File Nos. 333-129680, 333-134279 and 333-141014).

VITALE, CATURANO & COMPANY, P.C.

Boston, Massachusetts
March 23, 2009

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER

I, Jonathan Lewis, certify that:

1. I have reviewed this annual report on Form 10-K of ZIOPHARM Oncology, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15(d)-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 23, 2009

/s/ Jonathan Lewis

Jonathan Lewis, Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

I, Richard Bagley, certify that:

1. I have reviewed this annual report on Form 10-K of ZIOPHARM Oncology, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15(d)-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 23, 2009

/s/ Richard E. Bagley

Richard E. Bagley, President and Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of ZIOPHARM Oncology, Inc. (the "Company") on Form 10-K for the year ended December 31, 2008, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jonathan Lewis, Principal Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ Jonathan Lewis

Jonathan Lewis, Chief Executive Officer
(Principal Executive Officer)
March 23, 2009

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of ZIOPHARM Oncology, Inc. (the "Company") on Form 10-K for the year ended December 31, 2008, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Richard Bagley, Principal Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ Richard E. Bagley

Richard E. Bagley, President and Chief Financial Officer
(Principal Financial and Accounting Officer)
March 23, 2009