ZIOPHARM ONCOLOGY INC
Form 10KSB
February 21, 2008

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-KSB

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

For the fiscal year ended December 31, 2007

OR

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

For the transition period from _____ to _____

Commission File Number 0-32353

ZIOPHARM Oncology, Inc.
(Exact Name of Small Business Issuer 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(g) of the Act:
Common Stock (par value $0.001 per share)

Check whether the issuer is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act. o

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

Check if there is no disclosure of delinquent files pursuant to Item 405 of Regulation S-B is not contained in this form, and no disclosure 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-KSB or any amendment to this form 10-KSB. o

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

The registrant had no revenue for the most recent fiscal year.

As of February 19, 2008, the aggregate market value of common stock held by non-affiliates of the registrant approximated $69,221,633 based upon the closing price of the common stock on the NASDAQ Capital Market as of the close of business on that date. Shares of common stock held by each executive officer and director and by each entity that owns 10% or more of the 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 February 19, 2008, there were 21,298,964 shares of the issuer’s common stock, $.001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the definitive proxy statement for our 2008 annual meeting of stockholders, which is to be filed within 120 days after the end of the fiscal year ended December 31, 2007, are incorporated by reference into Part III of this Form 10-KSB, to the extent described in Part III.

Traditional Small Business Disclosure Format (check one): Yes x No o

---

ZIOPHARM Oncology, Inc.
Index to Annual Report on Form 10-KSB

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 13. Exhibits").

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 "Description of Business - Corporate Developments - Acquisition of ZIOPHARM, Inc."

Special Note Regarding Forward Looking Statements

This Annual Report on Form 10-KSB 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 or Plan 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-KSB are described under the heading "Risk Factors."

PART I

Item 1. Description of 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 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. While we expect to commercialize our products on our own in North America, we also recognize that promising clinical trial results might also be addressed in partnership with another company with the requisite financial resources. Currently, we are in phase I and/or II studies for three product candidates identified as darinaparsin ("ZIO-101"), palifosfamide ("ZIO-201"), and indibulin ("ZIO-301"). We intend to continue the clinical development of IV darinaparsin for the treatment of certain lymphomas and other hematological malignancies or liver cancer. We also continue to explore the clinical utility of the oral form of darinaparsin in solid tumors. Currently underway are clinical trials to evaluate IV palifosfamide to treat advanced sarcoma. We are also seeking clearance from the U.S. Food and Drug Administration ("FDA") in the form of an

investigational new drug (“IND”) application to explore the clinical utility of oral administration of palifosfamide. Clinical studies with oral indibulin either alone or in combination for the treatment of an as-yet undetermined solid tumor indication(s) are initiated. We will continue with preclinical studies of our product candidates, and analogs thereof, while evaluating additional candidates for licensing.

Our corporate office is located at 1180 Avenue of the Americas, 19th Floor, New York, NY 10036, and our telephone number is (646) 214-0700. Our business and development operations are located in Boston, Massachusetts.

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 includes 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 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 and often targeted 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

Darinaparsin ("ZIO-101")

General. Darinaparsin is an organic arsenic compound 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 on the compendia listing for the therapy of multiple myeloma 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 phase II clinical studies, darinaparsin has been safely administered at doses significantly higher than are approved for 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 Indications: lymphoma, advanced myeloma, and liver cancer Three phase II studies evaluating hematological malignancies, i.e., APL and lymphomas, advanced myeloma, and liver cancer, are planned to have accrual completed by the second half of 2008. Preliminary data from the hematological malignancies and lymphomas and advanced myeloma studies have been reported, namely, a complete response noted in a heavily pretreated patient with peripheral T-cell lymphoma and prolonged disease stabilization in advanced myeloma.

Clinical Development Plan for darinaparsin: Intravenously administered darinaparsin safety, pharmacokinetics, and drug activity has been evaluated in phase I studies. These trials have involved different patient populations, namely solid tumors, multiple myeloma and hematologic malignancies. The data reported had noted that darinaparsin was well tolerated and showed preliminary signs of activity at the recommended phase II dose. Three phase II studies evaluating hematological malignancies and lymphomas, advanced myeloma and liver cancer have started and accrual is expected to be completed by the second quarter of 2008. Based on the efficacy data generated in these studies and commercial evaluation, a lead indication is expected to be selected for further development.

In addition, an oral darinaparsin phase I program is ongoing and continues to accrue patients. Depending upon the number of cohorts required to achieve the maximum tolerated dose ("MTD"), a recommended phase II dose for the oral program is expected to be determined in the second half of 2008.

Palifosfamide ("ZIO-201")

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 alkylating 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 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.

The phase II portion of the advanced sarcoma trial has completed accrual. Interim data from the study were reported in the fourth quarter of 2007. The trial indicated that palifosfamide was well tolerated, with renal toxicity being the most clinically relevant adverse event. Preliminary efficacy has been reported in a subject with liposarcoma that lasted 35 weeks. In addition, stable disease ("SD") was observed in 44% of the evaluable subjects.

The Company has initiated a study in which palifosfamide is administered in combination with doxorubicin, which is the most commonly used agent for treating advanced sarcoma. Should no additional safety concerns emerge during the phase I portion of this study, the Company anticipates planning a pivotal sarcoma study at the end of 2008. This is planned to be preceded by an End of Phase II meeting with the FDA to discuss a Fast Track development program for advanced sarcoma, under a special protocol assessment ("SPA").

In addition, an oral palifosfamide phase I program is planned for the near future under an IND submitted to the U.S. FDA. Depending upon the number of cohorts required to determine the maximum tolerated dose ("MTD"), a recommended phase II dose for the oral program could be achieved in mid-to-late 2008.

Indibulin ("ZIO-301")

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 as a the treatment of cancer. A number of other tubulin-targeting drugs are currently on the market, including paclitaxel (Taxol®) and vinca alkaloids (vincristine, vinorelbine). 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 convenience to patients, since no oral formulations of paclitaxel or related compounds have been developed thus far.

Indibulin has a different pharmacological profile from other tubulin inhibitors currently on the market (paclitaxel, docetaxel, vinorelbine, vincristine, and vinblastin). 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.

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

Potential Lead Indications for Indibulin: NSCLC, head and neck, prostate, colorectal, breast. At the current time, the Company anticipates pursuing a Fast Track development program following the completion of phase I/II testing that it plans to initiate this year. Registration in one of these indications would then be followed by label expansion trials. In addition, the development of an IV formulation could further expand the market opportunity.

Clinical Development Plan for Indibulin. The phase I program with indibulin will evaluate safety, pharmacokinetics ("PK"), pharmacodynamics, biomarkers, MTD, and dose limiting toxicity ("DLT") in patients with advanced solid tumors; these trials are expected to complete in the first half of 2008. MTD has not yet been reached in phase I studies. Indibulin is well tolerated and clinical activity has been observed in patients with several histologic subtypes. This data will be used to select a phase II dose. Preclinical combination studies demonstrated synergy with erlotinib, docetaxel, and capecitabine. Two combination studies with erlotinib and capecitabine are planned to start in the first half of 2008; the phase I portion of the erlotinib combination trial has been initiated. Depending upon the number of cohorts needed to determine a recommended dose; these studies will be expanded in a phase II portion that will evaluate the efficacy of these combinations. Following a detailed review of data, additional studies will be proposed.

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 does the Company, 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 is intense.

In addition to third-party competition, 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 include 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. 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 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 will expire in 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 ("SRI"). On December 22, 2004, we entered into an Option Agreement with 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 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 and also paid an additional $15,000 for the annual patent and license maintenance fee. 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 two U.S. Patents (U.S. Patent Nos. 6,232,327 and 6,693,119) and thirty-one (31) foreign patents covering methods of using indibulin as a cancer therapeutic, as well as four 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.

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 its 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 42 employees all of which are full time. Several additional employees are expected to be hired prior to the end of 2008.

Corporate Developments

Reverse Stock Split

On August 24, 2005, we (EasyWeb, Inc.) effected a 1-for-40 share combination (i.e., reverse stock split) of our capital stock. The share combination was approved by our stockholders at a special stockholder meeting held on February 28, 2005. As a result of the share combination, we had 189,922 shares of common stock outstanding immediately prior to the merger transaction with ZIOPHARM, Inc., which is discussed immediately below.

Acquisition of ZIOPHARM, Inc.

Pursuant to an Agreement and Plan of Merger dated August 3, 2005 (the "Merger Agreement") by and among us, ZIO Acquisition Corp., a Delaware corporation and our wholly owned subsidiary, and ZIOPHARM, Inc., a Delaware corporation, 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." The Merger was effective as of September 13, 2005, upon the filing of a certificate of merger with the Delaware Secretary of State. In consideration for their shares of ZIOPHARM, Inc. capital stock and in accordance with the Merger Agreement, the stockholders of ZIOPHARM, Inc. received an aggregate of 6,967,941 shares or approximately 97.3% of our common stock. In addition, all securities convertible into and exercisable for shares of ZIOPHARM, Inc. capital stock outstanding immediately prior to the Merger were cancelled, and the holders thereof received similar securities convertible into an aggregate of 1,366,846 shares of our common stock.

All share and per-share data in this report have been adjusted to give effect to the conversions effected as part of the Merger.

The Merger Agreement was filed as Exhibit 10.1 to our current report on Form 8-K filed with the Securities and Exchange Commission on August 9, 2005, and is incorporated herein by reference. The foregoing description of the Merger Agreement and the Merger do not purport to be complete and is qualified in its entirety by reference to the Merger Agreement.

On September 13, 2005, our board of directors approved a transaction pursuant to which 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.

Changes in Board of Directors

At the effective time of the Merger, the board of directors was reconstituted by the appointment of Dr. Jonathan Lewis, Richard Bagley, Dr. Murray Brennan, James Cannon, Senator Wyche Fowler, Jr., Gary S. Fragin, Timothy McInerney, and Dr. Michael Weiser as directors (all of whom were directors of ZIOPHARM, Inc. immediately prior to the Merger) and with the resignations of David C. Olson and David Floor from their previous positions as our directors.

RISK FACTORS

An investment in our common stock is very risky. In addition to the other information in this Annual Report on Form 10-KSB, 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 or result of our operations would suffer and, in that event, the trading price of our common stock could decline. Therefore, we urge you to carefully review this entire 10-KSB and consider the following risk factors:

Risks Related to our Business

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

We have never generated revenue and have incurred significant net losses in each year since our inception. For the year ended December 31, 2007, we had a net loss of $26.6 million and we had incurred approximately $59.8 million of cumulative net losses since our inception in 2003. We expect to continue to incur significant operating and capital expenditures and anticipate that our expenses will increase substantially in the foreseeable 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.

Because we expect to incur losses for the foreseeable future, we will need to generate significant revenues in order to achieve and maintain profitability. 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. If we are unable to raise additional capital when needed, we may have to discontinue our product development programs. The manner in which we raise any additional funds may affect the value of your investment in our common stock.

As of December 31, 2007, we had incurred approximately $59.8 million of cumulative net losses and had approximately $35.0 million of cash, cash equivalents, and short-term investments. Currently, we expect that we will have sufficient cash to fund our operations late into the second quarter of 2009. Although we expect our cash on-hand to fund our operations into the second quarter of 2009, 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 to us when needed, if at all. If we fail to advance 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 obtaining additional financing. To the extent that we raise additional capital by issuing equity securities, our stockholders may experience dilution. 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.

If we do not succeed in raising additional funds on acceptable terms, we may be unable to complete planned preclinical and clinical trials or obtain approval of any product candidates from the FDA and other regulatory authorities. In addition, we could be forced to discontinue product development, reduce or forego sales and marketing efforts, forego attractive business opportunities, or discontinue our operations altogether.

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, Richard E. Bagley, our 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 2008, 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 are hopeful that we may be able to obtain “Fast Track” and or “Orphan Drug” status from the FDA for one or more of 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 will be granted Fast Track or Orphan Drug 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.

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 have 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.

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.

Because we became public by means of a reverse merger, we may not be able to attract the attention of major brokerage firms.

Additional risks may exist as a result of our becoming a public reporting company through a "reverse merger." Security analysts of major brokerage firms may not provide coverage of the Company. Because we became public through a reverse merger, there is no incentive to brokerage firms to recommend the purchase of our common stock. No assurance can be given that brokerage firms will want to provide analyst coverage of our Company in the future.

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 2. Description of Property

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. Our business and development operations in Boston occupy approximately 13,000 square feet located in Boston, Massachusetts 02129. The main Boston office space consists of two floors which are under 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 additional 1,000 square feet of the Boston space generates a monthly charge of approximately $5,500 per month and is not subject to any long-term lease agreements. The Company also has a small office in New Haven, Connecticut that is leased until September 30, 2009, and generates monthly payments ranging from $3,667 at the beginning of the lease to $3,889 at the end of the lease

term.

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, 2007.

PART II:

Item 5. Market for Common Equity and related Stockholders Matters

Prior to the consummation of the Merger, our common stock traded on the OTCBB under the symbol "ESWB." As a result of the Company's name change to ZIOPHARM Oncology, Inc., our common stock now trades under the symbol "ZIOP." On September 22, 2006, the Company's common shares began trading on the NASDAQ Capital Market under the symbol ZIOP. The following table sets forth the high and low sale or bid prices for our common stock for each quarter within the last two fiscal years as reported by NASDAQ and the OTCBB, as applicable. The OTCBB quotations reflect inter-dealer prices, without retail markup, markdown or commission, and may not represent actual transactions.

	Price Range	
Fiscal Year 2007 (Quarter Ended)	**High**	**Low**
December 31, 2007	$ 3.60	$ 2.08
September 30, 2007	$ 5.45	$ 3.06
June 30, 2007	$ 6.50	$ 4.59
March 31, 2007	$ 5.97	$ 4.35

Fiscal Year 2006 (Quarter Ended)	**High**	**Low**
December 31, 2006	$ 5.97	$ 5.60
September 30, 2006	$ 5.19	$ 4.90
June 30, 2006	$ 5.50	$ 5.20
March 31, 2006	$ 4.80	$ 4.80

The approximate number of stockholders of record of our common stock as December 31, 2007 was 292. 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.

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, 2007 with respect to the 2003 Plan:

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

	(A)			Column (A)
Equity compensation plans approved by security holders:				
2003 Stock Option Plan	2,797,000	$	3.81	1,100,317
Total:	2,797,000	$	3.81	1,100,317
Equity compensation plans not approved by stockholders:				
None.	-		-	-
Total	-		-	-

Item 6. Management Discussion and Analysis or Plan of Operation

Overview:

ZIOPHARM Oncology, Inc. is a biopharmaceutical company that is seeking to develop 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 drug candidates that are related to cancer therapeutics that are already on the market or in development and which can be administered by IV and/or oral dosing. We believe this strategy will result in lower risk and expedited drug development programs. While we expect to commercialize our products on our own in North America, we also recognize that promising clinical trial results might be addressed in a commercial partnership with another company with the requisite financial resources. Currently, we are in phase I and/or II studies for three product candidates known as darinaparsin ("ZIO-101"), palifosfamide ("ZIO-201") and indibulin ("ZIO-301"):

- Darinaparsin is an organic arsenic compound covered by issued patents and pending patent applications in the U.S. and foreign countries. A form of commercially available inorganic arsenic (arsenic trioxide [Trisenox®]; "ATO") has been approved for the treatment of acute promyelocytic leukemia ("APL"), a precancerous condition, 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. 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 heart toxicity. Similar results have been reported for other organic species. *In vitro* testing of darinaparsin using the National Cancer Institute's human cancer cell panel detected activity against 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. Preclinical studies have also established anti-angiogenic properties of darinaparsin and also support the development of an oral form of the drug.

Overview…Continued

Phase I testing of the intravenous ("IV") form of darinaparsin in both solid tumors and hematological cancers has been completed. The Company has reported encouraging signs of clinical activity along with an expected safety profile in both of these studies. The Company is presently conducting phase II studies in advanced myeloma, certain other hematological cancers, and primary liver cancer, and has reported on early patient treatment in both of the blood cancer trials. The Company has recently opened a phase I study for an oral form of darinaparsin, ahead of schedule. Study results from the oral phase I trial and the ongoing IV phase II trials, in conjunction with the changing marketplace with regard to other therapies, will determine the expected registration pathway for darinaparsin.

· Several proprietary forms of palifosfamide, or isophosphoramide mustard ("IPM"), a metabolite of ifosfamide that is also related to cyclophosphamide, have been developed. A patent application for pharmaceutical composition has been filed in the U.S. and internationally. Cyclophosphamide and ifosfamide are alkylating agents. The Company believes that cyclophosphamide is the most widely used alkylating agent in cancer therapy and it is used to treat breast cancer and non-Hodgkin's lymphoma. Ifosfamide has been shown to be effective in high dose by itself or in combination in treating sarcoma and lymphoma and is approved by the FDA as a treatment for 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. FDA. 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. Ifosfamide is metabolized to IPM. In addition to IPM, another metabolite of ifosfamide is acrolein, which is toxic to the kidneys and bladder. The presence of acrolein can mandate the administration of a protective agent called mesna, which is inconvenient and expensive. Chloroacetaldehyde is another metabolite of ifosfamide and 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 independently active without acrolein or chloroacetaldehyde metabolites, the Company believes that the administration of palifosfamide (without the co-administration of mesna) may avoid many of the toxicities of ifosfamide and cyclophosphamide without compromising efficacy. In some instances palifosfamide appears to show activity in ifosfamide- and/or cyclophosphamide-resistant cancer cells.

  Phase I and phase II testing of the intravenous form of palifosfamide to treat advanced sarcoma is ongoing in the U.S. Palifosfamide has been administered without the "uroprotectant" mesna, and the toxicities associated with acrolein and chloroacetaldehyde have not been observed. Kidney toxicity has been identified as the dose limiting toxicity. The Company has reported encouraging signs of clinical activity in the phase II study to date, which is now nearing completion. The Company expects this phase II study, following discussions with appropriate health authorities, will serve as a basis for a registration trial. The Company has filed an U.S. Investigational New Drug Application for an oral form of palifosfamide.

Overview…Continued

- Indibulin is a novel small molecular-weight tubulin polymerization inhibitor that was acquired from Baxter Healthcare. An ongoing phase I study in the Netherlands and a recently initiated phase I study in the U.S. (with continuous dosing) are currently underway to evaluate safety, pharmacokinetics ("PK"), maximum tolerated dose ("MTD"), and dose-limiting toxicity ("DLT") in patients with advanced solid tumors. The Company expects to complete these and other studies as the basis for a phase II single agent study for a solid tumor indication, as well as phase I/II combination studies with other agents; the first of these combination studies is now underway.

  The microtubule component tubulin is one of the best-established anti-tumor targets currently available. A number of anticancer drugs are on the market that target tubulin, such as paclitaxel (Taxol®) and the vinca alkaloid family (vincristine, vinorelbine). 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 also associated with significant toxicities, notably peripheral neurotoxicity. In contrast, indibulin has not shown peripheral neurotoxicity either in preclinical testing or in clinical studies to date.

  Indibulin is an orally available compound. Preclinical studies demonstrate significant and broad activity (including in taxane refractory and multi-drug resistant cell lines and xenografts) and it is potentially safer than other tubulin inhibitors (there has been no neurotoxicity at therapeutic doses in animals and in the ongoing phase I trials). At the current time, the Company anticipates pursuing a Fast Track development program in a niche indication following the completion of the phase I/II testing. In addition, the availability of an IV formulation would further expand the market opportunity and will be explored in 2008. The availability of an oral formulation of indibulin creates significant commercial opportunity, since no oral formulations of paclitaxel or related compounds are currently on the market.

Although we intend to continue with clinical development of darinaparsin for various indications, palifosfamide for advanced sarcoma and other indications, and indibulin in 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.

Plan of Operation

Our plan of operation for the next twelve months is to continue implementing our business strategy, including the clinical development of our three lead product candidates, darinaparsin, palifosfamide, and indibulin. We also intend to expand our drug candidate portfolio by seeking additional drug candidates through in-licensing arrangements. We expect our principal expenditures during those 12 months to include:

- Fees and milestone payments required under the license agreements relating to our existing product candidates;
- Clinical trial expenses, including the costs incurred with respect to the conduct of clinical trials for darinaparsin, palifosfamide and indibulin, and preclinical costs associated with back-up candidates;
- Costs related to the scale-up and manufacture of darinaparsin, palifosfamide and indibulin;
- Rent for our facilities; and
- General corporate and working capital, including general and administrative expenses.

As part of our plan for additional employees, we anticipate hiring several additional full-time employees in the regulatory, clinical and finance functions. In addition, we intend to use senior advisors, consultants, clinical research organizations, and third parties to perform certain aspects of product development, manufacturing, clinical, and preclinical development, and regulatory and quality assurance functions.

At our current and desired pace of clinical development of darinaparsin, palifosfamide, indibulin, other back-up candidates, and ongoing in-licensing efforts over the next 12 months, we expect to spend approximately $3.0 million on preclinical and regulatory expenses, $12.1 million on clinical expenses (including clinical trials and milestone payments that we expect to be triggered under the license agreements relating to our product candidates), approximately $4.4 million on manufacturing costs, approximately $600,000 on facilities, rent, and other facilities-related costs, and approximately $5.2 million on general corporate and working capital. With the proceeds from the common stock offering of February 23, 2007, we believe that we currently have sufficient capital to fund development and commercialization activities of darinaparsin, palifosfamide, and indibulin into May of 2009.

Product Candidate Development and Clinical Trials

Darinaparsin, organic arsenic, is being developed presently to treat advanced myeloma, other hematological malignancies, and liver cancer. Three separate phase II trials have been initiated. A phase I trial with an oral form of darinaparsin is ongoing. We will continue to explore different indications, dosing schedules, forms, and formulations. Preclinical development will continue with back-up compounds and additional compounds are being synthesized. Technology transfer and scale-up for the commercial manufacture of the active pharmaceutical ingredient, its lyophilization, and final product specification for both the IV and oral formulations will continue through the period to a registration trial.

Stabilized palifosfamide, which is isophosphoramide mustard (“IPM”), is being developed presently to treat advanced sarcoma. A phase II trial in advanced sarcoma is nearing completion. Other trials, including different indications and an oral form of administration are in the advanced planning stages. An IV palifosfamide trial in combination with doxorubicin has commenced. We expect to initiate a registration trial in advanced sarcoma following the completion of the phase II study. Technology transfer and scale-up for the commercial manufacture of the active pharmaceutical ingredient, its lyophilization, and final product specification will continue. Preclinical development will continue with back-up analogues.

Indibulin, a novel anti-cancer agent that targets mitosis like the taxanes, is available as an oral form and potentially an intravenous form. The oral form is currently in a phase I trial in Europe and a separate trial in the United States (using continuous dosing) has been initiated in the United States as is a third trial to determine drug activity. The phase I portion of a phase I/II trial in combination with Tarceva® has just initiated.

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 the current year period are 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 is 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 is 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 is 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 is 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.

Results of Operations for the fiscal year ended December 31, 2006 versus December 31, 2005

Revenues. We had no revenues for years ended December 31, 2006 and 2005.

Research and development expenses. For the year ended December 31, 2006, research and development expenses increased by $4,797,452, or 85.8%, to $10,391,302 from $5,593,850 in the year ended December 31, 2005. A significant portion of the increase is due to the purchased research and development of $1.2 million for indibulin. Increased research and development expenses in the current year period can also be attributable to an increase of approximately $0.4 million in milestone expenses in relation to darinaparsin and palifosfamide. In addition, the increase is attributable to an increase of approximately $0.9 million in the cost of clinical trials, an increase of approximately $0.6 million in manufacturing-related costs, and an increase of approximately $0.1 million in travel expense. The increase in expenses is also attributable to an increase of approximately $1.0 million in stock compensation expense related to stock options, approximately $0.5 million in employee-related costs, and approximately $0.1 million increase in recruiting costs.

General and administrative expenses. For the year ended December 31, 2006, general and administrative expenses increased by $4,526,738, or 107.9%, to $8,720,290 from $4,193,552 in the year ended December 31, 2005. The increase is attributable to an increase of approximately $2.5 million in stock compensation expense related to stock options; approximately $0.5 million for investors relations services, approximately $0.4 million in legal, accounting, and filing fee costs; approximately $0.2 million in travel expenses; approximately $0.1 million in recruiting costs; approximately $0.1 million in insurance-related expenses; approximately $0.1 in facility, depreciation, and equipment rental expenses; and approximately $0.7 million in employee-related costs. These increases were incurred as a result of building our infrastructure to support our research and development efforts. In addition, there was a $0.2 million one-time settlement fee to Paramount BioCapital (see footnote 5 for more information). These costs were offset by a decrease of $0.4 million in merger-related costs that were incurred in the year ending December 31, 2005.

Other income (expense). Other income increased by $984,194, or 363.9%, to $1,254,673 in the year ended December 31, 2006 from $270,479 recorded in the year ended December 31, 2005. Other income during the year ended December 31, 2006 and 2005, respectively, was comprised of interest income. The increase is due to higher cash balances, which was derived from the May 3, 2006 private placement that was made available for investing purposes.

Net income (loss). For the reasons described above, the net loss increased by $8,339,997, or 87.6%, to $17,856,919 million in the year ended December 31, 2006 from $9,516,922 for the same period of 2005.

Liquidity and Capital Resources

As of December 31, 2007, we had approximately $35.0 million in cash and cash equivalents. With the proceeds from our 2007 common stock offering, completed on February 23, 2007, we believe that we currently have sufficient capital to fund development and commercialization activities of darinaparsin, palifosfamide, and indibulin late into the second quarter of 2009. However, our actual cash requirements may vary materially from those now planned because of a number of factors, including:

- Changes in the focus and direction of our research and development programs, including the acquisition and pursuit of development of new product candidates;
- Competitive and technical advances;
- Costs of commercializing any of the product candidates; and
- Costs of filing, prosecuting, defending and enforcing any patent claims and any other intellectual property rights; or other developments.

The Company anticipates that losses will continue for the foreseeable future. At December 31, 2007, the Company's accumulated deficit was approximately $59.8 million. The Company has incurred significant losses from operations and has an accumulated deficit that raises substantial doubt about the Company's ability to continue as a going concern. The Company's ability to continue operations after its current cash resources are exhausted depends upon its ability to obtain additional financing and achieve profitable operations, as to which no assurances can be given.

Because our business does not generate any cash flow, we will need to raise additional capital after we exhaust our current cash resources in order to continue to fund our research and development, including our long-term plans for clinical trials and new product development, as well as to fund operations generally. We expect to finance our cash needs through the sale of equity securities and possibly 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. 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. Each of these alternatives would likely 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 upon 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.

Liquidity and Capital Resources…Continued

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 the 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 estimated the fair value of these warrants at $4,724,169 using the Black-Scholes model, and using an assumed risk-free rate of 4.71% and an expected life of 5 years, volatility of 93%, and a dividend yield of 0%. The Company 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 $1,630,800 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 177,302 warrants at $708,624 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%.

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 offering (the "2006 Offering") that was completed on May 3, 2006. In addition to the Shares, the Company also issued to each investor a five-year warrant to purchase, at an exercise price of $5.56 per share, an additional number of shares of common stock equal to 30 percent of the shares purchased by such investor in the 2006 Offering. In the aggregate, these warrants entitle investors to purchase an additional 2,397,392 shares of common stock. The Company engaged Paramount BioCapital, Inc. and Griffin Securities, Inc. (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 aggregate cash commissions of $2,589,966 and issued 7-year warrants to the 2006 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 2006 Placement Agents for their accountable expenses incurred in connection with the 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. The Company engaged Paramount as a placement agent in the Series A Convertible Preferred Stock offering and granted Paramount a right of first refusal to act as the placement agent for the private sale of the Company's securities through May 31, 2008. On December 18, 2006 the Company paid Paramount a cash settlement of $180,000 in exchange for Paramount's agreement to terminate this right of first refusal.

At December 31, 2007, working capital was approximately $29.2 million, compared to working capital of approximately $25.9 million at December 31, 2006. The increase in working capital reflects the proceeds from the 2007 Offering offset by the use of funds for operations.

Capital expenditures were approximately $738,000 for the year ended December 31, 2007. We anticipate capital expenditures of approximately $700,000 for the fiscal year ended December 31, 2008.

The Company's significant lease obligation payable is as follows:

	Payments due by Period					
	Total	**2008**	**2009**	**2010**	**2011**	**2012 and thereafter**
Operating lease	$ 1,552,870	$ 485,477	$ 463,949	$ 287,319	$ 187,875	128,250

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 consolidated 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 Employees* , 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. Had we applied the fair value recognition provisions of SFAS No. 123, our net loss for the year ended December 31, 2005 would have increased by approximately $844,000. We expect to record additional non-cash compensation expense in the future, which may be significant.

Off-Balance Sheet Arrangements

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

Item 7. FINANCIAL STATEMENTS

INDEX TO FINANCIAL STATEMENTS

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, 2007 and 2006 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, 2007 and for the period from inception (September 9, 2003) through December 31, 2007. 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, 2007 and 2006 and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2007 and for the period from inception (September 9, 2003) through December 31, 2007 in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 2 to the financial statements, effective January 1, 2006, the Company adopted the provisions of Statement of Financial Accounting Standard No. 123R, "Share Based Payment".

Vitale, Caturano & Company, Ltd.
Boston, Massachusetts
February 7, 2008

PART I - FINANCIAL INFORMATION

ZIOPHARM Oncology, Inc.
(A Development Stage Enterprise)
Balance Sheets

	December 31, 2007	December 31, 2006
ASSETS		
Current assets:		
Cash and cash equivalents	$ 35,028,798	$ 26,855,450
Short-term investments	-	1,555,164
Prepaid expenses and other current assets	498,864	462,789
Total current assets	**35,527,662**	**28,873,403**
Property and equipment, net	746,421	451,247
Deposits	95,497	9,367
Other non current assets	356,881	178,080
Total assets	**$ 36,726,461**	**$ 29,512,097**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,909,170	$ 776,128
Accrued expenses	3,396,480	2,161,914
Total current liabilities	**6,305,650**	**2,938,042**
Deferred rent	**50,988**	**41,078**
Total Liabilities	**6,356,638**	**2,979,120**
Commitments and contingencies		
Stockholders' equity:		
Common stock, $.001 par value; 280,000,000 shares authorized; 21,298,964 and 15,272,899 shares issued and outstanding at December 31, 2007 and December 31, 2006, respectively	21,299	15,273
Preferred stock, $0.01 par value; 30,000,000 shares authorized and no shares issued and outstanding	-	-
Additional paid-in capital	69,674,151	44,667,878
Warrants issued	20,503,894	15,071,101
Deficit accumulated during the development stage	(59,829,521)	(33,221,275)
Total stockholders' equity	**30,369,823**	**26,532,977**
Total liabilities and stockholders' equity	**$ 36,726,461**	**$ 29,512,097**

F-2

ZIOPHARM Oncology, Inc.
(A Development Stage Enterprise)
Statements of Operations
For the years ended December 31, 2007, 2006, and 2005,
for the period from inception (September 9, 2003) through December 31, 2007

	For the year ended December 31, 2007	For the year ended December 31, 2006	For the year ended December 31, 2005	For the Period from Inception (September 9, 2003) through December 31, 2007
Research contract revenue	$ -	$ -	$ -	$ -
Operating expenses:				
Research and development, including costs of research contracts	18,992,635	10,391,302	5,593,850	37,104,394
General and administrative	9,577,858	8,720,290	4,193,552	26,234,294
Total operating expenses	28,570,493	19,111,592	9,787,402	63,338,688
Loss from operations	(28,570,493)	(19,111,592)	(9,787,402)	(63,338,688)
Interest income	1,962,247	1,254,673	270,479	3,509,167
Net loss	$ (26,608,246)	$ (17,856,919)	$ (9,516,922)	$ (59,829,521)
Basic and diluted net loss per share	$ (1.41)	$ (1.42)	$ (2.32)	
Weighted average common shares outstanding used to compute basic and diluted net loss per share	18,832,351	12,571,951	4,101,514	

ZIOPHARM Oncology, Inc.
(A Development Stage Enterprise)
Statements of Cash Flows
For the years ended December 31, 2007, 2006, and 2005,
for the period from inception (September 9, 2003) through December 31, 2007

	For the year ended December 31, 2007	For the year ended December 31, 2006	For the year ended December 31, 2005	For the Period from Inception (September 9, 2003) through December 31, 2007
Cash flows from operating activities:				
Net loss	$ (26,608,246)	$ (17,856,919)	$ (9,516,923)	$ (59,829,521)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	433,353	173,920	101,232	742,458
Stock-based compensation	1,438,588	2,882,658	98,755	5,123,117
(Gain)loss on disposal of fixed assets	9,588	(1,165)	-	8,423
Change in operating assets and liabilities:				
(Increase) decrease in:				
Prepaid expenses and other current assets	(36,075)	(250,952)	(94,266)	(498,864)
Other noncurrent assets	(178,801)	(53,737)	(124,343)	(356,881)
Deposits	(86,130)	(3,667)	54,346	(95,497)
Increase (decrease) in:				
Accounts payable	2,133,042	(59,869)		