

ZIOPHARM ONCOLOGY INC  
Form 10KSB  
February 13, 2007

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, DC 20549**

**FORM 10-KSB**

- ANNUAL REPORT UNDER SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended December 31, 2006

OR

- TRANSITION REPORT UNDER SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934  
For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number 0-32353

**ZIOPHARM Oncology, Inc.**

(Exact Name of Small Business Issuer as Specified in Its Charter)

**Delaware**

(State or Other Jurisdiction of Incorporation or  
Organization)

**84-1475642**

(IRS Employer Identification No.)

**1180 Avenue of the Americas, 19 th Floor, New York,  
NY**

(Address of Principal Executive Offices)

**10036**

(Zip Code)

**(646) 214-0700**

(Issuer's Telephone Number, Including Area Code)

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(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.

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  No

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.

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

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

As of February 12, 2007, the aggregate market value of common stock held by non-affiliates of the registrant approximated \$78,349,972 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 12, 2007, there were 15,272,899 shares of the issuer's common stock, \$.001 par value per share, outstanding.

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DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the definitive proxy statement for our 2007 annual meeting of stockholders, which is to be filed within 120 days after the end of the fiscal year ended December 31, 2006, 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  No

2

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

		Page
<b>PART I</b>		
Item 1.	Description of Business	4
Item 2.	Description of Property	23
Item 3.	Legal Proceedings	24
Item 4.	Submission of Matters to a Vote of Security Holders	24
<b>PART II</b>		
Item 5.	Market for Common Equity, Related Stockholders Matters and Small Business Issuer Purchases of Equity Securities	24
Item 6.	Management's Discussion and Analysis or Plan of Operation	24
Item 7.	Financial Statements	33
Item 8.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosures	34
Item 8A.	Controls and Procedures	34
Item 8B.	Other Information	34
<b>PART III</b>		
Item 9.	Directors, Executive Officers, Promoters and Control Persons; Compliance with Section 16(a) of the Exchange Act	35
Item 10.	Executive Compensation	35
Item 11.	Security Owners of Certain Beneficial Owners and Management and Related Stockholders Matters	35
Item 12.	Certain Relationships and Related Transactions	35
Item 13.	Exhibits	36
Item 14.	Principal Accountant Fees and Services	36
	Signatures	37
	Exhibit Index	38

## **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-sub subsidiary merger, we relinquished our prior corporate name, EasyWeb, Inc., and assumed in its place the name "ZIOPHARM Oncology, Inc." The parent-sub 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 - Recent 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 candidate families that are related to cancer therapeutics that are already on the market or in development. We believe this strategy will result in lower risk and expedited drug development programs. We expect to commercialize our products on our own in North America but recognize that promising clinical trial results in cancers with a high incidence and prevalence might also 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 identified as ZIO-101, ZIO-201, and ZIO-301. We intend to continue with clinical development to register ZIO-101 for the treatment of advanced myeloma, ZIO-201 to treat advanced sarcoma and ZIO-301 for an as yet undetermined solid tumor indication. We will continue with preclinical study of our products and back-up candidates, dosing forms and schedules, while evaluating additional later stage clinical candidates.

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 Charlestown, 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.

4

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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. Sarcomas begin in tissue that connects, supports or surrounds other tissues and organs. Lymphomas are cancers of the lymph system, the 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, or 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.

In 2007, the American Cancer Society estimates that 559,650 Americans are expected to die from cancer, more than 1,500 every day. The cost of cancer to the healthcare system 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. There are many different drugs that are used to treat cancer, including cytotoxics or antineoplastics, hormones, and biologics. There are also many experimental treatments under investigation including radiation sensitizers, vaccines, gene therapy and immunotoxins. We believe cancer treatment represents a significant unmet medical need.

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

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

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

Cytotoxic agents act primarily by disrupting cellular pathways involved in maintaining cellular integrity, repair or activity which affects the production or function of DNA, RNA or protein. Although there are many cytotoxic agents, there is a considerable amount of 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 the 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, one of the most common side effects of chemotherapy is nausea and vomiting. Several drugs have been developed to help prevent and control chemotherapy-induced nausea and vomiting, including 5HT<sub>3</sub> receptor antagonists, like ondansetron, which is a selective blocking agent of the hormone serotonin.

5

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## Product Candidates

### ZIO-101

*General.* ZIO-101 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<sup>®</sup>) or ATO) has been approved for the treatment of acute promyelocytic leukemia (APL) and is on the compendia listing for the therapy of multiple myeloma as well as having been studied for the treatment of various other cancers. ATO has been shown to be toxic to the heart, nerves and liver, limiting its use as a broad anti-cancer agent. Our preclinical studies demonstrated that ZIO-101 is considerably less toxic than ATO, particularly with regard to heart toxicity. In phase I testing, significantly higher doses of ZIO-101 have been safely administered than the approved dose of Trisenox<sup>®</sup>, confirming preclinical findings.

*In vitro* testing of ZIO-101 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, ZIO-101 has potent anti-angiogenic activity as demonstrated in *in vitro* as well as *in vivo* studies.

In a murine leukemia model, ZIO-101 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.

*Clinical Lead Indication: Multiple Myeloma.* We expect that advanced myeloma, a hematologic cancer, will be the target indication for our first regulatory approval for ZIO-101. Myeloma is a group of plasma cell cancers associated with the overproduction of monoclonal immunoglobulin (M-protein). Each year approximately 17,000 patients are diagnosed with multiple myeloma in the United States, while 65,000 patients are living with the disease. Primary treatment for myeloma is chemotherapy. Approximately 15-20% of patients with myeloma are resistant to aggressive primary treatment. Patients that initially respond to treatment usually develop resistance to primary therapy after several years. The average survival of patients with progressive or resistant disease is three to four years.

The standard of care for progressive or resistant multiple myeloma is in transition. Velcade<sup>®</sup> and Revlimid<sup>®</sup> are approved to treat patients with myeloma that have had at least one prior therapy. Recent clinical trials offer evidence supporting the use of these therapies either alone or in combination with other agents. However, neither treatment is universally effective. The ongoing need for new and non-cross resistant therapies for the treatment of myeloma suggests that as new therapeutic options come to market, the market will continue to grow. Penetration into the market for new agents is to a large extent independent of the number of therapies available, as most patients generally will fail all available agents at some point. A more rapid market penetration can be expected for new therapies with a wide therapeutic window and where efficacy is equal to or greater than currently available agents.

*Clinical Development Plan for ZIO-101.* ZIO-101 safety, pharmacokinetics, and drug activity continue to be evaluated in phase I studies. These trials have involved different patient populations, namely solid tumors, multiple myeloma, and hematologic malignancies. One study is completed (multiple myeloma) while two studies are nearing completion. In summary, ZIO-101 has shown single agent activity in hematologic cancers (including multiple myeloma), and solid tumors. Phase II clinical trials in each of these populations have been initiated. In addition, a number of additional studies are planned, including a phase I trial utilizing an oral formulation of ZIO-101.

Upon the completion of the phase II multiple myeloma program in 2007, the Company anticipates having an end of phase II meeting with the FDA to discuss a Fast Track development program for advanced myeloma under Special Protocol Assessment (SPA) .

## *ZIO-201*

*General.* ZIO-201, or isophosphoramidate 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 (the “FDA”).

Our preclinical studies have shown that, in animal and laboratory models, ZIO-201 evidences activity against leukemia and solid tumors. These studies also indicate that ZIO-201 has a better pharmacokinetic and safety profile than ifosfamide or cyclophosphamide, offering the possibility of safer and more efficacious therapy with ZIO-201.

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 ZIO-201 is independently active—without acrolein or chloroacetaldehyde metabolites—the Company believes that the administration of ZIO-201 (without the administration of mesna) may avoid many of the toxicities of ifosfamide without compromising efficacy.

In addition to anticipated lower toxicity, ZIO-201 may have other advantages over ifosfamide and cyclophosphamide. ZIO-201 cross-links DNA differently than the active metabolite of cyclophosphamide, resulting in a different activity profile. Moreover, in some preclinical studies, ZIO-201 shows activity in cisplatin-, ifosfamide- and/or cyclophosphamide-resistant cancer cells. In xenografts of human breast cancer and in a mouse leukemia model, ZIO-201 has anti-tumor activity when administered orally, a potential additional advantage over ifosfamide and cyclophosphamide.

*Potential Lead Indications for ZIO-201. Sarcomas.* 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 age greater than 60 years, tumors larger than five centimeters, and high-grade histology. While small, low-grade tumors are usually curable by surgery alone; higher-grade or larger sarcomas are associated with higher local treatment failure rates and increased metastatic potential.

ZIO-201 may be a useful agent that, either alone or in combination with other agents, can 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 and some types of non-Hodgkin’s lymphomas and other solid tumors. The Company believes that ZIO-201 may be able to replace ifosfamide in any or all of these combination protocols.

*Clinical Development Plan for ZIO-201.* ZIO-201 has now been evaluated in two phase I studies, one in advanced cancers and one in advanced sarcoma. In both phase I trials, ZIO-201 was given without mesna. There was no hemorrhagic cystitis or CNS-toxicity. Bone marrow toxicity was modest. One subject with mesothelioma had stable disease >13 months and two patients with sarcoma had a response of at least stable disease.

A phase II trial in advanced sarcoma has been initiated while the phase I study in advanced cancers continues. A number of additional studies are planned for 2007 including a phase II study in lymphoma, a phase I/II study in pediatric malignancies, and a possible phase I study with an oral formulation. Other routes of administration where alkylating agents are active are being evaluated i.e., intrathecal and intraperitoneal.

The Company anticipates evaluating the phase II sarcoma study in the second half of 2007, followed by an end of phase II meeting with the FDA to discuss a Fast Track development program for advanced sarcoma under an SPA.

7

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### *ZIO-301*

*General.* ZIO-301 (indibulin) is a novel small molecular weight tubulin polymerization inhibitor that has been acquired from Baxter Healthcare. The microtubule component, tubulin, is one of the best established anti-tumor targets in the treatment of cancer today. A number of other tubulin targeting drugs are currently on the market, including paclitaxel (Taxol®) and the vinca alkaloids (vincristine, vinorelbine). The use of these drugs is associated with important toxicities, notably peripheral neuropathy. In contrast, no peripheral neurotoxicity has been observed with ZIO-301 either in preclinical testing or in phase I testing to date. In addition, its activity as an oral formulation could offer significant patient convenience, since to date no oral formulations of paclitaxel or related compounds have been developed.

ZIO-301 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 (MDR-1, MRP-1) and taxane resistant tumors. ZIO-301 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 ZIO-301 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 of different organ origin. *In vivo*, ZIO-301 is active in a number of xenograft and rodent tumor models. Its unique pharmacodynamic properties in preclinical studies and its excellent safety profile observed so far in the ongoing phase I study warrants further evaluation in the clinic.

*Potential Lead Indications for ZIO-301. Bladder, head & neck, prostate, colorectal, renal.* At the current time, the Company anticipates pursuing a Fast Track development program in a niche indication following the completion of phase II testing that would initiate this year. Registration in one of these indications would then be followed by label expansion trials that will have been already initiated in anticipation of registration. In addition, the development of an IV formulation could further expand the market opportunity.

*Clinical Development Plan for ZIO-301.* A phase I study is currently underway in the Netherlands with ZIO-301 to evaluate safety, pharmacokinetics (PK), maximum tolerated dose (MTD) and dose limiting toxicity (DLT) in patients with advanced solid tumors. MTD has not yet been reached in the phase I study. Drug activity has been observed in patients with several histologic subtypes. The clinical regulatory strategy is to include a phase II study of ZIO-301 in the United States in 2007.

### ***Competition***

The development and commercialization for new products to treat cancer is highly competitive, and there will be considerable competition from major pharmaceutical, biotechnology, and specialty cancer companies. Many of our competitors have substantially more resources than the Company, including both financial and technical. In addition, many of these companies have more experience than the Company 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.

There are a number of companies developing chemotherapies for cancer and in particular for multiple myeloma and sarcoma. Millennium Pharmaceuticals, Inc. and Celgene Corporation have marketed products to treat multiple myeloma, and many other product candidates are in clinical trials and preclinical research. There is a more limited number of competitors developing new approaches to treat sarcoma, Ariad Pharmaceuticals principal among them.

In addition to competitive companies, 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, to preserve our trade secrets, and to operate without infringing 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 includes ZIO-101.

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-(simethylarsino) glutathione as treatments for cancer." The patent was granted on June 28, 2005 as U.S. Patent No. 6,911,471. The patent application claims both therapeutic uses and pharmaceutical compositions containing a novel class of organic arsenicals, including ZIO-101, for the treatment of cancer. In February 2006, we announced that a second organic arsenic case has been issued under U.S. Patent No. 6,995,188. This patent provides further coverage of cancer treatment using organic arsenic, including ZIO-101, in combination with other agents or therapies. In addition, there were seven (7) patents related to ZIO-101 that issued in various foreign countries in 2006.

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 approximately \$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. The option will vest and become exercisable with respect to another 50% of its shares upon completion of the dosing of the last patient for both the blood and solid tumor phase I trials for ZIO-101 and 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 ZIO-101). 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 ZIO-101 in May 2005 and \$250,000 upon the dosing of the first patient in the Registrant-sponsored phase II clinical trial for ZIO-101 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. We have the exclusive right to all intellectual property rights resulting from such research pursuant to the terms of the agreements. One of these agreements has now been extended to a third year by mutual agreement.

The agreement also contains other provisions customary and common in 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, ZIO-201.

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 the 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, which option vested with respect to 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 ZIO-201. DEKK-Tec is entitled to receive royalty payments on the sales of ZIO-201 should it be approved for commercial sale. The license agreement also contains other provisions customary and common in similar agreements within the industry.

*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 license maintenance fee, and \$100,000 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. The purchase price includes the entire indibulin intellectual property portfolio as well as existing drug substance and capsule inventories.

*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 isophosphoramidate 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 isophosphoramidate mustard analogs. The option agreement must be exercised within 60 days of December 22, 2006.

*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, or the



“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 will automatically become effective 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 can proceed. The Company cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin.

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

Clinical trials typically are conducted in three sequential phases, but the phases may overlap. The study protocol and informed consent information for study subjects in clinical trials must also be approved by an Institutional Review Board for each institution where the trials 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 to (i) evaluate dosage tolerance and appropriate dosage; (ii) identify possible adverse effects and safety risks; and (iii) evaluate preliminarily the efficacy of the drug for specific indications. Phase III trials usually further evaluate clinical efficacy and test further 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, a 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 an effectiveness claim in an NDA application. This process is known as Special Protocol Assessment and can be a somewhat lengthy process. If an agreement is reached, the Agency will reduce the agreement to writing and make it part of the administrative record. 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 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 agencies review 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 drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing 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, that 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 sure that any of its drugs will qualify for any of these programs, or that, if a drug does qualify, that 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. 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 been met to 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 product, such as adding new indications, making certain manufacturing changes, or making certain additional labeling claims, are subject to further FDA review and approval. Before a company can market products for additional indications, it must obtain additional approvals 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: (i) report certain adverse reactions to the FDA, (ii) comply with certain requirements concerning advertising and promotional labeling for their products, and (iii) continue to have quality control and manufacturing procedures conform to cGMP after approval. The FDA periodically inspects the sponsor's records related to safety reporting and/or manufacturing facilities; this latter effort includes assessment of compliance with cGMP. 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 current report, the Company has 28 employees, all of which are full-time employees. Several additional employees are expected to be hired prior to the end of 2007.

### **Recent 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-subsiary merger, we relinquished our prior corporate name, EasyWeb, Inc., and assumed in its place the name "ZIOPHARM Oncology, Inc." The parent-subsiary 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 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 the 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, 2006, we had a net loss of \$17.9 million and we had incurred approximately \$33.2 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, 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. Until and unless 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 earn 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, 2006, we had incurred approximately \$33.2 million of cumulative net losses and had approximately \$28.4 million of cash, cash equivalents, and short-term investments. Currently, we expect that we will have sufficient cash to fund our operations into the first quarter of 2008. Although we expect our cash on-hand to fund our operations into the first quarter of 2008, 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 or forego attractive business opportunities, or discontinue our operations altogether.

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

Prior to the Merger, ZIOPHARM, Inc. was 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, undertaking preclinical trials and clinical trials of our product candidates ZIO-101, ZIO-201 and ZIO-301, and manufacturing ZIO-101 and ZIO- 201 and soon ZIO-301. 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.

***We intend to acquire rights to develop and commercialize additional product candidates. 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. The success of our strategy depends upon our ability to identify, select and acquire pharmaceutical 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 us and have significantly more financial resources than we do. Our competitors may have stronger relationships with certain third parties with whom we are interested in partnering, such as academic research institutions, and may, therefore, have 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 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 manufactured or produced economically or commercialized successfully. If we are unable to successfully manage our growth, our business may be harmed.

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 these capabilities. Any future growth will place a significant strain on our management and on our administrative, operational and financial resources. 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. 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.***

Our success will depend upon the expansion of our operations and the effective management of our growth, which will place a significant strain on our management and on our administrative, operational and financial resources. 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 2008 and July 2007, 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 any of our 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.

***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.

***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 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.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of pharmaceutical products we develop, alone or with collaborators. We currently carry clinical trial insurance and product liability insurance.

#### **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, ZIO-101, ZIO-201 and ZIO-301, 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 (NDA), 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 considers 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 our product candidates, ZIO-101, ZIO-201 and ZIO-301. Failure to obtain FDA approval of 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.

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, ZIO-101, ZIO-201, and ZIO-301 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.

***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 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 sure 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 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 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 on 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 can be no assurance that we will be able to establish or maintain our own sales operations or affect collaborative arrangements, or that if we are able to do so, our collaborators will have effective sales forces. 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 which may not be successful and which will be only partially in our control. Our product revenues would likely be lower than if we marketed and sold our products directly.

***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, or the 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 issue;
- 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 which 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 policy generally to require our employees, consultants, advisors and contractors to enter into agreements which 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 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 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 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, management continues to evaluate this segregation of duties. Our management is working to continuously monitor the segregation of duties as well as reviewing internal controls. We have engaged the services of a Sarbanes-Oxley consultant to tighten our internal controls and ensure adherence to the regulations once finalized. In the event we identify significant deficiencies or material weaknesses 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 \$10,100 until December 31, 2007, with such payments increasing to approximately \$11,000 thereafter through the remainder of the term of the lease. Our business and development operations in Charlestown occupy approximately 6,000 square feet located at 197 Eighth Street, Charlestown, Massachusetts 02129. The main Charlestown office space consists of two suites and is subject to a five-year lease agreement that expires in October 2009. Under the terms of the lease, we lease approximately 3,630 square feet and are required to make monthly rental payments that range from \$5,675 during the current year of the lease to \$6,350 during the last year of the lease. The additional 2,400 square feet of the Charlestown space generates a monthly charge of approximately \$6,940 per month and is not subject to any long-term lease agreements. The Company also has a small office in New Haven, Connecticut which is leased until October 31, 2009 and generates monthly payments that range from \$3,667 at the beginning of the lease to \$3,889 at the end of the lease term. The Company expects to lease additional square footage in the Boston area in 2007 to meet its expanding

needs.

23

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**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, 2006.

**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 bid prices for our common stock as reported by NASDAQ since September 22, 2006 and the OTCBB since our common stock began trading over the counter in 2004. The OTCBB quotations reflect inter-dealer prices, without retail markup, markdown or commission, and may not represent actual transactions. Prices set forth below for periods prior to August 24, 2005 do not reflect the 1-for-40 share combination effected on that date.

Fiscal Year 2006 (Quarter Ended)	Price Range	
	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
<b>Fiscal Year 2005 (Quarter Ended)</b>		
	High	Low
December 31, 2005	\$ 6.00	\$ 3.25
September 30, 2005	\$ 0.40	\$ 0.00
June 30, 2005	\$ 0.05	\$ 0.00
March 31, 2005	\$ 0.05	\$ 0.00
<b>Fiscal Year 2004 (Quarter Ended)</b>		
	High	Low
December 31, 2004	\$ 0.00	\$ 0.00
September 30, 2004	\$ 0.00	\$ 0.00
June 30, 2004	\$ 0.00	\$ 0.00
March 31, 2004	\$ 0.00	\$ 0.00

The approximate number of stockholders of record of our common stock as December 31, 2006 was 332. 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.

**Item 6. Management Discussion and Analysis or Plan of Operation****Overview:**

ZIOPHARM Oncology, Inc. is a biopharmaceutical company that is seeking to develop and commercialize a diverse, risk-sensitive portfolio of in-licensed cancer drugs that address unmet medical needs. Our principal focus is on the licensing and development of proprietary drug candidate families that are related to cancer therapeutics that are already on the market or in development. We believe this strategy will result in lower risk and expedited drug development programs. We expect to commercialize our products on our own in North America but recognize that promising clinical trial results in cancers with a high incidence and prevalence might also 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 ZIO-101, ZIO-201 and ZIO-301:

- ZIO-101 is an organic arsenic compound covered by issued U.S. patents and applications internationally. A form of commercially available inorganic arsenic (arsenic trioxide (Trisenox<sup>®</sup>) or ATO) has been approved for the treatment of acute promyelocytic leukemia (APL), a precancerous condition, and is on the compendia listing for the therapy of multiple myeloma as well as having been studied for the treatment of various other cancers. Nevertheless, ATO has been shown to be toxic to the heart, liver, and brain, limiting 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 generally is correlated to its accumulation in organs and tissues. Our preclinical and clinical studies to date have demonstrated that ZIO-101 (and organic arsenic in general) is considerably less toxic than inorganic arsenic, particularly with regard to heart toxicity. *In vitro* testing of ZIO-101 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 study has also established antiangiogenic properties of ZIO-101 and also support the use of an oral form of the drug.

Phase I testing of the intravenous (IV) form of ZIO-101 is still ongoing with two safety and dose finding studies to be completed in the near future. The Company has seen encouraging signs of clinical activity in both of these studies. The Company has completed the phase I portion of an ongoing phase I/II study in advanced multiple myeloma, also with encouraging signs of clinical activity. Following phase II studies in advanced myeloma, the Company expects to pursue registration in the U.S. with a potentially pivotal trial under Special Protocol Assessment (“SPA”) and to initiate patient treatment in early 2008. The Company has initiated additional phase II studies in other hematological and solid tumor cancers while also exploring different dosing schedules and expects to file a U.S. Investigational New Drug Application for the clinical study of an oral form of ZIO-101 in 2007.

ZIO-201, or isophosphoramidate mustard (IPM), is a proprietary stabilized metabolite of ifosfamide that is also related to cyclophosphamide. A patent application for pharmaceutical composition has been filed in the U.S. and internationally. Cyclophosphamide and ifosfamide are alkylating agents. The Company believes cyclophosphamide is the most widely used alkylating agent in cancer therapy and 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. Although ifosfamide-based treatment generally represents the standard of care for sarcoma, it is not licensed for this indication by the Food and Drug Administration. Our preclinical studies have shown that, in animal and laboratory models, IPM evidences activity against leukemia and solid tumors. These studies also indicate that ZIO-201 has a better pharmacokinetic and safety profile than ifosfamide or cyclophosphamide, offering the possibility of safer and more efficacious therapy with ZIO-201. 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 ZIO-201 is independently active without acrolein or chloroacetaldehyde metabolites, the Company believes that the administration of ZIO-201 may avoid many of the toxicities of ifosfamide and cyclophosphamide without compromising efficacy. In addition to anticipated lower toxicity, ZIO-201 (and without the co-administration of mesna) may have other advantages over ifosfamide. In preclinical studies ZIO-201 likely cross-links DNA differently than ifosfamide or cyclophosphamide metabolites, resulting in a different activity profile. Moreover, in some instances ZIO-201 appears to show activity in ifosfamide- and/or cyclophosphamide-resistant cancer cells.

Phase I and phase II testing of the intravenous (“IV”) form of ZIO-201 is ongoing in the U.S. IPM has been administered without the “uroprotectant” mesna and the toxicities associated with acrolein and chloroacetaldehyde have not been observed. Electrolyte imbalances seen with ifosfamide have occurred in the higher dose cohorts. The Company has seen encouraging signs of clinical activity in the phase I study. The Company has completed a phase I study in advanced sarcoma and a phase II is ongoing. The Company expects to pursue registration in the U.S. for the treatment of advanced sarcoma with a potentially pivotal trial under SPA to initiate patient treatment early in 2008. The Company also expects to start additional phase II studies in other cancers and using different dosing schedules and routes of administration and to file a U.S. Investigational New Drug Application for an oral form of ZIO-201 in 2007.



ZIO-301 (indibulin) is a novel small molecular weight tubulin polymerization inhibitor that has been acquired from Baxter Healthcare. A phase I study is currently underway with ZIO-301 to evaluate safety, pharmacokinetics (PK), maximum tolerated dose (MTD) and dose limiting toxicity (DLT) in patients with advanced solid tumors.

The microtubule component tubulin is one of the more well established anti-tumor targets in the treatment of cancer today. A number of drugs are on the market that target tubulin, for example paclitaxel (Taxol®) and the vinca alkaloid family (vincristine, vinorelbine). The use of these drugs is associated with important toxicities. Notably paclitaxel causes significant peripheral neurotoxicity. In contrast, ZIO-301 has not shown peripheral neurotoxicity either in preclinical testing or in the clinic to date.

This class of agents is typically the mainstay of chemotherapy in a wide variety of cancer indications. ZIO-301 is an orally available compound with preclinical data that indicates significant and broad activity (including taxane refractory and multi-drug resistant cell lines and xenografts) and it is potentially safer than other tubulin inhibitors (no neurotoxicity at curative doses in animals and in the ongoing phase I trial). At the current time, the Company anticipates pursuing a Fast Track development program in a niche indication following the completion of phase II testing. Potential initial indications would include but are not limited to: bladder, head & neck, prostate, colorectal, and renal cancer. Registration in one of these indications would then be followed by label expansion via trials that will have been initiated in anticipation of registration. In addition, the availability of an IV formulation would further expand the market opportunity and will be explored in 2007. Availability of an oral formulation of ZIO-301 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 ZIO-101 for advanced myeloma and ZIO-201 for advanced sarcoma, and ZIO-301 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 these approvals, 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.

### **Recent Developments**

On November 3, 2006, the Company signed a definitive Asset Purchase Agreement (for indibulin) and License Agreement (to Baxter's proprietary nanosuspension technology) with affiliates of Baxter Healthcare Corporation. Indibulin, referred to by the Company as ZIO-301, is a novel anti-cancer agent that binds to tubulin, one of the essential proteins for chromosomal segregation, and targets mitosis like the taxanes and vinca alkaloids. It is available as both an oral and a proprietary nanosuspension intravenous form. Molecules that target mitosis and inhibit cell division (antimitotic agents) are a major focus of cancer research and they are among the most widely used anti-cancer drugs in oncology today. Among the more well known antimitotic drugs are the taxanes (paclitaxel, docetaxel) and the vinca alkaloids (vincristine, vinblastine). The terms of the agreement include an upfront cash payment of approximately \$1.125 million has been expensed as purchased research and development in the year ended December 31, 2006, \$15,000 was paid for annual license maintenance fee, and \$100,000 payment 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. The purchase price includes the entire indibulin intellectual property portfolio as well as existing drug substance and capsule inventories.





## 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 two lead product candidates, ZIO-101, ZIO-201 and the newly acquired ZIO-301. 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 ZIO-101 and ZIO-201, ZIO-301, and preclinical costs associated with back-up candidates ZIO-102 and ZIO-202;
- Costs related to the scale-up and manufacture of ZIO-101, ZIO-201, and ZIO-301;
- 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 ZIO-101, ZIO-201, newly acquired ZIO-301, and other back-up candidates and ongoing in-licensing efforts over the next 12 months we expect to spend approximately \$3.1 million on preclinical and regulatory expenses, \$12.5 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 \$6.7 million on manufacturing costs, approximately \$475,000 on facilities, rent (including additional space not presently contracted) and other facilities related costs, and approximately \$5.4 million on general corporate and working capital. We believe that we currently have sufficient capital to fund development and commercialization activities of ZIO-101 and ZIO-201, as well as newly acquired ZIO-301, into the first quarter of 2008 with the proceeds, and interest earned herein, from the common stock offering received on May 3, 2006.

### *Product Candidate Development and Clinical Trials*

*ZIO-101.* ZIO-101, organic arsenic, is being developed presently to treat advanced myeloma and the phase II portion of a phase I/II trial in advanced multiple myeloma is underway. We will continue to explore the use of ZIO-101 in other phase II trials as well as exploring different dosing schedules and forms. Preclinical development will continue with a back-up compound designated as ZIO-102. Additional compounds are being synthesized under an extension of our agreement with The University of Texas M.D. Anderson Cancer Center and the Texas A&M University System. 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 forms will continue through the period leading to the expected registration trial. Preclinical development will continue with additional compounds.

*ZIO-201.* ZIO-201, stabilized isophosphoramidate mustard, is being developed presently to treat advanced sarcoma. As a follow-on to the ongoing phase I trial, a phase II trial in advanced sarcoma is well underway. Other trials, including different dosing schedules and additional forms are in the advanced planning stage. We expect to initiate a registration trial in advanced sarcoma following the completion of phase II study. 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 forms) will continue. Preclinical development will continue with back-up analogues.

*ZIO-301.* ZIO-301, a novel anti-cancer agent that targets mitosis like the taxanes, is available as an oral and potentially an intravenous form. The oral form is currently in a phase I trial, with phase II expected to initiate in 2007 under an Investigational New Drug Application filed in the United States.

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

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

*Research and development expenses.* For the year ended December 31, 2006, research and development expenses increased by \$4.8 million, or 85.7%, to \$10.4 million from \$5.6 million 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 ZIO-301. 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 ZIO -101 and ZIO-201. 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 \$4.5 million, or 108.0%, to \$8.7 million from \$4.2 million 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 as we have built infrastructure to support the 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 \$1.0 million, or 363.9%, to \$1.3 million in the year ended December 31, 2006 from \$0.3 million 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 \$8.3, or 87.6%, to \$(17.9) million in the year ended December 31, 2006 from \$(9.5) million for the same period of 2005.

## **Results of Operations for the fiscal year ended December 31, 2005 versus December 31, 2004**

*Revenues.* We had no revenues for the fiscal year ended December 31, 2005 and 2004.

*Research and development expenses.* For the year ended December 31, 2005, research and development expenses increased to approximately \$5.6 million from approximately \$2.1 million in the twelve-month period ended December 31, 2004, an increase of approximately 163%. The increase is attributable to an increase of \$1.2 million spent on clinical trials, \$1.9 in manufacturing related costs, \$0.2 million in pre-clinical costs, and \$0.3 million in employee related costs as we built infrastructure to support the research and development efforts. For the next year, we expect research and development spending to continue to increase as we continue to progress our clinical trials and continue with commercial scale-up manufacturing activities.

*General and administrative expenses.* For the year ended December 31, 2005, general and administrative expenses increased to approximately \$4.2 million from approximately \$3.6 million in the year ended December 31, 2004, and increase of approximately 17%. The increase is primarily attributable to a nonrecurring payment of \$0.4 million due

on closing of the merger.

28

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*Other income (expense)* . Other income increased to approximately \$0.3 million in the year ended December 31, 2005 from approximately \$0.02 million in the year ended December 31, 2004, an increase of approximately 1171%. Other income during the year ended December 31, 2005 was primarily comprised of interest income. The increase in the period is due to higher cash balances available for investing purposes.

*Net income (loss)*. For the reasons described above, the net loss increased to approximately \$3.8 million in the year ended December 31, 2005 to \$9.5 million from approximately \$5.7 million in the year ended December 31, 2005, an increase of approximately 67%.

### **Liquidity and Capital Resources**

As of December 31, 2006, we had approximately \$28.4 million in cash, cash equivalents and short-term investments. With the proceeds from our 2006 common stock offering, which was completed on May 3, 2006, we believe we currently have sufficient capital to fund development and commercialization activities of ZIO-101, ZIO-201, and ZIO-301 early into the first quarter of 2008. Because our business does not generate any cash flow, however, we will need to raise additional capital to continue development of the product candidates beyond that time or to fund development efforts related to new product candidates. We anticipate raising such additional capital by either borrowing money or by selling shares of our capital stock. To the extent additional capital is not available when we need it, we may be forced to abandon some or all of our development and commercialization efforts, which would have a material adverse effect on the prospects of our business. Further, our assumptions relating to the expected costs of development and commercialization and timeframe for completion are dependent on numerous factors other than available financing, including significant unforeseen delays in the clinical trial and regulatory approval process, which could be extremely costly. In addition, our estimates assume that we will be able to enroll a sufficient number of patients in each clinical trial.

The Company anticipates that losses will continue for the foreseeable future. At December 31, 2006, the Company's accumulated deficit was approximately \$33.2 million. The Company's ability to continue operations after its current cash resources are exhausted depends on its ability to obtain additional financing and achieve profitable operations, as to which no assurances can be given.

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

In order to continue our long-term plans for clinical trials and new product development, we will need to raise additional capital to continue to fund our research and development as well as operations after we exhaust our current cash resources. We expect to finance our cash needs through the sale of equity securities and 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.

Since inception, our primary source of funding for our operations has been the private sale of our securities. For the twelve months ended December 31, 2006, we received gross proceeds of approximately \$37 million (\$34,280,120 net of cash issuance costs) as a result of the sale of an aggregate of 7,991,256 shares (the “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 (each a “Warrant”) to purchase, at an exercise price of \$5.56 per share, an additional number of shares of common stock equal to 30 percent of the Shares purchased by such investor in the Offering. In the aggregate, these Warrants entitle investors to purchase an additional 2,397,392 shares of common stock. The Company engaged Paramount BioCapital, Inc. and Griffin Securities, Inc. (the “Placement Agents”) as co-placement agents in connection with the Offering. In consideration for their services, the Company paid the Placement Agents and certain selected dealers engaged by the Placement Agents aggregate cash commissions of \$2,589,966 and issued 7-year warrants to the Placement Agents and their designees to purchase an aggregate of 799,126 shares at an exercise price of \$5.09 per share. The Company also agreed to reimburse the Placement Agents for their accountable expenses incurred in connection with the Offering. Immediately following the completion of Offering, the Company had 15,264,248 shares of common stock outstanding.

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

At December 31, 2006, working capital was approximately \$25.9 million, compared to working capital of approximately \$6.8 million at December 31, 2005. The increase in working capital reflects the proceeds from the May 2006 offset by the use of funds for operations.

Capital expenditures were approximately \$354,000 for the twelve months ended December 31, 2006. We anticipate capital expenditures of approximately \$425,000 for the fiscal year ended December 31, 2007.

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

	Total	Payments due by Period			After 5 Years
		Less than 1 Year	1 - 3 Years	3 - 5 Years	
Operating lease	\$ 813,020	\$ 262,139	\$ 485,091	\$ 65,790	-

### 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.

### Research and Development

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 only being applied 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 and 2004 would have increased by approximately \$844,000 and \$110,000, respectively. 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**

	<b>Page</b>
Audited Financial Statements of ZIOPHARM Oncology, Inc.:	
Report of Independent Registered Public Accounting Firm	F-1
Balance Sheets as of December 31, 2006 and 2005	F-2
Statements of Operations for the Years Ended December 31, 2006, 2005, and 2004, and for the Period from inception (September 9, 2003) through December 31, 2006	F-3
S Statements of Cash Flows for the Years Ended December 31, 2006, 2005, and 2004, and for the Period from inception (September 9, 2003) through December 31, 2006	F-4
Statements of Changes in Convertible Preferred Stock and Stockholders' Equity (Deficit) for the Year Ended December 31, 2006, 2005, and 2004	F-5
Notes to Financial Statements	F-6

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the balance sheets of ZIOPHARM Oncology, Inc. (a development stage company) as of December 31, 2006 and 2005 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, 2006 and in the period from inception (September 9, 2003) through December 31, 2006. 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 audit 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, 2006 and 2005 and the results of their operations and their cash flows for each of the years in the three year period ended December 31, 2006 and in the period from inception (September 9, 2003) through December 31, 2006 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 6, 2006

F-1

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**ZIOPHARM Oncology, Inc.**  
**(A Development Stage Enterprise)**  
**Balance Sheets**  
**As of December 31, 2006 and 2005**

	December 31, 2006	December 31, 2005
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 26,855,450	\$ 8,880,717
Short-term investments	1,555,164	-
Prepaid expenses and other current assets	462,789	211,837
Total current assets	28,873,403	9,092,554
Property and equipment, net	451,247	269,702
Deposits	9,367	5,700
Other non current assets	178,080	124,343
Total assets	\$ 29,512,097	\$ 9,492,299
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 776,128	\$ 835,997
Accrued expenses	2,161,914	1,418,819
Total current liabilities	2,938,042	2,254,816
Deferred rent	41,078	35,557
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Common stock, \$.001 par value; 280,000,000 shares authorized; 15,272,899 and 7,247,992 shares issued and outstanding at December 31, 2006 and 2005, respectively	15,273	7,248
Additional paid-in capital	44,667,878	20,580,494
Warrants issued	15,071,101	1,978,540
Deficit accumulated during development stage	(33,221,275)	(15,364,356)
Total stockholders' equity	26,532,977	7,201,926
Total liabilities and stockholders' equity	\$ 29,512,097	\$ 9,492,299

**ZIOPHARM Oncology, Inc.**  
**(A Development Stage Enterprise)**

Statements of Operations

For the years ended December 31, 2006, 2005, and 2004,  
and for the period from inception (September 9, 2003)  
through December 31, 2006

	For the year ended December 31, 2006	For the year ended December 31, 2005	For the year ended December 31, 2004	For the period from inception (September 9, 2003) through December 31, 2006
Research contract revenue	\$ -	\$ -	\$ -	\$ -
<b>Operating expenses and other income:</b>				
Research and development, including costs of research contracts	10,391,302	5,593,850	2,126,607	18,111,759
General and administrative	8,720,290	4,193,553	3,581,959	16,656,436
Total operating expenses	19,111,592	9,787,403	5,708,566	34,768,195
Loss from operations	(19,111,592)	(9,787,403)	(5,708,566)	(34,768,195)
Interest income	1,254,673	270,480	21,269	1,546,920
Net loss	\$ (17,856,919)	\$ (9,516,923)	\$ (5,687,297)	\$ (33,221,275)
Basic and diluted net loss per share	\$ (1.42)	\$ (2.32)	\$ (2.37)	
<b>Weighted average common shares outstanding used</b>				
to compute basic and diluted net loss per share	12,571,951	4,101,514	2,402,127	

**ZIOPHARM Oncology, Inc.**  
**(A Development Stage Enterprise)**

Statements of Cash Flows

For the years ended December 31, 2006, 2005, and 2004,  
and for the period from inception (September 9, 2003)  
through December 31, 2006

	For the year ended December 31, 2006	For the year ended December 31, 2005	For the year ended December 31, 2004	For the period from inception (September 9, 2003) through December 31, 2006
<b>Cash flows from operating activities:</b>				
Net loss	\$ (17,856,919)	\$ (9,516,923)	\$ (5,687,297)	\$ (33,221,275)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	173,920	101,232	33,953	309,105
Stock-based compensation	2,882,658	98,755	703,116	3,684,529
Gain on disposal of fixed assets	(1,165)			(1,165)
Change in operating assets and liabilities:				
Increase (decrease) in:				
Prepaid expenses and other current assets	(250,952)	(94,266)	(117,571)	(462,789)
Other noncurrent assets	(53,737)	(124,343)	-	(178,080)
Deposits	(3,667)	54,346	(60,046)	(9,367)
Increase (decrease) in:				
Accounts payable	(59,869)	126,050	647,448	776,128
Accrued expenses	743,095	539,443	879,376	2,161,914
Deferred rent	5,521	35,557	-	41,078
Net cash used in operating activities	(14,421,115)	(8,780,149)	(3,601,021)	(26,899,922)
<b>Cash flows from investing activities:</b>				
Purchases of property and equipment	(354,300)	(130,201)	(274,686)	(759,187)
Increase in short term investments	(1,555,164)	-	-	(1,555,164)
Net cash used in investing activities	(1,909,464)	(130,201)	(274,686)	(2,314,351)
<b>Cash flows from financing activities:</b>				
Stockholders' capital contribution	-	-	-	500,000
Proceeds from exercise of stock options	25,192	4,815	-	30,007
Proceeds from issuance of common stock, net	34,280,120	-	4,500,000	38,780,120
Proceeds from issuance of preferred stock, net	-	16,759,596	-	16,759,596
Net cash provided by financing activities	34,305,312	16,764,411	4,500,000	56,069,723

Net increase in cash and cash equivalents	17,974,733	7,854,061	624,293	26,855,450
Cash and cash equivalents, beginning of period	8,880,717	1,026,656	402,363	-
Cash and cash equivalents, end of period	\$ 26,855,450	\$ 8,880,717	\$ 1,026,656	\$ 26,855,450
<b>Supplementary disclosure of cash flow information:</b>				
Cash paid for interest	\$ -	\$ -	\$ -	\$ -
Cash paid for income taxes	\$ -	\$ -	\$ -	\$ -
<b>Supplementary disclosure of noncash investing and financing activities:</b>				
Warrants issued to placement agents and investors, in connection with private placement	\$ 13,092,561	\$ -	\$ -	\$ 13,092,561
Warrants issued to placement agent, in connection with preferred stock issuance	\$ -	\$ 1,682,863	\$ -	\$ 1,682,863
Preferred stock conversion to common stock	\$ -	\$ 16,759,596	\$ -	\$ 16,759,596
Warrants converted to common shares	\$ 17,844	\$ -	\$ -	\$ 17,844

F-4

**ZIOPHARM Oncology, Inc.**  
**(Development Stage Enterprise)**

Statement of changes in convertible preferred stock and stockholders' equity  
 For the years ended December 31, 2006, 2005, and 2004, and  
 for the period from inception (September 9, 2003)  
 through December 31, 2006

	Convertible Preferred Stock and Warrants			Stockholder's Equity					Deficit Accumulated During Development Stage
	Series A Convertible Preferred Stock		Warrants to Purchase Series A Convertible Preferred Stock	Common Stock		Additional Paid-in Capital		Warrants	
	Shares	Amount	Warrants	Shares	Amount	Capital	Warrants	Stag	
Stockholders' contribution, September 9, 2003	—	—	—	250,487	\$ 250.00	\$ 499,750.00	\$	—	—
Net loss	—	—	—	—	—	—	—	—	(16,842)
Balance at December 31, 2003 (audited)	0	0	0	250,487	250	499,750	—	—	(16,842)
Issuance of common stock	—	—	—	2,254,389	2,254	4,497,746	—	—	—
Issuance of common stock for services	—	—	—	256,749	257	438,582	—	—	—
Fair value of options/warrants issued for nonemployee services	—	—	—	—	—	13,240	251,037	—	—
Net loss	—	—	—	—	—	—	—	—	(5,682)
Balance at December 31, 2004	—	—	—	2,761,625	2,761	5,449,318	251,037	—	(5,842)
Issuance of Series A convertible preferred stock (net of expenses of \$1,340,263 and warrant cost of \$1,682,863)	4,197,946	15,076,733	—	—	—	—	—	—	—



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Fair value of warrants to purchase Series A convertible preferred stock	—	—	1,682,863	—	—	—	—	—
Issuance of Common stock to EasyWeb Shareholders	—	—	—	189,922	190	(190)	—	—
Conversion of Series A convertible preferred stock @ \$0.001 into \$0.001 common stock on September 13, 2005 at an exchange ratio of .500974	(4,197,946)	(15,076,733)	(1,682,863)	4,197,823	4,198	15,072,535	1,682,863	—
Issuance of common stock for options	—	—	—	98,622	99	4,716	—	—
Fair value of options/warrants issued for nonemployee services	—	—	—	—	—	54,115	44,640	—
Net loss	—	—	—	—	—	—	—	(9,510)
Balance at December 31, 2005	—	—	—	7,247,992	7,248	20,580,494	1,978,540	(15,360)
Issuance of common stock in private placement, net of expenses \$2,719,395	—	—	—	7,991,256	7,991	21,179,568	—	—
Issuance of warrants	—	—	—	—	—	—	13,092,561	—
Issuance of common stock for services rendered	—	—	—	25,000	25	106,225	—	—
Stock based compensation for employees	—	—	—	—	—	2,776,408	—	—
Issuance of common stock	—	—	—	5,845	6	25,186	—	—

due to exercise of stock options								
Issuance of common stock								—
due to exercise of stock warrants	—	—	—	2,806	3	(3)		
Net loss	—	—	—	—	—	—	—	(17,85)
Balance at December 31, 2006	-\$	-\$	-\$ 15,272,899	\$ 15,273	\$ 44,667,878	15,071,101	\$	(33,22)

F-5

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**ZIOPHARM Oncology, Inc.**  
**(A Development Stage Enterprise)**

Notes to Financial Statements

**1. ORGANIZATION**

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

The Company has operated at a loss since its inception in 2003 and has no revenues. The Company anticipates that losses will continue for the foreseeable future. At December 31, 2006, the Company’s accumulated deficit was approximately \$33.2 million. The Company’s ability to continue operations after its current cash resources are exhausted depends on its ability to obtain additional financing and achieve profitable operations, as to which no assurances can be given. Cash requirements may vary materially from those now planned because of changes in the focus and direction of our research and development programs, competitive and technical advances, patent developments or other developments. Additional financing will be required to continue operations after we exhaust our current cash resources and to continue our long-term plans for clinical trials and new product development. There can be no assurance that any such financing can be realized by the Company, or if realized, what the terms thereof may be, or that any amount that Company is able to raise will be adequate to support the Company’s working capital requirements until it achieves profitable operations.

On May 3, 2006, pursuant to Subscription Agreements (the “Subscription Agreements”) between the Company and certain institutional and other accredited investors, the Company completed the sale of an aggregate of 7,991,256 shares (the “Shares”) of the Company’s common stock at a price of \$4.63 per Share in a private placement (the “2006 Offering”). In addition to the Shares, the Company also issued to each investor a five-year warrant (each a “Warrant”) to purchase, at an exercise price of \$5.56 per share, an additional number of shares of common stock equal to 30 percent of the Shares purchased by such investor in the 2006 Offering. In the aggregate, these Warrants entitle investors to purchase an additional 2,397,392 shares of common stock. The Company estimated the fair value of these warrants at \$9,575,958 using the Black-Scholes model, using an assumed risk-free rate of 5.01% and an expected life of 5 years, volatility of 100% and a dividend yield of 0%. The total gross proceeds resulting from the 2006 Offering was approximately \$37 million, before deducting selling commissions and expenses.

The Company engaged Paramount BioCapital, Inc. (“Paramount”) and Griffin Securities, Inc. (together, the “Placement Agents”) as co-placement agents in connection with the 2006 Offering. In consideration for their services, the Company paid the Placement Agents and certain selected dealers engaged by the Placement Agents and their designees aggregate cash commissions of \$2,589,966 (of which \$1,726,644 was paid to Paramount; see Note 4 - Related Party Transactions) and issued 7-year warrants to the Placement Agents and their designees to purchase an aggregate of 799,126 shares of the Company’s common stock (10 percent of the Shares sold in the 2006 Offering) at an exercise price of \$5.09 per share (the “Placement Agent Warrants”). The Company estimated the fair value of these warrants at \$3,516,603 using the Black-Scholes model, using an assumed risk-free rate of 5.01% and an expected life of 7 years, volatility of 100% and a dividend yield of 0%. The Company made reimbursements of \$100,000 to the Placement Agents for their accountable expenses incurred in connection with the 2006 Offering.

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



***ZIOPHARM Oncology, Inc.***  
***(A Development Stage Enterprise)***  
Notes to Financial Statements

**1. ORGANIZATION... continued**

With respect to each investor in the 2006 Offering, the Company also agreed to use its reasonable commercial efforts to cause the registration statement to remain effective until the earliest of (i) the date on which the investor may sell all of the Shares and shares issuable upon exercise of the Warrants then held by the investor pursuant to Rule 144(k) of the Securities Act of 1933 without regard to volume restrictions; and (ii) such time as all of the securities held by the investor and registered under the Registration Statement have been sold pursuant to a registration statement, or in a transaction exempt from the registration and prospectus delivery requirements of the Securities Act of 1933 under Section 4(1) thereof so that all transfer restrictions and restrictive legends are removed upon the consummation of such sale. The Placement Agents have been afforded equivalent registration rights as the investors in the 2006 Offering with respect to the shares issuable upon exercise of the Placement Agent Warrants. Warrants issued in the 2006 Offering are classified as equity based on the determination that the penalty for failure to register is not uneconomic. On May 19, 2006, the Company filed a registration statement on Form S-3 with the Securities and Exchange Commission. The registration statement was declared effective on May 30, 2006, rendering the resale of the shares issued in the May 3, 2006 Offering registered under the Securities Exchange Act of 1933.

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

***ZIOPHARM Oncology, Inc.***  
***(A Development Stage Enterprise)***

Notes to Financial Statements

**1. ORGANIZATION... continued**

Although EasyWeb is the legal acquirer in the transaction, ZIOPHARM became the registrant with the Securities and Exchange Commission. Under generally accepted accounting principles, the transaction was accounted for as a reverse acquisition, whereby ZIOPHARM was considered the acquirer of EasyWeb for financial reporting purposes because ZIOPHARM's stockholders controlled more than 50% of the post-transaction combined entity, the management and the board were that of ZIOPHARM after the transaction, EasyWeb had no operating activity and limited assets and liabilities as of the transaction date and the continuing operations of the entity are those of ZIOPHARM.

Accordingly, the equity of EasyWeb has been adjusted to reflect a recapitalization of the stock and the equity of ZIOPHARM has been adjusted to reflect a financing transaction with the proceeds equal to the net asset value of EasyWeb immediately prior to the Merger. The historical financial statements of ZIOPHARM have become the historical financial statements of the Company. The historical stockholders' equity has been retroactively restated to adjust for the exchange of shares pursuant to the Merger Agreement. All share and per share information included in the accompanying financial statements and notes give effect to the exchange, except as otherwise stated.

On June 6, 2005, the Company completed an offering (the "Offering") of Series A Convertible Preferred Stock ("Series A Preferred Stock"). The Company issued 4,197,946 shares at \$4.31 for gross proceeds of approximately \$18.1 million. In connection with the Offering, the Company compensated Paramount BioCapital, Inc., placement agent for the Offering ("Paramount"), or its affiliates for its services through the payment of (a) cash commissions equal to 7% of the gross proceeds from the sale of the shares of Series A Preferred Stock, and (b) placement warrants to acquire 419,794 shares of Series A Preferred Stock (the "Series A Stock Warrants"), exercisable for a period of 7 years from the Closing Date at a per share exercise price equal to 110% of the price per share sold in the Offering. These commissions are also payable on additional sales by the Company of securities (other than in a public offering) to investors introduced to the Company by Paramount during the twelve (12) month period subsequent to the final closing of the Offering. The Company also paid Paramount an expense allowance of \$50,000 to reimburse Paramount for its out-of-pocket expenses. Also, for a period of 36 months from the final Closing, Paramount has the right of first refusal to act as the placement agent for any private sale of the Company's securities. Lastly, the Company has agreed to indemnify Paramount against certain liabilities, including liabilities under the Securities Act.

The Company has valued the Series A Stock Warrants using the Black-Scholes model and recorded a charge of \$1,682,863 against additional paid-in capital. The Company has estimated the fair value of such warrants using the Black-Scholes model, using an assumed risk-free rate of 3.93% and expected life of 7 years, volatility of 134% and dividend yield of 0%. The net proceeds from the Offering will be used for research and development, licensing fees and expenses, and for working capital and general corporate purposes.

***ZIOPHARM Oncology, Inc.***  
***(A Development Stage Enterprise)***

Notes to Financial Statements

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

Use of Estimates

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

Cash and Cash Equivalents

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

Concentrations of Credit Risk

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

Short-Term Investments

The Company accounts for its short-term investments in accordance with Statement of Financial Accounting Standards ("SFAS") No. 115, "Accounting for Certain Investments in Debt and Equity Securities." The Company's investments, which are carried at fair value, consist of funds comprised of certificate of deposits with maturities over ninety days, totaling \$1.6 million at December 31, 2006.

Fair Value of Financial Instruments

The carrying amounts of cash equivalents, accounts payable and accrued expenses approximate their fair value because of their short-term nature. Short-term investments are carried at aggregate fair value.

Income Taxes

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

Property and Equipment

Property and equipment are stated at cost. Depreciation and amortization are provided on the straight-line method over the estimated useful lives of the related assets, which is three to five years.

F-9

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**ZIOPHARM Oncology, Inc.**  
**(A Development Stage Enterprise)**

Notes to Financial Statements

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES...continued**

Research and Development Costs

Costs related to research and development are charged to expense when incurred. Such costs include proprietary research and development activities, purchased research and development, and expenses associated with research and development contracts, whether performed by the Company or contracted with independent third parties.

Accounting for Stock-Based Compensation

On January 1, 2006, the Company adopted 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 only being applied 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 recognized the full impact of its share-based employee payment plans in the statements of operations for the year ended December 31, 2006 under SFAS 123R and did not capitalize any such costs on the balance sheet. The following table presents share-based compensation expense included in the Company's statement of operations:

	<b>Twelve months ended December 31, 2006</b>
Research and development, including costs of research contracts	\$ 375,411
General and administrative	2,400,997
Share based employee compensation expense before tax	2,776,408
Income tax benefit	—
Net share-based employee compensation expense	\$ 2,776,408

F-10

**ZIOPHARM Oncology, Inc.**  
**(A Development Stage Enterprise)**

Notes to Financial Statements

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES...continued**

Accounting for Stock-Based Compensation... continued

The adoption of SFAS 123R resulted in incremental stock-based compensation expense of \$2,776,408 twelve months ended December 31, 2006 which caused the Company's net loss to increase by \$2,776,408 and its net loss per share to increase by \$0.22 per share for the twelve months ended December 31, 2006. The adoption had no impact on cash used in operating activities or cash provided by financing activities.

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.

The following table illustrates the effect on net loss and earnings per share if the company had applied the fair value recognition provisions of SFAS 123 to stock based awards for the twelve month periods ended December 31, 2005 and 2004, and for the period from inception (September 9, 2003) to December 31, 2005:

	For the years ended December 31,		For the period from inception (September 9, 2003) to December 31, 2005
	2005	2004	
Net loss:			
As reported	\$ (9,516,923)	\$ (5,687,297)	\$ (15,364,356)
Stock-based compensation expense included in reported net loss	98,755	703,116	801,871
Stock-based compensation expense under the fair value-based method	(942,888)	(813,095)	(1,755,983)
Pro forma net loss	\$ (10,361,056)	\$ (5,797,276)	\$ (16,318,468)
Basic and diluted net loss per share:			
As reported	\$ (2.32)	\$ (2.37)	
Pro forma	\$ (2.53)	\$ (2.41)	



**ZIOPHARM Oncology, Inc.**  
**(A Development Stage Enterprise)**

Notes to Financial Statements

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES...continued**

Accounting for Stock-Based Compensation...continued

The fair value of each stock option is estimated at the date of grant using the Black-Scholes option pricing model. The estimated weighted average fair value of stock options granted to employees in 2006, 2005 and 2004 was approximately \$4.10, \$3.43 and \$1.32 per share, respectively. The following table summarizes the assumptions used in the Black-Scholes option pricing model:

	2006	2005	2004
Expected life	5 years	5 years	5 years
Expected volatility	92% - 102%	109% - 114%	134%
Dividend yield	0%	0%	0%
Weighted average risk-free interest rate	4.53 - 5.02%	3.77 - 4.39%	3.6%
Forfeiture rate	0%	0%	0%

Net Loss Per Share

Consistent with Statement of Financial Accounting Standards No. 128, *Earnings Per Share*, basic loss per share amounts are based on the weighted average number of shares of common stock outstanding during the period. Diluted loss per share amounts are based on the weighted average number of shares of common stock and potentially dilutive common stock outstanding during the period. The impact of options and warrants to purchase 5,593,377, 1,576,988 and 728,262 shares of common stock have been excluded from the calculation of diluted weighted average share amounts as their inclusion would have been anti-dilutive for 2006, 2005 and 2004, respectively.

F-12

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**ZIOPHARM Oncology, Inc.**  
**(A Development Stage Enterprise)**

Notes to Financial Statements

**3. PROPERTY AND EQUIPMENT**

Property and equipment at December 31, 2006 and 2005 consisted of the following:

	Estimated Useful Life (Years)	2006	2005
Software, Office & Computer equipment	3	\$ 582,511	\$ 349,527
Leasehold Improvements	3	163,878	43,004
Manufacturing Equipment	5	12,357	12,357
		758,746	404,888
Less - accumulated depreciation and amortization		(307,499)	(135,186)
		\$ 451,247	\$ 269,702

Depreciation and amortization expense was \$173,920, \$101,232, \$33,953, and \$309,105 for the years ended December 31, 2006, 2005, and 2004 and for the period from inception (September 9, 2003) to December 31, 2006, respectively.

**4. ACCRUED EXPENSES**

Accrued expenses at December 31, 2006 and 2005, consisted of the following:

	2006	2005
Employee compensation	\$ 496,841	\$ 441,668
Professional services	107,737	76,649
Research and development consulting services	102,516	69,466
Clinical consulting services	518,712	369,439
Manufacturing services	773,019	388,563
Accrued vacation	22,094	6,765
Other	140,995	66,269
	\$ 2,161,914	\$ 1,418,819

***ZIOPHARM Oncology, Inc.***  
***(A Development Stage Enterprise)***

Notes to Financial Statements

**5. RELATED PARTY TRANSACTIONS**

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

In connection with the December 22, 2004 Option Agreement with Southern Research Institute (“SRI”), the Company entered into a Finders Agreement, dated December 23, 2004, with Paramount pursuant to which the Company has agreed to compensate Paramount, for services in connection with the Company’s introduction to SRI through the payment of (a) a cash fee of \$60,000 and (b) warrants to purchase 62,621 (125,000 pre-Merger) shares of the Company’s Common Stock at a price equal to \$4.75 (\$2.38 pre-Merger) per share. The Company has estimated the fair value of such warrants using the Black-Scholes model, using an assumed risk-free rate of 3.93%, and expected life of 7 years, volatility of 134% and dividend yield of 0%. In December 2004, the Company expensed the \$60,000 that was payable to Paramount and recognized compensation expense in the amount of \$251,037 for the issuance of the warrants.

In connection with the Series A Preferred Stock Offering, the Company and Paramount entered into an Introduction Agreement in January 2005, pursuant to which the Company had agreed to compensate Paramount for its services in connection with the Offering through the payment of (a) cash commissions equal to 7% of the gross proceeds from the sale of the shares of Series A Preferred Stock, and (b) placement warrants to acquire a number of shares of Series A Preferred Stock equal to 10% of the number of shares of Series A Preferred Stock issued in the Offering, exercisable for a period of 7 years from the Closing Date at a per Share exercise price equal to 110% of the price per Share sold in the Offering. These commissions are also payable on additional sales by the Company of securities (other than in a public offering) to investors introduced to the Company by Paramount during the twelve (12) month period subsequent to the final closing of the Offering. The Company also agreed to pay to Paramount a non-accountable expense allowance of \$50,000 to reimburse the Paramount for its out-of-pocket expenses. Also, for a period of 36 months from the final Closing, Paramount has the right of first refusal to act as the placement agent for the private sale of the Company’s securities. Lastly, the Company has agreed to indemnify Paramount against certain liabilities, including liabilities under the Securities Act.

In connection with the 2006 Offering, on May 3, 2006, the Company paid Paramount a cash commission equal to 7% of the gross proceeds from the sale of the Shares sold by Paramount in the 2006 Offering, resulting in a cash payment of approximately \$1,726,644. In addition, the Company issued 7-year warrants to the Placement Agents and their designees to purchase an aggregate of 799,126 shares (10 percent of the Shares sold in the Offering) of the Company’s common stock, of which 532,750 were issued at an exercise price of \$5.09 per share (the “Placement Agent Warrants”).

On December 18, 2006 the Company paid Paramount a cash settlement of \$180,000 in exchange for Paramount’s agreement to terminate certain of its rights under the 2005 and 2004 agreements. This amount was expensed in the year ended December 31, 2006.

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

F-14

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***ZIOPHARM Oncology, Inc.***  
***(A Development Stage Enterprise)***  
 Notes to Financial Statements

**6. COMMITMENTS AND CONTINGENCIES**

Lease Commitment

The Company leases office space in three locations under various agreements expiring in 2007, 2009, and 2010. The leases include payment increases over the term of the agreements. The total amount of the lease payments is being charged to expense using the straight-line method over the term of the agreement.

Future minimum lease payments under noncancelable operating leases as of December 31, 2006, were as follows:

	Operating Leases
2007	\$ 262,139
2008	251,086
2009	234,005
2010	65,790
2011	-
	\$ 813,020

License Agreement

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

On August 24, 2004, the Company entered into a patent and technology license agreement with The Board of Regents of the University of Texas System, acting on behalf of The University of Texas M. D. Anderson Cancer Center and the Texas A&M University System (collectively, the "Licensors"). Under this agreement, the Company was granted an exclusive, worldwide license to rights (including rights to US and foreign patent and patent applications and related improvements and know-how) for the manufacture and commercialization of two classes of organic arsenicals (water - and lipid-based) for human and animal use. The class of water-based organic arsenicals includes ZIO-101.

In October 2004, the Company received a notice of allowance for US Patent Application No. 10/337969, entitled "S-dimethylarsino-thiosuccinic acid S-dimethylarsino-2-thiobenzoic acid S-(simethylarsino) glutathione as treatments for cancer." The patent application claims both therapeutic uses and pharmaceutical compositions containing a novel class of organic arsenicals, including ZIO-101, for the treatment of cancer. In February 2006, we announced that a second organic arsenic case has been issued under U.S. Patent No. 6995188. This patent provides further coverage of cancer treatment using organic arsenic, including ZIO-101, in combination with other agents or therapies. In addition, there were seven (7) patents related to ZIO-101 that issued in various foreign countries in 2006.



**ZIOPHARM Oncology, Inc.**  
**(A Development Stage Enterprise)**

Notes to Financial Statements

**6. COMMITMENTS AND CONTINGENCIES ...continued**

License Agreement...continued

As partial consideration for the license rights obtained, the Company made an upfront payment of \$125,000 and granted the Licensors 250,487 (500,000 pre-Merger) shares of our Common Stock, as well as options to purchase up to an additional 50,222 (100,250 pre-Merger) shares of our Common Stock for \$0.002 per share, following the successful completion of certain clinical milestones (the "Anderson Options"). The Company expensed the \$125,000 upfront payment and recognized research and development compensation expense of \$426,339 in connection with the issuance of the Common Stock in the year ended December 31, 2004. The Anderson Options became immediately exercisable with respect to 12,555 (25,063 pre-Merger) shares of our Common Stock upon the filing of an Investigation New Drug Application ("IND") for ZIO-101 in the fiscal year ended December 31, 2005 and the company recognized compensation expense. The Anderson Options will vest and become exercisable with respect to an additional 25,111 (50,125 pre-Merger) shares upon the completion of dosing of the last patient for both phase I clinical trials, and will vest and become exercisable with respect to an additional 12,556 (25,062 pre-Merger) shares upon the commencement of a pivotal clinical trial. During 2005, the Company recognized research and development compensation expense of \$54,115 in connection with the vesting of the Anderson Options in respect to the filing of an IND for ZIO-101. The options are subject to variable plan accounting and are re-measured at each reporting period. In addition, the Licensors are entitled to receive certain milestone payments (the "Anderson Milestones"), including \$100,000 to be paid upon the commencement of phase I clinical trial for which the Company recognized the expense in the year ended December 31, 2005 and a \$250,000 upon the dosing of the first patient in the Registrant-sponsored Phase II clinical trial for ZIO-101 in the year ended December 31, 2006. The Company may be required to make additional payments upon achievement of certain other milestones, in varying amounts which on a cumulative basis could total up to \$4,850,000. In addition, the Licensors are entitled to receive royalty payments on sales from a licensed product should such a product be approved for commercial sale and sales of a licensed product be effected in the United States, Canada, the European Union or Japan. The Licensors also will be entitled to receive a portion of any fees that the Company may receive from a possible sublicense under certain circumstances. Finally, the Company agreed to remit to the Licensor \$200,000 for at least each of the next two years to be used by the Licensors to conduct scientific research funding. The Company will have the exclusive right to all intellectual property rights resulting from such research pursuant to the terms of the license agreement.

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

License Agreement with DEKK-Tec, Inc.

On October 15, 2004, the Company entered into a license agreement with DEKK-Tec, Inc., pursuant to which it was granted an exclusive, worldwide license to the second lead product candidate, ZIO-201. As part of the signing of license agreement with DEKK-Tec, the Company expensed a \$50,000 up-front payment in the year ended December 31, 2004.

***ZIOPHARM Oncology, Inc.***  
***(A Development Stage Enterprise)***  
Notes to Financial Statements

**6. COMMITMENTS AND CONTINGENCIES ...continued**

In consideration for our license rights, DEKK-Tec is entitled to receive milestone payments upon the occurrence of certain events. The Company may be required to make payments upon achievements of certain milestones, in varying amounts which on a cumulative basis may total \$3,900,000. Of the aggregate milestone payments, most of the total amount will be creditable 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. In 2004, the Company also issued DEKK-Tec an option to purchase 27,616 shares of our Common Stock for \$0.02 per share, which option vested with respect to 6,904 shares vested upon the execution of the license agreement and was exercised in the fiscal year ended December 31, 2005. The options are subject to accounting pursuant to EITF 96-18 and are re-measured at each reporting period. In 2004, the Company has estimated the fair value of such options using the Black-Scholes model, using an assumed risk-free rate of 3.35%, and expected life of 5 years, volatility of 134% and dividend yield of 0%. In 2004, the Company recorded a charge of \$12,190 to research and development expense for the vested options. 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 ZIO-201. DEKK-Tec is entitled to receive royalty payments on the sales of ZIO-201 should it be approved for commercial sale.

Option Agreement with Southern Research Institute (“SRI”)

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

Also on December 22, 2004, the Company entered into a Research Agreement with SRI pursuant to which the Company agreed to spend a sum not to exceed \$200,000 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 isophosphoramidate mustard analogs (the “SRI Research Program”). Under the terms of the Option Agreement, the Company’s exclusive right to exercise the SRI Option will expire sixty days after the termination or expiration of the SRI Research Program and the delivery of the reports required thereunder. (See Note 5- Related Party Transactions)

License Agreement with Baxter Healthcare Corporation.

On November 3, 2006, the Company signed a definitive Asset Purchase Agreement (for indibulin) and License Agreement to (to Baxter's proprietary nanosuspension technology) with affiliates of Baxter Healthcare Corporation. Indibulin, referred to by the Company as ZIO-301, is a novel anti-cancer agent that binds to tubulin, one of the essential proteins for chromosomal segregation, and targets mitosis like the taxanes and vinca alkaloids. It is available as both an oral and a proprietary nanosuspension intravenous form. Molecules that target mitosis and inhibit cell division (antimitotic agents) are a major focus of cancer research and they are among the most widely used anti-cancer drugs in oncology today. Among the more well known antimitotic drugs are the taxanes (paclitaxel, docetaxel) and the vinca alkaloids (vincristine, vinblastine). The terms of the agreement include an upfront cash payment of approximately \$1.125 million, which has been expensed as purchased research and development in the year ended December 31, 2006, \$15,000 was paid for annual license maintenance fee, and a \$100,000 payment for existing inventory. In addition to the upfront costs there will be follow-on milestone cash payments that could amount to approximately \$8 million in the aggregate and royalties on net sales. The purchase price includes the entire indibulin intellectual property portfolio as well as existing drug substance and capsule inventories.

Guarantees and indemnification Obligations

Certain officers and employees have agreements with the company that call for a guarantee bonus that is payable within 30 days after the employee's anniversary date. Certain officer and employees also have specific severance agreements. In conjunction with the 2005 Offering, the Company has agreed to indemnify Paramount against certain liabilities, including liabilities under the Securities Act. The Company has not recorded any expense or liabilities under FIN 45 Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtness of others - An Interpretation of FASB Statements No. 5, 57, and 107 and Rescission of FASB Interpretation No. 34.

F-17

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**ZIOPHARM Oncology, Inc.**  
**(A Development Stage Enterprise)**

Notes to Financial Statements

**7. INCOME TAXES**

The components of the net deferred tax asset (liability) are as follows:

	December 31, 2006	December 31, 2005
Net operating loss carryforwards	\$ 5,793,182	\$ 2,550,081
Start-up and organizational costs	6,132,679	3,392,774
Research and development credit carryforwards	703,276	293,606
Stock compensation	347,317	—
Accrued bonus	21,477	16,779
Depreciation	22,126	14,419
Other	129,551	56,042
Net deferred tax assets	13,149,608	6,323,701
Deferred tax asset valuation allowance	(13,149,608)	(6,323,701)
	\$ —	\$ —

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. As of December 31, 2006 and 2005, the Company has net operating loss carryforwards of approximately \$14,385,851 and \$6,332,000, respectively, available to offset future federal and state taxable income to the extent permitted under the Internal Revenue Code (IRC), expiring in varying amounts through 2024. Under the IRC, certain substantial changes in the Company's ownership may limit the amount of net operating loss carryforwards that can be utilized in any one year to offset future taxable income.

The Company has provided a valuation allowance for the full amount of these net deferred tax assets, since it is more likely than not that these future benefits will not be realized. However, these deferred tax assets may be available to offset future income tax liabilities and expenses. The valuation allowance increased by \$6,825,907 due primarily to net operating loss carryforward, stock based compensation, and the increase in research and development credits.

Income taxes using the federal statutory income tax rate differ from the Company's effective tax rate primarily due to the change in the valuation allowance on deferred tax assets.

**8. CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY**

On December 31, 2005 the Company has authorized capital of 280,000,000 shares which has been designated as Common Stock. On April 26, 2006, the date of the Company's annual stockholders meeting, the shareholders approved the adoption of an Amended and Restated Certificate of Incorporation pursuant to which the Company has 280,000,000 shares of authorized capital stock, of which 250,000,000 shares are designated as common stock, par value \$.001 per share (the "Common Stock"), and 30,000,000 shares are designated as preferred stock, par value \$.001 per share (the "Preferred Stock").

Common Stock of ZIOPHARM, Inc.

As of December 31, 2006, the Company has issued and outstanding 15,272,899 shares of Common Stock and no shares of preferred stock.



***ZIOPHARM Oncology, Inc.***  
***(A Development Stage Enterprise)***

Notes to Financial Statements

**8. CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY ...continued**

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

In January 2004, the Company issued 18,000,000 (before the split discussed below and pre-Merger) shares of Common Stock at \$0.25 per share for gross proceeds of \$4,500,000.

In February 2004, the Company amended its articles of incorporation to provide for the combination of the Company's common stock, par value \$0.001 per share on a 1-for-4 basis (unless stated otherwise all other share and per share amounts presented reflect the reverse split).

On June 6, 2005, the Company completed the 2005 Offering (see Note 1). As a result of the Merger, all shares of the Series A Preferred Stock were automatically converted into the number of shares of Common Stock that the holders of Series A Preferred Stock would have received if their shares of Series A Preferred Stock had been converted into Common Stock immediately prior to the Merger.

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

Convertible Preferred Stock of ZIOPHARM, Inc.

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

Voting Rights

The holders of Series A Preferred Stock would have been entitled to vote together with all other holders of the Company's voting stock on an "as-converted" basis on all matters submitted to a vote of holders generally. The holders of Series A Preferred Stock, voting as a separate class, would also have had the right to approve by a 66% supermajority certain actions proposed to be taken by the Company.

Dividend Rights

The holders of Series A Preferred Stock had been entitled to receive dividends on an equal basis with the holders of Common Stock when, as and if declared by the Board of Directors.

F-19

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***ZIOPHARM Oncology, Inc.***  
***(A Development Stage Enterprise)***

Notes to Financial Statements

**8. CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY ...continued**

Liquidation Preferences

The Series A Preferred Stock would have rank senior to the Common Stock and any future class of junior securities, and would have been entitled to a liquidation preference equal to the Stated Value, subject to adjustment (as defined in the Certificate of Designations for the Series A Preferred Stock), upon any liquidation, dissolution or winding up of the Company or upon a voluntary or involuntary bankruptcy of the Company.

Conversion Rights

Each share of Series A Preferred Stock would have been convertible into Common Stock at any time at the option of the holder thereof (the Series A Preferred Stock and the Common Stock issuable upon conversion of the Series A Preferred Stock are sometimes herein collectively referred to as the "Securities"). All of the outstanding shares of Series A Preferred Stock would have automatically convert into Common Stock upon the first date (the "Trading Date") on which the Common Stock (or securities received in exchange for Common Stock) trades on a national securities exchange or on NASDAQ, including the Over the Counter Bulletin Board (a "Trading Event"). The rate at which shares of Series A Preferred Stock will convert into Common Stock will initially be one-for-one, subject to adjustment in connection with certain anti-dilution protections and other adjustments.

F-20

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***ZIOPHARM Oncology, Inc.***  
***(A Development Stage Enterprise)***

Notes to Financial Statements

**8. CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY ...continued**

In the event of a reclassification, capital reorganization or other similar change in the outstanding shares of Common Stock, a consolidation or merger of the Company with or into another entity (other than a consolidation or merger in which the Corporation is the continuing entity and which does not result in a reclassification, capital reorganization or other change of outstanding shares of Common Stock other than the number thereof), or a sale of the property of the Company as, or substantially as, an entirety (other than a sale/leaseback, mortgage or other financing transaction), the Series A Preferred Stock became convertible into the kind and number of shares of stock or other securities or property (including cash) that the holders of Series A Preferred Stock would have received if the Series A Preferred Stock had been converted into Common Stock immediately prior to such reclassification, capital reorganization or other change, consolidation, merger or sale.

F-21

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***ZIOPHARM Oncology, Inc.***  
***(A Development Stage Enterprise)***  
Notes to Financial Statements

**9. STOCK OPTION PLAN**

The Company has adopted the 2003 Stock Option Plan (the "Plan"), under which the Company had reserved for the issuance of 1,252,436 shares of its Common Stock. The Plan was approved by the Company's stockholders on December 21, 2004. On April 26, 2006, the date of the Company's annual stockholders meeting, the shareholders approved an amendment to the Plan increasing the total shares reserved by 750,000 shares, for a total of 2,002,436 shares.

As of December 31, 2006 there were 1,913,035 shares that are issuable under its 2003 Stock Option Plan upon exercise of outstanding options to purchase Common Stock. As of December 31, 2006, the Company had issued to our employees outstanding options to purchase up to 1,642,611 shares of the Company's Common Stock. In addition, the Company has issued to our directors options to purchase up to 270,174 shares of the Company's Common Stock, as well as options to a consultant in connection with services rendered to purchase up to 250 shares of the Company's Common Stock. The Company had estimated the fair value of the options issued to the consultant using the Black-Scholes model, using an assumed risk-free rate of 4.23%, and expected life of 10 years, volatility of 134% and dividend yield of 0%. The options issued to the consultant were valued at \$1,050, and recorded as a charge to compensation expense in December 2004.

F-22

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**ZIOPHARM Oncology, Inc.**  
**(A Development Stage Enterprise)**

Notes to Financial Statements

**9. STOCK OPTION PLAN ...continued**

Currently, stock options are granted with an exercise price equal to the closing market price of the Company's common stock on the day before the date of grant. Stock options to employees generally vest ratably over three years and have contractual terms of ten years. Stock options to directors generally vest ratably over two years and have contractual terms of ten years. 359,188 options granted, in 2006, to the Board of Directors and some members of management vested immediately. Stock options are valued using the Black-Scholes option valuation method and compensation is recognized based on such fair value over the period of vesting on a straight-line basis. The Company has also reserved an aggregate of 70,934 additional shares for issuance under options granted outside of the 2003 Stock Option Plan. The options were granted to The University of Texas M.D. Anderson Cancer Center and DEKK-Tec, Inc. (See Note 6- Commitments and Contingencies).

Proceeds from the 2006 exercises amounted to \$25,192 and the intrinsic value of these options amounted to \$7,702. Proceeds from the 2005 exercises amounted to \$4,676 and the intrinsic value of these options amounted to \$286,119. The fair value of each option award is estimated on the date of grant using the Black-Scholes option-pricing model. Assumptions regarding volatility, expected term, dividend yield and risk-free interest rate are required for the Black-Scholes model. Volatility and expected term assumptions are based on comparable Company's historical experience. The risk-free interest rate is based on a U.S. treasury note with a maturity similar to the option award's expected life.

Transactions under the Plan for the years ending December 31, 2006, 2005, and 2004 were as follows:

	Number of Shares	Weighted- Average Exercise Price	Weighted- Average Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding, January 1, 2004	1,250	\$ 20.00		
Granted	586,553	1.25		
Exercised	—	—		
Canceled	—	—		
Outstanding, December 31, 2004	587,803	\$ 1.29		
Granted	542,389	3.60		
Exercised	(91,719)	0.05		
Canceled	(64,834)	3.29		
Outstanding, December 31, 2005	973,639	\$ 2.56		
Granted	988,180	5.42		
Exercised	(5,845)	4.31		
Canceled	(42,939)	4.50		
Outstanding, December 31, 2006	1,913,035	\$ 3.95	8.71	3,995,097
Options exercisable, December 31, 2006	1,083,514	\$ 3.58	8.47	2,593,897
Options available for future grants	75,187			

Stock options granted in the year ended December 31, 2006, 2005, and 2004 had a weighted-average grant date fair values of \$4.10, \$2.33, and \$0.64, respectively. At December 31, 2006, total unrecognized compensation costs related to non-vested stock options outstanding amounted to 2,362,664. The cost is expected to be recognized over a weighted-average period of 1.77 years.



**ZIOPHARM Oncology, Inc.**  
**(A Development Stage Enterprise)**

Notes to Financial Statements

**9. STOCK OPTION PLAN ...continued**

The following table summarizes information about stock options outstanding that are in the plan at December 31, 2006:

Exercise Price	Number Outstanding	Options Outstanding		Options Exercisable	
		Weighted-Average Remaining Contractual Life (Years)	Weighted-Average Exercise Price	Number Exercisable	Weighted-Average Exercise Price
\$0.08	268,654	7.07	\$ 0.08	179,102	\$ .08
\$0.44	25,111	7.07	\$ 0.44	16,740	\$ .44
\$1.70	176,750	7.52	\$ 1.70	117,832	\$ 1.70
\$4.05	138,250	8.96	\$ 4.05	46,083	\$ 4.05
\$4.31	375,086	8.41	\$ 4.31	255,318	\$ 4.31
\$4.60 - \$4.75	58,250	9.72	4.62	-	-
\$5.00 - \$5.35	619,934	9.37	5.08	467,188	5.01
\$5.65 - \$5.90	7,750	9.93	5.89	-	-
\$6.45 - \$6.49	242,000	9.96	\$ 6.49	-	\$ -
\$20.00	1,250	3.05	\$ 20.00	1,250	\$ 20.00
	1,913,035	8.71	\$ 3.95	1,083,513	\$ 3.58

**10. WARRANTS**

The Company also issued warrants to purchase 62,621 shares of the Company's Common Stock to Paramount as compensation for services rendered in connection with our entering into an option agreement with Southern Research Institute. In connection with the warrants issued, the Company recorded a charge of \$251,037 to general and administrative expense. The Company has estimated the fair value of such options using the Black-Scholes model, using an assumed risk-free rate of 3.93%, and expected life of 7 years, volatility of 134% and dividend yield of 0%.

In 2005, the Company also issued performance warrants to purchase 50,000 shares of the Company's Common Stock for services to be rendered to its investor relations consultant as compensation. In connection with the warrant issuance 12,500 shares are exercisable immediately and the Company recorded a charge of \$44,640 to general and administrative expense in the year ended December 31, 2005. The Company has estimated the fair value of such options using the Black-Scholes model, using an assumed risk-free rate of 4.39%, and expected life of 5 years, volatility of 109% and dividend yield of 0%. The remaining 37,500 warrants have been cancelled in the year ended December 31, 2006 due to performance objectives not being obtained at the expiration of agreement.

In connection with the 2005 Offering completed in June 2005, the Company compensated Paramount, placement agent for the Offering, or its affiliates for its services through the payment of placement warrants to acquire 419,794 (837,956 - pre-Merger) shares of Series A Preferred Stock (the Series A Stock Warrants), exercisable for a period of 7 years from the Closing Date at a per share exercise price equal to 110% of the price per share sold in the Offering. The Company valued the Series A Stock Warrants using the Black-Scholes model and recorded a charge of \$1,682,863 against additional paid-in capital. The Company has estimated the fair value of the Series A Stock Warrants using the

Black-Scholes model, using an assumed risk-free rate of 3.93% and expected life of 7 years, volatility of 134% and dividend yield of 0%.

In connection with the 2006 Offering completed on May 3, 2006, the Company issued warrants to purchase 2,397,392 shares of common stock to investors and 799,126 warrants to purchase common stock to the Placement Agents and their designees. The Company estimated the fair value of the warrants at \$9,575,958 and \$3,516,603, respectively, using the Black-Scholes model, using an assumed risk-free rate of 5.01% and an expected life of 5 and 7 years, volatility of 100% and a dividend yield of 0%. The fair value of the warrants was recorded as a permanent component of shareholders' equity.

F-24

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**ZIOPHARM Oncology, Inc.**  
**(A Development Stage Enterprise)**

Notes to Financial Statements

**10. WARRANTS ...continued**

The following is a summary of warrants outstanding as of December 31, 2006.

Number	Issued in connection with	Exercise Price	Expiration Date
62,621	Services performed	\$ 4.75	December 23, 2011
408,703	Placement warrants for services performed	\$ 4.75	May 31, 2012
12,500	Services performed	\$ 4.76	September 14, 2010
2,397,392	Investors warrants	\$ 5.56	May 3, 2011
799,126	Placement warrants for services performed	\$ 5.09	May 3, 2013
3,680,342			

**11. Employee Benefit Plan**

The Company sponsors a qualified 401(k) Retirement Plan ( the "Plan") under which employees are allowed to contribute certain percentages of their pay, up to the maximum allowed under Section 401(k) of the Internal Revenue Code. The Company does not presently make contributions to the Plan.

F-25

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***Item 8. Changes in and Disagreements with Accountants on Accounting and Financial Disclosures***

On November 9, 2005, the Company, upon the recommendation and approval of its audit committee, dismissed Cordovano and Honeck, P.C., independent registered public accounting firm, as its principal independent accountant. On the same date, the Company engaged Vitale, Caturano & Company, Ltd., independent registered public accounting firm, to serve as the Company's principal independent accountant.

Cordovano and Honeck's reports on the Company's financial statements for the past two years did not contain an adverse opinion or disclaimer of opinion, nor were they qualified or modified as to uncertainty, audit scope or accounting principles.

During the years ended December 31, 2004 and 2003, and subsequently through the date of Cordovano and Honeck's dismissal, there were no disagreements with Cordovano and Honeck on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure which, if not resolved to Cordovano and Honeck's satisfaction, would have caused it to make reference to the subject matter in connection with its report on the Company's financial statements for such fiscal years.

The Company provided Cordovano and Honeck with a copy of the foregoing disclosures and requested that Cordovano and Honeck furnish it with a letter addressed to the Securities and Exchange Commission stating whether it agrees with the above statements and, if not, stating the respects in which it does not agree. A copy of such letter was filed on November 11, 2005 as Exhibit 16.1 to the Form 10-QSB for the quarter ended September 30, 2005.

Vitale, Caturano & Company, Ltd. has served as the accountant for ZIOPHARM, Inc., a Delaware corporation that became the Company's wholly-owned subsidiary on September 13, 2005 and merged with and into the Company on September 14, 2005, since the date of ZIOPHARM, Inc.'s inception in September 2003. During the years ended December 31, 2004 and 2003, and subsequently through November 9, 2005, neither the Company nor anyone acting on its behalf consulted with Vitale, Caturano & Company, Ltd. regarding any of the matters or events set forth in Items 304(a)(2)(i) and (ii) of Regulation S-B.

The Company provided Vitale, Caturano & Company, Ltd. with a copy of the foregoing disclosures and provided Vitale, Caturano the opportunity to furnish a letter containing any new information, clarification of the above disclosures, or disagreements with the statements made herein.

***Item 8A. Controls and Procedures***

We maintain "disclosure controls and procedures" (as defined in the Securities and Exchange Act of 1934 Rules 13a-15(e) and 15(d)-15(e) designed to ensure that information required to be disclosed in reports filed under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), is recorded, processed, summarized and reported within the specified time periods. Under the supervision and with the participation of our management, including our Chief Executive Officer and our Treasurer, we conducted an evaluation of our disclosure controls and procedures as of December 31, 2006. Based on this evaluation, our Chief Executive Officer and Treasurer concluded that, while our disclosure controls and procedures are effective in timely alerting them to material information required to be included in our periodic filings with the SEC, there is a lack of segregation of duties at our company due to the limited number of employees dealing with general administrative and financial matters. At this time management believes that, given the individuals involved and the control procedures in place, the risks associated with such lack of segregation are not considered significant, and that the potential benefits of adding additional employees to segregate duties more clearly do not currently justify the associated added expense. However, management will reevaluate the situation periodically and will mitigate the current lack of segregation of duties within the general administrative functions if it believes the risks from such lack of segregation have increased or when additional capital is secured.

There have been no changes in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Rule 13a-15 or 15d-15 promulgated under the Exchange Act that occurred during the last fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. Management is aware that there is a lack of segregation of duties at our company due to the limited number of employees dealing with general administrative and financial matters. At this time management believes that, given the individuals involved and the control procedures in place, the risks associated with such lack of segregation are insignificant, and that the potential benefits of adding additional employees to segregate duties more clearly do not justify the associated added expense. Management will continue to evaluate this segregation of duties. In addition, management is aware that many of our currently existing internal controls are undocumented. Our management will be working to document such internal controls over the coming year.

***Item 8B. Other Information***

None.

34

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### **PART III**

#### **Item 9. Directors, Executive Officers, Promoters and Control Persons; Compliance with Section 16(a) of the Exchange Act**

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

Our Board of Directors adopted a Code of Business Conduct and Ethics to be applicable to all officers, directors and employees. The Code of Business Conduct and Ethics is intended to be designed to deter wrong-doing and promote honest and ethical behavior, full, fair, timely, accurate and understandable disclosure, and compliance with applicable laws. The Board adopted the Code of Business Conduct and Ethics in February 2006. A copy of the Code of Business Conduct and Ethics can be obtained and will be provided to any person without charge upon written request to the Company's President at the Company's headquarters address.

#### ***Item 10. Executive Compensation***

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

#### ***Item 11. Security Ownership of Certain Beneficial Owners and Management***

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

#### ***Item 12. Certain Relationships and Related Transactions***

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

**Item 13. EXHIBITS**

The following exhibits, as required by Item 601 of Regulation S-B are filed as a part of this report:

Exhibit No.	Description of Document
2.1	Agreement and Plan of Merger among the Registrant (formerly EasyWeb, Inc.), ZIO Acquisition Corp. and ZIOPHARM, Inc., dated August 3, 2005 (incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed August 9, 2005).
3.1	Amended and Restated Certificate of Incorporation, as filed with the Delaware Secretary of State on April 26, 2006 (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report of Form 8-K filed April 26, 2006).
3.2	Certificate of Merger dated September 13, 2005, relating to the merger of ZIO Acquisition Corp. with and into ZIOPHARM, Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's Form 8-K filed September 19, 2005).
3.3	Certificate of Ownership of the Registrant (formerly EasyWeb, Inc.) dated as of September 14, 2005, relating the merger of ZIOPHARM, Inc. with and into the Registrant and changing the Registrant's corporate name from EasyWeb, Inc. to ZIOPHARM Oncology, Inc. (incorporated by reference to Exhibit 3.2 to the Registrant's Form 8-K filed September 19, 2005).
3.4	Bylaws, as amended to date (incorporated by reference to Exhibit 3.3 to the Registrant's Form 8-K filed September 19, 2005).
4.1	Specimen common stock certificate. (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form SB-2 (SEC File No. 333-129020) filed October 14, 2005).
4.2	Form of Warrant issued to placement agents in connection with ZIOPHARM, Inc. 2005 private placement (incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form SB-2 (SEC File No. 333-129020) filed October 14, 2005).
4.3	Schedule identifying holders of Warrants in the form filed as Exhibit 4.2 to this Report (incorporated by reference to Exhibit 4.3 to the Registrant's Registration Statement on Form SB-2 (SEC File No. 333-129020) filed October 14, 2005).
4.4	Warrant for the Purchase of Shares of Common Stock dated December 23, 2004. (incorporated by reference to Exhibit 4.4 to the Registrant's Registration Statement on Form SB-2 (SEC File No. 333-129020) filed October 14, 2005).
4.5	Option for the Purchase of Common Stock dated October 15, 2004 and issued to DEKK-Tec, Inc. (incorporated by reference to Exhibit 4.5 to the Registrant's Annual Report on Form 10-KSB filed (SEC File No. 000-32353) March 20, 2006).
4.6	Form of Option for the Purchase of Shares of Common Stock dated August 30, 2004 and issued to The University of Texas M.D. Anderson Cancer Center. (incorporated by

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- reference to Exhibit 4.6 to the Registrant's Annual Report on Form 10-KSB filed (SEC File No. 000-32353) March 20, 2006).
- 4.7 Schedule identifying material terms of Options for the Purchase of Shares of Common Stock in the form filed as Exhibit 4.6 to this Report. (incorporated by reference to Exhibit 4.7 to the Registrant's Annual Report on Form 10-KSB filed (SEC File No. 000-32353) March 20, 2006).
  - 4.8 Form of Common Stock Purchase Warrant issued to investors in connection with ZIOPHARM Oncology, Inc. 2006 private placement (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report of Form 8-K filed May 3, 2006).
  - 4.9 Form of Common Stock Purchase Warrant issued to placement agents in connection with ZIOPHARM Oncology, Inc. 2006 private placement (incorporated by reference to Exhibit 4.2 to the Registrant's Current Report of Form 8-K filed May 3, 2006).
  - 10.1 2003 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form SB-2 (SEC File No. 333-129020) filed October 14, 2005).
  - 10.2 Amendment No. 1 to 2003 Stock Incentive Plan of ZIOPHARM Oncology, Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report of Form 8-K filed April 26, 2006).
  - 10.3 Employment Agreement dated January 8, 2004, between the Registrant and Dr. Jonathan Lewis (incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form SB-2 (SEC File No. 333-129020) filed October 14, 2005).
  - 10.4 Employment Agreement Extension dated December 21, 2006, between the Registrant and Dr. Jonathan Lewis (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed December 26, 2007).
  - 10.5 Employment Agreement dated January 15, 2004, between the Registrant and Dr. Robert Peter Gale (incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form SB-2 (SEC File No. 333-129020) filed October 14, 2005).
  - 10.6 Employment Agreement dated July 21, 2004, between the Registrant and Richard Bagley (incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form SB-2 (SEC File No. 333-129020) filed October 14, 2005).
  - 10.7 Patent and Technology License Agreement dated August 24, 2004, among ZIOPHARM, Inc. (predecessor to the Registrant), the Board of Regents of the University of Texas System on behalf of the University of Texas M.D. Anderson Cancer Center and the Texas A&M University System (incorporated by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form SB-2 (SEC File No. 333-129020) filed October 14, 2005).++
  - 10.8 License Agreement dated October 15, 2004, between ZIOPHARM, Inc. (predecessor to the Registrant) and DEKK-Tec, Inc. (incorporated by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form SB-2 (SEC File No. 333-129020) filed October 14, 2005).++

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- 10.9 Form of subscription agreement between the ZIOPHARM, Inc. and the investors in ZIOPHARM, Inc.'s private placement (incorporated by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form SB-2 (SEC File No. 333-129020) filed October 14, 2005).
- 10.10 Form of Incentive Stock Option Agreement granted under 2003 Stock Option Plan (incorporated by reference to Exhibit 10.7 to the Registrant's Annual Report on Form 10-KSB (SEC File No. 000-32353) filed March 20, 2006).
- 10.11 Form of Employee Non-Qualified Stock Option Agreement granted under 2003 Stock Option Plan (incorporated by reference to Exhibit 10.8 to the Registrant's Annual Report on Form 10-KSB (SEC File No. 000-32353) filed March 20, 2006).
- 10.12 Form of Director Non-Qualified Stock Option Agreement granted under 2003 Stock Option Plan (incorporated by reference to Exhibit 10.9 to the Registrant's Annual Report on Form 10-KSB (SEC File No. 000-32353) filed March 20, 2006).
- 10.13 Form of Subscription Agreement by and between ZIOPHARM Oncology, Inc. and investors in the ZIOPHARM Oncology, Inc. 2006 private placement (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report of Form 8-K filed May 3, 2006).
- 10.14 Asset Purchase Agreement dated November 3, 2006 by and among Baxter Healthcare S.A., Baxter International, Inc., Baxter Oncology GmbH and ZIOPHARM Oncology, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-QSB filed November 13, 2006). +
- 10.15 License Agreement dated November 3, 2006 by and among Baxter Healthcare S.A., Baxter International, Inc. and ZIOPHARM Oncology, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-QSB filed November 13, 2006). +
- 10.16 Consulting agreement dated January 15, 2007, between the Registrant and Robert Gale.
- 10.17 Amendment to incentive stock option agreements between Registrant and Robert Peter Gale, M.D., PH.D.
- 23.1 Consent of Independent Registered Public Accounting Firm - Vitale, Caturano & Company, Ltd.
- 31.1 Certification of Chief Executive Officer pursuant to Securities Exchange Act Rule 13a-15(e)/15d-15(e) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2 Certification of Chief Financial Officer pursuant to Securities Exchange Act Rule 13a-15(e)/15d-15(e) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1 Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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

99.1 Press Release dated February 13, 2006

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

++Confidential treatment has been granted as to certain portions of this exhibit pursuant to Rule 406 of the Securities Act of 1933, as amended.

#### **Item 14. Principal Accountant Fees and Services**

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

36

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**SIGNATURES**

In accordance with Section 13 or 15(d) of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**ZIOPHARM ONCOLOGY, INC.**

Date: February 13 , 2007

By: /s/ Jonathan Lewis

\_\_\_\_\_  
Jonathan Lewis  
Chief Executive Officer  
(Principal Executive Officer)

Date: February 13 , 2007

By: /s/ Richard Bagley

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

In accordance with the Securities Exchange Act, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Jonathan Lewis _____ Jonathan Lewis	Director and Chief Executive Officer (Principal Executive Officer)	February 13, 2007
/s/ Richard Bagley _____ Richard Bagley	Director, President, Chief Financial Officer, Treasurer and Chief Operating Officer (Principal Accounting and Financial Officer)	February 13, 2007
/s/ Murray Brennan _____ Murray Brennan	Director	February 13, 2007
/s/ James Cannon _____ James Cannon	Director	February 13, 2007
/s/ Timothy McInerney _____ Timothy McInerney	Director	February 13, 2007

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/s/ Wyche Fowler, Jr.

Director

February 13, 2007

Wyche Fowler, Jr.

/s/ Gary S. Fragin

Director

February 13, 2007

Gary S. Fragin

/s/ Michael Weiser

Director

February 13, 2007

Michael Weiser

37

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**EXHIBIT INDEX**

Exhibit No.	Description of Document
10.1	Consulting agreement dated January 15, 2007, between the Registrant and Robert Peter Gale, M.D., PH.D.
10.2	Amendment to incentive stock option agreements between Registrant and Robert Peter Gale, M.D., PH.D.
23.1	Consent of Independent Registered Public Accounting Firm - Vitale, Caturano & Company, Ltd.
31.1	Certification of Chief Executive Officer pursuant to Securities Exchange Act Rule 13a-15(e)/15d-15(e) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Securities Exchange Act Rule 13a-15(e)/15d-15(e) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
99.1	Press Release dated February 13, 2006