ZIOPHARM ONCOLOGY INC
Form 10KSB
March 20, 2006

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-KSB

x ANNUAL REPORT UNDER SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2005

OR

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

Commission File Number 0-32353

ZIOPHARM Oncology, Inc.
(Exact Name of Small Business Issuer as Specified in Its Charter)

Delaware	**84-1475642**
(State or Other Jurisdiction of Incorporation or Organization)	(IRS Employer Identification No.)
1180 Avenue of the Americas, 19th Floor, New York, NY	**10036**
(Address of Principal Executive Offices)	(Zip Code)

(646) 214-0700
(Issuer's Telephone Number, Including Area Code)

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

Securities registered pursuant to Section 12(g) of the Act:
Common Stock (par value $0.001 per share)

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

Check whether the issuer (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x Noo

Check if there is no disclosure of delinquent files pursuant to Item 405 of Regulation S-B is not contained in this form, and no disclosure will be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-KSB or any amendment to this form 10-KSB. o

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

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

As of March 3, 2006, the aggregate market value of common stock held by non-affiliates of the registrant approximated $23,404,379 based upon the closing price of the common stock on the OTC Bulletin Board 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 be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination of other purposes.

As of March 3, 2006, there were 7,272,992 shares of the issuer's common stock, $.001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the definitive proxy statement for our 2006 annual meeting of stockholders, which is to be filed within 120 days after the end of the fiscal year ended December 31, 2005, are incorporated by reference into Part III of this Form 10-KSB, to the extent described in Part III.

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

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Additional Information

Descriptions in this Report are qualified by reference to the contents of any contract, agreement or other documents and are not necessarily complete. Reference is made to each such contract or document filed as an exhibit to this report, or previously filed by the Company pursuant to regulations of the Securities and Exchange Commission (the "SEC"). (see "Item 13. Exhibits.")

References in this document to "us", "we", "our", "the Company", or "the Registrant" refer to ZIOPHARM Oncology, Inc. On September 13, 2005, our wholly-owned subsidiary, ZIO Acquisition Corp., merged with and into ZIOPHARM, Inc. with ZIOPHARM Inc. remaining as the surviving corporation and our wholly-owned subsidiary. This transaction is referred to throughout this report as the "Merger." On September 14, 2005, ZIOPHARM, Inc. merged with and into us, leaving us as the surviving corporation. In connection with this parent-subsidiary merger, we relinquished our prior corporate name, EasyWeb, Inc., and assumed in its place the name "ZIOPHARM Oncology, Inc." The parent-subsidiary merger and name change became effective on September 14, 2005. Unless provided otherwise, references in this document to "us", "we", "our", "the Company", or "the Registrant" for periods prior to these transactions refer to ZIOPHARM Inc. See "Description of Business - 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 development 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 U.S. phase I and I/II studies for two product candidates known as ZIO-101 and ZIO-201. We currently intend to continue with clinical development of ZIO-101 for advanced myeloma and ZIO-201 for advanced sarcoma and to study preclinically product candidates (ZIO-102, ZIO-202, etc.) in the same product families while licensing additional 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.

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 dangerous 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.

The cost of cancer to the healthcare system is significant. The National Institute of Health estimates that the overall cost of cancer in 2004 was $189.8 billion. This cost includes an estimate of $69.4 billion in direct medical expenses, $16.9 billion in indirect morbidity costs, and $103.5 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; and 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 can also be harmed with the use of cytotoxics, especially those that divide quickly. Harm to healthy cells is what causes side effects. These cells usually repair themselves after chemotherapy. Chemotherapy can be used for different purposes which include curing cancer (when the patient remains free of evidence of cancer cells), controlling cancer (by preventing the cancer from spreading), and to relieving symptoms of cancer (such as pain, helping patients live more comfortably).

Cytotoxic agents act primarily on macromolecular synthesis, 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.

Side effects, or complications of treatment cause inconvenience, discomfort, and occasionally, may even be fatal. Additionally and perhaps more importantly, side effects may also prevent doctors from delivering the prescribed dose of therapy at the specific time and schedule of the treatment plan. Therefore, side effects not only cause discomfort, but may also limit a patient's ability to achieve the best outcome from treatment by preventing the delivery of therapy at its optimal dose and time.

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, which have led to improvements in the management of symptoms associated with this cancer treatment, allowing for greater accuracy and consistency concerning the administration of cancer treatment. Nausea and vomiting induced by chemotherapy are treated by drugs such as 5HT3 receptor antagonists, like ondansetron, which is a selective blocking agent of the hormone serotonin.

Product Candidates

ZIO-101

General. 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®) 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. Nevertheless, ATO has been shown to be toxic to the heart, nerves and liver, 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 studies demonstrated that ZIO-101 (and organic arsenic in general) is considerably less toxic than inorganic arsenic, particularly with regard to heart toxicity. In phase I testing, significantly higher doses of ZIO-101 have been safely administered than the labeled dose of inorganic arsenic.

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. Leukemia is a cancer that begins in blood-forming tissue such as the bone marrow and causes large numbers of blood cells to be produced and enter the bloodstream. Lymphomas are cancers that begin in cells of the immune system. Myelodysplastic syndromes, also called preleukemia or smoldering leukemia, are diseases in which the bone marrow does not function normally.

Clinical Lead Indication: Multiple Myeloma. We expect that advanced myeloma, a hematologic cancer, will be the lead indication in which to seek 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. Usually following two to three years of treatment, resistance to therapy occurs. 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 may be in transition. Velcade® is approved to treat patients with myeloma that have had at least one prior therapy. Revlimid® and Thalomid® are currently in advanced trials for the treatment of myeloma. 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 every patient will fail all available agents at some point. A more rapid market penetration can be expected in the case where the therapeutic window is wide and efficacy is equal to or greater than currently available agents.

Clinical Development Plan for ZIO-101. We have commenced two phase I clinical trials (hematological and solid tumor) at The University of Texas M.D. Anderson Cancer Center using ZIO-101 in refractory disease. Phase I testing is primarily focused on assessing drug safety; however, some patients in the trials have evidenced either a response or other indications of drug activity without toxicity (as reported by the investigator). The starting dose in both phase I trials was approximately 14 times the labeled dose of inorganic arsenic.

The goal of these phase I trials is to determine dose-limiting toxicity and maximum tolerated dose. In addition, assessments of pharmacokinetic data will be obtained along with any indication of efficacy. In January 2006, the

Company initiated a follow-on study to these phase I trials with a phase I/II trial in advanced myeloma. Other trials are under consideration for initiation in 2006. It is expected that a pivotal trial in multiple myeloma would begin in 2007.

The solid tumor trial is seeking to confirm data collected during preclinical studies that indicated activity in a variety of solid tumors. While the current focus for product registration is myeloma, the study results will be instructive for further development plans in solid tumors.

ZIO-201

General. ZIO-201, or isophosphoramide mustard (IPM), is a proprietary stabilized metabolite of ifosfamide that is also related to cyclophosphamide. A patent application for pharmaceutical composition has been filed. Cyclophosphamide and ifosfamide are alkylating agents. 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 with other agents, 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 US Food and Drug Administration (the "FDA").

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 mandates 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 (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 likely cross-links DNA differently than ifosfamide or cyclophosphamide metabolites, resulting in a different activity profile. Moreover, in some instances in preclinical studies, ZIO-201 appears to show activity in ifosfamide- and/or cyclophosphamide-resistant cancer cells.

Potential Lead Indications for ZIO-201: Sarcomas. Sarcomas are cancers of the bone, cartilage, fat, muscle, blood vessels, or other connective or supportive tissue. Soft tissue sarcomas, the expected lead indication for ZIO-201, are relatively rare; there are 8,000 to 10,000 new cases each year in adults in the United States. However, in children, soft tissue sarcomas account for approximately 10% of all childhood cancers. There are more than 50 histological or tissue types of soft tissue sarcomas. The prognosis for patients with adult 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. Ifosfamide-based chemotherapy is a frequent standard of care for the treatment of metastatic tumors. It may also used in the adjuvant setting for high-risk primary tumors.

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. 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. A phase I clinical trial is being conducted at two centers with the objective of establishing maximum tolerated dose. The current dose level in this phase I trial is believed to be comparable to a relatively high dose of ifosfamide. The drug is being administered without mesna. Furthermore, one patient has evidence of stable disease. The Company initiated a phase I/II trial in advanced sarcoma in February 2006; additional phase II studies are in the planning stages. These trials would support the design and implementation of a registration study 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 are 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 (water- and lipid-based) for human and animal use. The class of water-based organic arsenicals 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. 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.

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 (such share amounts and option exercise price have been adjusted to reflect to the Merger). 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. 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. Finally, the license agreement provides that we will enter into two separate sponsored research agreements with the Licensors, each of which will require that we make annual payments of $100,000 for no less than two years. We will have the exclusive right to all intellectual property rights resulting from such research pursuant to the terms of the agreements.

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. We also issued DEKK-Tec an option to purchase up to 27,616 shares of our common stock for approximately $0.02 per share (such share amount and option exercise price have been adjusted to reflect to the Merger), which option vested with respect to 6,904 post-Merger shares 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. Finally, DEKK-Tec also 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.

Option and Research Agreements with Southern Research Institute ("SRI"). On December 22, 2004, we entered into an Option Agreement with SRI, pursuant to which we were granted an exclusive option to obtain an exclusive license to SRI's interest in certain intellectual property, including exclusive rights related to certain isophosphoramide mustard analogs. Also on December 22, 2004, we entered into a Research Agreement with SRI pursuant to which we agreed to spend a sum not to exceed $200,000 between the execution of the agreement and December 21, 2006, including a $25,000 payment that we made simultaneously with the execution of the agreement, to fund research and development work by SRI in the field of isophosphoramide mustard analogs. Under the terms of the option agreement, our exclusive right to exercise the option will expire 60 days after the termination or expiration of the SRI's research and development work in the field of isophosphoramide mustard analogs, and the delivery of the certain required reports.

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 concerns or questions about issues such as the conduct 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. These agreements may not be changed after the clinical studies begin, except in limited circumstances.

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 FDA has various programs, including phase 0, orphan drug, fast track, priority review, and accelerated approval, that are intended to expedite or simplify the process for 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. 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 17 employees, all of which are full-time employees. Several additional employees are expected to be hired prior to the end of 2006.

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