ZIOPHARM ONCOLOGY INC
Form 424B3
October 06, 2009

PROSPECTUS

Filed Pursuant to Rule 424(b)(3)
Registration No. 333-162160

ZIOPHARM Oncology, Inc.

5,683,291 Shares

Common Stock

This prospectus covers a total of 5,683,291 shares of our common stock, of which 2,910,954 shares are issuable upon the exercise of outstanding warrants, which may be disposed of by the selling stockholders set forth herein, or their transferees. We will not receive any proceeds from the disposition of these shares by the selling stockholders but will receive the proceeds of any cash exercises of the warrants.

Our common stock is listed on the Nasdaq Capital Market under the symbol "ZIOP." On September 24, 2009, the closing price of our common stock, as reported on the Nasdaq Capital Market, was $2.11. We urge prospective purchasers of our common stock to obtain current information about the market prices of our common stock.

The securities offered by this prospectus involve a high degree of risk.
See "Risk Factors" beginning on page 5.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is October 6, 2009.

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PROSPECTUS SUMMARY

The following is a summary of this prospectus. Because it is only a summary, it does not contain all of the detailed information contained elsewhere in this prospectus or in the documents incorporated by reference into this prospectus or included as exhibits to the registration statement of which this prospectus is a part. Accordingly, you should carefully review this prospectus, including all documents incorporated by reference into this prospectus, in its entirety. Unless otherwise indicated, "ZIOPHARM," the "Company," "we," "us," "our" and similar terms refer to ZIOPHARM Oncology, Inc.

Our Company

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

- ZIO-101, or darinaparsin (ZinaparTM), is an anti-mitochondrial (organic arsenic) compound covered by issued patents and pending patent applications in the U.S. and in foreign countries. A form of commercially available inorganic arsenic (arsenic trioxide [Trisenox ®]; "ATO") has been approved in the United States, the European Union, and Japan for the treatment of acute promyelocytic leukemia ("APL"), a precancerous condition. In the United States, ATO is on the compendia listing for the therapy of multiple myeloma, and has been studied for the treatment of various other cancers. Nevertheless, ATO has been shown to be toxic to the heart, liver, and brain, which limits its use as an anti-cancer agent. ATO carries a "black box" warning for ECG abnormalities since arsenic trioxide has been shown to cause QT interval prolongation and complete atrioventricular block. QT prolongation can lead to a torsade de pointes-type ventricular arrhythmia, which can be fatal. Inorganic arsenic has also been shown to cause cancer of the skin and lung in humans. The toxicity of arsenic is generally correlated to its accumulation in organs and tissues. Our preclinical and clinical studies to date have demonstrated that darinaparsin is considerably less toxic than inorganic arsenic, particularly with regard to cardiac toxicity. In vitro testing of darinaparsin using the National Cancer Institute's human cancer cell panel demonstrated activity against a series of tumor cell lines including lung, colon, brain, melanoma, ovarian, and kidney cancer. Moderate activity was shown against breast and prostate cancer tumor cell lines. In addition to solid tumors, in vitro testing in both the National Cancer Institute's cancer cell panel and in vivo testing in a leukemia animal model demonstrated substantial activity against hematological cancers (cancers of the blood and blood-forming tissues) such as leukemia, lymphoma, myelodysplastic syndromes, and multiple myeloma. Results indicate significant activity against the HuT 78 cutaneous T-cell lymphoma, the NK-G2MI natural killer-cell NHL, KARPAS-299 T-cell NHL, SU-DHL-8 B-cell NHL, SU-DHL-10 B-cell NHL and SU-DHL-16 B-cell NHL cell lines. Preclinical studies have also established

anti-angiogenic properties of darinaparsin and provided support for the development of an oral capsule form of the drug, and established synergy of darinaparsin in combination with other approved anti-cancer agents.

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Phase I testing of the intravenous (IV) form of darinaparsin in solid tumors and hematological cancers has been completed. The Company reported clinical activity and, importantly, a safety profile from these studies as predicted by preclinical results. The Company subsequently completed Phase II studies in advanced myeloma and primary liver cancer and is nearing completion of a Phase II study in certain other hematological cancers. In addition, the Company is completing two Phase I studies with an oral capsule form of darinaparsin. At the May 2009 annual meeting of the American Society of Clinical Oncology ("ASCO"), the Company reported favorable results from the trial with IV-administered darinaparsin in lymphoma, particularly peripheral T-cell lymphoma ("PTCL"). In the ongoing Phase I trials, also reported at the ASCO annual meeting, preliminary data primarily in solid tumors indicate the oral form is active and well tolerated. The Company is presently initiating data collection for completing the IV Phase II trial with the intention of meeting with the U.S. Food and Drug Administration ("FDA") to progress the IV program into a potentially pivotal trial in PTCL as early as the first half of 2010. The Company intends to fund that program using additional sources of funding including from partnering. The oral Phase I program will continue its ongoing clinical trials to completion with establishment of a maximum tolerated dose ("MTD").

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

Following Phase I study, Phase II testing of the intravenous form of palifosfamide as a single agent to treat advanced sarcoma has been completed. In both Phase I and Phase II testing, palifosfamide has been administered without the "uroprotectant" mesna, and the toxicities associated with acrolein and chloroacetaldehyde have not been observed. The Company reported clinical activity of palifosfamide when used alone in the Phase II study addressing advanced sarcoma. Following review of the preclinical combination studies, clinical data, and discussion with sarcoma experts, the Company initiated a Phase I dose escalation study of palifosfamide in combination with doxorubicin in patients with metastatic or unresectable soft tissue sarcoma. The Company reported favorable results and safety profile from this study at this year's ASCO annual meeting. In light of reported favorable Phase II clinical activity data and with the combination of palifosfamide with doxorubicin well tolerated in the Phase I trial and evidencing activity, the Company initiated a Phase II randomized controlled trial in the second half of last year to compare doxorubicin plus palifosfamide to doxorubicin alone in patients with front and second-line metastatic or unresectable soft tissue

sarcoma. Data from the initial patients in this trial are expected to shape a registration trial in the same setting which is expected to initiate as early as the first half of 2010. The study is currently actively enrolling and, in conjunction with ASCO, the initial drug safety monitoring committee meeting concluded to continue enrollment as planned. The Company is also developing an oral capsule form of palifosfamide to be studied clinically following further data from the IV trials and partnering or other sources of funding. The Company is also considering additional Phase II trials in other solid tumors as funding becomes available. Orphan Drug Designation for palifosfamide has been obtained in both the United States and the European Union for the treatment of soft tissue sarcomas.

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

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

Indibulin, as a single agent, has completed a Phase I trial in Europe and additional Phase I trials are nearing completion in the U.S. in patients with advanced solid tumors and the Company has reported clinical activity at well-tolerated doses using a continuous dosing scheme without the development of clinically relevant peripheral neuropathy. Following encouraging results obtained with indibulin in combination with erlotinib and 5-FU in preclinical models, two Phase I combination studies were initiated with Tarceva® in one and Xeloda® in another and are reaching completion. Favorable activity and safety profile of oral indibulin with oral Xeloda® were reported at ASCO's annual meeting in May 2009. Preclinical work with consultant Dr. Larry Norton to explore dose scheduling for the clinical setting have been completed and were also reported at the ASCO meeting, supporting the Company's plan to initiate the Phase I portion of a Phase I/II breast cancer trial using a dose schedule established preclinically.

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

Corporate Information

We were originally incorporated in Colorado in September 1998 (under the name Net Escapes, Inc.) and later changed our name to “EasyWeb, Inc.” in February 1999. We were re-incorporated in Delaware on May 16, 2005 under the same name. On September 13, 2005, we completed a “reverse” acquisition of privately held ZIOPHARM, Inc., a Delaware corporation. To effect this transaction, we caused ZIO Acquisition Corp., our wholly-owned subsidiary, to merge with and into ZIOPHARM, Inc., with ZIOPHARM, Inc. surviving as our wholly owned subsidiary. In accordance with the terms of the merger, the outstanding common stock of ZIOPHARM, Inc. automatically converted into the right to receive an aggregate of approximately 97.3% of our outstanding common stock (after giving effect to the transaction). Following the merger, we caused ZIOPHARM, Inc. to merge with and into us and we changed our name to “ZIOPHARM Oncology, Inc.” Although EasyWeb, Inc. was the legal acquirer in the transaction, we accounted for the transaction as a reverse acquisition under generally accepted accounting principles. As a result, ZIOPHARM, Inc. became the registrant with the SEC and the historical financial statements of ZIOPHARM, Inc. became our historical financial statements.

Our executive offices are located at 1180 Avenue of the Americas, 19th Floor, New York, NY 10036, and our telephone number is (646) 214-0700. Our internet site is www.ziopharm.com. None of the information on our internet site is part of this prospectus.

Recent Developments—September 2009 Financing

On September 15, 2009, we issued and sold in a private placement transaction an aggregate of 2,772,337 units, each unit consisting of (i) one share of common stock and (ii) a warrant to purchase one share of common stock at an exercise price of $2.04 per share, for a purchase price of $1.825 per unit. The total gross proceeds resulting from the sale of these units was approximately $5.06 million, before deducting selling commissions and expenses.

We engaged Rodman & Renshaw, LLC, a subsidiary of Rodman & Renshaw Capital Group, Inc., as our placement agent in connection with the offering. Riverbank Capital Securities, Inc. and Griffin Securities, Inc. each served as sub-placement agents. As consideration for their services, we paid aggregate cash commissions and fees of approximately $0.35 million and issued five-year placement agent warrants to purchase an aggregate of 138,617 common shares at an exercise price of $2.04 per share.

The shares being offered hereby consist of the 2,772,337 shares of common stock and the 2,772,337 shares issuable upon exercise of the warrants issued to the investors in the private placement, as well as the 138,617 shares issuable upon exercise of the placement agent warrants.

Risk Factors

As with most pharmaceutical product candidates, the development of ZIO-101, ZOI-201 and ZIO-301 is subject to numerous risks, including the risk of delays in or discontinuation of development from lack of financing, inability to obtain necessary regulatory approvals to market the products, unforeseen safety issues relating to the products and dependence on third-party collaborators to conduct research and development of the products. Because we are a development stage company with a limited history of operations, we are also subject to many risks associated with early-stage companies. For a more detailed discussion of the risks you should consider before purchasing shares of our common stock, you are urged to carefully review and consider the section entitled “Risk Factors” beginning on page 5 of this prospectus.

The Offering

This prospectus covers a total of 5,683,291 shares of our common stock, of which 2,910,954 shares are issuable upon the exercise of outstanding warrants.

Common stock covered hereby	5,683,291 shares
Common stock outstanding before the offering (1)	25,571,301 shares
Common stock outstanding after the offering (2)	28,482,255 shares
Common Stock Nasdaq Capital Market symbol	ZIOP

(1) Based on the number of shares outstanding as of September 24, 2009, not including 11,171,529 shares issuable upon exercise of various warrants and options to purchase common stock.

(2) Assumes the issuance of all shares covered hereby that are issuable upon exercise of outstanding warrants.

RISK FACTORS

An investment in our common stock involves a number of risks. Before deciding to invest in our common stock, you should carefully consider each of the following risk factors and all of the other information set forth in this prospectus. The following risks could materially harm our business, financial condition or future results. If any such risks materialize, the value of our common stock could decline, and you could lose all or part of your investment.

RISKS RELATED TO OUR BUSINESS

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

As of June 30, 2009, we had incurred approximately $89.2 million of cumulative net losses and had approximately $4.5 million of cash and cash equivalents. With the proceeds received from our September 2009 private placement of common stock and warrants, we anticipate we will have sufficient cash to fund our operations well into the second quarter of 2010. However, changes may occur that would consume our existing capital prior to that time, including the progress of our research and development efforts and changes in governmental regulation.

Currently, we have no committed sources of additional capital. We do not know whether additional financing will be available on terms favorable or acceptable to us when needed, if at all. Our business is highly cash-intensive and our ability to continue operations after our current cash resources are exhausted depends on our ability to obtain additional financing and achieve profitable operations, as to which no assurances can be given.

If adequate additional funds are not available when required, or if unsuccessful in entering into partnership agreements for the further development of its products, we will be required to delay, reduce or eliminate planned preclinical and clinical trials and terminate the approval process for our product candidates from the FDA or other regulatory authorities. In addition, we could be forced to discontinue product development, reduce or forego sales and marketing efforts, forego attractive business opportunities or pursue merger or divestiture strategies. In the event we are unable to continue as a going concern, we may be forced to cease operations altogether.

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

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

We may not be able to raise sufficient capital to continue clinical testing of our product candidates.

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

We believe we have sufficient capital to continue enrolling patients in our ongoing randomized Phase II trial for palifosfamide, to collect the necessary IV darinaparsin data to meet with FDA while continuing the oral Phase I trials to completion, and to initiate a Phase I portion of a Phase I/II trial with indibulin. We continue to seek additional financial resources to fund the further development of palifosfamide, darinaparsin and indibulin. If we are unable to obtain sufficient additional capital, one or more of these programs could be placed on hold. We are currently devoting a significant portion of our resources to the development of palifosfamide. As a result, further progress with the development of darinaparsin and indibulin, may be significantly delayed and may depend on the success of our ongoing clinical trial involving palifosfamide.

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 six months ended June 30, 2009, we had a net loss of $5.7 million and we had incurred approximately $89.2 million of cumulative net losses since our inception in 2003. We expect to continue to incur significant operating and capital expenditures. Although we have taken near-term cost cutting measures aimed at preserving capital while we pursue sources of potential additional financing, further development of our product candidates will likely require substantial increases in our expenses as we:

- continue to undertake clinical trials for product candidates;
- scale-up the formulation and manufacturing of our product candidates;
- seek regulatory approvals for product candidates;
- implement additional internal systems and infrastructure; and
- hire additional personnel.

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

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

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

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

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

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

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

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

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

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

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

We may not be able to successfully manage our growth.

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

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

Our contract research and development activities may involve the controlled use of hazardous materials and chemicals. Although we believe that our safety procedures for using, storing, handling and disposing of these materials comply with federal, state and local laws and regulations, we cannot completely eliminate the risk of

accidental injury or contamination from these materials. In the event of such an accident, we could be held liable for any resulting damages and any liability could have a materially adverse effect on our business, financial condition, and results of operations. In addition, the federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous or radioactive materials and waste products may require our contractors to incur substantial compliance costs that could materially adversely affect our business, financial condition, and results of operations.

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

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

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

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

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

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

- decreased demand for our product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- withdrawal of prior governmental approvals;
- costs of related litigation;
- substantial monetary awards to patients;
- product recalls;
- loss of revenue; and
- the inability to commercialize our product candidates.

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

RISKS RELATED TO THE CLINICAL TESTING, REGULATORY APPROVAL AND MANUFACTURING OF OUR PRODUCT CANDIDATES

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

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

- delay commercialization of, and our ability to derive product revenues from, our product candidates;
- impose costly procedures on us; and
- diminish any competitive advantages that we may otherwise enjoy.

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

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

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

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

approval thereof, will directly affect if and when we are able to generate revenues.

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

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

- unforeseen safety issues;
- determination of dosing issues;
- lack of effectiveness during clinical trials;
- slower than expected rates of patient recruitment;
- inability to monitor patients adequately during or after treatment; and
- inability or unwillingness of medical investigators to follow our clinical protocols.

We have received "Orphan Drug" status for palifosfamide in both the United States and Europe and we are hopeful that we may be able to obtain "Fast Track" and/or Orphan Drug status from the FDA for our other 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. Nevertheless, there is no guarantee that any of our product candidates, other than palifosfamide, will be granted Orphan Drug status or will be granted Fast Track status by the FDA or that, even if such product candidate is granted such status, the product candidate's clinical development and regulatory approval process will not be delayed or will be successful.

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

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

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

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

- perceptions by members of the health care community, including physicians, regarding the safety and effectiveness of our drugs;
- cost-effectiveness of our products relative to competing products;

- availability of reimbursement for our products from government or other healthcare payers; and
- effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

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

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

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

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

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

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

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

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

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

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

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

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RISKS RELATED TO OUR ABILITY TO COMMERCIALIZE OUR PRODUCT CANDIDATES

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

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

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

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

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

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

- developing drugs;
- undertaking preclinical testing and human clinical trials;
- obtaining FDA and other regulatory approvals of drugs;

- formulating and manufacturing drugs; and
- launching, marketing, and selling drugs.

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

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

- perceptions by members of the health care community, including physicians, about the safety and effectiveness of our drugs;
- pharmacological benefit and cost-effectiveness of our products relative to competing products;

- availability of reimbursement for our products from government or other healthcare payors;
- effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any; and
- the price at which we sell our products.

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

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

- government and health administration authorities;
- private health maintenance organizations and health insurers; and
- other healthcare payers.

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

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

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

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

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

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

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

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

- the degree and range of protection any patents will afford us against competitors, including whether third parties will find ways to invalidate or otherwise circumvent our patents;
- if and when patents will be issued;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications; or
- whether we will need to initiate litigation or administrative proceedings that may be costly whether we win or lose.

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

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

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

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

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

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

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

OTHER RISKS RELATED TO OUR COMPANY

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

As a public reporting company, we are subject to the Sarbanes-Oxley Act of 2002, as well as to the information and reporting requirements of the Securities Exchange Act of 1934 and other federal securities laws. As a result, we incur significant legal, accounting, and other expenses that we did not incur as a private company, including costs associated with our public company reporting requirements and corporate governance requirements. As an example of public reporting company requirements, we evaluate the effectiveness of disclosure controls and procedures and of our internal control over financing reporting in order to allow management to report on such controls. Pursuant to Sarbanes-Oxley, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting, as of December 31, 2009, in our Annual Report on Form 10-K for the fiscal year ending December 31, 2009. While management has not currently identified any material weaknesses in our internal control over financial reporting, there can be no assurance that our systems will be deemed effective when our independent registered public accounting firm reviews the systems during 2009 and tests transactions. In addition, any updates to our finance and accounting systems, procedures and controls, which may be required as a result of our ongoing analysis of internal controls, or results of testing by our independent auditor, may require significant time and expense.

As a company with limited capital and human resources, our management has identified that there is a potential for a lack of segregation of duties due to the limited number of employees within our company's financial and administrative functions. Management believes that, based on the employees involved and the control procedures in place, risks associated with such lack of segregation are not significant and that the potential benefits of adding employees to segregate duties more clearly do not justify the associated added expense. Nevertheless, our management is working to continuously monitor and improve internal controls and has set in place controls to mitigate the potential segregation of duties risk. We have engaged the services of a Sarbanes-Oxley consultant to tighten our internal controls and ensure adherence to the regulations. In the event significant deficiencies or material weaknesses are identified in our internal control over financial reporting that we cannot remediate in a timely manner, investors and others may lose confidence in the reliability of our financial statements and the trading price of our common stock and ability to obtain any necessary equity or debt financing could suffer. In addition, in the event that our independent registered public accounting firm is unable to rely on our internal controls over financial reporting in connection with its audit of our financial statements, and in the further event that it is unable to devise alternative procedures in order to satisfy itself as to the material accuracy of our financial statements and related disclosures, we may be unable to file our periodic reports with the SEC. This would likely have an adverse affect on the trading price of our common stock and our ability to secure any necessary additional equity or debt financing, and could result in the delisting of our common stock from the Nasdaq Capital Market, which would severely limit the liquidity of our common stock.

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

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

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

Our common stock is listed on The Nasdaq Capital Market. The listing standards of The Nasdaq Capital Market provide, among other things, that a company may be delisted if the bid price of its stock drops below $1.00 for a period of 30 consecutive business days. In addition, if our stockholders' equity falls below $2.5 million, we will fail to comply with The Nasdaq Capital Market's listing standards if shares of our common stock fail to have an aggregate market value of at least $35 million (or $1.37 per share based on our common stock outstanding at October 2, 2009) for ten consecutive business days. If we fail to comply with these or other listing standards applicable to us, our common stock may be delisted from The Nasdaq Capital Market. The delisting of our common stock would significantly affect the ability of investors to trade our securities and would significantly negatively affect the value and liquidity of our common stock. In addition, the delisting of our common stock could materially adversely affect our ability to raise capital on terms acceptable to us or at all. Delisting from The Nasdaq Capital Market could also have other negative results, including the potential loss of confidence by suppliers and employees, the loss of institutional investor interest and fewer business development opportunities.

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

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

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the documents that we incorporate by reference, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934 (the "Exchange Act"). Any statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and may be forward-looking. These statements are often, but not always, made through the use of words or phrases such as anticipate, estimate, plan, project, continuing, ongoing, expect, management believes, we believe, we intend and similar words or phrases. Accordingly, these statements involve estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed. Any forward-looking statements are qualified in their entirety by reference to the factors discussed in this prospectus or incorporated by reference.

Because the factors discussed in this prospectus or incorporated by reference could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements made by us or on our behalf, you should not place undue reliance on any such forward-looking statements. These statements are subject to risks and uncertainties—both known and unknown—which could cause actual results and developments to differ materially from those expressed or implied in such statements. Such risks and uncertainties relate to, among other factors: the development of our drug candidates; the regulatory approval of our drug candidates; our use of clinical research centers and other contractors; our ability to find collaborative partners for research, development and commercialization of potential products; acceptance of our products by doctors, patients or payors; our ability to market any of our products; our history of operating losses; our ability to compete against other companies and research institutions; our ability to secure adequate protection for our intellectual property; our ability to attract and retain key personnel; availability of reimbursement for our product candidates; the effect of potential strategic transactions on our business; our ability to obtain adequate financing; and the volatility of our stock price. These and other risks are detailed in this prospectus under the discussion entitled "Risk Factors," as well as in our reports filed from time to time under the Securities Act or the Exchange Act. You are encouraged to read these filings as they are made.

Finally, any forward-looking statement speaks only as of the date on which it is made, and we undertake no obligation to update any forward-looking statement or statements to reflect events or circumstances after the date on which such statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

USE OF PROCEEDS

We will not receive any proceeds from the disposition by the selling stockholders of any of the shares covered by this prospectus. We will, however, receive the proceeds of any cash exercises of warrants.

SELLING STOCKHOLDERS

This prospectus covers the disposition by the selling stockholders identified below, or their transferees, of a total of 5,683,291 shares of our common stock, including shares issuable upon the exercise of warrants. All of the shares included in this offering were issued, or are issuable upon the exercise of warrants originally issued, in connection with our September 2009 private placement described on page 4 above under the caption "Recent Developments—September 2009 Financing." Of the shares included in this offering, 138,617 are issuable upon the exercise of warrants issued to placement agents and other consultants that provided services to us in connection with the private placement. The warrants received by the investors and by the placement agents and consultants in the private placement are exercisable until September 15, 2014 at an exercise price of $2.04 per share.

The following table sets forth the number of shares of the common stock owned by the selling stockholders as of September 24, 2009, and after giving effect to this offering assuming all of the shares covered hereby are sold.

Selling Stockholder	Shares Beneficially Owned Before Offering (1)	Total Shares Offered By Selling Stockholder (2)	Shares Beneficially Owned After Offering (3)	Percentage of Beneficial Ownership After Offering (3)
Brookline Ziopharm Investment Fund, LLC (4)	1,863,012(5)	1,863,012	0	0%
Hartwell Davis Jr.	328,766(6)	328,766	0	0%
DAFNA LifeScience Ltd (7)	47,000(8)	47,000	0	0%
DAFNA LifeScience Market Neutral Ltd (7)	39,600(9)	39,600	0	0%
DAFNA LifeScience Select Ltd (7)	187,374(10)	187,374	0	0%
Placifor Investments Corp. (11)	547,944(12)	547,944	0	0%
Timothy McInerney (13)	396,703(14)	140,298	256,405	1.00%
Essex Woodlands Health Ventures Fund VI, L.P. (15)	2,954,184(16)	657,532	2,296,652	8.85%
Special Situations Life Sciences Fund, L.P. (17)	932,671(18)	547,946	384,725	1.50%
Joia and Joshua Kazam	79,036(19)	54,794	24,242	*
Domaco Venture Capital Fund (20)	27,400(21)	27,400	0	0%
Anthony G. Polak	27,400(22)	27,400	0	0%
Anthony G. Polak "S"	27,400(23)	27,400	0	0%
Jamie Polak	27,400(24)	27,400	0	0%
Emily L. Polak	27,400(25)	27,400	0	0%
IRA FBO Ronald M. Lazar, DTD 09/84, Pershing LLC as custodian (26)	27,400(27)	27,400	0	0%
RL Capital Partners (26)	109,600(28)	109,600	0	0%
Far Ventures, LLC (29)	30,019(30)	20,000	10,019	*
Ralph Finerman	21,916(31)	21,916	0	0%
Cynthia K. Finerman	10,958(32)	10,958	0	0%
AAR Associates, L.P. (33)	21,916(34)	21,916	0	0%
Hill Blalock, Jr.	132,683(35)	109,588	23,095	*
Cranshire Capital LP (36)	273,972(37)	273,972	0	0%
GCA Strategic Investment Fund Limited (38)	273,972(39)	273,972	0	0%
Kingsbrook Opportunities Master Fund LP (40)	109,590(41)	109,590	0	0%
Harold J. Meyers TTEE Harold J. & Paula P. Meyers Family Trust DTD 6/16/78 (42)	54,794(43)	54,794	0	0%

Rodman & Renshaw, LLC (44)	53,992(45)	53,992	0	0%
Noel Brown	5,267(46)	5,267	0	0%
Jainal Bhuiyan	3,292(47)	3,292	0	0%
Noam Rubinstein	3,292(48)	3,292	0	0%
Riverbank Capital Securities, Inc. (49)	23,045(50)	23,045	0	0%
Scott L. Navins	2,500(51)	2,500	0	0%
Griffin Securities, Inc. (52)	145,908(53)	6,931	138,977	*

* Less than 1%.

(1) Beneficial ownership is determined in accordance with SEC rules, beneficial ownership includes any shares as to which the security or stockholder has sole or shared voting power or investment power, and also any shares which the security or stockholder has the right to acquire within 60 days of the date hereof, whether through the exercise or conversion of any stock option, convertible security, warrant or other right. The indication herein that shares are beneficially owned is not an admission on the part of the security or stockholder that he, she or it is a direct or indirect beneficial owner of those shares.

(2) Includes outstanding shares of common stock and shares of common stock issuable upon the exercise of warrants held by the selling stockholder.

(3) Assumes sales of all shares offered under this prospectus by the selling stockholder.

(4) Madding King has voting and investment control over the shares held by the selling stockholder.

(5) Includes 931,506 shares issuable upon the exercise of warrants.

(6) Includes 164,383 shares issuable upon the exercise of warrants.

(7) Dr. Nathan Fischel has voting and investment control over the shares held by the selling stockholder.

(8) Includes 23,500 shares issuable upon the exercise of warrants.

(9) Includes 19,800 shares issuable upon the exercise of warrants.

(10) Includes 93,687 shares issuable upon the exercise of warrants.

(11) Stephen Robert Beidson, as director of the selling stockholder, has voting and investment control over the shares held by the selling stockholder.

(12) Includes 273,972 shares issuable upon the exercise of warrants.

(13) Mr. McInereney serves as a member of the Company’s Board of Directors.

(14) Includes 238,498 shares issuable upon the exercise of warrants and options to purchase common stock.

(15) R. Scott Barry, as a managing director of the selling stockholder, has voting and investment control over the shares held by the selling stockholder. Mr. Barry disclaim beneficial ownership of such shares.

(16) Includes 711,542 shares issuable upon the exercise of warrants.

(17) AWM Investment Company, Inc. (“AWM”) is the investment adviser to the Special Situations Life Sciences Fund, L.P. (the "Life Sciences Fund"). Austin W. Marxe and David M. Greenhouse are the principal owners of AWM. Through their control of AWM, Messrs. Marxe and Greenhouse share voting and investment control over the portfolio securities of the Life Sciences Fund.

(18) Includes 350,528 shares issuable upon the exercise of warrants.

(19) Includes 27,397 shares issuable upon the exercise of warrants.

(20) Jack Polak has voting and investment control over the shares held by the selling stockholder.

(21) Includes 13,700 shares issuable upon the exercise of warrants.

(22) Includes 13,700 shares issuable upon the exercise of warrants.

(23) Includes 13,700 shares issuable upon the exercise of warrants.

(24) Includes 13,700 shares issuable upon the exercise of warrants.

(25) Includes 13,700 shares issuable upon the exercise of warrants.

(26) Ronald Lazar has voting and investment control over the shares held by the selling stockholder.

(27) Includes 13,700 shares issuable upon the exercise of warrants.

(28) Includes 54,800 shares issuable upon the exercise of warrants.

(29) Steven M. Farber and S. Edmond Farber each has voting and investment control over the shares held by the selling stockholder.

(30) Includes 10,000 shares issuable upon the exercise of warrants.

(31) Includes 10,958 shares issuable upon the exercise of warrants.

(32) Includes 5,479 shares issuable upon the exercise of warrants.

(33) Ralph Finerman has voting and investment control over the shares held by the selling stockholder..

(34) Includes 10,958 shares issuable upon the exercise of warrants.

(35) Includes 54,794 shares issuable upon the exercise of warrants.

(36) Downsview Capital, Inc. ("Downsview") is the general partner of Cranshire Capital, L.P. ("Cranshire") and consequently has voting control and investment discretion over securities held by Cranshire. Mitchell P. Kopin ("Mr. Kopin"), President of Downsview, has voting control over Downsview. As a result of the foregoing, each of Mr. Kopin and Downsview may be deemed to have beneficial ownership (as determined under Section 13(d) of the Securities Exchange Act of 1934, as amended) of the shares of common stock beneficially owned by Cranshire.

(37) Includes 136,986 shares issuable upon the exercise of warrants.

(38) Lewis N. Lester Sr., as Director the selling stockholder, has voting and investment control over the shares held by the selling stockholder.

(39) Includes 136,986 shares issuable upon the exercise of warrants.

(40) Kingsbrook Partners LP ("Kingsbrook Partners") is the investment manager of Kingsbrook Opportunities Master Fund LP ("Kingsbrook Opportunities") and consequently has voting control and investment discretion over securities held by Kingsbrook Opportunities. Kingsbrook Opportunities GP LLC ("Opportunities GP") is the general partner of Kingsbrook Opportunities and may be considered the beneficial owner of any securities deemed to be beneficially owned by Kingsbrook Opportunities. KB GP LLC ("GP LLC") is the general partner of Kingsbrook Partners and may be considered the beneficial owner of any securities deemed to be beneficially owned by Kingsbrook Partners. Ari J. Storch, Adam J. Chill and Scott M. Wallace are the sole managing members of Opportunities GP and GP LLC and as a result may be considered beneficial owners of any securities deemed beneficially owned by Opportunities GP and GP LLC. Each of Kingsbrook Partners, Opportunities GP, GP LLC and Messrs. Storch, Chill and Wallace disclaim beneficial ownership of these securities.

(41) Includes 54,795 shares issuable upon the exercise of warrants.

(42) Harold J. Meyers, as Trustee of the selling stockholders, has voting and investment control over the shares held by the selling stockholder.

(43) Includes 27,397 shares issuable upon the exercise of warrants.

(44) John Bover, as Senior Managing Director of the selling stockholder, has voting and investment control over the shares held by the selling stockholder.

(45) Includes 53,992 shares issuable upon the exercise of warrants.

(46) Includes 5,267 shares issuable upon the exercise of warrants.

(47) Includes 3,292 shares issuable upon the exercise of warrants.

(48) Includes 3,292 shares issuable upon the exercise of warrants.

(49) David M. Tanen, Joshua A. Kazam and Peter M. Kash each has voting and investment control over the shares held by the selling stockholder.

(50) Includes 23,045 shares issuable upon the exercise of warrants.

(51) Includes 2,500 shares issuable upon the exercise of warrants.

(52) Adrian Stecyk has voting and investment control over the shares held by the selling stockholder.

(53) Includes 145,908 shares issuable upon the exercise of warrants.

PLAN OF DISTRIBUTION

We are registering the shares of common stock issued to the selling stockholders and issuable upon exercise of the warrants to permit the resale of these shares of common stock by the holders of the shares of common stock and warrants from time to time after the date of this prospectus. We will not receive any of the proceeds from the sale by the selling stockholders of the shares of common stock. We will bear all fees and expenses incident to our obligation to register the shares of common stock.

The selling stockholders may sell all or a portion of the shares of common stock beneficially owned by them and offered hereby from time to time directly or through one or more underwriters, broker-dealers or agents. If the shares of common stock are sold through underwriters or broker-dealers, the selling stockholders will be responsible for underwriting discounts or commissions or agent's commissions. The shares of common stock may be sold in one or more transactions at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale, or at negotiated prices. These sales may be effected in transactions, which may involve crosses or block transactions. The selling stockholders may use any one or more of the following methods when selling shares:

- on any national securities exchange or quotation service on which the securities may be listed or quoted at the time of sale;
- in the over-the-counter market;
- in transactions otherwise than on these exchanges or systems or in the over-the-counter market;
- through the writing of options, whether such options are listed on an options exchange or otherwise;
- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales entered into after the effective date of the registration statement of which this prospectus is a part;
- broker-dealers may agree with the selling securityholders to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

The selling stockholders may also sell shares under Rule 144 under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the selling stockholders may arrange for other brokers-dealers to participate in sales. If the selling stockholders effect such transactions by selling shares of common stock to or through underwriters, broker-dealers or agents, such underwriters, broker-dealers or agents may receive commissions in the form of discounts, concessions or commissions from the selling stockholders or commissions from purchasers of the shares of common stock for whom they may act as agent or to whom they may sell as principal. Such commissions will be in amounts to be negotiated, but, except as set forth in a supplement to this prospectus, in the case of an agency transaction will not be in excess of a customary brokerage commission in compliance with FINRA Rule 2440; and in the case of a principal transaction a markup or markdown in compliance with FINRA IM-2440 or the successor to such FINRA rules.

In connection with sales of the shares of common stock or otherwise, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the shares of common stock in the course of hedging in positions they assume. The selling stockholders may also sell shares of common stock short and if such short sale shall take place after the date that this Registration Statement is declared effective by the Commission, the selling stockholders may deliver shares of common stock covered by this prospectus to close out short positions and to return borrowed shares in connection with such short sales. The selling stockholders may also loan or pledge shares of common stock to broker-dealers that in turn may sell such shares. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The selling stockholders may pledge or grant a security interest in some or all of the warrants or shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock from time to time pursuant to this prospectus or any amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act of 1933, as amended, amending, if necessary, the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus. The selling stockholders also may transfer and donate the shares of common stock in other circumstances in which case the transferees, donees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

The selling stockholders and any broker-dealer participating in the distribution of the shares of common stock may be deemed to be “underwriters” within the meaning of the Securities Act, and any commission paid, or any discounts or concessions allowed to, any such broker-dealer may be deemed to be underwriting commissions or discounts under the Securities Act. At the time a particular offering of the shares of common stock is made, a prospectus supplement, if required, will be distributed which will set forth (i) the name of each such selling stockholder and of the participating broker-dealer(s), (ii) the number of shares involved, (iii) the price at which such the shares of common stock were sold, (iv) the commissions paid or discounts or concessions allowed to such broker-dealer(s), where applicable, (v) that such broker-dealer(s) did not conduct any investigation to verify the information set out or incorporated by reference in this prospectus, and (vi) other facts material to the transaction. In no event shall any broker-dealer receive fees, commission and markups that, in the aggregate, would exceed eight percent (8%). In addition, upon the Company being notified in writing by a selling stockholder that a donee or pledgee intends to sell more than 500 shares of common stock, a supplement to this prospectus will be filed if then required in accordance with applicable securities law.

Under the securities laws of some states, the shares of common stock may be sold in such states only through registered or licensed brokers or dealers. In addition, in some states the shares of common stock may not be sold unless such shares have been registered or qualified for sale in such state or an exemption from registration or qualification is available and is complied with.

There can be no assurance that any selling stockholder will sell any or all of the shares of common stock registered pursuant to the shelf registration statement, of which this prospectus forms a part.

We have advised each selling stockholder that it may not use shares registered on the registration statement of which this prospectus is a part to cover short sales of common stock made prior to the date on which the registration statement shall have been declared effective by the SEC. If a selling stockholder uses this prospectus for any sale of shares of our common stock, it will be subject to the prospectus delivery requirements of the Securities Act. The selling stockholders and any other person participating in such distribution will be subject to applicable provisions of the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder, including, without

limitation, Regulation M of the Exchange Act, which may limit the timing of purchases and sales of any of the shares of common stock by the selling stockholders and any other participating person. Regulation M may also restrict the ability of any person engaged in the distribution of the shares of common stock to engage in market-making activities with respect to the shares of common stock. All of the foregoing may affect the marketability of the shares of common stock and the ability of any person or entity to engage in market-making activities with respect to the shares of common stock.

We will pay all expenses of the registration of the shares of common stock pursuant to the registration rights agreement, including, without limitation, SEC filing fees and expenses of compliance with state securities or "blue sky" laws; provided, however, that a selling stockholder will pay all underwriting discounts and selling commissions, if any and any related legal expenses incurred by it. We will indemnify the selling stockholders against liabilities, including some liabilities under the Securities Act, in accordance with the registration rights agreements, or the selling stockholders will be entitled to contribution. We may be indemnified by the selling stockholders against civil liabilities, including liabilities under the Securities Act, which may arise from any written information furnished to us by the selling stockholder specifically for use in this prospectus, in accordance with the related registration rights agreements, or we may be entitled to contribution.

Upon completion of this offering and assuming the issuance of all of the shares covered by this prospectus that are issuable upon the exercise of outstanding warrants, there will be 28,482,255 shares of our common stock issued and outstanding. The shares purchased in this offering will be freely tradable without registration or other restriction under the Securities Act, except for any shares purchased by an "affiliate" of our Company, as that term is defined in Rule 405 under the Securities Act. After the date of this prospectus, we cannot predict the effect, if any, that sales of our common stock or the availability of our common stock for sale will have on the market price prevailing from time to time. Nevertheless, sales by existing stockholders of substantial amounts of our common stock could adversely affect prevailing market prices for our stock.

DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES

Pursuant to our certificate of incorporation and bylaws, we may indemnify an officer or director who is made a party to any proceeding, because of his position as such, to the fullest extent authorized by Delaware General Corporation Law, as the same exists or may hereafter be amended. In certain cases, we may advance expenses incurred in defending any such proceeding.

To the extent that indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling our company pursuant to the foregoing provisions, or otherwise, we have been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable. If a claim for indemnification against such liabilities (other than the payment by us of expenses incurred or paid by a director, officer or controlling person of our company in the successful defense of any action, suit or proceeding) is asserted by any of our directors, officers or controlling persons in connection with the securities being registered, we will, unless in the opinion of our counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by us is against public policy as expressed in the Securities Act and will be governed by the final adjudication of that issue.

ABOUT THIS PROSPECTUS

This prospectus is not an offer or solicitation in respect to these securities in any jurisdiction in which such offer or solicitation would be unlawful. This prospectus is part of a registration statement that we filed with the SEC. The registration statement that contains this prospectus (including the exhibits to the registration statement) contains additional information about our company and the securities offered under this prospectus. That registration statement can be read at the SEC web site or at the SEC's offices mentioned below under the heading "Where You Can Find More Information." We have not authorized anyone else to provide you with different information or additional information. You should not assume that the information in this prospectus, or any supplement or amendment to this prospectus, is accurate at any date other than the date indicated on the cover page of such documents.

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WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-3 (including exhibits to such registration statement) under the Securities Act, with respect to the shares of our common stock offered by this prospectus. This prospectus does not contain all the information set forth in the registration statement. For further information with respect to our Company and the shares of our common stock to be sold under this prospectus, we refer you to the registration statement (SEC File No. 333-). Statements contained in this prospectus as to the contents of any contract, agreement or other document to which we make reference are not necessarily complete. In each instance, we refer you to the copy of such contract, agreement or other document filed as an exhibit to the registration statement, each such statement being qualified in all respects by the more complete description of the matter involved.

We are currently subject to the reporting and information requirements of the Exchange Act and, as a result, we are required to file periodic and current reports, and other information with the SEC. You may read and copy this information at the Public Reference Room of the SEC located at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the Public Reference Room. Copies of all or any part of the registration statement may be obtained from the SEC's offices upon payment of fees prescribed by the SEC. The SEC maintains an internet site that contains periodic and current reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of the SEC's website is http://www.sec.gov.

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

We are allowed to incorporate by reference information contained in documents that we file with the SEC. This means that we can disclose important information to you by referring you to those documents and that the information in this prospectus is not complete and you should read the information incorporated by reference for more detail. We incorporate by reference in two ways. First, we list certain documents that we have already filed with the SEC. The information in these documents is considered part of this prospectus. Second, the information in documents that we file in the future will update and supersede the current information in, and incorporated by reference in, this prospectus.

We incorporate by reference the documents listed below and any future filings we will make with the SEC under Section 13(a), 13(c), 14 or 15(d) of the Exchange Act (other than information furnished in Current Reports on Form 8-K filed under Item 2.02 or 7.01 of such form), including filings made after the date of the initial registration statement of which this prospectus is a part and prior to the effective date of such registration statement:

- Annual Report on Form 10-K for the fiscal year ended December 31, 2008, filed on March 23, 2009;
- Quarterly Reports on Form 10-Q for the quarters ended March 31 and June 30, 2009, filed on May 15 and August 14, 2009, respectively;
- Current Reports on Form 8-K filed on each of June 1, 2009, June 4, and September 15, 2009; and
- The description of our common stock set forth in the registration statement on Form 8-A registering our common stock under Section 12 of the Exchange Act, which was filed with the SEC on September 20, 2006.

We will provide to each person, including any beneficial owner, to whom a prospectus is delivered, a copy of any or all of the information that has been incorporated by reference in this prospectus but not delivered with this prospectus. You may request a copy of this information at no cost, by writing or telephoning us at the following address or telephone number:

ZIOPHARM Oncology, Inc.
1180 Avenue of the Americas, 19th Floor
New York, NY 10036
Attention: President
Telephone: (646) 214-0700

You should rely only on the information incorporated by reference or provided in this prospectus or any supplement. We have not authorized anyone else to provide you with different information. The selling stockholders will not make an offer of these shares in any state where the offer is not permitted. You should not assume that the information in this prospectus or any supplement is accurate as of any date other than the date on the front of these documents.

VALIDITY OF COMMON STOCK

Legal matters in connection with the validity of the shares offered by this prospectus will be passed upon by Maslon Edelman Borman & Brand, LLP, of Minneapolis, Minnesota.

EXPERTS

The balance sheets of ZIOPHARM Oncology, Inc. as of December 31, 2008 and 2007 and the related statements of operations, changes in convertible preferred stock and stockholders' equity (deficit) and cash flows for each of the years in the three-year period ended December 31, 2008 and for the period from September 9, 2003 (date of inception) through December 31, 2008, incorporated by reference into the registration statement of which this prospectus is a part, have been included herein in reliance on the report, dated March 16, 2009, of Vitale, Caturano & Company, P.C., (whose name has been changed to Caturano and Company, P.C. effective May 1, 2009) independent registered public accounting firm, given on the authority of that firm as experts in auditing and accounting.

5,683,291 Shares

Common Stock

ZIOPHARM Oncology, Inc.

PROSPECTUS

October 6, 2009