

ZIOPHARM ONCOLOGY INC
Form POS AM
June 30, 2006

As filed with the Securities and Exchange Commission June 30,
2006

Registration No. 333-129680

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

POST EFFECTIVE AMENDMENT NO. 2
ON FORM S-3** TO FORM SB-2
REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

ZIOPHARM Oncology, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or jurisdiction
of incorporation or organization)

84-1475642

(I.R.S. Employer
Identification No.)

**1180 Avenue of the Americas, 19th Floor
New York, NY 10036
(646) 214-0700**

(Address and telephone number of registrant's principal executive offices and principal place of business)

Dr. Jonathan Lewis

Chief Executive Officer

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(Name, address and telephone number of agent for
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Approximate date of proposed sale to the public: From time to time after the effective date of this Registration Statement, as shall be determined by the selling stockholders identified herein.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box:

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. _____

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If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o _____

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. o

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. o

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

** Filed as a Post-effective Amendment on Form S-3 to such Form SB-2 Registration Statement pursuant to the provisions of Rule 401(e)

Subject to completion, dated June 30, 2006

ZIOPHARM Oncology, Inc.

7,140,702 Shares

Common Stock

The selling stockholders identified on pages 15-20 of this prospectus are offering on a resale basis a total of 7,140,702 shares of our common stock, of which 482,407 shares are issuable upon the exercise of outstanding warrants. We will not receive any proceeds from the sale of these shares by the selling stockholders.

Our common stock is quoted on the Over-the-Counter Bulletin Board under the symbol "ZIOP." On June 26, 2006, the last sale price for our common stock as reported on the OTC Bulletin Board was \$5.20.

**The securities offered by this prospectus involve a high degree of risk.
See "Risk Factors" beginning on page 6.**

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

The date of this Prospectus is _____, 2006.

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PROSPECTUS SUMMARY

This summary provides a brief overview of the key aspects of this offering. 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 that contains this prospectus. Accordingly, you are urged to carefully review this prospectus (including all documents incorporated by reference into this prospectus) in its entirety.

Our Company

We are a biopharmaceutical company that is seeking to develop and commercialize a diverse, risk-sensitive portfolio of in-licensed cancer drugs that address unmet medical needs. Our management and advisors are focused on licensing and developing proprietary drug candidate families that are related to cancer therapeutics on the market and where the application of new biology and our drug development expertise will facilitate clinical development, risk management and expedited regulatory approval. We expect to commercialize our products on our own in North America but recognize that promising clinical trial results in cancers with a high incidence and prevalence might also be addressed in a commercial partnership with one or more other companies with the requisite financial resources. Currently, we are in Phase I and Phase I/II studies for two product candidates known as ZIO-101 and ZIO-201. We currently intend to continue with clinical development of ZIO-101 for advanced myeloma and ZIO-201 for advanced sarcoma. None of our product candidates have been approved by the United States Food and Drug Administration (the "FDA") or any other regulatory body. Further, we have not received any commercial revenues to date, and until we receive the necessary approvals from the FDA or a similar foreign regulatory authority, we will not have any commercial revenues.

· ZIO-101 is an organic arsenic compound covered by issued U.S. patents and applications internationally. A form of commercially available inorganic arsenic (arsenic trioxide (Trisenox®) or ATO) has been approved for the treatment of acute promyelocytic leukemia (APL), a precancerous condition, and is on the compendia listing for the therapy of multiple myeloma as well as having been studied for the treatment of various other cancers. Nevertheless, ATO has been shown to be toxic to the heart, liver and brain, limiting its use as an anti-cancer agent. Inorganic arsenic has also been shown to cause cancer of the skin and lung in humans. The toxicity of arsenic generally is correlated to its accumulation in organs and tissues. Our preclinical and Phase I studies to date have demonstrated that ZIO-101 (and organic arsenic in general) is considerably less toxic than inorganic arsenic, particularly with regard to heart toxicity. In vitro testing of ZIO-101 using the National Cancer Institute's human cancer cell panel detected activity against lung, colon, brain, melanoma, ovarian and kidney cancer. Moderate activity was detected against breast and prostate cancer. In addition to solid tumors, in vitro testing in both the National Cancer Institute's cancer cell panel and in vivo testing in a leukemia animal model demonstrated substantial activity against hematological cancers (cancers of the blood and blood-forming tissues) such as leukemia, lymphoma, myelodysplastic syndromes and multiple myeloma.

Phase I testing of ZIO-101 is ongoing with two safety and dose finding studies at the University of Texas M. D. Anderson Cancer Center. The Company has seen encouraging signs of clinical activity in both of these studies including impact on blood and bone marrow blast cells in patients with acute myelogenous leukemia (AML) and including one patient with metastatic renal cell carcinoma where metastases to the brain resolved. The Company recently initiated a phase I/II advanced multiple myeloma (SGL2001) study to be conducted in the U.S., Canada and Europe designed to determine maximum tolerated dose and to assess clinical activity in this specific indication. The Company expects to pursue registration in the U.S. for the treatment of advanced multiple myeloma with a potentially pivotal trial to begin in 2007.

· ZIO-201, or isophosphoramidate mustard (IPM), is a proprietary stabilized metabolite of ifosfamide that is also related to cyclophosphamide. A patent application for pharmaceutical composition has been filed.

Cyclophosphamide and ifosfamide are alkylating agents. The Company believes cyclophosphamide is the most widely used alkylating agent in cancer therapy and is used to treat breast cancer and non-Hodgkin's lymphoma. Ifosfamide has been shown to be effective in high dose by itself, or in combination in treating sarcoma and lymphoma. Although ifosfamide-based treatment generally represents the standard of care for sarcoma, it is not licensed for this indication by the FDA. Our preclinical studies have shown that, in animal and laboratory models, IPM evidences activity against leukemia and solid tumors. These studies also indicate that ZIO-201 has a better pharmacokinetic and safety profile than ifosfamide or cyclophosphamide, offering the possibility of safer and more efficacious therapy with ZIO-201. Ifosfamide is metabolized to IPM. In addition to IPM, another metabolite of ifosfamide is acrolein, which is toxic to the kidneys and bladder. The presence of acrolein can mandate the administration of a protective agent called mesna, which is inconvenient and expensive. Chloroacetaldehyde is another metabolite of ifosfamide and is toxic to the central nervous system, causing "fuzzy brain" syndrome for which there is currently no protective measure. Similar toxicity concerns pertain to high-dose cyclophosphamide, which is widely used in bone marrow and blood cell transplantation. Because ZIO-201 is independently active—without acrolein or chloroacetaldehyde metabolites—the Company believes that the administration of ZIO-201 may avoid many of the toxicities of ifosfamide and cyclophosphamide without compromising efficacy. In addition to anticipated lower toxicity, ZIO-201 (and without the coadministration of mesna) may have other advantages over ifosfamide. In preclinical studies, ZIO-201 likely cross-links DNA differently than ifosfamide or cyclophosphamide metabolites, resulting in a different activity profile. Moreover, in some instances ZIO-201 appears to show activity in ifosfamide- and/or cyclophosphamide-resistant cancer cells.

Phase I testing of ZIO-201 is ongoing at two sites in the U.S. (Karmanos Cancer Center at Wayne State University in Detroit and Premiere Oncology in Los Angeles). IPM has been administered without the “uroprotectant” mesna and the toxicities associated with acrolein and chloroacetaldehyde have not been observed. Kidney toxicity seen with ifosfamide has occurred in the higher dose cohorts. One patient with advanced mesothelioma had stable disease following 18 cycles of therapy with ZIO-201 as a single agent. The Company recently initiated a phase I/II trial in advanced sarcoma at the University of Texas M. D. Anderson Cancer Center (the “MDACC”). Additional studies in patients with advanced sarcoma will begin shortly in the U.S. and plans for a phase I/II study in pediatric sarcoma are well advanced. The Company expects to pursue registration in the U.S. for the treatment of advanced sarcoma with a potentially pivotal trial to begin in 2007.

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 Easy Web was the legal acquirer in the transaction, ZIOPHARM, Inc. became the registrant with the Securities and Exchange Commission because under generally accepted accounting principles the transaction was accounted for as a reverse acquisition. Accordingly, the historical financial statements of ZIOPHARM, Inc. have become 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.

Risk Factors

As with most pharmaceutical product candidates, the development of ZIO-101 and ZOI-201 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 6 of this prospectus.

The Offering

The shares offered by this prospectus were previously covered by our prospectus dated April 14, 2006, as supplemented to date, which originally covered the resale of an aggregate of 7,462,095 shares of our common stock by the selling stockholders identified in such prospectus, of which 482,407 shares are issuable upon the exercise of outstanding warrants. The selling stockholders identified on pages 15-20 of this prospectus are offering an aggregate of 7,140,702 shares of our common stock, including 482,407 shares issuable upon the exercise of outstanding warrants. The shares offered by such selling stockholders reflect those shares of our common stock remaining unsold by the selling stockholders identified in our April 14, 2006 prospectus.

Common stock offered	7,140,702 shares
	15,264,248
Common stock outstanding before the offering ⁽¹⁾	shares
	15,746,655
Common stock outstanding after the offering ⁽¹⁾⁽²⁾	shares
Common Stock OTC Bulletin Board symbol	ZIOP

(1) Based on the number of shares outstanding as of June 26, 2006, not including shares issuable upon exercise of various warrants and options to purchase common stock.

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

RISK FACTORS

An investment in our common stock is very risky. You may lose the entire amount of your investment. Prior to making an investment decision, you should carefully review this entire prospectus and consider the following risk factors:

We currently have no product revenues and will need to raise additional capital to operate our business.

To date, we have generated no product revenues. Until and unless we receive approval from the FDA and/or other regulatory authorities for our product candidates, we cannot sell our drugs and will not have product revenues. Currently, our only product candidates are ZIO-101 (organic arsenic) and ZIO-201 (isophosphoramidate mustard), and they are not approved by the FDA for sale.

We will need to seek additional sources of financing which may not be available on favorable terms, if at all.

As of March 31, 2006, we had incurred approximately \$18.6 million of cumulative net losses and had approximately \$5.6 million of cash, cash equivalents and short-term investments. Our consolidated financial statements as of December 31, 2005 were prepared under the assumption that we will continue as a going concern for the year ending December 31, 2006. The Company's independent registered public accounting firm, Vitale, Caturano & Company, Ltd., issued a report dated March 9, 2006 that included an explanatory paragraph referring to our significant operating losses and expressing substantial doubt in its ability to continue as a going concern (See Note (1) in the Notes to Consolidated Financial Statements) without additional capital becoming available. As of May 3, 2006, and after receiving the proceeds from our May 3, 2006 offering of common stock and warrants, we had approximately \$39.2 million of cash, cash equivalents and short-term investments. Although we expect that the proceeds from this offering will provide us with sufficient cash to fund our operations into the first quarter of 2008, our ability to continue as a going concern beyond that time is dependent upon our ability to obtain additional equity or debt financing, attain further operating efficiencies and, ultimately, to generate revenue. Our financial statements do not include any adjustments that might result from the outcome of this uncertainty. Although we expect our cash on-hand to fund our operations into the first quarter of 2008, changes may occur that would consume our existing capital prior to that time, including the progress of our research and development efforts, changes in governmental regulation and acquisitions of additional product candidates. If we do not succeed in raising additional funds on acceptable terms, we may be unable to complete planned preclinical and clinical trials or obtain approval of any product candidates from the FDA and other regulatory authorities. In addition, we could be forced to discontinue product development, reduce or forego sales and marketing efforts or forego attractive business opportunities. Any additional sources of financing will likely involve the issuance of our equity securities, which will have a dilutive effect on our existing stockholders.

We are not currently profitable and may never become profitable.

We have a history of losses and expect to incur substantial losses and negative operating cash flow for the foreseeable future, and we may never achieve or maintain profitability. Even if we succeed in developing and commercializing one or more product candidates, we expect to incur substantial losses for the foreseeable future and may never become profitable. We expect also to continue to incur significant operating and capital expenditures and anticipate that our expenses will increase substantially in the foreseeable future as we:

- Continue to undertake preclinical development and clinical trials for product candidates;
- Scale up the formulation and manufacturing of our product candidates;
- Seek regulatory approvals for product candidates;
- Implement additional internal systems and infrastructure; and
- Hire additional personnel and expand office space.

We also expect to experience negative cash flow for the foreseeable future as we fund our operating losses and capital expenditures. This may result in a negative impact on the value of our common stock.

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

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

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

Our operations have been limited to organizing and staffing our Company, acquiring, developing and securing our proprietary product candidates, undertaking preclinical trials and clinical trials of our product candidates ZIO-101 and ZIO-201, and manufacturing ZIO-101 and ZIO- 201. These operations provide a limited basis for you to assess our ability to commercialize our product candidates and the advisability of investing in our securities.

We may not obtain the necessary U.S. or worldwide regulatory approvals to commercialize any product candidate.

We may not be able to obtain the approvals necessary to commercialize our product candidates, ZIO-101 and ZIO-201, or any product candidate that we may acquire or develop in the future for commercial sale. We will need FDA approval to commercialize our product candidates in the U.S. and approvals from regulatory authorities in foreign jurisdictions equivalent to the FDA to commercialize our product candidates in those jurisdictions. In order to obtain FDA approval of any product candidate, we must submit to the FDA a New Drug Application (NDA), demonstrating that the product candidate is safe for humans and effective for its intended use. This demonstration requires significant research and animal tests, which are referred to as preclinical studies, as well as human tests, which are referred to as clinical trials. Satisfaction of the FDA's regulatory requirements typically takes many years, depending upon the type, complexity and novelty of the product candidate, and will require substantial resources for research, development and testing. We cannot predict whether our research, development, and clinical approaches will result in drugs that the FDA considers safe for humans and effective for their intended uses. The FDA has substantial discretion in the drug approval process and may require us to conduct additional preclinical and clinical testing or to perform post-marketing studies. The approval process may also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals may:

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

Even if we comply with all FDA requests, the FDA may ultimately reject one or more of our NDAs. We cannot be sure that we will ever obtain regulatory clearance for our product candidates, ZIO-101 and ZIO-201. Failure to obtain FDA approval of our product candidates will severely undermine our business by leaving us without a saleable product, and therefore without any potential revenue source, until another product candidate can be developed. There is no guarantee that we will ever be able to develop or acquire another product candidate.

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

Our product candidates are in early stages of clinical trials, and we cannot be certain when we will be able to file an NDA with the FDA.

Our product candidates, ZIO-101 and ZIO-201, 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.

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

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

- Unforeseen safety issues;
- Determination of dosing issues;
- Lack of effectiveness during clinical trials;
- Slower than expected rates of patient recruitment;
- Inability to monitor patients adequately during or after treatment; and
- Inability or unwillingness of medical investigators to follow our clinical protocols.

We are hopeful that we may be able to obtain “Fast Track” and or “Orphan Drug” status from the FDA for one or more of our product candidates. Fast Track allows the FDA to facilitate development and expedite review of drugs that treat serious and life-threatening conditions so that an approved product can reach the market expeditiously. Fast Track status does not apply to a product alone, but applies to a combination of a product and the specific indications for which it is being studied. Therefore, it is a drug’s development program for a specific indication that receives Fast Track designation. Orphan Drug status promotes the development of products that demonstrate the promise for the diagnosis and treatment of one disease or condition and affords certain financial and market protection benefits to successful applicants. However, there is no guarantee that any of our product candidates will be granted Fast Track or Orphan Drug status by the FDA or that, even if such product candidate is granted such status, the product candidate’s clinical development and regulatory approval process will not be delayed or will be successful.

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

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

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

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

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

Availability of reimbursement for our products from government or other healthcare payers; and

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- 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.

Our drug development program materially depends upon third-party researchers who are outside 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.

We rely exclusively on third parties to formulate and manufacture our product candidates.

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 commercial scale 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.

We do not have experience selling, marketing or distributing products and we have no internal capability to do so.

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

If we 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 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.