ZIOPHARM ONCOLOGY INC
Form 424B5
January 23, 2012

Filed Pursuant to Rule 424(b)(5)
Registration No. 333-177793

Prospectus supplement
(to prospectus dated November 16, 2011)

9,650,000 shares

Common Stock

We are offering 9,650,000 shares of our common stock.

Shares of our common stock trade on the NASDAQ Capital Market under the symbol ZIOP. The last reported sale price on January 19, 2012 was $5.32 per share.

	Per Share	Total
Public offering price	$ 5.20	$ 50,180,000
Underwriting discounts and commissions	$ 0.312	$ 3,010,800
Proceeds, before expenses, to us	$ 4.888	$ 47,169,200

We have granted the underwriters an option for a period of up to 30 days from the date of this prospectus supplement to purchase up to 1,447,500 additional shares of common stock at the public offering price less the underwriting discounts and commissions to cover over-allotments, if any.

INVESTING IN OUR COMMON STOCK INVOLVES RISK. SEE RISK FACTORS BEGINNING ON PAGE S-7.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus supplement or the accompanying prospectus. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares on or about January 25, 2012.

Sole book-running manager

J.P. Morgan

Co-managers

Lazard Capital Markets
Collins Stewart

Piper Jaffray
Griffin Securities, Inc.

January 20, 2012

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Prospectus supplement

Prospectus

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About this prospectus supplement

This document is in two parts. The first part is this prospectus supplement, which describes the specific terms of this common stock offering and also adds to and updates information contained in the accompanying prospectus and the documents incorporated by reference herein. The second part, the accompanying prospectus, provides more general information. Generally, when we refer to this prospectus, we are referring to both parts of this document combined. To the extent there is a conflict between the information contained in this prospectus supplement and the information contained in the accompanying prospectus or any document incorporated by reference therein filed prior to the date of this prospectus supplement, you should rely on the information in this prospectus supplement; provided that if any statement in one of these documents is inconsistent with a statement in another document having a later date for example, a document incorporated by reference in the accompanying prospectus the statement in the document having the later date modifies or supersedes the earlier statement.

We further note that the representations, warranties and covenants made by us in any agreement that is filed as an exhibit to any document that is incorporated by reference herein were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreements, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

You should rely only on the information contained in this prospectus supplement or the accompanying prospectus, or incorporated by reference herein. We have not authorized, and the underwriters have not authorized, anyone to provide you with information that is different. The information contained in this prospectus supplement or the accompanying prospectus, or incorporated by reference herein is accurate only as of the respective dates thereof, regardless of the time of delivery of this prospectus supplement and the accompanying prospectus or of any sale of our common stock. It is important for you to read and consider all information contained in this prospectus supplement and the accompanying prospectus, including the documents incorporated by reference herein and therein, in making your investment decision. You should also read and consider the information in the documents to which we have referred you in the sections entitled Where you can find more information and Incorporation of information by reference in this prospectus supplement and in the accompanying prospectus.

We are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The distribution of this prospectus supplement and the accompanying prospectus and the offering of the common stock in certain jurisdictions may be restricted by law. Persons outside the United States who come into possession of this prospectus supplement and the accompanying prospectus must inform themselves about, and observe any restrictions relating to, the offering of the common stock and the distribution of this prospectus supplement and the accompanying prospectus outside the United States. This prospectus supplement and the accompanying prospectus do not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities offered by this prospectus supplement and the accompanying prospectus by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

Unless otherwise stated, all references in this prospectus to we, us, our, ZIOPHARM, the Company and similar designations refer to ZIOPHARM Oncology, Inc.

This prospectus supplement, the accompanying prospectus, and the information incorporated herein and therein by reference, include trademarks, service marks and trade names owned by us or other companies. All trademarks, service marks and trade names included or incorporated by reference into this prospectus supplement or the

accompanying prospectus are the property of their respective owners.

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Prospectus supplement summary

This summary highlights certain information about us, this offering and selected information contained elsewhere in or incorporated by reference in this prospectus supplement. This summary is not complete and does not contain all of the information that you should consider before deciding whether to invest in our common stock. For a more complete understanding of our company and this offering, we encourage you to read and consider carefully the more detailed information in this prospectus supplement and the accompanying prospectus, including the information referred to under the heading Risk factors in this prospectus supplement beginning on page S-7, the information incorporated by reference in this prospectus supplement and the accompanying prospectus, and the information included in any free writing prospectus that we have authorized for use in connection with this offering.

Company overview

ZIOPHARM Oncology, Inc. is a biopharmaceutical company that is seeking to develop and commercialize a diverse portfolio of cancer drugs that can address unmet medical needs. Our principal focus has been 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 that can be administered by intravenous, or IV, and/or oral dosing. Our clinical programs for our small molecule candidates include palifosfamide (Zymafos® or ZIO-201), darinaparsin (Zinapar® or ZIO-101) and indibulin (Zybulin™ or ZIO-301). We are also pursuing the development of novel DNA-based biotherapeutics in the field of cancer pursuant to a partnering arrangement with Intrexon Corporation, or Intrexon. Under the arrangement, we obtained rights to Intrexon s effector platform for use in the field of oncology, which includes two existing clinical stage product candidates, ZIN-CTI-001 (or DC-RTS-IL-12 + AL) and ZIN-ATI-001 (or Ad-RTS-IL-12 + AL). We plan to leverage Intrexon s synthetic biology platform to develop products to stimulate key pathways used by the body s immune system to inhibit the growth and metastasis of cancers, adding significantly to our small molecule drug development portfolio and utilizing our capabilities to translate science to the patient setting.

We believe that our strategy will result in expedited drug development programs for product candidates with a cost of manufacturing that, upon successful commercialization, would help to address changing worldwide product reimbursement requirements. We are currently in Phase 1, 2, and/or Phase 3 studies for our product candidates with a particular emphasis on completing a global palifosfamide pivotal Phase 3 trial to support registration in combination with doxorubicin in the front-line setting of metastatic soft tissue sarcoma.

Product candidates

ZIO-101, Darinaparsin, Zinapar

Darinaparsin is a novel mitochondrial- and sonic hedgehog-targeted agent (organic arsenic) in development with both IV and oral administration. Phase 1 testing of the IV form of darinaparsin in solid tumors and hematological cancers was completed and we reported clinical activity and, importantly, a safety profile from these studies as predicted by preclinical results. We subsequently completed Phase 2 studies in advanced myeloma, primary liver cancer and in certain other hematological cancers. At the May 2009 annual meeting of the American Society of Clinical Oncology (ASCO), we reported favorable results from the IV trial in lymphoma, particularly peripheral T-cell lymphoma, or PTCL. With a subsequent focus on the relapsed setting of PTCL, a Phase 1 study of darinaparsin in combination with the treatment regimen called CHOP in the front-line setting of PTCL was ended. A Phase 1 trial in solid tumors with

an oral form of darinaparsin is nearing completion. Data from the Phase I oral study will guide further study. We have obtained Orphan Drug Designation for darinaparsin in the United States and Europe for the treatment of PTCL and have entered into a licensing agreement with Solasia for the Asia/Pacific territory with a focus on IV-administered darinaparsin in PTCL.

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ZIO-201, Palifosfamide, Zymafos

Palifosfamide is a novel DNA cross-linker (stabilized active metabolite of ifosfamide) in class with bendemustine, ifosfamide, and cyclophosphamide and currently in development with IV administration (oral in late preclinical). Following Phase 1 study, we completed Phase 2 testing of the IV form of palifosfamide as a single agent to treat advanced sarcoma. In both Phase 1 and Phase 2 testing, palifosfamide has been administered without the uroprotectant mesna, as is required with ifosfamide, and the toxicities associated with other ifosfamide metabolites, acrolein and chloroacetaldehyde, have not been observed. We reported clinical activity of palifosfamide when used alone in the Phase 2 study addressing advanced sarcoma. Following review of preclinical combination studies, we initiated a Phase 1 dose escalation study of palifosfamide in combination with doxorubicin, primarily in patients with soft tissue sarcoma. We reported favorable results and safety profile from this study at ASCO s 2009 annual meeting. In light of reported favorable Phase 2 single agent clinical activity data and with the combination being well tolerated in the Phase 1 trial, we initiated a Phase 2 randomized controlled trial, which we refer to as PICASSO, in the second half of 2008 to compare doxorubicin plus palifosfamide to doxorubicin alone in patients with front- and second-line metastatic or unresectable soft tissue sarcoma. The study generated positive top line interim data in 2009. Upon successfully reaching a pre-specified efficacy milestone and following safety and efficacy data review by the Data Committee, sarcoma experts, and our Medical Advisory Board, we elected to suspend enrollment in the trial in October 2009. We subsequently presented further positive interim data from the trial at the 15th Annual Connective Tissue Oncology Society meeting held in November 2009 and again at the 2010 ASCO annual meeting in June 2010, where the presentation was selected for Best of ASCO. In July 2010, we announced the initiation of a worldwide registration trial on a protocol design developed through a U.S. Food and Drug Administration, or FDA, End-of-Phase 2 meeting and the Special Protocol Assessment, or SPA, process. Although we did engage in the SPA process, we, with guidance from the FDA, elected to initiate the trial without having obtained SPA agreement from the FDA. The Phase 3 trial is in front-line metastatic soft tissue sarcoma, entitled PICASSO 3, and is an international, randomized, double-blinded, placebo-controlled trial with a targeted enrollment of 424 patients. The study is designed to evaluate the safety and efficacy of palifosfamide administered with doxorubicin compared with doxorubicin administered with placebo, with no cross-over between the arms. Progression-free survival is the primary endpoint for accelerated approval, with overall survival as the primary endpoint for full approval. PICASSO 3 has no interim efficacy analysis, while the trial is monitored by a Data Monitoring Committee, or DMC, of outside, independent experts for safety and futility. The DMC has met twice to review trial data for safety and futility and on both occasions has recommended trial continuation. Orphan Drug Designation for palifosfamide has been obtained in both the United States and the European Union for the treatment of soft tissue sarcomas.

A Phase 1 trial is nearing completion with palifosfamide in combination with etoposide and carboplatin to determine appropriate safety for initiating a potentially pivotal, adaptive Phase 3 trial in front-line, extensive small-cell lung cancer, or SCLC, expected to initiate in the second half of 2012. An oral form of palifosfamide has been the subject of preclinical studies necessary for an Investigational New Drug, or IND, application to support commencing Phase 1 study. Based on an initial review, the FDA requested that we repeat an animal study, now completed and submitted to the FDA.

According to the American Cancer Society, it was estimated that 569,490 Americans would die from cancer in 2010 more than 1,500 each day. The cost of treating cancer is significant. The National Institute of Health estimated that the overall cost of cancer in 2010 was $263.8 billion. This cost included an estimate of $102.8 billion in direct medical expenses and $140.1 billion in indirect mortality costs.

Both front-line metastatic soft tissue sarcoma, or STS, and extensive SCLC represent significant unmet medical needs with standard of care considerably dated. We believe approximately 100,000 patients worldwide have been initially diagnosed with STS. For patients diagnosed with STS, primary care is surgery, sometimes with radiation therapy. Many patients enter a period of remission that is unpredictable

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and can even represent a cure. Metastatic STS arises when the disease has re-occurred and surgery is no longer an option. Chemotherapy is the standard of care for front-line metastatic STS and doxorubicin is the only front-line therapy approved in the United States for its treatment. The annual projection in the United States for front-line metastatic STS treatment is approximately 9,000 patients. While data sources for Europe are unavailable, we believe the annual projection in Europe for front-line metastatic STS treatment is approximately 14,000 patients, for a combined U.S. and European estimate of 23,000 patients annually. For SCLC, the estimated U.S. annual incidence is 30 35,000 patients, and 200,000 patients worldwide. Approximately 80 90% of patients have extensive disease, the population for the planned pivotal trial. Cis/carboplatin and etoposide are standard of care in the front-line setting. A formal retrospective mortality study also suggests that the SCLC population in China is substantial and projected from the study to be greater than 150,000 patients and growing. We believe there is more than $1.0 billion in total market potential for worldwide sales of cancer drugs relating to the treatment of STS and SCLC.

ZIO-301, Indibulin, Zybulin

Indibulin is a novel orally administered tubulin binding agent. Phase 1 study as a single agent in patients with advanced solid tumors has been completed. We have reported clinical activity at well-tolerated doses using a continuous dosing scheme without the development of clinically relevant peripheral neuropathy. Following encouraging preclinical results obtained with indibulin in combination with other chemotherapies, two Phase 1 combination studies were initiated with Tarceva™ and Xeloda™, respectively. The favorable activity and safety profile of oral indibulin with oral Xeloda™ was reported at ASCO s annual meeting in May 2009. In all studies, a maximum tolerated dose, or MTD, was not established. Preclinical work with our consultant established a dosing schedule to enhance activity and reduce toxicity, which is presently five days on drug and nine days off in a Phase 1 study in late stage metastatic breast cancer. In light of the lack of establishing an MTD and the need to administer many capsules several times a day, we have recently modified the dosage form to administer once a day dosing in the Phase 1 trial.

ZIN-CTI-001 (or DC-RTS-IL-12 + AL) and ZIN-ATI-001 (or Ad-RTS-IL-12 + AL)

We are also pursuing the development of novel DNA-based therapeutics in the field of cancer pursuant to an exclusive channel partnership with Intrexon. The partnership includes two existing clinical-stage product candidates. ZIN-CTI-001 is in a Phase 1b trial in the United States and employs intratumoral injection of modified dendritic cells from each patient and oral dosing of an activator ligand to turn on *in vivo* expression of interleukin-12, or IL-12. ZIN-CTI-001 uses a RheoSwitch Therapeutic System®, or RTS, to control the timing and level of transgene expression for gene and cell therapy. The RTS technology functions as a gene switch for the regulated expression of human IL-12 in the patients dendritic cells which are transduced with a replication deficient adenoviral vector carrying the IL-12 gene under the control of the RTS, and in this study, injected intratumorally for the treatment of patients with stage III or IV melanoma. The binding of the small molecule activator to the fusion proteins of RTS is intended to regulate the timing and level of IL-12 expression. In the absence of the activator ligand, the level of IL-12 is below detectable levels.

The activator ligand has been the subject of a number of preclinical, safety and pharmacology studies under FDA and International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use guidelines. Preclinical studies in the B16 mouse melanoma model consistently induced regression of established melanoma lesions, both in those directly injected and those elsewhere in the body. Preclinical studies have shown DC-RTS-IL-12, in combination with an activator ligand, to have strong activity against a broad array of cancers, including brain, colon, renal and pancreatic cancers and melanoma.

A Phase 1a clinical study of the activator ligand was conducted in 65 healthy volunteers, with the two most common side effects being dysgeusia (impairment of taste) and throat irritation. A subsequent Phase 1b trial, which is ongoing in patients with advanced melanoma, has been amended to study efficacy and

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immunological and biological effects in addition to safety with cohort-based dose escalation of the activator ligand during repeated treatment cycles. Initial positive clinical results from the Phase 1b trial were presented at the June 2011 ASCO annual meeting. The trial enrolled ten patients (median age 61) with unresectable Stage III or IV melanoma. Among eight evaluable patients, partial or complete regression of injected and some uninjected lesions was observed by computed axial tomography, or CT, scans in three patients, with one patient having a RECIST PR of >11 months and three patients demonstrating stable disease by RECIST, for an overall disease control rate of 50%. Treatment was generally well tolerated, and maximum tolerated dose has not yet been reached. Adverse events were mild to moderate, with one to two patients each experiencing nausea, vomiting, anorexia, arthralgia, fever or chills. One severe adverse event was reported 18 hours after treatment onset with 60 mg AL + ZIN-CTI-001, and included diarrhea, followed by hypotension and reversible acute renal failure, which completely resolved.

Clinical study of ZIN-ATI-001, essentially ZIN-CTI-001 without dendritic cells, has also initiated in Phase 1 study in advanced melanoma. The Phase 1 study will evaluate safety in addition to immunological and biological effects and efficacy of the therapeutic candidate in patients with melanoma.

We intend to evaluate both ZIN-CTI-001 and ZIN-ATI-001 with the intent to advance ZIN-ATI-001 into at least two Phase 2 trials, one a potentially pivotal trial for accelerated approval in an indication with significant unmet medical need.

We are also in late preclinical evaluation with respect to several additional potential product candidates under our channel partnership with Intrexon, and we anticipate continuing evaluation to select product candidates for clinical study, which could commence as early as this year. We also anticipate continuing discovery efforts aimed at identifying additional potential product candidates under the Intrexon channel partnership for study thereafter.

Development plans

We are currently pursuing several clinical programs, which include:

palifosfamide (Zymafos or ZIO-201) completing our Phase 3 pivotal trial in front-line metastatic soft tissue sarcoma, entitled PICASSO 3, and completing our Phase 1 trial with palifosfamide in combination with etoposide and carboplatin to determine appropriate safety for initiating the subsequent randomized trial in front-line, extensive small-cell lung cancer.

darinaparsin (Zinapar or ZIO-101) completing an ongoing Phase 1 study with an oral form.

indibulin (Zybulin or ZIO-301) entering the Phase 2 portion of the Phase 1/2 trial having established the MTD in Phase 1 with once daily dosing.

ZIN-CTI-001 completing a Phase 1b trial in patients with advanced melanoma that is on-going in the United States.

ZIN-ATI-001 completing the Phase 1 trial treatment of patients with late-stage malignant melanoma and advancing to Phase 2 study.

Our current plans involve using considerably internal financial resources to develop palifosfamide and to broaden extensively the synthetic biology program, with the intention of ultimately partnering or otherwise raising additional resources to support further development activities for all of our product candidates. 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

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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 product candidates in any market and, therefore, have not generated any revenues from our product candidates.

Risk factors

An investment in our common stock is subject to a number of risks and uncertainties. Before investing in our common stock, you should carefully consider the following, as well as the more detailed discussion of risk factors and other information included in this prospectus supplement.

We will require additional financial resources in order to continue on-going development of our product candidates; if we are unable to obtain these additional resources, we may be forced to delay or discontinue clinical testing of our product candidates.

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.

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

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

The technology on which our channel partnering arrangement with Intrexon Corporation is based in part on early stage technology in the field of human oncologic therapeutics.

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

Corporate information

We 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 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 Commission and the historical financial statements of ZIOPHARM, Inc. became our historical financial statements

Our principal executive offices are located at 1180 Avenue of the Americas, 20th Floor, New York, NY 10036, and our telephone number is (646) 214-0700. Our Internet site is *www.ziopharm.com.* Information found on, or accessible through, our website is not a part of, and is not incorporated into, this prospectus supplement or the accompanying prospectus, and you should not consider it part of this prospectus supplement or part of the accompanying prospectus.

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The offering

Common stock offered by us in this offering	9,650,000 shares
Common stock to be outstanding immediately after this offering	78,101,324 shares
Use of proceeds	We intend to use the net proceeds from this public offering for the overall development of our drug candidates, including palifosfamide and DNA therapeutics, and for general corporate and working capital purposes. See Use of Proceeds.
Risk factors	See Risk factors beginning on page S-7 for a discussion of some of the factors you should carefully consider before deciding to invest in shares of our common stock.
Option to purchase additional shares	We have granted the underwriters an option for a period of up to 30 days from the date of this prospectus supplement to purchase up to 1,447,500 additional shares of common stock at the public offering price less the underwriting discounts and commissions to cover over-allotments, if any.
NASDAQ Capital Market symbol	ZIOP

The number of shares of common stock to be outstanding immediately after this offering is based on 68,451,324 shares of common stock outstanding as of September 30, 2011, and does not include:

4,981,398 shares of our common stock issuable upon the exercise of stock options outstanding as of September 30, 2011, having a weighted average exercise price of $4.08 per share;
1,141,718 shares of our common stock available as of September 30, 2011 for future issuance pursuant to our 2003 Stock Option Plan;
13,179,885 shares of our common stock issuable upon the exercise of outstanding warrants as of September 30, 2011 with a weighted-average exercise price of $3.86 per share; and
3,636,926 shares of our common stock that will be issued contingent upon satisfaction of a development milestone under our Stock Purchase Agreement dated January 6, 2011 with Intrexon Corporation.

Except as otherwise indicated, all information in this prospectus supplement assumes no exercise by the underwriters of their over-allotment option.

Indication of interest

Intrexon Corporation, a corporation affiliated with Randal J. Kirk, who serves as a director of ours, agreed to purchase 1,923,075 shares of common stock in this offering.

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Risk factors

An investment in our common stock involves a high degree of risk. Before deciding whether to invest in our common stock, you should consider carefully the risks described below and discussed under the section captioned Risk Factors contained in our Quarterly Report on Form 10-Q for the period ended September 30, 2011, which is incorporated by reference in this prospectus supplement and the accompanying prospectus, in its entirety, together with other information in this prospectus supplement, the accompanying prospectus, the information and documents incorporated by reference, and in any free writing prospectus that we have authorized for use in connection with this offering. If any of these risks actually occurs, our business, financial condition, results of operations or cash flow could be harmed. This could cause the trading price of our common stock to decline, resulting in a loss of all or part of your investment. The risks described below and in the documents referenced above are not the only ones that we face. Additional risks not presently known to us or that we currently deem immaterial may also affect our business.

Risks related to our business

We will require additional financial resources in order to continue on-going development of our product candidates; if we are unable to obtain these additional resources, we may be forced to delay or discontinue clinical testing of our product candidates.

We have not generated significant revenue and have incurred significant net losses in each year since our inception. For the nine months ended September 30, 2011, we had a net loss of $50.5 million and we had incurred approximately $174.3 million of cumulative net losses since our inception in 2003. We expect to continue to incur significant operating expenditures. Further development of our product candidates, including product candidates that we may develop under our channel partnering arrangement with Intrexon, 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.

We continue to seek additional financial resources to fund the further development of our product candidates. If we are unable to obtain sufficient additional capital, one or more of these programs could be placed on hold. Because we are currently devoting a significant portion of our resources to the development of palifosfamide and to synthetic biology, further progress with the development of our other candidates may be significantly delayed and may depend on the success of our ongoing clinical trial involving palifosfamide.

We have no current 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 we are unsuccessful in entering into partnership agreements for the further development of our products, we will be required to delay, reduce or eliminate planned preclinical and clinical trials and may be forced to 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, forego attractive business opportunities or pursue merger or divestiture strategies. In the event we are unable to obtain additional financing, we may be forced to cease operations altogether.

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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 September 30, 2011, we had incurred approximately $174.3 million of cumulative net losses since our inception in 2003 and had approximately $118.9 million of cash and cash equivalents, anticipating that our cash resources will be sufficient to fund our operations until early 2013. However, changes may occur that would consume our existing capital prior to that time, including the scope and progress of our research and development efforts and changes in governmental regulation. Actual costs may ultimately vary from our current expectations, which could materially impact our use of capital and our forecast of the period of time through which our financial resources will be adequate to support our operations. Specifically, we commenced the PICASSO 3 pivotal trial for IV palifosfamide early in the third quarter of 2010. We have estimated the sufficiency of our cash resources based in part on this trial design and our current timing expectations for enrollment in the study, which may change based on the progression of enrollment. We have also assumed responsibility for two product candidates under our exclusive channel partnership with Intrexon and we expect that the costs associated with these and additional product candidates will increase the level of our overall research and development expenses significantly going forward.

Although our forecasts for expenses and the sufficiency of our capital resources takes into account our plans to develop the Intrexon products, we have only recently assumed development responsibility for these products and the actual costs associated therewith may be significantly in excess of forecast amounts. In addition to these factors our actual cash requirements may vary materially from our current expectations for a number of other factors that may include, but are not limited to, changes in the focus and direction of our development programs, competitive and technical advances, costs associated with the development of our product candidates, our ability to secure partnering arrangements, and costs of filing, prosecuting, defending and enforcing our intellectual property rights. If we exhaust our capital reserves more quickly than anticipated, regardless of the reason, and we are unable to obtain additional financing on terms acceptable to us or at all, we will be unable to proceed with development of some or all of our product candidates on expected timelines and will be forced to prioritize among them.