

CYTRX CORP  
Form 10-K  
March 13, 2012

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

Form 10-K

(Mark One)

T ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2011  
or

£ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF  
SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_ to  
\_\_\_\_\_

Commission file number 0-15327

CytRx Corporation  
(Exact name of Registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

58-1642740  
(I.R.S. Employer  
Identification No.)

11726 San Vicente Blvd, Suite 650,  
Los Angeles, California  
(Address of principal executive offices)

90049  
(Zip Code)

Registrant's telephone number, including area code: (310) 826-5648  
\_\_\_\_\_

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of exchange on which registered
Common Stock, \$0.001 par value per share	The NASDAQ Capital Market
Series A Junior Participating Preferred Stock Purchase Rights	

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Securities Registered Pursuant to Section 12(g) of the Act:  
None

Indicate by check mark if the Registrant is a well-known seasoned issuer (as defined in Securities Act Rule 405). Yes  No  R

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934. Yes  No  T

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months and (2) has been subject to such filing requirements for the past 90 days. Yes  T No  F

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  T No  F

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.  T

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer  Accelerated filer  T Non-accelerated filer  F Smaller reporting company  F

(Do not check if a smaller reporting company)

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

Based on the closing price of the Registrant's common stock as reported on The Nasdaq Capital Market, the aggregate market value of the Registrant's common stock held by non-affiliates on June 30, 2011 (the last business day of the Registrant's most recently completed second fiscal quarter) was approximately \$75.8 million. Shares of common stock held by directors and executive officers and any ten percent or greater stockholders and their respective affiliates have been excluded from this calculation, because such stockholders may be deemed to be "affiliates" of the Registrant. This is not necessarily determinative of affiliate status for other purposes. The number of outstanding shares of the Registrant's common stock as of March 12, 2012 was 148,427,069, exclusive of treasury shares.

CYTRX CORPORATION  
2011 ANNUAL REPORT ON FORM 10-K

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“SAFE HARBOR” STATEMENT

Some of the information contained in this Annual Report may include forward-looking statements that reflect our current views with respect to our research and development activities, business strategy, business plan, financial performance and other future events. These statements include forward-looking statements both with respect to us, specifically, and the biotechnology sector, in general. We make these statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Statements that include the words “expect,” “intend,” “plan,” “believe,” “project,” “estimate,” “may,” “should,” “anticipate,” “will” and similar statements of a future or forward nature identify forward-looking statements for purposes of the federal securities laws or otherwise.

All forward-looking statements involve inherent risks and uncertainties, and there are or will be important factors that could cause actual results to differ materially from those indicated in these statements. We believe that these factors include, but are not limited to, those factors set forth in the sections entitled “Business,” “Risk Factors,” “Legal Proceedings,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” “Quantitative and Qualitative Disclosures About Market Risk” and “Controls and Procedures” in this Annual Report, all of which you should review carefully. Please consider our forward-looking statements in light of those risks as you read this Annual Report. We undertake no obligation to publicly update or review any forward-looking statement, whether as a result of new information, future developments or otherwise, except as required by law.

If one or more of these or other risks or uncertainties materializes, or if our underlying assumptions prove to be incorrect, actual results may vary materially from what we anticipate. All subsequent written and oral forward-looking statements attributable to us or individuals acting on our behalf are expressly qualified in their entirety by this Statement.

## PART I

## Item 1. BUSINESS

In this Annual Report, we sometimes refer to CytRx Corporation as “CytRx,” to our former subsidiary, RXi Pharmaceuticals Corporation, as “RXi,” and to Innovive Pharmaceuticals, Inc., which we acquired in September 2008, as “Innovive.” References in this Annual Report to the “company,” “we,” “us” or “our” refer to CytRx, alone, unless otherwise indicated.

## COMPANY OVERVIEW

We are a biopharmaceutical research and development company specializing in oncology. Our oncology pipeline includes three programs in clinical development for cancer indications: INNO-206, tamibarotene and bafetinib. With our tumor-targeted doxorubicin conjugate INNO-206, we have initiated an international Phase 2b clinical trial as a treatment for soft tissue sarcomas, are completing our ongoing Phase 1b/2 clinical trial for primarily the same indication and plan to initiate a Phase 2 trial for an undisclosed solid tumor indication in the first half of 2012. Our pipeline also includes tamibarotene, which we are testing in a double-blind, placebo-controlled, international Phase 2b clinical trial in patients with non-small-cell lung cancer, and which is in a clinical trial as a treatment for acute promyelocytic leukemia (APL). We are evaluating bafetinib in the ENABLE Phase 2 clinical trial in high-risk B-cell chronic lymphocytic leukemia (B-CLL), and plan to seek a partner for further development of bafetinib. In 2011, we completed our strategy of monetizing our non-core assets through the sale of our molecular chaperone technology to Denmark-based Orphazyme ApS in a transaction valued at up to \$120 million, and the sale of our 19% interest in SynthRx to ADVENTRX Pharmaceuticals.

We are a Delaware corporation, incorporated in 1985. Our corporate offices are located at 11726 San Vicente Boulevard, Suite 650, Los Angeles, California 90049, and our telephone number is (310) 826-5648.

## OUR PRODUCT CANDIDATE PIPELINE

The following table summarizes our product candidates and their current or impending stages of development:

Technology	Product Candidate	Indication(s)	Stage of Development
Doxorubicin conjugate	INNO-206	Soft tissue sarcomas	Phase 1b/2
		Undisclosed solid tumor indication	Phase 2b
Synthetic retinoid	Tamibarotene	Non-small-cell lung cancer	Phase 2 (2Q12)
		APL (acute promyelocytic leukemia)	Phase 2
Tyrosine kinase inhibitor	Bafetinib	B-CLL (B-cell chronic lymphocytic leukemia)	Phase 2

## OUR CLINICAL DEVELOPMENT PROGRAMS

Our current clinical development programs are discussed below.

## INNO-206

INNO-206 (formerly DOXO-EMCH) is a tumor-targeted conjugate of the commonly prescribed chemotherapeutic agent doxorubicin. Specifically, it is the (6-Maleimidocaproyl) hydrazone of doxorubicin. Essentially, this chemical is doxorubicin (DOXO) attached to an acid sensitive linker (EMCH).

INNO-206 for the Treatment of Cancer. Anthracyclines are a class of drugs that are among the most commonly used agents in the treatment of cancer. Doxorubicin, the first anthracycline to gain FDA approval, has demonstrated efficacy in a wide variety of cancers including breast cancer, lung cancer, sarcomas, and lymphomas. However, due to the uptake of doxorubicin by various parts of the body, it is associated with side effects such as cumulative cardiotoxicity, myelosuppression (decreased production of blood cells by bone marrow), gastrointestinal disorders, mucositis (inflammation of the mucous membranes lining the digestive tract, including the mouth), stomatitis (inflammation of the mouth's soft tissue), and extravasation (the leakage of intravenous drugs from the vein into the surrounding tissue).

We believe INNO-206 has attributes that improve on native doxorubicin, including reduction of adverse events, improvement in efficacy and the ability to target the tumor more accurately than native doxorubicin.

Our anticipated mechanism of action for INNO-206 is as follows:

- after administration, INNO-206 rapidly binds circulating albumin through the EMCH linker;
- circulating albumin preferentially accumulates in tumors, bypassing concentration in other non-tumor sites, including the heart, liver and the gastrointestinal tract;
- once albumin-bound INNO-206 reaches the tumor, the acidic environment of the tumor causes cleavage of the acid sensitive linker; and
- free doxorubicin is released at the site of the tumor and is taken up by the cancer cells.

Pre-clinical data. In a variety of preclinical models, INNO-206 was superior to doxorubicin at equitoxic doses in its ability to allow an increase in the total doxorubicin dose, its antitumor efficacy, and its safety, including a reduction in cardiotoxicity. Animal studies conducted by INNO-206 inventor Dr. Felix Kratz, Department of Medical Oncology, Clinical Research, at the Tumor Biology Center in Freiburg, Germany, demonstrated statistically significant efficacy compared to either placebo or native doxorubicin against breast, ovarian, pancreatic and small cell lung cancers growing in immunodeficient mice.

Clinical data. A Phase 1 study of INNO-206 that demonstrated safety and objective clinical responses in several tumor types was completed in 2005 and presented at the March 2006 Krebskongress meeting in Berlin. In this study, doses were administered every 3 weeks at up to six times the standard dose of doxorubicin without an increase in side effects over those historically observed with native doxorubicin. Twenty-three of 35 evaluable patients had either an objective clinical (partial) response or stable disease. Objective clinical responses were observed in patients with sarcoma, breast, and small cell lung cancers.

We are conducting a Phase 1b/2 clinical trial with INNO-206 in patients with advanced solid tumors, and have initiated a Phase 2b international clinical trial in patients with advanced soft tissue sarcomas. Initial results in six patients who have completed four cycles with INNO-206 at the maximum tolerated dose in the Phase 1b/2 clinical trial, two patients have exhibited a partial tumor response (greater than 30% tumor shrinkage) and four patients have stable disease. Treatment is continuing and we expect to announce further results at the American Society for Clinical Oncology (ASCO) Meeting in June, 2012. Common side effects reported to date from the Phase 1b/2 trial include low neutrophil (white blood cell) and platelet counts, minor mouth ulcers and mild nausea, which are expected side effects of doxorubicin.

Development Plan. In December 2011, we initiated our international Phase 2b clinical trial to evaluate the preliminary efficacy and safety of INNO-206 as a first-line therapy in patients with advanced soft tissue sarcoma who are ineligible for surgery. The Phase 2b clinical trial will provide the first direct clinical trial comparison of INNO-206 with native doxorubicin, the only approved chemotherapy agent for the treatment of soft tissue sarcomas, which is dose-limited due to toxicity, as a first-line therapy.

The Phase 2b clinical trial with INNO-206 in patients with soft tissue sarcomas is an international trial under the direction of world-renowned expert in soft tissue sarcoma treatment Sant P. Chawla, M.D., F.R.A.C.P., Director of the Sarcoma Oncology Center in Santa Monica, Calif. Dr. Chawla also is acting as principal investigator for our ongoing Phase 1b/2 clinical trial with INNO-206.

The Phase 2b clinical trial's primary objectives are to measure the progression-free survival, tumor response and overall survival of patients with advanced soft tissue sarcomas treated with INNO-206. This clinical trial also will assess the safety of INNO-206 compared to doxorubicin in this patient population through a number of indicators, including the frequency and severity of adverse events. The open-label trial will enroll 105 patients with metastatic, locally advanced or unresectable soft tissue sarcoma at approximately 30 study centers in the U.S., Hungary, Romania, Ukraine, Russia, India and Australia.

In addition, we have announced plans to initiate a Phase 2 clinical trial with INNO-206 in an undisclosed solid tumor indication in the first half of 2012.



## Tamibarotene

Tamibarotene is an orally available, synthetic retinoid rationally designed to overcome resistance and reduce the toxic side effects of differentiation therapy with all-trans retinoic acid, or ATRA, a component of the current first-line treatment for APL.

Tamibarotene for the treatment of NSCLC. More than 220,000 new cases of lung cancer occur in the U.S. each year, and more than 1.5 million occur annually worldwide. Deaths due to lung cancer account for the majority of cancer-related deaths and the five-year survival ranges between 8%-15%. Non-small cell-lung cancer, or NSCLC, accounts for approximately 85% of all lung cancers, with the subsets adenocarcinoma representing 35%-40%, squamous cell carcinoma accounting for 25%-30% and large cell carcinoma accounting for 10%-15%.

A Phase 2 clinical trial conducted by Arrieta et al. and published in the peer-reviewed Journal of Clinical Oncology (2010; 28: 3463-3471) compared ATRA added to a regimen of paclitaxel plus cisplatin to a regimen of paclitaxel plus cisplatin alone as a treatment for patients with advanced NSCLC. The group administered ATRA plus the chemotherapy agents showed improved response rates of 55.8% versus 25.4%, and increased progression-free survival of 8.9 months versus 6.0 months. Median overall survival was increased from 9.5 months to 23.5 months when ATRA was added to the above chemotherapy regimen, representing a 14-month median extension of life.

Tamibarotene was developed to overcome resistance to ATRA. In vitro, tamibarotene is approximately ten times more potent than ATRA, and tamibarotene has a lower affinity for cellular retinoic acid binding protein, or CRABP, which we believe should allow increased cellular exposure after administration. This may enhance tamibarotene's potential efficacy, because patients may be able to experience benefits from the drug for a more prolonged period. Tamibarotene does not bind the RAR- $\gamma$  receptor, the major retinoic acid receptor in the dermal epithelium, which should lessen the occurrence of skin toxicities.

Development Plan. We have initiated an international, randomized Phase 2b clinical trial, in which patients with stage IIIB (with pleural effusions, or fluid in the chest cavity) or stage IV NSCLC will be treated with up to six cycles of paclitaxel plus carboplatin and either tamibarotene or placebo. The primary objective of the clinical trial is to determine the objective response rate (complete and partial responses) and progression-free survival. Secondly, the study will evaluate overall survival, quality-of-life and the pharmacokinetics of tamibarotene in this population. The clinical trial, which is expected to enroll approximately 140 patients, is being conducted in several clinical sites in the U.S., Mexico, Eastern Europe and India.

Tamibarotene for the treatment of APL. Acute promyelocytic leukemia, or APL, is a specific type of acute myeloid leukemia characterized by the t(15;17) translocation, which fuses the promyelocytic leukemia, or PML, gene on chromosome 15 to the retinoic acid receptor, or RAR $\alpha$  gene on chromosome 17. This fusion causes abnormal cell growth.

Differentiation therapy with ATRA, is the basis for the treatment of APL. Differentiation therapy causes leukemic promyelocytes to mature and undergo cell death. Patients typically receive ATRA in combination with chemotherapy as the initial therapy, followed by anthracycline-based consolidation therapy designed to produce complete remission. The majority of patients treated this way experience a complete remission of disease. Current National Comprehensive Cancer Network guidelines recommend that patients then undergo one to two years of maintenance therapy with ATRA to prevent a recurrence. ATRA therapy is associated with several toxicities, the most serious of which, retinoic acid syndrome, or RAS. RAS, which occurs in up to 25% of patients treated with ATRA, is a serious and potentially fatal complication characterized by fever, dyspnea (breathing difficulties), weight gain, pulmonary infiltrates (abnormal accumulation in the lungs), and pleural or pericardial effusions (excess fluid around the lungs or heart).

Patients that initially respond to front-line therapy with ATRA plus chemotherapy sometimes relapse, and some of these patients fail to respond to a second course of treatment with ATRA. Currently, patients who fail ATRA-based therapy are treated with arsenic trioxide, a compound administered intravenously and associated with significant toxicity, including irregular heartbeat. There currently is no standard of care for patients who do not respond to ATRA and arsenic trioxide, or who respond but subsequently relapse. In 2007, the FDA granted Orphan Drug Designation and Fast Track Designation for the use of tamibarotene in patients with APL who relapse after treatment with ATRA and chemotherapy, then ATRA plus arsenic trioxide.

Pre-clinical data. In preclinical models, tamibarotene was superior to ATRA in its ability to cause APL cells to differentiate and die. In the clinical setting, in vitro response to tamibarotene appeared predictive of clinical response, including activity in patients who had a poor response to ATRA.

Clinical data. Tamibarotene is approved in Japan under the brand name Amnolake for use in relapsed or refractory APL. The approval was based on data from two studies in Japanese patients. In the pivotal study, the effectiveness of orally administered tamibarotene was administered to 42 patients with APL, 39 of whom were evaluable for response. Patients included individuals who had never received treatment for APL and patients who had been previously treated with ATRA. Tamibarotene was administered orally at a dose of 6 mg/m<sup>2</sup>/day for eight weeks. The overall complete response rate in these patients was 61.5%. In patients who had a recurrence of APL following ATRA therapy, the response rate was 81%. RAS was reported in three patients, or 7.3% of the patient group.

Development Plan. There is currently a Special Protocol Assessment (SPA) in place with the FDA for a Phase 2 registration clinical trial, known as STAR-1, which is evaluating the efficacy and safety of tamibarotene as a third-line treatment for APL. The STAR-1 trial is ongoing at one clinical site in the U.S. We have reported that, of the 11 patients enrolled in the STAR-1 trial to date, three (27%) achieved a hematologic complete response, and four (36%) a morphologic leukemia-free state. We also treated a patient with a rare form of APL called sarcomatous acute promyelocytic leukemia or chloromas. This patient had relapsed after treatment with 5 different courses of chemotherapies that included ATRA plus chemotherapy, ATRA plus arsenic trioxide and hematopoietic stem cell transplantation, and had over 30 solid tumors when his physician contacted CytRx. Within 4 months after initiating treatment with tamibarotene the patient had a complete response to therapy which is ongoing for almost two years.

#### Bafetinib

Bafetinib (formerly INNO-406) is an orally bioavailable, rationally designed, inhibitor of several Src kinases developed by the Japanese pharmaceutical company Nippon Shinyaku, to overcome some of the limitations of Gleevec and other tyrosine kinase inhibitors in resistant chronic myelogenous leukemia, or CML. In addition to its Bcr-Abl inhibitory properties, bafetinib is a potent and specific inhibitor of Lyn and Fyn kinases. These kinases are reported to be involved in both solid and hematological cancers. Lyn kinase's involvement in the B-cell signaling pathway led us to evaluate bafetinib in B-cell malignancies such as chronic lymphocytic leukemia (CLL). We hold rights to bafetinib in all territories except Japan.

Phase 1 Study. In November 2008, we announced that bafetinib demonstrated clinical responses in patients with CML in a Phase 1 clinical trial conducted in patients with CML and other leukemias that have a certain mutation called the Philadelphia Chromosome (Ph+) and are intolerant of or resistant to Gleevec and, in some cases, second-line tyrosine kinase inhibitors such as dasatinib (Sprycel®) and nilotinib (Tasigna®). The clinical trial was designed to identify the optimal dose for possible future studies by escalating doses from 30 mg once per day to up to 480 mg twice per day in a total of 56 patients with Ph+ leukemias. Of the patients, 31 had CML in chronic phase (CML-CP), nine were in accelerated phase (CML-AP), seven were in blast phase (CML-BP), and nine had Ph+ acute lymphocytic leukemia. The clinical trial was conducted at seven clinical sites in the US, Germany, and Israel, with Hagop Kantarjian, M.D., Professor & Chairman, Department of Leukemia, The University of Texas, M.D. Anderson Cancer Center, serving as the Principal Investigator. In the 31 patients with CMP-CP, a major cytogenetic response rate of 19.4% was seen.

The maximum tolerated dose was determined to be 240-360 mg given twice per day, based on evidence of increasing potential liver toxicity at higher doses. Common adverse events (observed in greater than 20% of patients in the 240 mg twice per day dose group) were gastrointestinal toxicity, swelling, and fatigue. There was no evidence of fluid accumulating around the lungs, or significant changes in a certain heart rhythm called QTc prolongation, which are serious side effects known to occur in patients treated with approved drugs for this indication. Approximately 13% of patients across all dose groups discontinued dosing due to unacceptable toxicity.

Bafetinib for B-CLL. B-CLL is the most common form of leukemia in adults in Western countries. More than 16,000 new cases of B-CLL are reported in the United States, alone, each year; however up to an estimated 40% of cases may

not be reported due to under-diagnosis and lack of placement in cancer registries. Virtually all patients are older than 55 years at presentation, with an average age of 70 years. Patients in the high-risk B-CLL classification have a median overall survival period of one to five years.

Our Phase 2 proof-of-concept clinical trial to evaluate the preliminary efficacy and safety of its oncology drug candidate bafetinib in patients with high-risk B-cell chronic lymphocytic leukemia (B-CLL) was initiated in May 2010. In that clinical trial, high-risk B-CLL patients who had failed treatment with first-line agents were self-administered oral doses of bafetinib twice daily. We have announced that results from that clinical trial demonstrated bafetinib's clinical activity and preliminary safety in patients with relapsed or refractory B-CLL.

We plan to seek a partner for any further development of bafetinib.

### Disposition of Molecular Chaperone Assets

Until 2011, we owned the rights to two drug candidates, arimoclomol and irovanadine, based on molecular chaperone regulation technology that were designed to repair or degrade mis-folded proteins associated with disease. On May 13, 2011, we sold all pre-clinical and clinical data, intellectual property rights and other assets relating to those compounds to Orphazyme ApS in exchange for a cash payment of \$150,000 and the right to receive various future payments that are contingent upon the achievement of specified regulatory and business milestones, as well as royalty payments based on a specified percentage of any eventual net sales of products derived from the assets.

### Our Separation from RXi Pharmaceuticals Corporation

We formed RXi Pharmaceuticals Corporation in 2006 to develop our assets related to RNA interference technology. A dividend to of shares of RXi to our stockholders in 2008 reduced our ownership of RXi shares to less than 50%, and we reflected our investment in RXi based on the equity method of accounting. In 2009, the investment balance in RXi was reduced to zero, and we stopped recording our share of losses from RXi. On June 30, 2010, we sold 2.0 million common shares of RXi and our ownership in RXi was reduced to approximately 3.1 million shares of common stock. We thereafter began to account for those shares as available for sale, and increases or decreases in the value of these shares were included as part of comprehensive income or loss. This investment was shown on the balance sheet at market value, based on RXi's closing stock price as reported on The Nasdaq Capital Market. We sold our remaining number of shares of RXi common stock in December 2010 for approximately \$6.9 million.

### Innovive Acquisition Agreement

On September 19, 2008, we completed our merger acquisition of Innovive Pharmaceuticals, Inc., or Innovive, and its clinical-stage cancer product candidates, including INNO-206 and tamibarotene. Under the merger agreement by which we acquired Innovive, we agreed to pay the former Innovive stockholders up to \$1.01 per Innovive share of future earnout merger consideration, subject to our achievement of specified net sales under the Innovive license agreements. The earnout merger consideration, if any, will be payable in shares of our common stock, subject to specified conditions, or, at our election, in cash or by a combination of shares of our common stock and cash. Our common stock will be valued for purposes of any future earnout merger consideration based upon the trading price of our common stock at the time the earnout merger consideration is paid.

### Research and Development

Expenditures for research and development activities related to continuing operations were \$15.5 million, \$8.5 million and \$7.5 million for the years ended December 31, 2011, 2010 and 2009, or approximately 67%, 50% and 44%, respectively, of our total expenses. For further information regarding our research and development activities, see "Management's Discussion and Analysis of Financial Condition and Results of Operations" below.

### Manufacturing

We have no capability to manufacture supplies of any of our products, and rely on third-party manufacturers to produce materials needed for research and clinical trials. We have contracted with various contract manufacturing facilities for supply of our product candidates, including INNO-206 and tamibarotene, and we additionally have an arrangement with TMRC Co., Ltd., or TMRC, our licensor of tamibarotene, relating to supply of tamibarotene.

To be commercialized, our products also must be capable of being manufactured in commercial quantities in compliance with stringent regulatory requirements and at an acceptable cost. We intend to rely on third-party manufacturers to produce commercial quantities of any products for which we are able to obtain marketing approval.

We have not commercialized any product, and so we also have not demonstrated that any of our product candidates can be manufactured in commercial quantities in accordance with regulatory requirements or at an acceptable cost.

If our product candidates cannot be manufactured in suitable quantities and in accordance with regulatory standards, our clinical trials, regulatory approvals, and marketing efforts for such products may be delayed. Such delays could adversely affect our competitive position and our chances of generating significant recurring revenues. If our products are not able to be manufactured at an acceptable cost, the commercial success of our products may be adversely affected.

## Marketing

Our tentative plan is to establish our own sales force and marketing capability in order to commercialize our oncology drug candidates, including INNO-206, tamibarotene and bafetinib, in the U.S. and to seek a marketing partner for commercialization in other territories.

## Patents and Proprietary Technology

We actively seek patent protection for our technologies, processes, uses, and ongoing improvements and consider our patents and other intellectual property to be critical to our business. We regularly evaluate the patentability of new inventions and improvements developed by us or our collaborators, and, whenever appropriate, will endeavor to file U.S. and international patent applications to protect these new inventions and improvements. We cannot be certain that any of the current pending patent applications we have filed or licensed, or any new patent applications we may file or license, will ever be issued in the U.S. or any other country. There also is no assurance that any issued patents will be effective to prevent others from using our products or processes. It is also possible that any patents issued to us, as well as those we have licensed or may license in the future, may be held invalid or unenforceable by a court, or third parties could obtain patents that we would need to either license or to design around, which we may be unable to do. Current and future competitors may have licensed or filed patent applications or received patents, and may acquire additional patents and proprietary rights relating to compounds, products or processes that may be competitive with ours.

In addition to patent protection, we attempt to protect our proprietary products, processes and other information by relying on trade secrets and non-disclosure agreements with our employees, consultants and certain other persons who have access to such products, processes and information. Under the agreements, all inventions conceived by employees are our exclusive property, but there is no assurance that these agreements will afford significant protection against misappropriation or unauthorized disclosure of our trade secrets and confidential information.

As of March 12, 2012, our exclusive license to INNO-206 and related technologies includes two granted U.S., one allowed U.S. and 31 granted foreign patents or allowed applications, and one pending U.S. and 20 pending foreign applications. Patents and applications that cover pharmaceutical compositions of INNO-206, processes for their production, and their use in treatment methods (e.g., cancer, viral diseases, autoimmune diseases, and acute or chronic inflammatory diseases) have an unextended patent term until June 2020.

As of March 12, 2012, we hold exclusive licenses in one U.S. patent, one Canadian patent, one European patent and one pending U.S. and two pending European applications covering various crystal forms of tamibarotene, pharmaceutical compositions comprising these crystal forms, and methods for their production, as well as pharmaceutical compositions comprising combinations of tamibarotene with other anti-cancer drugs. We also hold exclusive licenses in one pending U.S. patent application, one pending Canadian patent application, one European patent application and one Mexican patent application covering a capsule preparation of tamibarotene and its use for blood cancer and solid cancer

As of March 12, 2012, our exclusive license to bafetinib and related technologies includes two granted U.S. and 29 granted foreign patents or allowed applications, and five pending foreign applications. Patents and applications that cover bafetinib, pharmaceutical compositions of bafetinib, and their use in treating leukemia have an unextended patent term until June 2023 or December 2024.

## LICENSE AGREEMENTS

### INNO-206

We have an agreement with KTB Tumorforschungs GmbH, or KTB, for the license of patent rights held by KTB for the worldwide development and commercialization of INNO-206. The license is exclusive and worldwide, applies to all product that may be subject to the licensed intellectual property and may be used in all fields of use. We may sublicense the intellectual property in our sole discretion. The agreement also grants us an option to include within the license any technology that is claimed or disclosed in the licensed patents and patent applications for use in the field of oncology and the right of first refusal on any license that KTB wishes to make to a third party regarding any technology that is claimed or disclosed in the licensed patents and patent applications for use in the field of oncology.



Under the agreement, we must make payments to KTB in the aggregate of \$7.5 million upon meeting clinical and regulatory milestones up to and including the product's second final marketing approval. We also agreed to pay:

- commercially reasonable royalties based on a percentage of net sales (as defined in the agreement);
- a percentage of non-royalty sub-licensing income (as defined in the agreement); and
- milestones of \$1 million for each additional final marketing approval that we obtain.

In the event that we must pay a third party in order to exercise our rights to the intellectual property under the agreement, we will deduct a percentage of those payments from the royalties due KTB, up to an agreed upon cap. This deduction includes a percentage of any payments that might be required to be made by us to Bristol-Myers Squibb. Bristol-Myers Squibb holds a patent on technology that might be considered to block the patents and patent applications that are the subject of the agreement with KTB.

Under the agreement with KTB, we must use commercially reasonable efforts to conduct the research and development activities we determine are necessary to obtain regulatory approval to market the product in those countries that we determine are commercially feasible. Under the agreement, KTB is to use its commercially reasonable efforts to provide us with access to suppliers of the API of the product on the same terms and conditions as may be provided to KTB by those suppliers.

The agreement will expire on a product-by-product basis upon the expiration of the subject patent rights. We have the right to terminate the agreement on 30 days notice, provided we pay a cash penalty to KTB. KTB may terminate the agreement if we are in breach and the breach is not cured within a specified cure period or if we fail to use diligent and commercial efforts to meet specified clinical milestones.

#### Tamibarotene

We have agreements with TMRC for the license of patent rights held by TMRC for North American and European development and commercialization of tamibarotene. The license is exclusive, applies to all products that may be subject to the licensed intellectual property and may be used in the treatment of APL and NSCLC. We may sublicense the intellectual property in our sole discretion. The agreement also grants us an option to include within the license the use of the drug in certain other cancers.

Under the agreement for North American rights, we must pay TMRC royalties based on net sales and make payments to TMRC in the aggregate of up to ¥ 490 million upon meeting clinical, regulatory, and sales milestones up to and including the first commercial sale of the product for the treatment of APL. Further milestone payments may become due upon certain events related to other indications.

Under the agreement for European rights, we must pay TMRC royalties based on net sales and make payments to TMRC in the aggregate of ¥ 480 million upon meeting clinical, regulatory and sales milestones up to and included the first commercial sale of the product for treatment of APL. Further milestone payments may become due upon certain events related to other indications.

Under the agreements, we must use commercially reasonable efforts to conduct the research and development activities we determine are necessary to obtain regulatory approval to market the product in those countries in North America and Europe that we determine are commercially feasible.

#### Bafetinib

We are party to an exclusive, worldwide (with the exception of Japan) royalty-bearing license agreement with Nippon Shinyaku, including the right to grant sublicenses, for the intellectual property relating to bafetinib in all fields. The license agreement will continue so long as we sell products subject to the license in any country. The bafetinib license covers two Patent Cooperation Treaty, or PTC, applications filed in 2003 and 2004, respectively.

Under the agreement, we are obliged to pay Nippon Shinyaku an aggregate of \$13.35 million (including \$5 million upon the product's initial final marketing approval) upon the achievement of clinical and regulatory milestones up to and including approvals in the U.S. and Europe. We also will be obliged to pay:

- commercially reasonable royalties based on a percentage of net sales (as defined in the Nippon Shinyaku license agreement), dependent on reaching certain revenue thresholds;
- annual minimum payments if sales of bafetinib do not meet specified levels; and
- a percentage of non-royalty sub-licensing income (as defined in the license agreement).

The agreement includes covenants that require us to, among other things, file an NDA by a specific date and use our commercially reasonable efforts to bring a licensed product to market. In the event that we breach a material term of the Nippon Shinyaku license agreement, Nippon Shinyaku has the option to terminate the agreement following the giving of notice and an opportunity to cure any such breach.

### Competition

INNO-206 is a tumor-targeted conjugate of doxorubicin, a widely used anti-cancer drug. Doxorubicin is part of the anthracycline class of chemotherapy agents. Anthracyclines, many of which are generic including doxorubicin, have been used throughout the world to treat various cancers for several decades. Due to their track record of broad anti-cancer activity, new types of anthracyclines and modified or reformulated versions continue to be developed to overcome toxicities which limit the use of these drugs.

INNO-206 is a chemically modified version of doxorubicin that incorporates an acid sensitive linker technology to improve targeting to the tumor. We believe that the albumin-binding ability of INNO-206 will allow the compound to overcome many of the side effect issues typically associated with anthracyclines. We also believe that using albumin as a targeted carrier will allow for higher dosing and greater efficacy.

Soft tissue sarcoma patients are typically treated with surgery followed by radiation therapy. Doxorubicin is the only approved drug for treating soft tissue sarcoma and is often used in combination with radiation. The National Comprehensive Cancer Network also includes the use of ifosfamide, epirubicin, gemcitabine, dacarbazine and liposomal doxorubicin marketed in the U.S. as Doxil by Johnson & Johnson. For patients ineligible for surgery, radiation and/or chemotherapy is the only option. Other approaches to treating soft tissue sarcoma are in late stage clinical development. These include ridaforolimus being developed by Ariad Pharmaceuticals and Merck & Co., Cell Therapeutics' brostallicin, GlaxoSmithKline's pazopanib, Sanofi-Aventis' AVE8062, Threshold Pharmaceuticals' TH-302, trabectedin being co-developed by Johnson and Johnson and PharmaMar and ZIOPHARM Oncology's palifosfamide.

Non-small-cell lung cancer, or NSCLC, is a competitive indication in which patients are treated with a variety of agents. The standard regimen for first-line locally advanced or metastatic NSCLC is a doublet comprised of a platinum agent combined with a taxane, vinka alkaloid or antimetabolite. The addition of Genentech/Roche's Avastin to the standard treatment doublet has resulted significant improvements in survival and rates of remission. Tarceva by OSI and Genentech/Roche and Iressa by AstraZeneca have shown benefit in second-line regimens for specific patients but have not conferred survival benefit. In 2011, Pfizer's Xalkori was approved for the treatment of advanced NSCLC patients with a specific and rare gene mutation. In addition, there are several drugs in late-stage development including Eisai's eribulin, Eli Lilly & Co.'s necitumumab and Pfizer's axitinib.

To our knowledge, there are no competitors in clinical development for refractory APL. Currently, treatment of APL is based on induction and maintenance therapy with ATRA and chemotherapy (typically idarubicin). ATRA and idarubicin are both generic compounds. Arsenic trioxide, currently marketed by Teva Pharmaceuticals, is approved for use in patients who have relapsed after ATRA-based therapy in APL. There are no FDA-approved therapies for patients who have failed arsenic trioxide. In practice, it appears that patients who fail arsenic trioxide are retreated

with ATRA.

There are currently three marketed competitors to bafetinib (formerly INNO-406) in the CML market, Gleevec®, Sprycel® and Tasigna. Gleevec is approved for treatment of newly diagnosed adult patients with Philadelphia chromosome–positive chronic myeloid leukemia (Ph+ CML) in the chronic phase and patients with Ph+ CML in blast crisis (BC), accelerated phase (AP), or in the chronic phase (CP) after failure of interferon-alpha therapy. Sprycel® and Tasigna® are approved for Gleevec-resistant CML and have since been approved for the treatment of newly diagnosed adult patients with Ph+ CML. Because of the highly competitive nature of the CML market including drug candidates in development, we have not pursued development for that indication. We selected B-CLL due to the potent and specific inhibitory properties of bafetinib against Lyn and Fyn kinases. Lyn and Fyn kinases are members of the Src family of kinases which are known to be involved in cell growth, and those kinases are overexpressed in B-CLL.

There are several drugs approved for the treatment of CLL. First-line therapy for CLL includes a variety of combination therapies including fludarabine, cyclophosphamide, Rituxan® and Campath®. Treatment for relapsed or refractory CLL includes several chemotherapy regimens including CHOP, CFAR, hyperCFAD and OFAR in addition to single agents including GlaxoSmithKline's Arzerra™ and Sanofi-Aventis' Oforta™. Arzerra was approved in October 2009 for CLL patients who are refractory to treatment with fludarabine and Campath. Oforta, an oral tablet formulation of fludarabine, was approved in December 2008 as a second-line treatment for CLL. Several drugs are in clinical trials for CLL including Gilead's GS-1101 (formerly CAL-101) and Pharmacyclics' PCI-32765.

Many companies, including large pharmaceutical and biotechnology firms with financial resources, research and development staffs, and facilities that may be substantially greater than those of ours or our strategic partners or licensees, are engaged in the research and development of pharmaceutical products that could compete with our potential products. To the extent that we seek to acquire, through license or otherwise, existing or potential new products, we will be competing with numerous other companies, many of which will have substantially greater financial resources, large acquisition and research and development staffs that may give those companies a competitive advantage over us in identifying and evaluating these drug acquisition opportunities. Any products that we acquire will be competing with products marketed by companies that in many cases will have substantially greater marketing resources than we have. The industry is characterized by rapid technological advances and competitors may develop their products more rapidly and such products may be more effective than those currently under development or that may be developed in the future by our strategic partners or licensees. Competitive products for a number of the disease indications that we have targeted are currently being marketed by other parties, and additional competitive products are under development and may also include products currently under development that we are not aware of or products that may be developed in the future.

#### Government Regulation

The U.S. and other developed countries extensively regulate the preclinical and clinical testing, manufacturing, labeling, storage, record-keeping, advertising, promotion, export, marketing and distribution of drugs and biologic products. The FDA, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act and other federal statutes and regulations, regulates pharmaceutical and biologic products.

To obtain approval of our product candidates from the FDA, we must, among other requirements, submit data supporting safety and efficacy for the intended indication as well as detailed information on the manufacture and composition of the product candidate. In most cases, this will require extensive laboratory tests and preclinical and clinical trials. The collection of these data, as well as the preparation of applications for review by the FDA involve significant time and expense. The FDA also may require post-marketing testing to monitor the safety and efficacy of approved products or place conditions on any approvals that could restrict the therapeutic claims and commercial applications of these products. Regulatory authorities may withdraw product approvals if we fail to comply with regulatory standards or if we encounter problems at any time following initial marketing of our products.

The first stage of the FDA approval process for a new drug involves completion of preclinical studies and the submission of the results of these studies to the FDA. These data, together with proposed clinical protocols, manufacturing information, analytical data and other information submitted to the FDA, in an investigational new drug application, or IND, must become effective before human clinical trials may commence. Preclinical studies generally involve FDA regulated laboratory evaluation of product characteristics and animal studies to assess the efficacy and safety of the product candidate.

After the IND becomes effective, a company may commence human clinical trials. These are typically conducted in three sequential phases, but the phases may overlap. Phase 1 trials consist of testing of the product candidate in a small number of patients or healthy volunteers, primarily for safety at one or more doses. Phase 2 trials, in addition to

safety, evaluate the efficacy of the product candidate in a patient population somewhat larger than Phase 1 trials. Phase 3 trials typically involve additional testing for safety and clinical efficacy in an expanded population at multiple test sites. A company must submit to the FDA a clinical protocol, accompanied by the approval of the Institutional Review Boards at the institutions participating in the trials, prior to commencement of each clinical trial.

To obtain FDA marketing authorization, a company must submit to the FDA the results of the preclinical and clinical testing, together with, among other things, detailed information on the manufacture and composition of the product candidate, in the form of a new drug application, or NDA.

The amount of time taken by the FDA for approval of an NDA will depend upon a number of factors, including whether the product candidate has received priority review, the quality of the submission and studies presented, the potential contribution that the compound will make in improving the treatment of the disease in question, and the workload at the FDA.

The FDA may, in some cases, confer upon an investigational product the status of a fast track product. A fast track product is defined as a new drug or biologic intended for the treatment of a serious or life-threatening condition that demonstrates the potential to address unmet medical needs for this condition. The FDA can base approval of an NDA for a fast track product on an effect on a surrogate endpoint, or on another endpoint that is reasonably likely to predict clinical benefit. If a preliminary review of clinical data suggests that a fast track product may be effective, the FDA may initiate review of entire sections of a marketing application for a fast track product before the sponsor completes the application.

We anticipate that our products will be manufactured by our strategic partners, licensees or other third parties. Before approving an NDA, the FDA will inspect the facilities at which the product is manufactured and will not approve the product unless the manufacturing facilities are in compliance with the FDA's cGMP, which are regulations that govern the manufacture, holding and distribution of a product. Our manufacturers also will be subject to regulation under the Occupational Safety and Health Act, the National Environmental Policy Act, the Nuclear Energy and Radiation Control Act, the Toxic Substance Control Act and the Resource Conservation and Recovery Act. Following approval, the FDA periodically inspects drug and biologic manufacturing facilities to ensure continued compliance with the good manufacturing practices regulations. Our manufacturers will have to continue to comply with those requirements. Failure to comply with these requirements subjects the manufacturer to possible legal or regulatory action, such as suspension of manufacturing or recall or seizure of product. Adverse patient experiences with the product must be reported to the FDA and could result in the imposition of marketing restrictions through labeling changes or market removal. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product occur following approval.

The labeling, advertising, promotion, marketing and distribution of a drug or biologic product also must be in compliance with FDA and Federal Trade Commission requirements which include, among others, standards and regulations for off-label promotion, industry sponsored scientific and educational activities, promotional activities involving the internet, and direct-to-consumer advertising. We also will be subject to a variety of federal, state and local regulations relating to the use, handling, storage and disposal of hazardous materials, including chemicals and radioactive and biological materials. In addition, we will be subject to various laws and regulations governing laboratory practices and the experimental use of animals. In each of these areas, as above, the FDA has broad regulatory and enforcement powers, including the ability to levy fines and civil penalties, suspend or delay issuance of product approvals, seize or recall products, and deny or withdraw approvals.

We will also be subject to a variety of regulations governing clinical trials and sales of our products outside the U.S. Whether or not FDA approval has been obtained, approval of a product candidate by the comparable regulatory authorities of foreign countries and regions must be obtained prior to the commencement of marketing the product in those countries. The approval process varies from one regulatory authority to another and the time may be longer or shorter than that required for FDA approval. In the European Union, Canada and Australia, regulatory requirements and approval processes are similar, in principle, to those in the U.S.

#### Employees

As of March 12, 2012, we had 15 employees, six of whom were engaged in clinical development activities and nine of whom were involved in management and administrative operations.

Available Information

We maintain a website at [www.cytrx.com](http://www.cytrx.com) and make available there, free of charge, our periodic reports filed with the Securities and Exchange Commission, or SEC, as soon as is reasonably practicable after filing. The public may read and copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains a website at <http://www.sec.gov> that contains reports, proxy and information statements, and other information regarding issuers such as us that file electronically with the SEC. We post on our website our Code of Business Conduct and Ethics.



## Item 1A. RISK FACTORS

### Risks Associated With Our Business

We have operated at a loss and will likely continue to operate at a loss for the foreseeable future.

We have operated at a loss due to our ongoing expenditures for research and development of our product candidates and for general and administrative purposes and lack of significant recurring revenue. We incurred a net loss of \$14.4 million for the year ended December 31, 2011, a net profit of \$0.4 million, attributable to gain from the sale of RXi shares and other marketable securities, for the year ended December 31, 2010, and a net loss of \$4.8 million for the year ended December 31, 2009, including gain from the sale of RXi shares. We had an accumulated deficit as of December 31, 2011 of approximately \$210.9 million. We are likely to continue to incur losses unless and until we are able to commercialize one or more of our product candidates. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity and working capital. Because of the numerous risks and uncertainties associated with our product development efforts, we are unable to predict when we may become profitable, if at all. If we do not become profitable or are unable to maintain future profitability, the market value of our common stock will be adversely affected.

Our common stock may be delisted from The Nasdaq Capital Market.

On February 15, 2012, we received a written notification from The NASDAQ Stock Market LLC ("NASDAQ") stating that because we had not regained compliance with the \$1.00 minimum bid price requirement for continued listing, as set forth in NASDAQ Listing Rule 5550(a)(2), our securities would be subject to delisting from The NASDAQ Capital Market unless we requested a hearing before a NASDAQ Hearings Panel on or before February 22, 2012. We have requested and have been granted a hearing before the panel, which has stayed any delisting action in connection with the notification letter, and which allows the continued listing of our common stock on The NASDAQ Capital Market until the panel renders a decision subsequent to the hearing. At the hearing, we intend to present a plan to regain compliance with the minimum bid price requirement and request that the panel allow us additional time within which to regain compliance. There can be no assurance that the panel will grant our request for continued listing on The NASDAQ Capital Market, or that our plans to exercise diligent efforts to maintain the listing of its securities on NASDAQ will be successful. If our common stock is delisted from The NASDAQ Capital Market, we expect prices for our common stock to be quoted on the Pink Sheets LLC or the OTC Bulletin Board. There is no assurance, however, that prices for our common stock would be quoted on one of these other trading systems or that an active trading market for our common stock would thereafter exist, which would materially and adversely impact the market value of our common stock.

Because we have no source of significant recurring revenue, we must depend on financing to sustain our operations.

Developing products and conducting clinical trials require substantial amounts of capital. To date, we have relied primarily upon proceeds from sales of our equity securities, sales of our shares of common stock of our former RXi subsidiary, and the exercise of options and warrants to generate funds needed to finance our business and operations. We will need to raise additional capital to, among other things:

- fund our clinical trials and pursue regulatory approval of our existing and possible future product candidates;
  - expand our research and development activities;
  - finance our general and administrative expenses;

- acquire or license new technologies;
- prepare, file, prosecute, maintain, enforce and defend our patent and other proprietary rights; and
- develop and implement sales, marketing and distribution capabilities to successfully commercialize any product for which we obtain marketing approval and choose to market ourselves.

Our revenues were \$0.3 million, \$0.1 million and \$9.5 million, respectively, for the years ended December 31, 2011, 2010 and 2009. Our revenues in 2009 included \$9.4 million of deferred revenue recognized from our sale in August 2006 of a one-percent royalty interest in worldwide sales of arimoclomol for the treatment of ALS to the privately funded ALS Charitable Remainder Trust, or ALSCRT. Pursuant to an amendment signed between us and the beneficiary of the ALSCRT on August 6, 2009, we were released from all restrictions on the use of any proceeds previously paid to us in connection with the arrangement. As a result, we recognized \$6.7 million as service revenue in the third quarter of 2009, which represented the remaining deferred revenue and previously un-recognized portion of the value received. We will have no significant recurring revenue unless we are able to commercialize one or more of our product candidates in development, which may require us to first enter into license or other strategic arrangements with third parties.

At December 31, 2011, we had cash and cash equivalents of approximately \$18.0 million and marketable securities of \$18.1 million. Management believes that our current resources will be sufficient to fund our operations for the foreseeable future. The belief is based, in part, upon our currently projected expenditures for 2012 of approximately \$23.7 million, which includes approximately \$7.0 million for our clinical programs for INNO-206, approximately \$5.3 million for our clinical program for tamibarotene, approximately \$0.4 million for our clinical programs for bafetinib, approximately \$4.5 million for general operation of our clinical programs, and approximately \$6.5 million for other general and administrative expenses. These projected expenditures are based upon numerous assumptions and subject to many uncertainties, and our actual expenditures may be significantly different from these projections.

If we obtain marketing approval as currently planned and successfully commercialize our product candidates, we anticipate it will take a minimum of several years, and likely longer, for us to generate significant recurring revenue, and we will be dependent on future financing until such time, if ever, as we can generate significant recurring revenue. Our ability to raise capital may be adversely affected by the weak economic recovery in the U.S. We have no commitments from third parties to provide us with any additional financing, and we may not be able to obtain future financing on favorable terms, or at all. Failure to obtain adequate financing would adversely affect our ability to operate as a going concern. If we raise additional funds by issuing equity securities, dilution to stockholders may result and new investors could have rights superior to holders of the shares issued in this offering. In addition, debt financing, if available, may include restrictive covenants. If adequate funds are not available to us, we may have to liquidate some or all of our assets or to delay or reduce the scope of or eliminate some portion or all of our development programs or clinical trials. We also may have to license to other companies our product candidates or technologies that we would prefer to develop and commercialize ourselves.

If we do not achieve our projected development goals in the time frames we estimate, the commercialization of our products may be delayed and our business prospects may suffer. Our financial projections also may prove to be materially inaccurate.

From time to time, we estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of scientific studies and clinical trials and the submission of regulatory filings such as the discussion in this Annual Report of the expected timing of certain milestones relating to our INNO-206, tamibarotene and bafetinib clinical development programs.

We also may disclose projected expenditures or other forecasts for future periods such as the statements above in this Annual Report supplement regarding our current projected expenditures for fiscal year 2012. These and other financial projections are based on management's current expectations and do not contain any margin of error or cushion for any specific uncertainties, or for the uncertainties inherent in all financial forecasting.

The actual timing of milestones and actual expenditures or other financial results can vary dramatically compared to our estimates, in some cases for reasons beyond our control. If we do not meet milestones or financial projections as announced from time to time, the development and commercialization of our products may be delayed and our business prospects may suffer. The assumptions management has used to produce these projections may significantly change or prove to be inaccurate. Accordingly, you should not unduly rely on any of these financial projections.

If our products are not successfully developed and approved by the FDA or foreign regulatory authorities, we may be forced to reduce or curtail our operations.

All of our product candidates in development must be approved by the U.S. Food and Drug Administration, or FDA, or corresponding foreign governmental agencies, before they can be marketed. The process for obtaining FDA and foreign government approvals is both time-consuming and costly, with no certainty of a successful outcome. This process typically includes the conduct of extensive pre-clinical and clinical testing, including post-approval testing, which may take longer or cost more than we or our licensees, if any, anticipate, and may prove unsuccessful due to numerous factors. Product candidates that may appear to be promising at early stages of development may not successfully reach the market for a number of reasons. The results of preclinical and initial clinical testing of these product candidates may not necessarily be predictive of the results that will be obtained from later or more extensive testing. Companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier trials.

Numerous factors could affect the timing, cost or outcome of our product development efforts, including the following:

- difficulty in enrolling patients in conformity with required protocols or projected timelines;
  - requirements for clinical trial design imposed by the FDA;
  - unexpected adverse reactions by patients in trials;
  - difficulty in obtaining clinical supplies of the product;
- changes in or our inability to comply with FDA or foreign governmental product testing, manufacturing or marketing requirements;
- regulatory inspections of clinical trials or manufacturing facilities, which may, among other things, require us or our manufacturers or licensees to undertake corrective action or suspend or terminate the affected clinical trials if investigators find them not to be in compliance with applicable regulatory requirements;
- inability to generate statistically significant data confirming the safety and efficacy of the product being tested;
  - modification of the product during testing; and
- reallocation of our limited financial and other resources to other clinical programs.

It is possible that none of the product candidates we develop will obtain the regulatory approvals necessary for us to begin selling them. The time required to obtain FDA and foreign governmental approvals is unpredictable, but often can take years following the commencement of clinical trials, depending upon the complexity of the product candidate. Any analysis we perform on data from clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval.

Furthermore, even if we obtain regulatory approvals, our products and the manufacturing facilities used to produce them will be subject to continual review, including periodic inspections and mandatory post-approval clinical trials by the FDA and other U.S. and foreign regulatory authorities. Any delay or failure in obtaining required approvals or to comply with post-approval regulatory requirements could have a material adverse effect on our ability to generate revenue from the particular product candidate. The failure to comply with any post-approval regulatory requirements

also could result in the rescission of the related regulatory approvals or the suspension of sales of the offending product.

Our current and planned clinical trials of our product candidates may fail to show that these product candidates are clinically safe and effective, or that they are better than alternative treatments.

INNO-206 was no more toxic than free doxorubicin in a Phase 1 clinical trial and showed limited biological responses against certain tumors. However, these conclusions may not be reproducible in larger clinical trials, including the ongoing Phase 1b/2 and Phase 2b clinical trials of INNO-206 as a treatment for soft tissue sarcomas.

Tamibarotene has been shown to be safe, well-tolerated, and efficacious in the Japanese APL population. However, it is possible that the response to the drug may be different in American or European populations. Furthermore, the efficacy studies that led to approval in Japan occurred prior to the advent of the use of arsenic trioxide, or ATO, for second-line therapy. It is possible that the current use of ATO could alter the safety or efficacy of tamibarotene. The FDA might not accept the Japanese studies as a database for safety in the U.S.. The majority of patients treated with ATRA as a first-line therapy will generally experience a complete remission of disease. As a result of the limited population of patients requiring third-line treatment for APL, there is no assurance that we will be successful in recruiting a sufficient number of patients into our ongoing clinical trial of tamibarotene as a third-line treatment for APL in order to demonstrate efficacy. Any FDA-required changes to our clinical development strategy could delay or increase the cost of the trial, adversely affect our ability to demonstrate the efficacy of tamibarotene in the trial or cause us not to pursue clinical development of tamibarotene for one or more of these considerations. Tamibarotene has never been tested in human clinical trials in patients with NSCLC, and there are no assurances that it will be effective in that indication.

Bafetinib demonstrated clinical responses in patients with CML in a Phase 1 clinical trial conducted in patients with CML and other leukemias that have a certain mutation called the Philadelphia Chromosome (Ph+) and are intolerant of or resistant to Gleevec and, in some cases, second-line tyrosine kinase inhibitors. However, bafetinib has never been tested in human clinical trials in patients with B-CLL, and there are no assurances that it will be effective in that indication.

Even if our current trials are successful, subsequent trials may not yield statistically significant data indicating that these product candidates are clinically effective. Accordingly, we, or any development partners, may ultimately be unable to provide the FDA with satisfactory data on clinical safety and efficacy sufficient to obtain FDA approval of INNO-206, tamibarotene or bafetinib for any indications.

We will rely upon third parties for the manufacture of our clinical product supplies.

We do not have the facilities or expertise to manufacture supplies of any of our product candidates. Accordingly, we are dependent upon third-party manufacturers, or potential future strategic alliance partners, to manufacture these supplies. We have manufacturing supply arrangements in place with respect to a portion of the clinical supplies needed for the clinical development programs for INNO-206, tamibarotene and bafetinib. However, we have no supply arrangements for the commercial manufacture of these product candidates or any manufacturing supply arrangements for any other potential product candidates, and we may not be able to secure needed supply arrangements on attractive terms, or at all. Our failure to secure these arrangements as needed could have a materially adverse effect on our ability to complete the development of our products or to commercialize them.

If our product candidates cannot be manufactured in suitable quantities and in accordance with regulatory standards, our clinical trials, regulatory approvals and marketing efforts for such products may be delayed. Such delays could adversely affect our competitive position and our chances of generating significant recurring revenues. If our products cannot be manufactured at an acceptable cost, the commercial success of our products may be adversely affected.

We may rely upon third parties in connection with the commercialization of our products.

The completion of the development of INNO-206, tamibarotene and bafetinib, as well as the marketing of these products, may require us to enter into strategic alliances, license agreements or other collaborative arrangements with other pharmaceutical companies under which those companies will be responsible for one or more aspects of the commercial development and eventual marketing of our products.

Our products may not have sufficient potential commercial value to enable us to secure strategic arrangements with suitable companies on attractive terms, or at all. If we are unable to enter into such arrangements, we may not have the financial or other resources to complete the development of any of our products and may have to sell our rights in them to a third party or abandon their development altogether.

To the extent we enter into collaborative arrangements, we will be dependent upon the timeliness and effectiveness of the development and marketing efforts of our contractual partners. If these companies do not allocate sufficient personnel and resources to these efforts or encounter difficulties in complying with applicable FDA and other regulatory requirements, we may not obtain regulatory approvals as planned, if at all, and the timing of receipt or the amount of revenue from these arrangements may be materially and adversely affected. By entering into these arrangements rather than completing the development and then marketing these products on our own, the profitability to us of these products may decline.



We may be unable to protect our intellectual property rights, which could adversely affect our ability to compete effectively.

We believe that obtaining and maintaining patent and other intellectual property rights for our technologies and potential products is critical to establishing and maintaining the value of our assets and our business. We will be able to protect our technologies from unauthorized use by third parties only to the extent that we have rights to valid and enforceable patents or other proprietary rights that cover them. Although we have rights to patents and patent applications directed to INNO-206, tamibarotene and bafetinib, these patents and applications may not prevent third parties from developing or commercializing similar or identical technologies. In addition, our patents may be held to be invalid if challenged by third parties, and our patent applications may not result in the issuance of patents.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date in the U.S. and in many foreign countries. The application and enforcement of patent laws and regulations in foreign countries is even more uncertain. Accordingly, we may not be able to effectively file, protect or defend our proprietary rights on a consistent basis. Many of the patents and patent applications on which we rely were issued or filed by third parties prior to the time we acquired rights to them. The validity, enforceability and ownership of those patents and patent applications may be challenged, and if a court decides that our patents are not valid, we will not have the right to stop others from using our inventions. There is also the risk that, even if the validity of our patents is upheld, a court may refuse to stop others on the ground that their activities do not infringe our patents.

Any litigation brought by us to protect our intellectual property rights could be costly and have a material adverse effect on our operating results or financial condition, make it more difficult for us to enter into strategic alliances with third parties to develop our products, or discourage our existing licensees from continuing their development work on our potential products. If our patent coverage is insufficient to prevent third parties from developing or commercializing similar or identical technologies, the value of our assets is likely to be materially and adversely affected.

We also rely on certain proprietary trade secrets and know-how, especially where we believe patent protection is not appropriate or obtainable. However, trade secrets and know-how are difficult to protect. Although we have taken measures to protect our unpatented trade secrets and know-how, including the use of confidentiality and invention assignment agreements with our employees, consultants and some of our contractors, it is possible that these persons may disclose our trade secrets or know-how or that our competitors may independently develop or otherwise discover our trade secrets and know-how.

If our product candidates infringe the rights of others, we could be subject to expensive litigation or be required to obtain licenses from others to develop or market them.

Our competitors or others may have patent rights that they choose to assert against us or our licensees, suppliers, customers or potential collaborators. Moreover, we may not know about patents or patent applications that our products would infringe. For example, because patent applications can take many years to issue, there may be currently pending applications, unknown to us, that may later result in issued patents that our product candidates would infringe. In addition, if third parties file patent applications or obtain patents claiming technology also claimed by us or our licensors in issued patents or pending applications, we may have to participate in interference proceedings in the U.S. Patent and Trademark Office to determine priority of invention. If third parties file oppositions in foreign countries, we may also have to participate in opposition proceedings in foreign tribunals to defend the patentability of our foreign patent applications.

If a third party claims that we infringe its proprietary rights, any of the following may occur:

- we may become involved in time-consuming and expensive litigation, even if the claim is without merit;
- we may become liable for substantial damages for past infringement if a court decides that our technology infringes a competitor's patent;
- a court may prohibit us from selling or licensing our product without a license from the patent holder, which may not be available on commercially acceptable terms, if at all, or which may require us to pay substantial royalties or grant cross licenses to our patents; and
- we may have to redesign our product candidates or technology so that it does not infringe patent rights of others, which may not be possible or commercially feasible.

If any of these events occurs, our business and prospects will suffer and the market price of our common stock will likely decline substantially.

Any drugs we develop may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which could have a material adverse effect on our business.

We intend to sell our products primarily to hospitals which receive reimbursement for the health care services they provide to their patients from third-party payors, such as Medicare, Medicaid and other domestic and international government programs, private insurance plans and managed care programs. Most third-party payors may deny reimbursement if they determine that a medical product was not used in accordance with cost-effective treatment methods, as determined by the third-party payor, or was used for an unapproved indication. Third-party payors also may refuse to reimburse for experimental procedures and devices. Furthermore, because our programs are in the early stages of development, we are unable at this time to determine their cost-effectiveness and the level or method of reimbursement. Increasingly, the third-party payors who reimburse patients are requiring that drug companies provide them with predetermined discounts from list prices, and are challenging the prices charged for medical products. If the price we are able to charge for any products we develop is inadequate in light of our development and other costs, our profitability could be adversely affected.

We currently expect that any drugs we develop may need to be administered under the supervision of a physician. Under currently applicable law, drugs that are not usually self-administered may be eligible for coverage by the Medicare program if:

- they are “incidental” to a physician’s services,
- they are “reasonable and necessary” for the diagnosis or treatment of the illness or injury for which they are administered according to accepted standard of medical practice,
- they are not excluded as immunizations, and
- they have been approved by the FDA.

We are subject to intense competition, and we may not compete successfully

We and our strategic partners or licensees may be unable to compete successfully against our current or future competitors. The pharmaceutical, biopharmaceutical and biotechnology industries are characterized by intense competition and rapid and significant technological advancements. Many companies, research institutions and universities are working in a number of areas similar to our primary fields of interest to develop new products. There also is intense competition among companies seeking to acquire products that already are being marketed. Many of the companies with which we compete have or are likely to have substantially greater research and product development capabilities and financial, technical, scientific, manufacturing, marketing, distribution and other resources than us and at least some of our present or future strategic partners or licensees.

As a result, these competitors may:

- succeed in developing competitive products sooner than us or our strategic partners or licensees;
- obtain FDA or foreign governmental approvals for their products before we can obtain approval of any of our products;
- obtain patents that block or otherwise inhibit the development and commercialization of our product candidate candidates;

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- develop products that are safer or more effective than our products;
- devote greater resources than us to marketing or selling products;
- introduce or adapt more quickly than us to new technologies and other scientific advances;
  - introduce products that render our products obsolete;

- withstand price competition more successfully than us or our strategic partners or licensees;
- negotiate third-party strategic alliances or licensing arrangements more effectively than us; and
  - take better advantage than us of other opportunities.

For a more detailed discussion of the competition we face, see “Business – Competition,” above.

We will be required to pay substantial milestone and other payments relating to the commercialization of our products.

The agreement relating to our worldwide rights to INNO-206 provides for our payment of an aggregate of \$7.5 million upon meeting specified clinical and regulatory milestones up to and including the product’s second final marketing approval. We also will be obliged to pay:

- commercially reasonable royalties based on a percentage of net sales (as defined in the agreement);
- a percentage of non-royalty sub-licensing income (as defined in the agreement); and
- milestones of \$1,000,000 for each additional final marketing approval that we might obtain.

The agreements under which we have North American and European rights to tamibarotene provide for our payment of royalties based on net sales of any products, as well as aggregate payments of ¥ 490 million for North America and ¥ 480 million for Europe upon meeting specified clinical, regulatory and sales milestones up to and including the first commercial sale of tamibarotene for the treatment of APL.

Our agreement relating to our worldwide (except Japan) rights to bafetinib provides for our payment of an aggregate of \$13.35 million (including \$5 million upon the product’s initial final marketing approval) upon the achievement of specified clinical and regulatory milestones up to and including approvals in the U.S. and Europe. We also will be obliged to pay:

- commercially reasonable royalties based on a percentage of net sales (as defined in the agreement), dependent on reaching certain revenue thresholds;
  - annual minimum payments if sales of bafetinib do not meet specified levels; and
  - a percentage of non-royalty sub-licensing income (as defined in the agreement).

If we are required to pay any third party in order to exercise our rights under the agreement, we will deduct a percentage of those payments from the royalties due under the agreement, up to an agreed-upon cap.

Under the merger agreement by which we acquired Innovive, we agreed to pay the former Innovive stockholders a total of up to approximately \$18.3 million of future earnout merger consideration, subject to our achievement of specified net sales under the Innovive license agreements. The earnout merger consideration, if any, will be payable in shares of our common stock, subject to specified conditions, or, at our election, in cash or by a combination of shares of our common stock and cash. Our common stock will be valued for purposes of any future earnout merger consideration based upon the trading price of our common stock at the time the earnout merger consideration is paid.

We are subject to potential liabilities from clinical testing and future product liability claims.

If any of our products are alleged to be defective, they may expose us to claims for personal injury by patients in clinical trials of our products or, if we obtain marketing approval and commercialize our products, by patients using our commercially marketed products. Even if the if one or more of our products is approved by the FDA, users may claim that such products caused unintended adverse effects. We maintain clinical trial insurance for our ongoing clinical trials, and we plan to seek to obtain similar insurance for any other clinical trials that we conduct. We also would seek to obtain product liability insurance covering the commercial marketing of our product candidates. We may not be able to obtain additional insurance, however, and any insurance obtained by us may prove inadequate in the event of a claim against us. Any claims asserted against us also may divert management's attention from our operations, and we may have to incur substantial costs to defend such claims even if they are unsuccessful.

We may be unable to successfully acquire additional technologies or products. If we require additional technologies or products, our product development plans may change and the ownership interests of our shareholders could be diluted.

We may seek to acquire additional technologies by licensing or purchasing such technologies, or through a merger or acquisition of one or more companies that own such technologies. We have no current understanding or agreement to acquire any technologies, however, and we may not be able to identify or successfully acquire any additional technologies. We also may seek to acquire products from third parties that already are being marketed or have been approved for marketing, although we have not currently identified any of these products. We do not have any prior experience in acquiring or marketing products approved for marketing and may need to find third parties to market any products that we might acquire.

We have focused our product development efforts on our oncology drug candidates, which we believe have the greatest revenue potential. If we acquire additional technologies or product candidates, we may determine to make further changes to our product development plans and business strategy to capitalize on opportunities presented by the new technologies and product candidates.

We may determine to issue shares of our common stock to acquire additional technologies or products or in connection with a merger or acquisition of another company. To the extent we do so, the ownership interest of our stockholders will be diluted accordingly.

We are conducting certain of our clinical trials in foreign countries, which exposes us to additional risks.

We are conducting international clinical development of INNO-206 and tamibarotene. The conduct of clinical trials outside the United States could have a significant impact on us. Risks inherent in conducting international clinical trials include:

- foreign regulatory requirements that could restrict or limit our ability to conduct our clinical trials;
- administrative burdens of conducting clinical trials under multiple foreign regulatory schema;
  - foreign exchange fluctuations;
  - diminished protection of intellectual property in some countries; and
  - possible nationalization and expropriation.

In addition, there may be changes to our business and political position if there is instability, disruption or destruction in a significant geographic region, regardless of cause, including war, terrorism, riot, civil insurrection or social unrest; and natural or man-made disasters, including famine, flood, fire, earthquake, storm or disease, which could seriously harm the development of our current operating strategy.

In the event of a dispute regarding our international clinical trials, it may be necessary for us to resolve the dispute in the foreign country of dispute, where we would be faced with unfamiliar laws and procedures.

The resolution of disputes in foreign countries can be costly and time consuming, similar to the situation in the United States. However, in a foreign country, we face the additional burden of understanding unfamiliar laws and procedures. We may not be entitled to a jury trial, as we might be in the United States. Further, to litigate in any foreign country, we would be faced with the necessity of hiring lawyers and other professionals who are familiar with the foreign laws. For these reasons, we may incur unforeseen expenses if we are forced to resolve a dispute in a

foreign country.

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## Risks Associated with Our Common Stock

Our anti-takeover measures may make it more difficult to change our management, or may discourage others from acquiring us, and thereby adversely affect stockholder value.

We have a stockholder rights plan and provisions in our bylaws that are intended to protect our stockholders' interests by encouraging anyone seeking control of our company to negotiate with our board of directors. These provisions may discourage or prevent a person or group from acquiring us without the approval of our board of directors, even if the acquisition would be beneficial to our stockholders.

We have a classified board of directors, which means that at least two stockholder meetings, instead of one, will be required to effect a change in the majority control of our board of directors. This applies to every election of directors, not just an election occurring after a change in control. The classification of our board increases the amount of time it takes to change majority control of our board of directors and may cause potential acquirers to lose interest in a potential purchase of us, regardless of whether our purchase would be beneficial to us or our stockholders. The additional time and cost to change a majority of the members of our board of directors makes it more difficult and may discourage our existing stockholders from seeking to change our existing management in order to change the strategic direction or operational performance of our company.

Our bylaws provide that directors may only be removed for cause by the affirmative vote of the holders of at least a majority of the outstanding shares of our capital stock then entitled to vote at an election of directors. This provision prevents stockholders from removing any incumbent director without cause. Our bylaws also provide that a stockholder must give us at least 120 days notice of a proposal or director nomination that such stockholder desires to present at any annual meeting or special meeting of stockholders. Such provision prevents a stockholder from making a proposal or director nomination at a stockholder meeting without us having advance notice of that proposal or director nomination. This could make a change in control more difficult by providing our directors with more time to prepare an opposition to a proposed change in control. By making it more difficult to remove or install new directors, these bylaw provisions may also make our existing management less responsive to the views of our stockholders with respect to our operations and other issues such as management selection and management compensation.

We are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which may also prevent or delay a takeover of us that may be beneficial to our stockholders.

Our outstanding options and warrants and the availability for resale of our shares issued in our private financings may adversely affect the trading price of our common stock.

As of December 31, 2011, there were outstanding stock options and warrants to purchase approximately 65.1 million shares of our common stock at a weighted-average exercise price of \$0.78 per share. Our outstanding options and warrants could adversely affect our ability to obtain future financing or engage in certain mergers or other transactions, since the holders of options and warrants can be expected to exercise them at a time when we may be able to obtain additional capital through a new offering of securities on terms more favorable to us than the terms of outstanding options and warrants. For the life of the options and warrants, the holders have the opportunity to profit from a rise in the market price of our common stock without assuming the risk of ownership. The issuance of shares upon the exercise of outstanding options and warrants will also dilute the ownership interests of our existing stockholders. Many of our outstanding warrants contain anti-dilution provisions pertaining to dividends with respect to our common stock. In the event that these anti-dilution provisions are triggered by us in the future, we would likewise be required to reduce the exercise price, and increase the number of shares underlying, those warrants, which would have a dilutive effect on our stockholders.

We have registered with the SEC the resale by the holders of all or substantially all shares of our common stock issuable upon exercise of our outstanding options and warrants. The availability of these shares for public resale, as well as actual resales of these shares, could adversely affect the trading price of our common stock.

We may issue preferred stock in the future, and the terms of the preferred stock may reduce the value of our common stock.

We are authorized to issue shares of preferred stock in one or more series. Our board of directors may determine the terms of future preferred stock offerings without further action by our stockholders. If we issue preferred stock, it could affect your rights or reduce the value of our outstanding common stock. In particular, specific rights granted to future holders of preferred stock may include voting rights, preferences as to dividends and liquidation, conversion and redemption rights, sinking fund provisions, and restrictions on our ability to merge with or sell our assets to a third party.

We may experience volatility in our stock price, which may adversely affect the trading price of our common stock.

The market price of our common stock has ranged from \$0.26 to \$1.05 per share since January 1, 2011, and it may continue to experience significant volatility from time to time. Factors that may affect the market price of our common stock include the following:

- announcements of regulatory developments or technological innovations by us or our competitors;
  - changes in our relationship with our licensors and other strategic partners;
  - our quarterly operating results;
  - litigation involving or affecting us;
- shortfalls in our actual financial results compared to our guidance or the forecasts of stock market analysts;
  - developments in patent or other technology ownership rights;
  - acquisitions or strategic alliances by us or our competitors;
  - public concern regarding the safety of our products; and
  - government regulation of drug pricing.

We do not expect to pay any cash dividends on our common stock.

We have not declared or paid any cash dividends on our common stock or other securities, and we currently do not anticipate paying any cash dividends in the foreseeable future. Because we do not anticipate paying cash dividends for the foreseeable future, our stockholders will not realize a return on their investment in our common stock except to the extent of any appreciation in the value of our common stock. Our common stock may not appreciate in value, or may decline in value.

#### Item 1B. UNRESOLVED STAFF COMMENTS

None.

#### Item 2. PROPERTIES

We lease our headquarters in Los Angeles, California. The lease covers approximately 5,270 square feet of office and storage space and expires in February 2015. This lease requires us to make monthly payments of approximately \$25,610, subject to annual increases.

We also acquired a sublease to approximately 5,526 square feet of office space at 555 Madison Avenue, New York, New York, in connection with our acquisition of Innovive in September 2008. This lease currently requires us to make annual payments of approximately \$210,000, plus certain taxes and operating expenses, and it expires on August 30, 2012. On December 4, 2008, we sub-subleased the space through August 29, 2012. Under the sub-sublease, we are entitled to base annual rent of approximately \$350,000, plus certain taxes and operating expenses.

Item 3. LEGAL PROCEEDINGS

We are occasionally involved in claims arising in the normal course of business. As of March 12, 2012, there were no such claims that we expect, individually or in the aggregate, to have a material adverse effect on us.

Item 4. MINE SAFETY DISCLOSURES

Not Applicable.

## PART II

## Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

## Market Information

Our common stock is traded on The NASDAQ Capital Market under the symbol "CYTR." The following table sets forth the high and low sale prices for our common stock for the periods indicated as reported by The NASDAQ Capital Market:

	High	Low
Fiscal Year 2011:		
Fourth Quarter	\$0.40	\$0.24
Third Quarter	\$0.83	\$0.30
Second Quarter	\$1.06	\$0.68
First Quarter	\$1.06	\$0.76
Fiscal Year 2010:		
Fourth Quarter	\$1.11	\$0.73
Third Quarter	\$0.97	\$0.62
Second Quarter	\$1.29	\$0.73
First Quarter	\$1.56	\$1.07

## Holders

On March 12, 2012, there were approximately 700 holders of record of our common stock. The number of record holders does not reflect the number of beneficial owners of our common stock for whom shares are held by brokerage firms and other nominees.

## Dividends

We have not paid any cash dividends since our inception and do not contemplate paying any cash dividends in the foreseeable future.

## Equity Compensation Plans

The following table sets forth certain information as of December 31, 2011, regarding securities authorized for issuance under our equity compensation plans:

Plan Category	(a) Number of Securities to be Issued Upon Exercise of	(b) Weighted-Average Exercise Price of Outstanding Options,	Number of Securities Remaining Available for Issuance Under Equity
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	Outstanding Options, Warrants and Rights	Warrants and Rights	Compensation Plans (Excluding Securities Reflected in Column (a))
Equity compensation plans approved by our security holders:			
2000 Long-Term Incentive Plan	7,296,960	\$ 1.08	—
2008 Stock Incentive Plan	6,055,500	0.59	3,944,500
Equity compensation plans not approved by our security holders:			
Outstanding warrants (1)	51,781,505	0.76	—
Total	65,133,965	\$ 0.78	3,944,500

(1) The warrants shown were issued in discreet transactions from time to time as compensation for services rendered by consultants, advisors or other third parties, and do not include warrants sold in private placement transactions. The material terms of such warrants were determined based upon arm's-length negotiations with the service providers. The warrant exercise prices approximated the market price of our common stock at or about the date of grant, and the warrant terms range from one to ten years from the grant date. The warrants contain customary anti-dilution adjustments in the event of a stock split, reverse stock split, reclassification or combination of our outstanding common stock and similar events and certain of the warrants contain anti-dilution adjustments triggered by other corporate events, such as dividends.

## Comparison of Cumulative Total Returns

The following line graph presentation compares cumulative total stockholder returns of CytRx with The NASDAQ Stock Market Index and the NASDAQ Pharmaceutical Index (the "Peer Index") for the five-year period from December 31, 2006 to December 31, 2011. The graph and table assume that \$100 was invested in each of CytRx's common stock, the NASDAQ Stock Market Index and the Peer Index on December 31, 2006, and that all dividends were reinvested. This data was furnished by Zacks Investment Research.

## Comparison of Cumulative Total Returns

	2007	2008	December 31,		
			2009	2010	2011
CytRx Corporation	148.69	22.81	85.15	76.80	21.29
NASDAQ Stock Market Index	110.65	66.42	96.54	114.07	113.17
NASDAQ Pharmaceutical Index	105.17	97.84	109.95	119.19	127.72

## Recent Issuances of Unregistered Securities

In March 2012, we issued a warrant to purchase a total of 400,000 shares of our common stock at an exercise price of \$0.33 per share, in connection with a consulting arrangement. The issuance of this warrant was exempt from registration under the Securities Act of 1933 pursuant to Section 4(2) of the Securities Act of 1933.

## Repurchase of Shares

We did not repurchase any of our shares during the year ended December 31, 2011.

## Item 6. SELECTED FINANCIAL DATA

## General

The following selected financial data are derived from our audited financial statements. Our financial statements for 2011, 2010 and 2009 have been audited by BDO USA, LLP, our independent registered public accounting firm. These historical results do not necessarily indicate future results. When you read this data, it is important that you also read our financial statements and related notes, as well as the “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Risk Factors” sections of this Annual Report. Financial information provided below has been rounded to the nearest thousand.

	2011	2010	2009	2008	2007
Statement of Operations Data:					
Revenues					
Service revenue	\$—	\$—	\$9,400,000	\$6,166,000	\$7,242,000
Licensing revenue	250,000	100,000	100,000	100,000	101,000
Grant revenue	—	—	—	—	116,000
Total revenues	\$250,000	\$100,000	\$9,500,000	\$6,266,000	\$7,459,000
Deemed dividend for anti-dilution adjustments made to outstanding common stock warrants					
	—	—	—	(757,000)	—
Net profit (loss) applicable to common stockholders	\$(14,424,545)	\$408,460	\$(4,800,000)	\$(27,803,000)	\$(21,890,000)
Basic and diluted profit (loss) per share applicable to common stock	\$(0.11)	\$0.00	\$(0.05)	\$(0.30)	\$(0.26)
Balance Sheet Data:					
Cash, cash equivalents and marketable securities					
	\$17,989,000	\$26,892,000	\$32,643,000	\$25,042,000	\$60,450,000
Total assets	\$37,854,000	\$36,697,000	\$35,277,000	\$28,324,000	\$64,146,000
Total stockholders’ equity	\$24,254,000	\$30,568,000	\$28,348,000	\$15,698,000	\$40,224,000

## Factors Affecting Comparability

In August 2011, we undertook a \$20.4 million underwritten public offering in which we sold and issued 39.2 million shares of common stock at a price of \$0.51 per share and warrants at a price of \$0.01 per warrant to purchase up to approximately 45.1 million shares of common stock at an exercise price of \$0.64 per share. Net of underwriting discounts, legal, accounting and other offering expenses, we received proceeds of approximately \$18.9 million (without giving effect to any proceeds that we may receive upon future exercises of the warrants sold in the offering).

In July 2009, we completed a \$20.0 million registered direct public offering of approximately 15.3 million shares of our common stock at a price of \$1.31 per share and warrants to purchase an additional approximately 4.7 million shares of common stock at an exercise price of \$1.70 per share. Net of investment banking commissions, advisory fees, legal, accounting and other fees related to the transaction, we received proceeds of approximately \$18.3 million



(without giving effect to any proceeds that we may receive upon future exercises of the warrants sold in the offering).

On September 19, 2008, we purchased all of the common stock of Innovive Pharmaceuticals in a transaction that for accounting purposes is considered an asset acquisition. The fair value of Innovive's assets and liabilities at September 19, 2008, in millions of dollars, are presented below:

In-process research and development	\$8.0
Leasehold interests	0.1
Prepaid expenses	0.3
Accounts payable	(6.1 )
Net assets acquired through issuance of common stock	\$2.3

As a result of the March 11, 2008 distribution by us to our stockholders of approximately 36% of the outstanding shares of RXi, we deconsolidated that previously majority-owned subsidiary. As part of the transaction, we deconsolidated \$3.7 million of total assets and \$4.6 million of total liabilities of RXi.

In connection with applicable antidilution adjustments to the price of certain outstanding warrants in March 2008, we recorded a deemed dividend of approximately \$757,000. The deemed dividend was recorded as a charge to accumulated deficit and a corresponding credit to additional paid-in capital.

In April 2007, we completed a \$37.0 million private equity financing in which we sold 8.6 million shares of our common stock at \$4.30 per share. Net of investment banking commissions, legal, accounting and other expenses related to the transaction, we received approximately \$34.2 million of sale proceeds.

In August 2006, we received marketable securities, which were subsequently sold by us for approximately \$24.3 million, from the privately-funded ALS Charitable Remainder Trust, or ALSCRT, in exchange for our commitment to continue research and development of arimoclomol and other potential treatments for ALS and a one percent royalty from worldwide sales of arimoclomol. We recorded the value received under the arrangement as deferred service revenue, which we recognize using the proportional performance method of revenue recognition. In August 2009, we were released from all restrictions on the use of any proceeds previously received by us in connection with the arrangement. As a result, we recognized in the third quarter \$6.7 million of service revenue, representing all of the remaining deferred revenue and previously un-recognized portion of the value received in the arrangement with ALSCRT. During 2009 and 2008, we recognized approximately \$9.4 million and \$6.2 million, respectively, of service revenue related to this transaction, respectively.

## Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read together with the discussion under "Selected Financial Data" and our consolidated financial statements included in this Annual Report. This discussion contains forward-looking statements, based on current expectations and related to future events and our future financial performance, that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many important factors, including those set forth under the caption "Risk Factors" and elsewhere in this Annual Report.

### Overview

#### CytRx Corporation

We are a biopharmaceutical research and development company specializing in oncology. Our oncology pipeline includes three programs in clinical development for cancer indications: INNO-206, tamibarotene and bafetinib. With our tumor-targeted doxorubicin conjugate INNO-206, we have initiated an international Phase 2b clinical trial as a treatment for soft tissue sarcomas, are completing our ongoing Phase 1b/2 clinical trial for primarily the same indication and plan to initiate a Phase 2 trial for an undisclosed solid tumor indication in the first half of 2012. Our pipeline also includes tamibarotene, which we are testing in a double-blind, placebo-controlled, international Phase 2b clinical trial in patients with non-small-cell lung cancer, and which is in a clinical trial as a treatment for acute promyelocytic leukemia (APL). We are evaluating bafetinib in the ENABLE Phase 2 clinical trial in high-risk B-cell chronic lymphocytic leukemia (B-CLL), and plan to seek a partner for further development of bafetinib. In 2011, we completed our strategy of monetizing our non-core assets through the sale of our molecular chaperone technology to Denmark-based Orphazyme ApS in a transaction valued at up to \$120 million, and the sale of our 19% interest in SynthRx to ADVENTRX Pharmaceuticals.

In order to fund our business and operations, we have relied primarily upon sales of our equity securities, including proceeds received upon the exercise of options and warrants, and sales of our shares of common stock of our former subsidiary, RXi Pharmaceuticals Corporation. We also have received limited payments from our strategic partners and licensees.

At December 31, 2011, we had cash and cash equivalents of approximately \$18.0 million and marketable securities of \$18.1 million. Management believes that our current resources will be sufficient to fund our operations for the foreseeable future. The belief is based, in part, upon our currently projected expenditures for 2012 of approximately \$23.7 million, which includes approximately \$7.0 million for our clinical programs for INNO-206, approximately \$5.3 million for our clinical program for tamibarotene, approximately \$0.4 million for our clinical programs for bafetinib, approximately \$4.5 million for general operation of our clinical programs, and approximately \$6.5 million for other general and administrative expenses. These projected expenditures are based upon numerous assumptions and subject to many uncertainties, and our actual expenditures may be significantly different from these projections. We will be required to obtain additional funding in order to execute our long-term business plans, although we do not currently have commitments from any third parties to provide us with capital. We cannot assure that additional funding will be available on favorable terms, or at all. If we fail to obtain additional funding when needed, we may not be able to execute our business plans and our business may suffer, which would have a material adverse effect on our financial position, results of operations and cash flows.

#### Our Separation from RXi Pharmaceuticals Corporation

RXi Pharmaceuticals Corporation was founded in April 2006 by us and four researchers in the field of RNAi, including Dr. Craig Mello, recipient of the 2006 Nobel Prize for Medicine for his co-discovery of RNAi. RNAi is a naturally occurring mechanism for the regulation of gene expression that has the potential to selectively inhibit the activity of any human gene. In January 2007, we transferred to RXi substantially all of our RNAi-related technologies and assets, and RXi began operating on a stand-alone basis for the purpose of accelerating the discovery of RNAi therapeutics previously sponsored by us. RXi's initial focus is on developing RNAi-based product candidates for treating neurological and metabolic disorders and cancer.

Until early 2008, we owned approximately 85% of the outstanding shares of common stock of RXi and our financial statements included the consolidated financial condition and results of operations of RXi. On February 14, 2008, our board of directors declared a dividend of one share of RXi common stock for each approximately 20.05 outstanding shares of our common stock, which was paid on March 11, 2008 and which reduced our ownership of RXi shares to less than 50%. As a result, our financial statements after March 11, 2008 no longer consolidate the financial condition and results of operation of RXi, but instead reflect our ongoing investment in RXi based on the equity method of accounting. In 2009, the investment balance in RXi was reduced to zero, and we stopped recording our share of losses from RXi. On June 30, 2010, we sold 2.0 million common shares of RXi and our ownership in RXi was reduced to approximately 3.1 million shares of common stock, approximately 17% of the outstanding shares of RXi. We thereafter began to account for those shares as available for sale, and increases or decreases were included as part of comprehensive income or loss. This investment was shown on the balance sheet at market value, based on RXi's closing stock price as reported on The NASDAQ Capital Market.

We sold our remaining shares of RXi common stock in December 2010.

#### Research and Development

Expenditures for research and development activities related to continuing operations were \$15.5 million, \$8.5 million and \$7.5 million for the years ended December 31, 2011, 2010 and 2009, or approximately 67%, 50% and 44%, respectively, of our total expenses.

Research and development expenses are further discussed below under "Critical Accounting Policies and Estimates" and "Results of Operations."

Our currently projected expenditures for 2012 include approximately \$7.0 million for our clinical programs for INNO-206, approximately \$5.3 million for our clinical program for tamibarotene, approximately \$0.4 million for our clinical programs for bafetinib, and approximately \$4.5 million for general operation of our clinical programs. The actual cost of our clinical programs could differ significantly from our current projections due to any additional requirements or delays imposed by the FDA in connection with our planned trials, or if actual costs are higher than current management estimates for other reasons, including complications with manufacturing. In the event that actual costs of our clinical program, or any of our other ongoing research activities, are significantly higher than our current estimates, we may be required to significantly modify our planned level of operations.

There is a risk that any drug discovery and development program may not produce revenue because of the risks inherent in drug discovery and development. The successful development of any product candidate is highly uncertain. We cannot reasonably estimate or know the nature, timing and costs of the efforts necessary to complete the development of, or the period in which material net cash inflows are expected to commence from any product candidate, due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- our ability to advance product candidates into pre-clinical and clinical trials;
- the scope, rate and progress of our pre-clinical trials and other research and development activities;
  - the scope, rate of progress and cost of any clinical trials we commence;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
  - future clinical trial results;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
  - the cost and timing of regulatory approvals;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the cost of establishing clinical and commercial supplies of our product candidates and any products that we may develop; and
  - the effect of competing technological and market developments.

Any failure to complete any stage of the development of our products in a timely manner could have a material adverse effect on our operations, financial position and liquidity. A discussion of the risks and uncertainties associated with our business is set forth in the “Risk Factors” section of this Annual Report.

#### Critical Accounting Policies and Estimates

Management’s discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an ongoing basis, management evaluates its estimates, including those related to revenue recognition, stock options, impairment of long-lived assets, including finite lived intangible assets, accrued liabilities and certain expenses. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ materially from these estimates under different assumptions or conditions.

Our significant accounting policies are summarized in Note 2 of the Notes to Financial Statements included in this Annual Report. We believe the following critical accounting policies are affected by our more significant judgments and estimates used in the preparation of our consolidated financial statements:

#### Revenue Recognition

Revenue consists of license fees from strategic alliances with pharmaceutical companies as well as service and grant revenues. Service revenue consists of contract research and laboratory consulting. Grant revenues consist of government and private grants.

Monies received for license fees are deferred and recognized ratably over the performance period in accordance with Financial Accounting Standards Board (“FASB”) Accounting Codification Standards (“ASC”) ASC 605-25, Revenue Recognition – Multiple-element Arrangements (“ASC 605-25”). Milestone payments will be recognized upon achievement of the milestone as long as the milestone is deemed substantive and we have no other performance obligations related to the milestone and collectability is reasonably assured, which is generally upon receipt, or recognized upon termination of the agreement and all related obligations. Deferred revenue represents amounts received prior to revenue recognition.

Revenues from contract research, government grants, and consulting fees are recognized over the respective contract periods as the services are performed, provided there is persuasive evidence or an arrangement, the fee is fixed or determinable and collection of the related receivable is reasonably assured. Once all conditions of the grant are met and no contingencies remain outstanding, the revenue is recognized as grant fee revenue and an earned but unbilled revenue receivable is recorded.

In August 2006, we received marketable securities, which we subsequently sold for approximately \$24.3 million, from the privately-funded ALS Charitable Remainder Trust (“ALSCRT”) in exchange for the commitment to continue research and development of arimoclomol and other potential treatments for ALS and a one percent royalty in the worldwide sales of arimoclomol. We accounted for the transaction under ASC 730-20, Research and Development Arrangements (“ASC 730-20”). Accordingly, we recorded the value received under the arrangement as deferred service revenue and recognize service revenue, using the proportional performance method of revenue recognition, on a dollar-for-dollar basis for each dollar of expense incurred for the research and development of arimoclomol and other potential ALS treatments. In August 2009, we were released from all restrictions on the use of any proceeds previously paid to us in connection with the arrangement. As a result, we recognized in the third quarter \$6.7 million of service revenue representing the remaining deferred revenue and previously un-recognized portion of the value received in the transaction with ALSCRT. For the year ended December 31, 2009, we recognized approximately \$9.4 million of service revenue related to this transaction. No service revenue related to the ALSCRT transaction was recognized in 2010 or 2011.

#### Research and Development Expenses

Research and development expenses consist of costs incurred for direct and overhead-related research expenses and are expensed as incurred. Costs to acquire technologies, including licenses, that are utilized in research and development and that have no alternative future use are expensed when incurred. Technology developed for use in its products is expensed as incurred until technological feasibility has been established.

#### Clinical Trial Expenses

Clinical trial expenses, which are included in research and development expenses, include obligations resulting from our contracts with various clinical research organizations in connection with conducting clinical trials for its product candidates. We recognize expenses for these activities based on a variety of factors, including actual and estimated labor hours, clinical site initiation activities, patient enrollment rates, estimates of external costs and other activity-based factors. We believe that this method best approximates the efforts expended on a clinical trial with the expenses we record. We adjust our rate of clinical expense recognition if actual results differ from our estimates. If our estimates are incorrect, clinical trial expenses recorded in any particular period could vary.

#### Stock-based Compensation

Our stock-based employee compensation plans are described in Note 15 of the Notes to our Financial Statements. We have adopted the provisions of ASC 718, Compensation - Stock Compensation (“ASC 718”), which requires the measurement and recognition of compensation expense for all stock-based awards made to employees and non-employees.

For stock options and stock warrants paid in consideration of services rendered by non-employees, we recognize compensation expense in accordance with the requirements of ASC 505-50, Equity-Base Payments to Non-Employees (“ASC 505-50”), as amended.



Non-employee option grants that do not vest immediately upon grant are recorded as an expense over the vesting period. At the end of each financial reporting period prior to performance, the value of these options, as calculated using the Black-Scholes option-pricing model, is determined, and compensation expense recognized or recovered during the period is adjusted accordingly. Since the fair market value of options granted to non-employees is subject to change in the future, the amount of the future compensation expense is subject to adjustment until the common stock options or warrants are fully vested.

#### Impairment of Long-Lived Assets

We review long-lived assets, including finite lived intangible assets, for impairment on an annual basis, as of December 31, or on an interim basis if an event occurs that might reduce the fair value of such assets below their carrying values. An impairment loss would be recognized based on the difference between the carrying value of the asset and its estimated fair value, which would be determined based on either discounted future cash flows or other appropriate fair value methods. If our estimates used in the determination of either discounted future cash flows or other appropriate fair value methods are not accurate as compared to actual future results, we may be required to record an impairment charge. The remaining fixed assets from our San Diego laboratory have been re-allocated from Equipment and Furnishings to Assets Held for Sale and were sold as of September 30, 2010.

## Net Income (Loss) Per Share

Basic net income (loss) per common share is computed using the weighted-average number of common shares outstanding. Diluted net income (loss) per common share is computed using the weighted-average number of common share and common share equivalents outstanding. Common share equivalents that could potentially dilute basic earnings per share in the future, and that were excluded from the computation of diluted loss per share, totaled approximately 57.7 million shares, 15.4 million shares and 24.4 million shares at December 31, 2011, 2010 and 2009, respectively.

## Quarterly Financial Data

The following table sets forth unaudited consolidated statements of operations data for each quarter during our most recent two fiscal years. This quarterly information has been derived from our unaudited consolidated financial statements and, in the opinion of management, includes all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of the information for the periods covered. The quarterly financial data should be read in conjunction with our consolidated financial statements and related notes. The operating results for any quarter are not necessarily indicative of the operating results for any future period.

	Quarter Ended			
	March 31	June 30	September 30	December 31
	(In thousands, except per share data)			
2011				
Total revenues	\$—	\$150	\$—	\$100
Net loss	(6,275 )	(3,120 )	(558 )	(4,472 )
Net loss applicable to common stockholders	\$(6,275 )	\$(3,120 )	\$(558 )	\$(4,472 )
Basic and diluted loss per share applicable to common stock	\$(0.06 )	\$(0.03 )	\$(0.00 )	\$(0.03 )
2010				
Total revenues	\$—	\$—	\$—	\$100
Net profit (loss)	(611 )	1,294	(4,414 )	4,140
Net profit (loss) applicable to common stockholders	\$(611 )	\$1,294	\$(4,414 )	\$4,140
Basic and diluted loss per share applicable to common stock	\$(0.01 )	\$0.01	\$(0.04 )	\$0.04

Quarterly and yearly loss per share amounts are computed independently of each other. Therefore, the sum of the per share amounts for the quarters may not equal the per share amounts for the year. In 2011 and 2010, we incurred \$1.4 million and \$1.6 million, respectively, in employee non-cash compensation expenses.

The comparability of our quarterly financial data may be affected by the same events and items described under “Selected Financial Data” above.

## Liquidity and Capital Resources

## General

In order to fund our business and operations, we have relied primarily upon sales of our equity securities, including proceeds received upon the exercise of options and warrants, and sales of our shares of RXi common stock. We also have received limited payments from our strategic partners and licensees.

At December 31, 2011, we had cash and cash equivalents of approximately \$18.0 million and marketable securities of \$18.1 million. Management believes that our current resources will be sufficient to fund our operations for the foreseeable future. The belief is based, in part, upon our currently projected expenditures for 2012 of approximately \$23.7 million, which includes approximately \$7.0 million for our clinical programs for INNO-206, approximately \$5.3 million for our clinical program for tamibarotene, approximately \$0.4 million for our clinical programs for bafetinib, approximately \$4.5 million for general operation of our clinical programs, and approximately \$6.5 million for other general and administrative expenses. These projected expenditures are based upon numerous assumptions and subject to many uncertainties, and our actual expenditures may be significantly different from these projections. We will be required to obtain additional funding in order to execute our long-term business plans, although we do not currently have commitments from any third parties to provide us with capital. We cannot assure you that additional funding will be available on favorable terms, or at all. If we fail to obtain additional funding when needed, we may not be able to execute our business plans and our business may suffer, which would have a material adverse effect on our financial position, results of operations and cash flows.

If we obtain marketing approval as currently planned and successfully commercialize our product candidates, we anticipate it will take a minimum of several years, and possibly longer, for us to generate significant recurring revenue, and we will be dependent on future financing until such time, if ever, as we can generate significant recurring revenue. We have no commitments from third parties to provide us with any additional financing, and we may not be able to obtain future financing on favorable terms, or at all. Failure to obtain adequate financing would adversely affect our ability to operate as a going concern. If we raise additional funds by issuing equity securities, dilution to stockholders may result and new investors could have rights superior to holders of the shares issued in this offering. In addition, debt financing, if available, may include restrictive covenants. If adequate funds are not available to us, we may have to liquidate some or all of our assets or to delay or reduce the scope of or eliminate some portion or all of our development programs or clinical trials. We also may have to license to other companies our product candidates or technologies that we would prefer to develop and commercialize ourselves.

#### Discussion of Operating, Investing and Financing Activities

Net loss for the year ended December 31, 2011 was \$14.4 million, and cash used for operating activities for that period was \$16.7 million. The net loss for the year reflects \$1.4 million for stock option and warrant expense as well as a non-cash gain of \$7.9 million on the fair value adjustment of the warrant liability.

Net profit for the year ended December 31, 2010 was \$0.4 million, and cash used for operating activities for that period was \$14.6 million. The net profit for the year reflects gain of \$15.8 million from the sale of RXi shares, \$1.6 million for stock option and warrant expense and a non-cash \$0.9 million fair value adjustment of the warrant liability.

Net loss for the year ended December 31, 2009 was \$4.8 million, and cash used for operating activities for that period was \$12.1 million. The net loss for the year reflects \$9.4 million of revenue recognized under the 2006 agreement with ALSCRT, \$2.9 million for stock option and warrant expense and a non-cash \$0.7 million fair value adjustment of the warrant liability.

For the year ended December 31, 2011, \$9.4 million was provided by investing activities. This included \$2.5 million net from the proceeds of sales of marketable securities and \$6.9 million received from the sale of RXi common shares.

For the year ended December 31, 2010, \$10.8 million was provided by investing activities. This included \$8.9 million received from the sale of RXi common shares and \$2.2 million net from the proceeds of sales of marketable securities, partially offset by \$0.3 million used to purchase equipment and furnishings.

For the year ended December 31, 2009, \$21.6 million was used in investing activities. This included \$22.8 million used to purchase marketable securities, which was partially offset by proceeds of \$1.2 million from the sale of 500,000 of our shares of common stock RXi.

Cash provided by financing activities for the year ended December 31, 2011 was \$18.9 million, which was attributable to the net proceeds received from our August 2011 public offering.

Cash provided by financing activities for the year ended December 31, 2010 was \$0.1 million, which was attributable to the exercise of previously outstanding stock options and warrants.

Cash provided by financing activities for the year ended December 31, 2009 was \$18.6 million. During 2009, we raised \$18.3 million in a private placement of our common stock and an additional \$0.3 million from the exercise of previously outstanding stock options and warrants.

#### Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements that have a material current effect or that are reasonably likely to have a material future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures, or capital resources.

## Contractual Obligations

We acquire assets still in development and enter into research and development arrangements with third parties that often require milestone and royalty payments to the third party contingent upon the occurrence of certain future events linked to the success of the asset in development. Milestone payments may be required, contingent upon the successful achievement of an important point in the development life-cycle of the pharmaceutical product (e.g., approval of the product for marketing by a regulatory agency). If required by the arrangement, we may have to make royalty payments based upon a percentage of the sales of the pharmaceutical product in the event that regulatory approval for marketing is obtained. Because of the contingent nature of these payments, they are not included in the table of contractual obligations.

These arrangements may be material individually, and in the event that milestones for multiple products covered by these arrangements were reached in the same period, the aggregate charge to expense could be material to the results of operations in any one period. In addition, these arrangements often give us the discretion to unilaterally terminate development of the product, which would allow us to avoid making the contingent payments; however, we are unlikely to cease development if the compound successfully achieves clinical testing objectives.

Our current contractual obligations that will require future cash payments are as follows (in thousands):

	Operating Leases (1)(2)	Employment Agreements (3)	Subtotal	Research and Development (4)	Total
2012	\$471	\$ 2,753	\$3,224	\$ 8,561	\$11,785
2013	332	—	332	5,521	5,853
2014	386	—	386	1,342	1,728
2015	55	—	55	—	55
2016 and thereafter	—	—	—	—	—
Total	\$ 1,244	\$ 2,753	\$3,997	\$ 15,424	\$19,421

(1) Operating leases are primarily facility lease related obligations, as well as equipment and software lease obligations with third party vendors.

(2) In 2012, we are entitled to receive \$235,000 of future rental income under subleases in place which would be offset against future operating lease obligations

(3) Employment agreements include management contracts, which have been revised from time to time, provide for minimum salary levels, adjusted annually at the discretion of our Compensation Committee, as well as for minimum bonuses that are payable.

(4) Research and development obligations relate primarily to clinical trials. Most of these purchase obligations are cancelable upon notice without liabilities to us.

We apply the disclosure provisions of ASC 460, Guarantees (“ASC 460”), to our contractual guarantees and Indemnities. We have provided contractual indemnities to investors and other parties against possible losses suffered or incurred by the indemnified parties in connection with various types of third-party claims, as well as indemnities to our officers and directors against third party claims arising from the services they provide to us. To date, we have not incurred material costs as a result of these indemnities, and we do not expect to incur material costs in the future;

further, we maintain insurance to cover certain losses arising from these indemnities. Accordingly, we have not accrued any liabilities in our consolidated financial statements related to these indemnities.

#### Net Operating Loss Carryforwards

At December 31, 2011, we had federal and state net operating loss carryforwards of \$148.0 million and \$96.0 million, respectively, available to offset against future taxable income, which expire in 2012 through 2031. As a result of a change in-control that occurred in our shareholder base in July 2002, approximately \$13.7 million in federal net operating loss carryforwards became limited in their availability to \$363,000 annually. Management currently believes that the remaining \$144.3 million in federal net operating loss carryforwards, and the \$82.3 million in state net operating loss carryforwards, are unrestricted. However, management is reviewing its recent equity transactions, including its underwritten public offering on July 27, 2011, to determine if they may have resulted in any further restrictions on our net operating loss carryforwards. As of December 31, 2011, we also had research and development and alternative minimum tax credits for federal and state purposes of approximately \$5.7 million and \$6.6 million, respectively, available for offset against future income taxes, which expire in 2022 through 2031. Based on an assessment of all available evidence including, but not limited to, our limited operating history in our core business and lack of profitability, uncertainties of the commercial viability of its technology, the impact of government regulation and healthcare reform initiatives, and other risks normally associated with biotechnology companies, we have concluded that it is more likely than not that these net operating loss carryforwards and credits will not be realized and, as a result, a 100% deferred tax valuation allowance has been recorded against these assets.

## Results of Operations

We incurred a net profit (loss) of (\$14.4 million), \$0.4 million and (\$4.8 million) for the years ended December 31, 2011, 2010 and 2009, respectively.

During 2010 and 2011, we recognized no service revenues. During 2009, we recognized \$9.4 million in service revenues relating to our \$24.3 million sale to the ALSCRT of a one-percent royalty interest in the worldwide sales of arimoclomol in August 2006. Pursuant to an amendment signed between us and the beneficiary of the ALSCRT on August 6, 2009, we were released from all restrictions on the use of any proceeds previously paid to us in connection with the arrangement. As a result, we recognized \$6.7 million as service revenue in the third quarter of 2009, which represented the remaining deferred revenue and previously un-recognized portion of the value received.

During 2011, 2010 and 2009, we earned an immaterial amount of license fees and grant revenue. All future licensing fees under our current licensing agreements are dependent upon successful development milestones being achieved by the licensor. During 2012, we are not anticipating the receipt of any significant service or licensing fees.

Our net loss may increase from current levels primarily due to expenses related to our ongoing and planned clinical trials, research and development programs, possible technology acquisitions, and other general corporate activities. We anticipate, therefore, that our operating results will fluctuate for the foreseeable future and period-to-period comparisons should not be relied upon as predictive of the results in future periods.

## Research and Development

	Years Ended December 31,		
	2011	2010	2009
	(In thousands)		
Research and development expenses	\$ 15,079	\$ 8,207	\$ 5,621
Non-cash research and development expenses	59	92	62
Impairment loss on fixed assets	—	—	1,187
Employee stock option expense	353	208	672
	\$ 15,491	\$ 8,507	\$ 7,542

Research expenses are expenses incurred by us in the discovery of new information that will assist us in the creation and the development of new drugs or treatments. Development expenses are expenses incurred by us in our efforts to commercialize the findings generated through our research efforts.

Research and development expenses incurred during 2011, 2010 and 2009 relate to our various development programs. In 2011, we initiated a Phase 1b/2 clinical trial with INNO-206 in patients with advanced solid tumors, a Phase 2b clinical trial with INNO-206 in patients with soft tissue sarcomas, while expanding the number of sites in our international Phase 2 clinical trial with tamibarotene in patients with non-small-cell lung cancer, or NSCLC, which resulted in an increase in research and development expenses over 2010. Research and development expenses were similarly higher in 2010 than in 2009, due to the initiation in 2010 of clinical trials with bafetinib and tamibarotene, and our preparations for the clinical trials that were initiated in 2011. In 2011, our development costs associated included approximately \$6.6 million for our clinical programs for INNO-206, approximately \$5.0 million for our clinical program for tamibarotene, approximately \$0.8 million for our clinical programs for bafetinib, and approximately \$3.1 million for general operation of our clinical programs. None of our research and development costs have ever been capitalized.





As compensation to consultants, and in connection with the acquisition of technology, we sometimes issue shares of common stock, stock options and warrants to purchase shares of common stock. For financial statement purposes, we value these shares of common stock, stock options, and warrants at the fair value of the common stock, stock options or warrants granted, or the services received, whichever is more reliably measurable. We recorded charges of \$0.1 million, \$0.1 million and \$0.1 million in this regard during 2011, 2010 and 2009, respectively. In 2011, we recorded \$0.3 million of employee stock option expense, as compared to \$0.2 million in 2010 and \$0.7 million in 2009.

In 2012, we expect our research and development expenses to increase moderately as a result of our clinical programs with INNO-206 and tamibarotene.

#### General and administrative expenses

	Year Ended December 31,		
	2011	2010	2009
	(In thousands)		
General and administrative expenses	\$6,293	\$6,831	\$7,128
Stock, stock option and warrant expenses to non-employees and consultants	92	614	421
Employee stock option expense	932	791	1,579
	\$7,317	\$8,236	\$9,128

General and administrative expenses include all administrative salaries and general corporate expenses, including legal expenses associated with the prosecution of our intellectual property. Our general and administrative expenses, excluding common stock, stock options and warrants issued, and excluding depreciation expense, were \$6.3 million in 2011, \$6.8 million in 2010 and \$7.1 million in 2009. The \$0.5 million reduction in expenses from 2011 to the prior year was partially due to a reduction in executive bonuses of \$0.3 million, and a reduction in professional fees. In 2009, we incurred recruiting fees and additional payroll costs for a Business Development Officer who left in the first quarter of 2010. This additional 2009 expense of \$0.2 million, along with additional 2009 professional fees, accounts for the reduction in 2010.

From time to time, we issue shares of our common stock or warrants or options to purchase shares of our common stock to consultants and other service providers in exchange for services. For financial statement purposes, we value these shares of common stock, stock options, and warrants at the fair value of the common stock, stock options or warrants granted, or the services received, whichever we can measure more reliably. We recorded employee stock option expense of \$0.9 million in 2011, \$0.8 million in 2010, and \$1.6 million in 2009.

#### Depreciation and amortization

Depreciation and amortization expenses for the years ended December 31, 2011, 2010 and 2009 were \$95,517, \$107,666, and \$475,316, respectively. The depreciation expense reflects the depreciation of our fixed assets and the amortization expenses related to our molecular library. In 2009, the higher depreciation included depreciation of our laboratory equipment which was disposed of during that year due to the closure of our San Diego facility.

#### Other Income

In 2011, 2010 and 2009, we recognized non-cash gains of \$7.9 million, \$0.9 million and \$0.7 million, respectively, on the valuation of our warrant derivative liabilities related to warrants issued in August 2011 and July 2009. In 2010 and 2009, we recognized gains of \$15.8 and \$1.2 million, respectively, on the sale of RXi shares.

Interest income

Interest income was \$0.2 million in 2011, \$0.3 million in 2010 and \$0.3 million in 2009. The variances between years are attributable primarily to the amount of funds available for investment each year and, to a lesser extent, changes in prevailing market rates.

## Recent Accounting Pronouncements

In May 2009 and February 2010, the FASB issued new guidance for accounting for subsequent events. The new guidance, which is now part of ASC 855-10, Subsequent Events (“ASC 855-10”), is consistent with existing auditing standards in defining subsequent events as events or transactions that occur after the balance sheet date but before the financial statements are issued or are available to be issued. The new guidance defines two types of subsequent events: “recognized subsequent events” and “non-recognized subsequent events.” Recognized subsequent events provide additional evidence about conditions that existed at the balance sheet date and must be reflected in the company’s financial statements. Non-recognized subsequent events provide evidence about conditions that arose after the balance sheet date and are not reflected in the financial statements of a company. Certain non-recognized subsequent events may require disclosure to prevent the financial statements from being misleading. The new guidance was effective on a prospective basis for interim or annual periods ending after June 15, 2009. We adopted the provisions of ASC 855-10 as required.

In January, 2010, the FASB issued ASU 2010-06, Improving Disclosures about Fair Value Measurements. The standard amends ASC 820, Fair Value Measurements and Disclosures (“ASC 820”), to require additional disclosures related to transfers in and out of Levels 1 and 2 and for activity in Level 3 and clarifies other existing disclosures requirements. We adopted ASU 2010-06 beginning January 1, 2010. This update had no impact on our financial statements.

In April 2010, the FASB issued Accounting Standard Update (“ASU”) No. 2010-17, Milestone Method of Revenue Recognition, which provides guidance on applying the milestone method to milestone payments for achieving specified performance measures when those payments are related to uncertain future events. However, the FASB clarified that, even if the requirements in this ASU are met, entities would not be precluded from making an accounting policy election to apply another appropriate accounting policy that results in the deferral of some portion of the arrangement consideration. The ASU is effective for periods beginning on or after June 15, 2010. Entities can apply this guidance retrospectively as well as prospectively to milestones achieved after adoption. This update had no impact on our financial statements.

In May 2011, the Financial Accounting Standards Board (“FASB”) issued ASU 2011-04, Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and International Financial Reporting Standard (“IFRS”), to converge fair value measurement and disclosure guidance in U.S. GAAP with the guidance in the International Accounting Standards Board’s (“IASB”) concurrently issued IFRS 13, Fair Value Measurement. The amendments in ASU 2011-04 do not modify the requirements for when fair value measurements apply; rather, they generally represent clarifications on how to measure and disclose fair value under ASC 820. The amendments in the ASU 2011-04 are effective prospectively for interim and annual periods beginning after December 15, 2011. Early adoption is not permitted for public entities. Adoption of this standard is not expected to have a material impact on our consolidated financial statements.

In June 2011, the FASB issued a final standard, requiring entities to present net income and other comprehensive income in either a single continuous statement or in two separate, but consecutive, statements of net income and other comprehensive income. The new standard eliminates the option to present items of other comprehensive income in the statement of changes in equity. The new requirements do not change which components of comprehensive income are recognized in net income or other comprehensive income, or when an item of other comprehensive income must be reclassified to net income. Also, earnings per share computations do not change. The new requirements are effective for interim and annual periods beginning after December 15, 2011, with early adoption permitted. Full retrospective application is required. The adoption of this accounting standard did not have an impact on our consolidated financial statements.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk is limited primarily to interest income sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because a significant portion of our investments are in short-term debt securities issued by the U.S. government and institutional money market funds. The primary objective of our investment activities is to preserve principal. Due to the nature of our marketable securities, we believe that we are not exposed to any material market risk. We do not have any derivative financial instruments or foreign currency instruments. If interest rates had varied by 10% in the year ended December 31, 2011, it would not have had a material effect on our results of operations or cash flows for that period.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our consolidated financial statements and supplemental schedule and notes thereto as of December 31, 2011 and 2010, and for each of the three years in the period ended December 31, 2011, together with the reports thereon of our independent registered public accounting firms, are set forth on pages F-1 to F-20 of this Annual Report.

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

Item 9A. CONTROLS AND PROCEDURES

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

Our management, with the participation of our principal chief executive officer and principal chief financial officer, performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Securities Exchange Act Rule 13a-15(e)) as of December 31, 2011, the end of the period covered by this Annual Report. Based on this evaluation, our principal chief executive officer and principal chief financial officer have concluded that our disclosure controls and procedures were effective as of December 31, 2011.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2011 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we assessed the effectiveness of our internal control over financial reporting as of December 31, 2011. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in Internal Control-Integrated Framework. Based upon management's assessment using the criteria contained in COSO, our management has concluded that our internal control over financial reporting was effective as of December 31, 2011.

Our internal control over financial reporting as of December 31, 2011 has been audited by BDO USA, LLP, an independent registered public accounting firm, as stated in their report thereon set forth on page F-19, which is incorporated herein by reference.

Item 9B. OTHER INFORMATION

None.

## PART III

## Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The following table sets forth information concerning our directors and executive officers:

Name	Age	Class of Director(1)	Position
Max Link, Ph.D.	71	III	Director, Chairman of the Board (3) (4)
Steven A. Kriegsman	70	II	Director, Chief Executive Officer, President
Marvin R. Selter	84	II	Director, Vice Chairman of the Board (2) (3) (4)
Louis Ignarro, Ph.D.	70	I	Director
Joseph Rubinfeld, Ph.D.	79	I	Director (2) (4)
Richard L. Wennekamp	69	III	Director (2) (3) (4)
John Caloz	60	—	Chief Financial Officer
Daniel Levitt, M.D., Ph.D.	64	—	Chief Medical Officer
D. Scott Geyer	57	—	Sr. Vice President-Manufacturing
D. Scott Wieland	52	—	Sr. Vice President-Drug Development
Benjamin S. Levin	35	—	General Counsel, Vice President — Legal Affairs and Corporate Secretary
David J. Haen	33	—	Vice President – Business Development

(1) Our Class III director serves until the 2012 annual meeting of stockholders, our Class I directors serve until the 2013 annual meeting of stockholders and our Class II directors serve until the 2014 annual meeting of stockholders,

(2) Members of our Audit Committee. Mr. Selter is the Chairman of the Committee.

(3) Members of our Nominating and Corporate Governance Committee. Mr. Wennekamp is Chairman of the Committee.

(4) Members of our Compensation Committee. Dr. Rubinfeld is Chairman of the committee.

Max Link, Ph.D, our Chairman of the Board, has been a director since 1996. Dr. Link has been retired from business since 2003. From March 2002 until its acquisition by Zimmer Holdings, Dr. Link served as Chairman and CEO of Centerpulse, Ltd. From May 1993 to June 1994, Dr. Link served as the Chief Executive Officer of Corange Ltd. (the holding company for Boehringer Mannheim Therapeutics, Boehringer Mannheim Diagnostics and DePuy International). From 1992 to 1993, Dr. Link was Chairman of Sandoz Pharma, Ltd. From 1987 to 1992, Dr. Link was the Chief Executive Officer of Sandoz Pharma and a member of the Executive Board of Sandoz, Ltd., Basel. Prior to 1987, Dr. Link served in various capacities with the United States operations of Sandoz, including President and Chief Executive Officer. Dr. Link currently serves as a director of Alexion Pharmaceuticals, Inc., Celsion Corporation, Inc. and Discovery Laboratories, Inc., and has previously served on the Boards of Directors of Cell Therapeutics, Inc., Columbia Laboratories, Inc., Human Genome Sciences, Inc. and Protein Design Laboratories.

Dr. Link has extensive executive-level experience with a number of large pharmaceutical companies, including Sandoz Pharma, Ltd. In these positions, he was responsible for major strategic and other business initiatives, including new drug development, acquisitions and dispositions of new drug candidates and other technology, licensing, marketing and distribution agreements and other key contractual strategic arrangements that affect, or are likely to affect, our company's own business efforts. As an executive officer and board member of these other companies, he has experience with the regulatory schemes in foreign jurisdictions and also has been exposed to different approaches to corporate governance matters, potential conflicts of interest, and similar matters, which enables him to offer importance guidance to our Board of Directors.

Steven A. Kriegsman has been has been CytRx's President and Chief Executive Officer and a director since July 2002. He also serves as a director of Galena Biopharma and is Chairman of its Compensation and Transactions Committees. He previously served as Director and Chairman of Global Genomics from June 2000 until 2002. Mr. Kriegsman is an inactive Chairman and Founder of Kriegsman Capital Group LLC, a financial advisory firm specializing in the development of alternative sources of equity capital for emerging growth companies in the healthcare industry. During his career, he has advised such companies as SuperGen Inc., Closure Medical Corporation, Novoste Corporation, Miravant Medical Technologies, and Maxim Pharmaceuticals. In the past five years, Mr. Kriegsman has also served on the Board of Directors of Bradley Pharmaceuticals, Inc. and Hythiam, Inc. Mr. Kriegsman has a B.S. degree with honors from New York University in Accounting and completed the Executive Program in Mergers and Acquisitions at New York University, The Management Institute. Mr. Kriegsman is a graduate of the Stanford Law School Directors' College.



Mr. Kriegsman was formerly a Certified Public Accountant with KPMG in New York City. In February 2006, Mr. Kriegsman received the Corporate Philanthropist of the Year Award from the Greater Los Angeles Chapter of the ALS Association and in October 2006, he received the Lou Gehrig Memorial Corporate Award from the Muscular Dystrophy Association. Mr. Kriegsman has been a guest speaker and lecturer at various universities including California Institute of Technology (Caltech), Brown University, and New York University. Mr. Kriegsman has been active in various charitable organizations including the Biotechnology Industry Organization, the California Health Institute, the ALS Association, the Los Angeles Venture Association, the Southern California Biomedical Council, the American Association of Dance Companies and the Palisades-Malibu YMCA.

Mr. Kriegsman's extensive history as a member of management is vital to the Board of Directors' collective knowledge of our day-to-day operations. Mr. Kriegsman also provides great insight as to how CytRx grew as an organization and his institutional knowledge is an invaluable asset to the Board of Directors in effecting its oversight of CytRx's strategic plans. Mr. Kriegsman's presence on the Board of Directors also allows for a flow of information and ideas between the Board of Directors and management.

Marvin R. Selter has been a director since October 2003. He has been President and Chief Executive Officer of CMS, Inc. since he founded that firm in 1968. CMS, Inc. is a national management consulting firm. In 1972, Mr. Selter originated the concept of employee leasing. He served as a member of the Business Tax Advisory Committee—City of Los Angeles, Small Business Board—State of California and the Small Business Advisory Commission—State of California. Mr. Selter also serves on the Valley Economic Development Center as past Chairman and Audit Committee Chairman, the Board of Valley Industry and Commerce Association as past Chairman, the Advisory Board of the San Fernando Economic Alliance and the California State University—Northridge as Past Chairman of the Economic Research Center and President of the Olive View UCLA Medical Center Foundation. He has served, and continues to serve, as a member of boards of directors of various hospitals, universities, private medical companies and other organizations. Mr. Selter attended Rutgers—The State University, majoring in Accounting and Business Administration. He was an LPA having served as Controller, Financial Vice President and Treasurer at distribution, manufacturing and service firms. He has lectured extensively on finance, corporate structure and budgeting for the American Management Association and other professional teaching associations.

Mr. Selter has founded, operated, and grown his own successful businesses, which gives him a valuable insight into the financial constraints and operational challenges facing companies in the development stage and as they mature. He also has many years of involvement in various governmental agencies and charitable organizations, which affords him an important perspective on the business regulatory process and capital-raising activities. In addition, he has significant education and work experience in accounting and financial matters that he is able to utilize as the named financial expert on our Audit Committee.

Louis Ignarro, Ph.D. has been a director since July 2002. He previously served as a director of Global Genomics since November 20, 2000. Dr. Ignarro serves as the Jerome J. Belzer, M.D. Distinguished Professor of Pharmacology in the Department of Molecular and Medical Pharmacology at the UCLA School of Medicine. Dr. Ignarro has been at the UCLA School of Medicine since 1985 as a professor, acting chairman and assistant dean. Dr. Ignarro received the Nobel Prize for Medicine in 1998. Dr. Ignarro received a B.S. in pharmacy from Columbia University and his Ph.D. in Pharmacology from the University of Minnesota. Dr. Ignarro is a Nobel Laureate and an esteemed medical researcher whose experience enables him to offer importance scientific guidance to our Board of Directors.

Joseph Rubinfeld, Ph.D. has been a director since July 2002. He co-founded SuperGen, Inc. in 1991 and has served as its Chief Executive Officer and President and as a director since its inception until December 31, 2003. He resigned as Chairman Emeritus of SuperGen, Inc. on February 8, 2005. Dr. Rubinfeld was also Chief Scientific Officer of SuperGen from 1991 until September 1997. Dr. Rubinfeld is also a founder of JJ Pharma. Dr. Rubinfeld was one of the four initial founders of Amgen, Inc. in 1980 and served as a Vice President and its Chief of Operations until 1983.

From 1987 until 1990, Dr. Rubinfeld was a Senior Director at Cetus Corporation and from 1968 to 1980, Dr. Rubinfeld was employed at Bristol-Myers Company, International Division in a variety of positions. Dr. Rubinfeld received a B.S. degree in chemistry from C.C.N.Y. and an M.A. and Ph.D. in chemistry from Columbia University.

Dr. Rubinfeld served as a senior executive of several large pharmaceutical companies before leaving to co-found SuperGEN and served as Chief Executive Officer or in other senior executive capacities with highly successful companies. Dr. Rubinfeld's academic training and business experience enhances the breadth and scope of our Board's oversight of our company's management, business, strategic relationships, and other activities, while his vision adds to the long-range planning of our Board of Directors and management.

Richard L. Wennekamp has been a director since October 2003. He retired from Community Bank in June 2008 where he was the Senior Vice President-Credit Administration since October 2002. From September 1980 to July 2002, Mr. Wennekamp was an executive officer of Bank of America Corporation, holding various positions, including Managing Director-Credit Product Executive for the last four years of his 22-year term with the bank. From 1977 through 1980, Mr. Wennekamp was a Special Assistant to former President of the United States, Gerald R. Ford, and the Executive Director of the Ford Transition Office. Prior thereto, he served as Staff Assistant to the President of the United States for one year, and as the Special Assistant to the Assistant Secretary of Commerce of the U.S.

Mr. Wennekamp's senior executive experience in the banking and financial services industry distinguishes him from our other directors and adds unique capabilities and a different perspective to the deliberations of our Board of Directors. As a former chief credit officer at Bank of America and Community Bank, he understands the credit needs, financing requirements, and operational constraints of development-stage and mature businesses.

Daniel Levitt, M.D., Ph.D. joined us in October 2009 as our Chief Medical Officer. Dr. Levitt brings more than 24 years of senior management experience, having spearheaded numerous drug development programs to commercialization at leading biotechnology and pharmaceutical companies. Prior to joining CytRx, Dr. Levitt served from January 2007 to February 2009 as Executive Vice President, Research and Development at Cerimon Pharmaceuticals, Inc. Prior to that, from August 2003 to April 2006, he was Chief Medical Officer and Head of Clinical and Regulatory Affairs at Dynavax Technologies Corporation, managing clinical trials for four programs and overseeing multi-country regulatory strategies. From August 2002 to July 2003, Dr. Levitt was Chief Operating Officer and Head of Research and Development at Affymax, Inc., and prior to that he spent six years at Protein Design Labs, Inc., completing his tenure as that firm's President and Head of Research and Development. Dr. Levitt's past experience includes a position as Head of Drug Development at Geron Corporation, and Head of the Cytokine Development Unit and Global Clinical Oncology at Sandoz Pharmaceuticals Ltd., and as Director, Clinical Oncology and Immunology at Hoffmann-LaRoche, Inc. Dr. Levitt graduated Magna Cum Laude and Phi Beta Kappa with a Bachelor of Arts degree from Brandeis University. He earned both his M.D. and his Ph.D. in Biology from the University of Chicago, Pritzker School of Medicine. Dr. Levitt has received 10 major research awards and authored or co-authored nearly 200 papers and abstracts.

John Y. Caloz joined us in October 2007 as our Chief Accounting Officer. In January of 2009 Mr. Caloz was named Chief Financial Officer. He has a history of providing senior financial leadership in the life sciences sector, as Chief Financial Officer of Occulogix, Inc, a NASDAQ listed, a medical therapy company. Prior to that, Mr. Caloz served as Chief Financial Officer of IRIS International Inc., a Chatsworth, CA based medical device manufacturer. He served as Chief Financial Officer of San Francisco-based Synarc, Inc., a medical imaging company, and from 1993 to 1999 he was Senior Vice President, Finance and Chief Financial Officer of Phoenix International Life Sciences Inc. of Montreal, Canada, which was acquired by MDS Inc. in 1999. Mr. Caloz was a partner at Rooney, Greig, Whitrod, Filion & Associates of Saint Laurent, Quebec, Canada, a firm of Chartered Accountants specializing in research and development and high tech companies, from 1983 to 1993. Mr. Caloz, a Chartered Accountant, holds a degree in Accounting from York University, Toronto, Canada.

Scott Wieland, Ph.D, joined CytRx in 2005 as the Vice President, Clinical and Regulatory Affairs and was promoted to the position of Senior Vice President, Drug Development in December 2008. Prior to that, he served in senior level positions in the areas of Drug Development, Clinical and Regulatory Affairs at various biotech firms. He spent five years at NeoTherapeutics, Inc. serving as the Director of Product Development and was later promoted to Vice President of Product Development. From 1990 to 1997, he served as Director of Regulatory Affairs at CoCensys, Inc. Dr. Wieland has a Ph.D. in Biopsychology and an M.A. in Psychology from the University of Arizona. He has an MBA from Webster University. Dr. Wieland received his B.S. in Physiological Psychology from the University of California, Santa Barbara.

Scott Geyer joined CytRx in November 2009 as our Senior Vice President, Manufacturing. Prior to joining CytRx, he served since May 2009, and also from May 2007 through November 2008, as Vice President, Technical Operations at Cerimon Pharmaceuticals, Inc. He previously served from December 2008 through April 2009 as Senior Vice President, Technical Operations & Product Development at TRF Pharma, Inc., from October 2004 through April 2007 as Vice President, Technical Operation at Xencor, Inc., and from October 2003 through February 2004 as Vice President, Manufacturing and Process Development at BioMarin Pharmaceuticals Inc. Mr. Geyer's past experience includes holding senior positions at Onyx Pharmaceuticals and Protein Design Labs, Inc., as well as positions at Ares-Sorono Group and SmithKline Beckman, among others. Mr. Geyer has co-authored numerous publications in peer reviewed journals. He holds an M.S. in veterinary microbiology from Texas A&M University and a B.S. in microbiology from the University of Southwestern Louisiana.

Benjamin S. Levin, has been our General Counsel, Vice President — Legal Affairs and Corporate Secretary since July 2004. From November 1999 to June 2004, Mr. Levin was an associate in the transactions department of the Los Angeles office of O'Melveny & Myers LLP. Mr. Levin received his S.B. in Economics from the Massachusetts Institute of Technology, and a J.D. from Stanford Law School.

David J. Haen joined CytRx in October 2003 as Director of Business Development and was promoted to Vice President of Business Development in December 2007. From 1999 to 2003, Mr. Haen worked as an associate for Kriegsman Capital Group LLC, a financial advisory firm focused on emerging companies in the life sciences field. Mr. Haen received a B.A. in Communications and Business from Loyola Marymount University.

#### Diversity

Our board of directors, acting through the Nomination and Governance Committee, is responsible for assembling for shareholder consideration a group of director-nominees that, taken together, have the experience, qualifications, attributes, and skills appropriate for functioning effectively as a board. The Nomination and Governance Committee periodically reviews the composition of the board of directors in light of the company's changing requirements, its assessment of the board of directors' performance, and the input of shareholders and other key constituencies. The Nomination and Governance Committee looks for certain characteristics common to all board members, including integrity, strong professional reputation and record of achievement, constructive and collegial personal attributes, and the ability and commitment to devote sufficient time and energy to board service. In addition, the Nomination and Governance Committee seeks to include on the board of directors a complementary mix of individuals with diverse backgrounds and skills reflecting the broad set of challenges that the board of directors confronts. These individual qualities can include matters such as experience in the company's industry, technical experience (i.e., medical or research expertise), experience gained in situations comparable to the company's, leadership experience, and relevant geographical diversity.

#### Committees

Our business, property and affairs are managed by or under the direction of the board of directors. Members of the board are kept informed of our business through discussion with the chief executive and financial officers and other officers, by reviewing materials provided to them and by participating at meetings of the board and its committees.

Our board of directors currently has three committees. The Audit Committee consists of Mr. Selter, Mr. Wennekamp and Dr. Rubinfeld, the Compensation Committee consists of Dr. Rubinfeld, Dr. Link, Mr. Selter and Mr. Wennekamp, and the Nomination and Governance Committee consist of Mr. Wennekamp, Dr. Link and Mr. Selter. Such committees operate under a formal charter, copies of which are available on our website at [www.cytrx.com](http://www.cytrx.com), that governs their duties and conduct.

Our board of directors has determined that Mr. Selter, one of the independent directors serving on our Audit Committee, is an "audit committee financial expert" as defined by the SEC's rules. Our board of directors has determined that Messrs. Link, Selter and Wennekamp are "independent" under the current independence standards of both The NASDAQ Capital Market and the SEC.

#### Section 16(a) Beneficial Ownership Reporting Compliance

Each of our executive officers and directors and persons who owns more than 10% of our outstanding shares of common stock is required under Section 16(a) of the Securities Exchange Act to file with the SEC initial reports of ownership and reports of changes in ownership of our common stock and to furnish us with copies of those reports. Based solely on our review of copies of reports we have received and written representations from certain reporting

persons, we believe that our directors and executive officers and greater than 10% shareholders for 2011 complied with all applicable Section 16(a) filing requirements.

#### Code of Ethics

We have adopted a Code of Ethics applicable to all employees, including our principal executive officer, principal financial officer, and principal accounting officer or controller, a copy of which is available on our website at [www.cytrx.com](http://www.cytrx.com). We will furnish, without charge, a copy of our Code of Ethics upon request. Such requests should be directed to Attention: Corporate Secretary, 11726 San Vicente Boulevard, Suite 650, Los Angeles, California, or by telephone at 310-826-5648.

### Board Leadership Structure

Our Board has placed the responsibilities of Chairman with an independent non-employee member of the Board, which we believe provides better accountability between the Board and our management team. We believe it is beneficial to have an independent Chairman whose sole responsibility to us is guiding our Board members as they provide leadership to our executive team. Our Chairman is responsible for communication among the directors; setting the Board meeting agendas in consultation with the President and Chief Executive Officer; and presiding at Board meetings, executive sessions and stockholder meetings. This delineation of duties allows the President and Chief Executive Officer to focus his attention on managing the day-to-day business of the company. We believe this structure provides strong leadership for our Board, while positioning our President and Chief Executive Officer as the leader of the company in the eyes of our employees and other stakeholders.

### Board of Directors Role in Risk Oversight

In connection with its oversight responsibilities, our board of directors, including the Audit Committee, periodically assesses the significant risks that we face. These risks include, but are not limited to, financial, technological, competitive, and operational risks. Our board of directors administers its risk oversight responsibilities through our Chief Executive Officer and Chief Financial Officer, who review and