CYTRX CORP
Form 10-K
March 11, 2011

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, 2010
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	58-1642740
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
11726 San Vicente Blvd, Suite 650, Los Angeles, California	90049
(Address of principal executive offices)	(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	

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 £

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 £ No £

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 £ (Do not check if a smaller reporting company)	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, 2010 (the last business day of the Registrant's most recently completed second fiscal quarter) was approximately $84.5 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 11, 2011 was 109,227,169, exclusive of treasury shares.

CYTRX CORPORATION
2010 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 otherw indicated.

COMPANY OVERVIEW

We are a biopharmaceutical research and development company engaged in the development of high-value human therapeutics, specializing in oncology. Our drug development pipeline includes clinical development of three product candidates for cancer indications, including recently-initiated Phase 2 proof-of-concept clinical trials with bafetinib in patients with advanced, hormone-refractory prostate cancer and relapsed or refractory B-cell chronic lymphocytic leukemia, or B-CLL, an additional planned pharmacokinetic clinical trial with bafetinib in patients with brain cancer, two planned Phase 2 clinical trials for INNO-206 as a treatment for soft tissue sarcomas and pancreatic cancer following an abbreviated safety trial, and clinical trials with tamibarotene for the treatment of non-small-cell lung cancer and acute promyelocytic leukemia, or APL. In addition to our core oncology programs, we own rights to two drug candidates based on our molecular chaperone regulation technology, which are designed to repair or degrade mis-folded proteins associated with disease. Our current business strategy is to seek one or more strategic partnerships to pursue the development of this technology.

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 prodrug	INNO-206	Soft tissue sarcomas	Phase II (2H11)
		Pancreatic cancer	Phase II (2H11)
Tyrosine kinase inhibitor	Bafetinib	B-CLL (B-cell chronic lymphocytic leukemia)	Phase II
		Advanced prostate cancer	Phase II
		Brain cancer	Phase I
Synthetic retinoid	Tamibarotene	Non-small-cell lung cancer	Phase IIb
		APL (acute promyelocytic leukemia)	Pivotal Phase II

OUR CLINICAL DEVELOPMENT PROGRAMS

Our current clinical development programs are discussed below.

INNO-206

INNO-206 (formerly DOXO-EMCH) is a prodrug 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 reach the tumor more quickly.

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 uptake by 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 in its ability to increase the total doxorubicin dose, antitumor efficacy, and 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 against breast, ovarian, pancreatic and small cell lung cancers growing in immunodeficient mice.

Clinical data. A Phase I 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, single doses were administered every 3 weeks at up to six times the standard dosing of doxorubicin without an increase in side effects over those historically observed with 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.

Development Plan. Based on the objective clinical responses seen in the Phase I study, and preclinical data, two Phase 2 clinical trials are planned to be initiated for INNO-206 in 2011 in patients with pancreatic cancer and soft tissue sarcomas.

Bafetinib

Bafetinib (formerly INNO-406) is a novel drug 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 2010, we initiated Phase II clinical trials with bafetinib as a treatment for B-cell chronic lymphocytic leukemia, or B-CLL, and advanced, hormone-refractory prostate cancer, and a pharmacokinetic clinical trial with bafetinib in patients with brain cancer, due to the potent and specific inhibitory properties of bafetinib against Lyn and Fyn kinases, which are overexpressed in those cancers.

Potential Indications for Bafetinib. B-CLL is the most common form of leukemia in adults in Western countries. More than 17,000 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.

Prostate cancer is the second most common malignancy and second-leading cause of cancer death among American men, according to the American Cancer Society. Of those diagnosed, one in 35 men will die of prostate cancer. The

National Cancer Institute estimates that more than 217,000 new cases and more than 32,000 deaths will be attributed to prostate cancer in the U.S. this year. Treatment of the disease can vary significantly from watchful waiting to surgery, radiation or both, followed by hormonal treatment. Hormonal treatment can shrink the cancer, delay its growth and reduce symptoms; however, patients with metastatic prostate cancer usually stop responding to this therapy within two years. The disease at this stage, called metastatic hormone-refractory prostate cancer, is typically treated with chemotherapeutic agents, and patients have a median survival period of less than two years, according to the National Cancer Institute.

Brain tumors can be benign, with no cancer cells, or malignant, with cancer cells that grow quickly. There are two main types of brain cancer. Primary brain cancer, or glioma, starts in the brain and metastatic brain cancer starts somewhere else in the body and moves to the brain. Gliomas represent approximately 70% of the 22,500 malignant primary brain tumors diagnosed annually in American adults. Glioblastoma, the most common type of glioma in adults, is incurable with a median overall survival period of 12-15 months.

Phase I Study. In November 2008, we announced that bafetinib demonstrated clinical responses in patients with CML in a Phase I 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. A positive, dramatic decrease in the number of leukemia cells in the bone marrow was seen in 35% of the patients that were randomly chosen to begin their treatment with the optimal bafetinib dose of 240 mg twice per day.

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.

Development Plan. In 2010, we initiated Phase II clinical trials with bafetinib as a treatment for B-cell chronic lymphocytic leukemia (B-CLL) and advanced, hormone-refractory prostate cancer, and a pharmacokinetic clinical trial with bafetinib in patients with brain cancer.

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 this clinical trial, high-risk B-CLL patients who have failed treatment with first-line agents will self-administer oral doses of bafetinib twice daily. The bafetinib dose used in this trial is based on the highest dose that was best tolerated in the Phase 1 study described above. Patients will be monitored for clinical response, time to disease progression and cancer progression-free survival. Enrollment is expected to be completed 12 to 14 months following initiation of the trial, with potential interim data announcements . The dose of bafetinib may be escalated to 360 mg twice daily if relatively few side effects are observed at the 240 mg twice daily dose.

In September 2010, we initiated the Prostate Advanced Cancer Treatment (PROACT) Phase 2 proof-of-concept clinical trial to evaluate the efficacy and safety of bafetinib in patients with advanced prostate cancer. The open-label PROACT trial is being conducted at City of Hope Cancer Center, located just outside of Los Angeles, California. In the trial, up to 50 patients with metastatic hormone-refractory prostate cancer who have failed first-line therapy with chemotherapy could receive orally available bafetinib at 240 mg twice daily. The trial endpoints are reduction in prostate-specific antibodies and increases in progression-free survival compared to baseline and historical data. An assessment of response to bafetinib (tumor shrinkage, prostate-specific antigen (PSA) reduction and stabilization of disease) will occur after the first 21 patients have been treated with bafetinib for three months. The dose of bafetinib may be escalated to 360 mg twice daily if relatively few side effects are observed at the 240 mg twice daily dose.

In 2010, we also initiated a pharmacokinetic clinical trial with bafetinib in patients with recurrent brain tumors. Results from this trial are expected in the second quarter of 2011 and will be used in evaluating potential further clinical development of bafetinib in patients with brain cancer. Six to eight patients with recurrent primary brain cancer or recurrent brain metastases who have undergone brain surgery will be evaluated in the trial, which is being conducted at City of Hope Cancer Center. The trial's primary objective is to provide neuropharmacokinetic information, such as the ability of bafetinib to cross the blood:brain barrier and, if so, the percentage that enters the brain compared to the amount in systemic blood.

Tamibarotene

Tamibarotene is an orally available, synthetic retinoid rationally designed to overcome resistance and avoid 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 (180,000 in the U.S., 1.35 million worldwide) and the five-year survival ranges between 8%-15%. Non-small cell-lung cancer, or NSCLC, accounts for 85%-90% of all lung cancers, with subsets adenocarcinoma representing 35%-40%, squamous cell carcinoma accounting for 25%-30% and large cell carcinoma accounting for 10%-15%.

A recent 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 for sustained plasma levels during administration. This may enhance tamibarotene's potential efficacy, because patients may be able to experience benefits from the drug over a longer period of time. Tamibarotene does not bind the RAR-γ receptor, the major retinoic acid receptor in the dermal epithelium, which should lessen the occurrence of skin toxicities.

Development Plan. We have initiated a 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. Secondarily, 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. and Mexico.

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 RARα 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 generally 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 relapsed or refractory APL following treatment with ATRA and 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/m2/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 and currently includes six clinical sites in the U.S. We recently 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. In addition, in September 2009, we initiated a dose escalation clinical trial with tamibarotene combined with TRISENOX® (arsenic trioxide) injection (marketed by Cephalon, Inc.) in patients with relapsed APL.

Other Technologies

We own the rights to two drug candidates, arimoclomol and iroxanadine, that are based on our molecular chaperone regulation technology and are designed to repair or degrade mis-folded proteins associated with disease. Our current business strategy is to seek one or more strategic partnerships to pursue the development of that technology or an outright sale of the assets, and we have no current plan for our own further development of these drug candidates.

Our other current technologies are CRL-5861, an intravenous agent for treatment of sickle cell disease and other acute vaso-occlusive disorders, and TranzFect, a delivery technology for DNA-based and conventional vaccines and other potential uses. We currently have no plans for development of these technologies.

Our Separation from RXi Pharmaceuticals Corporation

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 any 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. 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.

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 active pharmaceutical ingredient, or API, for our product candidates. Pursuant to our license with TMRC Co., Ltd., or TMRC, relating to tamibarotene, TMRC will provide us with tamibarotene at a fixed

price and in a quantity and quality sufficient to meet our clinical and commercial needs.

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, bafetinib and tamibarotene, 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 acquired patents and patent applications, and have filed several new patent applications, in connection with our molecular chaperone program.

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 molecular chaperone amplification and other small molecule technology or other 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 11, 2011, our exclusive license to INNO-206 and related technologies includes two granted U.S. and 30 granted foreign patents or allowed applications, and 2 pending U.S. and 21 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 11, 2011, our exclusive license to bafetinib and related technologies includes two granted U.S. and 25 granted foreign patents or allowed applications, and 8 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.

As of March 11, 2011, we hold exclusive licenses in two U.S. patents, one Canadian patent, and one European patent application 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. These exclusive licenses also cover a general method of producing tamibarotene and its close analogs and cover certain intermediates related to this production method.

As of March 11, 2011, we hold ownership rights in 11 issued U.S. and 255 granted foreign patents or allowed applications, and seven pending U.S. and 42 pending foreign applications covering arimoclomol and iroxanadine, our proprietary molecular chaperone regulators, and related technologies. Patents that cover arimoclomol compositions have unextended patent terms until November 2016 or February 2020. Patents covering arimoclomol treatment methods, including insulin resistance, peripheral nervous system disorders, diabetes, central nervous system disorders (ALS, MS, Parkinson's), vascular and endothelial disorders, stroke, and diabetic wound healing, extends patent protection through February 2020 to May 2028. Patents covering iroxanadine compositions have unextended patent terms until August 2017, or until December 2019 for (-)-iroxanadine enantiomeric compositions. Patents that cover iroxanadine treatment methods, including vascular and endothelial disorders, central nervous system disorders (ALS, MS, Parkinson's), stroke, and diabetic wound healing extend patent protection through August 2017 to May 2028. Our molecular chaperone patent portfolio also includes three issued U.S. patents, 43 granted foreign patents, one pending U.S. application, and five pending foreign applications with unextended patent term until November 2016 which cover additional aspects of molecular chaperone technology.

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.

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 expire on a country-by-country basis upon the expiration of the subject patent rights. 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.

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 $4.165 million upon meeting clinical, regulatory, and sales milestones up to and including the first commercial sale of the product for the treatment of APL.

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.

The agreements will expire upon the expiration of the subject patent rights, or 15 years from the date of first commercial sale of product in North America or Europe, as applicable, whichever is later. The agreement may be terminated if either party is in breach and the breach is not cured within a required amount of time. We may also terminate the agreement in the event of a material change in the safety profile of the technology that makes continued development impossible.

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.

Competition

INNO-206 is a prodrug 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, Eli Lilly's Gemzar, 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, Threshhold Pharmaceuticals' TH-302, trabectedin being co-developed by Johnson and Johnson and PharmaMar and ZIOPHARM Oncology's palifosfamide.

Pancreatic cancer patients are typically treated with surgery, radiation and chemotherapy. Eli Lilly's Gemzar is currently approved for the first line treatment of locally advanced or metastatic pancreatic cancer. It is also indicated for the use in patients who have received prior treatment with 5-FU. OSI Pharmaceuticals' Tarceva was approved in 2005 for the use in combination with Gemzar. The NCCN believes the best management for these patients is in a clinical trial. Because of the tremendous unmet need for these patients, many companies are developing new drugs to treat pancreatic cancer. Late stage drugs in clinical trials include Abraxane by Abraxis BioScience, AGS-1C4D4 by Astellas Pharma Inc., and TS-1 by Taiho Pharmaceutical Co.

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 Cephalon, 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.

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 addition, there are several drugs in late-stage development including Eisai's eribulin, Eli Lilly & Co.'s necitumumab and Pfizer's axitinib and crizotinib.

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 recently 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 plan to develop bafetinib initially in cancers other than CML. We selected B-CLL, hormone refractory prostate cancer and brain cancer 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. Lyn and Fyn kinases are overexpressed in advanced prostate cancer and glioblastoma multiforme (GBM), the most common form of brain cancer. Lyn kinase is 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 ArzerraTM and Sanofi-Aventis' OfortaTM. 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.

There are products currently under development by other companies and organizations that could compete with bafetinib in advanced prostate cancer. Products such as chemotherapeutics, androgen metabolism or androgen receptor antagonists, endothelin A receptor antagonists, antisense compounds, angiogenesis inhibitors and gene therapies for cancer are also under development by a number of companies as well. Sanofi-Aventis' Taxotere® (docetaxel) Injection Concentrate was approved by the FDA in 2004 for the therapeutic treatment of metastatic, androgen-independent prostate cancer. In 2010, the FDA approved Dendreon's Provenge (sipuleucel-T) for hormone refractory prostate cancer. In addition, bafetinib may compete with late-stage oral therapies in development such as Johnson and

Johnson's abiraterone and Medivation's MDV3100.

Current therapy for glioblastoma multiforme, the most common form of brain cancer, is surgery followed by radiation therapy and chemotherapy. Merck's Temodar® is approved for treating newly diagnosed GBM concomitantly with radiotherapy and then as a maintenance treatment. Roche's Avastin was approved in May 2009 for treatment of recurrent GBM. We believe that bafetinib's ability to selectively inhibit Lyn and Fyn kinases and to penetrate the brain in an animal model of cancer will be an effective treatment for second-line therapy in GBM. Other drugs in development for GBM include Merck Serono's cilengitide, Myrexis' MPC-6827, and Arno Therapeutics' AR-67.

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 biologic or 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 I 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 II trials, in addition to safety, evaluate the efficacy of the product candidate in a patient population somewhat larger than Phase I trials. Phase III 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 Environmental Protection 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 11, 2011, 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 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 profit of $0.4 million, including gain from the sale of RXi shares and other marketable securities, for the year ended December 31, 2010, and net losses of $4.8 million and $27.0 million for the years ended December 31, 2009 and 2008, respectively. We had an accumulated deficit as of December 31, 2010 of approximately $196.5 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 if the stock price does not increase.

We received notice from The Nasdaq Stock Market on February 18, 2011 that we were not in compliance with the minimum $1.00 closing bid price required by Nasdaq Marketplace Rule 4310(c)(4) and, in accordance with Marketplace Rule 4310(c)(8)(D), could regain compliance if, by August 17, 2011, the closing bid price of our common stock is at or above $1.00 for 10 consecutive business days and we otherwise meet the Nasdaq's continuing listing requirements. In its notice to us, Nasdaq also informed us that, if we did not regain compliance by the stated deadline, we would be granted up to an additional 180 calendar days to regain full compliance while continuing to trade during such time if we meet the Nasdaq's initial listing requirements other than the minimum bid price rule. If we eventually fail to comply with this condition for continued listing and 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 RXi common stock, 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 $0.1 million, $9.5 million and $6.3 million, respectively, for the years ended December 31, 2010, 2009, and 2008. Our revenues in 2009 and 2008 included $9.4 million and $6.2 million, respectively, 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, 2010, we had cash and cash equivalents of approximately $6.3 million, marketable securities of $20.6 million and proceeds from sale of the balance of RXi shares of $6.9 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 2011 of approximately $20.1 million, which includes approximately $3.5 million for our clinical programs for INNO-206, approximately $2.2 million for our clinical programs for bafetinib, approximately $5.5 million for our clinical program for tamibarotene, approximately $2.0 million for general operation of our clinical programs, and approximately $6.8 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, bafetinib and tamibarotene 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 2011. 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, 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 securing centers to conduct trials;
- 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 also 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 I clinical trial and showed limited biological responses against certain tumors. However, these conclusions may not be reproducible in larger clinical trials, including the planned abbreviated safety clinical trial of INNO-206 and the planned Phase 2 clinical trials of INNO-206 as a treatment for soft tissue sarcomas and pancreatic cancer.

Bafetinib demonstrated clinical responses in patients with CML in a Phase I 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, prostate cancer or brain cancer, and there are no assurances that it will be effective in those indications.

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 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.

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, bafetinib and tamibarotene. 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, bafetinib and tamibarotene, 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 own or 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 arimoclomol, iroxanadine or other product candidates would infringe. In addition, if third parties file patent applications or obtain patents claiming technology also claimed by us 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;
- 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.

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).

The agreement under which we have North American rights to tamibarotene provides for our payment of royalties based on net sales of any products, as well as aggregate payments of $4.4 million upon meeting specified clinical, regulatory and sales milestones up to and including the first commercial sale of tamibarotene for the treatment of APL.

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.

Following our acquisition of Innovive in September 2008, we refocused our product development efforts on our oncology drug candidates, which we believe has 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.

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 you.

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, 2010, there were outstanding stock options and warrants to purchase approximately 18.9 million shares of our common stock at a weighted-average exercise price of $1.26 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 $0.62 to $1.56 per share since January 1, 2010, and it may continue to experience significant volatility from time to time. Our ability to raise capital has been materially and adversely affected by the continuing poor economy. Despite the recovery in the U.S. financial markets in 2009, the market remains depressed for private investment in public equity, or PIPEs, transactions on which we have relied for raising needed capital.

Other 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 2. PROPERTIES

We lease our headquarters in Los Angeles, California. The lease covers approximately 6,240 square feet of office and storage space and expires in March 2015. This lease requires us to make monthly payments of approximately $24,890, 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 11, 2011, there were no such claims that we expect, individually or in the aggregate, to have a material adverse affect on us.

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 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
Fiscal Year 2009:		
Fourth Quarter	$ 1.29	$ 0.71
Third Quarter	$ 1.72	$ 0.84
Second Quarter	$ 1.09	$ 0.34
First Quarter	$ 0.45	$ 0.24

Holders

On March 11, 2011, 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. On March 11, 2008, we distributed to holders of our common stock approximately 36% of the outstanding shares of RXi on an approximate 1-for-20 basis.

Equity Compensation Plans

The following table sets forth certain information as of December 31, 2010, regarding securities authorized for issuance under our equity compensation plans:

Plan Category	(a) Number of Securities to be Issued Upon Exercise of Outstanding Options,	(b) Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Issuance Under Equity Compensation

	Warrants and Rights			Plans (Excluding Securities Reflected in Column (a))
Equity compensation plans approved by our security holders:				
2000 Long-Term Incentive Plan	7,243,090	$	1.08	—
2008 Stock Incentive Plan	2,565,500		0.83	7,434,500
Equity compensation plans not approved by our security holders:				
Outstanding warrants (1)	9,062,074		1.47	—
Total	18,870,664	$	1.26	7,434,500

(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 and sales of equity below market price.

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, 2005 to December 31, 2010. 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, 2005, and that all dividends were reinvested. This data was furnished by Zacks Investment Research.

Comparison of Cumulative Total Returns

[Missing Graphic Reference]

	December 31,				
	2006	2007	2008	2009	2010
CytRx Corporation	185.43	275.72	42.29	157.89	142.41
NASDAQ Stock Market Index	110.39	122.14	73.32	106.58	125.93
NASDAQ Pharmaceutical Index	97.87	102.94	95.76	107.62	116.66

Recent Issuances of Unregistered Securities

During the three-month period ended December 31, 2010, we issued 50,000 shares of our common stock, and warrants to purchase a total of 800,000 shares of our common stock at exercise prices ranging from $0.87 to $3.50 per share, in connection with a consulting arrangement, and we issued another 40,000 shares of our common stock upon the cashless exercise of a warrant. The issuances of stock and warrants were exempt from registration under the Securities Act of 1933 pursuant to Section 4(2) of the Securities Act of 1933 and Regulation D under the Act.

Repurchase of Shares

We did not repurchase any of our shares during the year ended December 31, 2010.

Item 6. SELECTED FINANCIAL DATA

General

The following selected financial data are derived from our audited financial statements. Our financial statements for 2010, 2009 and 2008 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.

	2010	2009	2008	2007	2006
Statement of Operations Data:					
Revenues					
Service revenue	$—	$9,400,000	$6,166,000	$7,242,000	$1,859,000
Licensing revenue	100,000	100,000	100,000	101,000	101,000
Grant revenue	—	—	—	116,000	106,000
Total revenues	$100,000	$9,500,000	$6,266,000	$7,459,000	$2,066,000
Deemed dividend for anti-dilution adjustments made to outstanding common stock warrants	—	—	(757,000)	—	(488,000)
Net Profit (loss) applicable to common stockholders	$408,460	$(4,800,000)	$(27,803,000)	$(21,890,000)	$(17,240,000)
Basic and diluted profit (loss) per share applicable to common stock	$0.00	$(0.05)	$(0.30)	$(0.26)	$(0.25)
Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$26,892,000	$32,643,000	$25,042,000	$60,450,000	$30,381,000
Total assets	$36,697,000	$35,277,000	$28,324,000	$64,146,000	$31,636,000
Total stockholders' equity	$30,568,000	$28,348,000	$15,698,000	$40,224,000	$5,150,000

Factors Affecting Comparability

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	.1
Prepaid expenses	.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 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).

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.

Our Statements of Operations as of and for the years ended December 31, 2010, 2009 and 2008 reflect the impact of ASC 718 (previously SFAS No. 123(R), Share-Based Payment ("SFAS 123(R)")). In accordance with the modified prospective transition method, our results of operations for prior periods have not been restated to reflect the impact of SFAS 123(R). Share-based compensation expense recognized under SFAS 123(R) for the years ended December 31, 2010, 2009 and 2008 were $1.6 million, $2.7 million and $2.1 million, respectively. As of December 31, 2010, there was $3.0 million of unrecognized compensation cost related to outstanding options that is expected to be recognized as a component of our operating expenses through 2012. Compensation costs will be adjusted for future changes in estimated forfeitures.

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 engaged in the development of high-value human therapeutics, specializing in oncology. Our drug development pipeline includes clinical development of three product candidates for cancer indications, including recently-initiated Phase 2 proof-of-concept clinical trials with bafetinib in patients with advanced, hormone-refractory prostate cancer and relapsed or refractory B-cell chronic lymphocytic leukemia, or B-CLL, an additional planned pharmacokinetic clinical trial with bafetinib in patients with brain cancer, two planned Phase 2 clinical trials for INNO-206 as a treatment for soft tissue sarcomas and pancreatic cancer following an abbreviated safety trial, and clinical trials with tamibarotene for the treatment of non-small-cell lung cancer and acute promyelocytic leukemia, or APL. In addition to our core oncology programs, we own rights to two drug candidates based on our molecular chaperone regulation technology, which are designed to repair or degrade mis-folded proteins associated with disease. Our current business strategy is to seek one or more strategic partnerships to pursue the development of this technology or an outright sale of the assets.

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, 2010, we had cash and cash equivalents of approximately $6.3 million, marketable securities of $20.6 million and proceeds from sale of the balance of RXi shares of $6.9 million. Management believes that our current cash on hand, together with our marketable securities and proceeds from sale of RXi shares will be sufficient to fund our operations for the foreseeable future. The estimate is based, in part, upon our currently projected expenditures for 2011 of approximately $20.1 million (unaudited), which includes approximately $3.5 million (unaudited) for our clinical programs for INNO-206, approximately $2.2 million (unaudited) for our clinical programs for bafetinib, approximately $5.5 million (unaudited) for our clinical program for tamibarotene, approximately $2.0 million (unaudited) for general operation of our clinical programs, and approximately $6.8 million (unaudited) 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 $8.5 million, $7.5 million, and $10.5 million for the years ended December 31, 2010, 2009 and 2008, or approximately 50%, 44% and 35%, 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 2011 include approximately $3.5 million for our clinical programs for INNO-206, approximately $2.2 million for our clinical programs for bafetinib, approximately $5.5 million for our clinical program for tamibarotene, and approximately $2.0 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 Staff Accounting Bulletin (“SAB”) No. 104, Revenue Recognition. 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 (previously Statement of Financial Accounting Standards No. 68, Research and Development Arrangements). 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 years ended December 31, 2009 and 2008, we recognized approximately $9.4 million and $6.2 million, respectively, of service revenue related to this transaction. No service revenue related to the ALSCRT transaction was recognized in 2010.

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 the Company's 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 (previously SFAS No. 123(R), Share-Based Payment ("SFAS 123(R)")), 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 718 (previously SFAS No. 123(R)), ASC 505-50 (previously Emerging Issues Task Force Issue No. 96-18 ("EITF 96-18")), Accounting for Equity Instruments that are Issued to other than Employees for Acquiring, or in Conjunction with Selling Goods or Services and ASC 505

(previously EITF 00-18, Accounting Recognition for Certain Transactions involving Equity Instruments Granted to Other Than Employees), 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 15.4 million shares, 24.4 million shares and 15.2 million shares at December 31, 2010, 2009 and 2008, respectively.

As a result of our March 11, 2008 distribution by our stockholders of approximately 36% of the outstanding shares of RXi, we recorded a deemed dividend of approximately $757,000. The deemed dividend was reflected as an adjustment to net loss for the first quarter of 2008 to arrive at net loss applicable to common stockholders on the consolidated statement of operations and for purposes of calculating basic and diluted earnings per shares.

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.

	Quarters Ended			
	March 31	June 30	September 30	December 31
	(In thousands, except per share data)			
2010				
Total revenues	$—	$—	$—	$100
Net income (loss)	(611)	1,294	(4,414)	4,140
Net income (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
2009				
Total revenues	$1,483	$1,000	$6,954	$100
Net income (loss)	(3,973)	(2,226)	3,863	(2,983)
Net income (loss) applicable to common stockholders	$(3,973)	$(2,226)	$3,863	$(2,983)
Basic and diluted loss per share applicable to common stock	$(0.04)	$(0.02)	$0.04	$(0.03)

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 2010 and 2009, we incurred $1.6 million and $2.3 million, respectively, in employee non-cash compensation expenses.

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, 2010, we had cash and cash equivalents of approximately $6.3 million, marketable securities of $20.6 million and proceeds from sale of the balance of RXi shares of $6.9 million. Management believes that our current cash on hand, together with our marketable securities and proceeds from sale of RXI shares will be sufficient to fund our operations for the foreseeable future. The estimate is based, in part, upon our currently projected expenditures for 2011 of approximately $20.1 million, which includes approximately $3.5 million for our clinical programs for INNO-206, approximately $2.2 million for our clinical programs for bafetinib, approximately $5.5 million for our clinical program for tamibarotene, approximately $2.0 million for general operation of our clinical programs, and approximately $6.8 million for other general and administrative expenses. These projected expenditures are also based upon numerous other assumptions and subject to many uncertainties, and 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.

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. Our ability to raise capital has been materially and adversely affected by the continuing poor economy. Despite the recovery in the U.S. financial markets in 2009, the market remains severely depressed for private investment in public equities, or PIPEs, transactions on which we have relied for raising needed capital. 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 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 a gain of $15.8 million from the sale of RXi shares, $1.6 million of stock option and warrant expense and $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 of stock option and warrant expense and $0.7 million fair value adjustment of the warrant liability.

Net loss for the year ended December 31, 2008 was $27.0 million, and cash used for operating activities for that period was $19.4 million. The net loss for the year reflects $6.2 million of revenue recognized under the 2006 agreement with ALSCRT, a expense of $8.0 million related to the acquisition of Innovive's in-process research and development, a loss of $3.9 million in our equity in RXi, and $2.1 million of stock option and warrant expense.

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.

For the year ended December 31, 2008, $7.0 million was used in investing activities including $10.0 million of RXi funds resulting from converting marketable securities to cash equivalents that is not available to us due to the deconsolidation. The total cash outlay to acquire Innovive totaled $5.7 million, which related primarily to the payment of Innovive's accounts payable. The other $0.9 million was used for the purchase of equipment and furnishings, primarily associated with equipping the San Diego laboratory.

Cash provided by financing activities for the year ended December 31, 2010 was $0.2 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.

Cash provided by financing activities for the year ended December 31, 2008 was $1.0 million. During 2008, we received $1.0 million from the exercise of 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

2011	$547	$ 2,455	$3,002	$ 8,667	$11,669
2012	471	—	471	3,240	3,711
2013	332	—	332	—	332
2014	386	—	386	—	386
2015 and thereafter	55	—	55	—	55
Total	$1,791	$ 2,455	$4,246	$ 11,907	$16,153

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

(2) The Company is entitled to receive future rental income under subleases in place which would be offset against future operating lease obligations as follows: $350,000 in 2011 and $235,000 in 2012.

(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 the Company's 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.

We apply the disclosure provisions of ASC 460 (formerly FASB Interpretation No. ("FIN") 45, Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Other), 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, 2010, we had United States federal and state net operating loss carryforwards of $100.3 million and $79.4 million, respectively, available to offset against future taxable income, which expire in 2011 through 2030. Approximately $13.7 million of our federal net operating loss carryforwards are limited in their availability to $363,000 annually. Management currently believes that the remaining $86.6 million in federal net operating loss carryforwards, and the $65.7 million in state net operating loss carryforwards as of December 31, 2010, are unrestricted. However, management is reviewing its recent equity transactions to determine if they may have resulted in any further restrictions on the Company's net operating loss carryforwards. As of December 31, 2010, we also had research and development and alternative minimum tax credits for federal and state purposes of approximately $4.8 million and $5.2 million, respectively, available for offset against future income taxes, which expire in 2022 through 2030. 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 $0.4 million, ($4.8 million) and ($27.8 million) for the years ended December 31, 2010, 2009 and 2008, respectively.

During 2010, we recognized no service revenues. During fiscal 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. In the year ended December 31, 2008, we recognized $6.2 million in service revenues.

During 2010, 2009 and 2008, 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 fiscal 2010, 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,		
	2010	2009	2008
	(In thousands)		
Research and development expenses	$8,207	$5,621	$9,913
Non-cash research and development expenses	92	62	(224)
Impairment loss on fixed assets	—	1,187	—
Employee stock option expense	208	672	777
	$8,507	$7,542	$10,466

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 2010, 2009 and 2008 relate to our various development programs. In 2010, we initiated two Phase 2 clinical trials with bafetinib and one with tamibarotene, and made preparations to initiate several additional clinical trials with INNO-206, which resulted in an increase in research and development expenses over 2009. Research and development expenses in 2009 decreased as compared to 2008, as we substantially completed the initial phase of our new-drug discovery research in our laboratory facility in San Diego, California. In 2010, our development costs associated included approximately $2.0 million for our clinical programs for INNO-206, approximately $2.7 million for our clinical programs for bafetinib, $1.4 million for our clinical program for tamibarotene, and approximately $2.1 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 (recovery) of $0.1 million, $0.1 million and $(0.2 million) in this regard during 2010, 2009 and 2008, respectively. In 2010, we recorded $0.2 million of employee stock option expense, as compared to $0.7 million in 2009 and $0.8 million in 2008.

We also incurred an expenditure of $8.0 million in 2008 related to the acquisition of Innovive's in-process research and development, which has been reflected as a separate line item on our Consolidated Statements of Operations.

In 2011, we expect our research and development expenses to increase as a result of our clinical programs with INNO-206, bafetinib and tamibarotene.

General and administrative expenses

	Year Ended December 31,		
	2010	2009	2008
	(In thousands)		
General and administrative expenses	$6,831	$7,128	$9,134
Stock, stock option and warrant expenses to non-employees and consultants	614	421	189
Employee stock option expense	791	1,579	1,610
	$8,236	$9,128	$10,933

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 $6.8 million in 2010, $7.1 million in 2009 and $9.1 million in 2008. In 2008, we recognized RXi-related expenses for January and February only of $1.3 million. No RXi-related expenses were recognized in 2009 or 2010. 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 account 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 $0.8 million in 2010, $1.6 million in 2009 and $1.6 million in 2008.

Depreciation and amortization

Depreciation and amortization expenses for the years ended December 31, 2010, 2009 and 2008 were $108,000, $475,000, and $625,000, 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 2010 and 2009, we recognized gains of $0.9 million and $0.7 million, respectively, on the valuation of our warrant derivative liability related to warrants issued in July 2009. In 2010 and 2009, we recognized gains of $15.8 and $1.2 million, respectively, on the sale of RXi shares. In March 2008, we recognized a gain of $0.2 million on the transfer of some RXi common stock to certain employees.

Interest income

Interest income was $0.3 million in 2010, $0.3 million in 2009 and $1.2 million in 2008. 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.

Noncontrolling Interest in RXi

We offset $88,000 of losses in noncontrolling interest in RXi against our net loss for the months of January and February 2008. For the remainder of the year and thereafter, RXi's gain and losses were accounted for under the equity method, because we owned less than 50% of RXi following our March 11, 2008 distribution to our stockholders of RXi shares. The investment balance in RXi was eventually reduced to zero and we stopped recording our share of losses from RXi. As a consequence of our subsequent sales of common stock of RXi, we began to account for those shares as available for sale, and any increases or decreases were included as part of comprehensive income or loss and shown on the balance sheet at market value, based on RXi's closing stock price as reported on The Nasdaq Stock Market. We sold all of our remaining shares of RXi in December 2010.

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 (formerly, SFAS No. 165, Subsequent Events) 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 June 2009, the FASB amended ASC 860, (formerly SFAS No. 166, Accounting for Transfers of Financial Assets, an amendment to SFAS No. 140). ASC 860 eliminates the concept of a "qualifying special-purpose entity," changes the requirements for derecognizing financial assets, and requires additional disclosures in order to enhance information reported to users of financial statements by providing greater transparency about transfers of financial assets,

including securitization transactions, and an entity's continuing involvement in and exposure to the risks related to transferred financial assets. ASC 860 is effective for fiscal years beginning after November 15, 2009. The adoption of ASC 860 had no impact on our financial statements.

In June 2009, the FASB amended ASC 810 (formerly SFAS No.167, Amendments to FASB Interpretation No. 46). The amendments include: (1) the elimination of the exemption for qualifying special purpose entities, (2) a new approach for determining who should consolidate a variable-interest entity, and (3) changes to when it is necessary to reassess who should consolidate a variable-interest entity. ASC 810 is effective for the first annual reporting period beginning after November 15, 2009 and for interim periods within that first annual reporting period. The adoption of ASC 810 did not have a material impact on our financial statements.

In June 2009, the FASB issued new guidance which is now part of ASC 105-10 (formerly Statement of Financial Accounting Standards No. 168, The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles). ASC 105-10 replaces FASB Statement No. 162, "The Hierarchy of Generally Accepted Accounting Principles", and establishes the FASB Accounting Standards Codification as the source of authoritative accounting principles recognized by the FASB to be applied by nongovernmental entities in the preparation of financial statements in conformity with generally accepted accounting principles. ASC 105-10 is effective for interim and annual periods ending after September 15, 2009. The adoption of ASC 105-10 did not have a material impact on our financial statements.

In January, 2010, the FASB issued ASU 2010-06, Improving Disclosures about Fair Value Measurements. The standard amends ASC Topic 820, Fair Value Measurements and Disclosures, 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.

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, 2010, 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, 2010 and 2009, and for each of the three years in the period ended December 31, 2010, together with the reports thereon of our independent registered public accounting firms, are set forth on pages F-1 to F- 24 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, 2010, 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, 2010.

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, 2010 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, 2010. 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, 2010.

Our internal control over financial reporting as of December 31, 2010 has been audited by BDO USA, LLP, an independent registered public accounting firm, as stated in their report thereon set forth on pages F-22, 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.	70	III	Director, Chairman of the Board (2) (3) (4)
Steven A. Kriegsman	69	II	Director, Chief Executive Officer, President
Marvin R. Selter	83	II	Director, Vice Chairman of the Board (2) (3) (4)
Louis Ignarro, Ph.D.	69	I	Director
Joseph Rubinfeld, Ph.D.	78	I	Director
Richard L. Wennekamp	68	II	Director (2) (3) (4)
John Caloz	59	—	Chief Financial Officer
Daniel Levitt, M.D., Ph.D.	63	—	Chief Medical Officer
D. Scott Geyer	56	—	Sr. Vice President-Manufacturing
D. Scott Wieland	51	—	Sr. Vice President-Drug Development
Benjamin S. Levin	34	—	General Counsel, Vice President — Legal Affairs and Corporate Secretary
David J. Haen	32	—	Vice President – Business Development

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(1) Our Class II directors serve until the 2011 annual meeting of stockholders, our Class III director serves until the 2012 annual meeting of stockholders, and our Class I directors serve until the 2013 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. Mr. Wennekamp 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 also serves as a director of Alexion Pharmaceuticals, Inc., Celsion Corporation, Inc. and Discovery Laboratories, Inc.

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 RXi Pharmaceuticals Corporation and is Chairman of its Compensation and Transactions Committees. He previously served as Director and Chairman of Global Genomics from June 2000. 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, and the Palisades-Malibu YMCA.

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 and serves 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 1998 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, Compensation Committee, and Nomination and Governance Committee consist of Messrs. Selter, Link, and Wennekamp. Such committees operate under a formal charter, copies of which are available on our website at 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

Our executive officers and directors and persons who owns more than 10% of our outstanding shares of common stock are 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 2010 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. 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 nonexecutive 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 assess the operations of our business as well as operating management's identification, assessment and mitigation of the material risks affecting our operations.

Item 11. EXECUTIVE COMPENSATION

Compensation Discussion and Analysis

Overview of Executive Compensation Program

The Compensation Committee of our Board of Directors has responsibility for establishing, implementing and monitoring our executive compensation program philosophy and practices. Generally speaking, the Compensation Committee has advisory authority only with respect to the compensation of our Chief Executive Officer and other named executive officers. The final authority to make compensation decisions rests with our Board of Directors.

The Compensation Committee seeks to ensure that the total compensation paid to our named executive officers is fair, reasonable and competitive. Generally, the types of compensation and benefits provided to the named executive officers are similar to those provided to our other officers.

The Compensation Committee operates under a formal charter, copies of which are available on our website at www.cytrx.com, that governs its duties and conduct.

Throughout this Annual Report, the individuals included in the Summary Compensation Table below are referred to as our "named executive officers."

Compensation Philosophy and Objectives

The components of our executive compensation consist of salary, annual cash bonuses awarded based on the Compensation Committee's subjective assessment of the achievement of corporate goals and each individual executive's job performance during the past year, stock option grants to provide executives with longer-term incentives, and occasional special compensation awards (either cash, stock or stock options) to reward extraordinary efforts or results.

The Compensation Committee believes that an effective executive compensation program should provide base annual compensation that is reasonable in relation to individual executive's job responsibilities and reward the achievement of strategic goals of our company. We use annual and other periodic cash bonuses to reward an officer's achievement of specific goals, including goals related to the development of our drug candidates and management of working capital. We use employee stock options as a retention tool and as a means to align the executive's long-term interests with those of our stockholders, with the ultimate objective of affording our executives an appropriate incentive to improve stockholder value. The Compensation Committee evaluates both performance and compensation to maintain our company's ability to attract and retain excellent employees in key positions and to assure that compensation provided to key employees remains competitive relative to the compensation paid to similarly situated executives of comparable companies.

Each of the corporate goals determined and reviewed by the Compensation Committee results from a collaboration among our named executive officers, including the leadership of our President and Chief Executive Officer and the support of our principal legal, financial, clinical, medical and business development officers. The Committee's assessment of the relative contribution of each named executive officer is based on periodic reports to our full Board of Directors regarding the progress of these business accomplishments and the individual efforts of our named executive officers, and year-end consultations with our President and Chief Executive Officer that are a normal part of the Committee's compensation determinations. The Committee employs no objective measure of any individual's contribution.

The bonus amounts awarded to our eligible named executive officers are a function of their office and total compensation relative to the total compensation of our President and Chief Executive Officer, as adjusted by their relative employee evaluation, and with consideration given to comparable company data for similarly situated employees. The bonus amounts awarded to each named executive officer is set forth in the Summary Compensation Table.

Because of the size of our company, the small number of executive officers in our company, and our company's financial priorities, the Compensation Committee has not implemented any pension benefits, deferred compensation plans or other similar plans for our named executive officers.

Role of Executive Officers in Compensation Decisions

The Compensation Committee annually recommends the compensation of our named executive officers to our Board of Directors, which has the final decision-making authority. Our Board of Directors, at its discretion, may accept or reject the Committee's recommendations or require revisions to such recommendations.

Our President and Chief Executive Officer, or CEO, typically attends all meetings of the Compensation Committee, except for executive sessions. At the request of the Compensation Committee, our CEO provides his assessment of the performance of our named executive officers, other than himself. Our CEO also takes an active part in the discussions of the compensation of named executive officers other than himself and assists in the development of a review matrix of each executive's contributions to the goals of the company that forms the basis for some compensation determinations. The Compensation Committee grants due consideration to our CEO's assessments when making recommendations to our Board of Directors regarding the compensation of our named executive officers. All Compensation Committee deliberations and determinations regarding the compensation of our CEO are made without the presence of our CEO. All recommendations regarding our CEO's compensation are based on the Compensation Committee's own assessment and evaluation, which are reviewed and acted upon by our Board of Directors.

Setting Executive Compensation

Based on the foregoing objectives, the Compensation Committee has structured the company's annual cash and incentive-based cash and non-cash executive compensation to seek to motivate our named executives to achieve the company's business goals, including goals related to the development of the our drug candidates and management of working capital, to reward the executives for achieving such goals, and to retain the executives. In doing so, the Compensation Committee historically has not employed outside compensation consultants. However, during 2010, the Compensation Committee obtained three industry compensation surveys and used them in its compensation deliberations regarding cash and equity compensation for our executive officers. The surveys used were an Equilar survey of public companies with a market capitalization between $50 million and $200 million, a survey of public and private life sciences companies of all sizes provided by Radford, and a survey of public and private companies in Los Angeles provided by salary.com (which the Compensation Committee uses to adjust to geographic differences in cost of living).

The Compensation Committee utilized this data to set annual salary increases and bonus amounts for our executive officers at levels targeted at or around the third quartile of compensation amounts provided to executives at comparable companies, considering each individual's experience level related to their position with us. The Compensation Committee has no policy regarding the use of benchmarks, and we have no established policy or target for the allocation between cash and non-cash incentive compensation.

The Compensation Committee is authorized to retain its own independent advisors to assist in carrying out its responsibilities, but has not relied upon outside compensation consultants.

Performance-driven Compensation

We emphasize performance in annually reviewing and setting our executive officers' base salary, bonuses and equity incentive compensation. This emphasis on performance with respect to a substantial portion of compensation is intended to motivate our executive officers to pursue our corporate goals, reward them for achievement of these goals and align their interests with those of our stockholders.

Each year, we determine goals that we hope to achieve in the coming year, both on a corporate and individual basis. Our overall corporate performance as compared to these goals, and an individual's performance compared to his or her individual goals, primarily drive the recommendations that the compensation committee makes with respect to each executive officers' base salary, cash bonusand equity incentive compensation. Other factors, such as larger macroeconomic conditions of the industry and market in which we compete, as well as strategic business decisions and issues related to key employee retention, also influence compensation decisions. For example, for 2009, in response to the financial crisis in late 2008, our management and Compensation Committee determined that no salary increase would be made in 2009.

Individual performance goals for each year initially are identified and developed by senior executives through a self-evaluation and goal-setting process, and our CEO refines and documents those goals in conjunction with the Compensation Committee. At the end of the year, the Compensation Committee reviews each performance goal and determines the extent to which we achieved such goals, and our CEO assesses the achievement of specific performance goals relating to other executive officers.

In establishing performance goals, the Compensation Committee considers whether the goals could possibly result in an incentive for any executives to take unwarranted risks in our company's business and generally seeks to avoid creating any such incentives.

Company Performance Goals

For 2010, the Compensation Committee and the Board of Directors approved the following performance goals:

- Initiate up to three clinical trials for bafetinib in patients with CLL, prostate cancer and brain cancer
- Finalize INNO-206 formulation for clinical development
- Initiate up to three clinical trials for INNO-206 in patients with pancreatic cancer, soft tissue sarcomas and stomach cancer
- Continue development of tamibarotene for APL, and consider expansion of tamibarotene development into new indications
- Review potential in-licensing and acquisition opportunities in oncology
- Seek opportunities to spin out, sell or partner molecular chaperone assets
- Dispose of some or all of the Company's RXi stock to raise working capital
- Continue compliance with financial and legal regulations, remain in good standing with all financial and legal regulatory agencies

For 2010, the Compensation Committee determined that each of the corporate goals had either been achieved, or substantial progress towards achievement had been made, and noted the particular contributions of executive officers to the achievement of those goals.

Individual Performance

The Compensation Committee reviews our executive officers' performance based on overall achievement of the corporate goals and a review of individual goals developed for each executive officer every year. The Compensation Committee, with the assistance of our CEO, determines the relative achievement of the performance goals applicable to each executive officer, and assigns a performance rating based on a set of criteria set forth in an evaluation form. No specific formula is used with respect to setting any particular element of compensation based on the individual performance metrics. The score assigned to each officer was based on a subjective assessment by our Compensation Committee members of the officer's performance against the scoring standards of:

1 – Consistently Exceeds Expectations
2 – Sometimes Exceeds Expectations
3 – Meets Expectations
4 – Sometimes Meets Expectations
5 – Needs Improvement

The numerical job scores, with a 1 being the best, and 5 being the worst, are determined based on an initial self-assessment by the officer, which is subject to change based on an evaluation of the self-assessment by the officer's direct supervisor and on the Compensation Committee's own assessment of the officer's job performance.

For 2010, our Compensation Committee determined that the individual performance scores indicated below were merited by the officer's respective contributions to our key business achievements discussed above, as well as the performance of their day-to-day responsibilities. On an officer-by-officer basis, our Compensation Committee also considered the following:

Mr. Kriegsman's individual performance goals relate primarily to overall corporate objectives, including building stockholder value, managing working capital, management and successful operation of the executive management team, and development of personnel for future success. Based on those criteria, and noting our non-dilutive management of working capital through sales of RXi shares and successful completion of key strategic clinical goals, the Compensation Committee gave a rating of 1.2 to Mr. Kriegsman.

Mr. Caloz's individual performance goals relate primarily to achievement of key financial objectives, such as managing and raising working capital, controlling spending, managing accounting personnel and maintaining regulatory compliance. Based on those criteria, the Compensation Committee noted Mr. Caloz's role in the improved performance of the accounting department, its compliance with filing deadlines, and our non-dilutive sales of RXi shares, and gave a rating of 2.4 to Mr. Caloz.

Dr. Levitt's individual performance goals relate primarily to the achievement of key strategic and clinical objectives related to our clinical research programs, including ultimate oversight of the design and execution of our clinical programs, and analysis and implementation of new clinical opportunities improve stockholder value. Based on those criteria, the Compensation Committee noted Dr. Levitt's efforts towards our achievement of our key clinical goals, and his development of strategic plans to build value, and gave a rating of 1.1 to Dr. Levitt.

Mr. Levin's individual performance goals relate primarily to the management of the company's legal risk, advice provided to the Board of Directors and management, and maintaining regulatory compliance. Based on those criteria, the Compensation Committee noted Mr. Levin's timely and useful advice on key corporate matters that reduced corporate risk, and his work ensuring compliance with various regulations, and gave a rating of 1.2 to Mr. Levin.

Dr. Wieland's individual performance goals relate primarily to the execution of the objectives related to our clinical development, including planning, initiation, budgeting and management of our clinical programs. Based on those criteria, the Compensation Committee noted Dr. Wieland's role in our achievement of key clinical goals and gave a rating of 2.0 to Dr. Wieland.

2010 Executive Compensation Components

For 2010, as in recent years, the principal components of compensation for the named executive officers were:

- base salary;
- annual bonuses; and
- equity incentive compensation.

Base Salary

The Company provides named executive officers and other employees with base salary to compensate them for services rendered during the year. Generally, the base salary element of compensation is used to recognize the experience, skills, knowledge and responsibilities required of each named executive officer, and over time reflects our executive officers' overall sustained performance and contributions to our business.

During its review of base salaries for executives, the Compensation Committee primarily considers:

- the negotiated terms of each executive's employment agreement, if any;
- an internal review of the executive's compensation, both individually and relative to other named executive officers;
- each executive's individual performance; and
- to a lesser extent, base salaries paid by comparable companies.

Salary levels are typically considered annually as part of the company's performance review process, as well as upon a change in job responsibility. Merit-based increases to salaries are based on the company's available resources and the Compensation Committee's assessment of the individual's performance. Both assessments are based upon written evaluations of such criteria as job knowledge, communication, problem solving, initiative, goal-setting, and expense management. The increase in 2010 base salaries over 2009 was made in consideration of our successful achievement or substantial progress towards the corporate performance goals for 2010, achievement of individual performance goals as they related to each executive officer and the subjective assessment of each executive officer's performance of major job responsibilities. Each of the base salary increases was reviewed in light of the Equilar, Radford and salary.com survey data to validate that they were within acceptable ranges based on market salaries.

Annual and Special Bonuses

The Compensation Committee has not established an incentive compensation program with fixed performance targets. Because we do not generate significant revenues and have not commercially released any products, the Compensation Committee bases its discretionary annual bonus awards on the achievement of corporate and individual goals, efforts related to extraordinary transactions, effective fund-raising efforts, effective management of personnel and capital resources, and bonuses paid by comparable companies, among other criteria. Mr. Kriegsman's employment agreement entitles him to an annual cash bonus in an amount to be determined in our discretion, but not less than $150,000, and Dr. Levitt's employment agreement provides that his bonus will not be less than 25% of his base salary. Any cash bonuses to our other named executive officers are entirely in our discretion.

During 2010, the Compensation Committee granted Mr. Kriegsman an annual cash bonus of $450,000, and granted cash bonuses to the other named executive officers ranging from $25,000 to $135,000, principally based on their efforts in helping us advance the development of our products and raise capital.

Equity Incentive Compensation

We believe that strong long-term corporate performance is achieved with a corporate culture that encourages a long-term focus by our executive officers through the use of equity awards, the value of which depends on our stock performance. We have established equity incentive plans to provide all of our employees, including our executive officers, with incentives to help align those employees' interests with the interests of our stockholders and to enable them to participate in the long-term appreciation of our stockholder value. Additionally, equity awards provide an important retention tool for key employees, as the awards generally are subject to vesting over an extended period of time based on continued service with us.

Typically, equity awards are granted annually at the end of each year based primarily on corporate performance as a whole during the preceding year. In addition, we may grant equity awards upon the occurrence of certain events during the year, for example, upon an employee's hire or achievement of a significant business objective.

No formula is used in setting equity award grants and the determination of whether to grant equity awards, as well as the size of such equity awards, to our executive officers; rather, it involves subjective assessments by our Board of Directors, Compensation Committee and, with respect to executive officers other than himself, our CEO. Generally, annual equity awards are driven by our retention of experienced employees, and we consider individual performance and contributions during the preceding year to the extent our Board of Directors and Compensation Committee believe such factors are relevant. As with base salary and cash bonuses, for 2010 our Board of Directors and compensation Committee also considered data from three surveys in determining equity award grants to our executive officers.

In 2010, the Compensation Committee granted to Mr. Kriegsman nonqualified options to purchase 750,000 shares of our common stock at a price of $1.01 per share, which equaled the closing market price on the date of grant. The option vests monthly over three years, unless Mr. Kriegsman's employment is terminated by us without "cause," or by Mr. Kriegsman for "good reason," in which case they vest immediately. In addition, in connection with the annual review of our other named executive officers, the Compensation Committee also granted stock options to those named executive officers. All of these other stock options had an exercise price equal to the closing market price on the date of grant, and also vest monthly over three years, provided that such executives remain in our employ through such monthly vesting periods.

Generally speaking, we have not taken into consideration any amounts realized by our named executive officers from prior stock option or stock awards in determining whether to grant new stock options or stock awards. No named executive officers have exercised options since 2003.

Retirement Plans, Perquisites and Other Personal Benefits

Our executive officers are eligible to participate in the same group insurance and employee benefit plans as our other salaried employees. These benefits include medical, dental, vision, and disability benefits and life insurance.

We have adopted a tax-qualified employee savings and retirement plan, our 401(k) Plan, for eligible U.S. employees, including our named executive officers. Eligible employees may elect to defer a percentage of their eligible compensation in the 401(k) Plan, subject to the statutorily prescribed annual limit. We may make matching contributions on behalf of all participants in the 401(k) Plan in an amount determined by our board of directors. We did not make any matching contribution to the 401(k) Plan for 2010. Matching contributions, if any, are subject to a vesting schedule; all employee contributions are at all times fully vested. We intend the 401(k) Plan, and the accompanying trust, to qualify under Sections 401(k) and 501 of the Internal Revenue Code so that contributions by employees to the 401(k) Plan, and income earned (if any) on plan contributions, are not taxable to employees until withdrawn from the 401(k) Plan, and so that we will be able to deduct our contributions, if any, when made. The trustee under the 401(k) Plan, at the direction of each participant, may invest the assets of the 401(k) Plan in any of a number of investment options.

We do not provide any of our executive officers with any other perquisites or personal benefits, other than benefits to Mr. Kriegsman provided for in his employment agreement. As required by his employment agreement, during 2010 we paid insurance premiums with respect to a life insurance policy for Mr. Kriegsman which had a face value of approximately $1.4 million as of December 31, 2010 and under which Mr. Kriegsman's designee is the beneficiary. We periodically review the levels of perquisites and other personal benefits provided to our named executive officers, but no changes to these benefits were made during 2010, and we do not expect any such changes in the foreseeable future.

Employment Agreements and Severance Arrangements

We have entered into written employment agreements with each of our named executive officers. The main purpose of these agreements is to protect the company from business risks such as competition for the executives' service, loss of confidentiality or trade secrets, and solicitation of our other employees, and to define our right to terminate the employment relationship. The employment agreements also protect the executive from termination without "cause" (as defined) and, in Mr. Kriegsman's case, entitles him to resign for "good reason" (as defined). Each employment agreement was individually negotiated, so there are some minor variations in the terms among executive officers. Generally speaking, however, the employment agreements provide for termination and severance benefits that the Compensation Committee believes are consistent with industry practices for similarly situated executives. The Compensation Committee believes that the termination and severance benefits help the company retain the named

executive officers by providing them with a competitive employment arrangement and protection against unknowns such as termination without “cause” that go along with the position.

In the event of termination without “cause,” the named executive officers will be entitled to a lump-sum payment equal to six months of base salary (24 months in the case of Mr. Kriegsman). Mr. Kriegsman’s employment agreement also provides for our continuation of Mr. Kriegsman’s life insurance and medical benefits during his 24-month severance period. If Mr. Kriegsman’s employment is terminated by us without “cause,” or by Mr. Kriegsman for “good reason,” within two years following a change of control of CytRx, he also would be entitled under his employment agreement to receive a “gross-up” payment equal to the sum of any excise tax on his termination benefits (including any accelerated vesting of his options under our Plans as described below) plus any penalties and interest.

Change of Control Arrangements

The company's 2000 Long-Term Incentive Plan and 2008 Stock Incentive Plan provide generally that, upon a change of control of CytRx, all unvested stock options and awards under the Plans held by plan participants, including the named executive officers, will become immediately vested and exercisable immediately prior to the effective date of the transaction. The Compensation Committee believes that such "single trigger" change of control policy is consistent with the objective of aligning the interests of the named executive officer's and of the company's stockholders by allowing the executives to participate equally with stockholders in the event of a change of control transaction.

The foregoing severance and change of control arrangements, including the quantification of the payment and benefits provided under these arrangements, are described in more detail elsewhere in this Annual Report under the heading "Executive Compensation – Potential Payments Upon Termination or Change of Control."

Ownership Guidelines

The Compensation Committee has no requirement that each named executive officer maintain a minimum ownership interest in our company.

Our long-term incentive compensation consists solely of periodic grants of stock options to our named executive officers. The stock option program:

- links the creation of stockholder value with executive compensation;
- provides increased equity ownership by executives;
- functions as a retention tool, because of the vesting features included in all options granted by the Compensation Committee; and
- helps us to maintain competitive levels of total compensation.

We normally grant stock options to new executive officers when they join our company based upon their position with us and their relevant prior experience. The options granted by the Compensation Committee generally vest monthly over the first three years of the ten-year option term. Vesting and exercise rights generally (except in the case of Mr. Kriegsman) cease upon termination of employment (or, in the case of exercise rights, 90 days thereafter), except in the case of death (subject to a one-year limitation), disability or retirement. Prior to the exercise of an option, the holder has no rights as a stockholder with respect to the shares subject to such option, including voting rights and the right to receive dividends or dividend equivalents. In addition to the initial option grants, our Compensation Committee may grant additional options to retain our executives and reward, or provide incentive for, the achievement of corporate goals and strong individual performance. Our Board of Directors has granted our President and Chief Executive Officer discretion to grant up to 100,000 options to employees upon joining our company, and to make grants from an additional "discretionary pool" of up to 100,000 options during each annual employee review cycle. Options are granted based on a combination of individual contributions to our company and on general corporate achievements, which may include the attainment of product development milestones (such as commencement and completion of clinical trials) and attaining other annual corporate goals and objectives. On an annual basis, the Compensation Committee assesses the appropriate individual and corporate goals for our executives and provides additional option grants based upon the achievement by the new executives of both individual and corporate goals. We expect that we will continue to provide new employees with initial option grants in the future to provide long-term compensation incentives and will continue to rely on performance-based and retention grants to provide additional incentives for current employees. Additionally, in the future, the Compensation Committee may consider awarding additional or alternative

forms of equity incentives, such as grants of bonus stock, restricted stock and restricted stock units.

It is our policy to award stock options at an exercise price equal to The NASDAQ Capital Market's closing price of our common stock on the date of the grant. In certain limited circumstances, the Compensation Committee may grant options to an executive at an exercise price in excess of the closing price of the common stock on the grant date. The Compensation Committee has never granted options with an exercise price that is less than the closing price of our common stock on the grant date, nor has it granted options which are priced on a date other than the grant date. For purposes of determining the exercise price of stock options, the grant date is deemed to be the first day of employment for newly hired employees, or the date on which the Compensation Committee or the Chief Executive Officer, as applicable, approves the stock option grant to existing employees.

We have no program, practice or plan to grant stock options to our executive officers, including new executive officers, in coordination with the release of material nonpublic information. We also have not timed the release of material nonpublic information for the purpose of affecting the value of stock options or other compensation to our executive officers, and we have no plan to do so. We have no policy regarding the adjustment or recovery of stock option awards in connection with the restatement of our financial statements, as our stock option awards have not been tied to the achievement of specific financial goals.

Tax and Accounting Implications

Deductibility of Executive Compensation

As part of its role, the Compensation Committee reviews and considers the deductibility of executive compensation under Section 162(m) of the Internal Revenue Code, which provides that corporations may not deduct compensation of more than $1,000,000 that is paid to certain individuals. We believe that compensation paid to our executive officers generally is fully deductible for federal income tax purposes.

Accounting for Share-Based Compensation

Beginning on January 1, 2006, we began accounting for share-based compensation in accordance with the requirements of FASB Statement 123(R), Share-Based Payment. This accounting treatment has not significantly affected our compensation decisions. The Compensation Committee takes into consideration the tax consequences of compensation to the named executive officers, but tax considerations are not a significant part of the company's compensation policy.

Benchmarking

The Compensation Committee does not attempt to establish or measure executive compensation against any benchmarks. We have not established any policy regarding recoupment, or "clawback," of any performance-based compensation in the event our company's historical performance is subsequently revised or restated in a way that would have produced a lower compensation amount. We also have not relied upon wealth accumulation analyses, or "tally sheets," or internal pay equity analyses in making executive compensation decisions.

These policies remained in place throughout 2010, and we expect to continue to follow them for the foreseeable future.

Compensation Committee Interlocks and Insider Participation in Compensation Decisions

There are no "interlocks," as defined by the SEC, with respect to any member of the Compensation Committee. Max Link, Ph.D., Marvin R. Selter and Richard L. Wennekamp all served as members of the Compensation Committee during 2010.

Compensation Committee Report

The Compensation Committee has reviewed and discussed with management the "Compensation Discussion and Analysis" required by Item 402(b) of Regulation S-K and, based on such review and discussions, has recommended to our board of directors that the foregoing "Compensation Discussion and Analysis" be included in this Annual Report.

Richard L. Wennekamp, Chairman Marvin R. Selter Dr. Max Link

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Summary Compensation Table

The following table presents summary information concerning all compensation paid or accrued by us for services rendered in all capacities during 2010, 2009 and 2008 by Steven A. Kriegsman and John Y. Caloz, who are the only individuals who served as our principal executive and financial officers during the year ended December 31, 2010, and our three other most highly compensated executive officers who were serving as executive officers as of December 31, 2010:

Summary Compensation Table

Name and Principal Position	Year	Salary ($)	Bonus ($)(1)	Option Awards ($) (2)	All Other Compensation ($)(3)	Total ($)
Steven A. Kriegsman						
President and Chief Executive Officer	2010	650,000	450,000	564,750	10,000	1,674,750
	2009	550,000	450,000	906,000	10,000	1,916,000
	2008	551,000	150,000	517,800	10,000	1,228,800
John Y. Caloz						
Chief Financial Officer and Treasurer	2010	325,000	25,000	37,650	—	387,650
	2009	275,000	80,000	137,750	—	492,750
Daniel Levitt, M.D., M.D., Ph.D.						
Chief Medical Officer	2010	375,000	135,000	188,250	—	698,250
	2009	83,894	—	405,000	—	488,894