

CYTRX CORP  
Form 10-K  
March 13, 2012

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

Form 10-K

(Mark One)

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

For the fiscal year ended December 31, 2011  
or

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

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

Commission file number 0-15327

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

Delaware  
(State or other jurisdiction of  
incorporation or organization)

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

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

90049  
(Zip Code)

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

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

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

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

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

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

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

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

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

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

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

(Do not check if a smaller reporting company)

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

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

CYTRX CORPORATION  
2011 ANNUAL REPORT ON FORM 10-K

TABLE OF CONTENTS

	Page
“SAFE HARBOR” STATEMENT	3
PART I	
Item 1. BUSINESS	4
Item 1A. RISK FACTORS	14
Item 1B. UNRESOLVED STAFF COMMENTS	23
Item 2. PROPERTIES	23
Item 3. LEGAL PROCEEDINGS	23
Item 4. MINE SAFETY DISCLOSURES	23
PART II	
Item 5. MARKET FOR REGISTRANT’S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES	24
Item 6. SELECTED FINANCIAL DATA	26
Item 7. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	27
Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK	36
Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA	37
Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE	37
Item 9A. CONTROLS AND PROCEDURES	37
Item 9B. OTHER INFORMATION	37
PART III	
Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE	38
Item 11. EXECUTIVE COMPENSATION	42
Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS	58
Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE	59
Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES	60
PART IV	
Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES	61
SIGNATURES	65

“SAFE HARBOR” STATEMENT

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

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

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

## PART I

## Item 1. BUSINESS

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

## COMPANY OVERVIEW

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

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

## OUR PRODUCT CANDIDATE PIPELINE

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

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

## OUR CLINICAL DEVELOPMENT PROGRAMS

Our current clinical development programs are discussed below.

## INNO-206

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

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

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

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

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

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

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

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

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

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

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

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

## Tamibarotene

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

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

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

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

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

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

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

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

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

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

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

#### Bafetinib

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

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

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

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

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

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

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

### Disposition of Molecular Chaperone Assets

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

### Our Separation from RXi Pharmaceuticals Corporation

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

### Innovive Acquisition Agreement

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

### Research and Development

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

### Manufacturing

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

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

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

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

## Marketing

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

## Patents and Proprietary Technology

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

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

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

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

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

## LICENSE AGREEMENTS

### INNO-206

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

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

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

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

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

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

#### Tamibarotene

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

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

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

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

#### Bafetinib

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

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

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

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

### Competition

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

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

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

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

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

with ATRA.

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

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

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

#### Government Regulation

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

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

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

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

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

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

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

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

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

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

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

#### Employees

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

Available Information

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

## Item 1A. RISK FACTORS

### Risks Associated With Our Business

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

As a result, these competitors may:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

foreign country.

## Risks Associated with Our Common Stock

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

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

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

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

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

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

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

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

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

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

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

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

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