

CYTRX CORP
Form 10-K
March 11, 2016

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, 2015
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.)
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11726 San Vicente Blvd, Suite 650, Los Angeles, California (Address of principal executive offices)	90049 (Zip Code)
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Registrant's telephone number, including area code: (310) 826-5648

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

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

Securities Registered Pursuant to Section 12(g) of the Act:

None

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

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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

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 No

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

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

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

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, 2015 (the last business day of the Registrant's most recently completed second fiscal quarter) was approximately \$123 million. Shares of common stock held by directors and executive officers and any ten percent or greater stockholders and their respective affiliates have been excluded from this calculation, because such stockholders may be deemed to be "affiliates" of the Registrant. This is not necessarily determinative of affiliate status for other purposes. The number of outstanding shares of the Registrant's common stock as of March 11, 2016 was 66,480,065.

CYTRX CORPORATION
2015 ANNUAL REPORT ON FORM 10-K

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NOTE ON FORWARD-LOOKING STATEMENTS

References in this Annual Report to the "company," "we," "us" or "our" refer to CytRx Corporation. 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-looking 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 Note.

INDUSTRY DATA

Unless otherwise indicated, information contained in this Annual Report concerning our industry, including our general expectations and market opportunity, is based on information from our own management estimates and research, as well as from industry and general publications and research, surveys and studies conducted by third parties. Management estimates are derived from publicly available information, our knowledge of our industry and assumptions based on such information and knowledge, which we believe to be reasonable. In addition, assumptions and estimates of our and our industry's future performance are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described below in the "Risk Factors" section of this Annual Report. These and other factors could cause our future performance to differ materially from our assumptions and estimates.

TRADEMARKS

CytRx is one of our trademarks used in this Annual Report. This Annual Report also includes trademarks, trade names and service marks that are the property of other organizations. Solely for convenience, trademarks and trade names referred to in this Annual Report sometimes appear without the ® and ™ symbols, but those references are not intended to indicate that we will not assert, to the fullest extent under applicable law, our rights, or that the applicable owner will not assert its rights, to these trademarks and trade names.

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PART I

Item 1. BUSINESS

COMPANY OVERVIEW

We are a biopharmaceutical research and development company specializing in oncology. We currently are focused on the clinical development of aldoxorubicin (formerly known as INNO-206), our modified version of the widely-used chemotherapeutic agent, doxorubicin. We have reported positive top-line efficacy results (median progression-free survival, progression-free survival at six months, overall response rates, hazard ratios and overall survival) from our completed, global Phase 2b clinical trial with aldoxorubicin as a treatment for soft tissue sarcoma, or STS. Hazard ratios - the likelihood that the study endpoint (in this case tumor progression) will be reached during a given period - are an important measure of the reliability and uniformity of the absolute data for progression-free survival, or PFS. The trial investigated the efficacy and safety of aldoxorubicin compared with doxorubicin in subjects with first-line metastatic, locally advanced or unresectable STS. Aldoxorubicin combines the chemotherapeutic agent doxorubicin with a novel linker-molecule that binds specifically to albumin in the blood to allow for delivery of higher amounts of doxorubicin (3½ to 4 times) without the major dose-limiting toxicities seen with administration of doxorubicin alone.

In the first quarter of 2014, we initiated a pivotal Phase 3 trial of aldoxorubicin as a therapy for patients with STS whose tumors have progressed following treatment with chemotherapy, and we have received approval from the FDA to continue dosing patients with aldoxorubicin until disease progression in that clinical trial. The Phase 3 trial is being conducted under a Special Protocol Assessment, or SPA, granted by the U.S. Food and Drug Administration, or FDA. The SPA means that the FDA agrees that the design and analyses proposed in the Phase 3 trial protocol are acceptable to support regulatory approval of the product candidate with respect to effectiveness of the indication studied, and will not subsequently change its perspective on these matters, unless previously unrecognized public or animal health concerns were to arise or we were to subsequently modify the protocol. Thus, if the study demonstrates an acceptable benefit-risk profile as determined by the FDA, it would suffice as the single pivotal trial to demonstrate effectiveness and would support registration of aldoxorubicin for this indication. The clinical trial has completed its target enrollment of 400 patients at approximately 79 clinical sites in the U.S., Europe, Canada, Latin America and Australia. We expect to report the top-line results on PFS the trial's primary endpoint, in the first half of 2016.

We are currently evaluating aldoxorubicin in a global Phase 2b clinical trial in small cell lung cancer, a Phase 2 clinical trial in HIV-related Kaposi's sarcoma, a Phase 2 clinical trial in patients with late-stage glioblastoma (brain cancer), a Phase 1b trial in combination with ifosfamide in patients with soft tissue sarcoma, and a Phase 1b trial in combination with gemcitabine in subjects with metastatic solid tumors. We have completed a global Phase 2b clinical trial with aldoxorubicin as a first-line therapy for STS, a Phase 1b/2 clinical trial primarily in the same indication, a Phase 1b clinical trial of aldoxorubicin in combination with doxorubicin in patients with advanced solid tumors and a Phase 1b pharmacokinetics clinical trial in patients with metastatic solid tumors.

In addition to aldoxorubicin, we are currently completing pre-clinical development for DK049, a novel anti-cancer drug conjugate that utilizes our Linker Activated Drug Release (LADR™) technology. DK049 was created at our laboratory facility in Freiburg, Germany, and employs a proprietary linker that is both pH sensitive and requires a specific enzyme for the release of the cytotoxic payload. DK049 has demonstrated significant anti-tumor activity in multiple animal models implanted with human tumors, including non-small cell lung, ovarian and pancreatic cancers. We anticipate filing an Investigational New Drug Application (IND) in the second half of 2016 prior to initiating a Phase 1 clinical trial.

We plan to expand our pipeline of oncology candidates utilizing our LADR™ technology by creating both albumin-binding drug conjugates and antibody-drug conjugates. This technology allows for targeting to the tumor either by albumin or antibodies and can deliver anti-cancer agents that are 10-1000 times more potent than traditional chemotherapies.

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	Aldoxorubicin	Soft Tissue Sarcoma	Pivotal Global Phase 3 ongoing
		Small-Cell Lung Cancer	Global Phase 2b ongoing
		Glioblastoma Multiforme	Phase 2 ongoing
		Kaposi's Sarcoma	Phase 2 ongoing
		Combination with ifosfamide	Phase 1b ongoing
		Combination with gemcitabine	Phase 1b ongoing
LADR™	DK049	To be announced	Pre-clinical
LADR™ for albumin-binding drug conjugates	To be announced	To be announced	Pre-clinical
LADR™ for antibody-drug conjugates	To be announced	To be announced	Pre-clinical

OUR CLINICAL DEVELOPMENT PROGRAMS

Our current clinical development programs are discussed below.

Aldoxorubicin

Aldoxorubicin is a conjugate of the commonly prescribed chemotherapeutic agent doxorubicin that binds to circulating albumin in the bloodstream and is believed to concentrate the drug at the site of tumors. Specifically, it is comprised of (6-maleimidocaproyl) hydrazine, an acid-sensitive molecule that is conjugated to doxorubicin. In the first quarter of 2014, we initiated under an SPA granted by the FDA a pivotal, global Phase 3 trial of aldoxorubicin as a therapy for patients with STS whose tumors have progressed following treatment with chemotherapy.

Aldoxorubicin 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, ovarian 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 mouth and digestive tract), stomatitis (inflammation of soft tissue of the mouth), and necrotizing extravasation (damage due to the leakage of intravenous drugs from the vein into the surrounding tissue).

We believe aldoxorubicin has attributes that may improve on doxorubicin, alone, which we sometimes refer to as native doxorubicin, including the potential to increase the total doxorubicin dose, reduce certain adverse events associated with native doxorubicin, achieve increased drug concentration at tumor sites and improve efficacy.

Our postulated mechanism of action for aldoxorubicin is as follows:

- after administration, aldoxorubicin rapidly forms a covalent bond to circulating albumin through an acid-sensitive linker;

- circulating albumin preferentially accumulates in tumors, bypassing concentration in other non-tumor sites, including the heart, liver and gastrointestinal tract due to a mechanism called "Enhanced Permeability and Retention by Solid Tumors";

- once albumin-bound aldoxorubicin is taken up by the tumor, the acidic environment within the tumor and in the cancer cells themselves causes cleavage of the acid-sensitive linker; and

- free doxorubicin is then released in the tumor.

Pre-clinical data. In a variety of preclinical models, aldoxorubicin 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 aldoxorubicin inventor Dr. Felix Kratz demonstrated statistically significant efficacy compared to both placebo and native doxorubicin against breast, ovarian, pancreatic and small cell

lung cancers growing in immunodeficient mice.

We have also announced additional data from a study of aldoxorubicin in immunodeficient mice transplanted with human glioblastoma cells in their brain that showed those animals treated with aldoxorubicin had a median survival rate of more than 63 days, compared with approximately 25 days for animals treated with doxorubicin or saline. The data, published in the journal *Neoplasia* in October 2014, also indicated evidence of drug concentration inside tumors growing in the brain, but not in normal brain tissue, and significant tumor regression in aldoxorubicin-treated animals, while doxorubicin did not appear to enter the tumor or brain to any significant degree and showed little or no efficacy in the progression of these brain tumors. Aldoxorubicin significantly reduced the number of dividing cells within the brain tumors in this trial and showed a statistically relevant increased expression of apoptosis or cell death markers. Clinical data. A Phase 1 study of aldoxorubicin that demonstrated safety and objective clinical responses in several tumor types was completed in 2005, presented at the March 2006 Krebskongress meeting in Berlin, Germany, and published in *Clinical Cancer Research* in August 2007. In this study, doses were administered every three weeks at up to six times the standard dose of doxorubicin without an increase in the types of side effects compared with those historically observed with native doxorubicin. Of 35 evaluable patients, 23 had either an objective clinical (partial) response or stable disease. Objective clinical responses were observed in patients with STS, breast and small cell lung cancers.

We completed a Phase 1b/2 clinical trial with aldoxorubicin in patients with advanced solid tumors who had either relapsed or failed to respond to their prior chemotherapy and presented favorable data at the American Society for Clinical Oncology Meeting in June 2012. In that Phase 1b/2 clinical trial, clinical benefit (defined as partial response or stable disease of more than four months) was shown in ten of 13 (76.9%) evaluable patients with relapsed or refractory STS. The median number of cycles of aldoxorubicin administered at the maximum tolerable dose was eight. The results of this clinical trial were published in February 2015 in the peer-reviewed journal *Cancer* (*Cancer*, 2015 Feb 15; 121(4); 570-9).

In addition, best responses for the 13 evaluable STS trial subjects included the following: five (38.5%) achieved partial response, as defined as shrinkage of target tumors of more than 30%; six (46%) showed prolonged stable disease (defined as tumor shrinkage <30% from baseline or tumor growth <20% from the nadir); eight (61.5%) had tumor shrinkage; and five of eight patients (62.5%) who demonstrated either partial responses or prolonged stable disease after treatment with aldoxorubicin had been previously treated with doxorubicin and had failed to respond. There were no observed cardiac toxicities and no drug-related patient deaths. The most common adverse event, neutropenia, also observed with doxorubicin treatment, resolved prior to the start of the next treatment. Final observed median PFS for advanced STS patients in the trial was 11.25 months, and median overall survival was 21.71 months (Publication in *Cancer*, 2015 Feb 15). In addition, following 8 cycles of aldoxorubicin, two patients experienced no progression of disease for 23 and 15 months, respectively, despite no further treatment.

In connection with our Phase 1b pharmacokinetics clinical trial evaluating the pharmacokinetics and safety of aldoxorubicin in patients with metastatic solid tumors who have either relapsed or not responded to treatment with standard therapies, we announced data demonstrating that aldoxorubicin has a distribution half-life of approximately 20 to 24 hours, with a narrow volume of distribution to healthy tissue and slow clearance from the circulation. These characteristics distinguish aldoxorubicin from doxorubicin, which has a distribution half-life of about five minutes according to its package insert. Complete details from this Phase 1b trial were published online in the journal *Investigational New Drugs* in November 2014 (Publication in *Invest New Drugs*, 2015 Apr 15; (33(2):341-8).

We completed our global Phase 2b clinical trial to evaluate the preliminary efficacy and safety of aldoxorubicin as a first-line therapy in patients with advanced STS who are ineligible for surgery, which was initiated in December 2011. The Phase 2b clinical trial provided the first direct clinical trial comparison of aldoxorubicin and native doxorubicin, which is dose-limited due to toxicity, as a first-line therapy.

The Phase 2b clinical trial with aldoxorubicin in patients with STS was an international trial in 31 treatment centers under the direction of Sant P. Chawla, M.D., F.R.A.C.P., Director of the Sarcoma Oncology Center in Santa Monica, California. The Phase 2b clinical trial's primary objectives were to measure the PFS, tumor response and overall survival of patients with advanced STS treated with aldoxorubicin. This clinical trial also assessed the safety of aldoxorubicin compared to doxorubicin in this patient population through a number of indicators, including the frequency and severity of adverse events.

In our 123-subject clinical trial, subjects with advanced STS were administered either 350 mg/m² of aldorubicin (83 subjects) or 75 mg/m² of doxorubicin (40 subjects) every three weeks for up to six cycles. Subjects were followed every six weeks with CT scans to monitor tumor size. The primary endpoint was PFS as determined by a blinded radiology review performed at an independent central radiology laboratory. Secondary endpoints included overall response rates (complete and partial) and PFS at six months for each group, and overall survival. The results from this trial were published in the Journal of the American Medical Association (JAMA) Oncology in September 2015 (JAMA Oncol. 2015 Sep 17:1-9.).

The central radiology review, as well as the investigators' own assessments, showed an 80% to 100% improvement in PFS among patients treated with aldorubicin. In an intent-to-treat analysis, the investigator-assessed median PFS was 8.3 months for aldorubicin patients versus 4.6 months for doxorubicin patients ($p=0.0006$), while the blinded central radiology review indicated that median PFS for aldorubicin patients was 5.6 months versus 2.7 months for doxorubicin patients ($p=0.0228$). Per investigators, 68.1% of aldorubicin patients had not progressed at six months, compared with 33.0% of doxorubicin-treated patients ($p=0.008$). By blinded central radiology review, 45.7% of aldorubicin patients had not progressed at six months, compared with 22.9% of doxorubicin patients ($p=0.02$). The overall response rate as determined by the investigators was 22.9% for aldorubicin subjects (2.0% complete response and 21.3% partial response) versus 5.0% for doxorubicin subjects (0% complete response and 5.0% partial response). As assessed by blinded central radiology review, 25.0% of aldorubicin subjects had a partial response while none of the doxorubicin subjects exhibited any objective response.

Additional analysis determined hazard ratios for the primary endpoint of PFS by both investigators at study sites and by the blinded radiology review. The hazard ratio for investigator-read scans is 0.37 (95% confidence interval, range of 0.212 to 0.643) ($p=0.0004$), reflecting a 63% reduction in the risk of disease progression for patients treated with aldorubicin; and the hazard ratio for central lab scans is 0.586 (95% confidence interval, range of 0.358 to 0.960) ($p=0.034$), reflecting a 41% reduction in the risk of disease progression for the aldorubicin-treated patients. Hazard ratios are an important measure of the reliability and uniformity of the data for PFS, and where the upper limit is less than one indicates that there is a significant difference between the two study groups.

We also reported that a Kaplan-Meier analysis of the trial results, which analysis describes the time it takes for tumors to progress in individual patients, showed significant improvement in subjects treated with aldorubicin versus subjects treated with doxorubicin.

The overall survival results from the clinical trial demonstrated a 27 percent reduction in the risk of death compared to patients treated with doxorubicin (HR 0.73: 95% confidence interval 0.44-1.20), the current standard-of-care in this indication. In addition, aldorubicin-treated patients demonstrated a 41% likelihood of surviving more than 2 years, a 2-fold increase, compared to a 20% probability for doxorubicin-treated patients. Median overall survival was 15.8 months (95% confidence interval 13.1-not reached) for aldorubicin-treated patients versus 14.3 months (95% confidence interval 8.6-20.6) for doxorubicin treated patients ($p=0.21$). For treatment-naive patients, representing 90% of the patients in the clinical trial, median overall survival was 15.8 months (95% confidence interval 13.0-not reached) for aldorubicin-treated patients versus 13.8 months (95% confidence interval 8.6-19.8) for doxorubicin treated patients ($p=0.14$).

In the Phase 2b clinical trial, aldorubicin was found to be relatively safe and well-tolerated. Subjects treated with aldorubicin had an approximately two-fold increase in severe neutropenia compared with doxorubicin-treated subjects, but there was no difference in the incidence of febrile neutropenia (indicating an infection may be present) between the two groups. All adverse events in subjects treated with aldorubicin were consistent with the known side effects of doxorubicin, usually resolved before the administration of the next dose and did not require treatment discontinuation. There were no treatment-related deaths in the aldorubicin group.

In the first quarter of 2014, we initiated a pivotal global Phase 3 clinical trial to evaluate the efficacy and safety of aldorubicin as a second-line treatment for patients with STS under a Special Protocol Assessment with the FDA. This multicenter, randomized, open-label Phase 3 clinical trial is designed to enroll approximately 400 patients with metastatic, locally advanced or unresectable soft tissue sarcomas who have either not responded to, or have progressed following treatment with, one or more systemic regimens of non-adjuvant chemotherapies. Trial patients will be randomized 1:1 to be treated with aldorubicin or the investigator's choice of an approved chemotherapeutic regimen, including doxorubicin, ifosfamide dacarbazine, pazopanib (Votrient®), or gemcitabine plus docetaxel, with

up to three comparator regimens to be selected by the investigator at each clinical site. The primary endpoint of the study is progression-free survival (PFS), and secondary endpoints include overall survival, response rates and safety. In January 2014, the Company announced it has received approval from the FDA to amend the Phase 3 protocol to continue dosing patients with aldorubicin until disease progression (defined as an increase in the size of measurable tumors by 20% or the development of a new tumor lesion), which creates the potential for substantially improved Phase 3 efficacy results.

Following discussions with the FDA, the Phase 3 protocol was agreed upon under a Special Protocol Assessment (SPA). As part of that assessment, the FDA agreed that, barring unrecognized public or human health concerns, the design and planned analysis of the study adequately addresses the objectives necessary to support a regulatory submission for approval.

The clinical trial has completed its target enrollment of 400 patients at approximately 79 clinical sites in the U.S., Europe, Canada, Latin America and Australia. CytRx expects to report the top-line results on progression-free survival, the trial's primary endpoint, in the first half of 2016.

In September 2014, we initiated a global Phase 2b clinical trial evaluating aldorubicin compared to topotecan in subjects with extensive-stage small cell lung cancer (SCLC) who have relapsed or were refractory to prior chemotherapy. The open-label Phase 2b clinical trial is expected to enroll approximately 132 patients (1:1 randomization). The primary endpoint is PFS and the secondary endpoints are OS, overall response rates (partial and complete) and the safety of aldorubicin compared to topotecan in this population. The study is expected to involve approximately 40 clinical trial sites in the U.S., Spain and Hungary.

We are conducting a Phase 2 clinical trial to evaluate the preliminary efficacy and safety of aldorubicin in patients with unresectable glioblastoma whose tumors have progressed following prior treatment with surgery, radiation and with the drug temozolomide. The clinical trial has enrolled its target of 28 patients at sites including the John Wayne Cancer Center in Santa Monica, California, City of Hope in Duarte, California, and the LSU Medical Center in New Orleans, Louisiana.

We are conducting a Phase 2 clinical trial evaluating the preliminary efficacy of aldorubicin in patients with AIDS-related Kaposi's sarcoma, a tumor usually associated with HIV infection in the U.S. The current standard-of-care for severe dermatological and systemic Kaposi's sarcoma is liposomal doxorubicin (Doxil); however, a significant proportion of patients exhibit minimal or no clinical response to this agent, and the drug's toxicity often prevents continued therapy. The Phase 2 trial is expected to enroll up to 30 patients and is being conducted at the LSU Medical Center in New Orleans, Louisiana.

We are also conducting a Phase 1b trial in combination with ifosfamide in patients with STS, and a Phase 1b trial in combination with gemcitabine in subjects with metastatic solid tumors. Since most chemotherapy agents are administered in combination with other chemotherapeutics, these studies will demonstrate the dose of aldorubicin that can be safely combined with two other chemotherapies that are commonly used to treated patients with sarcomas, pancreatic cancer, ovarian cancer and lung cancer.

Drug Discovery Laboratory

Our laboratory, located in Freiburg, Germany, is conducting discovery and translational research to create drug candidates that utilize our LADR™ technologies to couple cytotoxic agents and proteins either inside the body or externally, and then concentrate drug in tumors. Led by Felix Kratz, Ph.D., Vice President of Drug Discovery and inventor of aldorubicin, and Andre Warnecke, Ph.D., Senior Director of Drug Discovery, the discovery team is working to expand our novel albumin-binding anti-cancer drug pipeline and using LADR™ linkers to create unique antibody-drug conjugates. We recently announced the development of DK049, a novel anti-cancer drug conjugate that utilizes our LADR™ technology, and anticipate filing an IND for DK049 in the second half of 2016 prior to initiating a Phase 1 clinical trial.

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.

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 aldorubicin and tamibarotene. Under the merger agreement by which we acquired Innovive, we agreed to pay the former Innovive stockholders 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. The earnout will be accrued if and when earned.

Research and Development

Expenditures for research and development activities related to continuing operations were \$43.4 million, \$36.7 million and \$17.5 million for the years ended December 31, 2015, 2014 and 2013, respectively, or approximately 68%, 74% and 63%, 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 do not have the facilities or expertise to manufacture clinical supplies of aldorubicin or any of our other product candidates, and we lack the resources and capability to manufacture any of our product candidates on a commercial scale. Accordingly, we are dependent upon third-party manufactures, 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 aldorubicin. In September, 2015, we entered into an agreement with a supplier to purchase doxorubicin hydrochloride both on a clinical as well as a commercial scale. However, we currently have no other supply arrangements for the commercial manufacture of aldorubicin 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 material adverse effect on our ability to complete the development of our products or to commercialize them.

Commercialization and Marketing

We recently hired Olivia Ware as our Chief Commercial Officer and have initiated activities to build our sales, marketing and commercial product distribution capabilities in preparation for the US launch of aldorubicin. If aldorubicin is approved, we expect to commercialize it in the U.S. with a small internal commercial group and an outsourced specialty field sales force.

We intend to commercialize aldorubicin outside the US starting in the EU-5 countries. Our commercial strategy may include the use of strategic partners, distributors, a contract sales force or the establishment of our own sales force. We plan to further evaluate these alternatives as we approach approval for aldorubicin.

As additional product candidates advance through our pipeline, our commercial plans may change. In particular, some of our pipeline assets target potentially large solid tumor indications. Factors such as clinical data, the size of the development programs, the size of the target market, the size of a commercial infrastructure, and manufacturing needs may influence our strategies in the U.S., the European Union, and other territories.

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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 December 31, 2015, we held rights in four granted U.S. patents, 55 granted foreign patents, three pending U.S. applications, and twenty-two pending foreign patent applications covering aldoxorubicin and related technologies.

Our intellectual property

holdings relating to aldoxorubicin and related technologies include an exclusive license from KTB Tumorforschungs GmbH, or KTB, to U.S. and foreign patents and patent applications. Patents and applications that cover pharmaceutical compositions of aldoxorubicin, processes for their production, and their use in treatment methods (e.g., cancer (including glioblastoma), viral diseases, autoimmune diseases, and acute or chronic inflammatory diseases) have unextended patent terms expiring between June 2020 and June 2034. Additionally, we have three pending U.S. provisional patent applications covering our LADRTM technology and DK049.

LICENSE AGREEMENTS

Aldoxorubicin

We have an agreement with KTB for the license of patent rights held by KTB for the worldwide development and commercialization of aldoxorubicin. The license is exclusive and applies to all products that may be subject to the licensed intellectual property in all fields of use. We may sublicense the intellectual property in our sole discretion. Pursuant to an amendment to the license agreement entered into in March 2014, we also have a non-exclusive worldwide license to any additional 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 up to \$7.5 million upon meeting clinical and regulatory milestones, and 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 any non-royalty sub-licensing income (as defined in the agreement); and
- milestones of \$1 million for each additional final marketing approval that we obtain.

Pursuant to the March 2014 license amendment, we agreed to make a \$500,000 milestone payment upon first dosing of a patient in a first phase I clinical trial for each product using the additional technology. In the event that by February 28, 2017, no such payment has become due, we have agreed to pay KTB \$500,000, which payment can be made, in our discretion, in cash or in shares of our common stock. If we elect to make the payment in shares of common stock, our shares will be valued at the volume-weighted average price (VWAP) over the preceding 60 trading days, to be calculated on February 28, 2017.

In the event that we must pay a third party in order to exercise our rights to the intellectual property under the agreement, we are entitled to deduct a percentage of those payments from the royalties due KTB, up to an agreed upon cap.

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 aldoxorubicin 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 active pharmaceutical ingredient, or API, of aldoxorubicin, 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.

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Competition

Aldoxorubicin is a conjugate of doxorubicin, a widely used anti-cancer drug. Doxorubicin is part of the anthracycline class of chemotherapy agents. Anthracyclines, many of which, including doxorubicin are generic, 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.

Aldoxorubicin is a chemically modified version of doxorubicin that incorporates an acid sensitive linker technology to improve concentration in the tumor. We believe that the albumin-binding ability of aldoxorubicin 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, greater concentration of the drug in tumors and greater efficacy.

STS patients are typically treated with surgery followed by radiation therapy. For patients ineligible for surgery, radiation or both, chemotherapy is the only option. Doxorubicin is the only approved first-line drug for treating STS patients who are ineligible for surgery and is often used in combination with radiation. The National Comprehensive Cancer Network also includes the use of ifosfamide, epirubicin, gemcitabine, gemcitabine with docetaxel, dacarbazine and liposomal doxorubicin marketed in the United States as Doxil® by Johnson & Johnson. GlaxoSmithKline's pazopanib (Votrient®) was approved in the United States and Europe in 2012 for the treatment of certain types of advanced STS following prior chemotherapy. In October 2015, the Janssen unit of Johnson & Johnson received approval for trabectedin (Yondelis®) for the treatment of patients with leiomyosarcoma and liposarcoma, that have previously received an anthracycline and ifosfamide or an anthracycline followed by another chemotherapy. In January 2016, the FDA approved Eisai's eribulin (Halaven®) as a treatment for patients with unresectable or metastatic liposarcoma who have received a prior anthracycline. Eli Lilly is conducting a Phase 3 clinical trial with olaratumab in combination with doxorubicin in first-line STS. Eli Lilly stated in October 2015 that they plan to submit a rolling new drug application based on the Phase 2 clinical trial results in STS. There are other approaches to treating STS in clinical development, including Morphotek's ontuxizumab in combination with chemotherapy, and Tracon Pharmaceuticals' TRC-105 in combination with pazopanib.

Patients with glioblastoma multiforme, or GBM, generally undergo invasive brain surgery, although disease progression following surgery is nearly 100%. The front-line therapy for GBM following surgery is radiation in combination with temozolomide (Temodar®). Bevacizumab (Avastin®) has been approved for the treatment of GBM in patients progressing after prior therapy. Drugs in development to treat GBM include nivolumab by Bristol-Myers Squibb, DCVax by Northwest Biotherapeutics, DelMar Pharmaceuticals' VAL-083, TRC-105 from Tracon Pharmaceuticals, veliparib by AstraZeneca and buparlisib by Novartis.

Treatment for newly diagnosed SCLC typically consists of cisplatin or carboplatin in combination with etoposide. Radiation may also be given for extensive-stage disease. While first-line treatment can yield overall response rates of 50-80%, the duration of response is often less than 90 days. For recurrent SCLC, topotecan (Hycamtin®) is standard therapy. SCLC patients who are sensitive to first-line treatment may receive topotecan or the generic chemotherapeutic drugs irinotecan, taxanes, gemcitabine or vinorelbine. Drugs in development for second-line SCLC include Bristol-Myers Squibb's nivolumab (Opdivo®) and ipilimumab (Yervoy®) and SC16LD6.5 by Stem CentRx, Inc.

Kaposi's sarcoma is generally treated with radiation, surgery and/or liposomal doxorubicin. Liposomal daunorubicin (DaunoXome®, Galen US), with or without paclitaxel, is also recommended as treatment for advanced disease. Other drugs in development for Kaposi's sarcoma include selumetinib by AstraZeneca and pomalidamide by Celgene.

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.

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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 trial, 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.

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Employees

As of March 11, 2016, we had thirty-one employees, nine of whom were engaged in clinical development activities, ten of whom were engaged in preclinical research at our Freiburg, Germany laboratory, and eleven of whom were involved in management and administrative operations.

Available Information

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

Item 1A. RISK FACTORS

You should carefully consider the risks and uncertainties facing our business. The risks described below are not the only ones facing us. Our business is also subject to the risks that affect many other companies, such as employment relations, general economic conditions and geopolitical events. Further, additional risks not currently known to us or that we currently believe are immaterial may in the future materially and adversely affect our business, operations, liquidity and stock price.

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 revenues. We incurred a net loss of \$58.6 million for the year ended December 31, 2015 and \$30.1 million for the year ended December 31, 2014 and had an accumulated deficit as of December 31, 2015 of \$365.1 million. We are likely to continue to incur losses unless and until we are able to commercialize aldoxorubicin or one or more of our other existing or possible future 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.

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 and proceeds from 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 aldoxorubicin and fund development of product candidates based on our LADR™ technology;
- expand our research and development activities;

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- 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 revenue was \$0.1 million, \$0.1 million and \$0.3 million, respectively, for the years ended December 31, 2015, 2014 and 2013. We will have no significant recurring revenue unless we are able to commercialize aldoxorubicin, our lead product candidate, or one or more of our existing or possible future product candidates, which may require us to first enter into license or other strategic arrangements with third parties.

At December 31, 2015, we had cash and cash equivalents of approximately \$22.3 million and short-term investments of \$35.0 million. On February 6, 2016, we announced the signing of a long-term loan agreement with Hercules Technology Growth Capital, Inc. and Hercules Technology III, L.P. for up to \$40.0 million in financing, of which we have received \$25.0 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 2016 of approximately \$58.9 million, which includes approximately \$34.3 million for our clinical programs for aldoxorubicin, approximately \$5.4 million for pre-clinical development of new albumin-binding cancer drugs, including DK049, approximately \$4.2 million for general operation of our clinical programs and approximately \$15.0 million for other general and administrative expenses, including pre-commercialization. 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 and successfully commercialize aldoxorubicin, or other product candidate, we anticipate it will take a minimum of two 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. 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 prospectus supplement of the expected timing of certain milestones relating to our aldoxorubicin clinical development programs.

We also may disclose projected expenditures or other forecasts for future periods. 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.

The regulatory approval process is lengthy, time consuming and inherently unpredictable, and 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 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, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate.

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. In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

Furthermore, even if we obtain regulatory approvals, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, import, export, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current good manufacturing practices, or cGMPs, and good clinical practices, or cGCPs, for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
 - refusal by the FDA to approve pending applications or supplements to approved applications filed by us or our strategic partners, or suspension or revocation of product license approvals;
 - product seizure or detention, or refusal to permit the import or export of products;
 - and
- injunctions or the imposition of civil or criminal penalties.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business. We will also be subject to periodic inspections and the potential for mandatory post-approval clinical trials required 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.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Our current and planned clinical trials of our lead product candidate may fail to show that it is clinically safe and effective, or that it is better than alternative treatments. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical development may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or safety profiles, notwithstanding promising results in earlier trials. For example, aldoxorubicin has shown encouraging preliminary clinical results in our Phase 2b clinical trial as a treatment for STS; however, these conclusions may not be reproduced in future clinical trial results, including the Phase 3 clinical trial testing aldoxorubicin as a treatment for STS. 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 aldoxorubicin for any indication.

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Further, we may experience delays in clinical trials of our product candidates. We do not know whether ongoing clinical trials will be completed on schedule or at all, or whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

- obtaining regulatory approval to commence a trial;
 - reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- obtaining institutional review board approval at each clinical trial site;
- recruiting suitable patients to participate in a trial;
- having patients complete a trial or return for post-treatment follow-up;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- adding new clinical trial sites; or
- manufacturing sufficient quantities of product candidate for use in clinical trials.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. Furthermore, we rely on third parties, such as CROs and clinical trial sites, to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their committed activities, we have limited influence over their actual performance.

We could encounter delays if prescribing physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles. Further, a clinical trial may be suspended or terminated by us, our collaborators, the institutional review boards, or IRBs, if the institutions in which such trials are being conducted, the Data Safety Monitoring Board, or DSMB, for such trial, or by the FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. For example, the FDA placed a partial clinical hold on our on-going clinical trials of aldoxorubicin in November 2014 following the death of an individual who was not enrolled in any of our clinical trials but who received aldoxorubicin pursuant to our compassionate use policy under a single-patient IND held by one of the clinical sites participating in our Phase 3 trial of aldoxorubicin in STS. The clinical hold resulted in our inability to enroll new patients in our aldoxorubicin studies until the hold was removed in February 2015. Although we have resumed enrollment in our studies, enrollment in our clinical trials and our projected development timelines may be adversely affected by residual effects of the former clinical hold or possible future clinical holds.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

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Our SPA with the FDA for our pivotal study of aldoxorubicin does not guarantee marketing approval in the U.S. We have an SPA with the FDA for the pivotal trial of aldoxorubicin for the treatment of STS. The SPA means that the FDA agrees that the design and analyses proposed in a protocol are acceptable to support regulatory approval of the product candidate with respect to effectiveness of the indication studied. However, an SPA agreement does not guarantee approval of a product candidate, and even if the FDA agrees to the design, execution, and analysis proposed in protocols reviewed under the SPA process, the FDA may revoke or alter its agreement in certain circumstances. In particular, an SPA agreement is not binding on the FDA if public health concerns emerge that were unrecognized at the time of the SPA agreement, other new scientific concerns regarding product safety or efficacy arise, the sponsor fails to comply with the agreed upon trial protocols, or the relevant data, assumptions or information provided by the sponsor in a request for the SPA change or are found to be false or omit relevant facts. In addition, even after an SPA agreement is finalized, the SPA agreement may be modified, and such modification will be deemed binding on the FDA review division, except under the circumstances described above, if the FDA and the sponsor agree in writing to modify the protocol and such modification is intended to improve the study. The FDA retains significant latitude and discretion in interpreting the terms of the SPA agreement and the data and results from any study that is the subject of the SPA agreement. Moreover, a final determination that the agreed-upon protocol satisfies a specific objective, such as the demonstration of efficacy and safety (positive benefit-risk ratio), or supports an approval decision, will be based on a complete review of all the data submitted to the FDA.

Adverse side effects or other safety risks associated with our product candidates could delay or preclude approval, cause us to suspend or discontinue clinical trials, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Undesirable side effects caused by our product candidates could result in the delay, suspension or termination of our clinical trials by us, our collaborators, IRBs, the FDA or other regulatory authorities. If we elect or are required to delay, suspend or terminate any clinical trial of any product candidates that we develop, the commercial prospects of such product candidates will be harmed and our ability to generate product revenues from any of these product candidates will be delayed or eliminated. Any of these occurrences may harm our business, financial condition and prospects significantly.

To date, patients treated with aldoxorubicin have experienced some of the same drug-related side effects associated with doxorubicin, including myelosuppression (decreased production of blood cells by bone marrow), gastrointestinal disorders (nausea and vomiting), mucositis (inflammation of the mucous membranes lining the digestive tract, including the mouth), stomatitis (inflammation of the mouth's soft tissue), fatigue, fever and other signs of infection associated with neutropenia (an abnormally low count of a type of white blood cells) and alopecia (hair loss). Results of our trials could reveal an unacceptable incidence of these or other side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. In addition, the drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Furthermore, if we or others later identify undesirable side effects caused by the product, a number of potentially significant negative consequences could result, including:

If our product candidates receive marketing approval, the FDA could require us to adopt a Risk Evaluation and Mitigation Strategy to ensure that the benefits of any approved product candidate outweigh its risks;

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of aldoxorubicin or the particular product candidate at issue, if approved, and could significantly harm our business, results of operations and prospects.

We rely on third parties to conduct our preclinical and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we and our collaborators may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We have agreements with third-party CROs to monitor and manage data for our preclinical and clinical programs. We rely heavily on these parties for execution of our preclinical and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with cGCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for products in clinical development. Regulatory authorities enforce these cGCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these CROs fails to comply with applicable cGCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the cGCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations, and will require a large number of test subjects. Our or our CROs' failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical and clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for aldoxorubicin would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Switching or adding additional CROs involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We rely upon third parties for the manufacture of our clinical product supplies, and we intend to rely on third parties to produce commercial supplies of any approved product candidate, and our commercialization of any product candidates, including aldoxorubicin, could be stopped, delayed or made less profitable if those third parties fail to obtain approval of the FDA, fail to provide us with sufficient quantities of drug product or fail to do so at acceptable quality levels or prices.

We do not have the facilities or expertise to manufacture supplies of aldoxorubicin or any of our other product candidates, and we lack the resources and capability to manufacture any of our product candidates on a clinical or commercial scale. 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 aldoxorubicin. In September 2015, we entered into an agreement with a supplier to purchase doxorubicin hydrochloride both for clinical and commercial use. However, we have no other supply arrangements for the commercial manufacture of this product candidate 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.

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be completed after we submit our NDA to the FDA. We do not control the manufacturing process of aldoxorubicin and are completely dependent on our contract manufacturing partners for compliance with the FDA's requirements for manufacture of aldoxorubicin. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the FDA's strict regulatory requirements, they will not be able to secure and/or maintain FDA approval for the manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates. If aldoxorubicin, our lead product candidate, or our other 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 any of our products that are approved for marketing cannot be manufactured at an acceptable cost, the commercial success of such product candidates may be adversely affected. We may rely upon third parties in connection with the commercialization of our products.

The marketing and commercialization of aldoxorubicin may require us to enter into strategic alliances or other collaborative arrangements with other pharmaceutical companies under which those companies will be responsible for one or more aspects of the eventual marketing and commercialization of aldoxorubicin, if it is approved for marketing. Any future product candidate, if approved for marketing, 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 commercialize our products and may have to sell our rights in them to a third party or abandon their commercialization 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 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 aldoxorubicin and other product candidates, 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 United States 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.

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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 do not publish for at least 18 months, if at all, and 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 products we develop may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which could have a material adverse effect on our business.

We intend to sell our products that may be approved for marketing primarily to hospitals, which generally 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.

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.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered and reimbursed. The Medicare program covers certain individuals aged 65 or older, disabled or suffering from end-stage renal disease. The Medicaid program, which varies from state-to-state, covers certain individuals and families who have limited financial means. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

Most third-party payors may deny coverage or 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 cover and 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, third-party payors 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.

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Healthcare legislative reform measures could hinder or prevent the commercial success of our products and product candidates.

In the United States, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system that could affect our future revenues and profitability. Federal and state lawmakers regularly propose and, at times, enact legislation that results in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. For example, in March 2010, President Obama signed one of the most significant healthcare reform measures in decades, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act. It contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which will impact existing government healthcare programs and will result in the development of new programs. The Affordable Care Act, among other things, (i) increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program, extends the rebate program to individuals enrolled in Medicaid managed care organizations, and addresses new methodologies by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, and for drugs that are line extension products; (ii) establishes annual fees and taxes on manufacturers of certain branded prescription drugs, and (iii) enacts a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect on April 1, 2013. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products once approved or additional pricing pressures.

We may also be subject to healthcare laws, regulation and enforcement and our failure to comply with those laws could adversely affect our business, operations and financial condition.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations may be directly, or indirectly through our customers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act, and physician sunshine laws and regulations. These laws may impact, among other things, our proposed sales, marketing, and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;
- the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government, and which may apply to entities that provide coding and billing advice to customers;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the federal physician sunshine requirements under the Affordable Care Act, which requires manufacturers of drugs, devices, biologics, and medical supplies to report annually to the Centers for Medicare & Medicaid Services information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their

immediate family members;
the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information; and
state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

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Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws. For example, the recently enacted Affordable Care Act, among other things, amends the intent requirement of the Federal Anti-Kickback Statute and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the Federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

Achieving and sustaining compliance with these laws may prove costly. In addition, any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, the exclusion from participation in federal and state healthcare programs, imprisonment, or the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results.

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

Aldoxorubicin is a conjugate of doxorubicin, a widely used anti-cancer drug. Doxorubicin is part of the anthracycline class of chemotherapy agents. Anthracyclines, many of which, including doxorubicin are generic, 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.

Aldoxorubicin is a chemically modified version of doxorubicin that incorporates an acid sensitive linker technology to improve concentration in the tumor. We believe that the albumin-binding ability of aldoxorubicin 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, greater concentration of the drug in tumors and greater efficacy.

STS patients are typically treated with surgery followed by radiation therapy. For patients ineligible for surgery, radiation or both, chemotherapy is the only option. Doxorubicin is the only approved first-line drug for treating STS patients who are ineligible for surgery and is often used in combination with radiation. The National Comprehensive Cancer Network also includes the use of ifosfamide, epirubicin, gemcitabine, gemcitabine with docetaxel, dacarbazine and liposomal doxorubicin marketed in the United States as Doxil® by Johnson & Johnson. Pazopanib (Votrient®), developed by GlaxoSmithKline and now marketed by Novartis, was approved in the United States and Europe in 2012 for the treatment of certain types of advanced STS following prior chemotherapy. In October 2015, the Janssen unit of Johnson & Johnson received approval for trabectedin (Yondelis®) for the treatment of patients with leiomyosarcoma and liposarcoma, that have previously received an anthracycline-containing regimen. In January 2016, the FDA approved Eisai's eribulin (Halaven®) as a treatment for patients with unresectable or metastatic liposarcoma who have received a prior anthracycline. Eli Lilly is conducting a Phase 3 clinical trial with olaratumab in combination with doxorubicin in first-line STS. Eli Lilly stated in October 2015 that they plan to submit a rolling new drug application based on the Phase 2 clinical trial results in STS. There are other approaches to treating STS in clinical development, including Morphotek's ontuxizumab in combination with chemotherapy, and Tracoon Pharmaceuticals' TRC-105 in combination with pazopanib.

Patients with glioblastoma multiforme, or GBM, generally undergo invasive brain surgery, although disease progression following surgery is nearly 100%. The front-line therapy for GBM following surgery is radiation in combination with temozolomide (Temodar®). Bevacizumab (Avastin®) has been approved for the treatment of GBM in patients progressing after prior therapy. Drugs in development to treat GBM include rindopepimut by Celldex Therapeutics, nivolumab by Bristol-Myers Squibb, DCVax by Northwest Biotherapeutics, TRC-105 from Tracoon Pharmaceuticals, veliparib by AstraZeneca and buparlisib by Novartis.

Treatment for newly diagnosed SCLC typically consists of cisplatin or carboplatin in combination with etoposide. Radiation may also be given for extensive-stage disease. While first-line treatment can yield overall response rates of 50-80%, the duration of response is often less than 90 days. For recurrent SCLC, topotecan (Hycamtin®) is standard therapy. SCLC patients who are sensitive to first-line treatment may receive topotecan or the generic chemotherapeutic drugs irinotecan, taxanes, gemcitabine or vinorelbine. Drugs in development for second-line SCLC include Bristol-Myers Squibb's ipilimumab (Yervoy®) and SC16LD6.5 by Stem CentRx, Inc.

Kaposi's sarcoma is generally treated with radiation, surgery and/or liposomal doxorubicin. Liposomal daunorubicin (DaunoXome®, Galen US), with or without paclitaxel, is also recommended as treatment for advanced disease. Other drugs in development for Kaposi's sarcoma include selumetinib by AstraZeneca and pomalidamide by Celgene.

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.

As a result, these competitors may:

- succeed in developing competitive products sooner than us or our strategic partners or licensees;
- obtain FDA or foreign governmental approvals for their products before we can obtain approval of any of our products;
- obtain patents that block or otherwise inhibit the development and commercialization of our product candidate candidates;
- develop products that are safer or more effective than our products;
- devote greater resources than us to marketing or selling products;
- introduce or adapt more quickly than us to new technologies and other scientific advances;
- introduce products that render our products obsolete;
- withstand price competition more successfully than us or our strategic partners or licensees;
- negotiate third-party strategic alliances or licensing arrangements more effectively than us; and
- take better advantage than us of other opportunities.

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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 aldoxorubicin provides for our payment of up to 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 any 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.

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 rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively.

We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively. We maintain sensitive data pertaining to our Company on our computer networks, including information about our development activities, our intellectual property and other proprietary business information. Our internal computer systems and those of third parties with which we contract may be vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures, despite the implementation of security measures. System failures, accidents or security breaches could cause interruptions to our operations, including material disruption of our development activities, result in significant data losses or theft of our intellectual property or proprietary business information, and could require substantial expenditures to remedy. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications or inappropriate disclosure of confidential or proprietary information, we could incur liability and our development programs could be delayed, any of which would harm our business and operations.

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 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.

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

We are conducting international clinical development of aldoxorubicin. 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.

Drug discovery is a complex, time-consuming and expensive process, and we may not succeed in creating new product candidates.

Conducting drug discovery and pre-clinical development of our albumin-binding technology is a complex and expensive process that will take many years. Accordingly, we cannot be sure whether or when our drug discovery and pre-clinical development activities will succeed in developing any new product candidates. In addition, any product candidates that we develop in pre-clinical testing may not demonstrate success in clinical trials required for marketing approval.

Any deficiency in the design, implementation or oversight of our drug discovery and pre-clinical testing programs could cause us to incur significant additional costs, experience significant delays, prevent us from obtaining marketing approval for any product candidate that may result from these programs or abandon development of certain product candidates. If any of these risks materializes, it could harm our business and cause our stock price to decline.

We have a limited operating history in drug discovery, which is inherently risky, and we may not succeed in addressing these risks.

We have operated our drug discovery laboratory and LADR™ development program since October 2014. Accordingly, we have a limited operating history in conducting our own drug discovery programs. In December 2015, we announced the selection of DK049 as the first new product candidate utilizing our LADR™ technology. Consequently, there is limited information for investors to use as basis for assessing the viability of our drug discovery efforts.

Investors must consider the risks and difficulties inherent in drug discovery and pre-clinical activities, including the following:

- difficulties, complications, delays and other unanticipated factors in connection with the development of new drugs;
- competition from companies that have substantially greater assets and financial resources than we have;

our ability to anticipate and adapt to a competitive market and rapid technological developments; our need to rely on multiple levels of complex financing agreements with outside funding due to the length of drug development cycles and governmental approved protocols associated with the pharmaceutical industry; and our dependence upon key scientific personnel, including Felix Kratz, Ph.D., our Vice President of Drug Discovery and Andre Warnecke, Ph.D., our Senior Director of Drug Discovery.

We cannot be certain that we will successfully address these risks or that our drug discovery efforts will be successful. In the event that we do not successfully address these risks, our business, prospects, financial condition and results of operations could be materially and adversely affected. We also may be required to reduce or discontinue altogether our drug discovery and pre-clinical programs.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes (such as research and development tax credits) to offset its post-change income and taxes may be limited. In general, an "ownership change" occurs if there is a cumulative change in our ownership by "5% shareholders" that exceeds 50 percentage points over a rolling three-year period. Similar rules may apply under state tax laws. As a result of a previous ownership change, our annual utilization of approximately \$62.3 million in federal net operating loss carryforwards will be substantially limited. If we experience ownership changes as a result of future transactions in our stock, we may be further limited in our ability to use our net operating loss carryforwards and other tax assets to reduce taxes owed on the net taxable income that we earn. Any such limitations on the ability to use our net operating loss carryforwards and other tax assets could potentially result in increased future tax liability to us on any net income that we may earn in the future.

We cannot assure investors that we will be able to fully address the material weakness in our internal controls or that remediation efforts will prevent future material weaknesses.

We have identified a control deficiency in our financial reporting process concerning a non-routine and unusual item that constitutes a material weakness, for the year ended December 31, 2015. We have initiated certain measures, including performing a comprehensive review of significant and unusual transactions, to remediate this weakness, and plan to implement additional appropriate measures as part of this effort. The Company had previously never had a material weakness in its history. There can be no assurance that we will be able to fully remediate our existing material weakness or that the comprehensive review of certain significant and unusual transactions will remediate or prevent these weaknesses from re-occurring in the future.

Further, there can be no assurance that we will not suffer from other material weaknesses in the future. If we fail to remediate these material weaknesses or fail to otherwise maintain effective internal controls over financial reporting in the future, such failure could result in a material misstatement of our annual or quarterly financial statements that would not be prevented or detected on a timely basis and which could cause investors and other users to lose confidence in our financial statements, limit our ability to raise capital and have a negative effect on the trading price of our common stock. Additionally, failure to remediate the material weaknesses or otherwise failing to maintain effective internal controls over financial reporting may also negatively impact our operating results and financial condition, impair our ability to timely file our periodic and other reports with the SEC, subject us to additional litigation and regulatory actions and cause us to incur substantial additional costs in future periods relating to the implementation of remedial measures.

Risks Associated with Our Common Stock

You may experience future dilution as a result of future equity offerings or other equity issuances.

To raise additional capital, we may in the future offer additional shares of our common stock, preferred stock or other securities convertible into or exchangeable for our common stock. We cannot assure you that we will be able to sell shares or other securities in any other offering at a price per share that is equal to or greater than the price per share that you may pay for the shares of our common stock offered hereby. The price per share at which we sell additional shares of our common stock or other securities convertible into or exchangeable for our common stock in future transactions may be higher or lower than the price per share that you may pay for the shares of our common stock offered hereby.

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 in 2015 ranged from \$1.98 to \$5.42 per share, and it may continue to experience significant volatility from time to time. Factors that may affect the market price of our common stock include the following:

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

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

As of December 31, 2015, there were outstanding stock options and warrants to purchase approximately 21.4 million shares of our common stock at a weighted-average exercise price of \$3.50 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 have been, and in the future may be, subject to legal or administrative actions that could adversely affect our results of operations and our business.

We announced in December 2015 and January 2016 that we agreed to settle federal securities class actions and stockholder derivative lawsuits filed in 2014 against us and certain of our officers and directors. Securities-related class action lawsuits and derivative litigation have often been brought against companies, including many biotechnology companies, which experience volatility in the market price of their securities. This risk is especially relevant for biotechnology and biopharmaceutical companies such as ours, which often experience significant stock price volatility in connection with their product development programs.

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 restated by-laws, as amended, 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 by-laws 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 by-laws 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.

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Our restated by-laws, as amended, designate the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.

Our by-laws provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, or (iv) any action asserting a claim that is governed by the internal affairs doctrine. Any person purchasing or otherwise acquiring any interest in any shares of our capital stock shall be deemed to have notice of and to have consented to this provision of our by-laws. This choice-of-forum provision may limit our stockholders' ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits. Alternatively, if a court were to find this provision of our amended and restated by-laws inapplicable or unenforceable with respect to one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business and financial condition.

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

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

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

We lease our headquarters in Los Angeles, California. The lease covers approximately 5,739 square feet of office and storage space and expires in February 2020. Our monthly rent is \$19,226, which is subject to annual increases. In addition to the monthly rent, we are responsible for paying our allocable portion of operating expenses. We have an option to extend the term of the lease for a five-year period and a right of first offer during the extended lease term to lease any available space on the sixth floor of the premises, subject to the terms and conditions set forth in the lease agreement. We also lease additional storage space for approximately 540 square feet. This lease expires in February 2020, and requires us to make monthly payments of \$1,110, subject to annual increases.

We lease laboratory space in Freiburg, Germany, covering approximately 376 square meters (4,047 square feet). In January, 2016, we signed a lease amendment increasing the space to 752 square meters (8,094 square feet), effective August 1, 2016. The amended lease expires on September 30, 2018, and will require us to increase our monthly payments from €4,498 (approximately \$5,038) to €10,329 (approximately \$11,568), subject to annual increases. We have an option to extend the term of the lease for up to three additional three-year periods.

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Item 3. LEGAL PROCEEDINGS

The Company is occasionally involved in legal proceedings and other matters arising from the normal course of business. As previously reported in the Company's Quarterly Report filed with the SEC on November 3, 2015, on June 13, 2014, three purported securities class action lawsuits pending against us and certain of our officers and directors in the United States District Court for the Central District of California were consolidated in the matter of *In re CytRx Corporation Securities Litigation*, 2:14-CV-01956-GHK (PJWx) (the "Federal Class Action"), and lead plaintiff and lead counsel were appointed. On October 1, 2014, plaintiffs filed a consolidated amended complaint on behalf of all persons who purchased or otherwise acquired our publicly traded securities between November 20, 2013 and March 13, 2014, against us, certain of our officers and directors, a freelance writer, and certain underwriters, including Jefferies LLC, Oppenheimer & Co., LLC, Aegis Corp., and H.C. Wainwright & Co., LLC. The complaint alleges that certain of the defendants violated the Securities Exchange Act of 1934 by making materially false and misleading statements in press releases, promotional articles, SEC filings and other public statements. The complaint further alleges that certain of the defendants violated the Securities Act of 1933 by making materially misleading statements and omitting material information in our shelf Registration Statement on Form S-3 filed with the SEC on December 6, 2012 and Prospectus Supplement under Rule 424(b)(2) filed with the SEC on January 31, 2014. These allegations arise out of our alleged retention of The DreamTeam Group and MissionIR, external investor and public relations firms unaffiliated with us, as well as our December 9, 2013 grant of stock options to certain board members and officers. The consolidated amended complaint seeks damages, including interest, in an unspecified amount, reasonable costs and attorneys' fees, and any equitable, injunctive, or other relief that the court may deem just and proper. On December 5, 2014, we and the individual defendants filed a motion to dismiss the complaint. The Court was scheduled to hear argument on this motion on March 2, 2015. On February 25, 2015, the Court took this motion under submission and took the hearing off calendar. On July 13, 2015, the Court issued an order granting in part and denying in part the motions to dismiss filed by us, the individual defendants and the underwriters. On August 7, 2015, the plaintiffs amended their complaint and on September 8, 2015, the defendants moved to dismiss the amended complaint, in part. On October 23, 2015, the Court took the motion to dismiss under submission and, as a result of the settlement of the case as set forth below, the motion to dismiss has not been ruled on by the Court. On April 3, 2014, a purported class action lawsuit was filed against us and certain of our officers and each of our directors, as well as certain underwriters, in the Superior Court of California, County of Los Angeles, captioned *Rajasekaran v. CytRx Corporation, et al.*, BC541426. The complaint purports to be brought on behalf of all shareholders who purchased or otherwise acquired our common stock pursuant or traceable to our public offering that closed on February 5, 2014. The complaint alleges that defendants violated the federal securities laws by making materially false and misleading statements in our filings with the SEC. The complaint seeks compensatory damages in an unspecified amount, rescission, and attorney's fees and costs. On October 14, 2014, the Court granted the parties' joint ex parte motion to stay this proceeding pending resolution of motions to dismiss in the related federal action, *In re CytRx Corporation Securities Litigation*, 2:14-CV-01956-GHK (PJWx). On December 29, 2015, as a result of the parties informing the Court that the settlement of the Federal Class Action also resolved the claims and allegations in the *Rajasekaran* case, the Superior Court deemed the case closed.

On December 10, 2015, we announced that we had reached an agreement to settle the federal consolidated securities class action and filed a Stipulation of Settlement with the Court. A hearing on plaintiffs' motion for preliminary approval of the settlement was held on January 11, 2016. The agreement contains no admission of liability or wrongdoing and includes a full release of CytRx and the current and former directors and officers in connection with the allegations. The settlement is subject to definitive documentation, shareholder notice, and Court approval. The terms of the agreement provide for a settlement payment to the class of \$4,000,000, of which at least \$3,500,000 will be paid by our insurance carriers. We will also issue the equivalent number of shares of our common stock to the class of \$4,500,000 at the prevailing stock price at the time of the Court's final approval of the settlement agreement, but not less than a minimum of 1,200,000 shares and not more than a maximum of 1,800,000 shares. On January 9, 2016, the Court preliminarily approved the settlement, and set a settlement fairness hearing for final approval of the settlement for May 9, 2016.

On July 3, 2014, a shareholder derivative lawsuit was filed in the United States District Court for the Central District of California, captioned *Fishman v. Kriegsman, et al.*, 2:14-cv-05169, purportedly on our behalf against certain of our officers and each of our directors. The complaint alleges breach of fiduciary duties, corporate waste, gross mismanagement, and unjust enrichment in connection with our alleged retention of DreamTeamGroup and MissionIR. The complaint seeks damages, restitution, corporate governance reforms, and attorney's fees and costs. On September 3, 2014, plaintiff filed a notice to voluntarily dismiss this action against all parties without prejudice, which the Court granted on September 9, 2014.

On September 10, 2014, the Delaware Court of Chancery consolidated *Schwartz v. Ignarro, et al.*, Case No. 9864, *Johnson v. Ignarro, et al.*, Case No. 9884, and *Silverberg v. Kriegsman, et al.*, Case No. 9919, three shareholder derivative lawsuits described in our Quarterly Report filed with the SEC on August 6, 2014. The allegations in the Schwartz and Johnson complaints relate to our December 9, 2013 grant of stock options to certain board members and officers. The allegations in the Silverberg complaint relate to our December 9, 2013 grant of stock options to certain board members and officers, as well as our alleged retention of DreamTeamGroup and MissionIR. A consolidated complaint concentrated on the stock-option grant claims was filed on October 9, 2014. The consolidated lawsuit is captioned *In re CytRx Corp. Stockholder Derivative Litigation*, C.A. No. 9864-VCL. On November 10, 2014, we and the individual defendants filed a motion to dismiss the consolidated complaint or, in the alternative, to stay the action. The Court heard argument on the motions on January 8, 2015. The Court denied the motion to dismiss and granted in part and denied in part the motion to stay the Delaware case pending the Federal Class Action. On June 2, 2015, we announced that we had reached an agreement to settle the Delaware stockholder derivative action. Under the settlement, we agreed to re-price outstanding stock options to purchase a total of 2,095,000 shares of our common stock that were granted on December 10, 2013 to certain of our directors and officers from the original exercise price of \$2.39 to an exercise price of \$4.66 (the share price at market closing on December 20, 2013). The settlement also provides that we will implement certain corporate governance changes and modify our governance practices regarding the granting of stock options. The parties reached an agreement on an award of \$1.1 million of fees and expenses to plaintiffs' attorneys. On November 20, 2015, the Delaware Court approved the settlement and award of attorneys' fees and expenses, and entered a final order and judgment. This amount was paid by our insurance carriers in December, 2015.

On August 14, 2014, a shareholder derivative lawsuit, captioned *Pankratz v. Kriegsman, et al.*, 2:14-cv-06414-PA-JPR, was filed in the United States District Court for the Central District of California purportedly on our behalf against certain of our officers and each of our directors. On August 15, 2014, a virtually identical complaint was filed, captioned *Taylor v. Kriegsman, et al.*, 2:14-cv-06451. Each complaint alleges breach of fiduciary duties, unjust enrichment, gross mismanagement, abuse of control, insider selling and misappropriation of information in connection with our alleged retention of DreamTeamGroup and MissionIR, as well as our December 9, 2013 grant of stock options to certain board members and officers. The complaint seeks unspecified damages, corporate governance and internal procedures reforms, restitution, disgorgement of all profits, benefits, and other compensation obtained by the individual defendants, and the costs and disbursements of the action. On October 8, 2014, the Court in *Pankratz* and *Taylor* consolidated the cases and appointed lead plaintiffs and co-lead counsel. On October 20, 2014, we and the individual defendants filed motions to dismiss the consolidated *Pankratz* and *Taylor* cases or, in the alternative, to stay the cases. On January 9, 2015, the Court stayed the action pending the resolution of the consolidated Delaware derivative action. On February 27, 2015, the *Pankratz* and *Taylor* plaintiffs filed a motion to vacate the stay. On June 24, 2015, the Court granted the motion to lift the stay in light of the pending settlement of the Delaware derivative litigation discussed above. The Court further denied the motion to dismiss without prejudice and invited us to move to dismiss the case within 30 days pursuant to the doctrine of *forum non conveniens* based on our forum-selection bylaw, which mandates that derivative actions be filed in Delaware. The Court advised that it would consider any *forum non conveniens* motion before considering a subsequent motion to dismiss under Rule 12. On November 2, 2015, the Court granted the defendants' motion on grounds of *forum non conveniens*, and the case was dismissed without prejudice to plaintiffs refiling the action in the Delaware Court of Chancery. Plaintiffs then filed an appeal with the Ninth Circuit Court of Appeals. On January 5, 2016, we announced that we reached an agreement to settle the consolidated stockholder derivative lawsuits, *In Re CytRx Corporation Stockholder Derivative Litigation*, pending in the U.S. Court of Appeals for the Ninth Circuit Court, on appeal from the United States District

Court for the Central District of California. The settlement includes no financial or equity compensation. It provides that we will implement certain corporate governance changes and modify certain governance practices. The settlement agreement contains no admission of liability or wrongdoing and includes a full release of the current and former directors and officers in connection with the allegations. The settlement is subject to the drafting of definitive documentation, notice to stockholders, and District Court approval. Plaintiffs' counsel is expected to petition the District Court for an award of attorneys' fees and costs.

On December 14, 2015, a shareholder derivative complaint, captioned *Niedermeyer et al. v. Kriegsman et al.*, C.A. No. 11800, was filed in the Delaware Court of Chancery purportedly on the Company's behalf against certain of its officers and directors. The complaint alleges breach of fiduciary duty, unjust enrichment, and gross mismanagement in connection with the Company's alleged retention of DreamTeamGroup and MissionIR, as well as its December 2013 grant of stock options to certain board members and officers. The complaint seeks unspecified damages, corporate governance and internal procedures reforms, restitution, disgorgement of all profits, benefits, and other compensation obtained by the individual defendants, and the costs and disbursements of the action. On February 26, 2016, the Company and the defendants filed two motions with the Court of Chancery. First, we moved to dismiss because the Niedermayer complaint fails to state a claim upon which relief can be granted and because the allegations and claims in the Niedermayer complaint are effectively resolved by the settlement of the consolidated stockholder derivative lawsuits, *In Re CytRx Corporation Stockholder Derivative Litigation*, pending in the United States District Court for the Central District of California, and the settlement of the derivative lawsuits already approved by the Delaware Court of Chancery, *In re CytRx Corp. Stockholder Derivative Litigation*, C.A. No. 9864-VCL. Second, we moved to stay the Niedermayer case until the Central District of California completes the approval process for the settlement of the consolidated derivative actions pending in that court, *In Re CytRx Corporation Stockholder Derivative Litigation*

Item 4. MINE SAFETY DISCLOSURES

Not Applicable.

PART II

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

Market Information

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

	High	Low
Fiscal Year 2015:		
Fourth Quarter	\$3.41	\$2.32
Third Quarter	\$4.20	\$1.98
Second Quarter	\$5.42	\$3.30
First Quarter	\$3.88	\$2.51

Fiscal Year 2014:

Fourth Quarter	\$3.20	\$2.08
Third Quarter	\$4.25	\$2.54
Second Quarter	\$5.46	\$2.78
First Quarter	\$8.35	\$3.15

Holders

On March 11, 2016, there were approximately 670 holders of record of our common stock. The number of record holders does not reflect the number of beneficial owners of our common stock for whom shares are held by brokerage firms and other nominees.

Dividends

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

Equity Compensation Plans

The following table sets forth certain information as of December 31, 2015, regarding securities authorized for issuance under our equity compensation plans:

Plan Category	(a) Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	(b) Weighted-Average Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))
Equity compensation plans approved by our security holders:			
2000 Long-Term Incentive Plan	593,615	\$ 7.15	—
2008 Stock Incentive Plan	13,580,251	2.91	6,419,749
Equity compensation plans not approved by our security holders:			
Outstanding warrants (1)	7,225,472	4.28	—
Total	21,399,338	\$ 3.49	6,419,749

The warrants shown were issued in discrete transactions from time to time as compensation for services rendered by consultants, advisors or other third parties, and do not include warrants sold in capital-raising transactions. The material terms of such warrants were determined based upon arm's-length negotiations with the service providers.

- (1) The warrant exercise prices approximate the market price of our common stock at or about the date of grant, and the warrant terms range from two to ten years from the grant date. The warrants contain customary anti-dilution adjustments in the event of a stock split, reverse stock split, reclassification or combination of our outstanding common stock and similar events and certain of the warrants contain anti-dilution adjustments triggered by other corporate events, such as dividends. On August 1, 2016, 6,371,899 warrants priced at \$4.48 expire.

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Comparison of Cumulative Total Returns

The following line graph presentation compares cumulative total stockholder returns of CytRx with The NASDAQ Stock Market Index and The NASDAQ Pharmaceutical Index (the "Peer Index") for the five-year period from December 31, 2011 to December 31, 2015. The graph and table assume that \$100 was invested in each of our common stock, The NASDAQ Stock Market Index and the Peer Index on December 31, 2010, and that all dividends were reinvested. This data was furnished by Zacks Investment Research.

Comparison of Cumulative Total Returns

	December 31,				
	<u>2011</u>	<u>2012</u>	<u>2013</u>	<u>2014</u>	<u>2015</u>
CytRx Corporation	27.72	26.45	88.68	38.76	37.48
The NASDAQ Stock Market Index	99.17	116.48	163.21	187.27	200.31
The NASDAQ Pharmaceutical Index	107.04	142.41	234.79	306.46	324.29

Recent Issuances of Unregistered Securities

None.

Repurchase of Shares

We did not repurchase any of our shares during the year ended December 31, 2015.

Item 6. SELECTED FINANCIAL DATA

General

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

	2015	2014	2013	2012	2011
Statement of Operations Data:					
Revenue					
Licensing revenue	\$ 100,000	\$ 100,000	\$ 300,000	\$ 100,000	\$ 250,000
Total revenue	\$ 100,000	\$ 100,000	\$ 300,000	\$ 100,000	\$ 250,000
Net loss applicable to common stockholders					
	\$(58,587,000)	\$(30,118,000)	\$(47,485,000)	\$(17,964,000)	\$(14,425,000)
Basic and diluted loss per share applicable to common stock					
	\$(0.97)	\$(0.55)	\$(1.44)	\$(0.78)	\$(0.80)
Balance Sheet Data:					
Cash, cash equivalents and short-term investments					
	\$ 57,297,000	\$ 77,840,000	\$ 38,568,000	\$ 38,344,000	\$ 36,046,000
Total assets	\$ 67,024,000	\$ 85,693,000	\$ 41,500,000	\$ 40,232,000	\$ 37,854,000
Total stockholders' equity	\$ 44,079,000	\$ 67,911,000	\$ 10,661,000	\$ 30,166,000	\$ 24,254,000

Factors Affecting Comparability

In July, 2015, we completed a \$28.7 million underwritten public offering, in which we sold and issued approximately 10.5 million shares of common stock at a price of \$2.75 per share. Net of underwriting discounts, legal, accounting and other offering expenses, the Company received proceeds of approximately \$26.8 million.

In February 2014, we completed an \$86.0 million underwritten public offering, in which we sold and issued 13.2 million shares of common stock at a price of \$6.50 per share. Net of underwriting discounts, legal, accounting and other offering expenses, we received proceeds of approximately \$80.5 million.

In October 2013, we completed a \$25.9 million underwritten public offering, in which we sold and issued 11.5 million shares of common stock at a price of \$2.25 per share. Net of underwriting discounts, legal, accounting and other offering expenses, we received proceeds of approximately \$24.1 million.

In October 2012, we completed a \$23.0 million underwritten public offering, in which we sold and issued 9.2 million shares of common stock at a price of \$2.50 per share. Net of underwriting discounts, legal, accounting and other offering expenses, we received proceeds of approximately \$21.5 million.

In August 2011, we completed a \$20.4 million underwritten public offering in which we sold and issued 5.6 million shares of common stock at a price of \$3.57 per share and warrants at a price of \$0.07 per warrant to purchase up to approximately 6.4 million shares of common stock at an exercise price of \$4.48 per share. Net of underwriting discounts, legal, accounting and other offering expenses, we received proceeds of approximately \$18.9 million (without giving effect to any proceeds that we may receive upon future exercises of the warrants sold in the offering).

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

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

Overview

CytRx Corporation

We are a biopharmaceutical research and development company specializing in oncology. We currently are focused on the clinical development of aldoxorubicin (formerly known as INNO-206), our modified version of the widely-used chemotherapeutic agent, doxorubicin. We have reported positive top-line efficacy results (median progression-free survival, progression-free survival at six months, overall response rates, hazard ratios and overall survival) from our completed, global Phase 2b clinical trial with aldoxorubicin as a treatment for soft tissue sarcoma, or STS. Hazard ratios - the likelihood that the study endpoint (in this case tumor progression) will be reached during a given period - are an important measure of the reliability and uniformity of the absolute data for progression-free survival, or PFS. The trial investigated the efficacy and safety of aldoxorubicin compared with doxorubicin in subjects with first-line metastatic, locally advanced or unresectable STS. Aldoxorubicin combines the chemotherapeutic agent doxorubicin with a novel linker-molecule that binds specifically to albumin in the blood to allow for delivery of higher amounts of doxorubicin (3½ to 4 times) without the major dose-limiting toxicities seen with administration of doxorubicin alone.

In the first quarter of 2014, we initiated a pivotal Phase 3 trial of aldoxorubicin as a therapy for patients with STS whose tumors have progressed following treatment with chemotherapy, and we have received approval from the FDA to continue dosing patients with aldoxorubicin until disease progression in that clinical trial. The Phase 3 trial is being conducted under a Special Protocol Assessment, or SPA, granted by the U.S. Food and Drug Administration, or FDA. The SPA means that the FDA agrees that the design and analyses proposed in the Phase 3 trial protocol are acceptable to support regulatory approval of the product candidate with respect to effectiveness of the indication studied, and will not subsequently change its perspective on these matters, unless previously unrecognized public or animal health concerns were to arise or we were to subsequently modify the protocol. Thus, if the study demonstrates an acceptable benefit-risk profile as determined by the FDA, it would suffice as the single pivotal trial to demonstrate effectiveness and would support registration of aldoxorubicin for this indication. The clinical trial has completed its target enrollment of 400 patients at approximately 79 clinical sites in the U.S., Europe, Canada, Latin America and Australia. CytRx expects to report the top-line results on progression-free survival, the trial's primary endpoint, in the first half of 2016.

We are currently evaluating aldoxorubicin in a global Phase 2b clinical trial in small cell lung cancer, a Phase 2 clinical trial in HIV-related Kaposi's sarcoma, a Phase 2 clinical trial in patients with late-stage glioblastoma (brain cancer), a Phase 1b trial in combination with ifosfamide in patients with soft tissue sarcoma, and a Phase 1b trial in combination with gemcitabine in subjects with metastatic solid tumors. We have completed a global Phase 2b clinical trial with aldoxorubicin as a first-line therapy for STS, a Phase 1b/2 clinical trial primarily in the same indication, a Phase 1b clinical trial of aldoxorubicin in combination with doxorubicin in patients with advanced solid tumors and a Phase 1b pharmacokinetics clinical trial in patients with metastatic solid tumors.

In addition to aldoxorubicin, CytRx is currently completing pre-clinical development for DK049, a novel anti-cancer drug conjugate that utilizes the Company's Linker Activated Drug Release (LADR™) technology. DK049 was created at our laboratory facility in Freiburg, Germany, and employs a proprietary linker that is both pH sensitive and requires a specific enzyme for the release of the cytotoxic payload. DK049 has demonstrated significant anti-tumor activity in multiple animal models implanted with human tumors, including non-small cell lung, ovarian and pancreatic cancers. CytRx anticipates filing an Investigational New Drug Application (IND) in the second half of 2016 prior to initiating a Phase 1 clinical trial.

We plan to expand our pipeline of oncology candidates through our drug development activities at our laboratory facility in Freiburg, Germany, based on novel linker technologies that can be utilized with multiple chemotherapeutic

agents and may allow for greater drug concentration at tumor sites.

In order to fund our business and operations, we have relied primarily upon sales of our equity securities, including proceeds from the exercise of stock options and common stock purchase warrants and we recently secured long-term financing. We also have received limited funding from our strategic partners and licensees.

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At December 31, 2015, we had cash and cash equivalents of approximately \$22.3 million and short-term investments of \$35.0 million. On February 6, 2016, we announced the signing of a long-term loan agreement with Hercules Technology Growth Capital, Inc. and Hercules Technology III, L.P. for up to \$40.0 million in financing, of which we received \$25.0 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 2015 of approximately \$58.9 million, which includes approximately \$34.3 million for our clinical programs for aldoxorubicin, approximately \$5.4 million for pre-clinical development of new albumin-binding cancer drugs, including DK049; approximately \$4.2 million for general operation of our clinical programs and approximately \$15.0 million for other general and administrative expenses, including pre-commercialization expenses. These projected expenditures are based upon numerous assumptions and subject to many uncertainties, and our actual expenditures may be significantly different from these projections. We will ultimately be required to obtain additional funding in order to execute our long-term business plans, although we do not currently have commitments from any third parties to provide us with capital. We cannot assure that additional funding will be available on favorable terms, or at all. If we fail to obtain additional funding when needed, we may not be able to execute our business plans and our business may suffer, which would have a material adverse effect on