

CYTRX CORP
Form 10-K
March 15, 2017

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, 2016
or

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

For the transition period from to

Commission file number 0-15327

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

Delaware	58-1642740
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

11726 San Vicente Blvd, Suite 650, Los Angeles, California	90049
(Address of principal executive offices)	(Zip Code)

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

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

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

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 ☐ R

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 ☐ R 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 ☐ R 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. ☐ R

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 ☐ R 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 ☐ R

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, 2016 (the last business day of the Registrant's most recently completed second fiscal quarter) was approximately \$136 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 15, 2017 was 117,322,895.

CYTRX CORPORATION
2016 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, our modified version of the widely-used chemotherapeutic agent, doxorubicin. 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 ($3\frac{1}{2}$ to 4 times) without several of the major dose-limiting toxicities seen with administration of doxorubicin alone. Aldoxorubicin has received Orphan Drug Designation (ODD) by the U.S. FDA for the treatment of soft tissue sarcomas (STS). ODD provides several benefits including seven years of market exclusivity after approval, certain R&D related tax credits, and protocol assistance by the FDA. European regulators granted aldoxorubicin Orphan designation for STS which confers ten years of market exclusivity among other benefits. We are also developing new anti-cancer drug conjugates that utilize our Linker Activated Drug Release (LADRTM) technology.

In July 2016, we announced the initial analysis of top-line data from our on-going global, randomized Phase 3 clinical trial of aldoxorubicin as a treatment for patients with relapsed or refractory soft tissue sarcomas, or STS. The trial enrolled 433 patients at 79 sites in 15 countries, including the U.S. and Canada.

In November 2016, we announced positive updated results from our pivotal Phase 3 clinical trial evaluating aldoxorubicin compared to investigator's choice in patients with relapsed or refractory soft tissue sarcomas (STS). The study demonstrated a statistically significant improvement in progression-free survival (PFS) between aldoxorubicin and investigator's choice therapy in 246 patients with leiomyosarcoma and liposarcoma, ($p=0.007$). The hazard ratio (HR) was 0.62 (95% CI 0.44-0.88), representing a 38% reduction in the risk of tumor progression for patients receiving aldoxorubicin versus investigator's choice. Leiomyosarcoma and liposarcoma are the two most common types of STS and accounted for 57% of the patients enrolled in the trial.

Aldoxorubicin demonstrated a statistically significant improvement in PFS over investigator's choice in 312 patients treated in North America plus Australia ($p=0.028$; HR=0.71, 95% CI 0.53-0.97), which represented 72% of the total trial population. As previously reported, aldoxorubicin performed better than investigator's choice for the entire study population and narrowly missed statistical significance ($p=0.12$; HR=0.81, 95% CI 0.64-1.06). All responses and PFS were determined by an independent, blinded central lab assessment of scans.

Based upon the updated results of the Phase 3 trial, we have been granted a Type B pre-New Drug Application, or pre-NDA, meeting with the FDA to discuss the regulatory path forward for aldoxorubicin. Depending upon the outcome of the meeting, which is scheduled in March 2017, we intend to file an NDA with the FDA.

We are currently evaluating aldoxorubicin in a global Phase 2b clinical trial in second-line small cell lung cancer in which we currently expect to announce top-line data in the second quarter of 2017, as the number of deaths and/or progressions needed for data analysis have not yet been reached. We are also evaluating aldoxorubicin in a Phase 1b/2 trial in combination with ifosfamide in patients with STS. We previously completed Phase 2 clinical trials of aldoxorubicin in patients with late-stage glioblastoma (brain cancer) and HIV-related Kaposi's Sarcoma, a Phase 1b trial in combination with gemcitabine in subjects with metastatic solid tumors, a Phase 1b clinical trial of aldoxorubicin in combination with doxorubicin in patients with advanced solid tumors and a Phase 1b pharmacokinetics clinical trial of aldoxorubicin in patients with metastatic solid tumors.

We also are engaged at our laboratory facility in Freiburg, Germany in preclinical development in a new class of oncology candidates utilizing our LADRTM technology to attach ultra-high potency drugs to albumin (10-1000 times more potent than traditional chemotherapies; these drugs are attached only to antibodies as antibody-drug conjugates, ADCs) to target tumors.

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 web site is located at <http://www.cytrx.com>. We do not incorporate by reference into this Annual Report the information on, or

accessible through, our website, and you should not consider it as part of this Annual Report.

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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 completed
		Kaposi's Sarcoma	Phase 2 completed
		Combination with ifosfamide	Phase 1b ongoing
		Combination with gemcitabine	Phase 1b completed
LADR™ for high potency albumin-binding 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 a Special Protocol Assessment ("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.

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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 cancer models 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. In July 2016, we announced the initial analysis of top-line data from our on-going global, randomized Phase 3 clinical trial of aldoxorubicin as a treatment for patients with relapsed or refractory soft tissue sarcomas, or STS. The trial enrolled 433 patients at 79 sites in 15 countries including the U.S. and Canada. Aldoxorubicin performed better than investigator's choice for the entire study population, and narrowly missed statistical significance in progression-free survival, or PFS ($p=0.12$; $HR=0.81$, 95% CI 0.64-1.06), the trial's primary endpoint. All responses were determined by an independent, blinded central radiology lab assessment of scans. Since the initial analysis, we have continued to follow patients for overall survival (OS), a secondary endpoint of the trial.

On November 29, 2016, we announced updated results from the Phase 3 clinical trial, which demonstrated a statistically significant improvement in PFS between aldoxorubicin and investigator's choice therapy in 246 patients with either leiomyosarcoma or liposarcoma, ($p=0.007$). The hazard ratio (HR) was 0.62 (95% CI 0.44-0.88), representing a 38% reduction in the risk of tumor progression for patients receiving aldoxorubicin versus investigator's choice. Leiomyosarcoma and liposarcoma, the two most common types of STS, accounted for 57% of the patients enrolled in the overall trial. Aldoxorubicin also demonstrated a statistically significant improvement in PFS over investigator's choice in 312 patients treated in North America plus Australia ($p=0.028$; $HR=0.71$, 95% CI 0.53-0.97). In the entire study population, aldoxorubicin achieved a statistically significant improvement in the disease control rate, or DCR (defined as objective response rate, or ORR, plus stable disease for at least four months) of 29.4% versus 20.5% for the patients treated with investigator's choice ($p=0.030$). In North American patients, the benefit was more pronounced, with aldoxorubicin-treated patients exhibiting a DCR of 32.9%, compared to 19.2% for patients treated with investigator's choice ($p=0.007$), an overall improvement of 71%. ORR in North American patients also favored aldoxorubicin over investigator's choice, 8.7% versus 3.3% ($p=0.058$).

Aldoxorubicin did not cause clinically significant cardiac, renal, or hepatic toxicities. For the global trial population, the most commonly reported adverse events were neutropenia and anemia consistent with prior clinical trials with aldoxorubicin. Grade 3 or higher adverse events were manageable with supportive care and occurred at a rate of 61% for patients receiving aldoxorubicin and 46% in patients treated with investigator's choice. Treatment-emergent adverse events leading to discontinuation occurred in 4.2% of patients treated with aldoxorubicin, compared to 6.3% for patients receiving investigator's choice. Serious adverse events, primarily febrile neutropenia that resolved and rarely led to treatment termination occurred more frequently in patients administered aldoxorubicin. Three treatment-related deaths occurred in aldoxorubicin-treated patients, while there were no treatment-related deaths among patients receiving investigators' choice of drugs.

Based upon the updated results of the Phase 3 trial, we requested and the FDA granted us a Type B pre-NDA meeting which will occur in the first quarter of 2017. Subject to the outcome of this meeting, we intend to file an NDA with the FDA.

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.

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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 Oncology 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-naïve 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.

A Phase 1 study of aldorubicin 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 aldorubicin 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 idoxorubicin 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).

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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).

In September 2016, we completed enrollment in our global Phase 2b clinical trial evaluating aldoxorubicin 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 enroll approximately 135 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 aldoxorubicin compared to topotecan in this population. Top-line results from this study are expected in the second quarter of 2017.

We completed a Phase 2 clinical trial evaluating the preliminary efficacy and safety of aldoxorubicin 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 and demonstrated that an albumin-binding therapy can enter the brain and have anti-tumor activity. At the 2016 American Society for Clinical Oncology (ASCO) Annual Meeting, the trial results were presented including the median overall survival of 8.6 months.

We completed a Phase 2 clinical trial evaluating the preliminary efficacy of aldoxorubicin 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 was conducted at the LSU Medical Center in New Orleans, Louisiana. Results were presented at the 2016 ASCO Annual Meeting showing that aldoxorubicin localized in the tumor lesions and compared to non-tumor tissues. Eleven of 13 patients (85%) treated with low dose aldoxorubicin achieved a partial response at week four.

We are also conducting a Phase 1b/2 trial in combination with ifosfamide in patients with STS, and completed 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 aldoxorubicin that can be administered 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 create high potency cytotoxic drug conjugates that bind albumin in the body, and then concentrate drug in tumors. Led by Felix Kratz, Ph.D., Vice President of Drug Discovery and inventor of aldoxorubicin, the discovery team is working to expand our novel albumin-binding anti-cancer drug pipeline using LADR™ linkers to create unique drug conjugates.

Disposition of Molecular Chaperone Assets

Until 2011, we owned the rights to two drug candidates, arimoclomol and iroscanadine, 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.

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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 aldoxorubicin 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 \$35.9 million, \$43.4 million and \$36.7 million for the years ended December 31, 2016, 2015 and 2014, respectively, or approximately 68%, 68% and 74%, 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 aldoxorubicin 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 aldoxorubicin. 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 aldoxorubicin 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 currently have no sales, marketing or commercial product distribution capabilities or experience in marketing products. If aldoxorubicin is approved, we would likely look to a strategic partner to commercialize aldoxorubicin in the United States.

We have not yet defined our commercial strategy for aldoxorubicin for markets outside the United States, which strategy may include the use of strategic partners, distributors or a contract sales force. We plan to further evaluate these alternatives as we approach potential approval for aldoxorubicin.

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.

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, 2016, we held rights in four granted U.S. patents, 55 granted foreign patents, three pending U.S. applications, and eighteen 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 one pending international application covering our LADR™ technology and DK049. The unextended patent term of patents that issue covering our LADR™ technology and DK049 is June 2036.

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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. First-line therapy for STS patients typically includes doxorubicin either by itself or in combination with olaratumab (Lartruvo™) marketed by Eli Lilly & Co., or ifosfamide. The National Comprehensive Cancer Network also includes the use of ifosfamide, epirubicin, gemcitabine, gemcitabine with docetaxel, dacarbazine and liposomal doxorubicin. Novartis'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. Trabectedin (Yondelis®) was approved in 2015 for patients with leiomyosarcoma or liposarcoma that have had prior treatment with an anthracycline such as doxorubicin. In 2016, eribulin (Halaven®) was approved for patients with liposarcoma that have had prior treatment with an anthracycline. There are other approaches to treating STS in clinical development, including Morphotek's ontuxizumab in combination with chemotherapy, and Traccon 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 Traccon 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 the FDA-approved 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 rovalpituzumab tesirine by AbbVie, 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.

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Government Regulation

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

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

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

After the IND becomes effective, a company may commence human clinical trials. These are typically conducted in three sequential phases, but the phases may overlap. Phase 1 trials consist of testing of the product candidate in a small number of patients or healthy volunteers, primarily for safety at one or more doses. Phase 2 trials, in addition to safety, evaluate the efficacy of the product candidate in a patient population somewhat larger than Phase 1 trials. Phase 3 trials typically involve additional testing for safety and clinical efficacy in an expanded population at multiple test sites. A company must submit to the FDA a clinical protocol, accompanied by the approval of the Institutional Review Boards at the institutions participating in the 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.

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

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

Employees

As of March 11, 2017, we had twenty-seven employees, six of whom were engaged in clinical development activities, thirteen of whom were engaged in preclinical research at our Freiburg, Germany laboratory, and eight 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 \$50.8 million for the year ended December 31, 2016 and \$58.6 million for the year ended December 31, 2015 and had an accumulated deficit as of December 31, 2016 of \$416.2 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 capital raising to sustain our operations, and our ability to raise capital may be severely limited.

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 under our "shelf" registration statements on Form S-3 filed with the SEC 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;
- 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.

The depressed market price of our common stock may severely limit our ability to continue to raise capital, because the aggregate or market value of our common stock held by non-affiliates, referred to as our "public float," as of the file date of this Annual Report is less than \$75 million. As a result, under Instruction I.B.6 to Form S-3 the aggregate amount of securities that we can offer and sell under our "shelf" registration statements in any 12-month period cannot exceed one-third of our public float, or approximately \$15.6 million as of March 15, 2017. If our public float increases to \$75 million or more, we will no longer be subject to this limitation.

At December 31, 2016, we had cash and cash equivalents of approximately \$57.0 million, but we are required under the terms of our outstanding loan-term debt to maintain cash on hand of not less than three months projected cash burn or \$10 million, whichever is greater. 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 2017 of approximately \$39.8 million, which includes approximately \$16.4 million for our clinical programs for aldoxorubicin, approximately \$3.7 million for pre-clinical development of high potency cytotoxic albumin-binding cancer drugs, approximately \$3.2 million for general operation of our clinical programs, approximately \$8.0 million for other general and administrative expenses, and \$8.5 million for interest and payments on our outstanding term loan. These projected expenditures and payments assume that we will not suffer a "material adverse event" which could trigger the lenders' acceleration of our outstanding term loan, and are based upon numerous other assumptions and subject to many uncertainties, and our actual expenditures may be significantly different from these projections. If we receive a negative response from the FDA in our planned pre-NDA meeting, we may reduce our headcount and discontinue certain development programs and drug discovery activities. For these reasons and others, our operating results may fluctuate from period to period, and the results of prior periods should not be relied upon as predictive of the results in future periods. Furthermore, if we obtain marketing approval and successfully commercialize aldoxorubicin, or another 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 discussions in this Annual Report of the expected timing of the pre-NDA meeting with the FDA and of certain other milestones relating to our aldoxorubicin clinical development programs.

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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.

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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; for instance, the Phase 3 pivotal clinical trial testing aldoxorubicin as a treatment for STS narrowly missed statistical significance although it demonstrated a statistically significant improvement in PFS over investigator's choice in 312 patients treated in North America plus Australia. 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.

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:

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- 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.

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.

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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 aldorubicin 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.

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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.

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.

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If a third-party claims that we are infringing on 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;

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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.

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 Tracon Pharmaceuticals' TRC-105 in combination with pazopanib.

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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, TRC-105 from Traccon 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 ipilumimab (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.

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

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

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

We are conducting international clinical development of 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.

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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. 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.

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.

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.

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

On August 24, 2016, we received notice from The NASDAQ Capital Market ("Nasdaq") that the closing bid price for our common stock had been below \$1.00 for the previous 30 consecutive business days, and that we are therefore not in compliance with the minimum bid price requirement for continued inclusion on The Nasdaq Capital Market under Nasdaq Listing Rule 5550(a)(2). The notice indicates that we will have 180 calendar days, or until February 21, 2017, to regain compliance with this requirement. On February 22, 2017, Nasdaq notified us that we are eligible for an extension to comply with the minimum \$1.00 bid price requirement through August 21, 2017, by which date we must evidence compliance for at least ten consecutive business days. If compliance cannot be demonstrated by August 21, 2017, Nasdaq will provide written notification that our common stock will be delisted. In the event of such a notification, we may appeal Nasdaq's determination, but there can be no assurance Nasdaq would grant any such request for continued listing.

If it appears to Nasdaq that we will not be able to cure the deficiency, or if we are otherwise not eligible, we expect that Nasdaq will notify us that our common stock will be subject to delisting.

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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 2016 ranged from \$0.36 to \$3.66 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, 2016, we had outstanding stock options to purchase 17,479,770 shares of our common stock at a weighted-average exercise price of \$2.37 per share and outstanding warrants to purchase 32,502,790 shares of common stock at a weighted-average exercise price of \$0.68 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.

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We cannot assure investors that our internal controls will prevent future material weaknesses.

As of December 31, 2015, we identified a control deficiency in our financial reporting process concerning a non-routine and unusual item that constituted a material weakness in our internal controls. Since then, we have performed a comprehensive review of significant and unusual transactions, and during the quarter ended September 30, 2016, we implemented new controls and strengthened existing controls over the identification and accounting for significant and unusual transactions. As of September 30, 2016, our management concluded that the controls were operating effectively and that the material weakness as of December 31, 2015 had been fully remediated. There can be no assurance, however, that the new controls will prevent the weakness from re-occurring in the future.

There also 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.

We are subject to legal actions that could adversely affect our financial condition.

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. In July 2016, 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.

As described further in Item 3 of Part I of this Annual Report, our directors and certain of our officers are subject to stockholder derivative claims pending in the Delaware Court of Chancery and we and certain of our officers are subject to class-action complaints filed in the U.S. District Court for the Central District of California. Although we carry director's and officer's and other liability insurance, we must pay the first legal fees and other litigation expenses incurred up to the application retention, or deductible, amounts under our insurance policies, and the insurance may not be sufficient to cover all of the liabilities that we may incur in connection with the pending or possible future legal actions. As a result, the pending legal proceedings and any future legal actions may adversely affect our financial condition.

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 \$20,752, 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 \$1,185, 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. Our monthly rent is €10,070 (approximately \$11,143), which is subject to annual increases. The amended lease expires on September 30, 2018, and 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 9, 2016, the following actions are currently outstanding:

Shareholder Derivative Action in California. 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 of the complaints alleged 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 consolidated the Pankratz and Taylor cases and appointed lead plaintiffs and co-lead counsel. After a series of procedural events including an intervening stay of the action, on November 2, 2015, the Court granted the defendants' motion to dismiss the consolidated action on grounds of forum non conveniens, largely based on our by-law requiring derivative actions to be filed in the Delaware Court of Chancery. On November 17, 2015, Plaintiffs filed an appeal with the Ninth Circuit Court of Appeals. While the case was pending on appeal, on December 22, 2015, the parties executed a Memorandum of Understanding to settle the derivative action. On April 4, 2016, the plaintiffs filed a Motion for Preliminary Approval of the Shareholder Derivative Settlement in the District Court. On May 31, 2016, however, the Court denied without prejudice the Motion for Preliminary Approval of the Settlement on procedural grounds that included the Court's view that the settlement could not be considered until the Court's November 2 judgment dismissing the case was vacated. The Court granted the parties the opportunity to file a motion to set aside the November 2 judgment. However, on August 17, 2016, the Court denied the parties' motion to set aside the judgment. No party took an appeal. Accordingly, the derivative litigation in California has concluded.

Shareholder Derivative Actions in Delaware. There are two competing derivative complaints pending in the Delaware Court of Chancery alleging claims related to our alleged retention of DreamTeamGroup and MissionIR. On December 14, 2015, a shareholder derivative complaint, captioned *Niedermeyer et al. v. Kriegsman et al.*, C.A. No. 11800, was filed against certain of our officers and directors, for which a second amended complaint was filed on October 12, 2016. On September 6, 2016, one of the plaintiffs in the California litigation (discussed above) effectively refiled his complaint in the Delaware Court of Chancery, with the case captioned *Taylor v. Kriegsman*, C.A. No. 12720. Following competing motions for appointment of a lead plaintiff and lead counsel, on February 22, 2017, the Court of Chancery appointed Niedermeyer et al. as the lead plaintiffs in the complaint. We and the defendant officers and defendants will be responding appropriately to the operative complaint.

Class Action in California. On July 25 and 29, 2016, nearly identical class action complaints were filed in the U.S. District Court for the Central District of California, titled *Crihfield v. CytRx Corp., et al.*, Case No. 2:16-cv-05519 and *Dorce v. CytRx Corp.*, Case No. 2:16-cv-05666 alleging that we and certain of our officers violated the Securities Exchange Act of 1934 by allegedly making materially false and/or misleading statements, and/or failing to disclose material adverse facts to the effect that the clinical hold placed on the Phase 3 trial of aldoxorubicin for STS would prevent sufficient follow-up for patients involved in the study, thus requiring further analysis, which could cause the trial's results and/or FDA approval to be materially adversely affected or delayed. The plaintiffs allege that such wrongful acts and omissions caused significant losses and damages to a class of persons and entities that acquired our securities between November 18, 2014 and July 11, 2016, and seek an award of compensatory damages, costs and expenses, including counsel and expert fees, and such other and further relief as the Court may deem just and proper. On October 26, 2016, the Court entered an Order consolidating the actions titled *In re: CytRx Corporation Securities Litigation*, Master File No. 16-cv-05519-SJO and appointing a Lead Plaintiff and Lead Counsel. On January 13, 2017, a first amended complaint was filed in the Crihfield matter, which is now the controlling pleading. We and the individual defendants filed a motion to dismiss the first amended complaint on March 14, 2017.

We intend to vigorously defend against the foregoing complaints. We have directors' and officers' liability insurance, which will be utilized in the defense of these matters. The liability insurance may not cover all of the future liabilities

we may incur in connection with the foregoing matters. These claims are subject to inherent uncertainties, and management's view of these matters may change in the future.

We evaluate developments in legal proceedings and other matters on a quarterly basis. If an unfavorable outcome becomes probable and reasonably estimable, we could incur charges that could have a material adverse impact on our financial condition and results of operations for the period in which the outcome becomes probable and reasonably estimable

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Item 4. MINE SAFETY DISCLOSURES

Not Applicable.

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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 2016:		
Fourth Quarter	\$0.74	\$0.36
Third Quarter	\$2.67	\$0.55
Second Quarter	\$3.66	\$2.13
First Quarter	\$3.08	\$1.55

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

Holders

On March 15, 2017, there were approximately 387 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, 2016, regarding securities authorized for issuance under our equity compensation plans:

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Plan Category	(a) Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	(b) Number of Issued Shares of Restricted Stock	(c) Weighted-Average Exercise Price of Outstanding Options, Restricted Stock, Warrants and Rights	Number of Securities Remaining Available for issuance Under Equity Compensation Plans (Excluding Securities Reflected in Columns (a) and (b))
Equity compensation plans approved by our security holders:				
2000 Long-Term Incentive Plan	487,690	—	\$ 6.89	—
2008 Stock Incentive Plan	16,992,080	2,325,581	2.14	12,112,719
Equity compensation plans not approved by our security holders:				
Outstanding warrants (1)	32,502,790	—	0.68	—
Total	49,982,560	2,325,581	\$ 1.23	12,112,719

(1) 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. 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.

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, 2012 to December 31, 2016. 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, 2011, and that all dividends were reinvested. This data was furnished by Zacks Investment Research.

Comparison of Cumulative Total Returns

	<u>December 31,</u>				
	<u>2012</u>	<u>2013</u>	<u>2014</u>	<u>2015</u>	<u>2016</u>
CytRx Corporation	95.41	319.90	139.80	135.20	18.88
The NASDAQ Stock Market Index	117.45	164.57	188.84	201.98	219.89
The NASDAQ Pharmaceutical Index	133.05	219.35	286.31	302.95	236.32

Recent Issuances of Unregistered Securities
None.

Repurchase of Shares

We did not repurchase any of our shares during the year ended December 31, 2016.

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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).

	2016	2015	2014	2013	2012
Statement of Operations Data:					
Revenue					
Licensing revenue	\$200,000	\$100,000	\$100,000	\$300,000	\$100,000
Total revenue	\$200,000	\$100,000	\$100,000	\$300,000	\$100,000
Net loss	\$(50,771,000)	\$(58,587,000)	\$(30,118,000)	\$(47,485,000)	\$(17,964,000)
Basic and diluted loss per share applicable to common stock	\$(0.63)	\$(0.97)	\$(0.55)	\$(1.44)	\$(0.78)
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	\$56,959,000	\$57,297,000	\$77,840,000	\$38,568,000	\$38,344,000
Total assets	\$62,770,000	\$67,024,000	\$85,693,000	\$41,500,000	\$40,232,000
Total stockholders' equity	\$24,777,000	\$44,079,000	\$67,911,000	\$10,661,000	\$30,166,000

Factors Affecting Comparability

In December 2016, we completed a public offering of 11.5 million shares of our common stock and 3,300 shares of our Series B Convertible Preferred Stock and re-priced outstanding July 2016 warrants to purchase 19.4 million shares of our common stock and extended the term of the warrants to July 2018. Net of underwriting discounts, legal, accounting and other offering expenses, we received proceeds of approximately \$7.5 million.

In July 2016, we completed a public offering issuing 28.6 million shares of our common stock and one-year warrants to purchase an equal number of shares of our common stock in a public offering. Net of underwriting discounts, legal, accounting and other offering expenses, the Company received proceeds of approximately \$18.3 million.

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.

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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, our modified version of the widely-used chemotherapeutic agent, doxorubicin. 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 several of the major dose-limiting toxicities seen with administration of doxorubicin alone. Aldoxorubicin has received Orphan Drug Designation (ODD) by the U.S. FDA for the treatment of soft tissue sarcomas (STS). ODD provides several benefits including seven years of market exclusivity after approval, certain R&D related tax credits, and protocol assistance by the FDA. European regulators granted aldoxorubicin Orphan designation for STS which confers ten years of market exclusivity among other benefits. We are also developing new anti-cancer drug conjugates that utilize our Linker Activated Drug Release (LADR™) technology.

In July 2016 we announced the initial analysis of top-line data from our on-going global, randomized Phase 3 clinical trial of aldoxorubicin as a treatment for patients with relapsed or refractory soft tissue sarcomas, or STS. The trial enrolled 433 patients at 79 sites in 15 countries including the U.S. and Canada.

In November 2016 we announced updated results from our pivotal Phase 3 clinical trial evaluating aldoxorubicin compared to investigator's choice in patients with relapsed or refractory soft tissue sarcomas (STS). The study demonstrated a statistically significant improvement in progression-free survival (PFS) between aldoxorubicin and investigator's choice therapy in 246 patients with leiomyosarcoma and liposarcoma, (p=0.007). The hazard ratio (HR) was 0.62 (95% CI 0.44-0.88), representing a 38% reduction in the risk of tumor progression for patients receiving aldoxorubicin versus investigator's choice. Leiomyosarcoma and liposarcoma are the two most common types of STS and accounted for 57% of the patients enrolled in the trial.

Aldoxorubicin demonstrated a statistically significant improvement in PFS over investigator's choice in 312 patients treated in North America plus Australia (p=0.028; HR=0.71, 95% CI 0.53-0.97). As previously reported, aldoxorubicin performed better than investigator's choice for the entire study population and narrowly missed statistical significance (p=0.12; HR=0.81, 95% CI 0.64-1.06). All responses and PFS were determined by an independent, blinded central lab assessment of scans.

Based upon the updated results of the Phase 3 trial, we have been granted a Type B pre-New Drug Application, or pre-NDA, meeting with the FDA to discuss the regulatory path forward for aldoxorubicin. Depending upon the outcome of the meeting, which is scheduled to occur in March 2017, we intend to file an NDA with the FDA.

We are currently evaluating aldoxorubicin in a global Phase 2b clinical trial in second-line small cell lung cancer in which we currently expect to announce top-line data in the second quarter of 2017, as the number of deaths and/or progressions needed for data analysis have not yet been reached. We are also evaluating aldoxorubicin in a Phase 1b/2 trial in combination with ifosfamide in patients with STS. We previously completed Phase 2 clinical trials of aldoxorubicin in patients with late-stage glioblastoma (brain cancer) and HIV-related Kaposi's Sarcoma, a Phase 1b trial in combination with gemcitabine in subjects with metastatic solid tumors, a Phase 1b clinical trial of aldoxorubicin in combination with doxorubicin in patients with advanced solid tumors and a Phase 1b pharmacokinetics clinical trial of aldoxorubicin in patients with metastatic solid tumors.

We are also engaged at our laboratory facility in Freiburg, Germany in preclinical development in a new class of oncology candidates utilizing our LADRTM technology to attach ultra-high potency drugs to albumin (10-1000 times more potent than traditional chemotherapies; these drugs are attached only to antibodies as antibody-drug conjugates, ADCs) to target tumors.

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.

At December 31, 2016, we had cash and cash equivalents of approximately \$57.0 million but we are required under the terms of our outstanding long-term debt to maintain cash on hand of not less than three months' projected cash burn or \$10 million, whichever is greater. 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 2017 of approximately \$39.8 million, which includes approximately \$16.4 million for our clinical programs for aldoxorubicin, approximately \$3.7 million for pre-clinical development of new high potency cytotoxic albumin-binding cancer drugs, approximately \$3.2 million for general operation of our clinical programs, approximately \$8.0 million for other general and administrative expenses and \$8.5 million of interest and principal payments on our outstanding term loan. These projected expenditures are based upon numerous assumptions and subject to many uncertainties, and our actual expenditures may be significantly different from these projections. While these projections represent our current expected expenditures, we have the ability to reduce the amounts and alter the timing of research and development expenditures as needed to manage our liquidity needs while still advancing our primary research and development objectives. 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 our financial position, results of operations and cash flows.

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Research and Development

Expenditures for research and development activities related to continuing operations were \$35.9 million, \$43.4 million and \$36.7 million, respectively, for the years ended December 31, 2016, 2015 and 2014, or approximately 68%, 68% and 74%, respectively, of our total expenses.

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

Our currently projected expenditures for 2017 include approximately \$16.4 million for our clinical programs for aldoxorubicin, approximately \$3.7 million for pre-clinical development of new high potency cytotoxic albumin-binding cancer drugs, and approximately \$3.2 million for general operation of our clinical programs. The actual cost of our clinical programs could differ significantly from our current projections due to any additional requirements or delays imposed by the FDA in connection with our planned trials, or if actual costs are higher than current management estimates for other reasons, including complications with manufacturing. In the event that actual costs of our clinical programs, or any of our other ongoing research activities, are significantly higher than our current estimates, we may be required to significantly modify our planned level of operations.

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. A discussion of these and other risks and uncertainties associated with our business is set forth in the "Risk Factors" section of this Annual Report.

Critical Accounting Policies and Estimates

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

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

Revenue Recognition

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

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

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

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Research and Development Expenses

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

Clinical Trial Expenses

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

Stock-based Compensation

Our stock-based employee compensation plans are described in Note 14 of the Notes to Financial Statements. We follow the provisions of ASC 718, Compensation - Stock Compensation ("ASC 718"), which requires the measurement and recognition of compensation expense for all stock-based awards made to employees.

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

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

Net Income (Loss) Per Share

Basic net income (loss) per common share attributable to common shareholders is computed using the weighted-average number of common shares outstanding. Diluted net income (loss) per common share is computed using the weighted-average number of common shares and common share equivalents outstanding. Potentially dilutive stock options and warrants to purchase approximately 50.0 million, 21.4 million and 17.4 million shares at December 31, 2016, 2015 and 2014, respectively, were excluded from the computation of diluted net income (loss) per share, because the effect would be anti-dilutive.

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Liquidity and Capital Resources

General

In order to fund our business and operations, we have relied primarily upon sales of our equity securities, including proceeds from the exercise of stock options and common stock purchase warrants and we a long-term loan financing completed in February 2016. We also have received limited funding from our strategic partners and licensees. At December 31, 2016, we had cash and cash equivalents of approximately \$57.0 million but we are required under the terms of our outstanding long-term debt to maintain cash on hand of not less than three months' projected cash burn or \$10 million, whichever is greater. 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 2017 of approximately \$39.8 million, which includes approximately \$16.4 million for our clinical programs for aldoxorubicin, approximately \$3.7 million for pre-clinical development of new high potency cytotoxic albumin-binding cancer drugs approximately \$3.2 million for general operation of our clinical programs, approximately \$8.0 million for other general and administrative expenses and \$8.5 million for interest and payments on our outstanding term loan. These projected expenditures are based upon numerous assumptions and subject to many uncertainties, and our actual expenditures may be significantly different from these projections. While these projections represent our current expected expenditures, we have the ability to reduce the amounts and alter the timing of research and development expenditures as needed to manage our liquidity needs while still advancing our primary research and development objectives. 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 long term debt or capital. We cannot assure that additional funding will be available on favorable terms, or at all. If we fail to obtain additional funding when needed, we may not be able to execute our business plans and our business may suffer, which would have a material adverse effect on our financial position, results of operations and cash flows.

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

Discussion of Operating, Investing and Financing Activities

Net loss for the year ended December 31, 2016 was \$50.8 million, and cash used for operating activities for that period was \$49.9 million. The net loss reflects \$6.7 million of stock option and warrant expense, and a non-cash gain of \$3.8 million on the fair value adjustment of the warrant liability.

Net loss for the year ended December 31, 2015 was \$58.6 million, and cash used for operating activities for that period was \$47.6 million. The net loss reflects \$7.4 million of stock option and warrant expense, and a non-cash gain of \$4.4 million on the fair value adjustment of the warrant liability.

Net loss for the year ended December 31, 2014 was \$30.1 million, and cash used for operating activities for that period was \$40.6 million. The net loss reflects \$6.6 million of stock option and warrant expense, and a non-cash gain of \$19.1 million on the fair value adjustment of the warrant liability.

For the year ended December 31, 2016, \$34.0 million was provided by investing activities. This included \$35.0 million of net proceeds from the sale of short-term investments partially offset by the purchase of equipment and furnishings of \$1.0 million, primarily for our laboratory in Freiburg, Germany.

For the year ended December 31, 2015, \$10.3 million was provided by investing activities. This included \$10.6 million net proceeds from the sale of short-term investments and the difference for purchase of equipment and furnishings, primarily for our laboratory in Freiburg, Germany.

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For the year ended December 31, 2014, \$19.5 million was used for investing activities. This included \$18.5 million net for the purchase of short-term investments.

Cash provided by financing activities for the year ended December 31, 2016 was \$50.5 million, which included \$25.8 million of net proceeds received from our December and July 2016 public offerings. We also received net proceeds of \$24.0 million from our long-term loan financing in February 2016 and \$0.7 million from the exercise of stock options and warrants.

Cash provided by financing activities for the year ended December 31, 2015 was \$27.4 million, which included \$26.8 million of net proceeds received from our July 2015 public offering.

Cash provided by financing activities for the year ended December 31, 2014 was \$80.8 million, which included \$80.5 million of net proceeds received from our February 2014 public offering.

Off-Balance Sheet Arrangements

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

Contractual Obligations

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

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

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

Payments due by periods as of December 31,
2016

			Years 2	Years 4 and	Years 6
	Total	Year 1	and 3	5	and beyond
Contractual Obligations					
Operating lease obligations (1)	\$1,107	\$397	\$651	\$59	\$ —
Employment obligations (2)	8,110	3,257	2,739	2,114	—
Term loan obligation (3)	30,706	8,037	19,290	3,379	—
R&D contract obligations (4)	19,409	19,325	84	—	—
Total contractual obligations	\$59,332	\$31,016	\$22,764	\$5,552	\$ —

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

(2) Employment agreements include management contracts that provide for minimum salary levels, adjusted periodically at the discretion of our Compensation Committee, as well as minimum bonuses and employee benefits, in some cases.

(3) Term loan obligation includes principal and interest payments and an end fee payment.

(4) Research and development obligations relate primarily to our clinical trials. All of these obligations are cancelable upon notice without liability to us.

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

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Net Operating Loss Carryforwards

At December 31, 2016, we had federal and state net operating loss carryforwards of \$333.5 million and \$224.0 million, respectively, available to offset against future taxable income, which expire in 2017 through 2036.

As a result of a change in-control that occurred in the CytRx shareholder base, approximately \$62.3 million in federal net operating loss carryforwards became substantially limited in their annual availability. We currently believe that the remaining \$271.2 million in federal net operating loss carryforwards, and the \$224.0 million in state net operating loss carryforwards, are unrestricted.

As of December 31, 2016, we also had research and development and alternative minimum tax credits for federal and state purposes of approximately \$16.0 million and \$21.2 million, respectively, available for offset against future income taxes, which expire in 2022 through 2036. Based on an assessment of all available evidence including, but not limited to, our limited operating history in its core business and lack of profitability, uncertainties of the commercial viability of its technology, the impact of government regulation and healthcare reform initiatives, and other risks normally associated with biotechnology companies, we have concluded that it is more likely than not that these net operating loss carryforwards and credits will not be realized and, as a result, a 100% deferred tax valuation allowance has been recorded against these assets.

Results of Operations

We incurred a net loss of \$50.8 million, \$58.6 million and \$30.1 million for the years ended December 31, 2016, 2015 and 2014, respectively.

During 2016, 2015 and 2014, we recognized no service revenue and earned an immaterial amount of license fees and grant revenue. All future licensing fees under our current licensing agreements are dependent upon successful development milestones being achieved by our licensees. During 2017, we are not anticipating any significant service or license fees revenue.

If we receive a negative response from the FDA in our planned pre-NDA meeting, we may further reduce our headcount and discontinue certain development programs and drug discovery activities. For these reasons and others, our operating results may fluctuate from period to period, and the results of prior periods should not be relied upon as predictive of the results in future periods.

Research and Development

	Years Ended December 31,		
	2016	2015	2014
	(In thousands)		
Research and development expenses	\$34,107	\$41,805	\$34,203
Non-cash research and development expenses	—	—	1,543
Employee stock and stock option expense	1,823	1,591	932
Total	\$35,930	\$43,396	\$36,678

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

Research and development expenses incurred during 2016, 2015 and 2014 relate to our various development programs. In 2016, our research and development expenses decreased over 2015 primarily due to a reduction in costs for our pivotal, global Phase 3 clinical trial for STS with aldoxorubicin. The costs of our global Phase 2b clinical trial in SCLC remained consistent with the prior year. These expenses included approximately \$27.1 million for our clinical programs for aldoxorubicin, approximately \$2.3 million at our drug discovery laboratory, and approximately \$4.3 million for general operation of our clinical programs. In 2015, research and development expenses totaled approximately \$37.0 million for our clinical programs for aldoxorubicin, which included a full year of costs in our pivotal, global Phase trial, approximately \$1.7 million at our drug discovery laboratory, and approximately \$3.6 million for general operation of our clinical programs. In 2014, we initiated our pivotal, global Phase 3 clinical trial and completed our global Phase 2b clinical trial with aldoxorubicin as a first-line treatment for STS. In 2014, we also continued our Phase 2 clinical trial with aldoxorubicin in patients with late-stage glioblastoma (brain cancer), and initiated our global Phase 2b clinical trial in small cell lung cancer, a Phase 2 clinical trial in HIV-related Kaposi's

sarcoma, 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. In 2014, our development costs included approximately \$29.9 million for our clinical programs for aldoxorubicin, approximately \$1.0 million for pre-clinical development of new albumin-binding cancer drugs and approximately \$3.3 million for general operation of our clinical programs. None of our research and development costs have ever been capitalized.

As compensation to consultants, or in connection with the acquisition of technology, we sometimes issue shares of common stock, stock options and warrants to purchase shares of common stock. For financial statement purposes, we value these shares of common stock, stock options, and warrants at the fair value of the common stock, stock options or warrants granted, or the services received, whichever is more reliably measurable. In 2016 and 2015, we recorded \$0 of non-cash expense, as compared to \$1.5 million in 2014. In 2014, we issued 200,000 common shares to the licensor of aldoxorubicin in connection with the establishment of the Company's Freiburg, Germany research and development laboratory. The fair value of the shares was \$0.8 million; in addition we issued restricted stock to Dr. Dan Levitt, the Company's Chief Medical Officer with a fair value of \$0.6 million. In 2016, we recorded \$1.8 million of employee stock and stock option expense, as compared to \$1.6 million in 2015 and \$0.9 million in 2014.

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General and Administrative

	Year Ended December 31,		
	2016	2015	2014
	(In thousands)		
General and administrative expenses	\$ 11,078	\$ 13,871	\$ 8,724
Stock, stock option and warrant expenses to non-employees and consultants	236	226	1,737
Employee stock and stock option expense	4,677	5,568	2,384
Total	\$ 15,991	\$ 19,665	\$ 12,845

General and administrative expenses include all administrative salaries and general corporate expenses, including legal expenses associated with the prosecution of our intellectual property. Our general and administrative expenses, excluding common stock, stock options and warrants issued, were \$11.1 million, \$13.9 million and \$8.7 million in 2016, 2015 and 2014, respectively. In 2016, the general and administrative expenses decreased by 19.8%, primarily due to a significant decrease in legal fees of \$4.2 million, offset by costs incurred from pre-commercialization activities of \$1.6 million, which includes salaries and consultants. In July 2016, we ceased pre-commercialization activities pending updated results of our pivotal Phase 3 trial of aldoxorubicin in STS. In 2015, these expenses increased by 59.0 % or approximately \$5.1 million over 2014, as the litigation settlement expense was \$5.5 million (of which a non-cash amount of \$4.5 million was settled through the issuance of our common shares) and insurance premiums increased by \$0.3 million, offset by a decrease in professional fees of \$0.5 million, a decrease in payroll of \$0.1 million and other small decreases.

From time to time, we issue shares of our common stock or warrants or options to purchase shares of our common stock to consultants and other service providers in exchange for services. For financial statement purposes, we value these shares of common stock, stock options, and warrants at the fair value of the common stock, stock options or warrants granted, or the services received whichever we can measure more reliably. In 2016, we recorded \$0.2 million of such expenses, as compared to \$0.2 million and \$1.7 million in 2015 and 2014, respectively. We recorded employee stock option expense of \$4.7 million, \$5.6 million and \$2.4 million in 2016, 2015 and 2014, respectively.

Depreciation and Amortization

Depreciation and amortization expenses for the years ended December 31, 2016, 2015 and 2014 were approximately \$0.5 million, \$0.3 million and \$0.2 million, respectively. The depreciation expense reflects the depreciation of our equipment and furnishings.

Other Income

In 2016, 2015 and 2014, we recognized non-cash gains of \$3.8 million, \$4.4 million and \$19.1 million, respectively, on the revaluation of our warrant derivative liabilities related to warrants issued in July 2016 and August 2011.

Interest Income

Interest income was \$0.3 million in 2016, \$0.2 million in 2015 and \$0.3 million in 2014. The variances between years are attributable primarily to the amount of funds available for investment each year and, to a lesser extent, changes in prevailing market interest rates.

Interest Expense

On February 5, 2016, we entered into a loan and security agreement with Hercules Technology Growth Capital, Inc. ("HTGC"), as administrative agent and lender, and Hercules Technology III, L.P., as lender. The lenders made term loans on February 8, 2016 in the aggregate principal amount of \$25 million, and at an interest rate 9.5%. On December 15, 2016, the interest rate increased to 9.75%. Total interest expense in 2016 was \$2.8 million, as compared to \$0 in both 2015 and 2014.

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Recent Accounting Pronouncements

In January 2017, the FASB issued an ASU entitled "Intangibles - Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment." The objective of the ASU is to simplify how an entity is required to test goodwill for impairment by eliminating Step 2 from the goodwill impairment test. Step 2 measures a goodwill impairment loss by comparing the implied fair value of a reporting unit's goodwill with the carrying amount of that goodwill. This ASU is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption is permitted. We do not believe that the adoption of this guidance will have a material impact on our financial statements.

In August 2016, the Financial Accounting Standards Board issued ASU No. 2016-15 "Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments (a consensus of the Emerging Issues Task Force)." The objective of ASU No. 2016-15 is to provide specific guidance on eight cash flow classification issues and how to reduce diversity in how certain cash receipts and cash payments are presented and classified in the statement of cash flows under Topic 230, Statement of Cash Flows, and other Topics. The amendments in this update are effective for public business entities for fiscal years beginning after December 15, 2017 and interim periods within those fiscal years. We are still in the process of determining the impact that the implementation of ASU 2016-15 will have on the Company's financial statements.

In March 2016, the FASB issued Accounting Standards Update 2016-09, Compensation—Stock Compensation ("ASU 2016-09"). ASU 2016-09 includes several areas of simplification to stock compensation including simplifications to the accounting for income taxes, classification of excess tax benefits on the Statement of Cash Flows and forfeitures. ASU 2016-09 is effective for annual reporting periods beginning after December 15, 2016. An entity that elects early adoption must adopt all of the amendments in the same period. We do not believe that the adoption of this guidance will have a material impact on our financial statements.

In February 2016, the FASB issued ASU No. 2016-02, "Leases (Topic 842)," which requires companies to recognize all leases as assets and liabilities on the consolidated balance sheet. This ASU retains a distinction between finance leases and operating leases, and the classification criteria for distinguishing between finance leases and operating leases are substantially similar to the classification criteria for distinguishing between capital leases and operating leases in the current accounting literature. The result of retaining a distinction between finance leases and operating leases is that under the lessee accounting model in Topic 842, the effect of leases in a consolidated statement of comprehensive income and a consolidated statement of cash flows is largely unchanged from previous GAAP. The amendments in this ASU are effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Earlier application is permitted. We are currently evaluating the impact that the adoption of this ASU will have on our financial statements.

In January 2016, the FASB issued ASU No. 2016-01 "Financial Instruments-Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities." ASU 2016-01 amends various aspects of the recognition, measurement, presentation, and disclosure for financial instruments. With respect to our financial statements, the most significant impact relates to the accounting for equity investments. It will impact the disclosure and presentation of financial assets and liabilities. ASU 2016-01 is effective for annual reporting periods, and interim periods within those years beginning after December 15, 2017. Early adoption by public entities is permitted only for certain provisions. We are currently in the process of evaluating the impact of the adoption of this standard on our financial statements.

In November 2015, the FASB issued ASU No. 2015-17 "Income Taxes: Balance Sheet Classification of Deferred Taxes". ASU 2015-17 simplifies the balance sheet classification of deferred taxes and requires that all deferred taxes be presented as noncurrent. ASU 2015-17 is effective for fiscal years beginning after December 15, 2016 with early adoption permitted. The adoption of this update will not have a material effect on our financial statements.

In April 2015, the FASB issued ASU No. 2015-03, "Simplifying the Presentation of Debt Issuance Costs" ("ASU 2015-03"), which requires that debt issuance costs be reported in the balance sheet as a direction deduction from the face amount of the related liability, consistent with the presentation of debt discounts. Further, ASU 2015-03 requires the amortization of debt issuance costs to be reported as interest expense. Similarly, debt issuance costs and any discount or premium are considered in the aggregate when determining the effective interest rate on the debt. ASU 2015-03 is effective for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. ASU 2015-03 must be applied retrospectively. Entities may choose to adopt the new requirements as of an earlier date for financial statements that have not been previously issued. We adopted this Accounting Standard effective January 1, 2016.

In May 2014, the FASB issued ASU No. 2014-09, "Revenue from Contracts with Customers" ("ASU 2014-09"), which supersedes nearly all existing revenue recognition guidance under accounting principles generally accepted in United States ("U.S. GAAP"). The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services. ASU 2014-09 defines a five step process to achieve this core principle and, in doing so, more judgment and estimates may be required within the revenue recognition process than are required under existing U.S. GAAP.

In August 2015, the FASB issued ASU No. 2015-14, "Revenue from Contracts with Customers" ("ASU 2015-14") which deferred the effective date by one year to December 15, 2017 for interim and annual reporting periods beginning after that date. Early adoption is permitted only as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period.

When effective, ASU 2014-09 will use either of the following transition methods: (i) a full retrospective approach reflecting the application of the standard in each prior reporting period with the option to elect certain practical expedients; or (ii) a retrospective approach with the cumulative effect of initially adopting ASU 2014-09 recognized at the date of adoption (which includes additional footnote disclosures). We are currently evaluating the impact of our pending adoption of ASU 2014-09 on our consolidated financial statements and have not yet determined the method by which we will adopt the standard.

In August 2014, the FASB issued ASU No. 2014-15, "Presentation of Financial Statements – Going Concern (Subtopic 205-40)". The new guidance addresses management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. Management's evaluation should be based on relevant conditions and events that are known and reasonably knowable at the date that the financial statements are issued. The standard will be effective for the annual reporting periods ending after December 15, 2016, and for interim periods thereafter. The Company adopted this Accounting Standard on its financial statements in the year ended December 31, 2016.

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Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Historically, our exposure to market risk is limited primarily to interest income sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because a significant portion of our investments are in short-term debt securities issued by the U.S. government and institutional money market funds. The primary objective of our investment activities is to preserve principal. Due to the short-term nature of our investments, we believe that we are not exposed to any material market risk. We do not have any speculative or hedging derivative financial instruments or foreign currency instruments. If interest rates had varied by 10% in the year ended December 31, 2016, it would not have had a material effect on our results of operations or cash flows for that period.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our financial statements and supplemental schedule and notes thereto as of December 31, 2016 and 2015, and for each of the three years in the period ended December 31, 2016, together with the reports thereon of our independent registered public accounting firm, are set forth beginning on page F-1 of this Annual Report.

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

None.

Item 9A. CONTROLS AND PROCEDURES

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Securities Exchange Act Rule 13a-15(e)) as of December 31, 2016, the end of the period covered by this Annual Report. Based on this evaluation, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures were effective as of December 31, 2016, as described further below.

There were no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2016 that materially affected, or are reasonably likely to have a material effect, on our internal control over financial reporting.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). As previously disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015 we identified a material weakness related to our internal control over a significant and unusual non-cash transaction. The material weakness resulted in an inaccurate conclusion related to the accrual and presentation of an obligation incurred in connection with the litigation settlement referred to in Note 9 of the financial statements that was payable in a variable number of shares of our common stock. During the quarter ended September 30, 2016, we implemented new controls and strengthened existing controls over the identification and accounting for significant and unusual transactions. We have tested the remedial controls for a sufficient period of time and have concluded that these controls are operating effectively. Therefore, we have concluded that the material weakness in the Company's internal controls previously described over financial reporting has been fully remediated. Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we assessed the effectiveness of our internal control over financial reporting as of December 31, 2016. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in Internal Control-Integrated Framework (2013 Edition) ("the Framework"). Based upon management's assessment using the criteria contained in COSO, management has concluded that our internal control over financial reporting was effective as of December 31, 2016.

Our internal control over financial reporting as of December 31, 2016 has been audited by BDO USA, LLP, an independent registered public accounting firm, as stated in their report below.

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Report of Independent Registered Public Accounting Firm
Board of Directors and Stockholders
CytRx Corporation
Los Angeles, California

We have audited CytRx Corporation's internal control over financial reporting as of December 31, 2016, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). CytRx Corporation's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, CytRx Corporation maintained, in all material respects, effective internal control over financial reporting as of December 31, 2016, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets of CytRx Corporation as of December 31, 2016 and 2015, and the related statements of operations, stockholders' equity, cash flows and schedule for each of the three years in the period ended December 31, 2016 and our report dated March 15, 2017 expressed an unqualified opinion thereon.

/s/ BDO USA, LLP
Los Angeles, California
March 15, 2017
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Item 9B. OTHER INFORMATION

None.

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PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

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

Name	Age	Class of Director (1)	Position
Steven A. Kriegsman	75	II	Director, Chairman of the Board and Chief Executive Officer
Louis Ignarro, Ph.D.	75	I	Lead Director (2) (3) (4) (5)
Eric Selter	59	III	Director (2)
Anita J. Chawla, Ph.D.	58	II	Director (3) (5)
Earl Brien, M.D.	56	III	Director (2) (3) (4)
John Y. Caloz	65	—	Chief Financial Officer
Daniel J. Levitt, M.D., Ph.D.	69	—	Chief Operating Officer and Chief Medical Officer
Scott Wieland, Ph.D.	57	—	Senior Vice President-Drug Development

Our Class I director serves until the 2019 annual meeting of stockholders, our Class II directors serve until the (1) 2017 annual meeting of stockholders, and our Class III directors serve until the 2018 annual meeting of stockholders.

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

(3) Members of our Nominating and Corporate Governance Committee. Dr. Ignarro is Chairman of the Committee.

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

(5) Members of our Strategy Committee. Ms. Chawla is Chairwoman of the Committee

Steven A. Kriegsman has been CytRx's Chief Executive Officer and a director since July 2002. In October 2014, he was elected Chairman of the Board. Mr. Kriegsman served on the boards of directors of Galena Biopharma, Inc. from 2009 until 2016 and Catasys, Inc. from November 2013 to August 2015. He previously served as Director and Chairman of Global Genomics from June 2000 until 2002. Mr. Kriegsman is an inactive Chairman and the founder of Kriegsman Capital Group LLC, a financial advisory firm specializing in the development of alternative sources of equity capital for emerging growth companies in the healthcare industry. During his career, he has advised such companies as SuperGen Inc., Closure Medical Corporation, Novoste Corporation, Miravant Medical Technologies, and Maxim Pharmaceuticals. In the past, Mr. Kriegsman has also served on the Board of Directors of Bradley Pharmaceuticals, Inc. and Hythiam, Inc. Mr. Kriegsman has a B.S. degree with honors from New York University in Accounting and completed the Executive Program in Mergers and Acquisitions at New York University, The Management Institute. Mr. Kriegsman is a graduate of the Stanford Law School Directors' College. Mr. Kriegsman was formerly a Certified Public Accountant with KPMG in New York City. In February 2006, Mr. Kriegsman received the Corporate Philanthropist of the Year Award from the Greater Los Angeles Chapter of the ALS Association and in October 2006, he received the Lou Gehrig Memorial Corporate Award from the Muscular Dystrophy Association. Mr. Kriegsman has been a guest speaker and lecturer at various universities including California Institute of Technology (Caltech), Brown University, and New York University. He also was an instructor at York College in Jamaica (Queens), NY, where he taught business to a diverse group of students in York's adult education program. Mr. Kriegsman has been active in various charitable organizations including the Biotechnology Industry Organization, the California Health Institute, the ALS Association, the Los Angeles Venture Association, the Southern California Biomedical Council, the American Association of Dance Companies and the Palisades-Malibu YMCA.

Mr. Kriegsman's extensive history as a member of management is vital to the board of directors' collective knowledge of our day-to-day operations. Mr. Kriegsman also provides great insight as to how CytRx grew as an organization and his institutional knowledge is an invaluable asset to the board of directors in effecting its oversight of

CytRx's strategic plans. Mr. Kriegsman's presence on the board of directors also allows for a flow of information and ideas between the board of directors and management.

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Louis Ignarro, Ph.D. has been a director since July 2002. He previously served as a director of Global Genomics from November 2000 until 2002. Dr. Ignarro serves as the Jerome J. Belzer, M.D. Distinguished Professor of Pharmacology in the Department of Molecular and Medical Pharmacology at the UCLA School of Medicine. Retired in 2013, Dr. Ignarro had been at the UCLA School of Medicine since 1985 as a professor, acting chairman and assistant dean. Dr. Ignarro received the Nobel Prize for Medicine in 1998. Dr. Ignarro received a B.S. in pharmacy from Columbia University and his Ph.D. in Pharmacology from the University of Minnesota. Dr. Ignarro is a Nobel Laureate and an esteemed medical researcher whose experience enables him to offer importance scientific guidance to our Board of Directors. In December 2016, Dr. Ignarro was appointed Lead Director.

Eric Selter has been a director since April 2015. He has served in many capacities as an investment advisor with Morton Capital Management, LLC, and is currently an owner and a member of their investment committee. He served as President and Chief Executive Officer of National Staff Network, a nationally recognized and major leader in the employee leasing industry, from 1996 to 1998. He received his bachelor's degree from the University of Southern California where he graduated magna cum laude in 1979. He then attended Loyola Law School in Los Angeles where he was awarded his Juris Doctor degree in 1982.

Mr. Selter's senior executive experience in the financial services industry distinguishes him from our other directors and adds unique capabilities and a different perspective to the deliberations of our Board of Directors. He understands the credit needs, financing requirements, and operational constraints of development-stage and mature businesses, skills that he is able to utilize as the named financial expert on our Audit Committee.

Anita J. Chawla, Ph.D. joined the board in March 2015. She is an economist with more than 25 years of experience in the health care sector. She has extensive experience using economic analyses to support the business objectives of life sciences companies. In her work, Dr. Chawla has assessed the value of a wide range of therapies to inform health care decision makers. Dr. Chawla specializes in helping pharmaceutical, biotechnology, medical device, and diagnostic companies address market access challenges, particularly as they relate to coverage and reimbursement determination and evidence-based review, through all phases of product development and commercialization. Dr. Chawla graduated Phi Beta Kappa with a Bachelor of Arts degree in economics and political science from Wellesley College. She earned a PhD in economics from the University of Michigan. Dr. Chawla is a Managing Principal at Analysis Group, Inc. Prior to joining Analysis Group in 2007, she was head of the Health Economics & Outcomes Research department at Genentech, Inc. from 2001 to 2006. She has also held positions at Thomson Medstat (The MEDSTAT Group), Research and Policy Division (1993-2000) and the American Medical Association, Center for Health Policy Research (1989-1993). Dr. Chawla is no relation to any other Company employees named Chawla.

Earl Brien, M.D. joined our board of directors in December 2016. He is a renowned orthopedic and sarcoma surgeon who has served as a Professor of Orthopedic Surgery and as the Surgical Director of the Sarcoma Service at Cedars Sinai Medical Center in Los Angeles, California since February 2008. After completing his matriculation as a Fellow at Memorial Sloan Kettering Cancer Center and the Hospital for Special Surgery in musculoskeletal tumors and metabolic bone disease respectively, he became the Director of the Musculoskeletal Tumor Program and Metabolic Bone Disease Center at Orthopedic Hospital. Dr. Brien is the recipient of numerous grants, with an extensive bibliography of peer-reviewed articles spanning more than twenty years to his credit. He has also represented at national and international meetings for the past twenty years. From 1993 until 2004, he served as the Cancer Commission Chairman and Cancer Liaison Physician for the American College of Surgeons Commission on Cancer at Orthopedic Hospital.

Daniel J. Levitt, M.D., Ph.D. joined us in October 2009 as our Chief Medical Officer, and was promoted to the position of Chief Operating Officer in December, 2016. Dr. Levitt brings more than 25 years of senior management experience, having spearheaded numerous drug development programs to commercialization at leading biotechnology and pharmaceutical companies. Dr. Levitt has also served as a director on Aquinox Pharmaceuticals, a listed public company, since 2009, and is a member of its Compensation, Nominating and Governance Committees. Prior to joining CytRx, Dr. Levitt served from January 2007 to February 2009 as Executive Vice President, Research and Development at Cerimon Pharmaceuticals, Inc. Prior to that, from August 2003 to April 2006, he was Chief Medical Officer and Head of Clinical and Regulatory Affairs at Dynavax Technologies Corporation, managing clinical trials for four programs and overseeing multi-country regulatory strategies. From August 2002 to July 2003, Dr. Levitt was Chief Operating Officer and Head of Research and Development at Affymax, Inc., and prior to that he spent six years at Protein Design Labs, Inc., completing his tenure as that firm's President and Head of Research and Development.

Dr. Levitt's past experience includes a position as Head of Drug Development at Geron Corporation, and Head of the Cytokine Development Unit and Global Clinical Oncology at Sandoz Pharmaceuticals Ltd., and as Director, Clinical Oncology and Immunology at Hoffmann-LaRoche, Inc. Dr. Levitt graduated Magna Cum Laude and Phi Beta Kappa with a Bachelor of Arts degree from Brandeis University. He earned both his M.D. and his Ph.D. in Biology from the University of Chicago, Pritzker School of Medicine. Dr. Levitt has received ten major research awards and authored or co-authored nearly 200 papers and abstracts.

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

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

Diversity

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

Committees

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

Our board of directors currently has four committees. The Audit Committee consists of Mr. Selter, Dr. Ignarro and Dr. Brien. The Compensation Committee consists of Dr. Ignarro and Dr. Brien; the Nomination and Governance Committee consists of Dr. Ignarro, Dr. Chawla and Dr. Brien, and the Strategy Committee consists of Dr. Chawla and Dr. Ignarro. Such committees operate under formal charters that govern their duties and conduct. Copies of the charters are available on our website at www.cytrx.com.

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

Section 16(a) Beneficial Ownership Reporting Compliance

Each of our executive officers and directors and persons who own more than 10% of our outstanding shares of common stock is required under Section 16(a) of the Securities Exchange Act to file with the SEC initial reports of ownership and reports of changes in ownership of our common stock and to furnish us with copies of those reports. Based solely on our review of copies of reports we have received and written representations from certain reporting persons, we believe that our directors and executive officers and greater than 10% shareholders for 2016 complied

with all applicable Section 16(a) filing requirements.

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Code of Ethics

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

Board Leadership Structure

On October 15, 2014, our board of directors appointed Mr. Kriegsman as Chairman of the Board. The Chairman of the Board presides at all meetings of our board of directors (but not at its executive sessions) and exercises and performs such other powers and duties as may be assigned to him from time to time by the board or prescribed by our amended and restated bylaws.

Our board of directors has no established policy on whether it should be led by a Chairman who is also the Chief Executive Officer, but periodically considers whether combining, or separating, the role of Chairman and Chief Executive Officer is appropriate. At this time, our board is committed to the combined role given the circumstances of our company, including Mr. Kriegsman's knowledge of the pharmaceutical industry and our company's strategy. Our board believes that having a Chairman who also serves as the Chief Executive Officer allows timely communication with our board on company strategy and critical business issues, facilitates bringing key strategic and business issues and risks to the board's attention, avoids ambiguity in leadership within the company, provides a unified leadership voice externally and clarifies accountability for company business decisions and initiatives. In December 2016, Dr. Ignarro was appointed as an independent Lead Director to act as a liaison between the Chairman of the Board and the independent directors. Prior to his death in late 2016, our former director, Joseph Rubinfeld, Ph.D., served as our lead independent director. The board will continue to assess whether this leadership structure is appropriate and will adjust it as it deems appropriate.

Board of Directors Role in Risk Oversight

In connection with its oversight responsibilities, our board of directors, including the Audit Committee, periodically assesses the significant risks that we face. These risks include, but are not limited to, financial, technological, competitive, and operational risks. Our board of directors administers its risk oversight responsibilities through our Chief Executive Officer and Chief Financial Officer who review and assess the operations of our business, as well as operating management's identification, assessment and mitigation of the material risks affecting our operations.

Item 11. EXECUTIVE COMPENSATION

Compensation Discussion and Analysis

Overview of Executive Compensation Program

The Compensation Committee of our Board of Directors has responsibility for establishing, implementing and monitoring our executive compensation program philosophy and practices. Generally speaking, the Compensation Committee determines the compensation of our Chief Executive Officer and other named executive officers with the approval of our Board of Directors.

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

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

At the 2016 annual meeting of stockholders, the stockholders on a non-binding, advisory basis, approved the compensation of our executive officers as disclosed in our 2016 proxy statement. Based upon the results of this stockholder advisory vote, the Compensation Committee determined to continue its compensation policies and procedures.

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

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Compensation Philosophy and Objectives

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

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

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

The bonus amounts awarded to our eligible named executive officers are a function of their office and total compensation relative to the total compensation of our Chief Executive officer, based upon their employee evaluations, and with consideration given to comparable companies for similarly-situated employees. The bonus amounts awarded to each named executive officer is set forth in the Summary Compensation Table.

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

Role of Executive Officers in Compensation Decisions

The Compensation Committee annually determines the compensation of our named executive officers. Mr. Kriegsmann, our Chairman of the Board and Chief Executive Officer, typically attends all meetings of the Compensation Committee, except for executive sessions at which his compensation is discussed. At the request of the Compensation Committee, Mr. Kriegsmann provides his assessment of the performance of our named executive officers, other than himself. Mr. Kriegsmann also takes an active part in the discussions of the compensation of named executive officers other than himself and assists in the development of a review matrix of each executive's contributions to the goals of the company that forms the basis for some compensation determinations. The Compensation Committee grants due consideration to Mr. Kriegsmann's assessments when making determinations regarding the compensation of our named executive officers. All Compensation Committee deliberations and determinations regarding the compensation of Mr. Kriegsmann are made outside his presence.

Setting Executive Compensation

Based on the foregoing objectives, the Compensation Committee has structured the company's annual cash and incentive-based cash and non-cash executive compensation to seek to motivate our named executives to achieve our company's business goals, including goals related to the development of our drug candidates and management of working capital, to reward the executives for achieving such goals, and to retain the executives. In doing so, the Compensation Committee historically has not employed outside compensation consultants or legal advisors. During 2016, the Compensation Committee used three industry compensation surveys in its compensation deliberations regarding cash and equity compensation for our executive officers. The surveys used were an Equilar survey of public companies with a market capitalization between \$150 million and \$300 million, the Radford Global Life Sciences

Survey, which is a survey of public and private life sciences companies of all sizes, and a survey of public and private companies in Los Angeles provided by salary.com (which the Compensation Committee uses to consider geographic differences in cost of living).

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

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

Performance-driven Compensation

We emphasize performance in annually reviewing and setting our executive officers' base salaries, bonuses and equity incentive compensation. This emphasis on performance is intended to motivate our executive officers to pursue our corporate goals, reward them for achievement of these goals and align their interests with those of our stockholders. Each year, we determine goals that we hope to achieve in the coming year, both on a company and individual basis. Our overall corporate performance as compared to these goals, and an individual's performance compared to his or her individual goals, primarily drive the recommendations that the Compensation Committee with respect to each executive officer's base salary, cash bonus and equity incentive compensation. Other factors, such as larger macroeconomic conditions of the industry and market in which we compete, as well as strategic business decisions and issues related to key employee retention, also influence compensation decisions.

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

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

Company Performance Goals

For 2016, the Compensation Committee and our board of directors approved the following performance goals:

- Obtain results in the aldoxorubicin Phase 3 STS pivotal clinical trial;
- Complete enrollment in the Phase 2 SCLC clinical trial;
- Complete and report data from two Phase 1b combination studies;
- Publish results of the Phase 2 Kaposi's sarcoma study;
- Identify an in vivo proof of concept for one new drug candidate, focusing on high potency compounds in the pre-clinical laboratory in Freiburg, Germany;
- Completion of drug substance, drug product and diluent Registration batches for aldoxorubicin; and
- Raise additional capital.

For 2016, the Compensation Committee determined that, with the exception of the completion of registration batches for aldoxorubicin (for which the timeline was extended), each of the corporate goals had either been achieved, or substantial progress towards achievement had been made, and noted the particular contributions of executive officers to the achievement of those goals.

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Individual Performance

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

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

The numerical job scores, with a 5.0 being the best and 1.0 being the worst, are determined based on an initial self-assessment by the officer, which is subject to change based on an evaluation of the self-assessment by the officer's direct supervisor and on the Compensation Committee's own assessment of the officer's job performance.

For 2016, our Compensation Committee determined that the individual performance scores indicated below were merited by the officer's respective contributions to our key business achievements discussed above, as well as the performance of their day-to-day responsibilities. On an officer-by-officer basis, our Compensation Committee also considered the following:

Mr. Kriegsman's individual performance goals relate primarily to overall corporate objectives, including building stockholder value as reflected in our market capitalization and our working capital, managing and directing the executive management team, and successfully developing our company's operations and personnel for future success. Based on those criteria, and noting achievement of the obtainment of results in our global Phase 3 STS clinical trial and the completion of enrollment in the SCLC clinical trial, the Compensation Committee gave a rating of 4.9 to Mr. Kriegsman.

Mr. Caloz's individual performance goals relate primarily to achievement of key financial objectives, such as managing and raising working capital, controlling spending, managing accounting personnel and maintaining regulatory compliance. Based on those criteria, the Compensation Committee noted Mr. Caloz's role in obtaining needed working capital, his efforts to control expenditures, the continued improvement of our accounting department, and our compliance with filing deadlines, and gave a rating of 4.7 to Mr. Caloz.

Dr. Levitt's individual performance goals relate primarily to the achievement of key strategic and clinical objectives related to our clinical research programs, including ultimate oversight of the design and execution of our clinical programs, and analysis and implementation of new clinical opportunities improve stockholder value. Dr. Levitt was instrumental in the expansion of our laboratory facility in Freiburg, Germany, re-focusing its attention on high-potency compounds. Based on those criteria, the Compensation Committee noted Dr. Levitt's efforts towards our achievement of our key clinical goals, including the obtainment of results in our global Phase 3 STS clinical trial and completion of enrollment in the Phase 3 SCLC trial, his development of strategic plans to build value, and gave a rating of 4.8 to Dr. Levitt.

Dr. Wieland's individual performance goals relate primarily to the execution of the objectives related to our clinical development, including planning, initiation, budgeting and management of our clinical programs. Based on those criteria, the Compensation Committee noted Dr. Wieland's role in our achievement of key clinical goals, including the completion of enrollment in our global Phase 3 STS clinical trial, and gave a rating of 4.8 to Dr. Wieland.

2016 Executive Compensation Components

For 2016, as in recent years, the principal components of compensation for the named executive officers were:

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

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Base Salary

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

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

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

Salary levels are typically considered annually as part of our company's performance review process, as well as upon a change in job responsibility. Merit-based increases to salaries are based on our company's available resources and the Compensation Committee's assessment of the individual's performance. This assessment is based upon written evaluations of such criteria as job knowledge, communication, problem solving, initiative, goal-setting, and expense management. In 2016, the Compensation Committee considered our successful achievement or substantial progress towards our corporate performance goals, and with consideration of the challenging financial environment, and our anticipation of clinical significant clinical activities in 2017 and beyond, awarded a modest increase in base salary for 2016 for only one executive and no increase to the others. Base salaries were also reviewed in light of the Equilar, Radford and salary.com survey data to validate that they were within acceptable ranges based on market salaries.

Annual and Special Bonuses

As we do not generate significant revenue and have not commercially released any products, the Compensation Committee bases its discretionary annual bonus awards on the achievement of corporate and individual goals, efforts related to extraordinary transactions, effective fund-raising efforts, effective management of personnel and capital resources, and bonuses paid by comparable companies, among other criteria. Mr. Kriegsman's employment agreement entitles him to an annual cash bonus in an amount to be determined in our discretion, but not less than \$150,000, and Dr. Levitt's employment agreement entitles him to an annual bonus of not less than \$150,000. Any cash bonuses to our other named executive officers are entirely in our discretion.

During 2016, the Compensation Committee granted Mr. Kriegsman an annual cash bonus of \$150,000, granted Dr. Levitt an annual cash bonus of \$312,500, and granted cash bonuses to the other named executive officers ranging from \$50,000 to \$135,000, principally based on their efforts in helping us advance the development of aldoxorubicin. In December 2016, the Compensation Committee approved an award to Mr. Kriegsman of a \$1 million restricted stock grant, or 2,325,581 shares of our common stock based on the closing price of the Company's common stock at December 15th, the award date to vest in three equal annual installments. In December 2016, in recognition of his promotion to Chief Operating Officer, the Compensation Committee approved a bonus to Dr. Levitt of \$625,000 conditioned upon his entering into a new employment agreement satisfactory to the Company following the expiration of his then-current employment agreement on December 31, 2016. The bonus was paid in January 2017.

Equity Incentive Compensation

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

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Historically, equity awards have been granted annually at the end of each year based primarily on corporate performance as a whole during the preceding year. In addition, we may grant equity awards upon the occurrence of certain events during the year, for example, upon an employee's hire or achievement of a significant business objective such as positive results or other progress of our clinical trials or successful capital-raising efforts. On June 2, 2015, we announced that we had entered into an agreement to settle the Delaware stockholder derivative lawsuit, In Re CytRx Stockholder Derivative Litigation, as described in Item 3 of this Annual Report. In the agreement, we agreed to re-price certain outstanding stock options and to implement certain corporate governance practices.

In accordance with the settlement agreement reached in June 2015 and approved by the Court in November 2015, our board of directors approved the re-pricing of outstanding stock options under the 2008 Stock Incentive Plan, or the 2008 Plan, to purchase a total of 2,095,000 shares of our common stock held by our directors or former directors and our executive officers originally granted on December 10, 2013 at an exercise price of \$2.39. The new exercise price of these re-priced options is \$4.66, which was the closing price of our common stock as reported on The NASDAQ Capital Market on December 20, 2013.

Among the agreed-upon corporate governance practices are that we will grant stock options to directors, officers and employees only on pre-set dates established by the Compensation Committee prior to the fiscal year in which the options are to be granted. The Compensation Committee has established December 15 as the date for the annual grant of stock options. The December 15 date correlates to the approximate dates of our historical annual stock option grants, but otherwise was not based upon any particular methodology. We have agreed in the settlement agreement to publicly disclose the method used to determine the pre-set stock option grant dates and any future changes thereto at least 90 days before they become effective. We also have agreed in the settlement agreement that all stock option grants, other than initial stock option grants to new employees, will be made at a meeting, whether in-person or telephonic, of the Compensation Committee and not by unanimous written consent, and that the Compensation Committee will determine the grantees, amounts, dates, and prices of all stock options and will not delegate these responsibilities. The Compensation Committee has implemented the corporate governance practices called for in the settlement agreement.

No formula is used in setting equity award grants and the determination of whether to grant equity awards, or the size of such equity awards, to our executive officers; rather, it involves subjective assessments by our board of directors, Compensation Committee and, with respect to executive officers other than Mr. Kriegsmann. Generally, annual equity awards are intended to encourage retention of experienced employees, and we consider individual performance and contributions during the preceding year to the extent our board of directors and Compensation Committee believe such factors are relevant. As with base salary and cash bonuses, for 2016 our board of directors and Compensation Committee also considered data from three surveys in determining equity award grants to our executive officers.

At a meeting of the Compensation Committee on December 13, 2016, the Compensation Committee granted to Mr. Kriegsmann nonqualified stock options to purchase 1,250,000 shares of our common stock at a price of \$0.43 per share, which equaled the closing market prices on December 15, 2016, the specified grant date. The options vest monthly over three years, provided that Mr. Kriegsmann remains in our employ throughout such monthly vesting periods, unless Mr. Kriegsmann's employment agreement is not renewed by us or by him upon expiration of its term on December 31, 2021, or his employment is terminated by us without "cause," or by reason of his "disability", upon FDA approval of aldoxorubicin, or by Mr. Kriegsmann for "good reason," or due to his death. In any one of these events, the options will vest immediately and will remain exercisable for their full term. In addition, in connection with the annual review of our other named executive officers, at its December 13, 2016 meeting, the Compensation Committee granted to our other named executive officers nonqualified stock options to purchase an aggregate of 900,000 shares of our common stock. All of the stock options had an exercise price equal to \$0.43, the closing market price on December 15, 2016, the specified grant date, and vest monthly over three years, provided that such executives remain in our employ through such monthly vesting periods unless, with respect to Dr. Levitt, his employment is terminated by us without "cause" or by reason of his "disability," or upon FDA approval of aldoxorubicin, or by Dr. Levitt for "good reason" (each as defined in his employment agreement) or due to his death, in which cases the options will immediately vest in full and remain exercisable for their full term.

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

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Retirement Plans, Perquisites and Other Personal Benefits

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

We have adopted a tax-qualified employee savings and retirement plan, our 401(k) Plan, for eligible U.S. employees, including our named executive officers. Eligible employees may elect to defer a percentage of their eligible compensation in the 401(k) Plan, subject to the statutorily prescribed annual limit. We may make matching contributions on behalf of all participants in the 401(k) Plan in an amount determined by our board of directors. We made matching contributions to the 401(k) Plan for 2016 of \$101,000. Matching contributions immediately vest, as do all employee contributions. We intend the 401(k) Plan, and the accompanying trust, to qualify under Sections 401(k) and 501 of the Internal Revenue Code so that contributions by employees to the 401(k) Plan, and income earned (if any) on plan contributions, are not taxable to employees until withdrawn from the 401(k) Plan, and so that we will be able to deduct our contributions, if any, when made. The trustee under the 401(k) Plan, at the direction of each participant, may invest the assets of the 401(k) Plan in any of a number of investment options.

We generally do not provide any of our named executive officers with any other perquisites or personal benefits, other than benefits to Mr. Kriegsman provided for in his employment agreement. We are required by his employment agreement to carry a life insurance policy for Mr. Kriegsman in the amount of \$1.4 million under which Mr. Kriegsman's designee is the beneficiary. We purchased a policy with a face value of \$2 million, for which we pay the premium, and Mr. Kriegsman immediately reimburses us for the premium relating to the \$0.6 million of additional coverage. We periodically review the levels of perquisites and other personal benefits provided to our named executive officers. No changes to these benefits were made during 2016.

Employment Agreements and Severance Arrangements

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

In the event of termination without "cause," the named executive officers will be entitled to a lump-sum payment equal to six months' base salary (12 months in the case of Dr. Levitt and 24 month's base salary and minimum annual bonus under his employment agreement in the case of Mr. Kriegsman). The named executive officers' agreements also provide for our continuation of medical benefits during the severance period (including, for Mr. Kriegsman, payments for life insurance). If a named executive officer's employment is terminated by us without "cause" (or by Mr. Kriegsman or Dr. Levitt for "good reason") within two years following a change of control of the company, the named executive officers will be entitled to a lump-sum payment equal to 12 months' base salary (24 months' base salary in the case of Dr. Levitt and 36 month' base salary and minimum annual bonus in the case of Mr. Kriegsman), and Dr. Levitt and Mr. Kriegsman also would be entitled under their employment agreement to receive a "gross-up" payment equal to the sum of any excise tax on termination benefits (including any accelerated vesting of his options under our Plans as described below) plus any penalties and interest.

In December 2016, the Compensation Committee recommended, and our board of directors approved, an amendment to Mr. Kriegsman's employment agreement. On January 10, 2017, we entered into the amendment with Mr. Kriegsman, under which the term of his employment agreement was extended by three years to December 31, 2021. In the amendment, we acknowledge that Mr. Kriegsman is entitled to the award of \$1 million of restricted shares of our common stock that was made to him on December 15, 2016 as described above and clarify that Mr. Kriegsman is entitled under his employment agreement to the severance benefits described therein in the event of the termination of Mr. Kriegsman's employment for any reason on or following the expiration of the term of the amended and restated employment agreement, including in the event of the non-renewal thereof by either party. The amendment also

provides that we will pay any costs and expenses (including attorney's fees) incurred by Mr. Kriegsman in any proceeding to enforce his rights under his employment agreement in advance of a final disposition of the proceeding.
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We agree in Mr. Kriegsman's employment agreement that if there is a change in control and his employment agreement is either not renewed by either us or Mr. Kriegsman or, following the expiration of the employment agreement, we terminate Mr. Kriegsman's employment other than for "cause" or he resigns for "good reason," he will be entitled to the lump-sum severance and continuation of benefits described in the preceding paragraph for a change in control.

We agree in Dr. Levitt's employment agreement that if we do not offer to renew or extend the officer's employment agreement, and we had not theretofore terminated his employment, we will continue to pay him his annual salary thereunder during the period commencing upon expiration of his employment agreement and ending on December 31, 2018. We agree in the employment agreements with our other named executive officers (other than Mr. Kriegsman) that if we do not offer to renew or extend the officer's employment agreement, and we had not theretofore terminated their employment, we will continue to pay the officer his annual salary thereunder during the period commencing upon expiration of his employment agreement and ending on June 30, 2018, or the date of his re-employment with another employer, whichever is earlier.

In the event we terminate Dr. Levitt's or Mr. Kriegsman's employment without "cause," Dr. Levitt or Mr. Kriegsman resigns for "good reason" or his employment terminates due to his "disability" (each as defined in the employment agreement) or death, they will be entitled to full and immediate vesting of their restricted stock and stock options and any other equity awards based on our securities and all such awards will remain exercisable for their full term notwithstanding the termination of his employment (other than a termination by the company for "cause" or their resignation without "good reason").

Change of Control Arrangements

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

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

Ownership Guidelines

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

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

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

We normally grant stock options to new executive officers when they join our company based upon their position with us and their relevant prior experience. The options granted by the Compensation Committee generally vest monthly over the first three years of the ten-year option term. Vesting and exercise rights generally cease upon termination of employment (unless such termination is without cause or is a resignation for good reason), except in the case of death (exercisable for the full term of the option), disability (subject to a one year limitation) or retirement. Prior to the exercise of an option, the holder has no rights as a stockholder with respect to the shares subject to such option, including voting rights and the right to receive dividends or dividend equivalents. In addition to the initial option grants, our Compensation Committee may grant additional options to retain our executives and reward, or provide incentive for, the achievement of corporate goals and strong individual performance.

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On an annual basis, the Compensation Committee assesses the appropriate individual and corporate goals for our executives and provides additional option grants based upon the achievement by the new executives of both individual and corporate goals. We expect that we will continue to provide new employees with initial option grants in the future to provide long-term compensation incentives and will continue to rely on performance-based and retention grants to provide additional incentives for current employees. Additionally, in the future, the Compensation Committee may consider awarding additional or alternative forms of equity incentives, such as grants of bonus stock, restricted stock and restricted stock units.

It is our policy to award stock options at an exercise price equal to The NASDAQ Capital Market's closing price of our common stock on the date of the grant. In certain limited circumstances, the Compensation Committee may grant options to an executive at an exercise price in excess of the closing price of the common stock on the grant date. The Compensation Committee will not grant options with an exercise price that is less than the closing price of our common stock on the grant date, nor will it grant options which are priced on a date other than the grant date. For purposes of determining the exercise price of stock options, the grant date is deemed to be the first day of employment for newly hired employees. Among the corporate governance practices agreed upon in connection with the settlement of the former stockholder derivatives litigation described in Item 3 of Part I of this Annual Report, we agreed that we will grant stock options to directors, officers and employees only on pre-set dates established by the Compensation Committee prior to the fiscal year in which the options are to be granted. The Compensation Committee has established December 15 as the date for the annual grant of stock options. The December 15 date correlates to the approximate dates of our historical annual stock option grants, but otherwise was not based upon any particular methodology. We have agreed in the settlement agreement to publicly disclose the method used to determine the pre-set stock option grant dates and any future changes thereto at least 90 days before they become effective. We also have agreed in the settlement agreement that all stock option grants, other than initial stock option grants to new employees, will be made at a meeting, whether in-person or telephonic, of the Compensation Committee and not by unanimous written consent, and that the Compensation Committee will determine the grantees, amounts, dates and prices of all stock options and will not delegate these responsibilities.

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

Tax and Accounting Implications

Deductibility of Executive Compensation

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

Accounting for Share-Based Compensation

Beginning on January 1, 2006, we began accounting for share-based compensation in accordance with the requirements of ASC 718, Compensation – Stock Compensation. This accounting treatment has not significantly affected our compensation decisions. The Compensation Committee takes into consideration the tax consequences of compensation to the named executive officers, but tax considerations are not a significant part of the company's compensation policy.

These policies remained in place throughout 2016, and we expect to continue to follow them for the foreseeable future.

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Compensation Committee Interlocks and Insider Participation in Compensation Decisions

There are no "interlocks," as defined by the SEC, with respect to any member of the Compensation Committee. Joseph Rubinfeld, Ph.D., who passed away in late December, 2016, and Louis Ignarro, Ph.D. served as members of the Compensation Committee for all of 2016. Anita Chawla, Ph. D. and Eric Selter served as members of the Compensation Committee in 2016 until December 2, 2016. In December 2016, Dr. Earl Brien was appointed to the Compensation Committee when he joined the Board.

Compensation Committee Report

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

Chairman

Director

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Summary Compensation Table

The following table presents summary information concerning all compensation paid or accrued by us for services rendered in all capacities during 2016, 2015 and 2014 by Steven A. Kriegsmann and John Y. Caloz, who are the only individuals who served as our principal executive and financial officers during the year ended December 31, 2016, our two other most highly compensated executive officers who were serving as executive officers as of December 31, 2016 and one former executive officer who would have been our third other most highly compensated executive officer as of December 31, 2016 but for the fact that he was not serving as an executive officer on that date :

Summary Compensation Table

Name and Principal Position	Year	Salary (\$)(1)	Bonus (\$)(2)	Option Awards (\$)(3)	All Other Compensation (\$)(4)	Total (\$)
Steven A. Kriegsmann Chief Executive Officer	2016	850,000	150,000	1,388,750	13,700	2,402,450
	2015	850,000	150,000	1,593,000	13,700	2,606,700
	2014	825,000	450,000	903,000	13,700	2,191,700
John Y. Caloz Chief Financial Officer and Treasurer	2016	400,000	135,000	108,850	—	643,850
	2015	375,000	135,000	477,900	—	987,900
	2014	350,000	100,000	301,000	—	751,000
Daniel Levitt, M.D., Ph.D. Chief Operating Officer and Chief Medical Officer	2016	625,000	512,500	124,400	—	1,261,900
	2015	625,000	150,000	796,500	—	1,371,500
	2014	525,000	300,000	602,000	—	1,427,000
Scott Wieland, Ph.D., Senior Vice President – Drug Development	2016	400,000	50,000	46,650	—	496,650
	2015	400,000	75,000	159,300	—	634,300
	2014	350,000	300,000	301,000	—	951,000
Benjamin S. Levin General Counsel, Senior Vice-President and Secretary	2016	235,000	—	—	—	235,000
	2015	365,000	135,000	477,900	—	977,900
	2014	350,000	100,000	301,000	—	751,000

(1) Mr. Levin retired on May 31, 2016. Payments made to him include a Severance payment of \$230,000.

Bonuses to the named executive officers reported above were paid in December of the applicable year, except that in 2016, Dr. Levitt's received a \$200,000 retention bonus in January upon entering into of his employment agreement, and in 2015, Dr. Levitt received \$75,000 of his annual bonus in June, and Mr. Kriegsmann received a retention bonus in connection with the extension of his employment agreement in March 2014.

The values shown in this column represent the aggregate grant date fair value of equity-based awards granted during the fiscal year, inclusive of Mr. Kriegsmann's restricted stock award, in accordance with ASC 718, "Share Based-Payment." The fair value of the stock options at the date of grant was estimated using the Black-Scholes option-pricing model, based on the assumptions described in Note 14 of the Notes to Financial Statements included in this Annual Report.

(4) Represents life insurance premiums.

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2016 Grants of Plan-Based Awards

In 2016, we granted stock options to our named executive officers under our 2008 Stock Incentive Plan as follows:

2016 Grants of Plan-Based Awards

Name	Grant Date	All Other Option Awards (# of CytRx Shares)	Exercise Price of Option Awards (\$/Share)	Grant Date Fair Value of Stock and Option Awards (\$)
Steven A. Kriegsman Chief Executive Officer	12/15/2016	3,575,581(1)(2)	\$ 0.43	\$1,388,750
John Y. Caloz Chief Financial Officer and Treasurer	12/15/2016	350,000(1)	\$ 0.43	\$108,850
Daniel Levitt, M.D., Ph.D. Executive Vice President and Chief Medical Officer	12/15/2016	400,000(1)	\$ 0.43	\$124,400
Scott Wieland, Ph.D. Senior Vice President – Drug Development	12/15/2016	150,000(1)	\$ 0.43	\$46,650
Benjamin S. Levin General Counsel, Senior Vice-President and Secretary	—	—	—	—

Options vest in 36 equal monthly installments, subject to the named executive officer's remaining in our continuous employ through such dates, except that in the case of each of Mr. Kriegsman and Dr. Levitt, the unvested options (1) will vest, in full, upon termination of his employment by us without "cause", upon FDA approval to market aldoxorubicin, or by reason of his "disability" or by him for "good reason" or upon his death.

(2) Includes the award of 2,325,581 restricted shares of our common stock which will vest in three equal annual instalments.

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2000 Long-Term Incentive Plan and 2008 Stock Incentive Plan

The purpose of our 2000 Long-Term Incentive Plan, or 2000 Plan, and our 2008 Stock Incentive Plan, or 2008 Plan, is to promote our success and enhance our value by linking the personal interests of our employees, officers, consultants and directors to those of our stockholders. The 2000 Plan was originally adopted by our board of directors on August 24, 2000 and by our stockholders on June 7, 2001, with certain amendments to the Plan having been subsequently approved by our board of directors and stockholders. On May 11, 2009, our board of directors approved an amendment to the 2000 Plan to allow for a one-time stock option re-pricing program for our employees. The 2008 Plan was adopted by our board of directors on November 21, 2008 and by our stockholders on July 1, 2009.

2000 Plan and 2008 Plan Descriptions

The 2000 Plan and the 2008 Plan, or the Plans, are administered by the Compensation Committee of our board of directors. The Compensation Committee has the power, authority and discretion to:

- designate participants;
- determine the types of awards to grant to each participant and the number, terms and conditions of any award;
- establish, adopt or revise any rules and regulations as it may deem necessary or advisable to administer the Plan; and
- make all other decisions and determinations that may be required under, or as the Compensation Committee deems necessary or advisable to administer, the Plan.

Awards under the 2000 Plan

The 2000 Plan expired on August 6, 2010, and thus no shares are available for future grant under the 2000 Plan.

Awards under the 2008 Plan

The following is a summary description of financial instruments that may be granted to participants in our 2008 Plan by the Compensation Committee of our board of directors. The Compensation Committee to date has only granted stock options to participants in the 2008 Plan.

Stock Options. The Compensation Committee is authorized to grant both incentive stock options and non-qualified stock options. The terms of any incentive stock option must meet the requirements of Section 422 of the Internal Revenue Code. The exercise price of an option may not be less than the fair market value of the underlying stock on the date of grant, and no option may have a term of more than 10 years from the grant date.

Restricted Stock. The Compensation Committee may make awards of restricted stock, which will be subject to forfeiture to us and other restrictions as the Compensation Committee may impose.

Stock Bonus Awards. The Compensation Committee may make awards of stock bonus awards in consideration for past services actually rendered, which will be subject to repurchase by us and such other terms as the Compensation Committee may impose.

Limitations on Transfer; Beneficiaries. Stock Option awards under the 2008 Plan may generally not be transferred or assigned by participants other than by will or the laws of descent and distribution. Awards of Restricted Stock or Stock Bonus awards may be transferred or assigned only upon such terms and conditions as set forth in the award agreement or as determined by the Compensation Committee in its discretion.

Acceleration Upon Certain Events. In the event of a "Corporate Transaction" as defined in the 2008 Plan, all outstanding options will become fully vested, subject to the holder's consent with respect to incentive stock options, and exercisable and all restrictions on all outstanding awards will lapse. Unless the surviving or acquiring entity assumes the awards in the Corporate Transaction or the stock award agreement provides otherwise, the stock awards will terminate if not exercised at or prior to the Corporate Transaction.

Termination and Amendment

Our board of directors or the Compensation Committee may, at any time and from time to time, terminate or amend the 2000 Plan or the 2008 Plan without stockholder approval; provided, however, that our board or the Compensation Committee may condition any amendment on the approval of our stockholders if such approval is necessary or deemed advisable with respect to tax, securities or other applicable laws, policies or regulations. No termination or amendment of the Plans may adversely affect any award previously granted without the written consent of the participants affected. The Compensation Committee may amend any outstanding award without the approval of the participants affected, except that no such amendment may diminish or impair the value of an award.

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Holdings of Previously Awarded Equity

Equity awards held as of December 31, 2016 by each of our named executive officers were issued under our 2000 Plan and 2008 Plan. The following table sets forth outstanding equity awards held by our named executive officers as of December 31, 2016:

2016 Outstanding Equity Awards at Fiscal Year-End

Name	Option Awards Number of Securities Underlying Unexercised Options (#)		Option Exercise Price (2) (\$)	Option Expiration Date
	Exercisable	Unexercisable		
Steven A. Kriegsman President and Chief Executive Officer	—	(1) 1,250,000	0.43	12/14/26
	333,333	(1) 666,667	2.44	12/14/25
	400,000	(1) 200,000	2.15	12/09/24
	925,000	(2) —	4.66	12/09/2
	74,176	—	2.46	3/07/23
	500,000	—	1.83	12/10/22
	142,857	—	2.17	12/11/21
	107,143	—	7.07	12/14/20
	107,143	—	7.35	12/10/19
	42,857	—	2.59	11/21/18
	64,286	—	8.05	4/07/18
	50,000	—	8.05	4/18/17
John Y. Caloz Chief Financial Officer and Treasurer	—	(1) 350,000	0.43	12/14/26
	100,000	(1) 200,000	2.44	12/14/25
	133,333	(1) 66,667	2.15	12/14/24
	150,000	(2) —	4.66	12/09/23
	100,000	—	1.83	12/10/22
	28,571	—	2.17	12/11/21
	7,143	—	7.07	12/14/20
	17,857	—	7.35	12/10/19
	7,143	—	2.10	01/02/19
	7,143	—	2.59	11/21/18
	3,571	—	8.05	04/07/18
	3,571	—	8.05	12/06/17
	10,714	—	8.05	10/26/17
Daniel Levitt, M.D., Ph.D. Executive Vice President and Chief Medical Officer	—	(1) 400,000	0.43	12/14/26
	166,667	(1) 333,333	2.44	12/14/25
	266,667	(1) 133,333	2.15	12/14/24
	44,521	(3) —	n/a	n/a
	500,000	—	2.39	12/09/23
	46,751	(3) —	n/a	n/a
	71,429	—	2.17	12/11/21

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	35,714	—		7.07	12/14/20
	71,429	—		7.42	10/11/19
Scott Wieland, Ph.D.	—	(1)	150,000	0.43	12/14/26
Senior Vice President – Drug Development	33,333	(1)	66,667	2.44	12/14/25
	133,333	(1)	66,667	2.15	12/14/24
	150,000	—		2.39	12/09/23
	100,000	—		1.83	12/10/22
	28,571	—		2.17	12/11/21
	14,286	—		7.07	12/14/20
	14,286	—		7.35	12/10/19
	4,286	—		3.99	7/01/18
	7,143	—		2.59	11/21/18
	14,286	—		8.05	4/18/17
	3,571	—		8.05	12/06/17
Benjamin S. Levin					
General Counsel, Senior Vice-President and Secretary	100,000	(1)	200,000	2.44	12/14/25
	133,333	(1)	66,667	2.39	12/14/24
	300,000	(1)	—	4.66	12/09/23
	100,000	—		1.83	12/10/22
	35,714	—		2.17	12/11/21
	14,286	—		7.07	12/14/20
	14,286	—		7.35	12/10/19
	14,286				