

CYTRX CORP  
Form 424B3  
April 03, 2017

**Filed Pursuant to Rule 424(b)(3)**  
**Registration No. 333-215252**

## **PROSPECTUS**

### **28,515,071 Shares of Common Stock**

#### **Issuable Upon Exercise of July 2016 Warrants**

This prospectus relates to shares of our common stock issuable upon the exercise of our outstanding July 2016 warrants. The July 2016 warrants were offered and sold by us pursuant to a prospectus supplement dated July 15, 2016, as supplemented by a prospectus supplement amendment dated December 14, 2016, and a related base prospectus dated June 8, 2016. The prospectus supplement, as supplemented by a prospectus supplement amendment dated December 14, 2016, and base prospectus also covered the offer and sale by us of the shares of our common stock underlying the July 2016 warrants, but those prospectuses can no longer be used for this purpose. The ongoing offer for sale by us of the shares of our common stock issuable upon exercise of the July 2016 warrants is being made pursuant to this prospectus.

July 2016 warrants to purchase a total of 19,397,884 shares of our common stock are exercisable until July 20, 2018 at a current exercise price of \$0.5055 per share of our common stock and July 2016 warrants to purchase a total of 9,117,187 shares of our common stock are exercisable until July 17, 2017 at a current exercise price of \$0.70 per share of our common stock. The exercise prices of the July 2016 warrants are subject to adjustment in the events specified in the July 2016 warrants.

Our common stock is traded on The NASDAQ Capital Market under the symbol "CYTR." On March 17, 2017, the last reported sale price of our common stock was \$0.40 per share.

**An investment in our shares involves a high degree of risk. Before purchasing any shares, you should consider carefully the risks described under “Risk Factors” beginning on page 3.**

**NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED THESE SECURITIES OR DETERMINED THAT THIS PROSPECTUS IS COMPLETE OR ACCURATE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.**

**The date of this prospectus is March 27, 2017**

**Table of Contents**

	<b>Page</b>
<u>ABOUT THIS PROSPECTUS</u>	i
<u>NOTE ON FORWARD-LOOKING STATEMENTS</u>	i
<u>INDUSTRY DATA</u>	i
<u>TRADEMARKS</u>	i
<u>PROSPECTUS SUMMARY</u>	1
<u>RISK FACTORS</u>	3
<u>USE OF PROCEEDS</u>	20
<u>DIVIDEND POLICY</u>	20
<u>MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS</u>	21
<u>DILUTION</u>	21
<u>DESCRIPTION OF CAPITAL STOCK</u>	22
<u>DESCRIPTION OF JULY 2016 WARRANTS</u>	25
<u>PLAN OF DISTRIBUTION</u>	26
<u>WHERE YOU CAN FIND MORE INFORMATION</u>	26
<u>INCORPORATION OF CERTAIN INFORMATION BY REFERENCE</u>	26
<u>LEGAL MATTERS</u>	27
<u>EXPERTS</u>	27

Please read this prospectus carefully. It describes our business, financial condition, results of operations and prospects. We have prepared this prospectus so that you will have the information necessary to make an informed investment decision.

We have not authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares offered hereby, but only under the circumstances and in the jurisdictions where it is lawful to do so. The information contained in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

## ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement (Reg. No. 333-215252) that we filed with the Securities and Exchange Commission, or the “SEC,” to permit us to offer and sell the securities described in this prospectus in an ongoing transaction. The plan of distribution of the securities is described in this prospectus under the heading “Plan of Distribution.”

As permitted by the rules and regulations of the SEC, the registration statement filed by us includes additional information not contained in this prospectus. You may read the registration statement and the other reports we file with the SEC at the SEC’s web site or at the SEC’s offices described under the heading “Where You Can Find More Information” in this prospectus.

You should rely only on the information provided in this prospectus, including the historical information incorporated herein by reference. For more details on the historical information incorporated herein by reference, you should review the discussion under the heading “Incorporation of Certain Documents by Reference” in this prospectus. We have not authorized anyone to provide you with information different from that contained or incorporated by reference in this prospectus. We are offering the securities only in jurisdictions where offers are permitted. You should not assume that the information in this prospectus is accurate at any date other than the date indicated on the cover page of this prospectus.

## NOTE ON FORWARD-LOOKING STATEMENTS

Some of the statements contained in this prospectus 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 set forth under the caption “Risk Factors” in this prospectus. Please consider our forward-looking statements in light of those risks as you read this prospectus. We undertake no obligation to publicly update or review any forward-looking statement, whether as a result of new information, future developments or

otherwise.

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. Before purchasing any of our shares, you should consider carefully all of the factors set forth or referred to in this prospectus that could cause actual results to differ.

## **INDUSTRY DATA**

Unless otherwise indicated, information contained in this prospectus 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 referred to under the caption "Risk Factors" in this prospectus. These and other factors could cause our future performance to differ materially from our assumptions and estimates.

## **TRADEMARKS**

CytRx and LADR are some of our trademarks used in this prospectus. This prospectus 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 prospectus 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.

## PROSPECTUS SUMMARY

This summary highlights selected information appearing elsewhere in this prospectus, or in documents incorporated herein by reference, and does not contain all of the information that may be important to you or that you should consider before investing in our common stock. This prospectus includes information about the securities we are offering and incorporates by reference historical information regarding our business, management, executive compensation, legal proceedings, financial statements and related financial information. Before making an investment decision, you should read this prospectus in its entirety, including “Risk Factors” beginning on page 3 of this prospectus, as well as the historical information incorporated herein by reference.

### Company Overview

CytRx Corporation (“we,” “us,” “our” or the “company”) is 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. Food and Drug Administration, or 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 positive updated results from our pivotal Phase 3 clinical trial evaluating aldoxorubicin compared to investigator's choice in patients with relapsed or refractory 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 LADR™ 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) 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 on the worldwide web at <http://www.cytrx.com>. We do not incorporate by reference into this prospectus the information on, or accessible through, our website, and you should not consider it as part of this prospectus.

## The Offering

The July 2016 warrants were sold and issued in our public offering completed on July 20, 2016. See the “Plan of Distribution” section in this prospectus for more information regarding this offering.

Issuer	CytRx Corporation
Shares offered by us	28,515,071 shares of our common stock issuable upon exercise of our outstanding July 2016 warrants
Shares outstanding	111,322,895 shares as of December 31, 2016, excluding 49,982,560 shares subject to outstanding stock options and warrants, including the July 2016 warrants, and excluding 1,400,000 shares issuable upon conversion of outstanding shares of our Series B Convertible Preferred Stock
Shares outstanding following this offering	139,837,966 shares assuming all July 2016 warrants are exercised in full and without giving effect to any other issuances of common stock subsequent to December 31, 2016
Use of proceeds	We intend to use the net proceeds of any exercises of the July 2016 warrants pursuant to this offering to augment our working capital and for general corporate purposes



## RISK FACTORS

*Investing in our common stock involves significant risks. Prior to making a decision about investing in our common stock, you should carefully consider the risk factors discussed below. 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 \$415.9 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 \$17.5 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.

We also may disclose projected expenditures or other forecasts for future periods. These and other financial projections are based on management's current expectations and do not contain any margin of error or cushion for any specific uncertainties, or for the uncertainties inherent in all financial forecasting.

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

The regulatory approval process is lengthy, time consuming and inherently unpredictable, and if our products are not successfully developed and approved by the FDA or foreign regulatory authorities, we may be forced to reduce or curtail our operations.

All of our product candidates in development must be approved by the FDA or corresponding foreign governmental agencies before they can be marketed. The process for obtaining FDA and foreign government approvals is both time-consuming and costly, with no certainty of a successful outcome. This process typically includes the conduct of extensive pre-clinical and clinical testing, including post-approval testing, which may take longer or cost more than we or our licensees, if any, anticipate, and may prove unsuccessful due to numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate.

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

- difficulty in enrolling patients in conformity with required protocols or projected timelines;
- requirements for clinical trial design imposed by the FDA;
- unexpected adverse reactions by patients in trials;
- difficulty in obtaining clinical supplies of the product;

changes in or our inability to comply with FDA or foreign governmental product testing, manufacturing or marketing requirements;

regulatory inspections of clinical trials or manufacturing facilities, which may, among other things, require us or our manufacturers or licensees to undertake corrective action or suspend or terminate the affected clinical trials if investigators find them not to be in compliance with applicable regulatory requirements;

inability to generate statistically significant data confirming the safety and efficacy of the product being tested;

modification of the product during testing; and

reallocation of our limited financial and other resources to other clinical programs.

It is possible that none of the product candidates we develop will obtain the regulatory approvals necessary for us to begin selling them. The time required to obtain FDA and foreign governmental approvals is unpredictable, but often can take years following the commencement of clinical trials, depending upon the complexity of the product candidate. Any analysis we perform on data from clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

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

restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;

fines, warning letters or holds on clinical trials;

refusal by the FDA to approve pending applications or supplements to approved applications filed by us or our strategic partners, or suspension or revocation of product license approvals;

product seizure or detention, or refusal to permit the import or export of products; and

injunctions or the imposition of civil or criminal penalties.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business. We will also be subject to periodic inspections and the potential for mandatory post-approval clinical trials required by the FDA and other U.S. and foreign regulatory authorities. Any delay or failure in obtaining required approvals or to comply with post-approval regulatory requirements could have a material adverse effect on our ability to generate revenue from the particular product candidate. The failure to comply with any post-approval regulatory requirements also could result in the rescission of the related regulatory approvals or the suspension of sales of the offending product.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Our current and planned clinical trials of our lead product candidate may fail to show that it is clinically safe and effective, or that it is better than alternative treatments.

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

- 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.

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.

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 aldorubicin, 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 aldorubicin 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 aldorubicin. 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.

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.

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

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

a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

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

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

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

the federal Anti-Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government, and which may apply to entities that provide coding and billing advice to customers;

federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

the federal physician sunshine requirements under the Affordable Care Act, which requires manufacturers of drugs, devices, biologics, and medical supplies to report annually to the Centers for Medicare & Medicaid Services information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members;

the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information; and

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

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.

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 Tracon Pharmaceuticals, veliparib by AstraZeneca and buparlisib by Novartis.

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

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

Many companies, including large pharmaceutical and biotechnology firms with financial resources, research and development staffs, and facilities that may be substantially greater than those of ours or our strategic partners or licensees, are engaged in the research and development of pharmaceutical products that could compete with our potential products. To the extent that we seek to acquire, through license or otherwise, existing or potential new products, we will be competing with numerous other companies, many of which will have substantially greater

financial resources, large acquisition and research and development staffs that may give those companies a competitive advantage over us in identifying and evaluating these drug acquisition opportunities. Any products that we acquire will be competing with products marketed by companies that in many cases will have substantially greater marketing resources than we have. The industry is characterized by rapid technological advances and competitors may develop their products more rapidly and such products may be more effective than those currently under development or that may be developed in the future by our strategic partners or licensees. Competitive products for a number of the disease indications that we have targeted are currently being marketed by other parties, and additional competitive products are under development and may also include products currently under development that we are not aware of or products that may be developed in the future.

As a result, these competitors may:

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

- develop products that are safer or more effective than our products;
- devote greater resources than us to marketing or selling products;
- introduce or adapt more quickly than us to new technologies and other scientific advances;
- introduce products that render our products obsolete;
- withstand price competition more successfully than us or our strategic partners or licensees;
- negotiate third-party strategic alliances or licensing arrangements more effectively than us; and
- take better advantage than us of other opportunities.

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

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

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

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

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

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

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

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



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

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

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

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

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

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

- foreign regulatory requirements that could restrict or limit our ability to conduct our clinical trials;
- administrative burdens of conducting clinical trials under multiple foreign regulatory schema;
- foreign exchange fluctuations;

diminished protection of intellectual property in some countries; and

possible nationalization and expropriation.

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

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

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

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

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

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

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

We have operated our drug discovery laboratory and LADR™ development program since October 2014. Accordingly, we have a limited operating history in conducting our own drug discovery programs. 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 offered hereby.

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.

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.

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 December 31, 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 our most recent Annual Report on Form 10-K incorporated herein by reference, 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.

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.

#### Risks Associated With This Offering

You will experience immediate and substantial dilution in the net tangible book value per share of the stock you purchase.

If the exercise price per share of the July 2016 warrants is higher than the net tangible book value per share of our common stock when you exercise your July 2016 warrants, you will suffer immediate dilution in the net tangible book value of the common stock you acquire on exercise. See “Dilution” in this prospectus for a more detailed discussion of the dilution you may incur if you exercise your July 2016 warrants.

Our management will have broad discretion as to the use of the proceeds of this offering.

We have not designated the amount of net proceeds from this offering to be used for any particular purpose. Accordingly, our management will have broad discretion as to the application of the net proceeds and could use them for purposes other than those contemplated at the time of this offering. Our stockholders may not benefit from the manner in which our management chooses to allocate and spend the net proceeds.

You may not be able to resell your warrants.

There is no established trading market for the July 2016 warrants, and we do not expect such a market to develop. In addition, we do not intend to apply for listing of the July 2016 warrants on any securities exchange or other nationally recognized trading system, and you may not be able to resell your July 2016 warrants. If your July 2016 warrants cannot be resold, you will have to depend upon any appreciation in the value of our common stock over the exercise price of the warrants in order to realize a return on your investment in the July 2016 warrants.

Investors will have no rights as a common stockholder with respect to their warrants until they exercise their warrants and acquire our common stock.

Until you acquire shares of our common stock upon exercise of your July 2016 warrants, you will have no rights with respect to the shares of our common stock underlying your July 2016 warrants except as set forth in the July 2016 warrants. Upon exercise of your July 2016 warrants, you will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

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 exercise price per share paid in connection with any exercise of your July 2016 warrants. 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 exercise price per share of the July 2016 warrants.

## USE OF PROCEEDS

We do not know whether any of the July 2016 warrants will be exercised or, if any of the July 2016 warrants are exercised, when they will be exercised or at what price they will be exercised. It is possible that the July 2016 warrants may expire and never be exercised, or that the current exercise price of the July 2016 warrants may be reduced as a result of subsequent events that would trigger applicable anti-dilution adjustments under the July 2016 warrants. Also, as discussed in the “Description of Securities — July 2016 Warrants” section of this prospectus, there are certain circumstances under which the July 2016 warrants may be exercised on a cashless basis. In these

circumstances, even if the July 2016 warrants are exercised, we may not receive any proceeds, or the proceeds that we do receive may be significantly less than what we might expect. We estimate that the maximum net proceeds that we may receive from the exercise of the July 2016 warrants, assuming the exercise, in full, of the 19,397,884 July 2016 warrants with a current exercise price of \$0.5055 per share and of the 9,117,187 July 16, 2016 warrants with a current exercise price of \$0.70 per share, will be approximately \$16.2 million, before deducting estimated offering expenses payable by us.

We currently intend to use the net proceeds from the exercise of the July 2016 warrants, if any, to augment our working capital and for general corporate purposes.

The amounts and timing of our use of proceeds will vary depending on a number of factors, including the amount of cash used by our operations, and we will retain broad discretion in the allocation of the net proceeds from the exercise of the July 2016 warrants. In addition, while we have not entered into any agreements, commitments or understandings relating to any significant transaction as of the date of this prospectus, we may use a portion of the net proceeds to pursue acquisitions, joint ventures and other strategic transactions.

Pending the final application of the net proceeds from the exercise of the July 2016 warrants, we intend to invest such net proceeds in short-term, interest bearing, investment-grade securities.

#### DIVIDEND POLICY

We have never declared or paid cash dividends on our capital stock. We have agreed in the loan and security agreement relating to our term loans not to pay any cash dividend on any class of our stock, and do not anticipate paying cash dividends in the foreseeable future. Payment of future dividends, if any, will be at the discretion of our board of directors after taking into account various factors, including our financial condition, operating results, and current and anticipated cash needs.

## MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

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:

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

Fiscal Year 2016:	High	Low
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 2017	High	Low
First Quarter (through March 15)	\$ 0.51	\$ 0.38

### 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.

### DILUTION

Our net tangible book value as of December 31, 2016 was approximately \$0.22 per share of common stock. Net tangible book value per share is calculated by subtracting our total liabilities from our total tangible assets, which is total assets less intangible assets, and dividing this amount by the number of shares of common stock outstanding. After giving effect to the issuance of shares of our common stock upon the exercise, in full, of the 19,397,884 July 2016 warrants with a current exercise price of \$0.5055 per share and of the 9,117,187 July 16, 2016 warrants with a

Edgar Filing: CYTRX CORP - Form 424B3

current exercise price of \$0.70 per share, and before deducting estimated offering expenses payable by us, we would have had a net tangible book value as of December 31, 2016 of \$40.7 million, or \$0.29 per share of common stock. This represents an immediate increase in the net tangible book value of \$0.04 per share to our existing stockholders and an immediate dilution in net tangible book value of between \$0.24 per share and \$0.44 per share to purchasers of shares of our common stock in this offering. The following table illustrates this per share dilution:

Exercise price per share		\$ 0.70	\$ 0.5055
Net tangible book value per share as of December 31, 2016	\$ 0.22		
Increase per share attributable to this offering	\$ 0.04		
As adjusted net tangible book per share after this offering		\$ 0.26	\$ 0.26
Net dilution per share to new investors		\$ 0.44	\$ 0.24

The number of shares of common stock shown above to be outstanding after this offering is based on 111,322,895 shares outstanding as of December 31, 2016 and excludes:

17,479,770 shares of our common stock subject to options outstanding as of December 31, 2016 having a weighted-average exercise price of \$2.37 per share;

10,682,335 shares of our common stock reserved for issuance in connection with future awards under our 2008 Stock Incentive Plan;

3,987,719 shares of our common stock subject to outstanding warrants (other than the July 2016 warrants) as of December 31, 2016 having a weighted-average exercise price of \$1.49 per share; and

28,515,071 shares of our common stock subject to the July 2016 warrants.

To the extent our outstanding options and warrants are exercised, you may experience further dilution. The above illustration of dilution per share to investors participating in this offering assumes no exercise of outstanding options or outstanding warrants to purchase shares of our common stock other than the July 2016 warrants. The exercise of outstanding options and warrants having an exercise price less than the exercise price of the July 2016 warrants will further increase dilution to investors in this offering.

## DESCRIPTION OF CAPITAL STOCK

As of December 31, 2016, our authorized capital stock consisted of 250,000,000 shares of common stock, \$0.001 par value per share, of which 111,322,895 shares were outstanding, and 5,000,000 shares of preferred stock, \$0.01 par value per share, of which 25,000 shares have been designated as Series A Junior Participating Preferred Stock and 3,900 shares have been designated as Series B Convertible Preferred Stock. There were 3,108 shares of our Series B Convertible Preferred Stock outstanding as of December 31, 2016, of which 2,712 shares had been converted into shares of our common stock and retired as of March 15, 2017.

The following summary of certain provisions of our common and preferred stock does not purport to be complete. You should refer to our amended and restated certificate of incorporation and our restated by-laws, which are filed with or incorporated by reference in the registration statement relating to this offering filed by us with the SEC. The summary below is also qualified by reference to the provisions of applicable Delaware corporation law.

### Common Stock

Holders of our common stock are entitled to one vote per share on matters on which our stockholders vote, including with respect to the election of directors. Holders of common stock are entitled to receive dividends, if declared by our board of directors, out of funds that we may legally use to pay dividends. See the section of this prospectus entitled “Dividend Policy” for further information. If we liquidate or dissolve, holders of common stock are entitled to share

ratably in our assets once our debts and any liquidation preference owed to holders of any then-outstanding preferred stock are paid. No shares of preferred stock will be outstanding immediately after the closing of this offering. All shares of common stock that are outstanding as of the date of this prospectus are, and all shares that the selling security holder is offering for sale pursuant to this prospectus, upon their issuance and sale, will be, fully-paid and non-assessable. Holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions with respect to our common stock.

## Preferred Stock

### General

Our board of directors has the authority to issue shares of our authorized but unissued shares of preferred stock in one or more series and to fix the rights of each series. These rights may include dividend rights, dividend rates, conversion rights, voting rights, terms of redemption, redemption prices, liquidation preferences, sinking fund terms, and the number of shares that constitute any series. The board of directors may exercise this authority without any further action by our stockholders.

### Series A Junior Participating Preferred Stock

We have reserved all of the shares of our Series A Junior Participating Preferred Stock for issuance upon the exercise of the rights under our Shareholder Protection Rights Agreement described below.

### Series B Convertible Preferred Stock

*Conversion.* Each share of Series B Convertible Preferred Stock is convertible into shares of our common stock (subject to adjustment as provided in the related certificate of designation of preferences) at any time at the option of the holder, provided that the holder will be prohibited from converting Series B Convertible Preferred Stock into shares of our common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 4.99% of the total number of shares of our common stock then issued and outstanding. Any holder may increase or decrease such percentage to any other percentage not in excess of 9.99%, provided that any increase in such percentage shall not be effective until 61 days after such notice to us.



*Liquidation Preference.* In the event of a liquidation of the company, the holders of Series B Convertible Preferred Stock are entitled to participate on an as-converted-to-common stock basis with holders of common stock in any distribution of assets of the company to the holders of common stock.

*Voting Rights.* Shares of Series B Convertible Preferred Stock will generally have no voting rights, except as required by law and except that the consent of the holders of the outstanding Series B Convertible Preferred Stock will be required to amend any provision of our amended and restated certificate of incorporation that would have a materially adverse effect on the rights of the holders of the Series B Convertible Preferred Stock.

*Dividends.* Shares of Series B Convertible Preferred Stock will not be entitled to receive any dividends, unless and until specifically declared by our board of directors. The holders of the Series B Convertible Preferred Stock will participate, on an as-converted-to-common stock basis, in any dividends to the holders of common stock.

*Redemption.* We are not obligated to redeem or repurchase any shares of Series B Convertible Preferred Stock. Shares of Series B Convertible Preferred Stock are not otherwise entitled to any redemption rights or mandatory sinking fund or analogous fund provisions.

*Listing.* The Series B Convertible Preferred Stock is not listed for trading on The NASDAQ Capital Market, any national securities exchange or other nationally recognized trading system. We expect the common stock issuable upon conversion of the Series B Convertible Preferred Stock to be listed on The NASDAQ Capital Market.

#### Anti-Takeover Measures

#### Delaware Law

Section 203 of the Delaware General Corporation Law is applicable to takeovers of certain Delaware corporations, including us. Subject to exceptions enumerated in Section 203, Section 203 provides that a corporation shall not engage in any business combination with any “interested stockholder” for a three-year period following the date that the stockholder becomes an interested stockholder unless:

prior to that date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;

upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, though some shares may be excluded from the calculation; or

on or subsequent to that date, the business combination is approved by the board of directors of the corporation and by the affirmative votes of holders of at least two-thirds of the outstanding voting stock that is not owned by the interested stockholder.

Except as specified in Section 203, an interested stockholder is generally defined to include any person who, together with any affiliates or associates of that person, beneficially owns, directly or indirectly, 15% or more of the outstanding voting stock of the corporation, or is an affiliate or associate of the corporation and was the owner of 15% or more of the outstanding voting stock of the corporation, any time within three years immediately prior to the relevant date. Under certain circumstances, Section 203 makes it more difficult for an interested stockholder to effect various business combinations with a corporation for a three-year period, although the stockholders may elect not to be governed by this section, by adopting an amendment to the certificate of incorporation or by-laws, effective 12 months after adoption. Our amended and restated certificate of incorporation and our restated by-laws do not opt out from the restrictions imposed under Section 203. We anticipate that the provisions of Section 203 may encourage companies interested in acquiring us to negotiate in advance with the board because the stockholder approval requirement would be avoided if a majority of the directors then in office excluding an interested stockholder approve either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder. These provisions may have the effect of deterring hostile takeovers or delaying changes in control, which could depress the market price of our common stock and deprive stockholders of opportunities to realize a premium on shares of common stock held by them.

## Charter and By-Law Provisions

In addition to the board of directors' ability to issue shares of preferred stock, our amended and restated certificate of incorporation and restated by-laws contain the following provisions that may have the effect of discouraging unsolicited acquisition proposals:

- our restated by-laws classify the board of directors into three classes with staggered three-year terms;
- under our restated by-laws, our board of directors may enlarge the size of the board and fill the vacancies;
- our restated by-laws provide that a stockholder may not nominate candidates for the board of directors at any annual or special meeting unless that stockholder notifies us of its intention a specified period in advance and provides us with certain required information;
- stockholders who wish to bring business before the stockholders at our annual meeting must provide advance notice; and
- our restated by-laws provide that special meetings of stockholders may only be called by our board of directors or by an officer so instructed by our board.

Our restated by-laws also provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for:

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of the company to us or our stockholders;
- any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law; or
- any action asserting a claim governed by the internal affairs doctrine.

Our restated by-laws further provide that any person or entity purchasing or otherwise acquiring any interest in shares of capital stock of the company is deemed to have notice of and consented to the foregoing provision.

#### Shareholder Protection Rights Agreement

Our board of directors adopted a Shareholder Protection Rights Agreement, or Rights Agreement, dated April 16, 1997, as amended, between us and American Stock Transfer & Trust Co., as Rights Agent. The Rights Agreement will expire on April 16, 2022, unless renewed or extended by our board of directors. A series of our preferred stock, designated as Series A Junior Participating Preferred Stock, par value \$0.01 per share, was created in accordance with the Rights Agreement. The Rights Agreement is designed to deter coercive takeover tactics, including the accumulation of shares in the open market or through private transactions, and to prevent an acquirer from gaining control of us without offering a fair and adequate price and terms to all of our stockholders. As such, the Rights Agreement is intended to enhance our board of directors' ability to protect stockholder interests and help to assure that stockholders receive fair and equal treatment in the event any proposed takeover of our company is made in the future. Pursuant to the Rights Agreement, our board of directors declared a dividend distribution of one preferred stock purchase right for each outstanding share of our common stock. The preferred stock purchase rights are attached to, and trade with, our common stock. The purchase rights are exercisable only upon the occurrence of certain triggering events described in the Rights Agreement.

#### Transfer Agent

The transfer agent for our common stock is American Stock Transfer & Trust company, 40 Wall Street, New York, New York 10005.

## DESCRIPTION OF JULY 2016 WARRANTS

The following summary of the material terms and provisions of the July 2016 warrants is not complete and is subject to, and qualified in its entirety by the provisions of the July 2016 warrants, the form of which has been filed as an exhibit to the registration statement of which this prospectus is part:

### Term

July 2016 warrants to purchase a total of 19,397,884 shares of our common stock are exercisable at any time on or before July 20, 2018 and July 2016 warrants to purchase a total of 9,117,187 shares of our common stock are exercisable at any time on or before July 20, 2017.

### Exercise Price

The current exercise price of 9,117,187 shares of our common stock of the July 2016 warrants to purchase a total of 19,387,884 shares of our common stock is \$0.5055 per share and the current exercise price of 9,117,187 of the July 2016 warrants is \$0.70 per share. The exercise prices re subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, distributions of assets, reclassifications or similar events affecting our common stock.

### Exercisability

The July 2016 warrants are exercisable at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of the July 2016 warrants to the extent that the holder would own more than 4.99% of the outstanding common stock after exercise, except that upon at least 61 days' prior notice from the holder to us, the holder may increase the amount of ownership of outstanding stock after exercising the holder's July 2016 warrants to up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the July 2016 warrants.

### Cashless Exercise

If, at the time a holder exercises a July 2016 warrant, there is no effective registration statement registering, or the prospectus contained therein is not available for an issuance of the shares underlying the July 2016 warrant to the holder, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise, either in whole or in part, the net number of shares of common stock determined according to a formula set forth in the July 2016 warrants.

### Transferability

Subject to applicable laws, the July 2016 warrants may be transferred at the option of the holder upon surrender of the July 2016 warrants to us together with the appropriate instruments of transfer.

### Authorized Shares

During the period the July 2016 warrants are outstanding, we will reserve from our authorized and unissued common stock a sufficient number of shares to provide for the issuance of shares of common stock upon the exercise of the July 2016 warrants.

### Exchange Listing

The July 2016 warrants are not listed for trading on The NASDAQ Capital Market, any national securities exchange or other nationally recognized trading system.

### Fundamental Transactions

In the event of any fundamental transaction, as described in the July 2016 warrants and generally including any merger with or into another entity, sale of all or substantially all of our assets, tender offer or exchange offer, or reclassification of our common stock, then upon any subsequent exercise of a July 2016 warrant, the holder shall have the right to receive as alternative consideration, for each share of our common stock that would have been issuable

upon such exercise immediately prior to the occurrence of such fundamental transaction, the number of shares of common stock of the successor or acquiring corporation or of CytRx, if we are the surviving corporation, and any additional consideration receivable upon or as a result of such transaction by a holder of the number of shares of our common stock for which the July 2016 warrant is exercisable immediately prior to such event. In addition, in the event of a fundamental transaction that is an all-cash transaction, a “going private transaction” or a transaction with a person or entity not traded on an eligible securities market, then we or any successor entity shall pay at the holder’s option, exercisable at any time commencing on the earlier of the public disclosure of the fundamental transaction or the consummation of the fundamental transaction and continuing for 90 days after the public disclosure of the consummation of the fundamental transaction, an amount of cash equal to the value of the warrant as determined in accordance with the Black Scholes option pricing model.

## Right as a Stockholder

Except as otherwise provided in the July 2016 warrants or by virtue of such holder's ownership of shares of our common stock, the holders of the July 2016 warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their July 2016 warrants.

## Waivers and Amendments

Any term of the warrants issued in the offering may be amended or waived with our written consent and the written consent of the holders of warrants representing a majority of the shares of our common stock underlying the July 2016 warrants then outstanding, except that no such action may increase the exercise price of any July 2016 warrant or decrease the number of shares or class of stock obtainable upon exercise of any July 2016 warrant without the written consent of the holder of the July 2016 warrant.

## PLAN OF DISTRIBUTION

This prospectus relates to shares of our common stock issuable upon the exercise of our outstanding July 2016 warrants. The July 2016 warrants were offered and sold by us pursuant to a prospectus supplement dated July 15, 2016, as amended by a prospectus supplement amendment dated December 14, 2016, and a related base prospectus dated June 8, 2016. The prospectus supplement, as amended by a prospectus supplement amendment dated December 14, 2016, and base prospectus also covered the offer and sale by us of the shares of our common stock underlying the July 2016 warrants, but those prospectuses can no longer be used for this purpose. The ongoing offer for sale by us of the shares of our common stock issuable upon exercise of the July 2016 warrants is being made pursuant to this prospectus.

The July 2016 warrants are currently outstanding, and no additional July 2016 warrants will be issued. We will deliver shares of our common stock upon exercise of a July 2016 warrant, in whole or in part. We will not issue fractional shares. Each July 2016 warrant contains instructions for exercise. In order to exercise a July 2016 warrant, the holder must deliver to us, or our transfer agent, the information required by the July 2016 warrants, along with payment of the exercise price for the shares to be purchased. We will then deliver shares of our common stock in the manner described above in the section titled "Description of July 2016 Warrants."

## WHERE YOU CAN FIND MORE INFORMATION



We file annual, quarterly and current reports, proxy statements and other information with the SEC. Our SEC filings are available to the public over the Internet at the SEC's website at <http://www.sec.gov>. The SEC's website contains reports, proxy and information statements and other information regarding issuers such as us that file electronically with the SEC. You may also read and copy any document we file with the SEC at the SEC's Public Reference Room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549, and may obtain copies of these documents at prescribed rates by writing to the SEC. Please call the SEC at 1-800-SEC-0330 for further information on the operation of its Public Reference Room.

Information about us is also available at our website at [www.cytrx.com](http://www.cytrx.com); however, information on our website is not incorporated into this prospectus and is not a part of this prospectus, except historical information incorporated herein by reference.

#### INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC allows us to "incorporate by reference" the information we have filed with it, which means that we can disclose important historical information to you by referring you to another document that we have filed separately with the SEC. You should read the information incorporated by reference because it is an important part of this prospectus. Any statement in a document we incorporate by reference into this prospectus will be considered to be modified or superseded to the extent a statement contained in this prospectus modifies or supersedes that statement. The modified or superseded statement will not be considered to be a part of this prospectus, except as modified or superseded.

We incorporate by reference the following information or documents that we have filed with the SEC (excluding those portions of any document that are “furnished” and not “filed” in accordance with SEC rules):

- our Annual Report on Form 10-K for the year ended December 31, 2016 filed with the SEC on March 15, 2017; and
- our Current Reports on Form 8-K and Form 8-K/A filed with the SEC on January 6, 2017, January 13, 2017, February 24, 2017 and March 15, 2017, respectively.

You may access the foregoing documents on our website at [www.cytrx.com](http://www.cytrx.com).

Statements made in this prospectus or in any document incorporated by reference in this prospectus as to the contents of any contract or other document referred to herein or therein are not necessarily complete, and in each instance reference is made to the copy of such contract or other document filed as an exhibit to the documents incorporated by reference, each such statement being qualified in all material respects by such reference.

You may obtain a copy of the foregoing documents from us without charge by writing or calling us at the following address and telephone number: 11726 San Vicente Blvd., Suite 650 Los Angeles, California 90049, Attention: Corporate Secretary; (310) 826-5648.

## LEGAL MATTERS

The validity of the securities being offered hereby has been passed upon for us by TroyGould PC, Los Angeles, California. TroyGould PC and some of its attorneys own shares of our common stock constituting in the aggregate less than 1% of our outstanding shares of common stock.

## EXPERTS

The financial statements and schedule as of December 31, 2016 and 2015 and for each of the three years in the period ended December 31, 2016 and management’s assessment of the effectiveness of internal control over financial reporting as of December 31, 2016 incorporated by reference in this prospectus have been so incorporated in reliance on the reports of BDO USA, LLP, an independent registered public accounting firm, incorporated herein by reference,

given on the authority of said firm as experts in auditing and accounting.

**PROSPECTUS**

**28,515,071 Shares of Common Stock**

**Issuable Upon Exercise of July 2016 Warrants**

**The date of this prospectus is March 27, 2017**