

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Steven A. Kriegsman

Chairman and Chief Executive Officer

CytRx Corporation

11726 San Vicente Boulevard, Suite 650

Los Angeles, California 90049

(310) 826-5648

(Name, address, including zip code, and telephone number, including area code, of agent for service)

With a copy to:

Dale E. Short

TroyGould PC

1801 Century Park East, Suite 1600

Los Angeles, California 90067

Telephone: (310) 789-1259

Facsimile: (310) 789-1459

Approximate date of commencement of proposed sale to public: From time to time after the effective date of this registration statement.

Edgar Filing: CYTRX CORP - Form S-3/A

If the only securities being registered on this form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. ☐

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. ☒

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. ☐

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. ☐

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

Large accelerated filer ☐ Accelerated filer ☒ Non-accelerated filer ☐ (Do not check if a smaller reporting company) Smaller reporting company ☐

Non-accelerated filer ☐ (Do not check if a smaller reporting company) Smaller reporting company ☐

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount to be registered(1)	Proposed maximum offering price per share(2)	Proposed maximum aggregate offering price(2)	Amount of registration fee
Common stock, par value \$.001 per share	9,117,187 shares	\$0.70	\$6,382,031	\$—
Common stock, par value \$.001 per share	19,397,884 shares	\$0.5055	\$9,805,631	\$—
Total	—	—	\$16,187,662	\$1,876.15(3)

- (1) Represents shares issuable upon exercise of outstanding warrants. The warrants were sold and issued under the registration statement on Form S-3 (Reg. No. 333-192597) declared effective on December 23, 2013, and the shares issuable upon exercise of the warrants were originally offered for sale under that prior registration statement. In accordance with Rule 416, there is also being registered hereunder such indeterminate number of additional shares of common stock as may become issuable upon exercise of the warrants to prevent dilution resulting from stock splits, stock dividends or similar transactions.
- (2) The price is estimated in accordance with Rule 457(g) under the Securities Act of 1933 solely for the purpose of calculating the registration fee based upon the respective exercise prices of the warrants.
- (3) Previously paid.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until this registration statement shall become effective on such date as the commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission becomes effective. This prospectus is not an offer to sell these securities, and it is not a solicitation of an offer to buy these securities, in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, March 20, 2017

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 _____, 2017

Table of Contents

	Page
<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 \$15.6 million as of March 15, 2017. If our public float increases to \$75 million or more, we will no longer be subject to this limitation.

At December 31, 2016, we had cash and cash equivalents of approximately \$57.0 million, but we are required under the terms of our outstanding loan-term debt to maintain cash on hand of not less than three months projected cash burn or \$10 million, whichever is greater. Management believes that our current resources, will be sufficient to fund our operations for the foreseeable future. The belief is based, in part, upon our currently projected expenditures for 2017 of approximately \$39.8 million, which includes approximately \$16.4 million for our clinical programs for aldoxorubicin, approximately \$3.7 million for pre-clinical development of high potency cytotoxic albumin-binding cancer drugs, approximately \$3.2 million for general operation of our clinical programs, approximately \$8.0 million for other general and administrative expenses, and \$8.5 million for interest and payments on our outstanding term loan. These projected expenditures and payments assume that we will not suffer a “material adverse event” which could trigger the lenders’ acceleration of our outstanding term loan, and are based upon numerous other assumptions and subject to many uncertainties, and our actual expenditures may be significantly different from these projections.

If we receive a negative response from the FDA in our planned pre-NDA meeting, we may reduce our headcount and discontinue certain development programs and drug discovery activities. For these reasons and others, our operating results may fluctuate from period to period, and the results of prior periods should not be relied upon as predictive of the results in future periods. Furthermore, if we obtain marketing approval and successfully commercialize aldoxorubicin, or another product candidate, we anticipate it will take a minimum of two years, and likely longer, for us to generate significant recurring revenue, and we will be dependent on future financing until such time, if ever, as we can generate significant recurring revenue. We have no commitments from third parties to provide us with any additional financing, and we may not be able to obtain future financing on favorable terms, or at all. Failure to obtain adequate financing would adversely affect our ability to operate as a going concern. If we raise additional funds by issuing equity securities, dilution to stockholders may result and new investors could have rights superior to holders of the shares issued in this offering. In addition, debt financing, if available, may include restrictive covenants. If adequate funds are not available to us, we may have to liquidate some or all of our assets or to delay or reduce the scope of or eliminate some portion or all of our development programs or clinical trials. We also may have to license to other companies our product candidates or technologies that we would prefer to develop and commercialize ourselves.

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

From time to time, we estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of scientific studies and clinical trials and the submission of regulatory filings such as the discussions in this Annual Report of the expected timing of the pre-NDA meeting with the FDA and of certain other milestones relating to our aldoxorubicin clinical development programs.

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