CYTRX CORP
Form 10-K
March 29, 2019

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

[X] **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2018

or

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

For the transition period from _____ to _____

Commission file number 0-15327

CytRx Corporation

(Exact name of Registrant as specified in its charter)

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

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

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

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

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

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

None

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

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

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

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

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

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

Large accelerated filer [ ]	Accelerated filer [ ]	Non-accelerated filer [X]	Smaller reporting company [X] Emerging growth company [ ]

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. [ ]

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

Based on the closing price of the Registrant's common stock as reported on The NASDAQ Capital Market, the aggregate market value of the Registrant's common stock held by non-affiliates on June 29, 2018 (the last business day of the Registrant's most recently completed second fiscal quarter) was approximately $37.0 million. Shares of common stock held by directors and executive officers and any ten percent or greater stockholders and their respective affiliates have been excluded from this calculation, because such stockholders may be deemed to be "affiliates" of the Registrant. This is not necessarily determinative of affiliate status for other purposes. The number of outstanding shares of the Registrant's common stock as of March 29, 2019 was 33,637,501.

CYTRX CORPORATION

2018 ANNUAL REPORT ON FORM 10-K

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NOTE ON FORWARD-LOOKING STATEMENTS

References throughout this Annual Report on Form 10-K, the “Company,” “CytRx,” “we,” “us,” and “our,” except where the context requires otherwise, refer to CytRx Corporation and its wholly-owned subsidiary.

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

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

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

INDUSTRY DATA

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

TRADEMARKS

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

PART I

Item 1. *BUSINESS*

COMPANY OVERVIEW

We are a biopharmaceutical research and development company specializing in oncology. Our focus has been on the discovery, research and clinical development of novel anti-cancer drug candidates that employ novel linker technologies to enhance the accumulation and release of cytotoxic anti-cancer agents at the tumor. During 2017, CytRx's discovery laboratory, located in Freiburg, Germany, synthesized and tested over 75 rationally designed drug conjugates with highly potent payloads, culminating in the creation of two distinct classes of compounds. Four lead candidates (LADR-7, LADR-8, LADR-9 and LADR-10) were selected based on *in vitro* and animal preclinical studies, including stability and manufacturing feasibility. In 2018, additional animal efficacy and toxicology testing of these lead candidates was conducted. In addition, a novel albumin companion diagnostic, ACDx™, was developed to identify patients with cancer who are most likely to benefit from treatment with these drug candidates.

On June 1, 2018, CytRx launched Centurion BioPharma Corporation ("Centurion"), a wholly owned subsidiary, and transferred all of its assets, liabilities and personnel associated with the laboratory operations in Freiburg, Germany. In connection with said transfer, the Company and Centurion entered into a Management Services Agreement whereby the Company agreed to render advisory, consulting, financial and administrative services to Centurion, for which Centurion shall reimburse the Company for the cost of such services plus a 5% service charge. The Management Services Agreement may be terminated by either party at any time. Centurion is focused on the development of personalized medicine for solid tumor treatment. On December 21, 2018, CytRx announced that Centurion had concluded the pre-clinical phase of development for its four LADR drug candidates, and for its albumin companion diagnostic (ACDx™). As a result of completing this work, operations taking place at the pre-clinical laboratory in Freiburg, Germany would no longer be needed and, accordingly, the laboratory was closed at the end of January 2019.

We are a Delaware corporation, incorporated in 1985. Our corporate offices are located at 11726 San Vicente Boulevard, Suite 650, Los Angeles, California 90049, and our telephone number is (310) 826-5648. Our web site is located at http://www.cytrx.com. We do not incorporate by reference into this Annual Report the information on, or accessible through, our website, and you should not consider it as part of this Annual Report.

LADR Drug Discovery Platform and Centurion

Centurion's LADR™ (Linker Activated Drug Release) technology platform is a discovery engine combining our expertise in linker chemistry and albumin biology to create a pipeline of anti-cancer molecules that will avoid unacceptable systemic toxicity while delivering highly potent agents directly to the tumor. They have created a "toolbox" of linker technologies that have the ability to significantly increase the therapeutic index of ultra-high potency drugs (10-1,000 times more potent than traditional chemotherapies) by controlling the release of the drug payloads and improving drug-like properties.

Their efforts were focused on two classes of ultra-high potency albumin-binding drug conjugates. These drug conjugates combine the proprietary LADR™ linkers with novel derivatives of the auristatin and maytansinoid drug classes. These payloads historically have required a targeting antibody for successful administration to humans. Their drug conjugates eliminate the need for a targeting antibody and provide a small molecule therapeutic option with potential broader applicability.

Centurion's postulated mechanism of action for the albumin-binding drug conjugates is as follows:

after administration, the linker portion of the drug conjugate forms a rapid and specific covalent bond to the cysteine-34 position of circulating albumin;

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

once localized at the tumor, the acid-sensitive linker is cleaved due to the specific conditions within the tumor and in the tumor microenvironment; and

free active drug is then released into the tumor.

Centurion's novel companion diagnostic, ACDx™ (albumin companion diagnostic), was developed to identify patients with cancer who are most likely to benefit from treatment with the four LADR lead assets.

Current Business Strategy

Currently, the Company is working on identifying partnership opportunities for LADR™ ultra-high potency drug conjugates and their albumin companion diagnostic. We have concluded all research and development on LADR and its companion diagnostic and are now focused solely on identifying these partnership opportunities In addition, the Company is investigating new opportunities and lines of business.

Aldoxorubicin

Until July 2017, we were focused on the research and 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.

On July 27, 2017, we entered into an exclusive worldwide license with NantCell, Inc. ("NantCell"), granting to NantCell the exclusive rights to develop, manufacture and commercialize aldoxorubicin in all indications, and our company is no longer directly working on development of aldoxorubicin. As part of the license, NantCell made a strategic investment of $13 million in CytRx common stock at $6.60 per share (adjusted to reflect our 2017 reverse stock split), a premium of 92% to the market price on that date. We also issued NantCell a warrant to purchase up to 500,000 shares of common stock at $6.60, which expired on January 26, 2019. We are entitled to receive up to an aggregate of $343 million in potential milestone payments contingent upon achievement of certain regulatory approvals and commercial milestones. We are also entitled to receive ascending double-digit royalties for net sales for soft tissue sarcomas and mid to high single digit royalties for other indications.

Aldoxorubicin is a conjugate of the commonly prescribed chemotherapeutic agent doxorubicin that binds to circulating albumin in the bloodstream and is believed to concentrate the drug at the site of the tumor. Aldoxorubicin, our lead clinical candidate, has been tested in over 600 patients with various types of cancer. Specifically, it is comprised of (6-maleimidocaproyl) hydrazine, an acid-sensitive molecule that is conjugated to doxorubicin. The initial indication for aldoxorubicin is for patients with advanced soft tissue sarcomas (STS).

Aldoxorubicin has received Orphan Drug Designation (ODD) by the U.S. FDA for the treatment of 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.

During 2018, we announced that NantCell was expanding aldoxorubicin's use by combining it with immunotherapies and cell-based treatments, in metastatic pancreatic cancer, in advanced squamous cell carcinoma of the head, in neck and in advanced pancreatic cancer. In January 2019, we announced NantCell expanded aldoxorubicin's use combining it in patients with relapsed or refractory colorectal cancer.

Disposition of Molecular Chaperone Assets

In 2011, CytRx sold the rights to arimoclomol and iroxanadine, based on molecular chaperone regulation technology, to Orphazyme A/S (formerly Orphazyme ApS) in exchange for a one-time, upfront payment and the right to receive up to a total of $120 million (USD) in milestone payments upon the achievement of certain pre-specified regulatory and business milestones, as well as royalty payments based on a specified percentage of any net sales of products derived from arimoclomol. Orphazyme is testing arimoclomol in three additional indications beyond ALS, including Niemann-Pick disease Type C (NPC), Gaucher disease and sporadic Inclusion Body Myositis (sIBM). CytRx received a milestone payment of $250,000 in September 2018. Orphazyme has highlighted positive Phase2/3 clinical trial data in patients with NPC and in February 2019 announced they will initiate filing preparations and seek to meet with the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) mid-2019 to discuss the path to approval. Orphazyme communicated their plan to submit the regulatory filing to the FDA and EMA during the first half of 2020, with potential action expected during the second half of 2020. CytRx will be entitled to a milestone payment of $4 million upon EMA approval and $6 million upon FDA approval, with royalties from potential sales and potential additional milestone payments.

Innovive Acquisition Agreement

On September 19, 2008, we completed our merger acquisition of Innovive Pharmaceuticals, Inc., or Innovive, and its clinical-stage cancer product candidates, including aldoxorubicin and tamibarotene. Under the merger agreement by which we acquired Innovive, we agreed to pay the former Innovive stockholders up to approximately $18.3 million of future earnout merger consideration, subject to our achievement of specified net sales under the Innovive license agreements. The earnout merger consideration, if any, will be payable in shares of our common stock, subject to specified conditions, or, at our election, in cash or by a combination of shares of our common stock and cash. Our common stock will be valued for purposes of any future earnout merger consideration based upon the trading price of our common stock at the time the earnout merger consideration is paid. The earnout will be accrued if and when earned.

Research and Development

Expenditures for research and development activities related to continuing operations were $0.4 million in 2018 and $19.8 million for the year ended December 31, 2017, or approximately 5% and 60%, respectively, of our total expenses. For further information regarding our research and development activities, see “Management’s Discussion and Analysis of Financial Condition and Results of Operations” below.

Manufacturing

We do not have the facilities or expertise to manufacture clinical supplies of aldoxorubicin or any of our other product candidates, and we lack the resources and capability to manufacture any of our product candidates on a commercial scale. Accordingly, we are dependent upon third-party manufactures, or potential future strategic alliance partners, to manufacture these supplies. Currently, we are no longer responsible for manufacturing aldoxorubicin, having entered into an exclusive licensing agreement with NantCell, Inc.

Commercialization and Marketing

We currently have no sales, marketing or commercial product distribution capabilities or experience in marketing products.

We are searching for a development and commercialization partner for our LADR drug candidates and do not currently plan on commercializing them ourselves.

Patents and Proprietary Technology

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

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

As of December 31, 2018, we have one pending U.S. patent application, fourteen pending foreign patent applications and two pending international applications covering our LADR™-related technology including LADR-7, LADR-8, LADR-9 and LADR-10. The un-extended patent term of patents that issue covering our LADR™-related technology is between June 2036 and November 2038. We also have one pending provisional U.S. patent application covering our albumin companion diagnostic (ACDx™). The un-extended patent term of patents that issue covering our ACDx™ is July 2039. The patents and patent applications covering our LADR™-related technology, and ACDx™ are assigned to Centurion BioPharma Corporation. In conjunction with our July 27, 2017 NantCell licensing agreement, we granted NantCell an exclusive license to all our aldoxorubicin-related patents, including the rights in four granted U.S. patents, forty-eight granted foreign patents, three pending U.S. patent applications, and eleven pending foreign patent applications covering aldoxorubicin and related technologies. Our intellectual property holdings relating to aldoxorubicin and related technologies include an exclusive license from Vergell Medical, S.A. or Vergell, to U.S. and foreign patents and patent applications. Patents and applications that cover pharmaceutical compositions of aldoxorubicin, processes for their production, and their use in treatment methods (e.g., cancer (including glioblastoma), viral diseases, autoimmune diseases, and acute or chronic inflammatory diseases) have un-extended patent terms expiring between June 2020 and June 2034.

LICENSE AGREEMENTS

Aldoxorubicin

We are the licensee of patent rights held by KTB for the worldwide development and commercialization of aldoxorubicin under a license agreement dated April 17, 2006. In February 2017, we received notice that KTB had transferred and assigned its rights and obligations under the license to Vergell Medical, S.A. The license is exclusive and applies to all products that may be subject to the licensed intellectual property in all fields of use. We may sublicense the intellectual property in our sole discretion. Pursuant to an amendment to the license agreement entered into in March 2014, we also have a non-exclusive worldwide license to any additional technology that is claimed or disclosed in the licensed patents and patent applications for use in the field of oncology.

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

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

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

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

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

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our LADR™ technology platform and ultra-high potency albumin-bind drug conjugates provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and governmental agencies and public and private research institutions. Any drug candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

Many competitors and potential competitors have substantially greater scientific, research and product development capabilities, as well as greater financial, marketing and human resources than we do. In addition, many specialized biotechnology firms have formed collaborations with large, established companies to support the research, development and commercialization of products that may be competitive with ours.

There are many companies developing antibody-drug conjugates (ADC) for the treatment of cancer that use the same classes of cytotoxic payloads as we are currently using. These include Takeda Pharmaceutical Co. Ltd. and Seattle Genetics Inc. who market Adcetris®, and F. Hoffmann-LaRoche Ltd./Genentech who market Kadcyla®. According to www.clinicaltrials.gov, there are approximately 75 clinical trials testing an ADC that are either on-going or currently enrolling. Other companies have created or have programs to create potent cell-killing agents for attachment to antibodies or other targeting agents. These companies may compete with us for technology out-license arrangements.

In addition to ADCs, we face competition from other nanomedicine platforms developing targeted therapies, including platforms focused on nanoparticles and liposomes. Non-ADC therapies may be in development for the cancer types we or our partners elect to pursue. Further, these companies may also compete with us for technology out-license arrangements.

Continuing development of conventional and targeted chemotherapeutics by large pharmaceutical companies and biotechnology companies may result in new compounds that may compete with our product candidates. More recently, immuno-oncology therapies that stimulate the body’s own defense system to attack cancers are being developed by certain of these companies and some have been approved for use as cancer therapeutics. In the future, immuno-oncology agents including cell therapies, targeted therapies or cytotoxic treatments may compete with our product candidates. Other companies have created or have programs to create potent cell-killing agents for attachment to tumor targeting agents. These companies may compete with us for technology out-license arrangements.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are more effective, have fewer or less severe side effects, are more convenient or are less expensive than any

products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we obtain approval for ours. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products. If our drug candidates achieve marketing approval, we expect that they will be priced at a significant premium over competitive generic products.

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

Government Regulation

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

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

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

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

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

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

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

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

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

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

Employees

As of March 29, 2019, we had six employees.

Available Information

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

Potential Strategic Alternatives

From time to time, we may consider strategic alternatives available to us to enhance shareholder value. Strategic alternatives could include the acquisition of or strategic partnership with one or more parties or the licensing of some of our proprietary technologies. See “Item 1A – Risk Factors – The impact and results of our exploration of strategic alternatives are uncertain and may not be successful.”

Item 1A. RISK FACTORS

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

Risks Associated With Our Business

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

We have operated at a loss due to our ongoing expenditures for research and development of our product candidates and for general and administrative purposes, and lack of significant recurring revenues. We incurred a net loss of $12.7 million for the year ended December 31, 2018 and $35.0 million for the year ended December 31, 2017 and had an accumulated deficit as of December 31, 2018 of $456.9 million. We are likely to continue to incur losses unless and until we are able to earn milestones and royalties from our existing licensing agreements and/or conclude a successful strategic partnership for our LADR technology. 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 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 filing 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. Furthermore, as of March 29, 2019, we only have approximately 5.3 million shares of common stock that are authorized and unissued or unreserved. We would need approval of our stockholders to increase our authorized shares of our common stock in order to raise additional capital in excess of this amount.

At December 31, 2018, we had cash and cash equivalents of approximately $21.4 million. Management believes that our current resources will be sufficient to fund our operations for the foreseeable future. This estimate is based, in part, upon our currently projected expenditures for 2019 and the first three months of 2020 of approximately $7.5 million (unaudited), which includes approximately $0.8 million (unaudited) for payments related to our Freiburg lab, and approximately $6.7 million (unaudited) for other general and administrative expenses. These projected expenditures are also based upon numerous other assumptions and subject to many uncertainties, and actual expenditures may be significantly different from these projections. We will ultimately be required to obtain additional funding in order to execute our long-term business plans, although we do not currently have commitments from any third parties to provide us with long term debt or capital. We cannot assure that additional funding will be available on favorable terms, or at all. If we fail to obtain additional funding when needed, we may not be able to execute our business plans and our business may suffer, which would have a material adverse effect on our financial position, results of operations and cash flows.

If we 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 delay or reduce the scope of or eliminate some portion or all of our development programs. We also may have to license to other companies our product candidates or technologies that we would prefer to develop and commercialize ourselves.

If NantCell fails to successfully develop aldoxorubicin or our exclusive licensing arrangement with NantCell is otherwise unsuccessful, our business prospects will be materially adversely affected.

In July 2017, we entered into an exclusive licensing agreement with NantCell to complete the clinical development of and commercialization of aldoxorubicin. Under this agreement, NantCell has committed to provide substantial funding, as well as significant capabilities in clinical development, regulatory affairs, marketing and sales.

If, for any reason, NantCell does not devote sufficient time and resources to the development and commercialization of aldoxorubicin, we will not realize the potential commercial benefits of the arrangement, and our results of operations will be adversely affected. In addition, if NantCell were to breach or terminate its arrangement with us, the development and commercialization of aldoxorubicin could be delayed, curtailed or terminated, and we may not have sufficient financial resources or capabilities to continue development and commercialization of aldoxorubicin on our own.

Under our agreement with NantCell, they may opt out of a project by giving us twelve months' prior written notice. If NantCell were to exercise its right to opt out of a program or to terminate the licensing agreement, the development and commercialization of aldoxorubicin would be adversely affected, our potential for generating revenue from this program would be adversely affected and attracting new partners would be made more difficult.

Much of the potential revenue from our existing and future arrangement with NantCell will consist of contingent payments, such as payments for achieving development and commercialization milestones and royalties payable on commercial sales of successfully developed aldoxorubicin. The milestone, royalty and other revenue that we may receive under this arrangement will depend upon our, and NantCell's ability to successfully develop, introduce, market and sell aldoxorubicin. We will not be directly involved in this process and will depend entirely on NantCell, which may fail to develop or effectively commercialize aldoxorubicin because they:

- decide not to devote the necessary resources due to internal constraints, such as limited personnel with the requisite scientific expertise, limited cash resources or specialized equipment limitations, or the belief that other drug development programs may have a higher likelihood of obtaining regulatory approval or may potentially generate a greater return on investment;
- do not have sufficient resources necessary to carry aldoxorubicin through clinical development, regulatory approval and commercialization;
- cannot obtain the necessary regulatory approvals for aldoxorubicin; or
- decide to pursue a competitive drug candidate.

If NantCell fails to develop or effectively commercialize aldoxorubicin or for any of the other reasons described above, we may not be able to develop and commercialize that drug independently, or replace NantCell with another suitable partner in a reasonable period of time and on commercially reasonable terms, if at all.

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.

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.

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, our development partner 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.

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

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

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

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

We 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 our 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.

The results of pre-clinical studies or early clinical trials are not necessarily predictive of future results, and our ultra-high potency albumin-binding drug conjugates may not have favorable results in later clinical trials or receive regulatory approval.

Success in pre-clinical studies and early clinical trials does not ensure that later clinical trials will generate adequate data to demonstrate the efficacy and safety of our ultra-high potency albumin-binding drug conjugates. A number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience than we have, have suffered significant setbacks in clinical trials, even after seeing promising results in earlier clinical trials. Despite the results reported in earlier preclinical trials for our ultra-high potency albumin-binding drug conjugates, we do not know whether the clinical trials we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market them in any particular jurisdiction. If our clinical trials do not produce favorable results, our ability to achieve regulatory approval for these drug candidates will be adversely impacted and the value of our stock may decline.

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, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act, became law in the United States It contains a number of provisions, including those governing enrollments 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.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the PPACA. As a result, there have been delays in the implementation of, and action taken to repeal or replace, certain aspects of the PPACA. In January 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the PPACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. On October 13, 2017, President Trump signed an Executive Order terminating the cost-sharing subsidies that reimburse insurers under the ACA. Further, on December 14, 2018, U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than $12 billion in ACA risk corridor payments to third-party payors who argued were owed to them. In addition, CMS has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. Further, each chamber of Congress has put forth multiple bills this year designed to repeal or repeal and replace portions of the ACA. While Congress has not passed repeal legislation, the Tax Reform Act includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate.” Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole.” Congress may consider other legislation to repeal and replace elements of the ACA. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

Additionally, in the United States, the Biologics Price Competition and Innovation Act of 2009 created an abbreviated approval pathway for biologic products that are demonstrated to be “highly similar” or “biosimilar or interchangeable” with an FDA-approved biologic product. This new pathway could allow competitors to reference data from biologic products already approved after 12 years from the time of approval. This could expose us to potential competition by lower-cost biosimilars even if we commercialize a product candidate faster than our competitors. Moreover, the creation of this abbreviated approval pathway does not preclude or delay a third party from pursuing approval of a competitive product candidate via the traditional approval pathway based on their own clinical trial data. Other legislative changes have been proposed and adopted in the United States since the PPACA was enacted. For example, in August 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 2012 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 of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2027 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to certain providers, and increased the time for Medicare contractors to recoup Medicare overpayments to providers from three to five years. Additionally, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs.

Further, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which have resulted in several recent Congressional inquiries and proposed and enacted bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. In addition, the United States government, state legislatures, and foreign governments have shown significant interest in implementing cost containment programs, including price-controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs to limit the growth of government paid health care costs. For example, the United States government has passed legislation requiring pharmaceutical manufacturers to provide rebates and discounts to certain entities and governmental payors to participate in federal healthcare programs. Further, Congress and the current administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs, and the current administration recently released a “Blueprint”, or plan, to reduce the cost of drugs. The current administration’s Blueprint contains certain measures that the U.S. Department of Health and Human Services is already working to implement. Individual states in the United States have also been increasingly passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Additional changes that may affect our business include those governing enrollment in federal healthcare programs, reimbursement changes, fraud and abuse enforcement, and expansion of new programs, such as Medicare payment for performance initiatives.

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.

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.

Our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Natural disasters could severely disrupt our operations or the operations of manufacturing facilities and have a material adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as manufacturing facilities, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and may not prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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.

The impact and results of our exploration of any strategic alternatives are uncertain and may not be successful.

From time to time, we may consider strategic alternatives available to us to enhance shareholder value. Strategic alternatives could include acquisition transactions and/or strategic partnerships with one or more parties, the licensing of some of our proprietary technologies, or other possible transactions. Any strategic transaction that is completed ultimately may not deliver the anticipated benefits or enhance shareholder value. Further, we may devote a significant amount of our management resources to such a transaction, which could negatively impact our operations. We may incur significant costs in connection with seeking certain acquisitions or other strategic opportunities regardless of whether the transaction is completed, which could materially and adversely affect our liquidity and capital resources. In the event that we consummate an acquisition or strategic alternative in the future, there is no assurance that we would fully realize the potential benefits of such a transaction. Integration may be difficult and unpredictable, and acquisition-related integration costs, including certain non-recurring charges, could materially and adversely affect our results of operations. Moreover, integrating assets and businesses may significantly burden management and internal resources, including the potential loss or unavailability of key personnel. If we fail to successfully integrate any assets and businesses we acquire, we may not fully realize the potential benefits we expect, and our operating results could be adversely affected. If we pay for an acquisition in cash, it would reduce our cash available for operations or cause us to incur additional debt, and if we pay with our stock it could be dilutive to our stockholders.

In the event of a dispute regarding our international drug development, 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; and
- 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.

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 $136.8 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

If we fail to meet the requirements for continued listing on the NASDAQ Stock Market, our common stock would likely be delisted from trading on NASDAQ, which would likely reduce the liquidity of our common stock and could cause our trading price to decline.

Our common stock is currently listed for quotation on the NASDAQ Stock Market. We are required to meet specified financial and trading requirements in order to maintain our listing on NASDAQ, including maintaining a trading price of our common stock of at least $1.00 per share. On November 23, 2018, we received notice from Nasdaq that the closing bid 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 NASDAQ under Nasdaq Listing Rule 5550(a)(2). The notice indicates that we will have 180 calendar days, or until May 23, 2019, to regain compliance with this requirement.

We can regain compliance with the $1.00 minimum bid listing requirement if the closing bid price of our common stock is at least $1.00 for a minimum of ten consecutive business days during the 180-day compliance period. If we do not regain compliance during the initial compliance period, we may be eligible for additional time to regain compliance. To qualify, we will be required to meet the continued listing requirement for market value of our publicly held shares and all other NASDAQ initial listing standards, except the bid price requirement, and will need to provide written notice to NASDAQ of our intention to cure the deficiency during the second compliance period. If we meet these requirements, we expect that NASDAQ will grant us an additional 180 calendar days to regain compliance with the minimum bid price requirement. 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.

If we fail to satisfy NASDAQ’s continued listing requirements, our common stock would likely be delisted from NASDAQ and our common stock would instead trade on the OTC Markets, such as OTCQX. Any potential delisting of our common stock from NASDAQ would likely result in decreased liquidity and increased volatility of our common stock, and would likely cause our trading price to decline.

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.

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 2018 ranged from $0.33 to $2.35 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, 2018, we had outstanding stock options to purchase 2,555,835 shares of our common stock at a weighted-average exercise price of $10.69 per share and outstanding warrants to purchase 693,196 shares of common stock at a weighted-average exercise price of $7.16 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.

Section 404 of the Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. We are required to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment needs to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting.

There can be no assurance that we will not suffer from 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 consolidated 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 consolidated 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.

From time to time, we are involved in legal proceedings that arise in ordinary course of business. Securities-related class action and derivative lawsuits 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.

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, any future legal actions may adversely affect out 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.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

We lease our headquarters in Los Angeles, California. The lease covers approximately 5,739 square feet of office and storage space and expires in February 2020. Our monthly rent is $21,008, which is subject to annual increases. In addition to the monthly rent, we are responsible for paying our allocable portion of operating expenses. We have an option to extend the term of the lease for a five-year period and a right of first offer during the extended lease term to lease any available space on the sixth floor of the premises, subject to the terms and conditions set forth in the lease agreement. We also lease additional storage space for approximately 540 square feet. This lease expires in February 2020, and requires us to make monthly payments of $1,257, subject to annual increases.

We lease laboratory space in Freiburg, Germany, covering approximately 752 square meters (8,094 square feet). Our monthly rent is €10,070 (approximately $11,377). The amended lease expires on September 30, 2020, and we have an option to extend the term of the lease for up to three additional three-year periods, although we are currently negotiating to either sub-lease or sell these rights.

Item 3. LEGAL PROCEEDINGS

We are occasionally involved in legal proceedings and other matters arising from the normal course of business. During 2018, we resolved various shareholder derivative actions and a class action lawsuit that were pending against us. As of December 31, 2018, we were not involved in any material pending legal proceedings.

We intend to vigorously defend against any complaint. We have directors' and officers' liability insurance, which will be utilized in the defense of any such matter.

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

Item 4. MINE SAFETY DISCLOSURES

Not Applicable.

PART II

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

Market Information

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

	High	Low
Fiscal Year 2018:		
Fourth Quarter	$1.10	$0.33
Third Quarter	$1.29	$1.00
Second Quarter	$2.05	$1.06
First Quarter	$2.35	$1.50
Fiscal Year 2017:		
Fourth Quarter	$2.94	$1.65
Third Quarter	$6.00	$2.40
Second Quarter	$5.94	$2.52
First Quarter	$3.06	$2.28

Holders

On March 29, 2019, there were approximately 282 holders of record of our common stock. The number of record holders does not reflect the number of beneficial owners of our common stock for whom shares are held by brokerage firms and other nominees.

Dividends

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

Equity Compensation Plans

The following table sets forth certain information as of December 31, 2018, regarding securities authorized for issuance under our equity compensation plans:

Plan Category	(a) Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	(b) Number of Issued Shares of Restricted Stock	(c) Weighted-Average Exercise Price of Outstanding Options, Restricted Stock, Warrants and Rights	Number of Securities Remaining Available for issuance Under Equity Compensation Plans (Excluding Securities Reflected in Columns (a) and (b)
Equity compensation plans approved by our security holders:				
2000 Long-Term Incentive Plan	15,207	—	$ 37.22	—
2008 Stock Incentive Plan	2,540,628	775,194	8.57	—
Equity compensation plans not approved by our security holders:				
Outstanding warrants (1)	693,196	—	7.16	—
Total	3,249,031	775,194	$ 8.44	—

(1) The warrants shown were issued in discrete transactions from time to time as compensation for services rendered by consultants, advisors or other third parties, and do not include warrants sold in capital-raising transactions. The material terms of such warrants were determined based upon arm’s-length negotiations with the service providers. The warrant exercise prices approximate the market price of our common stock at or about the date of grant, and the warrant terms range from two to ten years from the grant date. The warrants contain customary anti-dilution adjustments in the event of a stock split, reverse stock split, reclassification or combination of our outstanding common stock and similar events and certain of the warrants contain anti-dilution adjustments triggered by other corporate events, such as dividends.

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Comparison of Cumulative Total Returns

The following line graph presentation compares cumulative total stockholder returns of CytRx with The NASDAQ Stock Market Index and The NASDAQ Pharmaceutical Index (the “Peer Index”) for the five-year period from December 31, 2014 to December 31, 2018. The graph and table assume that $100 was invested in each of our common stock, The NASDAQ Stock Market Index and the Peer Index on December 31, 2013, and that all dividends were reinvested. This data was furnished by Zacks Investment Research.

	December 31,				
	2014	2015	2016	2017	2018
CytRx Corporation	-56.29	-3.28	-85.97	-24.22	-73.44
The NASDAQ Stock Market Index	14.75	6.96	8.87	29.64	-2.84
The NASDAQ Pharmaceutical Index	30.51	5.82	-21.99	19.61	-4.76

Recent Issuances of Unregistered Securities

None.

Repurchase of Shares

We did not repurchase any of our shares during the year ended December 31, 2018.

Item 6. SELECTED FINANCIAL DATA

Not applicable

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

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

Overview

CytRx Corporation

We are a biopharmaceutical research and development company specializing in oncology. Our focus has been on the discovery, research and clinical development of novel anti-cancer drug candidates that employ novel linker technologies to enhance the accumulation and release of cytotoxic anti-cancer agents at the tumor. During 2017, CytRx's discovery laboratory, located in Freiburg, Germany, synthesized and tested over 75 rationally designed drug conjugates with highly potent payloads, culminating in the creation of two distinct classes of compounds. Four lead candidates (LADR-7, LADR-8, LADR-9 and LADR-10) were selected based on *in vitro* and animal preclinical studies, stability, and manufacturing feasibility. In 2018, additional animal efficacy and toxicology testing of these lead candidates was conducted. In addition, a novel albumin companion diagnostic, ACDx™, was developed to identify patients with cancer who are most likely to benefit from treatment with these drug candidates.

On June 1, 2018, CytRx launched Centurion BioPharma Corporation ("Centurion"), a private wholly owned subsidiary, and transferred all of its assets, liabilities and personnel associated with the laboratory operations in Freiburg, Germany. In connection with said transfer, the Company and Centurion entered into a Management Services Agreement whereby the Company agreed to render advisory, consulting, financial and administrative services to Centurion, for which Centurion shall reimburse the Company for the cost of such services plus a 5% service charge. The Management Services Agreement may be terminated by either party at any time. Centurion is focused on the development of personalized medicine for solid tumor treatment. On December 21, 2018, CytRx announced that Centurion had concluded the pre-clinical phase of development for its four LADR drug candidates, and for its albumin companion diagnostic (ACDx™). As a result of completing this work, operations taking place at the pre-clinical laboratory in Freiburg, Germany would no longer be needed and, accordingly, the lab was closed at the end of January 2019 and the pre-clinical laboratory was treated as discontinued operations.

LADR Drug Discovery Platform and Centurion

Centurion's LADR™ (Linker Activated Drug Release) technology platform is a discovery engine combining our expertise in linker chemistry and albumin biology to create a pipeline of anti-cancer molecules that will avoid unacceptable systemic toxicity while delivering highly potent agents directly to the tumor. They have created a "toolbox" of linker technologies that have the ability to significantly increase the therapeutic index of ultra-high potency drugs (10-1,000 times more potent than traditional chemotherapies) by controlling the release of the drug payloads and improving drug-like properties.

Their efforts were focused on two classes of ultra-high potency albumin-binding drug conjugates. These drug conjugates combine the proprietary LADR™ linkers with novel derivatives of the auristatin and maytansinoid drug classes. These payloads historically have required a targeting antibody for successful administration to humans. Their drug conjugates eliminate the need for a targeting antibody and provide a small molecule therapeutic option with potential broader applicability.

Centurion's postulated mechanism of action for the albumin-binding drug conjugates is as follows:

- after administration, the linker portion of the drug conjugate forms a rapid and specific covalent bond to the cysteine-34 position of circulating albumin;
- circulating albumin preferentially accumulates at the tumors, bypassing concentration in other non-tumor sites, including the heart, liver and gastrointestinal tract due to a mechanism called "Enhanced Permeability and Retention";
- once localized at the tumor, the acid-sensitive linker is cleaved due to the specific conditions within the tumor and in the tumor microenvironment; and
- free active drug is then released into the tumor.

Centurion's novel companion diagnostic, ACDx™ (albumin companion diagnostic), was developed to identify patients with cancer who are most likely to benefit from treatment with the four LADR lead assets.

During much of 2018, CytRx and Centurion have been working on identifying partnership opportunities for LADR™ ultra-high potency drug conjugates and its albumin companion diagnostic.

Aldoxorubicin

Until July 2017, we were focused on the research and 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.

On July 27, 2017, we entered into an exclusive worldwide license with NantCell, Inc. ("NantCell"), granting to NantCell the exclusive rights to develop, manufacture and commercialize aldoxorubicin in all indications, and our company is

no longer directly working on development of aldoxorubicin. As part of the license, NantCell made a strategic investment of $13 million in CytRx common stock at $6.60 per share (adjusted to reflect our 2017 reverse stock split), a premium of 92% to the market price on that date. We also issued NantCell a warrant to purchase up to 500,000 shares of common stock at $6.60, which expired on January 26, 2019. We are entitled to receive up to an aggregate of $343 million in potential milestone payments, contingent upon achievement of certain regulatory approvals and commercial milestones. We are also entitled to receive ascending double-digit royalties for net sales for soft tissue sarcomas and mid to high single digit royalties for other indications.

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

At December 31, 2018, we had cash and cash equivalents of approximately $21.4 million Management believes that our current resources will be sufficient to fund our operations for the foreseeable future. This estimate is based, in part, upon our currently projected expenditures for 2019 and the first three months of 2020 of approximately $7.5 million (unaudited), which includes approximately $0.8 million (unaudited) for payments related to our Freiburg lab, and approximately $6.7 million (unaudited) for other general and administrative expenses. These projected expenditures are also based upon numerous other assumptions and subject to many uncertainties, and actual expenditures may be significantly different from these projections. While these projections represent our current expected expenditures, we have the ability to reduce the amounts and alter the timing of research and development expenditures as needed to manage our liquidity needs while still advancing our research and development objectives. We will ultimately be required to obtain additional funding in order to execute our long-term business plans, although we do not currently have commitments from any third parties to provide us with long term debt or capital. We cannot assure that additional funding will be available on favorable terms, or at all. If we fail to obtain additional funding when needed, we may not be able to execute our business plans and our business may suffer, which would have a material adverse effect on our financial position, results of operations and cash flows.

Disposition of Molecular Chaperone Assets

In 2011, CytRx sold the rights to arimoclomol and iroxanadine, based on molecular chaperone regulation technology, to Orphazyme A/S (formerly Orphazyme ApS) in exchange for a one-time, upfront payment and the right to receive up to a total of $120 million (USD) in milestone payments upon the achievement of certain pre-specified regulatory and business milestones, as well as royalty payments based on a specified percentage of any net sales of products derived from arimoclomol. Orphazyme is testing arimoclomol in three additional indications beyond ALS, including Niemann-Pick disease Type C (NPC), Gaucher disease and sporadic Inclusion Body Myositis (sIBM). CytRx received a milestone payment of $250,000 in September 2018. Orphazyme has highlighted positive Phase2/3 clinical trial data in patients with NPC and in February 2019 announced they will initiate filing preparations and seek to meet with the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) mid-2019 to discuss the path to approval. Orphazyme communicated their plan to submit the regulatory filing to the FDA and EMA during the first half of 2020, with potential action expected during the second half of 2020. CytRx will be entitled to a milestone payment of $4 million upon EMA approval and $6 million upon FDA approval, along with royalties from potential sales and potential additional milestone payments.

Research and Development

Expenditures for research and development activities related to continuing operations were $0.4 million in 2018 and $19.8 million for the year ended December 31, 2017 or approximately 5% and 60%, respectively, of our total expenses.

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

Our currently projected expenditures for 2019 includes approximately $0.8 million for payments related to the Freiburg lab closure. The actual cost of our pre-clinical program could differ significantly from our current projections due to any additional requirements or delays, or if actual costs are higher than current management estimates for other reasons. In the event that actual costs of our clinical programs, or any of our other ongoing research activities, are significantly higher than our current estimates, we may be required to significantly modify our planned level of operations.

All of our product candidates in development must be approved by the FDA or corresponding foreign governmental agencies before they can be marketed. The process for obtaining FDA and foreign government approvals is both time-consuming and costly, with no certainty of a successful outcome. A discussion of these and other risks and uncertainties associated with our business is set forth in the “Risk Factors” section of this Annual Report.

Discontinued Operations

On December 21, 2018, the Company announced that its pre-clinical lab operations had successfully completed its objectives – namely, it has developed four lead compounds, LADR 7, LADR-8, LADR-9 and LADR 10 along with a companion diagnostic (ACDx). Accordingly, the Company terminated the contracts of all its employees at this location and closed the lab at the end of January 2019.

The Company currently has a lease expiring in September 2020 at a cost of 10,070 Euros ($11,377) monthly. However it is currently negotiating with a third party to sub-lease the premises or take over the entire liability of the lease. The Company sold its analytical equipment in March 2019 and accordingly has classified these assets as current assets held for sale and has written down these assets by $0.2 million. In addition, it plans on selling the office and lab furniture along with the leasehold improvements to a third party. The Company estimates the value of these assets are greater than their net book value and so no write-down has been recorded. The results of these discontinued operations are presented separately on the Company's Consolidated Statement of Operations.

Critical Accounting Policies and Estimates

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

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

Cash Equivalents

The Company considers all highly liquid debt instruments with an original maturity of 90 days or less to be cash equivalents. Cash equivalents consist primarily of amounts invested in money market accounts.

Revenue Recognition

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

government and private grants.

In May 2014, the FASB issued a comprehensive new standard which amends revenue recognition principles. We adopted the new standard on January 1, 2018 by applying the modified retrospective method to all contracts that were not completed as of that date. Under the new guidance, revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration expected to be received in exchange for those goods or services. Revenue is recognized through a five-step process: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) a performance obligation is satisfied. We only apply the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, we assess the goods or services promised within each contract and determines those that are performance obligations. Revenue is recognized when each distinct performance obligation is satisfied. CytRx will include the variable consideration related to milestones from strategic alliances if it no longer considers it probable that including these payments in the transaction price would not result in the reversal of cumulative revenue recognized. Monies received for license fees are deferred and recognized ratably over the performance period in accordance with Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) ASC 605-25, *Revenue Recognition – Multiple-element Arrangements* (“ASC 605-25”). Milestone payments will be recognized upon achievement of the milestone as long as the milestone is deemed substantive and we have no other performance obligations related to the milestone and collectability is reasonably assured, which is generally upon receipt, or recognized upon termination of the agreement and all related obligations. Deferred revenue represents amounts received prior to revenue recognition.

Research and Development Expenses

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

Clinical Trial Expenses

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

Stock-based Compensation

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

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

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

Net Loss Per Share

Basic net loss per common share attributable to common shareholders is computed using the weighted-average number of common shares outstanding. Diluted net loss per common share is computed using the weighted-average number of common shares and common share equivalents outstanding. Potentially dilutive stock options and warrants to purchase approximately 3.2 million and 7.6 million at December 31, 2018 and 2017, respectively, were excluded from the computation of diluted net loss per share, because the effect would be anti-dilutive.

Potential Strategic Alternatives

From time to time, we may consider strategic alternatives available to us to enhance shareholder value. Strategic alternatives could include the acquisition of or strategic partnership with one or more parties or the licensing of some of our proprietary technologies. See “Item 1A – Risk Factors – The impact and results of our exploration of strategic alternatives are uncertain and may not be successful.”

Liquidity and Capital Resources

General

In order to fund our business and operations, we have relied primarily upon sales of our equity securities, including proceeds from the exercise of stock options and common stock purchase warrants and long-term loan financing. We also have received limited funding from our strategic partners and licensees. At December 31, 2018, we had cash and cash equivalents of approximately $21.4 million Management believes that our current resources will be sufficient to fund our operations for the foreseeable future. This estimate is based, in part, upon our currently projected expenditures for 2019 and the first three months of 2020 of approximately $7.5 million (unaudited)**,** which includes approximately $0.8 million (unaudited) for payments related to our Freiburg lab, and approximately $6.7 million (unaudited) for other general and administrative expenses. These projected expenditures are also based upon numerous other assumptions and subject to many uncertainties, and actual expenditures may be significantly different from these projections. While these projections represent our current expected expenditures, we have the ability to reduce the amounts and alter the timing of research and development expenditures as needed to manage our liquidity needs while still advancing our research and development objectives. We will ultimately be required to obtain additional funding in order to execute our long-term business plans, although we do not currently have commitments from any third parties to provide us with long term debt or capital. We cannot assure that additional funding will be available on favorable terms, or at all. If we fail to obtain additional funding when needed, we may not be able to execute our business plans and our business may suffer, which would have a material adverse effect on our financial position, results of operations and cash flows.

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

Discussion of Operating, Investing and Financing Activities

Net loss for the year ended December 31, 2018 was $12.7 million, and cash used for operating activities for that period was $10.9 million. The net loss reflects $1.6 million of stock option and warrant expense, interest expense on the Term Loan of $1.2 million and a non-cash gain of $0.5 million on the fair value adjustment of the warrant liability.

Net loss for the year ended December 31, 2017 was $35.0 million, and cash used for operating activities for that period was $27.1 million. The net loss reflects $3.3 million of stock option and warrant expense, interest expense on the Term Loan of $3.8 million and a non-cash gain of $1.4 million on the fair value adjustment of the warrant liability.

For the year ended December 31, 2018, no money was provided by investing activities, and $11,000 was used for the purchase of equipment and furnishings.

For the year ended December 31, 2017, no money was provided by investing activities, and $0.1 million was used for the purchase of equipment and furnishings.

Cash provided by financing activities for the year ended December 31, 2018 was $6.5 million, which were the net proceeds received from our May 2018 public offering. We also made principal Term Loan payments of $10.0 million and a loan end fee payment of $1.8 million.

Cash provided by financing activities for the year ended December 31, 2017 was $8.0 million, which included $14.0 million of net proceeds received from our May 2017 public offering. We also received $6.1 million from the sale of

common shares and warrants to NantCell, Inc. We also received net proceeds of $3.2 million from the exercise of stock options and warrants and made principal Term Loan payments of $15.0 million.

Term Loan Facility

On February 5, 2016, we entered into a loan and security agreement with Hercules Technology Growth Capital, Inc. ("HTGC"), as administrative agent and lender, and Hercules Technology III, L.P., as lender ("Hercules"), pursuant to which the lenders made term loans to us on February 8, 2016 in the aggregate principal amount of $25 million (the "Term Loans"). The Term Loans bear interest at the daily variable rate per annum equal to 6.0% plus the prime rate, or 11.0%, whichever is greater. CytRx was required to make interest-only payments on the Term Loans through February 28, 2017, and beginning on March 1, 2017 blended equal monthly installments of principal amortization and accrued interest until the maturity date of the Term Loans on February 1, 2020. As security under their obligations, the Company issued to the lenders warrants to purchase a total of 105,691 shares of its common stock at an exercise price of $12.30. These warrants are classified as equity warrants with a fair value of $633,749. All outstanding principal and accrued interest on the term loans was paid in full on the maturity date of August 1, 2018.

As a result of the NantCell exclusive licensing transaction, on July 28, 2017, CytRx entered into a First Amendment to Loan and Security Agreement with Hercules to amend its existing long-term loan facility (the "Loan Agreement"). The amendment provided for payment, on July 28, 2017, of $5.0 million in outstanding principal and unpaid interest due under the Loan Agreement, plus a $100,000 prepayment charge, and for repayment, on or prior to September 30, 2017, of an additional $5.0 million outstanding principal and unpaid interest due under the Loan Agreement, plus a second $100,000 prepayment charge. CytRx also agreed to an updated schedule of monthly payments and a new maturity date of August 1, 2018. Pursuant to the amendment, a portion of the warrants (representing 80% of the total number of shares issuable upon exercise of the warrants) was amended to change the exercise price of that portion of the warrants from $12.30 per share to $4.62 per share, which was calculated based upon the 30-day volume-weighted average price of our common stock over the 30-day period beginning 15 days before the July 28, 2017 announcement of the NantCell license transaction. CytRx evaluated the amended debt agreement under ASC 470 and determined it to be a modification and that in accordance with accounting guidance for debt modifications, the incremental fair value of the repriced warrants of $77,000 and the $200,000 fee paid to the lender was recorded as additional loan discount to be recognized using the interest method over the remaining life of the loan.

Off-Balance Sheet Arrangements

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

Contractual Obligations

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

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

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

	Payments due by periods as of December 31, 2018				
Contractual Obligations	Total	Year 1	Years 2 and 3	Years 4 and 5	Years 6 and beyond
Operating lease obligations	$579	$416	$163	$—	$—
Employment obligations	3,571	1,457	2,114	—	—
Total contractual obligations	$4,150	$1,873	$2,277	$—	$—

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

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

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

Net Operating Loss Carryforwards

At December 31, 2018, we had federal and state net operating loss carryforwards of $323.4 million and $248.3 million, respectively, available to offset against future taxable income, which expire in 2019 through 2038.

As a result of a change in-control that occurred in the CytRx shareholder base in 2013, approximately $74.5 million in federal net operating loss carryforwards became substantially limited in their annual availability. We currently believe that the remaining $248.3 million in federal net operating loss carryforwards, and the $248.3 million in state net operating loss carryforwards, are unrestricted.

As of December 31, 2018, we also had research and development tax credits for federal and state purposes of approximately $16.0 million and $22.0 million, respectively, available for offset against future income taxes, which expire in 2023 through 2038. Based on an assessment of all available evidence including, but not limited to, our limited operating history in its core business and lack of profitability, uncertainties of the commercial viability of its technology, the impact of government regulation and healthcare reform initiatives, and other risks normally associated with biotechnology companies, we have concluded that it is more likely than not that these net operating loss carryforwards and credits will not be realized and, as a result, a 100% deferred tax valuation allowance has been recorded against these assets.

Results of Operations

We incurred a net loss of $12.7 million and $35.0 million for the years ended December 31, 2018 and 2017, respectively.

During 2018 and 2017, we recognized no service revenue and earned an immaterial amount of license fees and grant revenue. All future licensing fees under our current licensing agreements are dependent upon successful development milestones being achieved by our licensees

Due to the nature of research and development, our operating results may fluctuate from period to period, and the results of prior periods should not be relied upon as predictive of the results in future periods.

Research and Development from Continuing Operations

	Years Ended December 31,	
	2018	2017
	(In thousands)	
Research and development expenses	$389	$15,509
Non-cash research and development expenses	—	12
Employee stock and stock option expense	—	326
Total	$389	$15,847

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

Research and development expenses incurred during 2018 were minimal since the expenses related to our Freiburg Germany drug discovery program are presented in the discontinued operations. In 2017 these expenses related to our various development programs, which wound down during 2017. These 2017 expenses included $11.7 million for our clinical programs for aldoxorubicin and approximately $3.8 million for general operations of our clinical program, including licensing fees.

As compensation to consultants, or in connection with the acquisition of technology, we sometimes issue shares of common stock, stock options and warrants to purchase shares of common stock. For financial statement purposes, we value these shares of common stock, stock options, and warrants at the fair value of the common stock, stock options or warrants granted, or the services received, whichever is more reliably measurable. In 2018, we recorded no such non-cash expense as compared to $11,600 in 2017. In 2018, we recorded no employee stock and stock option expense as compared to $0.3 million in 2017.

General and Administrative from Continuing Operations

	Year Ended December 31,	
	2018	2017
	(In thousands)	
General and administrative expenses	$ 6,459	$ 9,718
Stock, stock option and warrant expenses to non-employees and consultants	73	874
Employee stock and stock option expense	1,548	1,910
Total	8,080	$ 12,502

General and administrative expenses include all administrative salaries and general corporate expenses, including legal expenses associated with the prosecution of our intellectual property. Our general and administrative expenses, excluding common stock, stock options and warrants issued, were $6.5 million and $9.7 million in 2018 and 2017, respectively. In 2018, the general and administrative expenses decreased by 33%, due to a decrease of $2.5 million in professional fees with the wrap-up of litigation and $0.5 million in insurance premiums due to a one-time refund in premiums. In 2017, the general and administrative expenses decreased by 12.3%, primarily due to a decrease in salaries, since 2016 included pre-commercialization activities in the first half of the year.

From time to time, we issue shares of our common stock or warrants or options to purchase shares of our common stock to consultants and other service providers in exchange for services. For financial statement purposes, we value these shares of common stock, stock options, and warrants at the fair value of the common stock, stock options or warrants granted, or the services received whichever we can measure more reliably. In 2018, we recorded $0 million of such expenses, as compared to $0.9 million in 2017. We recorded employee stock option expense of $1.5 million and $1.9 million in 2018 and 2017, respectively.

Depreciation and Amortization

Depreciation and amortization expenses for the years ended December 31, 2018 and 2017 were approximately $29,000 and $0.1 million, respectively. The depreciation expense reflects the depreciation of our equipment and furnishings.

Interest Income

Interest income was $0.4 million in 2018 and $0.4 million in 2017. The variance between years is attributable primarily to the amount of funds available for investment each year and, to a lesser extent, changes in prevailing market interest rates.

Interest Expense

On February 5, 2016, we entered into a loan and security agreement with Hercules Technology Growth Capital, Inc. ("HTGC"), as administrative agent and lender, and Hercules Technology III, L.P., as lender, which was fully repaid on August 1, 2018. Total interest expense in 2018 was $1.7 million and $3.8 million in 2017.

Recently Adopted Accounting Pronouncement

On January 1, 2018 CytRx adopted Accounting Standards Update 2014-09, *Revenue from Contracts with Customers* ("ASC 606") using the modified retrospective method for contracts that were not completed as of January 1, 2018. Results for reporting periods beginning after January 1, 2018 are presented under the new standard, while prior period amounts are not adjusted and continue to be reported under the accounting standards in effect for the prior period. The cumulative effect of initially applying ASC 606 was an adjustment to decrease the opening balance of Accumulated Deficit by $6.7 million as of January 1, 2018.

The guidance provides for a five-step analysis of transactions to determine when and how revenue is recognized. Other major provisions include capitalization of certain contract costs, consideration of the time value of money in the transaction price, and allowing estimates of variable consideration to be recognized before contingencies are resolved in certain circumstances. The guidance also requires enhanced disclosures regarding the nature, amount, timing and uncertainty of revenue and cash flows arising from an entity's contracts with customers.

Under the new standard the NantCell Licensing Agreement, which was determined to be a functional license agreement, as the underlying intellectual property had standalone functionality, was recognizable in 2017 when NantCell obtained the right to use the intellectual property. The subsequent Reimbursement Agreement was determined to be a contract modification that introduced variable contra revenue for the Company's reimbursement obligations. In accordance with ASC 606, management estimated its obligations under the Reimbursement Agreement to be $3.2 million which is recognized as a contract liability at the time of revenue recognition. These costs were previously recognized as research and development expense in 2017 in accordance with prior accounting standards. This contract liability was reduced to $0.3 million as of January 1, 2018 as a result of costs incurred under the Reimbursement Agreement. The contract liability was further reduced to $50,000 as of December 31, 2018.

Additionally, CytRx is eligible to receive tiered high single to low double-digit royalties on product sales. The royalty term is determined on a licensed-product-by-licensed-product and country-by-country basis and begins on the first commercial sale of a licensed product in a country and ends on the expiration of the last to expire of specified patents or regulatory exclusivity covering such licensed product in such country or, with a customary royalty reduction, ten years after the first commercial sale if there is no such exclusivity. These revenues will be recognized when earned.

In January 2016, the FASB issued Accounting Standards Update 2016-01, *Recognition and Measurement of Financial Assets and Financial Liabilities* ("ASU 2016-01"). ASU 2016-01 eliminates the requirement to disclose the methods and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost on the balance sheet. The standard also clarifies the need to evaluate a valuation allowance on a deferred tax asset related to available-for-sale securities in combination with our other deferred tax assets. The update 2016-01 is effective for annual reporting periods beginning after December 15, 2017. The adoption of this standard did not have a material impact on our consolidated financial statements.

Recent Accounting Pronouncements

In June 2018, the FASB issued ASU 2018-07: *Compensation – Stock Compensation (Topic 718)*: Improvements to Nonemployee Share-Based Payment Accounting. This ASU expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from non-employees, and as a result, the accounting for share-based payments to non-employees will be substantially aligned. ASU 2018-07 is effective for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year, early adoption is permitted but no earlier than an entity's adoption date of Topic 606. The Company is currently evaluating the impact this new guidance will have on its consolidated financial statements and related disclosures.

In February 2018, the FASB issued a new standard that would permit entities to make a one time reclassification from accumulated other comprehensive income (AOCI) to retained earnings for the stranded tax effects resulting from the newly enacted corporate tax rates under the Tax Cuts and Jobs Act (the "Act"), effective for the year ended December

31, 2017. The amount of the reclassification is calculated on the basis of the difference between the historical tax rate and newly enacted tax rate. The standard is effective for interim and annual periods beginning after December 15, 2018 with early adoption permitted. We do not believe that the adoption of this guidance will have a material impact on our consolidated financial statements.

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

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842) (“ASC 842”), which amends the existing accounting standards for leases. The new standard requires lessees to record a right-of-use (“ROU”) asset and a corresponding lease liability on the balance sheet (with the exception of short-term leases), whereas under current accounting standards the Company’s lease portfolio consists primarily of operating leases and is not recognized on its consolidated balance sheets. The new standard also requires expanded disclosures regarding leasing arrangements. The new standard is effective for the Company beginning January 1, 2019. In July 2018, the FASB issued ASU No. 2018- 11, Leases (Topic 842): Targeted Improvements, which provides an alternative modified transition method. Under this method, the cumulative-effect adjustment to the opening balance of retained earnings is recognized on the date of adoption with prior periods not restated.

The Company will adopt ASC 842 as of January 1, 2019, using the alternative modified transition method and will record a cumulative-effect adjustment to the opening balance of retained earnings as of that date. Prior periods will not be restated. The Company has also substantially completed its evaluation of the impact on the Company’s lease portfolio. As a result of the implementation of this ASU, we expect to recognize right-of-use assets of approximately $0.5 million, offset by a corresponding lease liability.

Item 7A. *QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK*

Historically, our exposure to market risk is limited primarily to interest income sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because a significant portion of our investments are in short-term debt securities issued by the U.S. government and institutional money market funds. The primary objective of our investment activities is to preserve principal. Due to the short-term nature of our investments, we believe that we are not exposed to any material market risk. We do not have any speculative or hedging derivative financial instruments or foreign currency instruments. If interest rates had varied by 10% in the year ended December 31, 2018, it would not have had a material effect on our results of operations or cash flows for that period.

Item 8. *CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA*

Our consolidated financial statements and supplemental schedule and notes thereto as of December 31, 2018 and 2017, and for each of the three years in the period ended December 31, 2018, together with the reports thereon of our independent registered public accounting firm, are set forth beginning on page F-1 of this Annual Report.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. CONTROLS AND PROCEDURES

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Securities Exchange Act Rule 13a-15(e)) as of December 31, 2018, the end of the period covered by this Annual Report. Based on this evaluation, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures were effective as of December 31, 2018, as described further below.

There were no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2018 that materially affected, or are reasonably likely to have a material effect, on our internal control over financial reporting.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we assessed the effectiveness of our internal control over financial reporting as of December 31, 2018. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in *Internal Control-Integrated Framework (2013 Edition)* ("the Framework"). Based upon management's assessment using the criteria contained in COSO, management has concluded that our internal control over financial reporting was effective as of December 31, 2018.

PART III

Item 10. *DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE*

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

Name	Age	Class of Director (1)	Position
Steven A. Kriegsman	77	II	Director, Chairman of the Board and Chief Executive Officer
Louis Ignarro, Ph.D.	77	I	Lead Director (2) (3) (4) (5)
Joel Caldwell	63	III	Director (2) (4) (5)
Earl Brien. M.D.	58	III	Director (2) (3) (4) (5)
Eric Curtis	51	—	Chief Operating Officer and President
John Y. Caloz	67	—	Chief Financial Officer

(1) Our Class I director serves until the 2019 annual meeting of stockholders, our Class II directors serve until the 2020 annual meeting of stockholders, and our Class III directors serve until the 2021 annual meeting of stockholders.

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

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

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

(5) Members of our Strategy Committee. Dr. Brien is Chairman of the Committee.

Steven A. Kriegsman has been CytRx's Chief Executive Officer and a director since July 2002. In October 2014, he was elected Chairman of the Board. Mr. Kriegsman served on the boards of directors of Galena Biopharma, Inc. from 2009 until 2016 and Catasys, Inc. from November 2013 to August 2015. He previously served as Director and Chairman of Global Genomics from June 2000 until 2002. Mr. Kriegsman is an inactive Chairman and the founder of Kriegsman Capital Group LLC, a financial advisory firm specializing in the development of alternative sources of equity capital for emerging growth companies in the healthcare industry. During his career, he has advised such companies as SuperGen Inc., Closure Medical Corporation, Novoste Corporation, Miravant Medical Technologies,

and Maxim Pharmaceuticals. In the past, Mr. Kriegsman has also served on the Board of Directors of Bradley Pharmaceuticals, Inc. and Hythiam, Inc. Mr. Kriegsman has a B.S. degree with honors from New York University in Accounting and completed the Executive Program in Mergers and Acquisitions at New York University, The Management Institute. Mr. Kriegsman is a graduate of the Stanford Law School Directors' College

Mr. Kriegsman was formerly a Certified Public Accountant with KPMG in New York City. In February 2006, Mr. Kriegsman received the Corporate Philanthropist of the Year Award from the Greater Los Angeles Chapter of the ALS Association and in October 2006, he received the Lou Gehrig Memorial Corporate Award from the Muscular Dystrophy Association. Mr. Kriegsman has been a guest speaker and lecturer at various universities including California Institute of Technology (Caltech), Brown University, and New York University. He also was an instructor at York College in Jamaica (Queens), NY, where he taught business to a diverse group of students in York's adult education program. Mr. Kriegsman has been active in various charitable organizations including the Biotechnology Industry Organization, the California Health Institute, the ALS Association, the Los Angeles Venture Association, the Southern California Biomedical Council, the American Association of Dance Companies and the Palisades-Malibu YMCA.

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

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

Joel Caldwell joined our Board of Directors on July 12, 2017. He brings more than 30 years of experience in tax matters, finance, and internal auditing. He retired from Southern California Edison, one of the nation's largest public utilities, where he had been employed for 28 years in various executive-level accounting and finance positions covering Internal Audits, Executive Compensation, Long Term Finance, Employee Benefits and, most recently prior to his retirement, Sarbanes-Oxley Internal Controls Compliance. He also worked in public accounting at the firm of Arthur Andersen & Co. In 1980, Mr. Caldwell earned his MBA with a major in finance from the University of California at Berkeley. Prior to that, he received a Bachelor of Science degree in Accounting and Finance, also from the University of California at Berkeley. He has been a Certified Public Accountant in California since 1982 and a Certified Internal Auditor since 1986. Mr. Caldwell volunteers his business skills, serving as a financial advisor on the board of trustees of a charitable organization, and continues his involvement with track and field sports by volunteering as a meet official at Pacific Palisades Charter High School. He is a member of both the American Institute of Certified Public Accountants and the California Society of Certified Public Accountants.

Mr. Caldwell's diverse background in accounting, auditing and finance, along with his accreditation as a member of both the American Institute of Certified Public Accountants and the California Society of Certified Public Accountants will provide the board with a balanced perspective to enhance its stewardship and fulfill his role as the named financial expert on our Audit Committee.

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

Eric Curtis joined us in May 2018 as our Chief Operating Officer and President, following a brief tenure providing strategic consultancy services to us. Mr. Curtis also serves as the Chief Executive Officer of our wholly-owned subsidiary, Centurion BioPharma Corporation. He brings 25 years of life science leadership experience, with oncology and orphan diseases his specialty. Mr. Curtis was instrumental in the US and global development and commercialization of many successful drugs, including Votrient®, Doxil®, Velcade®, Benlysta®, Tykerb® and Adempas®. Prior to joining CytRx, Mr. Curtis served as President, U.S. Commercial at Aegerion Pharmaceuticals (now Novelion Therapeutics), Vice President and General Manager – Rare Disease/Cardiopulmonary Business Unit at Bayer Healthcare, and in positions of increasing responsibility at GlaxoSmithKline, culminating in his role as Vice President, Marketing and Global Commercial Leader. Mr. Curtis earned a Master of Business Administration degree from Pennsylvania State University and holds a Bachelor of Science degree from the University of Pittsburgh, where he double-majored in Business and Psychology.

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

Diversity

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

Committees

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

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

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

Section 16(a) Beneficial Ownership Reporting Compliance

Each of our executive officers and directors and persons who own more than 10% of our outstanding shares of common stock is required under Section 16(a) of the Securities Exchange Act to file with the SEC initial reports of ownership and reports of changes in ownership of our common stock and to furnish us with copies of those reports. Based solely on our review of copies of reports we have received and written representations from certain reporting persons, we believe that our directors and executive officers and greater than 10% shareholders for 2014 complied with all applicable Section 16(a) filing requirements.

Code of Ethics

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

Board Leadership Structure

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

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

Board of Directors Role in Risk Oversight

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

Item 11. *EXECUTIVE COMPENSATION*

Summary Compensation Table

The following table presents summary information concerning all compensation paid or accrued by us for services rendered in all capacities during 2018 and 2017 by Steven A. Kriegsman, John Y. Caloz and Felix Kratz, who are considered our "named executive officers" during the year ended December 31, 2018.

Summary Compensation Table

Name and Principal Position	Year	Salary ($)	**Bonus ($) (1)**	**Option Awards ($)(2)**	**All Other Compensation ($)(3)**	**Total ($)**
Steven A. Kriegsman Chief Executive Officer	2018	850,000	150,000	—	13,700	1,013,700
	2017	850,000	150,000	953,300	13,700	1,967,000
John Y. Caloz Chief Financial Officer and Treasurer	2018	400,000	100,000	—	—	500,000
	2017	400,000	100,000	77,000	—	577,000
Felix Kratz, Ph.D., Vice President – Drug Development (4)	2018	225,000				