(Mark One)

[X]

was required to submit and post such files). Yes [X] No [ ]

the Exchange Act. (Check one):

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## Form 10-K

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

| For the fiscal year ended December 31, 2019   |  |
|---|--|
|   | or   |
| [ ] TRANSITION REPORT PURSUANT TO SECTION 13 O  | R 15(d) OF SECURITIES EXCHANGE ACT OF 1934   |
| For the transition period from to   |  |
| Commission  | n file number 0-15327  |
|   | Corporation strant as specified in its charter)  |
| <b>Delaware</b> (State or other jurisdiction of incorporation or organization)  | 58-1642740<br>(I.R.S. Employer<br>Identification No.)  |
| 11726 San Vicente Blvd, Suite 650,<br>Los Angeles, California<br>(Address of principal executive offices)   | <b>90049</b><br>(Zip Code)   |
| Registrant's telephone num  | aber, including area code: (310) 826-5648  |
| Securities Registered I   | Pursuant to Section 12(b) of the Act:<br>None  |
| Securities Registered I   | Pursuant to Section 12(b) of the Act:  |
| <u>Title of each class</u> Common Stock, \$0.001 par value per share Series B Junior Participating Preferred Stock Purchase Rights                          | Name of exchange on which registered OTC Market OTC Market   |
| Securities Registered I   | Pursuant to Section 12(g) of the Act:<br>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 pure $[X]$   | suant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934. Yes [ ] No                                      |
| Indicate by check mark whether the Registrant (1) has filed all reports red the preceding 12 months and (2) has been subject to such filing requirements to | quired to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during for the past 90 days. Yes [X] No [ ] |

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

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

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

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 OTC Market, the aggregate market value of the Registrant's common stock held by non-affiliates on June 28, 2019 (the last business day of the Registrant's most recently completed second fiscal quarter) was approximately \$11.8 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 26, 2020 was 33,637,501.

# CYTRX CORPORATION 2019 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 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 nature identify forward-looking statements for purposes of the federal securities laws or otherwise.

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

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

#### INDUSTRY DATA

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

#### TRADEMARKS

CytRx, 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 TM 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**

CytRx Corporation ("CytRx") is a biopharmaceutical research and development company specializing in oncology and rare diseases. The Company's 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 through 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<sup>TM</sup>, 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 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 preclinical phase of development for its four LADR drug candidates, and for its albumin companion diagnostic (ACDx<sup>TM</sup>). 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.

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<sup>TM</sup> (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 cytotoxins) by controlling the release of the drug payloads and improving drug-like properties.

Centurion's efforts were focused on two classes of ultra-high potency albumin-binding drug conjugates. These drug conjugates combine the proprietary LADR<sup>TM</sup> linkers with novel derivatives of the auristatin and maytansinoid drug classes. These payloads historically have required a targeting antibody for successful administration to humans. These 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<sup>TM</sup> (albumin companion diagnostic), was developed to identify patients with cancer who are most likely to benefit from treatment with the four LADR lead assets.

CytRx and Centurion have been working on identifying partnership opportunities for LADR<sup>TM</sup> ultra-high potency drug conjugates and its albumin companion diagnostic. However, no partnerships or any source of financing has become available after two years of effort.

#### Current Business Strategy

Currently, the Company continues to work on identifying partnership or financing opportunities for LADR<sup>TM</sup> ultra-high potency drug conjugates and their albumin companion diagnostic. We have concluded all research and development on LADR and its companion diagnostic and continue to focus on identifying partnership or financing opportunities. In addition, the Company is investigating new lines of business.

#### Aldoxorubicin

Until July 2017, we were concentrating on the research and clinical development of aldoxorubicin, our modified version of the widely-used cytotoxin agent, doxorubicin. Aldoxorubicin combines the 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 ImmunityBio, Inc. (formerly known as NantCell, Inc. ("ImmunityBio")), granting to ImmunityBio the exclusive rights to develop, manufacture and commercialize aldoxorubicin in all indications, and our company is no longer working on development of aldoxorubicin. As part of the license, ImmunityBio made a strategic investment of \$13 million in CytRx common stock at \$6.60 per share, a premium of 92% to the market price on that date. We also issued ImmunityBio 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 cytotoxin agent doxorubicin that binds to circulating albumin in the bloodstream and is believed to concentrate the drug at the site of the tumor. Aldoxorubicin, 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.

In addition to STS, ImmunityBio has expanded aldoxorubicin's use by combining it with immunotherapies and cell-based treatments, in advanced and metastatic pancreatic cancer, in advanced squamous cell carcinoma of the head and neck, in triple negative breast cancer and in colorectal cancer. ImmunityBio has submitted for a randomized metastatic pancreatic study with the FDA.

#### **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 four indications, including Niemann-Pick disease Type C (NPC), Gaucher disease, sporadic Inclusion Body Myositis (sIBM) and Amyotrophic Lateral Sclerosis (ALS). Orphazyme has highlighted positive Phase 2/3 clinical trial data in patients with NPC and have announced they will be submitting a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) and a Marketing Authorization Application (MAA) with the European Medicines Agency (EMA) in the first half and second half of 2020, respectively. Orphazyme has also received FDA Breakthrough Therapy Designation for arimoclomol for NPC. CytRx will be entitled to a milestone payment of \$6 million upon FDA approval, \$4 million upon EMA approval and \$2 million upon approval in Japan, 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. As of December 31, 2019 and 2018 no amounts were due under this Agreement.

#### **Research and Development**

Expenditures for research and development activities related to continuing operations were \$0.4 million in 2019 and \$0.4 million for the year ended December 31, 2018, or approximately 5% and 5%, 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.

## 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 or a financing for our LADR drug candidates and do not currently plan on commercializing them ourselves. Over the past two years, we have been unable to attract a development and commercial partner nor a financing for this endeavor; however we are continuing to pursue all possibilities.

#### **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, 2019, we have one pending U.S. patent application, fourteen pending foreign patent applications and two pending international applications covering our LADR<sup>TM</sup>-related technology including LADR-7, LADR-8, LADR-9 and LADR-10. The un-extended patent term of patents that issue covering our LADR<sup>TM</sup>-related technology is between June 2036 and November 2038. We also have one pending international patent application covering our albumin companion diagnostic (ACDx<sup>TM</sup>). The un-extended patent term of patents that issue covering our ACDx<sup>TM</sup> is July 2039. The patents and patent applications covering our LADR<sup>TM</sup>-related technology, and ACDx<sup>TM</sup> are assigned to Centurion BioPharma Corporation. In conjunction with our July 27, 2017 ImmunityBio licensing agreement, we granted ImmunityBio an exclusive license to all our aldoxorubicin-related patents, including the rights in five granted U.S. patents, forty-eight granted foreign patents, one pending U.S. patent applications, and ten 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<sup>TM</sup> 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 and some 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 over 200 clinical trials testing an ADC that are either on-going or currently enrolling. Other companies have created or have programs to create 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 cytotoxins 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 26, 2020, we had four 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 \$7.2 million for the year ended December 31, 2019 and \$12.7 million for the year ended December 31, 2018 and had an accumulated deficit as of December 31, 2019 of \$464.0 million. We are likely to continue to incur losses unless and until we are able to earn milestones and royalties from our existing licensing and sale agreements and/or conclude a successful strategic partnership or financing 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<sup>TM</sup> 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 26, 2020, we have no available 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, 2019, we had cash and cash equivalents of approximately \$16.1 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 2020 and the first three months of 2021 of approximately \$5.5 million (unaudited) to fund operating activities. 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 ImmunityBio fails to successfully develop aldoxorubicin or our exclusive licensing arrangement with ImmunityBio is otherwise unsuccessful, our business prospects will be materially adversely affected.

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

If, for any reason, ImmunityBio 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 ImmunityBio 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 ImmunityBio, they may opt out of a project by giving us twelve months' prior written notice. If ImmunityBio 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 ImmunityBio 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 ImmunityBio's ability to successfully develop, introduce, market and sell aldoxorubicin. We will not be directly involved in this process and will depend entirely on ImmunityBio, 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 ImmunityBio 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 ImmunityBio 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 or those we have sold or licensed 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 or those licensed or sold 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 or have sold or licensed will obtain the regulatory approvals necessary for us to begin selling them or of receiving milestone and royalty payments. 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 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.

Further, there has been heightened governmental scrutiny over the manner in which drug 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 prescription drug 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 drug 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.

We anticipate there will continue to be proposals by legislators at both the federal and state levels, regulators and commercial payers to reduce prescription drug costs while expanding individual healthcare benefits. 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. The ultimate implementation of any healthcare reform legislation and any new laws and regulations, and its impact on us, is impossible to predict. Any significant reforms made to the healthcare system in the U.S., or in other jurisdictions, may have an adverse effect on our business, financial condition, results of operations and prospects.

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. For instance, the California Consumer Privacy Act, or the CCPA, became effective on January 1, 2020. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used by requiring covered companies to provide new disclosures to California consumers (as that term is broadly defined) and provide such consumers new ways to opt-out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Although there are limited exemptions for clinical trial data and the CCPA's implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, the CCPA may increase our compliance costs and potential liability. Many similar privacy laws have been proposed at the federal level and in other states.

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 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.

#### Aldoxorubicin

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.

## **Arimoclomol**

The agreement relating to our worldwide rights to arimoclomol provides for our payment of up to an aggregate of \$3.65 million upon receipt of milestone payments from Orphayzme A/S.

## **Innovive**

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.

#### The COVID-19 pandemic could adversely impact our business and prospects, including active and planned clinical trials by ImmunityBio and Orphazyme.

In December 2019, a novel strain of coronavirus, COVID-19, was first identified in China and has surfaced in several regions across the world. In March 2020, the disease was declared a pandemic by the World Health Organization. The outbreak has reached most developed countries and resulted in the implementation of significant governmental measures, including lockdowns, closures, quarantines and travel bans, intended to control the spread of the virus.

As the situation with Covid-19 continues to evolve, the companies which are working to develop and commercialize our products, ImmunityBio and Orphazyme, could be materially and adversely affected by the risks, or the public perception of the risks, related to this pandemic, which could cause delays in the Company's potential timing of receipts of milestones and royalties within the disclosed time periods and expected costs. The disruptions to ImmunityBio and Orphazyme could include:

- delays or difficulties in recruiting and enrolling new patients in their clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as their clinical trial sites and hospital staff supporting the conduct of their clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others;
- limitations in employee resources that would otherwise be focused on the conduct of their clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- interruption in global shipping that may affect the transport of clinical trial supplies and materials, such as investigational drug product used in their clinical trials;
- delays in receiving approval from the FDA and local regulatory authorities to initiate their planned clinical trials;
- changes in FDA and local regulation as part of a response to the COVID-19 coronavirus outbreak which may change the ways in which clinical trials are
  conducted of discontinue clinical trials altogether;
- delays in necessary interactions with regulators, ethics committees and other important agencies and contractors due to limitations in employee resources
  or forced furlough of government employees;
- delay in the timing of other interactions with the FDA due to absenteeism by federal employees or by the diversion of their efforts and attention to approval of other therapeutics or other activities related to COVID-19; and
- refusal of the FDA to accept data from clinical trials in affected geographies outside the United States.

The global outbreak of the COVID-19 coronavirus continues to rapidly evolve. The extent to which the COVID-19 coronavirus may impact our business and prospects will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

#### 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 operated our drug discovery laboratory and LADR<sup>TM</sup> development program from October 2014 through January 2019. 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 prechange 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 \$72.7 million in federal net operating loss carryforwards will be substantially limited. If we experience ownership changes as a result of future transactions in our stock, we may be further limited in our ability to use our net operating loss carryforwards and other tax assets to reduce taxes owed on the net taxable income that we earn. Any such limitations on the ability to use our net operating loss carryforwards and other tax assets could potentially result in increased future tax liability to us on any net income that we may earn in the future.

#### Risks Associated with Our Common Stock

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

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

#### 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 2019 ranged from \$0.25 to \$0.76 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, 2019, we had outstanding stock options to purchase 7,741,349 shares of our common stock at a weighted-average exercise price of \$8.60 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 \$21,639. In addition to the monthly rent, we are responsible for paying our allocable portion of operating expenses. In January 2020, we signed a new four-year lease which covers approximately 2,771 square feet of office and storage space. This lease is effective March 1, 2020 and extends through February 29, 2024, with a right to extend the term for an additional five-year period, subject to the terms and conditions set forth in the lease agreement. Our monthly rent will be \$13,855, subject to annual increases of 3.5 percent. 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 \$1,294, subject to annual increases. In February 2020, we renewed this lease, which requires us to make monthly payments of \$1,370, subject to a 2.5 percent annual increase.

## **Item 3. LEGAL PROCEEDINGS**

We are occasionally involved in legal proceedings and other matters arising from the normal course of business. As of December 31, 2019, 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 matter involving our directors or officers.

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.

## 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 OTC 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 OTC Market:

|                   | High       | Low        |
|-------------------|------------|------------|
| Fiscal Year 2019: |            |            |
| Fourth Quarter    | \$<br>0.32 | \$<br>0.25 |
| Third Quarter     | \$<br>0.38 | \$<br>0.30 |
| Second Quarter    | \$<br>0.68 | \$<br>0.31 |
| First Quarter     | \$<br>0.76 | \$<br>0.51 |
| Fiscal Year 2018: |            |            |
| Fourth Quarter    | \$<br>1.10 | \$<br>0.33 |
| Third Quarter     | \$<br>1.29 | \$<br>1.00 |
| Second Quarter    | \$<br>2.05 | \$<br>1.06 |
| First Quarter     | \$<br>2.35 | \$<br>1.50 |

#### Holders

On March 26, 2020, there were approximately 257 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, 2019, regarding securities authorized for issuance under our equity compensation plans:

Number of

| Plan Category  | (a) Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights | (b)<br>Number of Issued<br>Shares of<br>Restricted Stock | Exerc<br>Out<br>Option<br>Stock | (c)<br>ted-Average<br>ise Price of<br>tstanding<br>s, Restricted<br>c, Warrants<br>d Rights | 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                          | 5,091   | _  | \$                              | 24.25   | _  |
| 2008 Stock Incentive Plan                              | 2,336,258   | 775,194  |                                 | 8.31  | _  |
| Equity compensation plans not approved by our security |   |  |                                 |   |  |
| holders:   |   |  |                                 |   |  |
| 2019 Stock Incentive Plan                              | 5,400,000   | _  | \$                              | 0.26  | _  |
| Outstanding warrants (1)                               | 193,196   | _  |                                 | 8.60  | _  |
| Total  | 7,934,545   | 775,194  | \$                              | 3.34  |  |
|  |   |  |                                 |   |  |

<sup>(1)</sup> 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.

## **Recent Issuances of Unregistered Securities**

None.

#### Repurchase of Shares

We did not repurchase any of our shares during the year ended December 31, 2019.

## 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

CytRx Corporation ("CytRx") is a biopharmaceutical research and development company specializing in oncology and rare diseases. The Company's 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 through 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<sup>TM</sup>, 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 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 preclinical phase of development for its four LADR drug candidates, and for its albumin companion diagnostic (ACDx<sup>TM</sup>). 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.

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<sup>TM</sup> (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 cytotoxins) by controlling the release of the drug payloads and improving drug-like properties.

Centurion's efforts were focused on two classes of ultra-high potency albumin-binding drug conjugates. These drug conjugates combine the proprietary LADR<sup>TM</sup> 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.

CytRx and Centurion have been working on identifying partnership opportunities for LADR<sup>TM</sup> ultra-high potency drug conjugates and its albumin companion diagnostic. However, no partnerships or any source of financing has become available after two years of effort.

## **Current Business Strategy**

CytRx and Centurion continue to work on identifying partnership or financing opportunities for LADR<sup>TM</sup> ultra-high potency drug conjugates and their albumin companion diagnostic. We have concluded all research and development on LADR and its companion diagnostic and continue to focus on identifying these partnership or financing opportunities. In addition, the Company is investigating new 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 ImmunityBio, Inc. (formerly known as NantCell, Inc.) ("ImmunityBio"), granting to ImmunityBio the exclusive rights to develop, manufacture and commercialize aldoxorubicin in all indications, and our company is no longer working on development of aldoxorubicin. As part of the license, ImmunityBio made a strategic investment of \$13 million in CytRx common stock at \$6.60 per share, a premium of 92% to the market price on that date. We also issued ImmunityBio 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 cytotoxin agent doxorubicin that binds to circulating albumin in the bloodstream and is believed to concentrate the drug at the site of the tumor. Aldoxorubicin 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.

In addition to STS, ImmunityBio has expanded aldoxorubicin's use by combining it with immunotherapies and cell-based treatments, in advanced and metastatic pancreatic cancer, in advanced squamous cell carcinoma of the head and neck, in triple negative breast cancer and in colorectal cancer. ImmunityBio has submitted for a randomized metastatic pancreatic study with the FDA.

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, 2019, we had cash and cash equivalents of approximately \$16.1 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 2020 and the first three months of 2021 of approximately \$5.5 million (unaudited) to fund operating activities. 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 four indications, including Niemann-Pick disease Type C (NPC), Gaucher disease, sporadic Inclusion Body Myositis (sIBM) and Amyotrophic Lateral Sclerosis (ALS). Orphazyme has highlighted positive Phase2/3 clinical trial data in patients with NPC and have announced they will be submitting a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) and a Marketing Authorization Application (MAA) with the European Medicines Agency (EMA) in the first half and second half of 2020, respectively. Orphazyme has also received FDA Breakthrough Therapy Designation for arimoclomol for NPC. CytRx will be entitled to a milestone payment of \$6 million upon FDA approval, \$4 million upon EMA approval and \$2 million upon approval in Japan, 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 2019 and \$0.4 million for the year ended December 31, 2018 or approximately 5% and 5%, respectively, of our total expenses.

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

We do not currently project incurring any material research and development expenditures in 2020. Should the Company's subsidiary, Centurion BioPharma be successful in raising capital to further develop its LADR compounds along with a companion diagnostic, only then would the Company incur research and development expenditures.

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 its Freiburg location and closed the lab at the end of January 2019. 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 certificates of deposit and 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.

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 ImmunityBio Licensing Agreement, which was determined to be a functional license agreement, as the underlying intellectual property had standalone functionality, was recognizable in 2017 when ImmunityBio 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. This amount was further reduced to \$50,000 as of December 31, 2018 and \$9,000 as of December 31, 2019.

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.

## 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

We periodically issue common stock and stock options to officers, directors, and consultants for services rendered. Options vest and expire according to terms established at the issuance date of each grant. Stock grants, which are generally time vested, are measured at the grant date fair value and charged to operations ratably over the vesting period. The Company's stock-based employee compensation plans are described in Note 10. The Company has adopted the provisions of ASC 718, which requires the fair value measurement and recognition of compensation expense for all stock-based awards made to employees.

Through December 31, 2018, stock options and stock warrants paid in consideration of services rendered by non-employees, the Company recognized compensation expense in accordance with the requirements of ASC 505-50, *Equity* ("ASC 505"), as amended. Non-employee option grants that do not vest immediately upon grant were recorded as an expense over the vesting period. At the end of each financial reporting period prior to performance, the value of these options, was calculated using the Black-Scholes option-pricing model, is determined, and compensation expense recognized or recovered during the period was 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 was subject to adjustment until the common stock options or warrants are fully vested.

In accordance with the Company's adoption of Accounting Standards Update 2018-07, Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting (see "Recently Adopted Accounting Pronouncements" below), effective January 1, 2019, stock options granted to outside consultants are now accounted for consistent with the accounting for stock-based payments to officers and directors, as described above, by measuring the cost of services received in exchange for equity awards utilizing the grant date fair value of the awards, with the cost recognized as compensation expense on the straight-line basis in the Company's financial statements over the vesting period of the awards.

#### 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 7.9 million and 3.2 million at December 31, 2019 and 2018, 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, 2019, we had cash and cash equivalents of approximately \$16.1 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 2020 and the first three months of 2021 of approximately \$5.5 million (unaudited) to fund operating activities. 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 ImmunityBio 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. There are also no certainties that Orphazyme will be successful in obtaining FDA and EMA approval for arimoclomol or choose to commercialize arimoclomol. 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, 2019 was \$7.2 million, and cash used for operating activities for that period was \$5.7 million. The net loss reflects \$2.0 million of stock option and warrant expense.

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.

For the year ended December 31, 2019, we received \$0.5 million from the sale of fixed assets held for sale, and \$7,500 was used for the purchase of equipment and furnishings.

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.

There were no financing activities for the year ended December 31, 2019.

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.

## **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):

|                               |             | Paym | ents aue by | y perio | as as of De | cembe | r 31, 2019    |                      |
|-------------------------------|-------------|------|-------------|---------|-------------|-------|---------------|----------------------|
| Contractual Obligations       | <br>Total   | Ŋ    | Year 1      | Yea     | rs 2 and    | Yea   | rs 4 and<br>5 | <br>s 6 and<br>eyond |
| Operating lease obligations   | \$<br>840   | \$   | 209         | \$      | 396         | \$    | 235           | \$                   |
| Employment obligations        | 5,593       |      | 1,441       |         | 2,076       |       | 2,076         | _                    |
| Total contractual obligations | \$<br>6,433 | \$   | 1,650       | \$      | 2,472       | \$    | 2,311         | \$<br>               |

- (1) Operating leases are primarily our facility lease obligations, as well as equipment and software lease obligations with third party vendors. The future cash payments for our operating lease obligations include facility leases which were renewed in March 2020.
- (2) Employment agreements include management contracts that provide for minimum salary levels, adjusted periodically at the discretion of our Compensation Committee, as well as minimum bonuses and employee benefits, in some cases.
- (3) 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, 2019, the Company had federal and state net operating loss carryforwards of \$321.8 million and \$246.7 million, respectively, available to offset against future taxable income, which expire in 2024 through 2037. The federal operating losses from 2018 and 2019 of \$5.7 million and \$5.5 million, respectively, carry forward indefinitely.

As a result of a change in-control that occurred in the CytRx shareholder base, approximately \$72.7 million in federal net operating loss carryforwards became substantially limited in their annual availability. Management currently believes that the remaining \$249.1 million in federal net operating loss carryforwards, and the \$235.6 million in state net operating loss carryforwards, are unrestricted.

As of December 31, 2019, CytRx 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 2022 through 2036. Based on an assessment of all available evidence including, but not limited to, the Company's 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, the Company has 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 \$7.2 million and \$12.7 million for the years ended December 31, 2019 and 2018, respectively.

During 2019 and 2018, 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

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 during 2019 totaled \$403,000 and related primarily to licensing fees. 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.

Year Ended December 31,

### General and Administrative from Continuing Operations

|   | <u></u> | 2019    | 2       | 2018  |
|---|---------|---------|---------|-------|
|   | ·       | (In tho | usands) |       |
| General and administrative expenses                                       | \$      | 5,430   | \$      | 6,459 |
| Stock, stock option and warrant expenses to non-employees and consultants |         | 55      |         | 73    |
| Employee stock and stock option expense                                   |         | 1,953   |         | 1,548 |
| Total   |         | 7,438   | \$      | 8,080 |

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 \$5.4 million and \$6.5 million in 2019 and 2018, respectively. In 2019, the general and administrative expenses decreased by 16%, due to a decrease of approximately \$0.5 million in professional fees, a decrease of \$0.4 million in salaries due to a reduction in head-count, and additional reduction in overall general and administrative expense.

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 2019 and 2018, we recorded \$0.1 million of such expenses. We recorded employee stock option expense of \$2.0 million and \$1.5 million in 2019 and 2018, respectively.

#### Depreciation and Amortization

Depreciation and amortization expenses for the years ended December 31, 2019 and 2018 were approximately \$21,000 and \$29,000, respectively. The depreciation expense reflects the depreciation of our equipment and furnishings.

#### Interest Income

Interest income was \$0.4 million in 2019 and \$0.4 million in 2018. 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 August 1, 2018, we fully repaid loans entered into on February 5, 2016 with Hercules Technology Growth Capital, Inc. ("HTGC"), as administrative agent and lender, and Hercules Technology III, L.P., as lender. There were no interest expenses in 2019, as compared to \$1.7 million in 2018.

# **Recently Adopted Accounting Pronouncements**

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 ImmunityBio Licensing Agreement, which was determined to be a functional license agreement, as the underlying intellectual property had standalone functionality, was recognizable in 2017 when ImmunityBio 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 and \$9,000 respectively, as of December 31, 2018 and at December 31, 2019

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 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. 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.

On January 1, 2019, CytRx adopted Accounting Standards Update ("ASU") No. 2016-02, "Leases (Topic 842)," which requires the recognition of right-of-use ("ROU") assets and lease liabilities on the consolidated balance sheet. This ASU retains a distinction between finance leases and operating leases, and the classification criteria for distinguishing between finance leases and operating leases are substantially similar to the classification criteria for distinguishing between capital leases and operating leases in the current accounting literature. Under the standard, disclosures are required to meet the objective of enabling users of financial statements to assess the amount, timing, and uncertainty of cash flows arising from leases. We elected the available practical expedients on adoption. Adoption of the new standard resulted in total lease liabilities of \$310,000 and ROU assets of \$290,000 as of January 1, 2019. At December 31, 2019, the total lease liabilities were \$70,000 and the ROU assets were \$66,000.

#### **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. Effective January 1, 2019, we adopted ASU 2018-07 and there was no cumulative-effect adjustment to the Company's accumulated deficit.

# 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, 2019, 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, 2019 and 2018, and for each of the two years ended December 31, 2019 and 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, 2019, 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, 2019, as described further below.

There were no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2019 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, 2019. 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, 2019.

#### PART III

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

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

|                      |     | Class of     |   |
|----------------------|-----|--------------|---|
| Name                 | Age | Director (1) | Position  |
| Steven A. Kriegsman  | 78  | II           | Director, Chairman of the Board and Chief Executive Officer |
| Louis Ignarro, Ph.D. | 78  | I            | Lead Director (2) (3)                                       |
| Joel Caldwell        | 64  | III          | Director (2) (3)  |
| Earl Brien. M.D.     | 59  | III          | Director  |
| Eric Curtis          | 52  | _            | Chief Operating Officer and President (4)                   |
| John Y. Caloz        | 68  | _            | Chief Financial Officer                                     |

- Our Class I and 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 Compensation Committee. Dr. Ignarro is Chairman of the Committee.
- (4) On March 10, 2020, Mr. Curtis stepped down from these roles to pursue another opportunity.

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 served in the US Army from 1963-1969.

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 received the Nobel Prize for Medicine in 1998. 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 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 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 two committees. The Audit Committee consists of Mr. Caldwell and Dr. Ignarro. The Compensation Committee consists of 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 OTC 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 2019 and 2018 by Steven A. Kriegsman and John Y. Caloz, who are considered our "named executive officers" during the year ended December 31, 2019.

# **Summary Compensation Table**

. . . . . .

| Name and Principal Position           | Year | Salary (\$) | Bonus (\$) (1) | Option<br>Awards<br>(\$) (2) | All Other<br>Compensation<br>(\$) (3) | Total<br>(\$) |
|---------------------------------------|------|-------------|----------------|------------------------------|---------------------------------------|---------------|
| Steven A. Kriegsman                   |      | · <u> </u>  | ' <u></u>      |                              |                                       |               |
| Chief Executive Officer               | 2019 | 850,000     | 190,000        | 654,000                      | 13,700                                | 1,707,700     |
|                                       | 2018 | 850,000     | 150,000        | _                            | 13,700                                | 1,013,700     |
| John Y. Caloz                         |      |             |                |                              |                                       |               |
| Chief Financial Officer and Treasurer | 2019 | 400,000     | 100,000        | 76,300                       | _                                     | 576,300       |
|                                       | 2018 | 400,000     | 100,000        | _                            | _                                     | 500,000       |
| Felix Kratz, Ph.D.,                   |      |             |                |                              |                                       |               |
| Vice President -                      |      |             |                |                              |                                       |               |
| Drug Development (4)                  | 2019 |             | _              |                              | _                                     | _             |
|                                       | 2018 | 225,000     | 77,000         | _                            | _                                     | 302,000       |

- (1) Bonuses to the named executive officers reported above were paid in December of the applicable year.
- (2) The values shown in this column represent the aggregate grant date fair value of equity-based awards granted during the fiscal year, inclusive of Mr. Kriegsman's restricted stock award, in accordance with ASC 718, "Share Based-Payment." The fair value of the stock options at the date of grant was estimated using the Black-Scholes option-pricing model, based on the assumptions described in Note 10 of the Notes to Consolidated Financial Statements included in our 2019 Annual Report.
- (3) Represents life insurance premiums.
- (4) Dr. Kratz's employment contract was not renewed for 2019.

#### 2019 Grants of Plan-Based Awards

In 2019, we granted stock options to our named executive officers under our 2019 Stock Incentive Plan as follows:

#### 2019 Grants of Plan-Based Awards

| Name   | Grant Date | All Other<br>Option Awards<br>(# of CytRx<br>Shares) | Opt | cise Price of<br>ion Awards<br>\$/Share) | Fair V | rant Date Value of Stock and ion Awards (\$) |
|--|------------|--|-----|--|--------|--|
| Steven A. Kriegsman<br>Chief Executive Officer         | 12/13/2019 | 3,000,000(1)   | \$  | 0.26                                     | \$     | 654,000                                      |
| John Y. Caloz<br>Chief Financial Officer and Treasurer | 12/13/2019 | 350,000(1)   | \$  | 0.26                                     | \$     | 76,300                                       |

<sup>(1)</sup> These options were fully vested on the grant date.

# 2000 Long-Term Incentive Plan, 2008 Stock Incentive Plan and the 2019 Stock Incentive Plan

The purpose of our 2000 Long-Term Incentive Plan, or 2000 Plan, our 2008 Stock Incentive Plan, or 2008 Plan, and our 2019 Stock Incentive Plan, or 2019 Plan, is to promote our success and enhance our value by linking the personal interests of our employees, officers, consultants and directors to those of our stockholders. The 2000 Plan was originally adopted by our board of directors on August 24, 2000 and by our stockholders on June 7, 2001, with certain amendments to the Plan having been subsequently approved by our board of directors and stockholders. On May 11, 2009, our board of directors approved an amendment to the 2000 Plan to allow for a one-time stock option re-pricing program for our employees. The 2008 Plan was adopted by our board of directors on November 21, 2008 and by our stockholders on July 1, 2009 with certain amendments to that Plan having been subsequently approved by our board of directors and stockholders. The 2019 Plan was adopted by our board of directors on November 15, 2019.

# 2000 Plan, the 2008 Plan and the 2019 Plan Descriptions

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

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

#### Awards under the 2000 Plan

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

#### Awards under the 2008 Plan

The 2008 Plan expired on November 20, 2018, and thus no shares are available for future grant under the 2008 Plan.

#### Awards under the 2019 Plan

The following is a summary description of financial instruments that may be granted to participants in our 2019 Plan by the Compensation Committee of our board of directors.

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

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

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

Limitations on Transfer; Beneficiaries. Stock Option awards under the 2019 Plan may generally not be transferred or assigned by participants other than by will or the laws of descent and distribution. Awards of Restricted Stock or Stock Bonus awards may be transferred or assigned only upon such terms and conditions as set forth in the award agreement or as determined by the Compensation Committee in its discretion.

Acceleration Upon Certain Events. In the event of a "Corporate Transaction" as defined in the 2019 Plan, all outstanding options will become fully vested, subject to the holder's consent with respect to incentive stock options, and exercisable and all restrictions on all outstanding awards will lapse. Unless the surviving or acquiring entity assumes the awards in the Corporate Transaction or the stock award agreement provides otherwise, the stock awards will terminate if not exercised at or prior to the Corporate Transaction.

#### **Termination and Amendment**

Our board of directors or the Compensation Committee may, at any time and from time to time, terminate or amend the 2019 Plan without stockholder approval; provided, however, that our board or the Compensation Committee may condition any amendment on the approval of our stockholders if such approval is necessary or deemed advisable with respect to tax, securities or other applicable laws, policies or regulations. No termination or amendment of the Plans may adversely affect any award previously granted without the written consent of the participants affected. The Compensation Committee may amend any outstanding award without the approval of the participants affected, except that no such amendment may diminish or impair the value of an award.

## **Holdings of Previously Awarded Equity**

Equity awards held as of December 31, 2019 by each of our named executive officers were issued under our 2000 Plan, our 2008 Plan and our 2019 Plan. The following table sets forth outstanding equity awards held by our named executive officers as of December 31, 2019:

**Option Awards** 

| Number of   |
|-------------|
| Securities  |
| Underlying  |
| Unexercised |
| Options     |
| (#)         |

|                                       |              | _             | Option Exercise | Option Expiration |
|---------------------------------------|--------------|---------------|-----------------|-------------------|
| Name                                  | Exercisable  | Unexercisable | Price (\$)      | Date              |
| Steven A. Kriegsman                   | 3,000,000(1) |               | 0.26            | 12/12/29          |
| President and Chief Executive Officer | 138,889(1)   | 69,445        | 1.75            | 12/14/27          |
|                                       | 645,995(4)   | 129,199       | n/a             | n/a               |
|                                       | 208,334      | _             | 2.58            | 12/14/26          |
|                                       | 166,666      | _             | 14.64           | 12/14/25          |
|                                       | 100,000      | _             | 12.90           | 12/09/24          |
|                                       | 154,167(3)   | _             | 27.96           | 12/09/23          |
|                                       | 12,363       | _             | 14.76           | 3/07/23           |
|                                       | 83,334       | _             | 10.98           | 12/10/22          |
|                                       | 23,810       | _             | 13.02           | 12/11/21          |
|                                       | 17,858       | _             | 42.42           | 12/14/20          |
| John Y. Caloz                         | 350,000(1)   | _             | 0.26            | 12/12/29          |
| Chief Financial Officer and Treasurer | 38,889(1)    | 19,444        | 1.75            | 12/14/27          |
|                                       | 58,333       | _             | 2.58            | 12/14/26          |
|                                       | 50,000       | _             | 14.64           | 12/14/25          |
|                                       | 33,334       |               | 12.90           | 12/14/24          |
|                                       | 25,000(3)    | _             | 27.96           | 12/09/23          |
|                                       | 16,667       | _             | 10.98           | 12/10/22          |
|                                       | 4,762        | _             | 13.02           | 12/11/21          |
|                                       | 1,191        | _             | 42.42           | 12/14/20          |

- (1) These options vest in 36 equal monthly installments, subject to the named executive officer's remaining in our continuous employ through such dates. All stock options held by Mr. Kriegsman provide for (a) vesting, in full, of the stock options in the event of, and upon, FDA approval to market aldoxorubicin and in the event of the termination of his employment by us without "cause" or due to his "disability," his resignation for "good reason" or his death and (b) the extended exercisability for their full term of all vested options in the event of the termination of his employment other than a termination by us with "cause" or his resignation without "good reason."
- (2) These options vest in equal bi-monthly installments, subject to the named executive officer's remaining in our continuous employ through such dates.
- (3) The options were re-priced from \$14.34 to \$27.96 on June 1, 2015, with no change to the expiration date of the options.
- (4) Represents restricted stock fully-vested at December 31, 2019. On December 15, 2017, Mr. Kriegsman was granted 387,597 shares of restricted stock, which vest over three years in equal amounts. On December 15, 2016, Mr. Kriegsman was granted 387,597 shares of restricted stock, which vest over three years in equal annual amounts.

#### Employment Agreements and Potential Payment upon Termination or Change in Control

# ${\it Employment Agreement with Steven A. Kriegsman}$

On December 13, 2019, CytRx entered into a First Amendment to Amended and Restated Employment Agreement with Mr. Kriegsman pursuant to his continued employment as Chief Executive Officer. The employment agreement, as amended, will expire on December 31, 2024 but will automatically renew following the expiration date for successive additional one-year periods, unless either Mr. Kriegsman or we elect not to renew it.

Under his employment agreement, Mr. Kriegsman is currently entitled to receive a base salary of \$850,000. Our board of directors (or its Compensation Committee) reviews the base salary annually and may increase (but not decrease) it in its sole discretion. In addition to his annual salary, Mr. Kriegsman is eligible to receive an annual bonus as determined by our board of directors (or its Compensation Committee) in its sole discretion, but not to be less than \$150,000, and Mr. Kriegsman received a grant of fully-vested stock options to purchase 3,000,000 shares of Common Stock in connection with the First Amendment. In addition, Mr. Kriegsman, during his lifetime, and thereafter to his heirs, is entitled to receive payments equal to ten percent (10%) of the gross milestone and royalty payments received by the Company from Orphazyme A/S (or its successor or assigns) in respect of Arimoclomol and certain covered diseases following the sale of certain assets relating to the Company's molecular chaperone regulation technology to Orphazyme pursuant to the Asset Purchase Agreement, dated May 13, 2011, less any applicable tax withholdings.

Mr. Kriegsman is eligible to receive additional grants of options to purchase shares of our common stock. The number and terms of those options, including the vesting schedule, will be determined by our board of directors (or its Compensation Committee) in its sole discretion. In his employment agreement, however, we have agreed that all stock options held by Mr. Kriegsman will provide for (a) vesting, in full, of the stock options in the event of, and upon, FDA approval to market aldoxorubicin and in the event of the termination of Mr. Kriegsman's employment by us without "cause" or due to his "disability," his resignation for "good reason" or his death and (b) ) the extended exercisability for their full term of all vested options in the event of the termination of his employment by us without "cause," his resignation for "good reason," due to his disability or his death.

In Mr. Kriegsman's employment agreement, we have agreed that, if he is made a party, or threatened to be made a party, to a suit or proceeding by reason of his service to us, we will indemnify and hold him harmless from all costs and expenses to the fullest extent permitted or authorized by our certificate of incorporation or bylaws, or any resolution of our board of directors, to the extent not inconsistent with Delaware law. We also have agreed to advance to Mr. Kriegsman such costs and expenses upon his request if he undertakes to repay such advances if it ultimately is determined that he is not entitled to indemnification with respect to the same. These employment agreement provisions are not exclusive of any other rights to indemnification to which Mr. Kriegsman may be entitled and are in addition to any rights he may have under any policy of insurance maintained by us.

If his employment agreement is not renewed by us or by Mr. Kriegsman, or in the event we terminate Mr. Kriegsman's employment without "cause" (as defined), or if Mr. Kriegsman terminates his employment with "good reason" (as defined), in either case whether during or following the term of his employment agreement (i) we have agreed to pay Mr. Kriegsman a lump-sum equal to his salary and prorated minimum annual bonus through to his date of termination, plus his salary and minimum annual bonus for a period of three years after his termination date, or until the expiration of the employment agreement, whichever is later, (ii) he will be entitled to immediate vesting of all stock options or other awards based on our equity securities, and (iii) he will also be entitled to continuation of his life insurance premium payments and continued participation in any of our health plans through to the later of the expiration of the amended and restated employment agreement or three years following his termination date. Mr. Kriegsman will have no obligation in such events to seek new employment or offset the severance payments to him by any compensation received from any subsequent reemployment by another employer.

Under Mr. Kriegsman's employment agreement, he and his affiliated company, The Kriegsman Group LLC, are to provide us during the term of his employment with the first opportunity to conduct or take action with respect to any acquisition opportunity or any other potential transaction identified by them within the biotech, pharmaceutical or health care industries and that is within the scope of the business plan adopted by our board of directors. Mr. Kriegsman's employment agreement also contains confidentiality provisions relating to our trade secrets and any other proprietary or confidential information, which provisions shall remain in effect for five years after the expiration of the employment agreement with respect to proprietary or confidential information and for so long as our trade secrets remain trade secrets.

#### Potential Payment upon Termination or Change in Control for Steven A. Kriegsman

Mr. Kriegsman's employment agreement contains no provision for payment to him upon the event of a change in control of the company. If, however, a change in control (as defined in our 2000 Plan or our 2008 Plan) occurs and within two years after the date on which the change in control occurs, Mr. Kriegsman's employment is terminated by us without "cause" or by him for "good reason" (each as defined in his employment agreement), in either case, whether during or following the term of his employment agreement, then, in addition to the severance benefits described above, Mr. Kriegsman would be entitled to continued participation, for a period of thirty-six months that commences on the date of termination, of health plan benefits and with COBRA benefits commencing thereafter. To the extent that any payment or distribution of any type by us to or for the benefit of Mr. Kriegsman resulting from the termination of his employment is or will be subject to the excise tax imposed under Section 4999 of the Internal Revenue Code of 1986, as amended, we have agreed to pay Mr. Kriegsman, prior to the time the excise tax is payable with respect to any such payment (through withholding or otherwise), an additional amount that, after the imposition of all income, employment, excise and other taxes, penalties and interest thereon, is equal to the sum of (i) the excise tax on such payments plus (ii) any penalty and interest assessments associated with such excise tax.

# Employment Agreement with John Y. Caloz

John Y. Caloz is employed as our Chief Financial Officer and Treasurer pursuant to an employment agreement dated as of January 8, 2020 that is to expire on December 31, 2020. Mr. Caloz is paid an annual base salary of \$400,000 and is eligible to receive an annual bonus as determined by our board of directors (or our Compensation Committee) in its sole discretion. In the event we terminate Mr. Caloz's employment without cause (as defined), we have agreed to pay him a lump-sum equal to his accrued but unpaid salary and vacation, plus an amount equal to six months' salary under his employment agreement.

We agree in Mr. Caloz's employment agreement that if we do not offer to renew or extend his employment agreement, and that his employment had not theretofore been terminated, we will continue to pay him his annual salary thereunder during the period commencing upon expiration of his employment agreement and ending on June 30, 2021.

#### **Quantification of Termination Payments and Benefits**

The table below reflects the amount of compensation to each of our named executive officers in the event of termination of such executive's employment without "cause" or his resignation for "good reason," termination following a change in control and termination upon the executive's death of permanent disability. The named executive officers are not entitled to any payments other than accrued compensation and benefits in the event of their voluntary resignation. The amounts shown in the table below assume that such termination was effective as of December 31, 2019, and thus includes amounts earned through such time, and are estimates only of the amounts that would be payable to the executives. The actual amounts to be paid will be determined upon the occurrence of the events indicated.

#### **Termination Payments and Benefits**

Termination w/o Cause or, for Mr. Kriegsman, for Good Reason

|                         |                       | Before Change in | After Change in |            |                 | Change in    |
|-------------------------|-----------------------|------------------|-----------------|------------|-----------------|--------------|
| Name                    | Benefit               | Control (\$)     | Control (\$)    | Death (\$) | Disability (\$) | Control (\$) |
| Steven A. Kriegsman     | Severance Payment (4) | 6,800,000        | 6,800,000       | 6,800,000  | 6,800,000       | _            |
| Chief Executive Officer | Stock Options (1)     | _                | _               | _          | _               | _            |
|                         | Health Insurance (2)  | 210,000          | 210,000         | 210,000    | 210,000         | _            |
|                         | Life Insurance (2)    | 109,300          | 109,300         | _          | 109,300         | _            |
|                         | Bonus                 | 1,200,000        | 1,200,000       | 1,200,000  | 1,200,000       | _            |
|                         | Tax Gross Up (3)      | _                | _               | _          | _               | _            |
| John Y. Caloz           | Severance Payment (4) | 200,000          | 400,000         | _          | _               | _            |
| Chief Financial Officer | Stock Options (1)     | _                | _               | _          | _               | _            |
|                         | Health Insurance      | _                | _               | 22,500     | 22.500          | _            |

- (1) Represents the aggregate value of stock options that vest and become exercisable immediately upon each of the triggering events listed as if such events took place on December 31, 2019, determined by the aggregate difference between the stock price as of December 31, 2019 and the exercise prices of the underlying options.
- (2) Represents the cost as of December 31, 2019 for benefits provided to Mr. Kriegsman for a period of eight years.
- This table reflects the terms of Mr. Kriegsman's amended and restated employment agreement dated as of December 13, 2019. Mr. Kriegsman's employment agreement provides that if a change in control (as defined in our 2000 Plan or our 2008 Plan) occurs during the term of the employment agreement, and if, during the term and within three years after the date on which the change in control occurs, Mr. Kriegsman's employment is terminated by us without "cause" or by him for "good reason" (each as defined in their respective employment agreement), then, to the extent that any payment or distribution of any type by us to or for the benefit of Mr. Kriegsman resulting from the termination of his respective employment is or will be subject to the excise tax imposed under Section 4999 of the Internal Revenue Code of 1986, as amended, we will pay Mr. Kriegsman prior to the time the excise tax is payable with respect to any such payment (through withholding or otherwise), an additional amount that, after the imposition of all income, employment, excise and other taxes, penalties and interest thereon, is equal to the sum of (i) the excise tax on such payments plus (ii) any penalty and interest assessments associated with such excise tax. Based on Mr. Kriegsman's past compensation and the estimated payment that would result from a termination of employment following a change in control, we have estimated that a gross-up payment would not be required. "Good reason" as defined in Mr. Kriegsman's employment agreement includes any change in Mr. Kriegsman's duties or title, as applicable, that are inconsistent with his respective positions. Mr. Kriegsman's employment agreement provides that, if the employment agreement is not renewed by us or by Mr. Kriegsman upon the expiration of its term on December 31, 2024, Mr. Kriegsman will be entitled to the termination payments and benefits described above.
- (4) Severance payments are prescribed by our employment agreements with the named executive officer and represent a factor of their annual base compensation of six months, except for Mr. Kriegsman, which is the later of December 2024, the expiration of his agreement, plus three years.

# **Compensation of Directors**

We use a combination of cash and stock-based compensation to attract and retain qualified candidates to serve on our board of directors. Directors who also are employees of our company currently receive no compensation for their service as directors or as members of board committees. In setting director compensation, we consider the significant amount of time that directors dedicate to the fulfillment of their director responsibilities, as well as the competency and skills required of members of our board. The directors' current compensation schedule has been in place since December 2013. The directors' annual compensation year begins with the annual election of directors at the annual meeting of stockholders. The annual retainer year period has been in place for directors since 2003. Periodically, our board of directors reviews our director compensation policies and, from time to time, makes changes to such policies based on various criteria the board deems relevant.

Our non-employee directors receive a quarterly retainer of \$6,000 (plus an additional \$5,000 for the Chairmen of the Audit and Compensation and Strategy Committees, and \$1,500 for the Chairman of the Nomination and Governance Committee), a fee of \$3,000 for each board meeting attended (\$750 for board actions taken by unanimous written consent), \$2,000 for each meeting of the Audit Committee and Compensation Committee attended, and \$1,000 for each meeting of the Nomination and Governance Committee meeting attended. Non-employee directors who serve as the chairman of a board committee receive an additional \$2,000 for each meeting of the Nomination and Governance Committee attended and an additional \$2,500 for each meeting of the Audit, Compensation or Strategy Committees attended. In 2019, we disbanded both the Nomination and Governance Committee and the Strategy Committee, to reduce our expenses.

The following table sets forth the compensation paid to our directors other than our Chief Executive Officer for 2019:

# **Director Compensation Table**

|                                     | Fees Earned or    |            |
|-------------------------------------|-------------------|------------|
|                                     | Paid in Cash (\$) |            |
| Name (1)                            | (2)               | Total (\$) |
| Louis Ignarro, Ph.D., Lead Director | 106,250           | 106,250    |
| Earl Brien, M.D., Director          | 46,750            | 46,750     |
| Joel Caldwell, Director             | 80,750            | 80,750     |

- (1) Steven A. Kriegsman does not receive additional compensation for his role as Chairman of the Board. For information relating to Mr. Kriegsman's compensation as Chief Executive Officer, see the Summary Compensation Table above.
- (2) The amounts in this column represent cash payments made to Non-Employee Directors for annual retainer fees, committee and/or chairmanship fees and meeting fees during the year.

#### Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Based solely upon information made available to us, the following table sets forth information with respect to the beneficial ownership of our common stock as of March 26, 2020 by (1) each person who is known by us to beneficially own more than five percent of our common stock; (2) each of our directors; (3) the named executive officers listed in the Summary Compensation Table under Item 11 who were serving as named Executive Officers as of March 26, 2020; and (4) all of our executive officers and directors as a group. Beneficial ownership is determined in accordance with the SEC rules. Shares of common stock subject to any warrants or options that are presently exercisable, or exercisable within 60 days of March 29, 2020 (which are indicated by footnote) are deemed outstanding for the purpose of computing the percentage ownership of the person holding the warrants or options, but are not treated as outstanding for the purpose of computing the percentage ownership of any other person. The percentage ownership reflected in the table is based on 33,637,501 shares of our common stock outstanding as of March 29, 2020. Except as otherwise indicated, the holders listed below have sole voting and investment power with respect to all shares of common stock shown, subject to applicable community property laws. An asterisk represents beneficial ownership of less than 1%.

### Shares of Common Stock

|  | Common    | Stock    |
|--|-----------|----------|
| Name of Beneficial Owner                                       | Number    | Percent  |
| Named Executive Officers and Directors                         |           |          |
| Louis Ignarro, Ph.D.   | 872,427   | 2.6%(1)  |
| Steven A. Kriegsman  | 4,797,495 | 14.3%(2) |
| Joel Caldwell  | 510,000   | 1.5%(3)  |
| Earl Brien, M.D.   | 590,247   | 1.8%(4)  |
| John Y. Caloz  | 583,793   | 1.7%(5)  |
| All executive officers and directors as a group (five persons) | 7,353,962 | 21.9%(6) |
| 5% Beneficial Owners   |           |          |
| ImmunityBio, Inc.  | 1,969,697 | 5.9%     |

- (1) Includes 870,238 shares subject to options or warrants.
- (2) Includes 3,922,783 shares subject to options or warrants.
- (3) Includes 510,000 shares subject to options or warrants.
- (4) Includes 580,000 shares subject to options or warrants.
- (5) Includes 583,036 shares subject to options or warrants.
- (6) Includes 6,466,057 shares subject to options or warrants.

# **Equity Compensation Plans**

The information required is incorporated herein by reference to Item 5 of this Annual Report relating to our Equity Compensation Plans as set forth on page 27.

# Item 13. CERTAIN RELATIONSHIPS, RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

#### **Director Independence**

Although the Company is no longer listed on NASDAQ, our board of directors has determined that Messrs. Ignarro, Brien and Caldwell are "independent" under the current independence standards of both The NASDAQ Capital Market and the SEC, and have no material relationships with us (either directly or as a partner, shareholder or officer of any entity) that are inconsistent with a finding of their independence as members of our board of directors. Our board has determined that Messrs. Ignarro and Caldwell also are "independent" for purposes of service as the members of our Audit Committee. In making these determinations, our board of directors has broadly considered all relevant facts and circumstances, recognizing that material relationships can include commercial, banking, consulting, legal, accounting, and familial relationships, among others.

#### Transactions with Related Persons

#### General

Our Audit Committee is responsible for reviewing and approving, as appropriate, all transactions with related persons, in accordance with its Charter.

Transactions between us and one or more related persons may present risks or conflicts of interest or the appearance of conflicts of interest. Our Code of Ethics requires all employees, officers and directors to avoid activities or relationships that conflict, or may be perceived to conflict, with our interests or adversely affect our reputation. It is understood, however, that certain relationships or transactions may arise that would be deemed acceptable and appropriate so long as there is full disclosure of the interest of the related parties in the transaction and review and approval by disinterested directors to ensure there is a legitimate business reason for the transaction and that the transaction is fair to us and our stockholders.

As a result, the procedures followed by the Audit Committee to evaluate transactions with related persons require:

- that all related person transactions, all material terms of the transactions, and all the material facts as to the related person's direct or indirect interest in, or relationship to, the related person transaction must be communicated to the Audit Committee; and
- that all related person transactions, and any material amendment or modification to any related person transaction, be reviewed and approved or ratified by the Audit Committee, as required by OTC Market Rules.

Our Audit Committee will evaluate related person transactions based on:

- information provided by members of our board of directors in connection with the required annual evaluation of director independence;
- pertinent responses to the Directors' and Officers' Questionnaires submitted periodically by our officers and directors and provided to the Audit Committee by our management; and
- any other relevant information provided by any of our directors or officers.
- In connection with its review and approval or ratification, if appropriate, of any related person transaction, our Audit Committee is to consider whether the transaction will compromise standards included in our Code of Ethics. In the case of any related person transaction involving an outside director or nominee for director, the Audit Committee also is to consider whether the transaction will compromise the director's status as an independent director as prescribed in the OTC Market Rules.

There were no related person transactions in 2019.

#### **Applicable Definitions**

For purposes of our Audit Committee's review:

- "related person" has the meaning given to such term in Item 404(a) of Securities and Exchange Commission Regulation S-K ("Item 404(a)"); and
- "related person transaction" means any transaction for which disclosure is required under the terms of Item 404(a) involving us and any related persons.

#### Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Weinberg & Co, or Weinberg, was appointed to serve as our independent registered public accounting firm effective June 21, 2019 and audited our consolidated financial statements for the year ended December 31, 2019.

BDO USA, LLP, or BDO, served as our independent registered public accounting firm and audited our consolidated financial statements for the year ended December 31,2018.

#### **Audit Fees**

The fees for 2019 from Weinberg for professional services rendered in connection with the audit of our annual consolidated financial statements and reviews of our unaudited consolidated financial statements for the periods ended June 30<sup>th</sup> and September 30<sup>th</sup>, 2019 were approximately \$90,000. The fees from BDO for the review of our unaudited consolidated financial statements for the period ended March 31, 2019 and for transitional fees were \$29,900. The fees from BDO for professional services rendered in connection with the audit of our annual consolidated financial statements and reviews of our unaudited consolidated financial statements and Form S-3 registration statements for 2018 were \$180,220.

#### Tax Fees

The aggregate fees billed by Weinberg for professional services for tax compliance were \$10,450 for 2019. The aggregate fees billed by BDO for professional services for tax compliance were \$1,360 for 2019.

The aggregate fees billed by BDO for professional services for tax compliance, tax advice and tax planning were \$35,165 for 2018.

#### All Other Fees

No other services were rendered by either Weinberg or BDO in either 2019 or 2018.

### **Pre-Approval Policies and Procedures**

It is the policy of our Audit Committee that all services to be provided by our independent registered public accounting firm, including audit services and permitted audit-related and non-audit services, must be pre-approved by our Audit Committee. Our Audit Committee pre-approved all services, audit and non-audit, provided to us by Weinberg and BDO for 2019 and 2018.

#### PART IV

# Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

- (a) The following documents are filed as part of this 10-K:
- (1) Consolidated Financial Statements

Our consolidated financial statements and the related report of the independent registered public accounting firm thereon are set forth on pages F-1 to F-20 of this Annual Report. These consolidated financial statements are as follows:

Consolidated Balance Sheets as of December 31, 2019 and 2018

Consolidated Statements of Operations for the Years Ended December 31, 2019 and 2018

Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2019 and 2018

Consolidated Statements of Cash Flows for the Years Ended December 31, 2019 and 2018

Notes to Consolidated Financial Statements

Reports of Independent Registered Public Accounting Firm

(2) Financial Statement Schedule

All schedules are omitted because they are not required, not applicable, or the information is provided in the consolidated financial statements or notes thereto.

(b) Exhibits

See Exhibit Index to this Annual Report, which is incorporated herein by reference.

# CytRx Corporation Form 10-K Exhibit Index

**Incorporated By Reference to** 

|                   | <del>-</del>   |      |         |             | Filed /               |
|-------------------|--|------|---------|-------------|-----------------------|
| Exhibit<br>Number | Description  | Form | Exhibit | Filing Date | Furnished<br>Herewith |
| 2.1               | Agreement and Plan of Merger, dated as of June 6, 2008, among  CytRx Corporation, CytRx Merger Subsidiary, Inc., Innovive  Pharmaceuticals, Inc., and Steven Kelly               | 8-K  | 2.1     | 6/9/2008    |                       |
| 3.1               | Restated Certificate of Incorporation of CytRx Corporation, as amended   | 10-K | 3.1     | 3/13/2012   |                       |
| 3.2               | Certificate of Amendment of Restated Certificate of Incorporation  | 8-K  | 3.1     | 5/15/2012   |                       |
| 3.3               | Certificate of Designation of Preferences, Rights and Limitations of<br>Series B Convertible Preferred Stock, Pursuant to Section 151 of<br>the Delaware General Corporation Law | 8-K  | 3.1     | 12/14/2016  |                       |
| 3.4               | Certificate of Amendment of Restated Certificate of Incorporation  | 8-K  | 3.1     | 11/1/2017   |                       |
| 3.5               | Amended and Restated By-Laws of CytRx Corporation  | 8-K  | 99      | 6/22/2018   |                       |
| 3.6               | Certificate of Designation of B Junior Participating Preferred Stock   | 8-K  | 3.1     | 12/19/2019  |                       |
| 3.7               | Certificate of Elimination of Designation of Series A Junior Participating Preferred Stock   | 8-K  | 3.2     | 12/19/2019  |                       |
| 3.8               | Certificate of Elimination of Series B Convertible Preferred Stock   | 8-K  | 3.3     | 12/19/2019  |                       |
| 4.1               | Rights Agreement, dated as of December 13, 2019, by and between CytRx Corporation and American Stock Transfer & Trust Company, LLC, as rights agent                              | 8-K  | 4.1     | 12/19/2019  |                       |
| 4.2               | Common Stock Purchase Warrant issued by CytRx Corporation to Alexander Capital, L.P.   | 10-K | 4.5     | 3/11/2016   |                       |
| 4.3               | Form of Common Stock Purchase Warrant issued by CytRx Corporation, dated July 20, 2016   | 10-K | 4.6     | 3/15/2017   |                       |
| 4.4               | Contingent Common Stock Purchase Warrant Agreement dated as of December 5, 2016 issued by CytRx Corporation to Bristol Capital Advisors, LLC on February 10, 2017                | 10-K | 4.7     | 3/15/2017   |                       |
| 4.5               | Warrant Agreement dated as of February 5, 2016 issued by CytRx Corporation to Hercules Technology Growth Capital, LLC  | 8-K  | 10.2    | 2/9/2016    |                       |
| 4.5.1             | First Amendment to Warrant Agreement, dated July 28, 2017, issued by CytRx Corporation to Hercules Capital, Inc.   | 8-K  | 10.5    | 8/1/2017    |                       |
| 4.6               | Warrant Agreement dated as of February 5, 2016 issued by CytRx Corporation to Hercules Technology III, L.P.  | 8-K  | 10.3    | 2/9/2016    |                       |
| 4.6.1             | <u>First Amendment to Warrant Agreement, dated July 28, 2017, issued by CytRx Corporation to Hercules Technology III, L.P.</u>   | 8-K  | 10.6    | 8/1/2017    |                       |
| 4.7               | Warrant, dated as of July 27, 2017, issued by CytRx Corporation to NantCell, Inc.  | 8-K  | 10.3    | 8/1/2017    |                       |
| 10.1*             | CytRx Corporation Amended and Restated 2008 Stock Incentive Plan   | 10-K | 10.6    | 3/13/2012   |                       |
|                   | 53   |      |         |             |                       |

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|-------------------|--|----------------|---------|-------------|----------------------------------|
| Exhibit<br>Number | Description  | Form           | Exhibit | Filing Date | Filed /<br>Furnished<br>Herewith |
| 10.1.1*           | Sixth Amendment to Amended and Restated CytRx Corporation 2008 Stock Incentive Plan  | 14A<br>(proxy) | Annex B | 5/5/2015    |                                  |
| 10.1.2*           | Seventh Amendment to Amended and Restated CytRx Corporation 2008 Stock Incentive Plan  | 14A<br>(proxy) | Annex A | 5/20/2016   |                                  |
| 10.1.3*           | <u>Eighth Amendment to Amended and Restated CytRx Corporation</u> 2008 Stock Incentive Plan  | 14A<br>(proxy) | Annex B | 5/20/2016   |                                  |
| 10.1.4*           | Form of Non-qualified Stock Option for grants to non-employee directors under Amended and Restated 2008 Stock Incentive Plan.  | 10-K           | 10.11   | 3/11/2016   |                                  |
| 10.1.5*           | Form of Non-qualified Stock Option for grants to executive officers under Amended and Restated 2008 Stock Incentive Plan.  | 10-K           | 10.12   | 3/11/2016   |                                  |
| 10.2*             | Form of Non-qualified Stock Option for grants to Steven A.  Kriegsman and Daniel J. Levitt, M.D., Ph.D., under Amended and Restated 2008 Stock Incentive Plan.                               | 10-K           | 10.13   | 3/11/2016   |                                  |
| 10.2.1*           | Amendment No. 1 to Stock Option Agreements of Daniel J. Levitt, M.D., Ph.D., dated December 31, 2015.  | 10-K           | 10.14   | 3/11/2016   |                                  |
| 10.2.2*           | Amendment No. 1 to Stock Option Agreements (2000 Long-Term Incentive Plan) of Steven A. Kriegsman, dated March 8, 2016.  | 10-K           | 10.15   | 3/11/2016   |                                  |
| 10.2.3*           | Amendment No. 1 to Stock Option Agreements (2008 Stock Incentive Plan) of Steven A. Kriegsman, dated March 8, 2016   | 10-K           | 10.16   | 3/11/2016   |                                  |
| 10.3†             | <u>License Agreement, dated December 7, 2001, by and between</u> <u>CytRx Corporation and Vical Incorporated</u>   | 8-K            | 99      | 12/21/2001  |                                  |
| 10.4              | Office Lease between The Kriegsman Capital Group, LLC and Douglas Emmett Joint Venture, dated April 13, 2000 Assignment, Assumption and Consent, effective July 1, 2003, by                  | 10-K           | 10.63   | 5/14/2004   |                                  |
| 10.4.1            | and among CytRx Corporation, The Kriegsman Capital Group,  LLC and Douglas Emmett Joint Venture, concerning Office Lease dated April 13, 2000  | 10-K           | 10.64   | 5/14/2004   |                                  |
| 10.4.2            | Fourth Amendment to Office Lease dated February 10, 2014, by and between CytRx Corporation and Douglas Emmett 1993, LLC  | 8-K            | 10.1    | 2/13/2014   |                                  |
| 10.4.3            | Fifth Amendment to Office Lease dated January 13, 2020 by and between CytRx Corporation and Douglas Emmett 1993, LLC   |                |         |             | **                               |
| 10.5†             | License Agreement dated April 17, 2006 between Innovive Pharmaceuticals, Inc. and KTB Tumorforschungs GmbH   | 10-Q           | 10.15   | 11/14/2006  |                                  |
| 10.5.1            | Amendment dated March 14, 2014 to License Agreement between  CytRx Corporation and KTB Tumorforschungs GmbH  | 8-K            | 1.1     | 3/17/2014   |                                  |
| 10.6              | Exclusive License Agreement, dated as of July 27, 2017, by and between CytRx Corporation and NantCell, Inc.  | 8-K            | 10.1    | 8/1/2017    |                                  |
| 10.7              | Amended and Restated Employment Agreement, dated March 26, 2019, by and between CytRx Corporation and Steven A.  Kriegsman  First Amended and Research and December 10, 2010, to Amended and | 10-K           | 10.18   | 3/29/2019   |                                  |
| 10.7.1            | First Amendment, dated December 19, 2019, to Amended and Restated Employment Agreement, dated March 26, 2019, by and between CytRx Corporation and Steven A. Kriegsman                       | 8-K            | 10.1    | 12/19/2019  |                                  |
| 23.1              | Consent of Weinberg & Co.  |                |         |             | **                               |
| 23.2              | Consent of BDO USA, LLP  54  |                |         |             | *****                            |

| Incorporated | By Reference to |  |
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| Exhibit<br>Number | Description   | Form | Exhibit | Filing Date | Filed /<br>Furnished<br>Herewith |
|-------------------|---|------|---------|-------------|----------------------------------|
|                   | Certification of Chief Executive Officer Pursuant to 15 U.S.C.    |      |         |             |                                  |
| 31.1              | Section 7241, as adopted pursuant to Section 302 of the Sarbanes- |      |         |             | **                               |
|                   | Oxley Act of 2002   |      |         |             |                                  |
|                   | Certification of Chief Financial Officer Pursuant to 15 U.S.C.    |      |         |             |                                  |
| 31.2              | Section 7241, as adopted pursuant to Section 302 of the Sarbanes- |      |         |             | **                               |
|                   | Oxley Act of 2002   |      |         |             |                                  |
|                   | Certification of Chief Executive Officer Pursuant to 18 U.S.C.    |      |         |             |                                  |
| 32.1              | Section 1350, as adopted pursuant to Section 906 of the Sarbanes- |      |         |             | ***                              |
|                   | Oxley Act of 2002   |      |         |             |                                  |
|                   | Certification of Chief Financial Officer Pursuant to 18 U.S.C.    |      |         |             |                                  |
| 32.2              | Section 1350, as adopted pursuant to Section 906 of the Sarbanes- |      |         |             | ***                              |
|                   | Oxley Act of 2002   |      |         |             |                                  |
| 101.INS++         | XBRL Instance Document.   |      |         |             | **                               |
| 101.SCH++         | XBRL Taxonomy Extension Schema Document.                          |      |         |             | **                               |
| 101.CAL++         | XBRL Taxonomy Extension Calculation Linkbase Document.            |      |         |             | **                               |
| 101.DEF++         | XBRL Taxonomy Extension Definition Linkbase Document.             |      |         |             | **                               |
| 101.LAB++         | XBRL Taxonomy Extension Label Linkbase Document.                  |      |         |             | **                               |
| 101.PRE++         | XBRL Taxonomy Extension Presentation Linkbase Document.           |      |         |             | **                               |
|                   |   |      |         |             |                                  |

<sup>\*</sup> Indicates a management contract or compensatory plan or arrangement.

### Item 16. FORM 10-K SUMMARY

None

<sup>\*\*</sup> Filed herewith.

<sup>\*\*\*</sup> Furnished herewith.

<sup>†</sup> Confidential treatment has been requested or granted for certain portions which have been blanked out in the copy of the exhibit filed with the Securities and Exchange Commission. The omitted information has been filed separately with the Securities and Exchange Commission.

<sup>++</sup> Pursuant to applicable securities laws and regulations, the Registrant is deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and is not subject to liability under any anti-fraud provisions of the federal securities laws as long as the Registrant has made a good faith attempt to comply with the submission requirements and promptly amends the interactive data files after becoming aware that the interactive data files fails to comply with the submission requirements. These interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and otherwise are not subject to liability under these sections.

# **SIGNATURES**

In accordance with Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

# CYTRX CORPORATION

Date: March 27, 2020

By: /s/STEVEN A. KRIEGSMAN

Steven A. Kriegsman

Chairman and Chief Executive Officer

In accordance with the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant in the capacities and on the dates indicated.

| Signature                                   | Title  | Date           |
|---|--|----------------|
| /s/ STEVEN A. KRIEGSMAN Steven A. Kriegsman | Chairman of the Board and Chief Executive Officer<br>(Principal Executive Officer) | March 27, 2020 |
| /s/ JOHN Y. CALOZ<br>John Y. Caloz          | Chief Financial Officer (Principal Financial and Accounting Officer)               | March 27, 2020 |
| /s/ LOUIS IGNARRO Louis Ignarro, Ph.D.      | Director   | March 27, 2020 |
| /s/ EARL BRIEN EARL Brien, M.D.             | Director   | March 27, 2020 |
| /s/ JOEL CALDWELL Joel Caldwell             | Director   | March 27, 2020 |
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# INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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# Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders

CytRx Corporation Los Angeles, California

#### **Opinion on the Consolidated Financial Statements**

We have audited the accompanying consolidated balance sheet of CytRx Corporation (the "Company") and subsidiary as of December 31, 2019, the related consolidated statements of operations, stockholders' equity, and cash flows for the year ended December 31, 2019, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company and its subsidiary at December 31, 2019, and the results of their operations and their cash flows for the year ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

#### **Basis for Opinion**

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ Weinberg & Co

We have served as the Company's auditor since 2019.

Los Angeles, California

March 27, 2020

# Report of Independent Registered Public Accounting Firm

Stockholders and Board of Directors CytRx Corporation Los Angeles, California

#### **Opinion on the Consolidated Financial Statements**

We have audited the accompanying consolidated balance sheet of CytRx Corporation (the "Company") and subsidiary as of December 31, 2018, the related consolidated statements of operations, stockholders' equity, and cash flows for the year then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company and subsidiary at December 31, 2018, and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

# **Basis for Opinion**

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ BDO USA, LLP

We served as the Company's auditor from 2004 to 2019.

Los Angeles, California

March 29, 2019

# CYTRX CORPORATION CONSOLIDATED BALANCE SHEETS

|  | December 31, |               |    |               |
|--|--------------|---------------|----|---------------|
|  |              | 2019          |    | 2018          |
| ASSETS   |              |               |    |               |
| Current assets:  |              |               |    |               |
| Cash and cash equivalents  | \$           | 16,130,410    | \$ | 21,373,273    |
| Receivables  |              | 7,628         |    | 148,527       |
| Prepaid expenses and other current assets  |              | 1,066,497     |    | 913,162       |
| Current assets held for sale   |              |               |    | 81,182        |
| Total current assets   |              | 17,204,535    |    | 22,516,144    |
| Equipment and furnishings, net   |              | 42,893        |    | 44,326        |
| Other assets   |              | 7,590         |    | 40,642        |
| Non-current assets held for sale   |              | _             |    | 324,853       |
| Total assets   | \$           | 17,255,018    | \$ | 22,925,965    |
| LIABILITIES AND STOCKHOLDERS' EQUITY   |              |               |    |               |
| Current liabilities:   |              |               |    |               |
| Accounts payable   | \$           | 887,835       | \$ | 1,234,762     |
| Accrued expenses and other current liabilities   |              | 1,162,471     |    | 726,191       |
| Current liabilities of discontinued operations   |              | _             |    | 602,713       |
| Total current liabilities  |              | 2,050,306     |    | 2,563,666     |
| Commitments and contingencies  |              | _             |    | _             |
| Stockholders' equity:  |              |               |    |               |
| Preferred Stock, \$0.01 par value, 833,333 shares authorized, including 50,000 shares of Series B Junior         |              |               |    |               |
| Participating Preferred Stock; no shares issued and outstanding at December 31, 2019                             |              |               |    |               |
| Preferred Stock, \$0.01 par value, 833,334 shares authorized, including 4,167 shares of Series A Junior          |              |               |    |               |
| Participating Preferred Stock; no shares issued and outstanding at December 31, 2018                             |              |               |    |               |
| Preferred Stock, \$0.01 par value, stated value \$1,000, 650 shares authorized of Series B Convertible Preferred |              |               |    |               |
| Shares at \$2.52 per share, no shares issued and outstanding at December 31, 2018                                |              | _             |    | _             |
| Common stock, \$0.001 par value, 41,666,666 shares authorized; 33,637,501 and 33,637,501 shares issued and       |              |               |    |               |
| outstanding at December 31, 2019 and 2018, respectively  |              | 33,637        |    | 33,637        |
| Additional paid-in capital   |              | 479,197,849   |    | 477,192,747   |
| Accumulated deficit  |              | (464,026,774) |    | (456,864,085) |
| Total stockholders' equity   |              | 15,204,712    |    | 20,362,299    |
| Total liabilities and stockholders' equity   | \$           | 17,255,018    | \$ | 22,925,965    |

# CYTRX CORPORATION CONSOLIDATED STATEMENTS OF OPERATIONS

|   | Years Ended    | Years Ended December 31, |  |  |  |  |  |
|---|----------------|--------------------------|--|--|--|--|--|
|   | 2019           | 2018                     |  |  |  |  |  |
| Revenue:  |                |                          |  |  |  |  |  |
| Licensing revenue                                     | <u>\$</u>      | \$ 250,000               |  |  |  |  |  |
| Expenses:   |                |                          |  |  |  |  |  |
| Research and development                              | 403,006        | 388,841                  |  |  |  |  |  |
| General and administrative                            | 7,437,809      | 8,079,861                |  |  |  |  |  |
| Depreciation and amortization                         | 20,659         | 29,423                   |  |  |  |  |  |
|   | 7,861,474      | 8,498,125                |  |  |  |  |  |
| Loss before other income (expense)                    | (7,861,474)    | (8,248,125)              |  |  |  |  |  |
| Other income (expense):                               |                |                          |  |  |  |  |  |
| Interest income                                       | 351,968        | 355,558                  |  |  |  |  |  |
| Interest expense                                      | _              | (1,715,733)              |  |  |  |  |  |
| Other income (expense), net                           | (12,516)       | 2,676                    |  |  |  |  |  |
| Gain on warrant liabilities                           | <del>_</del>   | 527,025                  |  |  |  |  |  |
| Loss before provision for income taxes                | (7,522,022)    | (9,078,599)              |  |  |  |  |  |
| Provision for income taxes                            | (800)          | (800)                    |  |  |  |  |  |
| Loss from continuing operations                       | (7,522,822)    | (9,079,399)              |  |  |  |  |  |
| Income (loss) from Discontinued operations (Note 3)   | 360,133        | (3,634,209)              |  |  |  |  |  |
| Net loss  | \$ (7,162,689) | \$ (12,713,608)          |  |  |  |  |  |
| Basic and diluted earnings (loss) per share           |                |                          |  |  |  |  |  |
| Continuing operations                                 | \$ (0.23)      | \$ (0.29)                |  |  |  |  |  |
| Discontinued operations                               | \$ 0.01        | \$ (0.12)                |  |  |  |  |  |
| Total basic and diluted loss per share                | \$ (0.22)      | \$ (0.41)                |  |  |  |  |  |
| Basic and diluted weighted average shares outstanding | 33,261,938     | 30,947,650               |  |  |  |  |  |

# CYTRX CORPORATION CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

|  | Series B<br>Preferred<br>Shares<br>Issued | Common<br>Shares<br>Issued | Preferred<br>Stock<br>Amount | Common<br>Stock<br>Amount | Additional<br>Paid-in<br>Capital | Accumulated<br>Deficit | Total         |
|--|---|----------------------------|------------------------------|---------------------------|----------------------------------|------------------------|---------------|
| Balance at January 1, 2018   |   | 28,037,501                 |                              | \$ 28,037                 | 468,969,445                      | \$ (450,852,427)       | \$ 18,145,055 |
| Cumulative affect of adopting ASC 606 Adoption   |   |                            |                              |                           |                                  | 6,701,950              | 6,701,950     |
| Stock issued in connection with a public offering Issuance of stock options/warrants for |   | 5,600,000                  |                              | 5,600                     | 6,506,551                        |                        | 6,512,151     |
| compensation and services  | _   | _                          | _                            |                           | 1,716,751                        | _                      | 1,716,751     |
| Net loss   |   |                            |                              |                           |                                  | (12,713,608)           | (12,713,608)  |
| Balance at December 31, 2018   |   | 33,637,501                 |                              | \$ 33,637                 | \$477,192,747                    | \$ (456,864,085)       | \$ 20,362,299 |
| Issuance of stock options/warrants for   |   |                            |                              |                           |                                  |                        |               |
| compensation and services  | _   | _                          | _                            | _                         | 2,005,102                        |                        | 2,005,102     |
| Net loss   |   |                            |                              |                           |                                  | (7,162,689)            | (7,162,689)   |
| Balance at December 31, 2019   |   | 33,637,501                 |                              | \$ 33,637                 | \$479,197,849                    | \$ (464,026,774)       | \$ 15,204,712 |

# CYTRX CORPORATION CONSOLIDATED STATEMENTS OF CASH FLOWS

|  | Years Ended December 31, |             |    | er 31,       |
|--|--------------------------|-------------|----|--------------|
|  |                          | 2019        |    | 2018         |
| Cash flows from operating activities:  |                          |             | _  |              |
| Net loss   | \$                       | (7,162,689) | \$ | (12,713,608) |
| Income (loss) from discontinued operations   |                          | 360,133     |    | (3,634,209)  |
| Loss from continuing operations  |                          | (7,522,822) |    | (9,079,399)  |
| Adjustments to reconcile loss from continuing operations to net cash used in operating activities: |                          |             |    |              |
| Depreciation and amortization  |                          | 20,659      |    | 29,423       |
| Loss on retirement of equipment and furnishings  |                          | 5,432       |    |              |
| Fair value adjustment on warrant liabilities   |                          | _           |    | (527,025)    |
| Loss on goodwill impairment  |                          | _           |    | 183,780      |
| Amortization of loan cost and discount   |                          |             |    | 1,157,817    |
| Stock-based compensation expense   |                          | 2,007,774   |    | 1,621,266    |
| Changes in assets and liabilities:   |                          |             |    |              |
| Receivable   |                          | 140,899     |    | 7,356,229    |
| Prepaid expenses and other current assets  |                          | (153,335)   |    | 1,000,915    |
| Accounts payable   |                          | (346,927)   |    | (2,831,236)  |
| Other assets   |                          | 33,052      |    | (17,709)     |
| Accrued expenses and other current liabilities   |                          | 436,280     |    | (7,377,978)  |
| Net cash used in continuing operations   |                          | (5,378,988) |    | (8,483,917)  |
| Net cash used in discontinued operations   |                          | (339,359)   |    | (2,383,562)  |
| Net cash used in operating activities  |                          | (5,718,347) |    | (10,867,479) |
| Cash flows from investing activities:  |                          |             |    |              |
| Purchases of equipment and furnishings for continuing operations                                   |                          | (24,658)    |    | (11,478)     |
| Sale of fixed assets held for sale from discontinued operations                                    |                          | 500,142     |    | _            |
| Net cash provided by (used in) investing activities  |                          | 475,484     |    | (11,478)     |
| Cash flows from financing activities:  |                          |             |    |              |
| Proceeds from common stock issued in public offering, net of fees                                  |                          | _           |    | 6,512,151    |
| Term loan principal repayment  |                          | _           |    | (9,986,362)  |
| Loan end fee payment   |                          | _           |    | (1,771,250)  |
| Net cash used in financing activities  |                          |             |    | (5,245,461)  |
| The dash asea in interioring activities  |                          |             |    | (3,243,401)  |
| Net decrease in cash and cash equivalents  |                          | (5,242,863) |    | (16,124,418) |
| Cash and cash equivalents at beginning of year   |                          | 21,373,273  |    | 37,497,691   |
| Cash and cash equivalents at end of year   | \$                       | 16,130,410  | \$ | 21,373,273   |
| Supplemental disclosures of non-cash financing/investing activities:                               |                          |             |    |              |
| Acquisition of fixed assets included in accounts payable   | ¢                        | 17,170      | \$ |              |
| requisition of fixed assets included in accounts payable   | Φ                        | 1/,1/0      | Φ  |              |
| Supplemental disclosure of Cash Flow Information:  |                          |             |    |              |
| Cash paid during the year for income taxes   | \$                       | 800         | \$ | 800          |
| Cash paid during the year for interest   | \$                       |             | \$ | 647,308      |

#### CYTRX CORPORATION

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### 1. Nature of Business

CytRx Corporation ("CytRx") is a biopharmaceutical research and development company specializing in oncology and rare diseases. The Company's 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 through 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<sup>TM</sup>, 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 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 preclinical phase of development for its four LADR drug candidates, and for its albumin companion diagnostic (ACDx<sup>TM</sup>). As a result of completing this work, operations taking place at the pre-clinical laboratory in Freiburg, Germany were no longer needed and, accordingly, the lab was closed at the end of January 2019.

#### LADR Drug Discovery Platform and Centurion

Centurion's LADR<sup>TM</sup> (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 cytotoxins) 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<sup>TM</sup> 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;
- free active drug is then released into the tumor.

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

CytRx and Centurion have been working on identifying partnership opportunities for  $LADR^{TM}$  ultra-high potency drug conjugates and its albumin companion diagnostic. However no partnership or any source of financing has become available after two years of effort.

#### Aldoxorubicin

Until July 2017, the Company was focused on the research and clinical development of aldoxorubicin, their 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, the Company entered into an exclusive worldwide license with ImmunityBio, Inc. (formerly known as NantCell, Inc. ("ImmunityBio")), granting to ImmunityBio 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, ImmunityBio 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. The Company also issued ImmunityBio a warrant to purchase up to 500,000 shares of common stock at \$6.60, which expired on January 26, 2019. They 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. The Company is 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.

#### **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 A/S 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 have announced they will be submitting a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) and a Marketing Authorization Application (MAA) with the European Medicines Agency (EMA) in the first half and second half of 2020, respectively. Orphazyme has also received FDA Breakthrough Therapy Designation for arimoclomol for NPC. CytRx will be entitled to a milestone payment of \$6 million upon FDA approval and \$4 million upon EMA approval, along with royalties and potential additional milestones.

#### **Current Business Strategy**

Currently, the Company is working on identifying partnership or financing opportunities for LADR<sup>TM</sup> ultra-high potency drug conjugates and their albumin companion diagnostic. We have concluded all research and development on LADR and its companion diagnostic and continue to focus on identifying these partnership or financing opportunities. In addition, the Company is investigating new lines of business.

#### Liquidity

At December 31, 2019, we had cash and cash equivalents of approximately \$16.1 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 2020 and the first three months of 2021 of approximately \$5.5 million (unaudited) to fund operating activities. 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.

# 2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation — The accompanying Consolidated Financial Statements are prepared pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC") and accounting principles generally accepted in the United States ("GAAP"). The Consolidated Financial Statements include the accounts of CytRx Corporation and its subsidiary. All intercompany accounts are eliminated.

Revenue Recognition — Revenue consists of license fees from strategic alliances with pharmaceutical companies.

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 certificates of deposit and money market accounts.

Equipment and Furnishings — Equipment and furnishings are stated at cost and depreciated using the straight-line method based on the estimated useful lives (generally three to five years for equipment and furniture) of the related assets. Whenever there is a triggering event that might suggest impairment, management evaluates the realizability of recorded long-lived assets to determine whether their carrying values have been impaired. The Company records impairment losses on long-lived assets used in operations when events and circumstances indicate that the assets might be impaired and the non-discounted cash flows estimated to be generated by those assets are less than the carrying amount of those assets. Any impairment loss is measured by comparing the fair value of the asset to its carrying amount. There is an impairment loss of \$0 and \$0.2 million recognized in 2019 and 2018, respectively, as a result of the discontinued operations (see Note 3).

Fair Value Measurements — Assets and liabilities recorded at fair value on the consolidated balance sheets are categorized based upon the level of judgment associated with the inputs used to measure the fair value. Level inputs are as follows:

- Level 1 quoted prices in active markets for identical assets or liabilities.
- Level 2 other significant observable inputs for the assets or liabilities through corroboration with market data at the measurement date.

Level 3 – significant unobservable inputs that reflect management's best estimate of what market participants would use to price the assets or liabilities at the measurement date.

The following table summarizes fair value measurements by level at December 31, 2019 for assets and liabilities measured at fair value on a recurring basis:

| (In thousands)   |    | Level I |    | Level II |    | Level III |    | Total  |  |
|------------------|----|---------|----|----------|----|-----------|----|--------|--|
| Cash equivalents | \$ | 10,995  | \$ |          | \$ |           | \$ | 10,995 |  |

The following table summarizes fair value measurements by level at December 31, 2018 for assets and liabilities measured at fair value on a recurring basis:

| n thousands) Level I |    |        | L  | evel II | Level III |  | Total |        |
|----------------------|----|--------|----|---------|-----------|--|-------|--------|
| Cash equivalents     | \$ | 19,731 | \$ |         | \$        |  | \$    | 19,731 |

There were no transfers between Levels I, II and III during 2019 or 2018.

The Company considers carrying amounts of accounts receivable, accounts payable and accrued expenses to approximate fair value due to the short-term nature of these financial instruments.

Patents and Patent Application Costs — Although the Company believes that its patents and underlying technology have continuing value, the amount of future benefits to be derived from the patents is uncertain. Patent costs are therefore expensed as incurred.

Net Income (Loss) Per Common Share — Basic net income (loss) per common share is computed using the weighted-average number of common shares outstanding. Diluted net income (loss) per common share is computed using the weighted-average number of common share and common share equivalents outstanding. Potentially dilutive stock options and warrants to purchase approximately 7.9 million and 3.2 million shares at December 31, 2019 and 2018, respectively, were excluded from the computation of diluted net income (loss) per share, because the effect would be anti-dilutive.

Stock-based Compensation — The Company periodically issues common stock and stock options to officers, directors, and consultants for services rendered. Options vest and expire according to terms established at the issuance date of each grant. The Company's stock-based employee compensation plans are described in Note 10. The Company has adopted the provisions of ASC 718, which requires the fair value measurement and recognition of compensation expense for all stock-based awards made to employees.

Through December 31, 2018, stock options and stock warrants paid in consideration of services rendered by non-employees, the Company recognized compensation expense in accordance with the requirements of ASC 505-50, *Equity* ("ASC 505"), as amended. Non-employee option grants that do not vest immediately upon grant were recorded as an expense over the vesting period. At the end of each financial reporting period prior to performance, the value of these options, was calculated using the Black-Scholes option-pricing model, is determined, and compensation expense recognized or recovered during the period was 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 was subject to adjustment until the common stock options or warrants are fully vested.

In accordance with the Company's adoption of Accounting Standards Update 2018-07, Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting (see "Recently Adopted Accounting Pronouncements" below), effective January 1, 2019, stock options granted to outside consultants are now accounted for consistent with the accounting for stock-based payments to officers and directors, as described above, by measuring the cost of services received in exchange for equity awards utilizing the grant date fair value of the awards, with the cost recognized as compensation expense on the straight-line basis in the Company's financial statements over the vesting period of the awards.

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 and drugs, that are utilized in research and development and that have no alternative future use are expensed when incurred. Technology developed for use in its products 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 the Company's contracts with various clinical research organizations in connection with conducting clinical trials for its product candidates. The Company recognizes 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. The Company believes that this method best approximates the efforts expended on a clinical trial with the expenses it records. The Company adjusts its rate of clinical expense recognition if actual results differ from its estimates. If its estimates are incorrect, clinical trial expenses recorded in any particular period could vary. Non-refundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

Income Taxes — The Company accounts for income taxes in accordance with the provisions of FASB ASC 740-10, Income Taxes, ("ASC 740") which requires the recognition of deferred tax assets and liabilities for taxable temporary differences and deferred tax assets for deductible temporary differences and operating loss carry-forwards using enacted tax rates in effect in the years the differences are expected to reverse. Deferred income tax benefit or expense is recognized as a result of changes in net deferred tax assets or deferred tax liabilities. A valuation allowance is recorded when it is more likely than not that some or all of any deferred tax assets will not be realized.

The Company recognizes the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained upon examination by the taxing authorities based on the technical merits of the position. The Company's policy is to recognize any interest and penalties related to unrecognized tax benefits as a component of income tax expenses.

Concentrations of Risks — Financial instruments that potentially subject the Company to significant concentrations of credit risk consist principally of cash, cash equivalents and short-term investments. The Company maintains cash and cash equivalents in large well-capitalized financial institutions and the Company's investment policy disallows investment in any debt securities rated less than "investment-grade" by national ratings services. The Company has not experienced any losses on its deposits of cash or cash equivalents or its short-term investments. Cash and cash equivalents are maintained at financial institutions and, at times, balances may exceed federally insured limits. The Company has never experienced any losses related to these balances.

Use of Estimates — The preparation of the consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Significant estimates include the accrual for research and development expenses, valuation on deferred tax assets, contingent liabilities and the estimate of expense arising from the common stock options and warrants granted to employees and non-employees. Actual results could materially differ from those estimates.

Recently Adopted Accounting Pronouncements — On January 1, 2019, CytRx adopted Accounting Standards Update ("ASU") No. 2016-02, "Leases (Topic 842)," which requires the recognition of right-of-use ("ROU") assets and lease liabilities on the consolidated balance sheet. This ASU retains a distinction between finance leases and operating leases, and the classification criteria for distinguishing between finance leases and operating leases are substantially similar to the classification criteria for distinguishing between capital leases and operating leases in the current accounting literature. Under the standard, disclosures are required to meet the objective of enabling users of financial statements to assess the amount, timing, and uncertainty of cash flows arising from leases. We elected the available practical expedients on adoption. Adoption of the new standard resulted in total lease liabilities of \$310,000 and ROU assets of \$290,000 as of January 1, 2019. At December 31, 2019, the total lease liabilities were \$70,000 and the ROU assets were \$66,000, and are included in prepaid expenses and accrued expenses, respectively.

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 ImmunityBio Licensing Agreement, which was determined to be a functional license agreement, as the underlying intellectual property had standalone functionality, was recognizable in 2017 when ImmunityBio 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. This amount was further reduced to \$50,000 as of December 31, 2018 and \$9,000 as of December 31, 2019 and is included within accrued expenses and other current liabilities on the consolidated balance sheet as of December 31, 2019.

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.

Through December 31, 2018, the Company accounted for stock-based payments to officers and directors by measuring the cost of services received in exchange for equity awards utilizing the grant date fair value of the awards, with the cost recognized as compensation expense on the straight-line basis in the Company's financial statements over the vesting period of the awards. The Company accounted for stock-based payments to Scientific Advisory Committee members and consultants by determining the value of the stock compensation based upon the measurement date at either (a) the date at which a performance commitment was reached or (b) at the date at which the necessary performance to earn the equity instruments was complete.

In accordance with the Company's adoption of Accounting Standards Update 2018-07, Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting (see "Recent Accounting Pronouncements" below), effective January 1, 2019, stock options granted to outside consultants are now accounted for consistent with the accounting for stock-based payments to officers and directors, as described above, by measuring the cost of services received in exchange for equity awards utilizing the grant date fair value of the awards, with the cost recognized as compensation expense on the straight-line basis in the Company's financial statements over the vesting period of the awards.

Reclassifications — Certain amounts disclosed in prior period financial statements have been reclassified to conform to the current period presentation. These reclassifications had no material effect on net income, cash flows or total assets.

# 3. 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. For financial statement reporting purposes at December 31, 2018, the Company segregated \$81,182 of current assets, and \$324,853 of analytical equipment as long-term assets held for sale. In addition, the Company segregated \$602,713 of liabilities related to these operations.

In March 2019, the Company sold its analytical equipment for proceeds of \$500,142, and accordingly recognized a gain on sale of \$186,691 during the year ended December 31, 2019. In addition, the Company was able to settle \$601,403 of liabilities for payments of \$447,006 and accordingly, reflected a recovery of \$154,397.

The results of these discontinued operations are presented separately on the Company's Consolidated Statement of Operations.

|   | 1 3 | Years Ended December 31, |    |           |  |  |
|---|-----|--------------------------|----|-----------|--|--|
|   |     | 2019                     |    | 2018      |  |  |
| Current assets held for sale                    | \$  |                          | \$ | 81,182    |  |  |
| Equipment and furnishings, net                  | \$  |                          | \$ | 313,452   |  |  |
| Deposit   |     | _                        |    | 11,401    |  |  |
| Non-current assets held for sale                | \$  |                          | \$ | 324,853   |  |  |
| Accounts payable                                | \$  |                          | \$ | 323,736   |  |  |
| Accrued expenses and other current liabilities  |     | _                        |    | 278,977   |  |  |
| Current liabilities for sale                    | \$  |                          | \$ | 602,713   |  |  |
| Research and development (recovery)             | \$  | (154,397)                | \$ | 2,869,037 |  |  |
| Loss on impairment of equipment and furnishings |     | 7,100                    |    | 207,662   |  |  |
| Employee stock option expense (recovery)        |     | (2,672)                  |    | 95,485    |  |  |
| Gain on sale of equipment                       |     | (186,691)                |    | _         |  |  |
| Other income                                    |     | (23,473)                 |    | 2,519     |  |  |
| Depreciation expense                            |     | _                        |    | 459,506   |  |  |
| Loss (gain) from discontinued operations        | \$  | (360,133)                | \$ | 3,634,209 |  |  |

# 4. Foreign Currency Remeasurement

The U.S. dollar has been determined to be the functional currency for the net assets of the Company's laboratory in Freiburg, Germany. The transactions are recorded in the local currencies and are remeasured at each reporting date using the historical rates for nonmonetary assets and liabilities and current exchange rates for monetary assets and liabilities at the balance sheet date. Exchange gains and losses from the remeasurement of monetary assets and liabilities are recognized in other income (loss). The Company recognized a loss of approximately \$3,400 and \$2,500 for the years ended December 31, 2019 and 2018, respectively.

# 5. Equipment and Furnishings

Equipment and furnishings at December 31, 2019 and 2018 consist of the following (in thousands):

|                                 | 2019 |      | 2018 |      |
|---------------------------------|------|------|------|------|
| Equipment and furnishings       | \$   | 115  | \$   | 135  |
| Less — accumulated depreciation |      | (72) |      | (91) |
| Equipment and furnishings, net  | \$   | 43   | \$   | 44   |

Depreciation and amortization expense for the years ended December 31, 2019 and 2018 were \$20,659 and \$29,423, respectively.

# 6. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities at December 31, 2019 and 2018 are summarized below (in thousands).

|                                      |    |       | 2018 |     |
|--------------------------------------|----|-------|------|-----|
| Professional fees                    | \$ | 165   | \$   | 126 |
| Research and development costs       |    | 9     |      | 50  |
| Wages, bonuses and employee benefits |    | 268   |      | 211 |
| Royalties and milestones             |    | 716   |      | 316 |
| Other                                |    | 4     |      | 23  |
| Total                                | \$ | 1,162 | \$   | 726 |

#### 7. Leases

The Company determines whether an arrangement is, or contains, a lease at inception. Prior to 2019, the company generally accounted for operating lease payments by charging them to expense as incurred. The Company recognized rent expenses of \$276,450 in 2018 in the continuing operations. The Company recognized rent expenses of \$136,684 in 2018 in the discontinued operations. Beginning in 2019, operating leases that have commenced are included in other assets, other accrued expenses and other long-term liabilities in the consolidated balance sheet. Classification of operating lease liabilities as either current or noncurrent is based on the expected timing of payments due under the company's obligations.

Because most of the company's leases do not provide an implicit rate, the company estimates incremental borrowing rates based on the information available at the commencement date in determining the present value of lease payments. The company uses the implicit rate when readily determinable. Lease terms may include the effect of options to extend or terminate the lease when it is reasonably certain that the company will exercise that option.

We lease office space related primarily to the administrative activities and at December 31, 2019, the remaining term of these leases are less than 12 months.

Leases with lease terms of twelve-months or less are expensed on a straight-line basis over the lease term and are not recorded in the Consolidated Balance Sheets.

In addition, we elected the hindsight practical expedient to determine the lease term for existing leases.

As of December 31, 2019, balance of the right-of-use assets was approximately \$66,000, and balance of the total lease liabilities was approximately \$70,000. The remaining term of the leases were less than 12 months and as such, balances of the right-of-use assets and lease liabilities were included in prepaid expenses and other current assets, and accrued expenses and other current liabilities, respectively, on the accompanying consolidated balance sheets.

The components of rent expense and supplemental cash flow information related to leases for the year are as follows:

|   | ar Ended<br>nber 31, 2019 |
|---|---------------------------|
| <u>Lease Cost</u>   | <br>                      |
| Operating lease cost (included in General and administrative expenses in the Company's audited Consolidated Statements of Operations) | \$<br>281,488             |
| Other information   |                           |
| Cash paid for amounts included in the measurement of lease liabilities for the year ended December 31, 2019                           | \$<br>211,749             |
| Weighted average remaining lease term – operating leases (in years)   | 0.46                      |
| Average discount rate   | 5.5%                      |
| F-14  |                           |

# 8. Commitments and Contingencies

#### Commitments

#### Aldoxorubicin

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.

#### Arimoclomol

The agreement relating to our worldwide rights to arimoclomol provides for our payment of up to an aggregate of \$3.65 million upon receipt of milestone payments from Orphayzme A/S.

#### Innovive

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.

CytRx's current contractual obligations that will require future cash payments for the following Employment Agreements as follows (in thousands):

| 2020       | Employment Agreements (1) |       |  |  |
|------------|---------------------------|-------|--|--|
|            | \$                        | 1,441 |  |  |
| 2021       |                           | 1,038 |  |  |
| 2022       |                           | 1,038 |  |  |
| 2023       |                           | 1,038 |  |  |
| 2024       |                           | 1,038 |  |  |
| Thereafter |                           | 3,114 |  |  |
| Total      | \$                        | 8,707 |  |  |

<sup>(1)</sup> Employment agreements include management contracts which have been revised from time to time. The employment agreement for the Company's executive officers provide for minimum salaries, which are adjusted annually at the discretion of the Company's Compensation Committee, and in some cases provide for minimum annual bonuses and employee benefits, as well. New employment agreements for the Company's other executive officers are usually entered into annually.

# Contingencies

The Company applies the disclosure provisions of ASC 460, Guarantees ("ASC 460") to its agreements that contain guarantees or indemnities by the Company. The Company provides (i) indemnifications of varying scope and size to certain investors and other parties for certain losses suffered or incurred by the indemnified party in connection with various types of third-party claims; and (ii) indemnifications of varying scope and size to officers and directors against third party claims arising from the services they provide to the Company.

The Company evaluates developments in legal proceedings and other matters on a quarterly basis. The Company records accruals for loss contingencies to the extent that the Company concludes that it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated.

In December 2019, a novel strain of coronavirus, COVID-19, was first identified in China and has surfaced in several regions across the world. In March 2020, the disease was declared a pandemic by the World Health Organization. As the situation with Covid-19 continues to evolve, the companies which are working to further develop and commercialize our products, ImmunityBio and Orphazyme, could be materially and adversely affected by the risks, or the public perception of the risks, related to this pandemic.

# 9. Equity Transactions

There were no issuance of common stock or preferred stock in 2019.

On May 15, 2018, the Company issued 5.6 million of its common stock in a public offering and the Company received net proceeds of \$6.5 million.

# 10. Stock Options and Equity-Classified Warrants

### **Stock Options**

The Company has a 2000 Long-Term Incentive Plan under which 233,334 shares of common stock were originally reserved for issuance. As of December 31, 2019, there were 5,091 shares subject to outstanding stock options. This plan expired on August 6, 2010, and thus no further shares are available for future grant under this plan.

The Company also has a 2008 Stock Incentive Plan under which 5 million shares of common stock are reserved for issuance. As of December 31, 2019, there were approximately 2.3 million shares subject to outstanding stock options and approximately 0.8 million shares outstanding related to restricted stock grants issued from the 2008 Plan. This plan expired on November 20, 2018 and thus no further shares are available for future grant under this plan.

In 2019, the Company adopted a 2019 Stock Incentive Plan under which 5.4 million shares of common stock are reserved for issuance. As of December 31, 2019, there were 5.4 million shares subject to outstanding stock options. This Plan expires on November 14, 2029.

The Company follows the provisions of ASC 718, Compensation-Stock Compensation, which requires the measurement and recognition of compensation expense for all stock-based awards made to employees.

The fair value of the stock options at the date of grant was estimated using the Black-Scholes option-pricing model, based on the following assumptions:

|                         | 2019  | 2018  |
|-------------------------|-------|-------|
| Risk-free interest rate | 1.82% | 2.42% |
| Expected volatility     | 85%   | 92%   |
| Expected lives (years)  | 10    | 6     |
| Expected dividend yield | 0.00% | 0.00% |

The Company's computation of expected volatility is based on the historical daily volatility of its publicly traded stock. For option grants issued during years ended December 31, 2019 and 2018, the Company used a calculated volatility for each grant. The Company lacks adequate information about the exercise behavior at this time and has determined the expected term assumption under the simplified method provided for under ASC 718, which averages the contractual term of the Company's options of ten years with the average vesting term of three years for an average of six years. In 2018, the Company used the average term of six years. In 2019, since all of the issued options immediately vested, the Company used the full term of ten years. The dividend yield assumption of zero is based upon the fact the Company has never paid cash dividends and presently has no intention of paying cash dividends. The risk-free interest rate used for each grant is equal to the U.S. Treasury rates in effect at the time of the grant for instruments with a similar expected life. The Company accounts for forfeitures as they occur. No amounts relating to stock-based compensation have been capitalized.

At December 31, 2019, there remained approximately \$0.1 million of unrecognized compensation expense related to unvested stock options granted to current employees and directors, to be recognized as expense over a weighted-average period of 0.57 years. Presented below is the Company's stock option activity for employees and directors:

|   | Stock Options |           |    | Weighted Average<br>Exercise Price |    |       |  |
|---|---------------|-----------|----|------------------------------------|----|-------|--|
|   | 2019          | 2018      |    | 2019                               |    | 2018  |  |
| Outstanding — beginning of year                                       | 2,190,826     | 2,492,179 | \$ | 11.55                              | \$ | 11.35 |  |
| Granted   | 5,150,000     | 1,667     |    | 0.26                               |    | 1.89  |  |
| Exercised   | _             | _         |    | _                                  |    |       |  |
| Forfeited   | (186,512)     | (275,085) |    | 9.49                               |    | 7.64  |  |
| Expired   | (27,974)      | (27,935)  |    | 43.30                              |    | 31.87 |  |
| Outstanding — end of year   | 7,126,340     | 2,190,826 |    | 3.32                               |    | 11.55 |  |
| Exercisable at end of year  | 7,034,242     | 1,887,387 | \$ | 3.34                               | \$ | 13.08 |  |
| Weighted average fair value of stock options granted during the year: | \$ 0.22       | \$ 1.43   |    |                                    |    |       |  |

Through December 31, 2018, stock options paid in consideration of services rendered by non-employees, the Company recognizes compensation expense in accordance with the requirements of 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 are fully vested.

The Company recorded \$54,500 in expenses related to the issuance of stock options to certain consultants in exchange for services during 2019 and \$0 for 2018.

At December 31, 2019, there was no unrecognized compensation expense related to unvested non-employee stock options. Presented below is the Company's non-employee stock option activity:

|   | Stock ( | Weighted Average Exercise Price |    |      |    |       |
|---|---------|---------------------------------|----|------|----|-------|
|   | 2019    | 2018                            |    | 2019 |    | 2018  |
| Outstanding — beginning of year                                       | 365,000 | 373,333                         | \$ | 5.49 | \$ | 5.70  |
| Granted   | 250,000 | _                               |    | 0.26 |    |       |
| Exercised   | _       | _                               |    | _    |    | _     |
| Expired/Forfeited   | _       | (8,333)                         |    | 0    |    | 14.70 |
| Outstanding — end of year   | 615,000 | 365,000                         |    | 3.36 |    | 5.49  |
| Exercisable at end of year  | 615,000 | 365,000                         | \$ | 3.36 | \$ | 5.49  |
| Weighted average fair value of stock options granted during the year: | \$ 0.22 | \$                              |    |      |    |       |

The fair value of the stock options at the date of grant was estimated using the Black-Scholes option-pricing model, based on the following assumptions:

|                         | 2019  | 2018 |
|-------------------------|-------|------|
| Risk-free interest rate | 1.82% |      |
| Expected volatility     | 85%   | _    |
| Expected lives (years)  | 10    | _    |
| Expected dividend yield |       | _    |
|                         |       |      |

The following table summarizes significant ranges of outstanding stock options under the three plans at December 31, 2019:

| Range of<br>Exercise Prices | Number of<br>Options | Weighted Average<br>Remaining<br>Contractual Life<br>(years) | A  | eighted<br>verage<br>cise Price | Number of<br>Options<br>Exercisable | Weighted<br>Average<br>Contractual Life | Av | ighted<br>erage<br>cise Price |
|-----------------------------|----------------------|--|----|---------------------------------|-------------------------------------|---|----|-------------------------------|
| \$<br>0.26 - 1.00           | 5,400,000            | 9.96   | \$ | 0.26                            | 5,400,000                           | 9.96                                    | \$ | 0.26                          |
| \$<br>1.01 - 3.00           | 1,050,664            | 7.61   |    | 2.04                            | 958,564                             | 7.57                                    |    | 2.07                          |
| \$<br>3.01 — 15.00          | 852,362              | 4.97   |    | 12.56                           | 852,362                             | 4.97                                    |    | 12.56                         |
| \$<br>15.01 — 48.30         | 438,314              | 3.91   |    | 26.19                           | 438,314                             | 3.91                                    |    | 26.19                         |
|                             | 7,741,340            | 8.75   | \$ | 3.32                            | 7,649,242                           | 8.76                                    | \$ | 3.34                          |

There was no aggregate intrinsic value to the outstanding options, options vested, and options exercised during 2019.

The following table sets forth the total stock-based compensation expense resulting from stock options included in the Company's Statements of Operations:

|   | Years Ended December 31, |           |    |           |  |  |
|---|--------------------------|-----------|----|-----------|--|--|
|   | 2019                     |           |    | 2018      |  |  |
| Research and development – employee         | \$                       | (2,672)   | \$ | 95,485    |  |  |
| General and administrative – employee       |                          | 1,409,158 |    | 989,154   |  |  |
| Total employee stock-based compensation     | \$                       | 1,406,486 | \$ | 1,084,639 |  |  |
| General and administrative – non-employee   | \$                       | 54,500    |    |           |  |  |
| Total non-employee stock-based compensation | \$                       | 54,500    | \$ |           |  |  |

#### **Restricted Stock**

In December 2017, the Company granted to Steven Kriegsman, Chief Executive Officer, 387,597 shares of restricted common stock, pursuant to the 2008 Plan. This restricted stock vests in equal annual instalments over three years. The fair value of the restricted stock is based on the market price of the Company's shares on the grant date less the par value received as consideration. The fair value of the restricted stock on the grant date was \$679,000. In December 2016, the Company granted to Steven Kriegsman, Chief Executive Officer, 387,597 shares of restricted common stock, pursuant to the 2008 Plan. This restricted stock vests in equal annual instalments over three years. The Company recorded an employee stock-based compensation expense for restricted stock of approximately \$544,000 and \$559,000 for the years ended December 31, 2019 and 2018, respectively. No restricted stock was granted in 2019 nor 2018.

#### **Equity-Classified Warrants**

A summary of the Company's warrant activity and related information for the years ended December 31 are shown below.

|  | Warrants  |             |    | Weighted Average Exercise Price |    |      |  |
|--|-----------|-------------|----|---------------------------------|----|------|--|
|  | 2019      | 2018        |    | 2019                            |    | 2018 |  |
| Outstanding — beginning of year                                  | 693,916   | 3,980,781   | \$ | 7.16                            | \$ | 4.92 |  |
| Granted  | _         | _           |    | _                               |    |      |  |
| Exercised  | _         | _           |    |                                 |    |      |  |
| Forfeited  | _         | _           |    |                                 |    |      |  |
| Expired  | (500,000) | (3,287,585) |    | 6.60                            |    | 3.65 |  |
| Outstanding — end of year  | 193,916   | 693,916     |    | 8.60                            |    | 7.16 |  |
| Exercisable at end of year                                       | 193,916   | 693,916     | \$ | 8.60                            | \$ | 7.16 |  |
| Weighted average fair value of warrants granted during the year: | \$        | \$ —        |    |                                 |    |      |  |

The following table summarizes additional information concerning warrants outstanding and exercisable at December 31, 2019:

|                             |                     |   |    | arrants<br>standing       |                                      |  |    |                                 |
|-----------------------------|---------------------|---|----|---------------------------|--------------------------------------|--|----|---------------------------------|
| Range of<br>Exercise Prices | Number of<br>Shares | Weighted Average Remaining Contractual Life (years) | O  | ted Average<br>cise Price | Number of<br>Warrants<br>Exercisable | Weighted<br>Average<br>Contractual<br>Life | Av | eighted<br>verage<br>cise Price |
| \$<br>4.62 — 4.62           | 84,554              | 1.10  | \$ | 4.62                      | 84,554                               | 1.10                                       | \$ | 4.62                            |
| \$<br>10.44 —10.44          | 83,335              | 1.11  |    | 10.44                     | 83,335                               | 1.11                                       |    | 10.44                           |
| \$<br>12.30 - 12.30         | 21,140              | 1.10  |    | 12.30                     | 21,140                               | 1.10                                       |    | 12.30                           |
| \$<br>33.60 - 33.60         | 4,167               | 4.21  |    | 33.60                     | 4,167                                | 4.21                                       |    | 33.60                           |

<u>193,196</u> 1.17 \$ 8.60 <u>193,916</u> 1.17 \$ 8.60

#### 11. Stockholder Protection Rights Plan

On December 13, 2019, the Board of Directors of the Company adopted a stockholder rights plan, and authorized and declared a dividend to stockholders of record at the close of business on December 23, 2019 of one preferred share purchase right (a "Right") for each outstanding share of common stock, \$0.001 par value per share ("Common Stock"), of the Company. Each Right entitles the holder to purchase from the Company one one-thousandth (subject to adjustment) of one share of Series B Junior Participating Preferred Stock, \$0.01 par value per share ("Preferred Stock") of the Company at an exercise price of \$5.00 per one one-thousandth of a share of Preferred Stock. The complete terms of the Rights are set forth in a Rights Agreement (the "Rights Agreement"), dated as of December 13, 2019, by and between the Company and American Stock Transfer & Trust Company, LLC, as rights agent.

Rights will attach to all common stock certificates representing shares outstanding and no separate Rights certificates will be distributed. Subject to certain exceptions specified in the Rights Agreement, the Rights will separate from the Common Stock and become exercisable following the earlier of (i) the tenth (10th) business day after a public announcement that either discloses that a person or a group of related persons has acquired beneficial ownership of fifteen percent (15%) or more of the Common Stock other than as a result of repurchases of Common Stock by the Company or certain inadvertent acquisitions (an "Acquiring Person") or information which reveals the existence of an Acquiring Person, or (ii) the tenth (10th) business day or such later date as may be determined by the Board, after a person or a group of related persons announce or commence a tender or exchange offer that would result in a person or a group of related persons becoming an Acquiring Person. For purposes of the Rights Agreement, beneficial ownership is defined to include the ownership of derivative securities. The date on which the Rights separate from the Common Stock and become exercisable is referred to as the "Distribution Date."

The Rights will be redeemable at the Board's sole discretion for \$0.001 per Right (payable in cash, Common Stock or other consideration deemed appropriate by the Board) at any time ending on the earlier of (i) the tenth (10th) business day (or such later date as may be determined by the Board) after the public announcement that a person has acquired beneficial ownership of fifteen percent (15%) or more of the Common Stock and (ii) the final expiration date of the Rights Agreement. Until such time as the Rights are no longer redeemable by the Company, the Rights are not exercisable. Immediately upon the action of the Board ordering redemption, the Rights will terminate and the only right of the holders of the Rights will be to receive the \$0.001 redemption price. The redemption price will be adjusted if the Company undertakes a stock dividend, a stock split or similar transaction

At any time after the date on which a person beneficially owns fifteen percent (15%) or more of the Common Stock and prior to the acquisition by the person of fifty percent (50%) or more of the Common Stock, the Board may exchange the Rights (other than Rights owned by the Acquiring Person or any Related Person, which would have become void), in whole or in part, for Common Stock at an exchange ratio (subject to adjustment) of one share of Common Stock per Right (or, if insufficient shares are available, the Company may issue preferred stock, cash, debt or equity securities, property or a combination thereof in exchange for the Rights).

The Rights will expire at or prior to the earlier of (i) December 13, 2029, or (ii) the redemption or exchange of the Rights as described above.

In the event that, at any time after a person or group becomes an "Acquiring Person," (i) the Company is acquired in a merger or other business combination with another company and the Company is not the surviving corporation, (ii) another company consolidates or merges with the Company and all or part of the Common Stock is converted or exchanged for other securities, cash, or property, or (iii) 50% or more of the consolidated assets or earning power of the Company and its subsidiaries is sold or transferred to another company, then each holder of a Right (except Rights that previously have been voided) shall thereafter have the right to receive, upon exercise, Common Stock or other equity interest of the ultimate parent of such other company having a value equal to two times the exercise price of the Right.

The terms of the Rights and the Rights Agreement may be amended by action of the Board in any respect without the consent of the holders of the Rights on or prior to the time a person becomes an Acquiring Person. Thereafter, the terms of the Rights and the Rights Agreement may not be supplemented or amended in any manner that would adversely affect the interests of the holders of the Rights. Until a Right is exercised, the holder thereof, as such, will have no rights as a stockholder of the Company, including, without limitation, the right to vote or to receive dividends.

Commensurate with the adoption of the new Series B Junior Participating Preferred Stock, the Series A Junior Participating Preferred Stock was eliminated.

# 12. Income Taxes

At December 31, 2019, the Company had federal and state net operating loss carryforwards of \$321.8 million and \$246.7 million, respectively, available to offset against future taxable income, which expire in 2024 through 2037. The federal operating losses from 2018 and 2019 of \$5.7 million and \$5.5 million, respectively, carry forward indefinitely.

As a result of a change in-control that occurred in the CytRx shareholder base, approximately \$72.7 million in federal net operating loss carryforwards became substantially limited in their annual availability. Management currently believes that the remaining \$249.1 million in federal net operating loss carryforwards, and the \$235.6 million in state net operating loss carryforwards, are unrestricted.

As of December 31, 2019, CytRx 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 2022 through 2036. Based on an assessment of all available evidence including, but not limited to, the Company's 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, the Company has 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.

Deferred income taxes reflect the net effect of temporary differences between the financial reporting carrying amounts of assets and liabilities and income tax carrying amounts of assets and liabilities. The components of the Company's deferred tax assets and liabilities, all of which are long-term, are as follows (in thousands):

|                                  | December 31, |         |    |           |
|----------------------------------|--------------|---------|----|-----------|
|                                  | 2019         |         |    | 2018      |
| Deferred tax assets:             |              |         |    |           |
| Net operating loss carryforwards | \$           | 63,002  | \$ | 69,619    |
| Tax credit carryforwards         |              | 37,901  |    | 33,348    |
| Equipment, furnishings and other |              | 4,178   |    | 4,523     |
| Total deferred tax assets        | 1            | 05,081  |    | 107,490   |
| Deferred tax liabilities         |              | _       |    | _         |
| Net deferred tax assets          | 1            | 05,081  |    | 107,490   |
| Valuation allowance              | (1           | 05,081) |    | (107,490) |
|                                  | \$           |         | \$ |           |
|                                  |              | 05,081) | \$ |           |

For all years presented, the Company did not recognize any deferred tax assets or liabilities. The net change in valuation allowance for the years ended December 31, 2019 and 2018 was \$2.4 million and \$2.4 million, respectively.

The provision for income taxes differs from the provision computed by applying the Federal statutory rate to net loss before income taxes as follows (in thousands):

|  |    | Years ended December 31, |    |         |  |
|--|----|--------------------------|----|---------|--|
|  | 2  | 2019                     |    | 2018    |  |
| Federal benefit at statutory rate                      | \$ | (1,504)                  | \$ | (1,907) |  |
| State income taxes, net of Federal taxes               |    | (500)                    |    | (657)   |  |
| State credits  |    | 2                        |    | (112)   |  |
| Warrant liabilities                                    |    | _                        |    | (111)   |  |
| Other permanent differences                            |    | 45                       |    | 12      |  |
| Provision related to change in valuation allowance     |    | 2,409                    |    | (1,415) |  |
| Federal rate adjustment                                |    |                          |    |         |  |
| NQ Options   |    |                          |    |         |  |
| Current year tax credit                                |    |                          |    |         |  |
| NOL Adjustments  |    | _                        |    | _       |  |
| Termination/Cancellation of Equity Compensation Awards |    | _                        |    | 695     |  |
| Return to provision                                    |    | (452)                    |    | 664     |  |
| Other, net   |    | _                        |    | 2       |  |
|  | \$ |                          | \$ | 1       |  |

There have been no changes to the Company's liability for unrecognized tax benefits during the year ended December 31, 2019.

The Company files income tax returns in the U.S. Federal jurisdiction and various state jurisdictions. As of the year ended December 31, 2019, the tax returns for 2016 through 2019 remain open to examination by the Internal Revenue Service and for 2015 to 2019 for various state tax authorities.

The Company's policy is to recognize any interest and penalties related to unrecognized tax benefits as a component of income tax expense. As of the date of adoption of ASC 740 and the years ended December 31, 2019 and 2018, the Company had accrued no interest or penalties related to uncertain tax positions.

# 13. Subsequent events

In January 2020, the Company signed a new four-year lease which covers approximately 2,771 square feet of office and storage space. This lease is effective March 1, 2020 and extends through February 29, 2024, with a right to extend the term for an additional five-year period, subject to the terms and conditions set forth in the lease agreement. The monthly rent will be \$13,855, subject to annual increases of 3.5 percent. The Company also leases additional storage space of approximately 540 square feet. This lease expires in February 2020, and requires us to make monthly payments of \$1,294, subject to annual increases. In February 2020, the Company renewed this lease, which requires us to make monthly payments of \$1,370, subject to a 2.5 percent annual increase. The Company will record a right of use asset and lease liability obligation of \$735,306 upon inception of these leases.