

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

Form 10-K

(Mark One)

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

For the fiscal year ended December 31, 2021

or

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

For the transition period from _____ to _____

Commission file number 000-15327

CytRx Corporation

(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

58-1642740
(I.R.S. Employer
Identification No.)

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

90049
(Zip Code)

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

Securities Registered Pursuant to Section 12(b) of the Act:
None

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

Title of each class	Trading Symbol(s)	Name of exchange on which registered
Common Stock, \$0.001 par value per share Series B Junior Participating Preferred Stock Purchase Rights	CYTR	OTC Market

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

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

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

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

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 30, 2021 (the last business day of the Registrant's most recently completed second fiscal quarter) was approximately \$35.4 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 23, 2022 was 38,801,422.

CYTRX CORPORATION
2021 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 ™ 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. 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 studies, in several different cancer models, stability, and manufacturing feasibility. In addition, a novel albumin companion diagnostic, ACDx™, was developed to identify patients with cancer who are most likely to benefit from treatment with these drug candidates.

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

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

LADR Drug Discovery Platform and Centurion

Centurion’s LADR™ (Linker Activated Drug Release) is a platform for formulating cytotoxic cancer drugs that offer improved efficacy with reduced side effects. LADR combines our expertise in linker chemistry and albumin biology to create a pipeline of anti-cancer molecules that deliver prodrugs to the tumor environment and then activate the drug inside the tumor. Such a trojan horse strategy reduces off-target side effects outside the tumor, thus allowing 10-1,000 fold higher dosing to be given.

The first-generation (“gen”) product candidate employing our tumor targeting and drug release system is aldoxorubicin, described below. Our next-gen products are composed of two classes of ultra-high potency albumin-binding drug conjugates, termed LADR 7 through LADR 10. These drug conjugates combine the proprietary LADR™ linkers with novel derivatives of the auristatin and maytansinoid drug classes. These payloads historically have required a targeting antibody for successful administration to humans. Our 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.

On March 9, 2022, Centurion was merged into the Company.

Business Strategy for LADR™ Platform

Currently, the Company continues to work on identifying partnership or financing opportunities for LADR™ ultra-high potency drug conjugates and their albumin companion diagnostic. We have concluded all research and development on LADR and its companion diagnostic and continue to focus on identifying partnership or financing opportunities.

Aldoxorubicin

Until July 2017, we were concentrating on the research and clinical development of aldoxorubicin, which is the widely-used cytotoxin doxorubicin, modified with our LADR delivery and concentration system. Modifying doxorubicin with our LADR™ system allows 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. As a result, the Company is no longer working on development of aldoxorubicin (ImmunityBio merged with NantKwest, Inc. in March 2021). 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. There can be no assurance that ImmunityBio will achieve such milestones, approvals or sales with respect to aldoxorubicin. ImmunityBio has initiated a Phase 2, randomized, three-cohort, open-label registrational-intent study for first-line and second-line treatment of locally advanced or metastatic pancreatic cancer, which includes aldoxorubicin. On October 13, 2021, ImmunityBio announced that the trial's Cohort C was fully enrolled. In January 2022 at the ASCO Gastrointestinal Cancer Symposium, they reported that 27% of third-line or greater patients (17/63) remain on study and that the median overall survival in this highly advanced group of patients (who failed two to six prior lines of treatment) is 5.8 months (95% CI: 3.9, 6.9 months) exceeding the approximately three-month historical median overall survival. Of the 63 patients, 30 (48%) had progressed after two prior lines of therapy. Median overall survival in this group was 6.3 months (95% CI: 5.0, 9.8 months), more than doubling the historical overall survival. (Survival of three months as reported by Manax et al ASCO GI 2019). In Cohort C, four patients (7%) experienced treatment-related SAEs that included peripheral edema, pyrexia, anemia and atrial flutter. No treatment-related deaths were reported. Based on the strength of earlier data and the significant unmet medical need, ImmunityBio submitted an amendment to the U.S. Food and Drug Administration (the "FDA") to increase enrollment in Cohort C and plan to meet with the FDA in 2022 to discuss a potential path for the approval of combination therapies for pancreatic cancer.

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 was 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.

ImmunityBio also lists ongoing clinical studies in head and neck and triple-negative breast cancer and has submitted a protocol with the FDA for glioblastoma; it is currently reviewing its options in STS.

Molecular Chaperone Assets (Orphazyme)

In 2011, CytRx sold the rights to arimoclomol and irovanadine, 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 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. As a result of Orphazyme's disclosure that the pivotal phase 3 clinical trial for arimoclomol in Amyotrophic Lateral Sclerosis did not meet its primary and secondary endpoints, the maximum amount that CytRx has the right to receive is now approximately \$100 million. Orphazyme is testing arimoclomol in Niemann-Pick disease Type C ("NPC") and Gaucher disease. Orphazyme has highlighted positive Phase 2/3 clinical trial data in patients with NPC and previously submitted a New Drug Application ("NDA") with the FDA. On June 18, 2021, Orphazyme announced it had received a Complete Response Letter from the FDA indicating the need for additional data. In late October 2021, Orphazyme announced it held a Type A meeting with the FDA, at which the FDA recommended that Orphazyme submit additional data, information and analyses to address certain topics in the Complete Response Letter and engage in further interactions with the FDA to identify a pathway to resubmission. The FDA concurred with Orphazyme's proposal to remove the cognition domain from the NPC Clinical Severity Scale ("NPCCSS") endpoint, with the result that the primary endpoint is permitted to be recalculated using the 4- domain NPCCSS, subject to the submission of additional requested information which Orphazyme has publicly indicated that it intends to provide. To bolster the confirmatory evidence already submitted, the FDA affirmed that it would require additional in vivo or pharmacodynamic (PD)/pharmacokinetic (PK) data. Orphazyme is planning to request a Type C Meeting with the FDA in the second quarter of 2022. Subject to discussions with the regulatory body, Orphazyme has publicly indicated that it plans to resubmit the NDA for arimoclomol in the second half of 2022.

Orphazyme had also submitted a Marketing Authorization Application ("MAA") with the European Medicines Agency (the "EMA"). In February 2022, Orphazyme announced that although they had received positive feedback from the Committee for Medicinal Products for Human Use ("CHMP") of the EMA, they were notified by the CHMP of a negative trend vote on the MAA for arimoclomol for NPC following an oral explanation. The trend vote indicates that the CHMP's current orientation is to not approve arimoclomol when it convenes by the end of March 2022. Orphazyme has publicly indicated that it considers it unlikely that this position will change before the formal vote is undertaken in March 2022. Orphazyme has publicly indicated that it will assess its strategic options and provide an update to the market at the applicable time.

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, 2021 and 2020, no amounts were due under this agreement.

Research and Development

Expenditures for research and development activities related to continuing operations were \$0 for the year ended December 31, 2021 and \$0.8 million for the year ended December 31, 2020, or approximately 0% and 12%, 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, 2021, we have three pending U.S. patent applications and thirty-eight pending foreign patent applications and twenty-two granted foreign patents covering our LADRTM-related technology including LADR-7, LADR-8, LADR-9 and LADR-10. The un-extended patent term of patents that issue covering our LADRTM-related technology is between June 2036 and November 2038. We also have one pending US patent application and fourteen pending foreign patent applications covering our albumin companion diagnostic (ACDxTM). The un-extended patent term of patents that issue covering our ACDxTM is July 2039. The patents and patent applications covering our LADRTM-related technology, and ACDxTM 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 three granted U.S. patents, eighteen granted foreign patents and eight 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. Patents and applications that cover pharmaceutical compositions comprising aldoxorubicin and their use in treating cancer (including glioblastoma) have un-extended patent terms expiring between December 2033 and June 2034.

LICENSE AGREEMENTS

Aldoxorubicin

We are the licensee of patent rights held by KTB Tumorforschungs GmbH (“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., or Vergell. 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 aldorubicin 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 aldorubicin, 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.

Molecular Chaperone Assets

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

Competition

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

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

There are many companies developing antibody-drug conjugates (ADC) for the treatment of cancer 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, many other major pharmaceutical companies, including Celgene and GlaxoSmithKline are testing an ADC in either on-going or currently enrolling clinical trials. 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

Regulation of Pharmaceuticals in the United States

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. In the United States, the FDA, under the Federal Food, Drug, and Cosmetic Act (“FDCA”), the Public Health Service (“PHS”) Act and other federal statutes and regulations, regulates pharmaceutical and biologic products and product candidates, and the parties engaged in the development, testing, manufacture, distribution, storage, marketing, labeling, advertising, and/or commercialization thereof (in addition to any other related activities) are subject to rigorous pre- and post-market requirements.

To obtain FDA approval for a new drug candidate, we must, among other requirements, submit data supporting the candidate’s safety and efficacy for the intended indication(s), 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 and are inherently complex and uncertain. The FDA may not act quickly or favorably in reviewing these applications, and we (and/or any current or future partners in development) may encounter significant difficulties or costs in our (and/or their) efforts to obtain FDA approvals that could delay or preclude the U.S. commercialization of one or more of our product candidates.

The process required by the FDA before a new drug may be marketed in the U.S. generally involves some or all of the following key steps:

- completion of nonclinical studies, such as laboratory tests, animal studies, and formulation studies, performed in compliance with FDA regulations for good laboratory practices (“GLPs”) and other applicable regulations;
- design of a clinical protocol and its submission to the FDA as part of an Investigational New Drug application (“IND”), which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials according to good clinical practices (“GCPs”) to establish the safety and efficacy of the product candidate for its intended use;
- submission of an NDA to the FDA along with payment of the application user fee and FDA acceptance of that NDA as a complete submission eligible for substantive review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities at which the active pharmaceutical ingredient, or API, and finished drug product are produced and tested to assess readiness for commercial manufacturing and conformance to the manufacturing-related elements of the application, to conduct a data integrity audit, and to assess compliance with current good manufacturing practices (“cGMPs”), in order to assure that the facilities, methods and controls are adequate to preserve the drug candidate’s identity, strength, quality and purity;
- possible inspection of selected clinical study sites to confirm compliance with GCP requirements and data integrity; and
- FDA substantive review and approval of the NDA, including satisfactory completion of an FDA advisory committee review of the product candidate, if applicable, which must occur prior to any commercial marketing or sale of the drug product in the United States. *Preclinical Studies*

After a therapeutic candidate is identified for development, it enters the preclinical or nonclinical testing stage. Preclinical studies include laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies to assess potential safety and efficacy. Preclinical tests intended for submission to the FDA to support the safety of a product candidate must be conducted in compliance with GLP regulations and the United States Department of Agriculture's Animal Welfare Act, if applicable. A drug sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, among other things, to the FDA as part of an IND. Some nonclinical testing may continue after the IND is submitted. In addition to including the results of the nonclinical studies, the IND will include one or more clinical protocols detailing, among other things, the objectives of the clinical trial and the safety and effectiveness criteria to be evaluated.

An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence. A clinical hold may occur at any time during the life of an IND and may affect one or more specific studies or all studies conducted under the IND. Occasionally, clinical holds are imposed due to manufacturing issues that may present safety issues for the clinical study subjects.

Human Clinical Trials in Support of an NDA

The clinical investigation of an investigational new drug is divided into three phases that typically are conducted sequentially but may overlap or be combined. The three phases are as follows:

- *Phase 1.* Phase 1 includes initial clinical trials introducing an investigational new drug into humans and may be conducted in subjects with the target disease or healthy volunteers. These trials are designed to determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.
- *Phase 2.* Phase 2 includes the controlled clinical trials conducted to evaluate the effectiveness of the drug candidate for a particular indication or indications in subjects with the disease or condition under study and to determine the common short-term side effects and risks associated with the drug. Phase 2 trials are typically well controlled, closely monitored, and conducted in a relatively small number of subjects.
- *Phase 3.* Phase 3 trials are typically large trials performed after preliminary evidence suggesting effectiveness of the drug candidate has been obtained. They are intended to gather additional information about the effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling and product marketing approval. Phase 3 trials usually are conducted at geographically dispersed clinical study sites.

A clinical trial may combine the elements of more than one phase and the FDA often requires more than one Phase 3 trial to support marketing approval of a product candidate. A company's designation of a clinical trial as being of a particular phase is not necessarily indicative that the study will be sufficient to satisfy the FDA requirements of that phase because this determination cannot be made until the protocol and data have been submitted to and reviewed by the FDA. Human clinical trials are inherently uncertain and Phase 1, Phase 2 and Phase 3 testing may not be successfully completed.

A pivotal trial is a clinical trial that is believed to satisfy FDA requirements for the evaluation of a product candidate's safety and efficacy such that it can be used, alone or with other pivotal or non-pivotal trials, to support regulatory approval. Generally, pivotal trials are Phase 3 trials, but they may be Phase 2 trials if the design provides a well-controlled and reliable assessment of clinical benefit, particularly in an area of unmet medical need.

Clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with the FDA's GCP requirements. They must be conducted under protocols detailing the objectives of the trial, dosing procedures, research subject selection and exclusion criteria and the safety and effectiveness criteria to be evaluated. Each protocol, and any subsequent material amendment to the protocol, must be submitted to the FDA as part of the IND, and progress reports detailing the status of the clinical trials must be submitted to the FDA annually. Sponsors also must report to the FDA serious and unexpected adverse reactions in a timely manner, any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigation brochure or any findings from other studies or animal or *in vitro* testing that suggest a significant risk in humans exposed to the product or therapeutic candidate. The FDA may order the temporary or permanent discontinuation of a clinical trial at any time, via a clinical hold, or impose other sanctions if it believes that the clinical trial is not being conducted in accordance with FDA requirements or that the subjects are being exposed to an unacceptable health risk. An institutional review board ("IRB"), is responsible for ensuring that human subjects in clinical studies are protected from inappropriate study risks. An IRB at each institution participating in the clinical trial must review and approve the protocol before a clinical trial commences at that institution and must also approve the information regarding the trial and the consent form that must be provided to each research subject or the subject's legal representative, monitor the trial until completed and otherwise comply with IRB regulations. The IRB also may halt a study, either temporarily or permanently, for failure to comply with GCP or the IRB's requirements, or if the investigational new drug has been associated with unexpected serious harm to patients.

During the development of a new drug product candidate, sponsors are given opportunities to meet with the FDA at certain points; specifically, prior to the submission of an IND, at the end of Phase 2 and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date and for the FDA to provide advice on the next phase of development. Sponsors typically use the meeting at the end of Phase 2 to discuss their Phase 2 clinical results and present their plans for the pivotal Phase 3 clinical trial that they believe will support the approval of the new therapeutic.

Post-approval trials, sometimes referred to as "Phase 4" clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, FDA may mandate the performance of "Phase 4" clinical trials.

Concurrent with clinical trials, sponsors usually complete additional animal safety studies, develop additional information about the chemistry and physical characteristics of the product candidate and finalize a process for manufacturing commercial quantities of the product candidate in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other criteria, the sponsor must develop methods for testing the identity, strength, quality, and purity of the finished drug product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

Marketing Application Submission and FDA Review

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, detailed information on the product candidate is submitted to the FDA in the form of an NDA requesting approval to market the drug for one or more indications. An NDA includes all relevant data available from pertinent nonclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information on the product candidate's chemistry, manufacturing, and controls, or CMC, and proposed labeling, among other things. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the product candidate for its intended use to the satisfaction of the FDA.

Under the Prescription Drug User Fee Act ("PDUFA"), each NDA must be accompanied by a significant user fee. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual program fee for prescription drug products. Fee waivers or reductions are available in certain circumstances, such as where a waiver is necessary to protect the public health, where the fee would present a significant barrier to innovation, or where the applicant is a small business submitting its first human therapeutic application for review.

Under the goals and policies agreed to by the FDA under PDUFA, the FDA has ten months from receipt in which to complete its initial review of a standard NDA for a drug that is not a new molecular entity, and six months from the receipt date for an application with priority review. The FDA does not always meet its PDUFA goal dates, and the review process is often significantly extended by FDA requests for additional information or clarification and a sponsor's process to respond to such inquiries. As a result, the NDA review process can be very lengthy. Most innovative drug products (other than biological products) obtain FDA marketing approval pursuant to an NDA submitted under Section 505(b)(1) of the FDCA, commonly referred to as a traditional (or full) NDA.

The FDA conducts a preliminary review of all NDAs it receives to ensure that they are sufficiently complete for substantive review before it accepts them for filing. The FDA may refuse to file any NDA that it deems incomplete or not properly reviewable at the time of submission, and may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. The FDA has 60 days after submission of an NDA to conduct an initial review to determine whether it is sufficient to accept for filing. If the submission is accepted for filing, the FDA begins an in-depth substantive review of the NDA. The FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use, whether it has an acceptable purity profile and whether the product is being manufactured in accordance with cGMPs. During its review of an NDA, the FDA may refer the application to an advisory committee of independent experts for a recommendation as to whether the application should be approved. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it typically follows such recommendations. Data from clinical trials are not always conclusive, and the FDA or its advisory committee may interpret data differently than the NDA sponsor interprets the same data. The FDA may also re-analyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process.

Before approving an NDA, the FDA will typically inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving the NDA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND trial requirements and GCP requirements and to assure the integrity of the clinical data submitted to the FDA. To ensure cGMP and GCP compliance by its employees and third-party contractors, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production and quality control.

The FDA also may require the submission of a risk evaluation and mitigation strategy, or "REMS," if it determines that a REMS is necessary to ensure that the benefits of the drug outweigh its risks and to assure the safe use of the product. A REMS could include medication guides, physician communication plans, assessment plans and/or elements to assure safe use, such as restricted distribution methods, patient registries or other risk minimization tools. The FDA determines the requirement for a REMS, as well as the specific REMS provisions, on a case-by-case basis. If the FDA concludes a REMS is needed, the sponsor must include a proposed REMS within its NDA submission.

After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities where the drug product or its API will be produced and the clinical trial sites, the FDA will either issue an approval letter or, in some cases, a complete response letter ("CRL") that describes all of the specific deficiencies that the FDA has identified in the NDA. A CRL indicates that the review cycle of the application is complete but that the application will not be approved in its present form. The deficiencies identified may be minor (e.g., requiring labeling changes) or major (e.g., requiring additional clinical trials and/or other time-consuming and expensive measures to generate the requisite safety and/or efficacy data). After receiving a CRL, an applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter or withdraw the application. FDA will issue a letter within 30 days of an NDA resubmission acknowledging receipt and informing the applicant as follows. For resubmissions deemed to be complete responses to all deficiencies identified in the CRL, such letter will contain FDA's designation of the resubmission as Class 1 or Class 2 (based on the nature of information received therein) and the corresponding due date by which it will take action (2 months for Class 1 resubmissions and 6 months for Class 2. If FDA does not find the resubmission to be a complete response to all CRL deficiencies, the FDA will inform the applicant, and the FDA's "review clock" will not start until a complete response is received.

Even if a drug product receives NDA approval, the approval may be significantly limited to specific indications and dosages and/or subject to limitations, specific labeling requirements, and/or other conditions that must be met to lawfully market the product in the United States, any or all of which could restrict the commercial value of the product. For example, the FDA may require that certain contraindications, warnings, and/or precautions be included in the product's labeling. The FDA may also impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a REMS, or otherwise limit the scope of any approval. In addition, the FDA may require post marketing clinical trials, sometimes referred to as "Phase 4" clinical trials, designed to further assess a product's safety and effectiveness, and/or testing and surveillance programs to monitor the safety of approved products that have been commercialized.

Post-Approval Requirements for Prescription Drugs

Following approval of a new drug product, the manufacturer and the approved drug are subject to pervasive and continuing regulation by the FDA, including, among other things, monitoring and recordkeeping activities, reporting of adverse experiences with the product, product sampling and distribution restrictions, and promotion and advertising requirements.

Promotional communications must be carefully crafted to ensure compliance with all applicable FDA regulations pertaining to prescription-drug marketing and labeling. In particular, prescription-drug advertisements must generally (1) not be false or misleading, (2) present a “fair balance” of information describing both the risks and benefits associated with the drug, (3) include facts that are “material” to the product’s advertised uses, and (4) include a “brief summary” that mentions every risk described in the product’s labeling. Further, where the intended use of a prescription drug differs from the intended use approved by FDA, as listed in the product’s approved NDA, FDA has asserted that the product is an unapproved “new drug” and taken enforcement action against sponsors for introducing such unapproved new drugs into interstate commerce in violation of the FDCA. This prohibited practice is also called “off-label” promotion. Although physicians may prescribe legally available products for off-label uses, sponsors may not legally market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

To market an approved drug product for a new indication (i.e., beyond and/or differing from that set forth in the approved NDA), the sponsor must submit a new NDA (or NDA supplement), which, in many cases, will require the completion of adequate and well-controlled clinical trials to demonstrate the product’s safety and efficacy in the new indication. There is no guarantee that FDA will approve an NDA seeking an expansion of an approved drug’s labeling and/or indications for use more quickly than an NDA involving a novel product (i.e., that has never been approved for *any* indication) or ever. Relatedly, if the sponsor (or a contractor, partner, or other affiliated party) makes any post-market modifications to an approved drug or the production thereof, including changes in labeling or manufacturing processes or facilities, among other things, it may be required to submit and obtain FDA approval of a new NDA or an NDA supplement.

In addition, FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMPs. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports and returned or salvaged products. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and some state agencies, and are subject to periodic unannounced inspections by the FDA for compliance with cGMPs and other requirements. Changes to the manufacturing process, specifications or container closure system for an approved drug product are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require, among other things, the investigation and correction of any deviations from cGMPs and the imposition of reporting and documentation requirements upon the NDA sponsor and any third-party manufacturers involved in producing the approved drug product. Accordingly, both sponsors and manufacturers must continue to expend time, money, and effort on systems relating to production and quality control to maintain cGMP compliance and other aspects of quality control and quality assurance, and to ensure ongoing compliance with other statutory requirements the FDCA. We anticipate that the products we may commercialize in the United States (if any) will be manufactured by our strategic partners (including licensees) or contractors (including any third parties who may be engaged by us or one of our partners to conduct any commercialization activities, as well as downstream subcontractors, as applicable) and we may, thus, be subject to enforcement action for any such third parties’ failures to comply with the applicable postmarket regulations or otherwise be adversely affected by any of our partners’ or contractors’ compliance issues.

The FDA may withdraw its approval for a drug product if compliance with regulatory requirements is not maintained or unexpected problems occur after the product reaches the market. Later discovery of previously unknown problems with a drug, including serious and/or unexpected adverse experiences, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies to assess new safety risks; or the imposition of distribution or other restrictions under a REMS.

We and/or our present or future suppliers, contract manufacturers, and/or other affiliates involved in one or more of our current or future U.S. development and/or commercialization activities (if applicable) may not be able to comply with all FDA regulatory requirements. For example, we may believe that all clinical studies are being conducted in accordance with the FDA’s IND regulations and that none of our investigational products are being promoted with claims of safety and/or effectiveness for the intended use(s) for which they are under investigation, but the FDA may determine otherwise, which could subject us to enforcement action and/or delay or prevent the ultimate approval of our applicable product candidate(s). From a postmarket perspective, with regard to any products we may commercialize in the United States in the future, we may believe our manufacturing operations (including that of our partners and/or contractors, as applicable) are fully compliant with cGMPs and that all promotional communications disseminated by or on behalf of us are consistent with FDA’s prescription-drug marketing requirements, but the FDA may disagree and take enforcement action against us. Accordingly, we could be subject to a number of adverse enforcement actions and/or penalties in connection with any failure(s) to comply with the FDCA and/or its implementing regulations at any stage in development and/or commercialization (if applicable), including, but not limited to, the following:

- restrictions on the marketing or manufacturing of approved products, market withdrawal, recalls;

- fines, warning letters, untitled letters, public warnings, consumer advisories, “dear doctor” letters, and other similar publications or issuances;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs;
- seizure, detention, import alerts;
- injunctions or the imposition of civil or criminal penalties;
- consent decrees, corporate integrity agreements, debarment, or exclusion from federal healthcare programs; or
- mandated modification of promotional materials and labeling and the issuance of corrective information.

We and our manufacturers and other partners in development and/or (future) commercialization, as applicable, 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. 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.

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.

Other U.S. Healthcare Laws and Regulations

Healthcare Reform Measures

On March 23, 2010, former President Obama signed the “Patient Protection and Affordable Care Act” (P.L. 111-148) (the “ACA”) and on March 30, 2010, he signed the “Health Care and Education Reconciliation Act” (P.L. 111-152), collectively commonly referred to as the “Healthcare Reform Law.” The Healthcare Reform Law included a number of new rules regarding health insurance, the provision of healthcare, conditions to reimbursement for healthcare services provided to Medicare and Medicaid patients, and other healthcare policy reforms. Through the law-making process, substantial changes have been and continue to be made to the current system for paying for healthcare in the U.S., including changes made to extend medical benefits to certain Americans who lacked insurance coverage and to contain or reduce healthcare costs (such as by reducing or conditioning reimbursement amounts for healthcare services and drugs, and imposing additional taxes, fees, and rebate obligations on pharmaceutical and medical device companies). This legislation was one of the most comprehensive and significant reforms ever experienced by the U.S. in the healthcare industry and has significantly changed the way healthcare is financed by both governmental and private insurers. This legislation has impacted the scope of healthcare insurance and incentives for consumers and insurance companies, among others. Additionally, the Healthcare Reform Law’s provisions were designed to encourage providers to find cost savings in their clinical operations. Pharmaceuticals represent a significant portion of the cost of providing care. This environment has caused changes in the purchasing habits of consumers and providers and resulted in specific attention to the pricing negotiation, product selection and utilization review surrounding pharmaceuticals. This attention may result in our current commercial products, products we may commercialize or promote in the future, and our therapeutic candidates, being chosen less frequently or the pricing being substantially lowered. At this stage, it is difficult to estimate the full extent of the direct or indirect impact of the Healthcare Reform Law on us.

These structural changes could entail further modifications to the existing system of private payors and government programs (such as Medicare, Medicaid, and the State Children's Health Insurance Program), creation of government-sponsored healthcare insurance sources, or some combination of both, as well as other changes. Restructuring the coverage of medical care in the U.S. could impact the reimbursement for prescribed drugs and pharmaceuticals, including our current commercial products, those we and our development or commercialization partners are currently developing or those that we may commercialize or promote in the future. If reimbursement for the products we currently commercialize or promote, any product we may commercialize or promote, or approved therapeutic candidates is substantially reduced or otherwise adversely affected in the future, or rebate obligations associated with them are substantially increased, it could have a material adverse effect on our reputation, business, financial condition or results of operations.

Extending medical benefits to those who currently lack coverage will likely result in substantial costs to the U.S. federal government, which may force significant additional changes to the healthcare system in the U.S. Much of the funding for expanded healthcare coverage may be sought through cost savings. While some of these savings may come from realizing greater efficiencies in delivering care, improving the effectiveness of preventive care and enhancing the overall quality of care, much of the cost savings may come from reducing the cost of care and increased enforcement activities. Cost of care could be reduced further by decreasing the level of reimbursement for medical services or products (including our current commercial products, our development or commercialization partners or any product we may commercialize or promote, or those therapeutic candidates currently being developed by us), or by restricting coverage (and, thereby, utilization) of medical services or products. In either case, a reduction in the utilization of, or reimbursement for our current commercial products, any product we may commercialize or promote, or any therapeutic candidate, or for which we receive marketing approval in the future, could have a material adverse effect on our reputation, business, financial condition or results of operations.

Several states and private entities initially mounted legal challenges to the Healthcare Reform Law, in particular, the ACA, and they continue to litigate various aspects of the legislation. On July 26, 2012, the U.S. Supreme Court generally upheld the provisions of the ACA at issue as constitutional. However, the U.S. Supreme Court held that the legislation improperly required the states to expand their Medicaid programs to cover more individuals. As a result, states have a choice as to whether they will expand the number of individuals covered by their respective state Medicaid programs. Some states have not expanded their Medicaid programs and have chosen to develop other cost-saving and coverage measures to provide care to currently uninsured individuals. Many of these efforts to date have included the institution of Medicaid-managed care programs. The manner in which these cost-saving and coverage measures are implemented could have a material adverse effect on our reputation, business, financial condition or results of operations, particularly once we and/or any of our partners have products on the U.S. market, if ever.

Further, the healthcare regulatory environment has seen significant changes in recent years and is still in flux. Legislative initiatives to modify, limit, replace, or repeal the ACA and judicial challenges have continued. We cannot predict the extent to which our business may be impacted by legal challenges to the ACA or other aspects of the Healthcare Reform Law or other changes to the current laws and regulations. The financial impact of U.S. healthcare reform legislation over the next few years will depend on a number of factors, including the policies reflected in implementing regulations and guidance and changes in sales volumes for therapeutics affected by the legislation. From time to time, legislation is drafted, introduced and passed in the U.S. Congress that could significantly change the statutory provisions governing coverage, reimbursement, and marketing of pharmaceutical products. In addition, third-party payor coverage and reimbursement policies are often revised or interpreted in ways that may significantly affect our business and any products we or our partners may commercialize in the future, as well as the prospects and/or viability of our product candidates.

During his time in office, former President Trump supported the repeal of all or portions of the ACA. President Trump also issued an executive order in which he stated that it is his administration's policy to seek the prompt repeal of the ACA and in which he directed executive departments and federal agencies to waive, defer, grant exemptions from, or delay the implementation of the provisions of the ACA to the maximum extent permitted by law. Congress has enacted legislation that repeals certain portions of the ACA, including but not limited to the Tax Cuts and Jobs Act, passed in December 2017, which included a provision that eliminates the penalty under the ACA's individual mandate, effective January 1, 2019, as well as the Bipartisan Budget Act of 2018, passed in February 2018, which, among other things, repealed the Independent Payment Advisory Board (which was established by the ACA and was intended to reduce the rate of growth in Medicare spending).

Additionally, in December 2018, a district court in Texas held that the individual mandate is unconstitutional and that the rest of the ACA is, therefore, invalid. On appeal, the Fifth Circuit Court of Appeals affirmed the holding on the individual mandate but remanded the case back to the lower court to reassess whether and how such holding affects the validity of the rest of the ACA. The Fifth Circuit's decision on the individual mandate was appealed to the U.S. Supreme Court. On June 17, 2021, the Supreme Court held that the plaintiffs (comprised of the state of Texas, as well as numerous other states and certain individuals) did not have standing to challenge the constitutionality of the ACA's individual mandate and, accordingly, vacated the Fifth Circuit's decision and instructed the district court to dismiss the case. As a result, the ACA will remain in-effect in its current form for the foreseeable future; however, we cannot predict what additional challenges may arise in the future, the outcome thereof, or the impact any such actions may have on our business.

The Biden administration also introduced various measures in 2021 focusing on healthcare and drug pricing, in particular. For example, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021, and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. On the legislative front, the American Rescue Plan Act of 2021 was signed into law on March 11, 2021, which, in relevant part, eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source drugs and innovator multiple source drugs, beginning January 1, 2024. And, in July 2021, the Biden administration released an executive order entitled, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response, on September 9, 2021, HHS released a "Comprehensive Plan for Addressing High Drug Prices" that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. And, in November 2021, President Biden announced the "Prescription Drug Pricing Plan" as part of the Build Back Better Act (H.R. 5376) passed by the House of Representatives on November 19, 2021, which aims to lower prescription drug pricing by, among other things, allowing Medicare to negotiate prices for certain high-cost prescription drugs covered under Medicare Part D and Part B after the drugs have been on the market for a certain number of years and imposing tax penalties on drug manufacturers that refuse to negotiate pricing with Medicare or increase drug prices "faster than inflation." If enacted, this bill could have a substantial impact on our business. In the coming years, additional legislative and regulatory changes could be made to governmental health programs that could significantly impact pharmaceutical companies and the success of our product candidates. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological 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.

There is uncertainty as to what healthcare programs and regulations may be implemented or changed at the federal and/or state level in the U.S. or the effect of any future legislation or regulation. Furthermore, we cannot predict what actions the Biden administration will implement in connection with the Health Reform Law. However, it is possible that such initiatives could have an adverse effect on our or our partners' ability to obtain approval for and/or successfully commercialize products in the U.S. in the future.

Fraud and Abuse, Transparency, and Privacy

In the United States, we may be subject to various federal and state laws and regulations regarding fraud and abuse in the healthcare industry, as well as industry standards and guidance, such as the codes issued by the Pharmaceutical Research and Manufacturers of America (or "PhRMA Codes"), which some states reference or incorporate in their statutes and regulations. These laws, regulations, standards, and guidance may impact, among other things, our sales and marketing activities and our relationships with healthcare providers and patients. In addition, we may be subject to patient privacy regulations by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order, or recommendation of, an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, including the False Claim Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from the federal government, including Medicare, Medicaid, or other third-party payors, that are false or fraudulent;
 - The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which imposes federal criminal and civil liability for executing, or attempting to execute, a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;

- the federal transparency laws, including the Physician Payments Sunshine Act, which requires applicable manufacturers of covered drugs to disclose payments and other transfers of value provided to physicians and teaching hospitals and physician ownership and investment interests;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (“HITECH”), and its implementing regulations, also imposes certain requirements relating to the privacy, security, and transmission of individually identifiable 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, state laws that require pharmaceutical manufacturers to report certain pricing or payment information, 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 are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrow scope of the statutory or regulatory exceptions and safe harbors available, our current or future activities, policies, and/or arrangements could be challenged under one or more of these laws. In addition, the federal government has identified relationships between drug companies (and other medical-product manufacturers) and healthcare providers as particularly susceptible to fraud and abuse and, thus, our relationships may be subject to heightened regulatory scrutiny, particularly once we have one or more products on the U.S. market, if ever. Further, many of the applicable healthcare laws and regulations are subject to varying and/or evolving interpretations, which makes achieving and maintaining consistent compliance more difficult. We may have to devote substantial costs, resources, and time to compliance efforts, particularly once one or more of our product candidates, or any other products to which we may obtain commercialization rights in the future, is marketed in the United States. If any of our past, current, or future operations and/or arrangements are found to be in violation of If our operations are found to be in violation of any healthcare laws or regulations that may apply to us, we may be subject to significant civil, criminal, and/or administrative penalties; damages; fines; personal imprisonment; exclusion from government-funded programs, such as Medicare and Medicaid; additional reporting requirements and oversight under a corporate integrity (or deferred prosecution or other similar) agreement with the applicable federal or state agency or agencies (such as the U.S. Office of Inspector General (“OIG”), the U.S. Department of Justice (“DOJ”), or state attorneys general); and/or the curtailment or restructuring of our operations. Any adverse enforcement action initiated against us based on actual or alleged violations of one or more of the healthcare laws and regulations could have a material adverse effect on our business, even if we are ultimately successful in defending against such claims.

Employees

As of March 23, 2022, we had three full-time 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. Among other things, we post on our website our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments and Code of Business Conduct and Ethics. 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.

Item 1A. RISK FACTORS

We are subject to various risks that may materially harm our business, prospects, financial condition and results of operations. An investment in our common stock is speculative and involves a high degree of risk. In evaluating an investment in our common stock, you should carefully consider the risks described below, together with the other information included in this Form 10-K, including the consolidated financial statements and related notes.

You should carefully consider the risks and uncertainties facing our business. The risks described below are not the only risks we face. If any of the events described in the following risk factors actually occurs, or if additional risks and uncertainties later materialize, that are not presently known to us or that we currently deem immaterial, then our business, prospects, results of operations and financial condition could be materially adversely affected. In that event, the trading price of our common stock could decline, and you may lose all or part of your investment in our shares. The risks discussed below include forward-looking statements, and our actual results may differ substantially from those discussed in these forward-looking statements. 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.

Risk Factor Summary

Below is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading "Risk Factors" and should be carefully considered, together with other information in this Form 10-K and our other filings with the SEC, before making an investment decision regarding our common stock.

Risks Associated With Our Business:

- We have operated at a loss and will likely continue to operate at a loss for the foreseeable future.
- 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.
- If Orphazyme fails to successfully develop and commercialize arimoclomol, our business prospects will be materially adversely affected.
- 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.

Risks Associated With Drug Discovery and Development:

- If the projected development goals for our product candidates are not achieved in the expected time frames, the commercialization of our products may be delayed and our business prospects may suffer. Our financial projections also may prove to be materially inaccurate.
- 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.
- 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.
- We may be unable to protect our intellectual property rights, which could adversely affect our ability to compete effectively.
- 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.
- 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.
- Any products that we develop or are sold or licensed may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which could have a material adverse effect on our business.
- Healthcare legislative reform measures could hinder or prevent the commercial success of our products and product candidates.
- 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.
- We will be required to pay substantial milestone and other payments relating to the commercialization of our products.
- The COVID-19 pandemic could adversely impact our business and prospects, including active and planned clinical trials by ImmunityBio and Orphazyme.
- 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.
- Drug discovery is a complex, time-consuming and expensive process, and we may not succeed in creating new product candidates.
- We have a limited operating history in drug discovery, which is inherently risky, and we may not succeed in addressing these risks.

General Risk Factors:

- We are subject to intense competition, and we may not compete successfully.
- We are subject to potential liabilities from clinical testing and future product liability claims.
- 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.
- The impact and results of our exploration of any strategic alternatives are uncertain and may not be successful.
- 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.
- Our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.
- You may experience future dilution as a result of future equity offerings or other equity issuances.
- Our outstanding options and warrants and the availability for resale of the underlying shares may adversely affect the trading price of our common stock.
- We cannot assure investors that our internal controls will prevent future material weaknesses.
- We could be subject to legal actions that could adversely affect our financial condition.
- Our anti-takeover measures may make it more difficult to change our management, or may discourage others from acquiring us, and thereby adversely affect stockholder value.
- 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.
- We may issue preferred stock in the future, and the terms of the preferred stock may reduce the value of our common stock.
- We do not expect to pay any cash dividends on our common stock.

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 \$13.0 million for the year ended December 31, 2021 and \$6.7 million for the year ended December 31, 2020 and had an accumulated deficit as of December 31, 2021 of \$483.9 million. We are likely to continue to incur losses unless and until we are able to earn milestones and royalties from our existing licensing 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. These factors individually and collectively raise a substantial doubt about our ability to continue as a going concern.

Our independent registered public accounting firm has included an explanatory paragraph in its report as of and for the year ended December 31, 2021 expressing substantial doubt in our ability to continue as a going concern based on our recurring and continuing losses from operations and our need for additional funding to continue operations. Our consolidated financial statements do not include any adjustments that might result from the outcome of this going concern uncertainty and have been prepared under the assumption that we will continue to operate as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. If we are unable to continue as a going concern, we may be forced to liquidate our assets which would have an adverse impact on our business and developmental activities. In such a scenario, the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements. The reaction of investors to the inclusion of a going concern statement by our independent registered public accounting firm and our potential inability to continue as a going concern may materially adversely affect our stock price and our ability to raise new capital or to enter into strategic alliances.

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. In July 2021, we were able raise some capital through the sale of common stock registered under our "shelf" registration on Form S-3, as well as through the related private placement of certain warrants and the preferred investment option. We will likely need to raise additional capital to fund our general and administrative expenses and, if we determine to develop products based on Centurion's LADR™ technology platform, we will need to raise additional capital to fund development of product candidates, prepare, file, prosecute, maintain, enforce and defend patent and other proprietary rights, and develop and implement sales, marketing and distribution capabilities. However, we have no available authorized common shares to issue, making capital raising significantly more challenging.

At December 31, 2021, we had cash and cash equivalents of approximately \$6.8 million. Management believes that our current resources will be sufficient to fund our operations through December 31, 2022. This estimate is based, in part, upon our currently projected expenditures for 2022 and the first three months of 2023 of approximately \$6.5 million (unaudited) to fund our 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 current equity holders. 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.

On March 15, 2022, CytRx Corporation (the “Company”) held a special meeting of stockholders (the “Special Meeting”), which was originally opened and subsequently adjourned on September 23, 2021, at which meeting the Company’s stockholders, by an affirmative vote of the majority of the Company’s outstanding shares of capital stock, approved the amendment to the Company’s Restated Certificate of Incorporation (the “Certificate of Incorporation”) to effect an increase in the number of shares of authorized common stock, par value \$0.001 per share, from 41,666,666 shares to 62,393,940 shares, and to make a corresponding change to the number of authorized shares of capital stock in order to comply with the Company’s contractual obligations under a securities purchase agreement entered into on July 13, 2021 (the “Authorized Share Increase Amendment”). The number of shares of authorized preferred stock of the Company remains unchanged.

On March 15, 2022, the Company filed a Certificate of Amendment to Restated Certificate of Incorporation (the “Certificate of Amendment”) with the Secretary of State of Delaware to effect the Authorized Share Increase Amendment.

As of March 23, 2022, we have no additional shares of common stock that are authorized and unissued. 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 of shares.

If Orphazyme fails to successfully develop and commercialize arimoclochol, our business prospects will be materially adversely affected.

In 2011, CytRx sold the rights to arimoclochol and iroxadine, based on molecular chaperone regulation technology, to Orphazyme in exchange for a one-time, upfront payment and the right to receive up to a total of \$120 million in milestone payments upon the achievement of certain pre-specified regulatory and business milestones, as well as single- and double-digit royalty payments based on a specified percentage of any net sales of products derived from arimoclochol. Orphazyme announced in March and May of 2021 that pivotal phase 3 clinical trials assessing the safety and efficacy of arimoclochol in treating ALS and IBM, respectively, did not meet their primary or secondary endpoints and that it has ceased development of, and its pursuit of regulatory approvals for, arimoclochol for such indications. As a result, the maximum amount that we are eligible to receive in future milestone payments under the agreement with Orphazyme is now approximately \$100 million. There can be no assurance that said amount or any portion thereof will be realized, as such realization is contingent upon certain regulatory approvals of arimoclochol for indications other than the prevention or treatment of ALS or stroke and other contingencies over which we have no control. Orphazyme is testing arimoclochol in NPC and Gaucher disease. On June 18, 2021, Orphazyme announced it received a CRL from the FDA, identifying certain deficiencies in the NDA that precluded its approval. In particular, Orphazyme announced that the CRL was issued based on the need for additional confirmatory evidence, as well as additional qualitative and quantitative evidence to further substantiate the validity of the 5-domain NPC Clinical Severity Scale (“NPCCSS”), specifically the swallow domain, in the context of a lack of significant findings when using the FDA’s preferred and recommended statistical approach. In late October 2021, Orphazyme announced it held a Type A meeting with the FDA where the FDA recommended that Orphazyme submit additional data, information and analyses to address certain topics in the CRL and engage in further interactions with the FDA to identify a pathway to resubmission. The FDA concurred with Orphazyme’s proposal to remove the cognition domain from the NPCCSS endpoint, with the result that the primary endpoint is permitted to be recalculated using the 4-domain NPCCSS, subject to the submission of additional requested information which Orphazyme intends to provide. The FDA also affirmed that it would require additional *in vivo* or pharmacodynamic (PD)/pharmacokinetic (PK) data. Orphazyme is planning to request a Type C Meeting with the FDA in the second quarter of 2022 to discuss its progress in redressing the deficiencies identified in the CRL and plans for resubmission. Subject to FDA’s feedback in the Type C meeting and any other pertinent discussions with the regulatory body, Orphazyme plans to resubmit the NDA for arimoclochol in the second half of 2022. However, there are a number of uncertainties inherent in clinical investigation that may hinder Orphazyme’s plans for generating additional data, meeting with FDA, and/or resubmitting the NDA. And, even if Orphazyme properly implements FDA’s feedback and resubmits the NDA with the additional confirmatory evidence and qualitative and quantitative data that FDA requested, there is no guarantee that FDA will approve the resubmitted version of the NDA.

Orphazyme has also submitted a MAA with the EMA. In February 2022, Orphazyme announced that they were notified by the CHMP of a negative trend vote on the MAA for arimoclomol in NPC following an oral explanation. The trend vote indicates that the CHMP's current orientation is to not approve arimoclomol when it convenes by the end of March 2022. Orphazyme considers it unlikely that this position will change before the formal vote is undertaken in March 2022. They will assess their strategic options and provide an update to the market at the applicable time

The potential revenue from our arrangement with Orphazyme is based on contingent payments, which will depend upon Orphazyme's ability to achieve regulatory approvals and successfully market and sell products derived from arimoclomol. Our ability to realize the maximum amount of aggregate milestone payments initially set forth in our agreement with Orphazyme has been reduced by approximately \$20 million due to Orphazyme's unsuccessful pivotal studies of arimoclomol for ALS and IBM and subsequent decision to cease arimoclomol's development with regard such indications. While Orphazyme has progressed further in connection with its development of arimoclomol for NPC (than for ALS or IBM), its efforts to obtain the FDA and EMA approvals needed to lawfully market arimoclomol for NPC in the United States and the EU, respectively, have been unsuccessful thus far and may never succeed. We will not be involved in this process and will depend entirely on Orphazyme, which may fail to develop or effectively commercialize products derived from arimoclomol for many reasons, including if 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 arimoclomol through clinical development, regulatory approval and commercialization;
- cannot obtain the necessary regulatory approvals for arimoclomol; or
- decide to pursue a competitive drug candidate.

If Orphazyme does not obtain the regulatory approvals for arimoclomol that are necessary to trigger the corresponding milestone payments to us under our agreement, or if their research and development or commercialization efforts are, otherwise, unsuccessful, we will not realize the anticipated commercial benefits of the arrangement and our business prospects will be materially and adversely affected.

If ImmunityBio fails to successfully develop aldoxorubicin or our exclusive licensing arrangement with ImmunityBio is otherwise unsuccessful, our business prospects will be materially and 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 single- and double-digit 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, commercialize 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 for many reasons including if 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.

Risks Associated With Drug Discovery and Development

If the projected development goals for our product candidates are not achieved in the expected time frames, 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 or the control of companies that have licensed or purchased our product candidates. If these milestones or financial projections are not met, the development and commercialization of our product candidates 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. None of our product candidates in development or licensed or sold to third parties have received regulatory approval.

Numerous factors could affect the timing, cost or outcome of 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 making us eligible to receive milestone or 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 performed 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 regulatory approval was obtained, regulatory authorities may approve any product candidates for fewer or more limited indications than requested, may not approve the intended price for such 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 the product candidates that we develop, have sold or licensed.

Furthermore, even if regulatory approvals are obtained, 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 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. 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 and Australia. Accordingly, our development partner may ultimately be unable to provide the FDA and/or other U.S. and foreign regulatory authorities with satisfactory data on clinical safety and efficacy sufficient to obtain approval from the FDA of aldoxorubicin for any indication.

Further delays may occur in clinical trials of 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. 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. 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.

The successful commercialization of our product candidates that are approved for marketing in the United States, if any, and/or any other products that we or our partners may commercialize in the future will likely depend, in-part, on the coverage and reimbursement policies of third-party payors, which, if unfavorable, could have a material adverse effect on our business.

The commercial success of our product candidates that are approved for marketing in the United States, if any, as well as any other products that we may or our partners may commercialize in the future, may depend, in significant part, on the extent to which such products will be covered and reimbursed by third-party payors, including government healthcare programs, such as Medicare and Medicaid, private insurers, and managed care organizations. Patients for whom prescription drugs are prescribed and prescribing practitioners generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Without adequate coverage and reimbursement, patients and providers are unlikely to use or prescribe any products that we or our partners may commercialize or from which we may, otherwise, generate revenue in connection with commercial sales.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, there is no uniform policy of coverage and reimbursement. Accordingly, third-party payors, including private insurers and governmental payors, such as Medicare and Medicaid, 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, as well as certain people under 65 with disabilities and individuals suffering from end-stage renal disease. The Medicaid program, which varies from state-to-state, covers eligible individuals and families who have limited financial means. The Medicare and Medicaid programs are increasingly 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 and any other products we or our partners may commercialize or to which we may have commercialization rights or interests.

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, and most, if not all, payors will deny coverage for products used or administered for an unapproved indication. Third-party payors also typically refuse to cover and reimburse for experimental procedures and devices. Furthermore, third-party payors are increasingly challenging the prices charged for medical products and services. And, the U.S. government and state legislatures have shown significant interest in implementing healthcare cost-containment programs, including price controls, restrictions on reimbursement, discount and rebate requirements, and requirements for substitution of generic products. Such measures, and the enactment of any more restrictive updates thereto and/or new measures could further limit our potential profitability and commercial success in connection with any products we or our partners may market in the United States. We cannot predict whether, or the extent to which, government and/or private payors will cover any products we or our partners may commercialize in the future, and there can be no assurances that such coverage and reimbursement levels, as applicable, will be sufficient to allow us to profit from the commercial sale of such product(s) in light of our costs from development and other related activities and any current or future arrangements with our development and/or commercialization partners.

Any products that we develop or are sold or licensed may become subject to unfavorable pricing regulations and/or third-party coverage and reimbursement policies, which could have a material adverse effect on our business.

Our product candidates are intended to be marketed 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.

Such drugs will likely 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 (the “ACA”), as amended by the Health Care and Education Reconciliation Act, or collectively, the “Healthcare Reform Law,” became law in the United States. It contains a number of provisions regarding health insurance, the provision of healthcare, conditions to reimbursement for healthcare services provided to Medicare and Medicaid patients, and other healthcare policy reforms. Through the law-making process, substantial changes have been and continue to be made to the current system for paying for healthcare in the United States, including changes made to extend medical benefits to certain Americans who lacked insurance coverage and to contain or reduce healthcare costs (such as by reducing or conditioning reimbursement amounts for healthcare services and drugs, and imposing additional taxes, fees, and rebate obligations on pharmaceutical and medical device companies). This legislation was one of the most comprehensive and significant reforms ever experienced by the United States in the healthcare industry and has significantly changed the way healthcare is financed by both governmental and private insurers. This legislation has impacted the scope of healthcare insurance and incentives for consumers and insurance companies, among others. Additionally, the Healthcare Reform Law’s provisions were designed to encourage providers to find cost savings in their clinical operations. Pharmaceuticals represent a significant portion of the cost of providing care. This environment has caused changes in the purchasing habits of consumers and providers and resulted in specific attention to the pricing negotiation, product selection and utilization review surrounding pharmaceuticals. This attention may result in any products we may commercialize or promote in the future, and/or our therapeutic candidates, as applicable, being chosen less frequently or subject to substantially lowered pricing.

These structural changes could entail further modifications to the existing system of private payors and government programs (such as Medicare, Medicaid, and the State Children’s Health Insurance Program), creation of government-sponsored healthcare insurance sources, or some combination of both, as well as other changes. Restructuring the coverage of medical care in the U.S. could impact the reimbursement for prescribed drugs and pharmaceuticals, including our current commercial products, those we and our development or commercialization partners are currently developing or those that we may commercialize or promote in the future. If reimbursement for the products we currently commercialize or promote, any product we may commercialize or promote, or approved therapeutic candidates is substantially reduced or otherwise adversely affected in the future, or rebate obligations associated with them are substantially increased, it could have a material adverse effect on our reputation, business, financial condition or results of operations.

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 United States, 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 federal and state healthcare laws and regulations relating to our current and/or future operations, 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, the federal government has identified relationships between drug companies (and other medical-product manufacturers) and healthcare providers as particularly susceptible to fraud and abuse and, thus, our relationships may be subject to heightened regulatory scrutiny, particularly once we have one or more products on the U.S. market, if ever. Further, many of the applicable healthcare laws and regulations are subject to varying and/or evolving interpretations, which makes achieving and maintaining consistent compliance more difficult.

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 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.

The ongoing 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 COVID-19 pandemic has, from time to time, led to government-imposed quarantines, limitations on business activity and shelter-in-place mandates to mitigate or contain the virus, and has contributed to financial market volatility and uncertainty, significant disruptions in general commercial activity and the global economy.

As the COVID-19 pandemic continues to evolve, the companies which we 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 the COVID-19 pandemic, which could cause delays in our 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 or 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 extent to which the COVID-19 pandemic may impact our business and prospects will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the pandemic, new variants of the coronavirus, 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.

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. 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.

General Risk Factors

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

As a result, these competitors may:

- succeed in developing competitive products sooner than us or our strategic partners or licensees;
- obtain FDA or foreign governmental approvals for their products before we can obtain approval of any of our products;
- obtain patents that block or otherwise inhibit the development and commercialization of our product candidate candidates;
- develop products that are safer or more effective than our products;
- devote greater resources than us to marketing or selling products;
- introduce or adapt more quickly than us to new technologies and other scientific advances;
- introduce products that render our products obsolete;
- withstand price competition more successfully than us or our strategic partners or licensees;
- negotiate third-party strategic alliances or licensing arrangements more effectively than us; and
- take better advantage than us of other opportunities.

We 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 and neurodegenerative 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.

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.

Global, market and economic conditions may negatively impact our business, financial condition and share price.

Concerns over inflation, geopolitical issues, the U.S. financial markets, foreign exchange rates, capital and exchange controls, unstable global credit markets and financial conditions and the COVID-19 pandemic, have led to periods of significant economic instability, declines in consumer confidence and discretionary spending, diminished expectations for the global economy and expectations of slower global economic growth going forward, and increased unemployment rates. Our general business strategy may be adversely affected by any such economic downturns, volatile business environments and continued unstable or unpredictable economic and market conditions. If these conditions continue to deteriorate or do not improve, it may make any necessary debt or equity financing more difficult to complete, more costly, and more dilutive. In addition, there is a risk that one or more of our current or future service providers and other partners could be negatively affected by difficult economic times, which could adversely affect our ability to attain our operating goals on schedule and on budget or meet our business and financial objectives.

In addition, we face several risks associated with international business and are subject to global events beyond our control, including war, public health crises, such as pandemics and epidemics, trade disputes, economic sanctions, trade wars and their collateral impacts and other international events. Any of these changes could have a material adverse effect on our reputation, business, financial condition or results of operations. There may be changes to our business if there is instability, disruption or destruction in a significant geographic region, regardless of cause, including war, terrorism, riot, civil insurrection or social unrest; and natural or man-made disasters, including famine, flood, fire, earthquake, storm or disease. In February 2022, armed conflict escalated between Russia and Ukraine. The sanctions announced by the United States and other countries, following Russia's invasion of Ukraine against Russia to date include restrictions on selling or importing goods, services or technology in or from affected regions and travel bans and asset freezes impacting connected individuals and political, military, business and financial organizations in Russia. The United States and other countries could impose wider sanctions and take other actions should the conflict further escalate. It is not possible to predict the broader consequences of this conflict, which could include further sanctions, embargoes, regional instability, geopolitical shifts and adverse effects on macroeconomic conditions, currency exchange rates and financial markets, all of which could impact our business, financial condition and results of operations.]

We may not be successful in hiring and retaining key employees, which may harm our business.

Our business is highly dependent upon the continued services of our senior management and key personnel. As such, our future success depends on our ability to identify, attract, hire or engage, retain, and motivate well-qualified personnel. Our operations require qualified personnel with expertise in pharmaceutical development and clinical research. We must compete for qualified individuals with numerous companies, universities, and other research institutions. Competition for such individuals is intense, and, when the need arises, we may not be able to hire the personnel necessary to support our efforts. There can be no assurance that these professionals will be available in the market, or that we will be able to retain existing professionals or to meet or to continue to meet their compensation requirements.

An overall tightening and increasingly competitive labor market in the U.S. employment market generally, especially in response to the COVID-19 pandemic, has been recently observed in the United States. Sustained labor shortage or increased turnover rates within our employee base, caused by the COVID-19 pandemic or as a result of general macroeconomic factors, could lead to increased costs, such as increased overtime to meet demand and increased wage rates to attract and retain employees, and could negatively affect our ability to efficiently operate and our overall business. If we are unable to hire and retain employees capable of performing at a high-level, or if mitigation measures we may take to respond to a decrease in labor availability, such as third-party outsourcing have unintended negative effects, our business could be adversely affected. An overall labor shortage, lack of skilled labor, increased turnover or labor inflation, caused by the COVID-19 pandemic or as a result of general macroeconomic factors, could have a material adverse impact on our operations, results of operations, liquidity or cash flows.]

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 have paid for any of such securities that you currently hold. 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 have paid for previously for shares of our common stock. To the extent we raise additional capital by issuing equity securities or obtaining borrowings convertible into equity, ownership dilution to existing stockholders may result and future investors may be granted rights superior to those of existing stockholders.

Our outstanding options, warrants, convertible preferred shares, preferred investment option and the availability for resale of the underlying shares may adversely affect the trading price of our common stock.

As of December 31, 2021, we had outstanding stock options to purchase 2,827,829 shares of our common stock at a weighted-average exercise price of \$4.92 per share and outstanding warrants to purchase 4,147 shares of common stock at a weighted-average exercise price of \$33.60 per share. In addition, there are 8,240 preferred shares outstanding that can be converted into 9,336,637 shares of common stock, as well as preferred investment options that can be exercised for up to 11,363,637 shares of common stock at an exercise price of \$0.88 per share. These outstanding convertible instruments could adversely affect our ability to obtain future financing or engage in certain mergers or other transactions, since the holders of these outstanding securities can be expected to exercise or convert them (as applicable) 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 these outstanding convertible instruments. For the life of these outstanding convertible instruments, 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 or conversion (as applicable) of these outstanding convertible instruments 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 or conversion price (as applicable), and increase the number of shares underlying those convertible instruments, which would have a dilutive effect on our stockholders.

We have registered with the SEC the resale by the holders of some of the shares of our common stock issuable upon exercise or conversion (as applicable) of our outstanding convertible instruments. 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 may be involved in legal proceedings that arise in the 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.

We must pay the first legal fees and other litigation expenses incurred up to the application retention, or deductible, amounts under our insurance policies, including our director's and officer's and other liability 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 our financial condition.

Our anti-takeover measures may make it more difficult to change our management, or may discourage others from acquiring us, and thereby adversely affect stockholder value.

We have a stockholder rights plan and provisions in our restated by-laws, as amended, that are intended to protect our stockholders' interests by encouraging anyone seeking control of our company to negotiate with our board of directors. These provisions may discourage or prevent a person or group from acquiring us without the approval of our board of directors, even if the acquisition would be beneficial to our stockholders.

We have a classified board of directors, which means that at least two stockholder meetings, instead of one, will be required to effect a change in the majority control of our board of directors. This applies to every election of directors, not just an election occurring after a change in control. The classification of our board increases the amount of time it takes to change majority control of our board of directors and may cause potential acquirers to lose interest in a potential purchase of us, regardless of whether our purchase would be beneficial to us or our stockholders. The additional time and cost to change a majority of the members of our board of directors makes it more difficult and may discourage our existing stockholders from seeking to change our existing management in order to change the strategic direction or operational performance of our company.

Our by-laws provide that directors may only be removed for cause by the affirmative vote of the holders of at least a majority of the outstanding shares of our capital stock then entitled to vote at an election of directors. This provision prevents stockholders from removing any incumbent director without cause. Our by-laws also provide that a stockholder must give us not fewer than 120 days but not more than 150 days' notice of a proposal or director nomination that such stockholder desires to present at any annual meeting or special meeting of our 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 by-law 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.

The Series C Certificate of Designation contains covenants that could limit our financing options and liquidity position, which would limit our ability to grow our business.

Covenants in the certificate of designation (the “Series C Certificate of Designation”) for our Preferred Stock (as defined below) impose operating and financial restrictions on us. These restrictions prohibit or limit our ability to, among other things:

- pay cash dividends to our stockholders, subject to certain limited exceptions;
- redeem or repurchase our common stock or other equity; or
- issue any classes of stock senior to the Preferred Stock in right of dividends, redemption or distribution of assets upon certain liquidation events.

These restrictions may limit our ability to obtain additional financing, withstand downturns in our business or take advantage of business opportunities.

We may issue additional classes of 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. In the past, we have issued shares of preferred stock, including shares of our Preferred Stock issued in 2021. 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 it may decline in value.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an “ownership change,” the corporation’s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes (such as research and development tax credits) to offset its post-change income and taxes may be limited. In general, an “ownership change” occurs if there is a cumulative change in our ownership by “5% shareholders” that exceeds 50 percentage points over a rolling three-year period. Similar rules may apply under state tax laws. As a result of a previous ownership change, our annual utilization of approximately \$67.6 million in federal net operating loss carryforwards became 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.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

We lease our headquarters in Los Angeles, California. The lease covers approximately 2,771 square feet of office and storage space and expires in February 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 is \$14,340, subject to an annual increase of 3.5 percent. We also lease additional storage space for approximately 540 square feet. This lease expires in February 2024, and requires us to make monthly payments of \$1,405, subject to annual increases of 2.5 percent. In March 2022, we entered into a sub-lease for our office space that provides for a monthly rental income of \$8,867, subject to an annual increase of 3.5%.

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, 2021, 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.

PART II

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

Market Information

Our common stock is traded on The 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. The high and low prices reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

	High	Low
Fiscal Year 2021:		
Fourth Quarter	\$ 0.83	\$ 0.45
Third Quarter	\$ 1.00	\$ 0.54
Second Quarter	\$ 3.21	\$ 0.89
First Quarter	\$ 0.83	\$ 0.45
Fiscal Year 2020		
Fourth Quarter	\$ 1.90	\$ 0.53
Third Quarter	\$ 0.72	\$ 0.45
Second Quarter	\$ 0.81	\$ 0.37
First Quarter	\$ 0.83	\$ 0.36

Holdings

On March 23, 2022, there were approximately 193 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, 2021, regarding securities authorized for issuance under our equity compensation plans:

Plan Category	(a) Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	(b) Weighted- Average Exercise Price of Outstanding Options, Restricted Stock, Warrants and Rights	Number of Securities Remaining Available for issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))
Equity compensation plans approved by our security holders:			
2008 Stock Incentive Plan	2,277,829	\$ 9.98	—
Equity compensation plans not approved by our security holders:			
2019 Stock Incentive Plan	550,000	\$ 0.26	—
Outstanding warrants (1)	4,167	\$ 33.60	—
Total	2,831,996	\$ 8.13	—

(1) The warrants shown were issued in discrete transactions from time to time as compensation for services rendered by consultants, advisors or other third parties, and do not include warrants sold in capital-raising transactions. The material terms of such warrants were determined based upon arm's-length negotiations with the service providers. The warrant exercise price approximates the market price of our common stock at or about the date of grant, and the warrants expire in March 2024. 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.

For more information on the 2008 Stock Incentive Plan and the 2019 Stock Incentive Plan, see “Item 11. Executive Compensation—2008 Stock Incentive Plan and the 2019 Plan Descriptions”.

Recent Issuances of Unregistered Securities

All sales of unregistered securities during the year ended December 31, 2021, were previously disclosed in a Quarterly Report on Form 10-Q or Current Report on Form 8-K.

Repurchase of Shares

We did not repurchase any of our shares during the year ended December 31, 2021.

Item 6. [RESERVED].

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™, 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 pre-clinical phase of development for its four LADR™ drug candidates, and for its albumin companion diagnostic (ACDx™). As a result of completing this work, operations taking place at the pre-clinical laboratory in Freiburg, Germany would no longer be needed and, accordingly, the lab was closed at the end of January 2019.

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

LADR Drug Discovery Platform and Centurion

Centurion’s LADR™ (Linker Activated Drug Release) technology platform is a discovery engine combining our expertise in linker chemistry and albumin biology to create a pipeline of anti-cancer molecules that will avoid unacceptable systemic toxicity while delivering highly potent agents directly to the tumor. They have created a “toolbox” of linker technologies that have the ability to significantly increase the therapeutic index of ultra-high potency drugs (10-1,000 times more potent than traditional 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™ 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™ (albumin companion diagnostic), was developed to identify patients with cancer who are most likely to benefit from treatment with the four LADR lead assets.

On March 9, 2022, Centurion was merged into the Company.

Business Strategy for LADR™ Platform

Currently, the Company continues to work on identifying partnership or financing opportunities for LADR™ ultra-high potency drug conjugates and their albumin companion diagnostic. We have concluded all research and development on LADR and its companion diagnostic and continue to focus on identifying partnership or financing opportunities.

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. As a result, the Company is no longer working on development of aldoxorubicin (ImmunityBio merged with NantKwest, Inc. in March 2021). 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. There can be no assurance that ImmunityBio will achieve such milestones, approvals or sales with respect to aldoxorubicin. ImmunityBio has initiated a Phase 2, randomized, three-cohort, open-label registrational-intent study for first-line and second-line treatment of locally advanced or metastatic pancreatic cancer, which includes aldoxorubicin. On October 13, 2021, ImmunityBio announced that the trial’s Cohort C was fully enrolled. In January 2022 at the ASCO Gastrointestinal Cancer Symposium, they reported that 27% of third-line or greater patients (17/63) remain on study and that the median overall survival in this highly advanced group of patients (who failed two to six prior lines of treatment) is 5.8 months (95% CI: 3.9, 6.9 months) exceeding the approximately three-month historical median overall survival. Of the 63 patients, 30 (48%) had progressed after two prior lines of therapy. Median overall survival in this group was 6.3 months (95% CI: 5.0, 9.8 months), more than doubling the historical overall survival. (Survival of three months as reported by Manax et al ASCO GI 2019). In Cohort C, four patients (7%) experienced treatment-related SAEs that included peripheral edema, pyrexia, anemia and atrial flutter. No treatment-related deaths were reported. Based on the strength of earlier data and the significant unmet medical need, ImmunityBio submitted an amendment to the FDA to increase enrollment in Cohort C and plan to meet with the FDA in 2022 to discuss a potential path for the approval of combination therapies for pancreatic cancer.

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 was 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.

ImmunityBio also lists ongoing clinical studies in head and neck and triple-negative breast cancer and has submitted a protocol with the FDA for glioblastoma; it is currently reviewing its options in STS.

Molecular Chaperone Assets (Orphazyme)

In 2011, CytRx sold the rights to arimoclomol and irovanadine, 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 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. As a result of Orphazyme's disclosure that the pivotal phase 3 clinical trial for arimoclomol in Amyotrophic Lateral Sclerosis did not meet its primary and secondary endpoints, the maximum amount that CytRx has the right to receive is now approximately \$100 million. Orphazyme is testing arimoclomol in Niemann-Pick disease Type C ("NPC") and Gaucher disease. Orphazyme has highlighted positive Phase 2/3 clinical trial data in patients with NPC and previously submitted a New Drug Application ("NDA") with the U.S. Food and Drug Administration (the "FDA"). On June 18, 2021, Orphazyme announced it had received a Complete Response Letter from the FDA indicating the need for additional data. In late October 2021, Orphazyme announced it held a Type A meeting with the FDA, at which the FDA recommended that Orphazyme submit additional data, information and analyses to address certain topics in the Complete Response Letter and engage in further interactions with the FDA to identify a pathway to resubmission. The FDA concurred with Orphazyme's proposal to remove the cognition domain from the NPC Clinical Severity Scale ("NPCCSS") endpoint, with the result that the primary endpoint is permitted to be recalculated using the 4- domain NPCCSS, subject to the submission of additional requested information which Orphazyme has publicly indicated that it intends to provide. To bolster the confirmatory evidence already submitted, the FDA affirmed that it would require additional in vivo or pharmacodynamic (PD)/pharmacokinetic (PK) data. Based on []. Orphazyme is planning to request a Type C Meeting with the FDA in the second quarter of 2022. Subject to discussions with the regulatory body, Orphazyme has publicly indicated that it plans to resubmit the NDA for arimoclomol in the second half of 2022.

Orphazyme had also submitted a Marketing Authorization Application ("MAA") with the European Medicines Agency (the "EMA"). In February 2022, Orphazyme announced that although they had received positive feedback from the Committee for Medicinal Products for Human Use ("CHMP") of the EMA, they were notified by the CHMP of a negative trend vote on the MAA for arimoclomol for NPC following an oral explanation. The trend vote indicates that the CHMP's current orientation is to not approve arimoclomol when it convenes by the end of March 2022. Orphazyme has publicly indicated that it considers it unlikely that this position will change before the formal vote is undertaken in April 2022. Orphazyme will assess its strategic options and provide an update to the market at the applicable time.

Research and Development

Expenditures for research and development activities related to continuing operations were \$0 in the year ended December 31, 2021 and \$0.8 million for the year ended December 31, 2020 or approximately 0% and 12%, 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 2022. 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.

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.

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:

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

The fair value of the Company's stock option and restricted stock grants is estimated using the Black-Scholes-Merton Option Pricing model, which uses certain assumptions related to risk-free interest rates, expected volatility, expected life of the stock options or restricted stock, and future dividends. Compensation expense is recorded based upon the value derived from the Black-Scholes-Merton Option Pricing model and based on actual experience. The assumptions used in the Black-Scholes-Merton Option Pricing model could materially affect compensation expense recorded in future periods.

Basic and Diluted Net Loss Per Share of Common Stock

Basic and diluted net loss per share of common stock is computed based on the weighted-average number of shares of common stock outstanding for the period. Diluted net income (loss) per share is computed by dividing the net income (loss) applicable to common stockholders by the weighted average number of shares of common stock outstanding plus the number of additional shares of common stock that would have been outstanding if all dilutive potential common stock had been issued using the treasury stock method. Potential shares of common stock are excluded from the computation when their effect is antidilutive. Common stock equivalents that could potentially dilute net loss per share in the future, and which were excluded from the computation of diluted loss per share, were as follows:

	As of December 31,	
	2021	2020
Options to acquire common stock	2,827,829	3,162,700
Warrants to acquire common stock	4,167	193,196
Convertible preferred stock	9,363,637	—
Preferred Investment option	11,363,637	—
	<u>23,559,270</u>	<u>3,355,896</u>

Liquidity and Capital Resources

Going Concern

The Company's consolidated financial statements have been presented on the basis that it will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. During the year ended December 31, 2021, the Company incurred a net loss of \$13,176,663, utilized cash in operations of \$12,308,890, and the Company had an accumulated deficit of \$484,075,711 as of December 31, 2021. In addition, the Company has no recurring revenue. As a result, management has concluded that there is substantial doubt about the Company's ability to continue as a going concern. The Company's consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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. 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. We have approximately \$1.3 million of contractual obligations in 2022 and expect to pay these out of the Company's balance sheet cash. We have no material contractual obligations beyond 2022.

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 some or all of our existing equity holders. 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

Cash Flows from Operating Activities

Net cash used in operating activities for the year ended December 31, 2021 was \$12.3 million, which was primarily the result of a net loss from operations of \$13.2 million, offset by \$0.9 million in net cash inflows associated with changes in assets and liabilities. The net cash inflows associated with changes in assets and liabilities were primarily due to increases of \$0.9 million of accrued expenses and other current liabilities, \$0.2 million of amortization of right-of-use asset and \$0.1 million of insurance receivable, offset by reductions of \$0.2 million of prepaid expenses and other current assets and \$0.2 million of decrease in lease liabilities.

Net cash used in operating activities for the year ended December 31, 2020 was \$6.1 million, which was primarily the result of a net loss from operations of \$6.7 million, offset by \$0.2 million of adjustments associated with changes in assets and liabilities. The net cash inflows associated with changes in assets and liabilities were primarily due to increases of \$0.2 million in accounts payable, \$0.2 million of amortization of right-of-use asset, offset by reductions of \$0.1 million of prepaid expenses and other current assets and \$0.1 million of decrease in lease liabilities. We also recognized stock based compensation expense of \$-0.3 million.

Cash Flows from Investing Activities

We purchased \$7,000 of fixed assets in the year ended December 31, 2021 and \$25,000 of fixed assets in the year ended December 31, 2020, and do not expect any significant capital spending during the next 12 months.

Cash Flows from Financing Activities

Net cash provided by financing activities for the year ended December 31, 2021 was \$9.1 million, \$9.2 million of which is related to the sale of our common stock, Series C 10% Convertible Preferred Stock and preferred investment options described in Note 2 of our audited financial statements contained in this Annual Report and \$0.1 million from the exercise of stock options, offset slightly by \$0.2 million paid in respect of preferred stock dividend. In the year December 31, 2020, stock options were exercised, resulting in a cash infusion of \$39,000.

The registration rights agreement entered into between us and the Investor on July 13, 2021, contains a triggering event which would require us to pay to any holder of the Preferred Stock an amount in cash, as partial liquidated damages and not as a penalty, equal to the product of 2.0% multiplied by the aggregate subscription amount paid by such holder for shares of Series C Preferred Stock pursuant to the Purchase Agreement; provided, however, that such partial liquidated damages shall not exceed 24% of the aggregate subscription amounts paid by such holders pursuant to the Purchase Agreement or \$1,977,600. If we fail to pay any partial liquidated damages within seven days after the date payable, we will be required to pay interest on any such amounts at a rate equal to the lesser of 18% per annum or the maximum rate permitted by applicable law. We have been subject to the payment of such partial liquidated damages since September 2021. See "Results of Operations – Liquidated Damages".

We continue to evaluate potential future sources of capital, as we do not currently have commitments from any third parties to provide us with additional capital and we may not be able to obtain future financing on favorable terms, or at all. The results of our technology licensing efforts and the actual proceeds of any fund-raising activities will determine our ongoing ability to operate as a going concern. Our ability to obtain future financings through joint ventures, product licensing arrangements, royalty sales, equity financings, grants or otherwise is subject to market conditions and our ability to identify parties that are willing and able to enter into such arrangements on terms that are satisfactory to us. Depending upon the outcome of our fundraising efforts, the accompanying financial information may not necessarily be indicative of our future financial condition. Failure to obtain adequate financing would adversely affect our ability to operate as a going concern.

There can be no assurance that we will be able to generate revenues from our product candidates and become profitable. Even if we become profitable, we may not be able to sustain that profitability.

Results of Operations

We incurred a net loss of \$13.2 million and \$6.7 million for the years ended December 31, 2021 and 2020, respectively.

During the years ended December 31, 2021 and 2020, 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.

We incurred no research and development expenses during the year ended December 31, 2021 and research and development expenses of \$800,000 during the year ended December 31, 2020.

General and Administrative

	Year Ended December 31,	
	2021	2020
	(In thousands)	
General and administrative expenses	\$ 5,966	\$ 5,673
Employee stock and stock option expense	—	328
Total	<u>\$ 5,966</u>	<u>\$ 6,001</u>

General and administrative expenses include all administrative salaries and general corporate expenses, including legal expenses associated with the prosecution of our intellectual property. Our general and administrative expenses, excluding common stock, stock options and warrants issued, were \$6.0 million and \$5.7 million in the years ended December 31, 2021 and 2020, respectively.

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 the years ended December 31, 2021 and 2020, we had no such expense. We recorded employee stock option expense of \$0 and \$0.3 million in the years ended December 31, 2021 and 2020, respectively.

Settlement with former Chief Executive Officer

On January 3, 2022, in connection with the Separation Agreement, Steven A. Kriegsman, who served as the Chairman and Chief Executive Officer of CytRx Corporation, departed from his roles as an officer of the Company and the Chairman of the Company's board of directors. Mr. Kriegsman's departure as Chairman of the Board was not in connection with any disagreement between Mr. Kriegsman and the Company, its management, the Board or any committee of the Board on any matter relating to the Company's operations, policies or practices, or any other matter.

In connection with the execution of the Separation Agreement, Mr. Kriegsman's existing executive employment agreement, as amended (the "**Prior Employment Agreement**"), was terminated; provided, however, that certain surviving customary confidentiality provisions and milestone and royalty payments as defined in the Prior Employment Agreement remain in full force and effect. Pursuant to the Prior Employment Agreement and the Separation Agreement, Mr. Kriegsman received a lump sum cash payment equal to approximately \$6.0 million.

Depreciation and Amortization

Depreciation and amortization expenses for the years ended December 31, 2021 and 2020 were approximately \$14,000 and \$29,000, respectively. The depreciation expense reflects the depreciation of our equipment and furnishings.

Liquidated Damages

On July 13, 2021, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with a single institutional investor (the "Investor") for aggregate gross proceeds of \$10 million and net proceeds of approximately \$9.2 million. The transaction closed on July 16, 2021. Under the Purchase Agreement, the Company sold and issued (i) 2 million shares of its common stock at a purchase price of \$0.88 per share for total gross proceeds of approximately \$1.76 million in a registered direct offering (the "Registered Direct Offering") and (ii) 8,240 shares of Preferred Stock at a purchase price of \$1,000 per share, for aggregate gross proceeds of approximately \$8.24 million, in a concurrent private placement (the "Private Placement" and, together with the Registered Direct Offering, the "July 2021 Offerings"). The shares of the Preferred Stock are convertible, upon shareholder approval as described below, into an aggregate of up to 9,363,637 shares of common stock at a conversion price of \$0.88 per share. CytRx also issued to the Investor an unregistered preferred investment option (the "Preferred Investment Option") that allows for the purchase of up to 11,363,637 shares of common stock for additional gross proceeds of approximately \$10 million if the Preferred Investment Option is exercised in full. The Preferred Investment Option has a term equal to five and one-half years commencing upon the Company increasing its authorized common stock following shareholder approval.

In connection with the July 2021 Offerings, the Company entered into a registration rights agreement, dated as of July 13, 2021 (the “Registration Rights Agreement”), with the investor named therein, pursuant to which the Company will undertake to file, within five calendar days of the date of the filing of the proxy statement seeking the Stockholder Approval, a resale registration statement to register the shares of common stock issuable upon: (i) the conversion of the Preferred Stock sold in the Private Placement and (ii) the exercise of the Preferred Investment Option (collectively, the “Registrable Securities”); and to cause such registration statement to be declared effective under the Securities Act as promptly as possible after the filing thereof, but in any event no later than 75 days following the pricing date of this offering, or no later than 105 days following such date in the event of a “full review” by the SEC, and shall use its reasonable best efforts to keep such registration statement continuously effective under the Securities Act until the date that all Registrable Securities covered by such registration statement have been sold or are otherwise able to be sold pursuant to Rule 144.

The Registration Rights Agreement provides for liquidated damages to the extent that the Company does not file or maintain a registration statement in accordance with the terms thereof. The Registration Rights Agreement contains a triggering event which would require us to pay to any holder of the Preferred Stock an amount in cash, as partial liquidated damages and not as a penalty, on a monthly basis equal to the product of 2.0% multiplied by the aggregate subscription amount paid by such holder for shares of Preferred Stock pursuant to the Purchase Agreement; provided, however, that such partial liquidated damages shall not exceed 24% of the aggregate subscription amounts paid by such holders pursuant to the Purchase Agreement, or \$1,977,600. If we fail to pay any partial liquidated damages within seven days after the date payable, we will be required to pay interest on any such amounts at a rate equal to the lesser of 18% per annum or the maximum rate permitted by applicable law.

The Company was required to hold a special shareholders meeting to approve an increase in authorized common shares to allow for conversion of preferred shares. At the first such meeting, held on September 23, 2021, the proposal was not approved by shareholders. On March 15, 2022, the Company held a special meeting of stockholders, which was originally opened and subsequently adjourned on September 23, 2021, at which meeting the Company’s stockholders, by an affirmative vote of the majority of the Company’s outstanding shares of capital stock, approved the amendment to the Company’s Restated Certificate of Incorporation to effect an increase in the number of shares of authorized common stock, par value \$0.001 per share, from 41,666,666 shares to 62,393,940 shares, and to make a corresponding change to the number of authorized shares of capital stock in order to comply with the Company’s contractual obligations under a securities purchase agreement entered into on July 13, 2021 (the “Authorized Share Increase Amendment”). The number of shares of authorized preferred stock of the Company remains unchanged.

On March 15, 2022, the Company filed a Certificate of Amendment to Restated Certificate of Incorporation with the Secretary of State of Delaware to effect the Authorized Share Increase Amendment.

Since the proposal was not approved on September 23, 2021, the Company was liable for liquidated damages in the monthly amount of \$164,800, up to a maximum of approximately \$2 million, or twelve-monthly payments. In 2021, the Company made three monthly payments and has accrued additional payments through March 15, 2022, of \$615,000, for a total of approximately \$1.1 million. On March 15, 2022, the necessary proposal was approved by the shareholders and it is anticipated that there will no longer be any further liquidated damages beyond the end of March 2022. There were no such payments in 2020.

Interest Income

Interest income was \$17,000 in the year ended December 31, 2021 and \$0.1 million in the year ended December 31, 2020. 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.

Known Trends, Events and Uncertainties

The future events that would have the most material impact on the Company relate to the Registration Rights Agreement the Company entered into on July 13, 2021, whereby we are required to pay as partial liquidated damages an amount not to exceed \$1,977,600 up until the Company has and maintains an effective registration statement in accordance with the terms of the Registration Rights Agreement. It is anticipated however that there will be no further payments due beyond the end of March 2022. In addition, under the terms of the Securities Purchase Agreement entered into on July 13, 2021, we are required to pay, on a quarterly basis, a 10% dividend on the outstanding shares of Series C Preferred Stock, with an outstanding balance of \$8,240,000 as of December 31, 2021.

Recently Adopted Accounting Pronouncements

In June 2016, the FASB issued ASU No. 2016-13, Credit Losses - Measurement of Credit Losses on Financial Instruments (“ASC 326”). The standard significantly changes how entities will measure credit losses for most financial assets, including accounts and notes receivables. The standard will replace today’s “incurred loss” approach with an “expected loss” model, under which companies will recognize allowances based on expected rather than incurred losses. Entities will apply the standard’s provisions as a cumulative-effect adjustment to retained earnings as of the beginning of the first reporting period in which the guidance is effective. The standard is effective for interim and annual reporting periods beginning after December 15, 2019. The adoption of ASU 2016-13 is not expected to have a material impact on the Company’s financial position, results of operations, and cash flows.

Other recent authoritative guidance issued by the FASB (including technical corrections to the ASC), the American Institute of Certified Public Accountants, and the Securities and Exchange Commission (“SEC”) did not, or are not expected to, have a material impact on the Company’s consolidated financial statements and related disclosures.

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, 2021, it would not have had a material effect on our results of operations or cash flows for that period.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our consolidated financial statements and notes thereto as of December 31, 2021 and 2020, and for the years ended December 31, 2021 and 2020, 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

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, 2021, 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, 2021, as described further below.

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, 2021. 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, 2021.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the year ended December 31, 2021 that have materially affected, or are reasonably likely to have a material affect, our internal control over financial reporting.

Item 9B. OTHER INFORMATION

None.

Item 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

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

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

Name ⁽¹⁾	Age	Class of Director ⁽²⁾	Position
Louis Ignarro, Ph.D.	80	I	Chairman of the Board ⁽³⁾⁽⁴⁾
Joel Caldwell	66	III	Lead Director ⁽³⁾⁽⁴⁾
Jennifer K Simpson, Ph.D.	53	III	Director
Stephen Snowdy, Ph.D.	53	—	Chief Executive Officer
John Y. Caloz	70	—	Chief Financial Officer and Senior Vice-President

- (1) Dr. Ignarro is contractually obligated to step down as a director of the Board prior to the 2022 annual meeting of our stockholders.
- (2) Our Class I director serves until the 2022 annual meeting of our stockholders; our Class II director serves until the 2023 annual meeting of our stockholders, and our Class III directors serve until the 2024 annual meeting of our stockholders.
- (3) Members of our Audit Committee. Mr. Caldwell is Chairman of the Committee.
- (4) Members of our Compensation Committee. Dr. Ignarro is Chairman of the Committee.

Louis Ignarro, Ph.D. has been a director since July 2002 and was appointed Chairman of the Board on January 3, 2022. 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. Dr. Ignarro has agreed to not stand for re-election at the 2022 Annual Meeting.

Joel Caldwell joined our Board of Directors on July 12, 2017. Mr. Caldwell brings more than 30 years of experience in tax matters, finance, and internal auditing. Mr. Caldwell 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, Mr. Caldwell received a Bachelor of Science degree in Accounting and Finance, also from the University of California at Berkeley. Mr. Caldwell 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. Mr. Caldwell is a member of both the American Institute of Certified Public Accountants and the California Society of Certified Public Accountants. Mr. Caldwell was appointed Lead Director on January 3, 2022.

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.

Jennifer Simpson, Ph.D. joined our board of directors in July 2021. Dr. Simpson serves as President and Chief Executive Officer and as a member of the board of directors of Panbela Therapeutics since July 2020. She most recently served as President and Chief Executive Officer and as a member of the board of directors of Delcath Systems, Inc. from 2015 to June 2020. She had previously held various other leadership roles at Delcath since 2012. From 2011 to 2012, Dr. Simpson served as Vice President, Global Marketing, Oncology Brand Lead at ImClone Systems, Inc. (a wholly owned subsidiary of Eli Lilly and Company), where she was responsible for all product commercialization activities and launch preparation for one of the late-stage assets. From 2009 to 2011, Dr. Simpson served as Vice President, Product Champion and from 2008 to 2009 as the Associate Vice President, Product Champion for ImClone's product Ramucirumab. From 2006 to 2008, Dr. Simpson served as Product Director, Oncology Therapeutics Marketing at Ortho Biotech (now Janssen Biotech), a Pennsylvania-based biotech company that focuses on innovative solutions in immunology, oncology and nephrology. Earlier in her career, Dr. Simpson spent over a decade as a hematology/oncology nurse practitioner and educator. Dr. Simpson has served on the board of directors and nominating and corporate governance committee of Eagle Pharmaceuticals, Inc. since August 2019. has been a director since July 2002 and has served as the Chairman of the Board's Compensation Committee since December 2016. Dr. Simpson's experience in the field of clinical development and oncology will be very helpful to the Board and the Company.

Stephen Snowdy, Ph.D. was appointed Chief Executive Officer on January 3, 2022, effective January 10, 2022. Dr. Snowdy is a scientist, serial entrepreneur and medical venture capitalist with two decades of experience in life science investing and executive management. Dr. Snowdy joins from Visioneering Technologies, Inc. (ASX: VTI), where he was Chief Executive Officer and Executive Director. Dr. Snowdy previously served as Chief Executive Officer at Abby Med LLC, a start-up pharmaceutical company dedicated to the development of a novel class of cancer drugs. Prior to that, Dr. Snowdy was Chairman and Chief Executive Officer of Calosyn Pharma, Inc., a Phase 2 osteoarthritis company, and was a partner for several years at a top-tier medical venture capital firm. Dr. Snowdy simultaneously earned a PhD in Neurobiology and an MBA from the University of North Carolina. Dr. Snowdy studied Chemical Engineering and Chemistry at the University of Florida, where he also completed two years of postbaccalaureate study in cardiopharmacology. His academic training followed service in the United States Navy Special Forces.

John Y. Caloz joined us in October 2007 as our Chief Accounting Officer. In January 2009, Mr. Caloz was named Chief Financial Officer and in August of 2020 was appointed Senior Vice-President. Mr. Caloz 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. Mr. Caloz 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.

Family Relationships

There are no family relationships among our directors and executive officers.

Diversity

Our board of directors 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 Board periodically reviews its composition in light of our changing requirements, its assessment of its performance, and the input of stockholders and other key constituencies. The Board of Directors 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, they seek 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.

Corporate Governance

Board Committees, Meetings and Attendance

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 currently has two committees, the Audit Committee, in accordance with section 3(a)(58)(A) of the Exchange Act of 1934, as amended, and the Compensation Committee. The Audit Committee consists of Mr. Caldwell and Dr. Ignarro. The Chairman of the Audit Committee is Mr. Caldwell. The Compensation Committee consists of Dr. Ignarro and Mr. Caldwell. Dr. Ignarro is the Chairman of the Compensation Committee. The Audit Committee and the Compensation Committee 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 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 and Mr. Caldwell are “independent” under the current independence standards of both The OTC Market and the SEC.

In the year ended December 31, 2021, the Board met six times, the Audit Committee met four times and the Compensation Committee met once.

Section 16(a) Beneficial Ownership Reporting Compliance

Delinquent Section 16(a) Reports

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. To our knowledge, based solely on our review of copies of reports we have received and written representations from certain reporting persons, we believe that there was one delinquent filer. Dr. Simpson was deemed a director of the Company on July 29, 2021, and the Form 3 was not filed until August 11, 2021. Other than the aforementioned delinquent Section 16(a) report, we believe our directors and executive officers and greater than 10% shareholders for the year ended December 31, 2021 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 January 3, 2022, our board of directors appointed Dr. Ignarro as Chairman of the Board. The Chairman of the Board presides at all meetings of our Board (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 by-laws. On March 9, 2022, the Company announced that Dr. Ignarro will not stand for re-election at the 2022 Annual Meeting.

In January 2022, Mr. Caldwell 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 the years ended December 31, 2021 and 2020 by Steven A. Kriegsman and John Y. Caloz, who were considered our “named executive officers” for the year ended December 31, 2021.

Summary Compensation Table

Name and Principal Position	Year	Salary (\$)	Bonus (\$)(2)	Option Awards (\$)	All Other Compensation (\$)(3)(4)	Total (\$)
Steven A. Kriegsman(1) Chief Executive Officer	2021	850,000	150,000	—	6,013,700	7,013,700
	2020	850,000	150,000	—	13,700	1,013,700
John Y. Caloz Chief Financial Officer, Treasurer and Senior Vice-President	2021	400,000	100,000	—	—	500,000
	2020	400,000	100,000	—	—	500,000

(1) Mr. Kriegsman’s resigned from his position as Chief Executive Officer as of January 3, 2022.

(2) Bonuses to the named executive officers reported above were paid in December of the applicable year.

(3) Mr. Kriegsman received a Settlement payment of \$6 million, which was remitted to the payroll service in December, 2021 and paid to Mr. Kriegsman on January 3, 2022.

(4) \$13,700 represents life insurance premiums.

Outstanding Equity Awards at Fiscal Year-End

The following table sets forth outstanding equity awards held by our named executive officers as of December 31, 2021 issued under our 2008 Plan and our 2019 Plan:

Name	Number of Securities Underlying Options Exercisable	Number of Securities Underlying Unexercised Options	Option Exercise Price (\$)	Option Expiration Date
Steven A. Kriegsman	208,334		1.75	12/14/27
President and Chief Executive Officer	775,194 ⁽²⁾		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 ⁽¹⁾		27.96	12/09/23
	12,363		14.76	3/07/23
	83,334		10.98	12/10/22
John Y. Caloz	350,000		0.26	12/12/29
Chief Financial Officer, Treasurer and Senior Vice-President	58,333		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 ⁽¹⁾		27.96	12/09/23
	16,667		10.98	12/10/22

(1) 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.

(2) Represents restricted stock fully-vested at December 31, 2021. On December 15, 2017, Mr. Kriegsman was granted 387,597 shares of restricted stock, which vest over three years in equal annual amounts, and are now fully vested. On December 15, 2016, Mr. Kriegsman was granted 387,597 shares of restricted stock, which vest over three years in equal annual amounts, and are now fully vested.

2021 Grants of Plan-Based Awards

No stock options or restricted stock were granted in 2021.

2008 Stock Incentive Plan and the 2019 Stock Incentive Plan

The purpose of 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 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 and stockholders. The 2019 Plan was adopted by our board of directors on November 15, 2019.

2008 Plan and the 2019 Plan Descriptions

The 2008 Plan and the 2019 Plan, or the Plans, are administered by the Compensation Committee of our Board. 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 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.

Stock Options. The Compensation Committee is authorized to grant 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 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.

Employment Agreements and Potential Payment upon Termination or Change in Control

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 (Mr. Kriegsman exercised these options in 2020). 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 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.

On January 3, 2022 Mr. Kriegsman tendered his resignation as Chief Executive Officer. Upon his resignation, Mr. Kriegsman's employment agreement was terminated.

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 his employment agreement) 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 himself and his dependents in 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, Treasurer and Senior Vice-President pursuant to an employment agreement dated as of December 16, 2021 that is to expire on December 31, 2022. 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, but not to be less than \$100,000. 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, 2023.

Quantification of Termination Payments and Benefits

In January 2022, in connection with the execution of a General Release and Separation Agreement, Mr. Kriegsman's existing executive employment agreement, as amended (the "*Prior Employment Agreement*"), was terminated; provided, however, that certain surviving customary confidentiality provisions and milestone and royalty payments as defined in the Prior Employment Agreement remain in full force and effect. Pursuant to the Prior Employment Agreement and the Separation Agreement, Mr. Kriegsman received a lump sum cash payment equal to approximately \$6.0 million. This amount was accrued in the Company's financial results for 2021; however the payment was made in January 2022. In addition, Mr. Kriegsman will be entitled to receive continuing health benefits and life insurance premiums over the next six years at an approximate cost of \$43,000 per year. These future payments were also accrued in 2021.

Dr. Snowdy, the Company's Chief Executive Officer, is entitled to receive \$250,000 should he be terminated without cause, or his Employment Agreement not be renewed and \$500,000 should he be terminated upon a change in control.

Mr. Caloz, the Company's Chief Financial Officer, is entitled to receive \$250,000 should he be terminated without cause, or his Employment Agreement not be renewed and \$500,000 should he be terminated upon a change in control.

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 \$4,000 for each board meeting attended (\$750 for board actions taken by unanimous written consent) and \$3,000 for each meeting of the Audit Committee and Compensation Committee attended. Non-employee directors who serve as the chairman of a board committee receive an additional \$2,500 for each meeting of the Audit or Compensation Committees attended.

The following table sets forth the compensation paid to our directors other than our Chief Executive Officer for 2021:

Director Compensation Table

Name (1)	Fees Earned or Paid in Cash (\$) (2)	Total (\$)
Louis Ignarro, Ph.D., Chairman of the Board	123,250	123,250
Earl Brien, M.D., Director	28,000	28,000
Joel Caldwell, Lead Director	106,750	106,750
Jennifer Simpson, Ph.D., Director	14,750	14,750

- (1) Steven A. Kriegsman did not receive additional compensation when he was Chairman of the Board in 2021. On January 3, 2022, Mr. Kriegsman stepped down as Chairman and Dr. Ignarro was appointed Chairman. Mr. Caldwell became Lead Director on the same date. Dr. Brien stepped down from the Board in May 2021. For information relating to Mr. Kriegsman's compensation as Chief Executive Officer, see the Summary Compensation Table above. Mr. Kriegsman resigned from his position as director on March 9, 2022.
- (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 [22], 2022 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 [22], 2022; 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 [22], 2022 (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 38,801,442 shares of our common stock outstanding as of March [22], 2022. 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%.

Name and Address of Beneficial Owner (7)	Amount and Nature of Beneficial Ownership (Common Stock)	Percent of Class (Common Stock)
<i>Named Executive Officers and Directors</i>		
Louis Ignarro, Ph.D.	598,404	1.5%(1)
Steven A. Kriegsman	3,643,731	9.2%(2)
Joel Caldwell	335,373	*(3)
Jennifer Simpson, Ph.D.	25,000	*(4)
Stephen Snowdy, Ph.D.	—	*
John Y. Caloz	592,424	1.5%(5)
All executive officers and directors as a group (five persons)	5,194,932	12.8%(6)
<i>5% Beneficial Owners</i>		
ImmunityBio, Inc.	1,969,697	5.1%

- (1) Includes 167,857 shares subject to options.

- (2) Includes 933,198 shares subject to options.
- (3) Includes 60,000 shares subject to options.
- (4) Includes 25,000 restricted shares.
- (5) Includes 591,667 shares subject to options.
- (6) Includes 1,777,723 shares subject to options and restricted shares.
- (7) The address of each of the below listed named executive officers and directors is the Company's business address located at 11726 San Vicente Blvd, Ste 650, Los Angeles, CA 90049.

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 38.

Item 13. CERTAIN RELATIONSHIPS, RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

Director Independence

Although the Company is no longer listed on NASDAQ, our Board has determined that Dr. Ignarro, Mr. Caldwell and Dr. Simpson 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 Dr. Ignarro and Mr. 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

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.

In connection with Mr. Kriegsman's departure, the Company and Mr. Kriegsman entered into a General Release and Separation Agreement, dated January 3, 2022 (see Item 7). The transaction was approved by the Board in December 2021.

Item 14. *PRINCIPAL ACCOUNTANT FEES AND SERVICES*

Audit Fees

Weinberg & Company, or Weinberg, served as our independent registered public accounting firm and audited our consolidated financial statements for the years ended December 31, 2021 and 2020.

The fees for the year ended December 31, 2021 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 and Form S-3 registration statements were approximately \$130,000. The fees 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 were approximately \$117,000. The fees for Form S-3 registration statements were \$12,000.

Audit-Related Fees

None.

Tax Fees

The aggregate fees billed by Weinberg for professional services for tax compliance were approximately \$30,000 for 2021.

All Other Fees

No other services were rendered by Weinberg in either year ended December 31, 2021 or 2020.

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 for the years ended December 31, 2021 and 2020.

PART IV

Item 15. *EXHIBITS AND FINANCIAL STATEMENT SCHEDULES*

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

(1) 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-24 of this Annual Report. These consolidated financial statements are as follows:

Consolidated Balance Sheets as of December 31, 2021 and 2020

Consolidated Statements of Operations for the Years Ended December 31, 2021 and 2020

Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2021 and 2020

Consolidated Statements of Cash Flows for the Years Ended December 31, 2021 and 2020

Notes to Consolidated Financial Statements

Reports of Independent Registered Public Accounting Firm

(2) Financial Statement Schedules

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

(3) Exhibits

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

CytRx Corporation
Form 10-K Exhibit Index

Exhibit Number	Description	Incorporated By Reference to			Filed / Furnished Herewith
		Form	Exhibit	Filing Date	
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 Amendment of Restated Certificate of Incorporation	8-K	3.1	11/1/2017	
3.4	Certificate of Amendment of Restated Certificate of Incorporation	8-K	3.1	3/16/2022	
3.5	Certificate of Elimination of Designation of Series A Junior Participating Preferred Stock	8-K	3.2	12/19/2019	
3.6	Certificate of Elimination of Series B Convertible Preferred Stock	8-K	3.3	12/19/2019	
3.7	Amended and Restated Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock	8-K	3.1	11/17/2020	
3.8	Amended and Restated By-Laws of CytRx Corporation, effective November 12, 2020	8-K	3.2	11/17/2020	
3.9	Certificate of the Designations, Powers, Preferences and Rights of Series C 10.00% Convertible Preferred Stock	8-K	3.1	7/15/2021	
4.1	Amended and Restated Rights Agreement, dated as of November 16, 2020, by and between CytRx Corporation and American Stock Transfer & Trust Company, LLC, as rights agent	8-K	4.1	11/17/2020	
4.2	Warrant, dated as of July 27, 2017, issued by CytRx Corporation to NantCell, Inc.	8-K	10.3	8/1/2017	
4.3	Form of Preferred Investment Option	8-K	4.1	7/15/2021	
4.4	Description of Securities				**
10.1*	CytRx Corporation Amended and Restated 2008 Stock Incentive Plan	10-K	10.6	3/13/2012	
10.1.2*	Eighth Amendment to Amended and Restated CytRx Corporation 2008 Stock Incentive Plan	14A (proxy)	Annex B	5/20/2016	
10.1.3*	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	
10.1.4*	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	
10.1.5*	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	
10.1.6*	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	
10.1.7*	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	

Exhibit Number	Description	Incorporated By Reference to			Filed / Furnished Herewith
		Form	Exhibit	Filing Date	
10.1.8*	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	
10.2†	License Agreement, dated December 7, 2001, by and between CytRx Corporation and Vical Incorporated	8-K	99	12/21/2001	
10.3	Office Lease between The Kriegsman Capital Group, LLC and Douglas Emmett Joint Venture, dated April 13, 2000	10-K	10.63	5/14/2004	
10.3.1	Assignment, Assumption and Consent, effective July 1, 2003, by 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	
10.3.2	Fifth Amendment to Office Lease dated January 13, 2020 by and between CytRx Corporation and Douglas Emmett 1993, LLC	10-K	10.3.2	3/24/2021	
10.4†	License Agreement dated April 17, 2006 between Innovive Pharmaceuticals, Inc. and KTB Tumorforschungs GmbH	10-Q	10.15	11/14/2006	
10.4.1	Amendment dated March 14, 2014 to License Agreement between CytRx Corporation and KTB Tumorforschungs GmbH	8-K	1.1	3/17/2014	
10.5	Asset Purchase Agreement dated May 13, 2011 between CytRx Corporation and Orphazyme ApS	10-Q	10.1	5/17/2011	
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	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	
10.8*	Employment Agreement, dated December 16, 2021, by and between CytRx Corporation and John Y. Caloz				**
10.9	CytRx Corporation 2019 Stock Incentive Plan	8-K	10.1	11/15/2019	
10.10	Form of Securities Purchase Agreement, dated as of July 13, 2021, by and between the Company and the purchaser thereto	8-K	10.1	7/15/2021	
10.11	Form of Registration Rights Agreement, dated as of July 13, 2021, by and between the Company and the purchaser thereto	8-K	10.2	7/15/2021	
10.12	Amendment No. 1 to the Cooperation Agreement, dated September 2, 2021, by and between CytRx Corporation and Jerald A. Hammann	8-K	10.1	9/9/2021	
10.13*	Employment Agreement, January 3, 2022, by and between CytRx Corporation and Dr. Stephen Snowdy	8-K	10.1	1/4/2022	
10.14*	General Release and Separation Agreement, dated January 3, 2022, by and between CytRx Corporation and Steven A. Kriegsman.	8-K	10.2	1/4/2022	
21.1	Subsidiary List of CytRx Corporation				**
23.1	Consent of Weinberg & Company				**

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

* Indicates a management contract or compensatory plan or arrangement.

** Filed herewith.

*** Furnished herewith.

† 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.

Item 16. FORM 10-K SUMMARY

None.

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 23, 2022

By: /s/ STEPHEN SNOWDY

Dr. Stephen Snowdy
Chief Executive Officer (Principal Executive Officer)

By: /s/ JOHN Y. CALOZ

John Y. Caloz
Chief Financial Officer (Principal Financial and Accounting 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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ STEPHEN SNOWDY</u> Stephen Snowdy, Ph.D.	Chief Executive Officer (Principal Executive Officer)	March 23, 2022
<u>/s/ JOHN Y. CALOZ</u> John Y. Caloz	Chief Financial Officer (Principal Financial and Accounting Officer)	March 23, 2022
<u>/s/ LOUIS IGNARRO</u> Louis Ignarro, Ph.D.	Chairman	March 23, 2022
<u>/s/ JENNIFER SIMPSON</u> Jennifer Simpson, Ph.D.	Director	March 23, 2022
<u>/s/ JOEL CALDWELL</u> Joel Caldwell	Director	March 23, 2022

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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 sheets of CytRx Corporation (the “Company”) and subsidiary as of December 31, 2021 and 2020, the related consolidated statements of operations, stockholders’ equity, and cash flows for the years 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 its subsidiary as of December 31, 2021 and 2020, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has no recurring source of revenue, has incurred recurring operating losses and negative operating cash flows since inception and has an accumulated deficit at December 31, 2021. These matters raise substantial doubt about the Company’s ability to continue as a going concern. Management’s plans in regard to these matters are also described in Note 1 to the consolidated financial statements. These consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 audits. 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 audits 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 audits, 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 audits 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 audits 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 audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (1) relate to accounts or disclosures that are material to the financial statements and (2) involved especially challenging, subjective, or complex judgments. The communication of critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing separate opinions on the critical audit matter or on the accounts or disclosures to which it relates.

Financing under security purchase agreements

As discussed in Note 7 to the consolidated financial statements, the Company entered into a securities purchase agreement for aggregate gross proceeds of \$10 million and net proceeds of approximately \$9.2 million related to the issuance of (i) 2 million shares of its common stock (ii) 8,240 shares of Series C 10.00% Convertible Preferred Stock; and (iii) an investment option that allows for the purchase of up to 11,363,637 shares of common stock for additional gross proceeds of approximately \$10 million if fully exercised. The Company allocated the proceeds to the respective instruments on a relative fair value basis. In determining the fair value of the investment option, the Company used a Black Scholes Option Pricing Model, which uses certain assumptions related to expected life of the warrants, expected volatility, risk-free interest rates, and future dividends, to determine the fair value of the preferred investment option.

We identified the accounting and allocation of proceeds for the financing under the security purchase agreement as a critical audit matter because of the significance of the account balances, high estimation uncertainty due to significant judgments with respect to the selection of the valuation methodologies applied to determine the relative fair value of the investment option, and due to the complexity involved in assessing the classification and presentation of the common stock, the preferred stock and Preferred Investment Option. The auditing for these transactions required a high degree of audit judgement including evaluating the reasonableness of the significant judgements made by Management in determining the appropriate accounting.

The primary audit procedures we performed to address this critical audit matter included the following, among others:

- We inspected the security purchase agreements, and other relevant documentation.
- We evaluated the Company's conclusions regarding the application of relevant accounting guidance to the accounting for the security purchase agreement, including the classification and presentation of each respective instrument.
- We evaluated the reasonableness of the Company's methodology for allocation of proceeds including the Company's consideration of relevant accounting standards and reperformed the allocation.
- We evaluated the reasonableness and appropriateness of the Company's valuation models including testing the accuracy and completeness of such calculations which included an assessment of the data and assumption used by Management, such as expected life, expected volatility, the risk-free interest rate, and the dividend rate, and tested the mathematical accuracy of those calculations.
- We developed independent estimates for the fair value of the conversion feature and preferred investment option issued based on the assumptions and data used by Management.

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

/s/ Weinberg & Company

Los Angeles, California

March 23, 2022

CYTRX CORPORATION
CONSOLIDATED BALANCE SHEETS

	December 31,	
	2021	2020
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 6,769,603	\$ 10,003,375
Insurance claim receivable	200,000	325,105
Prepaid expenses and other current assets	1,310,382	1,094,675
Total current assets	8,279,985	11,423,155
Equipment and furnishings, net	32,784	39,758
Other assets	16,836	16,836
Operating lease right-of-use assets	397,172	580,478
Total assets	\$ 8,726,777	\$ 12,060,227
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,470,652	\$ 1,402,054
Accrued expenses and other current liabilities	2,064,506	1,190,910
Current portion of operating lease obligations	198,819	181,103
Total current liabilities	3,733,977	2,774,067
Operating lease liabilities, net of current portion	216,381	415,200
Total liabilities	3,950,358	3,189,267
Preferred Stock, Series C 10% Convertible, \$1,000 par value, 8,240 shares issued and outstanding	4,022,700	—
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, 2021 and 2020, respectively	—	—
Common stock, \$0.001 par value, 62,393,940 shares authorized; 38,780,038 and 36,480,038 shares issued and outstanding at December 31, 2021 and 2020, respectively	38,780	36,480
Additional paid-in capital	484,790,650	479,561,860
Accumulated deficit	(484,075,711)	(470,727,380)
Total stockholders' equity	753,719	8,870,960
Total liabilities and stockholders' equity	\$ 8,726,777	\$ 12,060,227

The accompanying notes are an integral part of these consolidated financial statements.

CYTRX CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31,	
	2021	2020
Revenue:		
Licensing revenue	\$ —	\$ —
Expenses:		
Research and development	—	799,577
General and administrative	5,966,415	6,000,537
Settlement with former Chief Executive Officer	6,096,597	—
Depreciation and amortization	13,978	29,037
	<u>12,076,990</u>	<u>6,829,151</u>
Loss from operations	(12,076,990)	(6,829,151)
Other income (expense):		
Liquidated damages expense	(1,109,653)	—
Interest income	16,822	119,274
Other income (expense), net	(6,842)	10,071
	<u>(1,100,673)</u>	<u>129,325</u>
Loss before provision for income taxes	(13,176,663)	(6,699,806)
Provision for income taxes	—	(800)
Net Loss	(13,176,663)	(6,700,606)
Dividends paid on preferred shares	(171,668)	—
Net loss attributable to common stockholders	\$ (13,348,331)	(6,700,606)
Basic and diluted loss per share	\$ (0.35)	\$ (0.19)
Basic and diluted weighted average shares outstanding	<u>37,584,695</u>	<u>34,651,334</u>

The accompanying notes are an integral part of these consolidated financial statements.

CYTRX CORPORATION
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Series B Preferred Shares Issued	Shares of Common Stock Issued	Preferred Stock Amount	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Total
Balance at January 1, 2020	—	33,637,501	—	\$ 33,637	479,197,849	\$(464,026,774)	\$ 15,204,712
Issuance of stock options/restricted stock for compensation and services	—	—	—	—	327,854	—	327,854
Exercise of stock options	—	2,842,537	—	2,843	36,157	—	39,000
Net loss	—	—	—	—	—	(6,700,606)	(6,700,606)
Balance at December 31, 2020	—	36,480,038	—	\$ 36,480	\$479,561,860	\$(470,727,380)	\$ 8,870,960
Issuance of common stock and preferred investment option	—	2,000,000	—	2,000	5,151,090	—	5,153,090
Exercise of stock options	—	300,000	—	300	77,700	—	78,000
Preferred dividend	—	—	—	—	—	(171,668)	(171,668)
Net loss	—	—	—	—	—	(13,176,663)	(13,176,663)
Balance at December 31, 2021	—	38,780,038	—	\$ 38,780	\$484,790,650	\$(484,075,711)	\$ 753,719

The accompanying notes are an integral part of these consolidated financial statements.

CYTRX CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,	
	2021	2020
Cash flows from operating activities:		
Net loss from operations	\$ (13,176,663)	\$ (6,700,606)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	13,978	29,037
Loss on retirement of equipment and furnishings	—	—
Stock-based compensation expense	—	327,854
Changes in assets and liabilities:		
Insurance receivable	125,105	7,628
Prepaid expenses and other current assets	(215,707)	(94,449)
Reduction of right of-use assets	183,306	201,103
Accounts payable	68,598	189,114
Other assets	—	(9,246)
Decrease in lease liabilities	(181,103)	(119,007)
Accrued expenses and other current liabilities	873,596	28,439
Net cash used in operating activities	<u>(12,308,890)</u>	<u>(6,140,133)</u>
Cash flows from investing activities:		
Purchases of equipment and furnishings	(7,004)	(25,902)
Net cash used in investing activities	<u>(7,004)</u>	<u>(25,902)</u>
Cash flows from financing activities:		
Net proceeds from Security Purchase Agreement	9,175,790	—
Preferred stock dividend	(171,668)	—
Proceeds from the exercise of stock options	78,000	39,000
Net cash provided by financing activities	<u>9,082,122</u>	<u>39,000</u>
Net decrease in cash and cash equivalents	(3,233,772)	(6,127,035)
Cash and cash equivalents at beginning of year	10,003,375	16,130,410
Cash and cash equivalents at end of year	<u>\$ 6,769,603</u>	<u>\$ 10,003,375</u>
Supplemental disclosures of Cash Flow Information:		
Recognition of operating lease right-of-use assets and obligations under ASC Topic 842	<u>\$ —</u>	<u>\$ 715,310</u>
Reclassification of right-of-use assets, from prepaid expenses	<u>\$ —</u>	<u>\$ 66,271</u>
Insurance claims to offset accounts payable	<u>\$ 200,000</u>	<u>\$ 325,105</u>

The accompanying notes are an integral part of these consolidated financial statements.

CYTRX CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of Business

CytRx Corporation (“CytRx”) is a biopharmaceutical research and development company specializing in oncology. 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 studies, in several different cancer models, stability, and manufacturing feasibility. In addition, a novel albumin companion diagnostic, ACDx™, was developed to identify patients with cancer who are most likely to benefit from treatment with these drug candidates.

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

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

LADR Drug Discovery Platform and Centurion

Centurion’s LADR™ (Linker Activated Drug Release) is a platform for formulating cytotoxic cancer drugs that offer improved efficacy with reduced side effects. LADR combines our expertise in linker chemistry and albumin biology to create a pipeline of anti-cancer molecules that deliver prodrugs to the tumor environment and then activate the drug inside the tumor. Such a trojan horse strategy reduces off-target side effects outside the tumor, thus allowing 10-1,000 fold higher dosing to be given.

The first-generation (“gen”) product candidate employing our tumor targeting and drug release system is aldoxorubicin, described below. Our next-gen products are composed of two classes of ultra-high potency albumin-binding drug conjugates, termed LADR 7 through LADR 10. These drug conjugates combine the proprietary LADR™ linkers with novel derivatives of the auristatin and maytansinoid drug classes. These payloads historically have required a targeting antibody for successful administration to humans. Our 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.

On March 9, 2022, Centurion was merged into the Company.

Business Strategy for LADR™ Platform

Currently, the Company continues to work on identifying partnership or financing opportunities for LADR™ ultra-high potency drug conjugates and their albumin companion diagnostic. We have concluded all research and development on LADR and its companion diagnostic and continue to focus on identifying partnership or financing opportunities.

Aldoxorubicin

Until July 2017, we were concentrating on the research and clinical development of aldoxorubicin, which is the widely-used cytotoxin doxorubicin, modified with our LADR delivery and concentration system. Modifying doxorubicin with our LADR™ system allows 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. As a result, our company is no longer directly working on development of aldoxorubicin (ImmunityBio has recently merged with NantKwest, Inc.). 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. The Company is 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. There can be no assurance that ImmunityBio will achieve such milestones, approvals or sales with respect to aldoxorubicin. ImmunityBio has initiated a Phase 2, randomized, two-cohort, open-label registrational-intent study for first-line and second-line treatment of locally advanced or metastatic pancreatic cancer, which includes aldoxorubicin.

Molecular Chaperone Assets (Orphazyme)

In 2011, CytRx sold the rights to arimoclomol and irovanadine, 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 single- and double-digit 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 Inclusion Body Myositis (IBM). CytRx received a milestone payment of \$250,000 in September 2018. Orphazyme has announced it expects read-outs for its registrational trials in IBM and ALS in the first half of 2021. Orphazyme has highlighted positive Phase 2/3 clinical trial data in patients with NPC and have submitted a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA), which is currently under Priority Review by the U.S. Food and Drug Administration (“FDA”) with a target action date of June 17, 2021. They also submitted a Marketing Authorization Application (MAA) with the European Medicines Agency (EMA). Orphazyme has established an Early Access Program in the U.S. as well as other select European countries. They also have established an Early Access Program in the U.S. as well as other select European countries. Orphazyme has also received FDA Breakthrough Therapy Designation for arimoclomol for NPC. They recently announced arimoclomol will be marketed globally under the tradename MIPLYFFA™. 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.

Going Concern

The Company’s consolidated financial statements have been presented on the basis that it will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. During the year ended December 31, 2021, the Company incurred a net loss of \$13,176,663, utilized cash in operations of \$12,308,890, and had an accumulated deficit of \$484,075,711 as of December 31, 2021. In addition, the Company has no recurring revenue. As a result, management has concluded that there is substantial doubt about the Company’s ability to continue as a going concern. The Company’s consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

At December 31, 2021, the Company had cash on hand in the amount of \$6.8 million. The continuation of the Company as a going concern is dependent upon its ability to obtain necessary debt or equity financing to continue operations until it begins generating positive cash flow. No assurance can be given that any future financing will be available or, if available, that it will be on terms that are satisfactory to the Company. Even if the Company is able to obtain additional financing, it may contain undue restrictions on our operations, in the case of debt financing or cause substantial dilution for our stockholders, in case of equity financing.

Current Business Strategy

Currently, the Company is working on identifying partnership or financing opportunities for LADR™ ultra-high potency drug conjugates and their albumin companion diagnostic. We have concluded all research and development on LADR and its companion diagnostic and continue to focus on identifying these partnership or financing opportunities.

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. During the years ended December 31, 2021 and 2020, no revenue was earned from license fees.

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.

Insurance recoveries — The Company has several policies with insurance underwriters that provide for the recovery of certain costs incurred by the Company. The Company’s policy is to record any liability as incurred, and then to record the estimated recovery from the insurance company for that cost as a receivable in accordance with terms of its existing policies. As of December 31, 2021, management has estimated that \$200,000 is recoverable from its insurance carriers under the terms of its policies.

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 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 Share of Common Stock — Basic net income (loss) per share is computed by dividing net income (loss) by the weighted average number of shares of common stock outstanding for the period. Diluted earnings per share is computed by dividing the net income applicable to common stockholders by the weighted average number of shares of common stock outstanding plus the number of additional shares of common stock that would have been outstanding if all dilutive potential shares of common stock had been issued using the treasury stock method. Potential shares of common stock are excluded from the computation when their effect is antidilutive. The dilutive effect of potentially dilutive securities is reflected in diluted net income per share if the exercise prices were lower than the average fair market value of common stock during the reporting period.

	As of December 31,	
	2021	2020
Options to acquire common stock	2,827,820	3,166,270
Warrants to acquire common stock	4,167	193,196
Convertible preferred stock	9,363,637	—
Preferred investment option	11,363,637	—
	<u>23,559,261</u>	<u>3,359,466</u>

Potentially dilutive stock options, warrants and securities from the table above were excluded from the computation of diluted net income (loss) per share, because the effect would be anti-dilutive.

Stock-based Compensation — The Company accounts for share-based awards to employees and nonemployees directors and consultants in accordance with the provisions of ASC 718, *Compensation—Stock Compensation*, and under the recently issued guidance following FASB’s pronouncement, ASU 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*. Under ASC 718, and applicable updates adopted, share-based awards are valued at fair value on the date of grant and that fair value is recognized over the requisite service, or vesting, period. The Company values its equity awards using the Black-Scholes option pricing model, and accounts for forfeitures when they occur.

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.

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 — Preparation of the Company’s consolidated financial statements in conformance with U.S. GAAP requires the Company’s management to make estimates and assumptions that impact the reported amounts of assets, liabilities, revenues and expenses, and the disclosure of contingent assets and liabilities in the Company’s consolidated financial statements and accompanying notes. The significant estimates in the Company’s consolidated financial statements relate to the valuation of equity awards, recoverability of deferred tax assets, insurance claims and estimated useful lives of fixed assets. The Company bases estimates and assumptions on historical experience, when available, and on various factors that it believes to be reasonable under the circumstances. The Company evaluates its estimates and assumptions on an ongoing basis, and its actual results may differ from estimates made under different assumptions or conditions.

New Accounting Pronouncements — In June 2016, the FASB issued ASU No. 2016-13, *Credit Losses - Measurement of Credit Losses on Financial Instruments* (“ASC 326”). The standard significantly changes how entities will measure credit losses for most financial assets, including accounts and notes receivables. The standard will replace today’s “incurred loss” approach with an “expected loss” model, under which companies will recognize allowances based on expected rather than incurred losses. Entities will apply the standard’s provisions as a cumulative-effect adjustment to retained earnings as of the beginning of the first reporting period in which the guidance is effective. The standard is effective for interim and annual reporting periods beginning after December 15, 2019. The adoption of ASU 2016-13 is not expected to have a material impact on the Company’s financial position, results of operations, and cash flows.

In August 2020, the FASB issued ASU 2020-06, Debt — Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity’s Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity’s Own Equity (“ASU 2020-06”). ASU 2020-06 simplifies the accounting for convertible debt by eliminating the beneficial conversion and cash conversion accounting models. Upon adoption of ASU 2020-06, convertible debt proceeds, unless issued with a substantial premium or an embedded conversion feature that is not clearly and closely related to the host contract, will no longer be allocated between debt and equity components. This modification will reduce the issue discount and result in less non-cash interest expense in financial statements. ASU 2020-06 also updates the earnings per share calculation and requires entities to assume share settlement when the convertible debt can be settled in cash or shares. For contracts in an entity’s own equity, the type of contracts primarily affected by ASU 2020-06 are freestanding and embedded features that are accounted for as derivatives under the current guidance due to a failure to meet the settlement assessment by removing the requirements to (i) consider whether the contract would be settled in registered shares, (ii) consider whether collateral is required to be posted, and (iii) assess shareholder rights. ASU 2020-06 is effective for fiscal years beginning after December 15, 2023. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, and only if adopted as of the beginning of such fiscal year. The Company adopted ASU 2020-06 effective January 1, 2021. The adoption of ASU 2020-06 did not have any impact on the Company’s consolidated financial statement presentation or disclosures.

In May 2021, the FASB issued ASU 2021-04, Earnings Per Share (Topic 260), Debt — Modifications and Extinguishments (Subtopic 470-50), Compensation — Stock Compensation (Topic 718), and Derivatives and Hedging — Contracts in Entity’s Own Equity (Subtopic 815-40): Issuer’s Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options (“ASU 2021-04”). ASU 2021-04 provides guidance as to how an issuer should account for a modification of the terms or conditions or an exchange of a freestanding equity-classified written call option (i.e., a warrant) that remains classified after modification or exchange as an exchange of the original instrument for a new instrument. An issuer should measure the effect of a modification or exchange as the difference between the fair value of the modified or exchanged warrant and the fair value of that warrant immediately before modification or exchange and then apply a recognition model that comprises four categories of transactions and the corresponding accounting treatment for each category (equity issuance, debt origination, debt modification, and modifications unrelated to equity issuance and debt origination or modification). ASU 2021-04 is effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. An entity should apply the guidance provided in ASU 2021-04 prospectively to modifications or exchanges occurring on or after the effective date. Early adoption is permitted, including adoption in an interim period. If an entity elects to early adopt ASU 2021-04 in an interim period, the guidance should be applied as of the beginning of the fiscal year that includes that interim period. The adoption of ASU 2021-04 is not expected to have any impact on the Company’s consolidated financial statement presentation or disclosures.

Other recent authoritative guidance issued by the FASB (including technical corrections to the ASC), the American Institute of Certified Public Accountants, and the Securities and Exchange Commission (“SEC”) did not, or are not expected to, have a material impact on the Company’s consolidated financial statements and related disclosures.

3. Foreign Currency Remeasurement

The U.S. dollar has been determined to be the functional currency for the net assets of the Company’s German operations. 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 gain (loss) of approximately \$(22,440) and \$26,800 for the years ended December 31, 2021 and 2020, respectively.

As of December 31, 2021 and 2020, the Company’s cash balances consisted of the following:

	2021	2020
U.S. Dollars	\$ 6,671,404	\$ 9,892,046
Euros – in US \$	98,199	111,329
Cash Balance	<u>\$6,769,603</u>	<u>\$ 10,003,375</u>

4. Equipment and Furnishings

Equipment and furnishings at December 31, 2021 and 2020 consist of the following:

	2021	2020
Equipment and furnishings	\$ 59,728	\$ 137,924
Less — accumulated depreciation	(26,944)	(98,166)
Equipment and furnishings, net	<u>\$ 32,784</u>	<u>\$ 39,758</u>

Depreciation and amortization expense for the years ended December 31, 2021 and 2020 were \$13,978 and \$29,037, respectively. During the year ended December 31, 2021, fully depreciated Equipment and furnishings of approximately \$85,000 were written off.

5. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities at December 31, 2021 and 2020 are summarized below.

	2021	2020
Professional fees	\$ 208,345	\$ 234,700
Liquidated damages— see Note 7	615,253	—
Research and development costs	—	9,296
Payable to former CEO	256,115	—
Wages, bonuses and employee benefits	261,375	215,191
Royalties and milestones	716,155	716,155
Other	7,263	15,568
Total	<u>\$ 2,064,506</u>	<u>\$ 1,190,910</u>

6. Leases

We lease office space and office copiers related primarily to the Company's administrative activities. The Company accounts for leases under ASC 842, *Leases*, which requires an entity to recognize a right-of-use asset and a lease liability for virtually all leases.

In January 2020, the Company signed a new four-year office 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 is \$14,340, subject to annual increases of 3.5 percent. In February 2020, the Company renewed its additional storage space lease, which requires us to make monthly payments of \$1,405, subject to a 2.5 percent annual increase. The Company recorded a right of use asset and lease liability obligation of \$715,310 upon inception of these leases. The Company also reclassified a previously existing right-of-use asset of \$66,271 from other assets to right-of-use asset.

As of December 31, 2021, the balance of right-of-use assets was approximately \$397,200, and the balance of total lease liabilities was approximately \$415,200.

Future minimum lease payments under non-cancelable operating leases under ASC 842 as of December 31, 2021 are as follows:

	Operating Lease Payments
Jan 2022 – Dec 2022	\$ 197,152
Jan 2023 – Dec 2023	200,927
Jan 2024 – Dec 2024	33,672
Total future minimum lease payments	431,751
Less: present value adjustment	(16,551)
Operating lease liabilities at December 31, 2021	415,200
Less: current portion of operating lease liabilities	(198,819)
Operating lease liabilities, net of current portion	\$ 216,381

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

	Year Ended December 31, 2021
Lease Cost	
Operating lease cost (included in General and administrative expenses in the Company's Consolidated Statements of Operations)	\$ 199,276
Other information	
Cash paid for amounts included in the measurement of lease liabilities for the year ended December 31, 2021	\$ 188,683
Weighted average remaining lease term – operating leases (in years)	2.2
Average discount rate	3.6%

7. Financing Under Security Purchase Agreement

On July 13, 2021, the Company entered into a Securities Purchase Agreement (the “Purchase Agreement”) with a single institutional investor (the “Investor”) for aggregate gross proceeds of \$10 million and net proceeds of approximately \$9.2 million. The transaction closed on July 16, 2021. Under the Purchase Agreement, the Company sold and issued (i) 2 million shares of its common stock at a purchase price of \$0.88 per share for total gross proceeds of approximately \$1.76 million in a registered direct offering (the “Registered Direct Offering”) and (ii) 8,240 shares of Series C 10.00% Convertible Preferred Stock (the “Preferred Stock”) at a purchase price of \$1,000 per share, for aggregate gross proceeds of approximately \$8.24 million, in a concurrent private placement (the “Private Placement” and, together with the Registered Direct Offering, the “July 2021 Offerings”). The shares of the Preferred Stock are convertible, upon shareholder approval as described below, into an aggregate of up to 9,363,637 shares of common stock at a conversion price of \$0.88 per share. Holders of the Preferred Stock shall be entitled to receive, and the Company shall pay, cumulative dividends at the rate per share (as a percentage of the stated value per share) of 10.00% per annum, payable quarterly on January 1, April 1, July 1 and October 1, beginning on the first such date after the date of issuance. The terms of the Preferred Stock include beneficial ownership limitations that preclude conversion that would result in the Investor owning in excess of 9.99% of the Company’s outstanding shares of common stock. CytRx also issued to the Investor an unregistered preferred investment option (the “Preferred Investment Option”) that allows for the purchase of up to 11,363,637 shares of common stock for additional gross proceeds of approximately \$10 million if the Preferred Investment Option is exercised in full. The exercise price for the Preferred Investment Option is \$0.88 per share. The Preferred Investment Option has a term equal to five and one-half years commencing upon the Company increasing its authorized common stock following shareholder approval. The Company held a special meeting of stockholders on September 23, 2021 at which time the shareholders did not approve the proposal to increase the Company’s authorized common stock. On March 15, 2022, the Company received stockholders’ approval to increase its authorized shares (see below). On October 1, 2021, the Company paid a quarterly 10% dividend to the Investor in the amount of \$171,668.

The Company accounted for these transactions as a single transaction for accounting purposes and allocated total proceeds to the respective instruments based upon the relative fair value of each instrument. The Company determined that the relative fair value of (i) the 2,000,000 shares of the common stock issued was \$859,218, (ii) the relative fair value of the 8,240 shares of Preferred Stock was \$4,022,700, and (iii) the relative fair value of the Preferred Investment Option was \$4,293,872 based upon a Black Scholes valuation model. As such, the Company recorded as Additional Paid in Capital the fair value of the common stock and Preferred Investment Option of \$5,153,090, and the fair value of the Series C Preferred Stock was \$4,022,700 which has been reflected as mezzanine (temporary equity) due to certain clauses of the Securities Purchase Agreement.

Terms of Series C Preferred Stock

Under the Certificate of the Designations, Powers, Preferences and Rights of Series C 10.00% Convertible Preferred Stock (the “**Certificate of Designations**”), each share of Series C Preferred Stock will be convertible, subject to the Beneficial Ownership Limitation (as defined below), at either the holder’s option or at the Company’s option (a “**Company Initiated Conversion**”) at any time following stockholder approval having been obtained to amend our restated certificate of incorporation to increase the number of authorized shares of common stock above 41,666,666 (the “Stockholder Approval”), into common stock at a conversion rate equal to the quotient of (i) the Series C Stated Value of \$1,000 (the “**Series C Stated Value**”) plus, in the case of a Company Initiated Conversion, all accrued and accumulated and unpaid dividends on such share of Series C Preferred Stock, divided by (ii) the initial conversion price of \$0.88, subject to specified adjustments for stock splits, stock dividends, reclassifications or other similar events as set forth in the Certificate of Designations.

The Certificate of Designations contains limitations that prevent the holder thereof from acquiring shares of common stock upon conversion that would result in the number of shares of common stock beneficially owned by such holder and its affiliates exceeding 9.99% of the total number of shares of common stock outstanding immediately after giving effect to the conversion (the “**Beneficial Ownership Limitation**”), except that upon notice from the holder to the Company, the holder may increase or decrease the amount of ownership of outstanding shares of common stock after converting the holder’s shares of Series C Preferred Stock, provided that the Beneficial Ownership Limitation in no event exceeds 9.99% of the number of outstanding shares of the common stock outstanding immediately after giving effect to the issuance of shares of common stock upon conversion of the shares of Series C Preferred Stock held by the holder and provided that any increase in the Beneficial Ownership Limitation shall not be effective until 61 days following notice to the Company

Each holder of shares of Preferred Stock is entitled to receive dividends, commencing from the date of issuance of the Preferred Stock. Such dividends may be paid only when, as and if declared by the Board of Directors of the Company (the “**Board**”), out of assets legally available therefore, quarterly in arrears on the first day of January, April, July and October in each year, commencing on the date of issuance, at the dividend rate of 10.00% per year. Such dividends are cumulative and continue to accrue on a daily basis whether or not declared and whether or not we have assets legally available therefore.

Under the Certificate of Designations, each share of Series C Preferred Stock carries a liquidation preference equal to the Series C Stated Value plus accrued and unpaid and accumulated dividends thereon. Such liquidation preference is payable upon certain change in control transactions and accordingly, this instrument is classified as mezzanine (temporary equity).

The holders of the Series C Preferred Stock may vote their shares of Preferred Stock on an as-converted basis, subject to the Beneficial Ownership Limitation (which Beneficial Ownership Limitation shall be calculated on a basis which includes the number of shares of common stock which are issuable upon conversion of the unconverted Series C Stated Value beneficially owned by a holder or any of its affiliates or attribution parties on all matters submitted to the holders of common stock for approval). The Company may not take the following actions without the prior consent of the holders of at least a majority of the Preferred Stock then outstanding: (a) alter or change adversely the powers, preferences or rights given to the Preferred Stock or alter or amend the Certificate of Designations, (b) authorize or create any class of stock ranking as to dividends, redemption or distribution of assets upon a Liquidation (as defined in the Certificate of Designations) senior to, or otherwise *pari passu* with, the Preferred Stock, (c) amend its Certificate of Incorporation or other charter documents in any manner that adversely affects any rights of the holders of the Preferred Stock, (d) increase the number of authorized shares of Preferred Stock, or (e) enter into any agreement with respect to any of the foregoing.

Terms of Preferred Investment Option

The Preferred Investment Option to purchase up to 11,363,637 shares of common stock is exercisable at a price of \$0.88 per share. The Preferred Investment Option have a term of five and one-half years from the Authorized Share Increase Date. The holders of the Preferred Investment Option may exercise the Preferred Investment Option on a cashless basis, solely to the extent there is no effective registration statement registering, or the prospectus in such registration statement is not available for the resale of the shares of common stock issuable at the time of exercise. The Company is prohibited from effecting an exercise of any Preferred Investment Option to the extent that such exercise would result in the number of shares of common stock beneficially owned by such holder and its affiliates exceeding 9.99% of the total number of shares of common stock outstanding immediately after giving effect to the exercise of the Preferred Investment Options by the holder (the “**PIO Beneficial Ownership Limitation**”), except that upon notice from the holder to the Company, the holder may increase or decrease the amount of ownership of outstanding shares of Common Stock after exercising the holder’s Preferred Investment Option, provided that the PIO Beneficial Ownership Limitation in no event exceeds 9.99% of the number of outstanding shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of common stock upon exercise of the Preferred Investment Option held by the holder and provided that any increase in the PIO Beneficial Ownership Limitation shall not be effective until 61 days following notice to the Company. The Preferred Investment Option provides for a Black-Scholes payout upon certain fundamental change transactions relating to the Company, as specified therein. If the fundamental change transaction is within the control of the Company, the payout will be in cash. Otherwise, the payout will be in the same form of consideration received by the common stockholders as a result of this transaction.

Until the Authorized Share Increase Date, the Company may not issue any shares of common stock upon exercise of the Preferred Investment Option.

Registration Rights Agreement

In connection with the July 2021 Offerings, the Company entered into a registration rights agreement, dated as of July 13, 2021 (the "Registration Rights Agreement"), with the investor named therein, pursuant to which the Company will undertake to file, within five calendar days of the date of the filing of the proxy statement seeking the Stockholder Approval, a resale registration statement to register the shares of common stock issuable upon: (i) the conversion of the Preferred Stock sold in the Private Placement and (ii) the exercise of the Preferred Investment Option (the "**Registrable Securities**"); and to cause such registration statement to be declared effective under the Securities Act as promptly as possible after the filing thereof, but in any event no later than 75 days following the pricing date of this offering, or no later than 105 days following such date in the event of a "full review" by the SEC, and shall use its reasonable best efforts to keep such registration statement continuously effective under the Securities Act until the date that all Registrable Securities covered by such registration statement have been sold or are otherwise able to be sold pursuant to Rule 144. The Registration Rights Agreement provided for liquidated damages to the extent that the Company does not file or maintain a registration statement in accordance with the terms thereof. The registration rights agreement entered into between us and the Investor on July 13, 2021, contains a triggering event which would require us to pay to any holder of the Preferred Stock an amount in cash, as partial liquidated damages and not as a penalty, on a monthly basis equal to the product of 2.0% multiplied by the aggregate subscription amount paid by such holder for shares of Preferred Stock pursuant to the Purchase Agreement; provided, however, that such partial liquidated damages shall not exceed 24% of the aggregate subscription amounts paid by such holders pursuant to the Purchase Agreement, or \$1,977,600. If we fail to pay any partial liquidated damages within seven days after the date payable, we will be required to pay interest on any such amounts at a rate equal to the lesser of 18% per annum or the maximum rate permitted by applicable law.

During the year ended December 31, 2021, the Company did not have enough authorized shares to issue the issuable shares under the Preferred Stock and Preferred Investment Option. The Company attempted, but was unsuccessful, to obtain stockholders' approval for the increase in authorized shares, and accordingly, the Company was unable to meet its registration rights obligation as of December 31, 2021.

As such, the Company recognized an aggregate of approximately \$1.1 million in liquidated damages during the year ended December 31, 2021, of which includes a provision of \$615,123 as an accrual for estimated damages until stockholders' approval is achieved and the Registration Statement is filed. On March 15, 2022, the Company received stockholders' approval to increase its authorized shares and Company expects to file a Registration Statement on or about March 23, 2022 and has provided for liquidated damages through that date.

8. Departure of Chairman and Chief Executive Officer

In connection with a Separation Agreement (as defined below), Steven A. Kriegsman, who served as the Chairman and Chief Executive Officer of CytRx Corporation (the "**Company**"), departed from his roles as an officer of the Company and the Chairman of the Company's board of directors (the "**Board**"), Mr. Kriegsman's departure as Chairman of the Board was not in connection with any disagreement between Mr. Kriegsman and the Company, its management, the Board or any committee of the Board on any matter relating to the Company's operations, policies or practices, or any other matter.

In connection with the execution of the Separation Agreement, Mr. Kriegsman's existing executive employment agreement, as amended (the "**Prior Employment Agreement**"), was terminated; provided, however, that certain surviving customary confidentiality provisions and milestone and royalty payments as defined in the Prior Employment Agreement remain in full force and effect. Pursuant to the Prior Employment Agreement and the Separation Agreement, Mr. Kriegsman received a lump sum cash payment equal to approximately \$6.0 million during the year ended December 31, 2021. In addition, the Company has accrued \$256,115 of health benefits payable to him as of December 31, 2021.

9. Stock Compensation

Stock Options

The Company has a 2008 Stock Incentive Plan under which 5 million shares of common stock are reserved for issuance. As of December 31, 2021, 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 November 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, 2021, there were 550,000 shares subject to outstanding stock options and 25,000 shares outstanding related to restricted stock grants from the 2019 Plan. This Plan expires on November 14, 2029.

There were no stock options issued to employees and directors in 2021 and 2020.

During the year ended December 31, 2021, options to acquire 300,000 shares of common stock were exercised resulting in net proceeds of \$78,000. During the year ended December 31, 2020, the Company issued an aggregate of approximately 2.8 million shares of its common stock upon the exercise of 4.55 million options. Of the 4.55 million option shares, holders of 4.4 million options exercised their shares on a cashless basis into approximately 2.69 million shares of the Company's common stock. The Company received \$39,000 for the exercise of the remaining 150,000 options shares in exchange for 150,000 shares of its common stock.

The following table sets forth the total stock-based compensation expense resulting from stock options and restricted stock included in our Consolidated Statements of Operations for the years ended December 31, 2021 and 2020:

	Years Ended December 31,	
	2021	2020
General and administrative – employee	\$ —	\$ 327,854
Total employee stock-based compensation	\$ —	\$ 327,854

There were no options granted to employees and directors during the years ended December 31, 2021 and 2020. Presented below is the Company's stock option activity for employees and directors:

	Stock Options		Weighted Average Exercise Price	
	2021	2020	2021	2020
Outstanding — beginning of year	2,801,270	7,126,340	\$ 7.68	\$ 11.55
Granted	—	—	—	—
Exercised	(300,000)	(4,300,000)	0.26	0.26
Forfeited	—	—	9.49	—
Expired	(38,450)	(25,070)	14.62	41.03
Outstanding — end of year	2,462,820	2,801,270	7.68	7.68
Exercisable at end of year	2,462,820	2,801,270	\$ 7.68	\$ 7.68
Weighted average fair value of stock options granted during the year:	\$ —	\$ —		

No options were issued to consultants in 2021 or 2020.

At December 31, 2021, 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 Options		Weighted Average Exercise Price	
	2021	2020	2021	2020
Outstanding — beginning of year	365,000	615,000	\$ 5.49	\$ 3.36
Granted	—	—	—	—
Exercised	—	(250,000)	—	0.26
Expired/Forfeited	—	—	—	—
Outstanding — end of year	365,000	365,000	5.49	5.49
Exercisable at end of year	365,000	365,000	\$ 5.49	\$ 5.49
Weighted average fair value of stock options granted during the year:	\$ —	\$ —		

The following table summarizes significant ranges of outstanding stock options under the two plans at December 31, 2021:

Range of Exercise Prices	Number of Options	Weighted-Average Remaining Contractual Life (years)	Weighted-Average Exercise Price	Number of Options Exercisable	Weighted-Average Remaining Contractual Life (years)	Weighted-Average Exercise Price
\$ 0.26 - \$1.00	550,000	7.95	\$ 0.26	550,000	7.95	\$ 0.26
\$ 1.01 - \$3.00	1,050,673	5.60	\$ 2.04	1,050,673	5.60	\$ 2.04
\$ 3.01 - \$15.00	817,482	3.10	\$ 12.54	817,482	3.10	\$ 12.54
\$ 15.01 - \$42.42	409,674	2.12	\$ 25.24	409,674	2.12	\$ 25.24
	<u>2,827,829</u>	4.83	\$ 8.09	<u>2,827,829</u>	4.83	\$ 8.09

The aggregate intrinsic value of the outstanding options and options vested as of December 31, 2021 was \$143,000.

Restricted Stock

In December 2021, the Company granted to Jennifer Simpson, who serves on our Board of Directors, 25,000 shares of restricted common stock, pursuant to the 2019 Plan. This restricted stock vests on the first anniversary of the date of the grant. 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 \$11,200. No restricted stock was granted in 2020. As of December 31, 2021, there is \$11,200 of unamortized stock compensation that will be amortized through December 2022,

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 and was amortized over the three-year term through 2020. The Company recorded an employee stock-based compensation expense for restricted stock of approximately \$216,000 for the year ended December 31, 2020.

Equity-Classified Warrants

A summary of the Company's warrant activity and related information for the years ended December 31, 2021 and 2020 are shown below.

	Warrants		Weighted Average Exercise Price	
	2021	2020	2021	2020
Outstanding — beginning of year	193,916	193,916	\$ 8.60	\$ 8.60
Granted	—	—	—	—
Exercised	—	—	—	—
Forfeited	—	—	—	—
Expired	(189,749)	—	8.04	—
Outstanding — end of year	<u>4,167</u>	<u>193,916</u>	33.60	8.60
Exercisable at end of year	<u>4,167</u>	<u>193,916</u>	\$ 33.60	\$ 8.60
Weighted average fair value of warrants granted during the year:	\$ —	\$ —		

The outstanding warrants as of December 31, 2021 had no intrinsic value.

9. Stockholder Protection Rights Plan

On December 13, 2019, the Board of Directors of the Company, authorized and declared a dividend of one right (a “Right”) for each of the Company’s issued and outstanding shares of common stock, par value \$0.001 per share. The dividend was paid to the stockholders of record at the close of business on December 23, 2019. Each Right entitled the registered holder, subject to the terms of the Original Rights Agreement (as defined below), to purchase from the Company one one-thousandth of a share of the Company’s Series B Junior Participating Preferred Stock, par value \$0.01 per share (the “Preferred Stock”), at a price of \$5.00 (the “Purchase Price”), subject to certain adjustments. The description and terms of the Rights were set forth in the Rights Agreement, dated as of December 13, 2019 (the “Original Rights Agreement”), by and between the Company and American Stock Transfer & Trust Company, LLC, as Rights Agent (the “Rights Agent”).

On November 12, 2020, the Board approved an amendment and restatement of the Original Rights Agreement (as amended and restated, the “Amended and Restated Rights Agreement”) to effect certain changes to the Original Rights Agreement, including (i) reducing the duration to a term of three years, subject to certain earlier expiration as described in more detail below, and (ii) lowering the beneficial ownership threshold at which a person or group of persons becomes an Acquiring Person (as defined below) to 4.95% or more of the Company’s outstanding shares of Common Stock, subject to certain exceptions. The Amended and Restated Rights Agreement is designed to discourage (i) any person or group of persons from acquiring beneficial ownership of more than 4.95% of the Company’s shares of Common Stock and (ii) any existing stockholder currently beneficially holding 4.95% or more of the Company’s shares of Common Stock from acquiring additional shares of the Company’s Common Stock.

The purpose of the Amended and Restated Rights Agreement is to protect value by preserving the Company’s ability to utilize its net operating losses and certain other tax attributes (collectively, the “Tax Benefits”) to offset potential future income tax obligations. The Company’s ability to use its Tax Benefits would be substantially limited if it experiences an “ownership change,” as such term is defined in Section 382 of the Internal Revenue Code of 1986, as amended (the “Tax Code”). A corporation generally will experience an ownership change if the percentage of the corporation’s stock owned by its “5-percent shareholders,” as defined in Section 382 of the Tax Code, increases by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. The Amended and Restated Rights Agreement is intended to reduce the likelihood the Company would experience an ownership change under Section 382 of the Tax Code.

The Rights will not be exercisable until the earlier to occur of (i) the close of business on the tenth business day after a public announcement or filing that a person or group of affiliated or associated persons has become an “Acquiring Person,” which is defined as a person or group of affiliated or associated persons that, at any time after the date of the Amended and Restated Rights Agreement, has acquired, or obtained the right to acquire, beneficial ownership of 4.95% or more of the Company’s outstanding shares of Common Stock, subject to certain exceptions or (ii) the close of business on the tenth business day after the commencement of, or announcement of an intention to commence, a tender offer or exchange offer the consummation of which would result in any person becoming an Acquiring Person (the earlier of such dates being called the “Distribution Date”) (provided, however, that if such tender or exchange offer is terminated prior to the occurrence of the Distribution Date, then no Distribution Date shall occur as a result of such tender or exchange offer).

The Rights, which are not exercisable until the Distribution Date, will expire at or prior to the earliest of (i) the close of business on November 16, 2023; (ii) the time at which the Rights are redeemed pursuant to the Amended and Restated Rights Agreement; (iii) the time at which the Rights are exchanged pursuant to the Amended and Restated Rights Agreement; (iv) the time at which the Rights are terminated upon the occurrence of certain mergers or other transactions approved in advance by the Board; and (v) the close of business on the date set by the Board following a determination by the Board that (x) the Amended and Restated Rights Agreement is no longer necessary or desirable for the preservation of the Tax Benefits or (y) no Tax Benefits are available to be carried forward or are otherwise available (the earliest of (i), (ii), (iii), (iv) and (v) is referred to as the “**Expiration Date**”).

Each share of Preferred Stock will be entitled, when, as and if declared, to a preferential per share quarterly dividend payment equal to the greater of (i) \$1.00 per share or (ii) an amount equal to 1,000 times the dividend declared per share of Common Stock. Each share of Preferred Stock will entitle the holder thereof to 1,000 votes on all matters submitted to a vote of the stockholders of the Company. In the event of any merger, consolidation or other transaction in which shares of Common Stock are converted or exchanged, each share of Preferred Stock will be entitled to receive 1,000 times the amount received per one share of Common Stock.

The Purchase Price payable, and the number of shares of Preferred Stock or other securities or property issuable, upon exercise of the Rights are each subject to adjustment from time to time to prevent dilution (i) in the event of a stock dividend on, or a subdivision, combination or reclassification of the Preferred Stock, (ii) upon the grant to holders of the Preferred Stock of certain rights or warrants to subscribe for or purchase Preferred Stock or convertible securities at less than the then-current market price of the Preferred Stock or (iii) upon the distribution to holders of the Preferred Stock of evidences of indebtedness or assets (excluding regular periodic cash dividends or dividends payable in Preferred Stock) or of subscription rights or warrants (other than those referred to above). The number of outstanding Rights and the number of one one-thousandths of a share of Preferred Stock issuable upon exercise of each Right are also subject to adjustment in the event of a stock split, reverse stock split, stock dividends and other similar transactions involving the Common Stock.

In the event that any person or group of affiliated or associated persons becomes an Acquiring Person, each holder of a Right, other than the Rights beneficially owned by the Acquiring Person, affiliates and associates of the Acquiring Person and certain transferees thereof (which will thereupon become null and void), will thereafter have the right to receive upon exercise of a Right that number of shares of Common Stock having a market value of two times the Purchase Price.

In the event that, after a person or a group of affiliated or associated persons has become an Acquiring Person, the Company is acquired in a merger or other business combination transaction, or 50% or more of the Company's assets or earning power are sold, proper provision will be made so that each holder of a Right will thereafter have the right to receive, upon the exercise thereof at the then-current purchase price of the Right, that number of shares of common stock of the acquiring company having a market value at the time of that transaction equal to two times the Purchase Price.

With certain exceptions, no adjustment in the Purchase Price will be required unless such adjustment would require an increase or decrease of at least one percent (1%) in the Purchase Price. No fractional shares of Preferred Stock will be issued (other than fractions which are integral multiples of one one-thousandth of a share of Preferred Stock, which may, at the election of the Company, be evidenced by depositary receipts) and, in lieu thereof, an adjustment in cash will be made based on the market price of the Preferred Stock on the trading day immediately prior to the date of exercise.

At any time after any person or group of affiliated or associated persons becomes an Acquiring Person and prior to the acquisition of beneficial ownership by such Acquiring Person of 50% or more of the outstanding shares of Common Stock, the Board, at its option, may exchange each Right (other than Rights owned by such person or group of affiliated or associated persons which will have become void), in whole or in part, at an exchange ratio of one share of Common Stock per outstanding Right (subject to adjustment).

In connection with any exercise or exchange of the Rights, no holder of a Right will be entitled to receive shares of Common Stock if receipt of such shares would result in such holder, together with such holder's affiliates and associates, beneficially owning more than 4.95% of the then-outstanding Common Stock (such shares, the "Excess Shares") and the Board determines that such holder's receipt of Excess Shares would jeopardize or endanger the value or availability of the Tax Benefits or the Board otherwise determines that such holder's receipt of Excess Shares is not in the best interests of the Company. In lieu of such Excess Shares, such holder will only be entitled to receive cash or a note or other evidence of indebtedness with a principal amount equal to the then-current market price of the Common Stock multiplied by the number of Excess Shares that would otherwise have been issuable.

At any time before the Distribution Date, the Board may redeem the Rights in whole, but not in part, at a price of \$0.001 per Right (subject to certain adjustments) (the "Redemption Price"). The redemption of the Rights may be made effective at such time, on such basis and with such conditions as the Board in its sole discretion may establish.

Immediately upon the action of the Board electing to redeem or exchange the Rights, the Company shall make a public announcement thereof, and upon such election, the right to exercise the Rights will terminate and the only right of the holders of Rights will be to receive the Redemption Price.

Until a Right is exercised or exchanged, 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.

The Board may amend or supplement the Amended and Restated Rights Agreement without the approval of any holders of Rights, including, without limitation, in order to (a) cure any ambiguity, (b) correct inconsistent provisions, (c) alter time period provisions, including the Expiration Date, or (d) make additional changes to the Amended and Restated Rights Agreement that the Board deems necessary or desirable. However, from and after the date any person or group of affiliated or associated persons becomes an Acquiring Person, the Amended and Restated Rights Agreement may not be supplemented or amended in any manner that would adversely affect the interests of the holders of Rights.

10. Income Taxes

At December 31, 2021, the Company had federal and state net operating loss carryforwards (“NOLs”) of \$335.0 million and \$259.9 million, respectively, available to offset against future taxable income. Of this amount, \$310.3 million of federal NOLs expire in 2024 through 2037. The federal operating losses after 2018 totaling \$24.4 million carry forward indefinitely but are only able to offset 80% of taxable income in future years. The California NOLs expire in 2029 through 2040.

As a result of a change in-control that occurred in the CytRx shareholder base, approximately \$67.6 million in federal net operating loss carryforwards became substantially limited in their annual availability. Management currently believes that the remaining \$267.4 million in federal net operating loss carryforwards, and the \$259.9 million in state net operating loss carryforwards, are unrestricted.

As of December 31, 2021, 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. The credits are subject to change-in-control limitations, which may affect their utilization in future years. 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,	
	2021	2020
Deferred tax assets:		
Net operating loss carryforwards	\$ 74,167	\$ 72,509
Tax credit carryforwards	37,866	37,901
Equipment, furnishings and other	4,174	4,174
Total deferred tax assets	116,207	114,584
Deferred tax liabilities	—	—
Net deferred tax assets	116,207	114,584
Valuation allowance	(116,207)	(114,584)
	<u>\$ —</u>	<u>\$ —</u>

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, 2021 and 2020 was \$1.6 million and \$9.5 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,	
	2021	2020
Federal benefit at statutory rate	\$ (2,745)	\$ (1,407)
State income taxes, net of Federal taxes	(913)	(592)
State credits	—	—
Warrant liabilities	—	—
Other permanent differences	1,685	7
Provision related to change in valuation allowance	1,947	1,996
Federal rate adjustment	—	—
NQ Options	—	—
Current year tax credit	—	—
NOL Adjustments	—	—
Termination/Cancellation of Equity Compensation Awards	—	—
Return to provision	26	(4)
Other, net	—	—
	\$ —	\$ —

There have been no changes to the Company's liability for unrecognized tax benefits during the year ended December 31, 2021.

The Company files income tax returns in the U.S. Federal jurisdiction and various state jurisdictions. As of the year ended December 31, 2021, the tax returns for 2018 through 2021 remain open to examination by the Internal Revenue Service and for 2017 to 2021 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, 2021 and 2020, the Company had accrued no interest or penalties related to uncertain tax positions.

11. 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.

As of December 31, 2021, no amounts are due under the above agreements.

Contractual obligations

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

	Employment Agreements (1)
2022	1,085
2023	—
2024	—
2025	—
Thereafter	—
Total	<u>\$ 1,085</u>

- (1) 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. Among other things, the active and planned clinical trials by ImmunityBio and Orphazyme and their regulatory approvals, if any, may be delayed or interrupted, which could delay or adversely affect the Company's potential receipt of milestone and royalty payments within the disclosed time periods and increase expected costs. As of the date of this filing, senior management and administrative staff are working primarily remotely and will return to their offices at a yet to be determined date.

12. Subsequent Events

On March 15, 2022, the Company held a special meeting of stockholders, which was originally opened and subsequently adjourned on September 23, 2021, at which meeting the Company's stockholders, by an affirmative vote of the majority of the Company's outstanding shares of capital stock, approved the amendment to the Company's Restated Certificate of Incorporation to effect an increase in the number of shares of authorized common stock, par value \$0.001 per share, from 41,666,666 shares to 62,393,940 shares, and to make a corresponding change to the number of authorized shares of capital stock in order to comply with the Company's contractual obligations under a securities purchase agreement entered into on July 13, 2021. The number of shares of authorized preferred stock of the Company remains unchanged.

On March 15, 2022, the Company filed a Certificate of Amendment to Restated Certificate of Incorporation with the Secretary of State of Delaware to effect the Authorized Share Increase Amendment.

On January 1, 2022, the Company paid a quarterly 10% dividend to the Investor in the amount of \$206,000.

Exhibit 4.4**DESCRIPTION OF SECURITIES**

The following description is intended as a summary and is qualified in its entirety by reference to our Restated Certificate of Incorporation, as amended (the "Certificate of Incorporation") and our Amended and Restated By-Laws (the "By-laws") as currently in effect, copies of which are filed as exhibits to this Amendment No. 1 to the Annual Report on Form 10-K and are incorporated by reference herein.

Authorized Capital Stock

As of March 23, 2022, we have authorized 63,227,273 shares of capital stock, par value \$0.001 per share, of which 62,393,940 are shares of common stock and 833,333 are shares of "blank check" preferred stock, par value \$0.01 per share, of which 50,000 are authorized as Series B Junior Participating Preferred Stock and 8,240 are authorized as Series C 10.00% Convertible Preferred Stock. As of March 23, 2022, there were 38,801,442 shares of common stock issued and outstanding and 8,240 shares of Series C 10.00% Convertible Preferred Stock issued and outstanding. We have reserved all of the shares of our Series B Junior Participating Preferred Stock for issuance upon the exercise of the rights under our Shareholder Protection Rights Agreement described below. The authorized and unissued shares of common stock and the authorized and undesignated shares of preferred stock are available for issuance without further action by our stockholders, unless such action is required by applicable law or the rules of any stock exchange on which our securities may be listed. Unless approval of our stockholders is so required, our board of directors does not intend to seek stockholder approval for the issuance and sale of our common stock or preferred stock.

Common Stock

Holders of our common stock are entitled to one vote per share on matters on which our stockholders vote, including with respect to the election of directors. Holders of common stock are entitled to receive dividends, if declared by our board of directors, out of funds that we may legally use to pay dividends. If we liquidate or dissolve, holders of common stock are entitled to share ratably in our assets once our debts and any liquidation preference owed to holders of any then-outstanding preferred stock are paid. All shares of common stock that are outstanding as of the date of this report are fully-paid and nonassessable. Holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions with respect to our common stock. Our common stock is listed on The OTC Market under the symbol "CYTR".

Classified Board of Directors

Pursuant to our Certificate of Incorporation and By-laws, the members of our board of directors shall be divided into three classes, designated as Classes I, II and III, with each class consisting as nearly as possible of one-third (1/3) of the total number of directors. One class of directors is to be elected at each annual meeting of stockholders to serve for a term of three years. In the election of directors, the directors shall be elected by a plurality of the votes cast by holders of each class of stock entitled to elect directors or a class of directors.

Preferred Stock

The board of directors is authorized, subject to any limitations prescribed by law, without further vote or action by the stockholders, to issue from time to time shares of preferred stock in one or more series. Each such series of preferred stock shall have such number of shares, designations, preferences, voting powers, qualifications, and special or relative rights or privileges as shall be determined by the board of directors, which may include, among others, dividend rights, voting rights, liquidation preferences, conversion rights and preemptive rights. Issuance of preferred stock by our board of directors may result in such shares having dividend and/or liquidation preferences senior to the rights of the holders of our common stock and could dilute the voting rights of the holders of our common stock.

Series B Junior Participating Preferred Stock

Each share of the Series B Junior Participating Preferred Stock is entitled to receive, when, as and if declared by the board of directors out of funds legally available for that purpose, quarterly dividends payable in cash on the last day of February, May, August, and December in each year (each such date being a “Quarterly Dividend Payment Date”), in an amount per share (rounded to the nearest cent) equal to the greater of (a) \$1.00 or (b) subject to certain adjustments, 1,000 times the aggregate per share amount of all cash dividends declared on shares of the common stock since the immediately preceding Quarterly Dividend Payment Date, and, subject to certain adjustments, quarterly distributions (payable in kind) on each Quarterly Dividend Payment Date in an amount per share equal to 1,000 times the aggregate per share amount of all non-cash dividends or other distributions (other than a dividend payable in shares of common stock or a subdivision of the outstanding shares of common stock, by reclassification or otherwise) declared on shares of common stock since the immediately preceding Quarterly Dividend Payment Date. The terms of the Series B Junior Participating Preferred Stock were amended on November 12, 2020. The description herein reflects such amended terms.

In the event of our liquidation or winding up of affairs, no distribution shall be made to the holders of shares of stock junior to Series B Junior Participating Preferred Stock, including common stock, unless the holders of shares of Series B Junior Participating Preferred Stock shall have received, the greater of either (a) \$1.00 per share plus an amount equal to accrued and unpaid dividends and distributions thereon, whether or not declared, to the date of such payment, or (b) the amount equal to 1,000 times the aggregate per share amount to be distributed to holders of shares of common stock, or to the holders of shares ranking *pari passu* with the Series B Preferred Stock, unless simultaneously therewith distributions are made ratably on shares of Series B Junior Participating Preferred Stock and all other shares of such *pari passu* shares in proportion to the total amounts to which the holders of shares of Series B Junior Participating Preferred Stock are entitled under clause (a) of this sentence and to which the holders of such *pari passu* shares are entitled, in each case upon such liquidation, dissolution or winding up.

If at any time dividends on any shares of Series B Junior Participating Preferred Stock are in arrears in an amount equal to six quarterly dividends, then the number of directors constituting the board of directors shall automatically be increased by two, and during the period (a “default period”) from such time until the time when all accrued and unpaid dividends for all previous quarterly dividend periods and for the current quarterly dividend period on all shares of Series B Junior Participating Preferred Stock have been declared and paid, the holders of the outstanding shares of Series B Junior Participating Preferred Stock, together with the holders of outstanding shares of any one or more other series of preferred stock entitled to like voting rights (voting together as a single class), shall have the right to elect two directors to the board of directors at our next annual meeting of stockholders, and may elect a successor to each of the two directors so long as such default period continues.

Options, Warrants and Convertible Securities

As of March 23, 2022, the Company had 2,827,820 shares of common stock issuable upon exercise of outstanding options, 4,167 shares of common stock issuable upon the exercise of warrants, 11,363,637 shares of common stock issuable upon the exercise of the preferred investment option and 9,363,637 shares of common stock issuable upon conversion of our preferred stock. There are no other outstanding warrants, options or restricted stock units at this time.

Anti-Takeover Law and Provisions of our Certificate of Incorporation and By-laws

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

- prior to that date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
 - upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, though some shares may be excluded from the calculation; or
 - on or subsequent to that date, the business combination is approved by the board of directors of the corporation and by the affirmative votes of holders of at least two-thirds of the outstanding voting stock that is not owned by the interested stockholder.
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The term “business combination” is defined to include, among other transactions between an interested stockholder and a corporation or any direct or indirect majority owned subsidiary thereof: a merger or consolidation; a sale, lease, exchange, mortgage, pledge, transfer or other disposition (including as part of a dissolution) of assets having an aggregate market value equal to 10% or more of either the aggregate market value of all assets of the corporation on a consolidated basis or the aggregate market value of all the outstanding stock of the corporation; certain transactions that would result in the issuance or transfer by the corporation of any of its stock to the interested stockholder; certain transactions that would increase the interested stockholder’s proportionate share ownership of the stock of any class or series of the corporation or such subsidiary; and any receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation or any such subsidiary.

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

Certificate of Incorporation and By-Law Provisions

In addition to the board of directors’ ability to issue shares of preferred stock, our Certificate of Incorporation and By-laws contain the following provisions that may have the effect of discouraging unsolicited acquisition proposals:

- our By-laws classify the board of directors into three classes with staggered three-year terms;
 - under our By-laws, our board of directors may enlarge the size of the board and fill the vacancies;
 - our By-laws provide that a stockholder may not nominate candidates for the board of directors at any annual or special meeting unless that stockholder notifies us of its intention a specified period in advance and provides us with certain required information;
 - stockholders who wish to bring business before the stockholders at our annual meeting must provide advance notice;
 - our By-laws provide that stockholders may only act by written consent in lieu of a meeting if such consent is unanimous; and
 - our By-laws provide that special meetings of stockholders may only be called by our board of directors or by an officer so instructed by our board.
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Our By-laws also provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for:

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

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

Shareholder Protection Rights Agreement

On December 13, 2019, our board of directors, authorized and declared a dividend of one right (a “Right”) for each of our issued and outstanding shares of common stock. The dividend was paid to the stockholders of record at the close of business on December 23, 2019. Each Right entitled the registered holder, subject to the terms of the Original Rights Agreement (as defined below), to purchase from us one one-thousandth of a share of our Series B Junior Participating Preferred Stock, par value \$0.01 per share (the “Preferred Stock”), at a price of \$5.00 (the “Purchase Price”), subject to certain adjustments. The description and terms of the Rights were set forth in the Rights Agreement, dated as of December 13, 2019 (the “Original Rights Agreement”), by and between us and American Stock Transfer & Trust Company, LLC, as Rights Agent (the “Rights Agent”).

On November 12, 2020, the board of directors approved an amendment and restatement of the Original Rights Agreement (as amended and restated, the “Amended and Restated Rights Agreement”) to effect certain changes to the Original Rights Agreement, including (i) reducing the duration to a term of three years, subject to certain earlier expiration as described in more detail below, and (ii) lowering the beneficial ownership threshold at which a person or group of persons becomes an Acquiring Person (as defined below) to 4.95% or more of our outstanding shares of common stock, subject to certain exceptions. The Amended and Restated Rights Agreement is designed to discourage (i) any person or group of persons from acquiring beneficial ownership of more than 4.95% of our shares of common stock and (ii) any existing stockholder currently beneficially holding 4.95% or more of our shares of common stock from acquiring additional shares of our common stock.

The purpose of the Amended and Restated Rights Agreement is to protect value by preserving the Company’s ability to utilize its net operating losses and certain other tax attributes (collectively, the “Tax Benefits”) to offset potential future income tax obligations. Our ability to use our Tax Benefits would be substantially limited if it experiences an “ownership change,” as such term is defined in Section 382 of the Internal Revenue Code of 1986, as amended (the “Tax Code”). A corporation generally will experience an ownership change if the percentage of the corporation’s stock owned by its “5-percent shareholders,” as defined in Section 382 of the Tax Code, increases by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. The Amended and Restated Rights Agreement is intended to reduce the likelihood we would experience an ownership change under Section 382 of the Tax Code. The rights are only exercisable upon the occurrence of certain triggering events described in the Amended and Restated Rights Agreement.

Transfer Agent

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

Exhibit 10.8

EMPLOYMENT AGREEMENT

This Employment Agreement (this “**Agreement**”) is made and entered into this 16th day of December, 2021, with an effective date of January 1, 2022 (the “**Effective Date**”) by and between CytRx Corporation, a Delaware corporation (“**Employer**”), and John Caloz, an individual and resident of the State of California (“**Executive**”).

WHEREAS, Employer desires to continue to employ Executive, and Executive is willing to continue to be employed by Employer, on the terms set forth in this Agreement.

NOW, THEREFORE, upon the above premises, and in consideration of the mutual covenants and agreements hereinafter contained, the parties hereto agree as follows.

1. Employment. Effective as of the Effective Date, Employer shall continue to employ Executive, and Executive shall serve, as Employer’s Chief Financial Officer and Senior Vice President on the terms set forth herein.

2. Duties; Place of Employment. Executive shall perform in a professional and business-like manner, and to the best of his ability, the duties described on **Schedule 1** to this Agreement and such other duties as are assigned to him from time to time by the Employer’s Board of Directors. Executive understands and agrees that his duties, title and authority may be changed from time to time in the discretion of Employer’s Board of Directors. Executive’s services hereunder shall be rendered from his home.

3. Time and Efforts. Executive shall devote all of his business time, efforts, attention and energies to Employer’s business and to discharge his duties hereunder.

4. Term. The term (the “**Term**”) of Executive’s employment hereunder shall commence on the Effective Date and shall expire on December 31, 2022 unless sooner terminated in accordance with Section 6 or otherwise extended or renewed by mutual agreement of the parties. Neither Employer nor Executive shall have any obligation to extend or renew this Agreement. In the event that Executive’s employment has not theretofore been terminated and Employer has not offered to extend or renew Executive’s employment under this Agreement, upon expiration of the Term Employer shall continue to pay Executive his salary as provided for in Section 5.1 during the period commencing on the final date of the Term and ending on (a) June 30, 2023 or (b) the date of Executive’s re-employment with another employer, whichever is earlier; provided that, as a condition to Employer’s obligations under this sentence, Executive shall have executed and delivered to Employer a General Release of All Claims in the form attached hereto as **Exhibit A**. Executive shall notify Employer immediately in the event Executive accepts such employment with another employer.

5. Compensation. As the total consideration for Executive's services rendered hereunder, Employer shall pay or provide Executive the following compensation and benefits:

5.1. Salary. Executive shall be entitled to receive an annual salary of Four Hundred Thousand Dollars (\$400,000), payable in accordance with Employer's normal payroll policies and procedures.

5.2. Bonus. Executive also shall be eligible for a bonus for his services during the Term in Employer's discretion, but not less than ONE HUNDRED THOUSAND DOLLARS (\$100,000.00). Any bonus payable to Executive shall be paid no later than the last regular payroll of 2022.

5.3. Expense Reimbursement. Employer shall reimburse Employee for reasonable and necessary business expenses incurred by Executive in connection with the performance of Executive's duties in accordance with Employer's usual practices and policies in effect from time to time.

5.4. Vacation. Executive shall continue to accrue vacation days without loss of compensation in accordance with Employer's usual policies applicable to all employees at a rate of four weeks' vacation time for each 12-month period during the Term.

5.5. Employee Benefits. Executive shall be eligible to participate in all employee benefit plans and programs (including reimbursement of all Medicare and related premiums), fringe benefits and perquisites as in effect generally with respect to other senior officers of Employer, which will include no less than Medical, Dental, Vision, and Life Insurance plans.

5.6. Payroll Taxes. Employer shall have the right to deduct from the compensation and benefits due to Executive hereunder any and all sums required for social security and withholding taxes and for any other federal, state, or local tax or charge which may be in effect or hereafter enacted or required as a charge on the compensation or benefits of Executive.

6. Termination. This Agreement may be terminated as set forth in this Section 6.

6.1. Termination by Employer for Cause. Employer may terminate Executive's employment hereunder for "Cause" upon notice to Executive. "Cause" for this purpose shall mean any of the following:

(a) Executive's breach of any material term of this Agreement; provided that the first occasion of any particular breach shall not constitute such Cause unless Executive shall have previously received written notice from Employer stating the nature of such breach and affording Executive at least ten days to correct such breach;

(b) Executive's conviction of, or plea of guilty or nolo contendere to, any misdemeanor, felony or other crime of moral turpitude;

(c) Executive's act of fraud or dishonesty injurious to Employer or its reputation;

(d) Executive's continual failure or refusal to perform his material duties as required under this Agreement after written notice from Employer stating the nature of such failure or refusal and affording Executive at least ten days to correct the same;

(e) Executive's act or omission that, in the reasonable determination of Employer's Board of Directors (or a Committee of the Board), indicates alcohol or drug abuse by Executive; or

(f) Executive's act or personal conduct that, in the judgment of Employer's Board of Directors (or a Committee of the Board), gives rise to a material risk of liability of Executive or Employer under federal or applicable state law for discrimination, or sexual or other forms of harassment, or other similar liabilities to subordinate employees.

Upon termination of Executive's employment by Employer for Cause, all compensation and benefits to Executive hereunder shall cease and Executive shall be entitled only to payment upon the effective date of termination of any accrued but unpaid salary and unused vacation as provided in Sections 5.1 and 5.4 as of the date of such termination and any unpaid bonus that may have been awarded Executive as provided in Section 5.2 prior to such date.

6.2. Termination by Employer without Cause or by Executive for Good Reason. Employer may also terminate Executive's employment without Cause upon ten days' notice to Executive. Upon termination of Executive's employment by Employer without Cause, all compensation and benefits to Executive hereunder shall cease and Executive shall be entitled to (1) any accrued but unpaid salary and unused vacation as of the date of such termination as required by California law, which shall be due and payable upon the effective date of such termination, (2) any unpaid bonus that may have been awarded to Executive under Section 5.2 prior to such date, which shall be due and payable in accordance with Employer's normal payroll practices or as otherwise required by California law, (3) all of Executive's vested stock options and other equity awards as of the date of termination of Executive's employment shall remain exercisable for their full term, (4) retain and have full ownership of all electronic devices provided to Executive (including, without limitation, a computer, telephone, tablet and printer), provided that all Employer confidential information shall be deleted by Employer from such devices before releasing them to Executive, (5) an amount, which shall be due and payable within ten days following the effective date of such termination, equal to six months' salary as provided in Section 5.1., provided, that if such termination occurs following a Change of Control (as hereinafter defined), then the amount described in this clause (5) shall be equal to 12 months' salary as provided in Section 5.1, any amount due under Section 5.2, and (6) continued participation, at Employer's cost and expense, of Executive and his dependents for a period of six months following such termination (12 months if such termination occurs following a Change of Control) in any Employer-sponsored group benefit plans (including reimbursement of all Medicare and related premiums) in which Executive was participating as of the date of termination. Executive's right to the compensation and benefits provided for in clauses (5) and (6) of this Section 6.2 shall be conditioned upon Executive having executed and delivered to Employer a General Release of All Claims in the form attached hereto as Exhibit A. For purposes of this Section 6.2:

(a) "**Change of Control**" shall have the meaning ascribed to the term "Corporate Transaction" in Employer's 2019 Stock Incentive Plan, as such Plan may be amended from time to time and, to the extent required to comply with Section 409A of the Code, shall mean a change in control within the meaning of Section 409A of the Code.

(b) “**Good Reason**” shall mean any material breach by Employer of the terms hereof that is not corrected by Employer within five (5) days after written notice by Executive to Employer, including, without limitation, (i) the assignment to Executive of any duties inconsistent in any respect with his position as Chief Financial Officer (including status, offices, titles, reporting requirements, authority, duties or responsibilities); or (ii) any failure by Employer to comply with its compensation obligations under this Agreement, inclusive of Executive Benefits afforded in Section 5.5. If Executive terminates his employment for Good Reason, subject to Employer’s right to cure as set forth above, the termination shall take effect on the effective date (determined under Section 15) of the written notice to Employer. Notwithstanding the foregoing, in the event Executive does not terminate his employment for Good Reason within thirty (30) days after the Employer’s failure to cure as provided herein, such condition giving rise to a “Good Reason” shall no longer constitute Good Reason for Executive to terminate his employment.

6.3 Death or Disability. In the event of Executive’s death or “Disability” (as defined below) during the Term, the Executive’s employment shall automatically cease and terminate as of the date of Executive’s death or the effective date of Employer’s written notice to Executive of its decision to terminate his employment by reason of his Disability, as the case may be, and Executive or his heirs or personal representative shall be entitled to the same payments and benefits, at the same times, as described in Section 6.2 for a termination of employment by Employer without Cause and all of Employee’s stock options and any other equity awards based on Employer securities held by Executive at the time of his death or Disability shall immediately vest in full and shall remain exercisable thereafter for their full term. In addition, Executive or his heirs or personal representative shall be entitled to retain and have full ownership of all electronic devices provided to Executive (including, without limitation, a computer, telephone and tablet); provided that all Employer confidential information shall be deleted by Employer from such devices before releasing them to Executive or such heirs or personal representatives. Notwithstanding the foregoing or any provision of Section 6.2, Employer’s obligation to pay Executive the salary called for in Section 6.2 for the Severance Period following termination of his employment by reason of his Disability shall be subject to offset and shall be reduced by any and all amounts paid to Executive under any disability insurance policy paid or provided for by Employer as provided in Section 5.6 or otherwise. Executive’s “Disability” shall have the meaning ascribed to such term in any policy of disability insurance maintained by Employer (or by Executive, as the case may be) with respect to Executive or, if no such policy is then in effect, shall mean Executive’s inability to fully perform his duties hereunder for any period of at least 75 consecutive days or for a total of 90 days, whether or not consecutive.

7. Confidentiality. While this Agreement is in effect and for a period of five years thereafter, Executive shall hold and keep secret and confidential all “trade secrets” (within the meaning of applicable law) and other confidential or proprietary information of Employer and shall use such information only in the course of performing Executive’s duties hereunder; provided, however, that with respect to trade secrets, Executive shall hold and keep secret and confidential such trade secrets for so long as they remain trade secrets under applicable law. Executive shall maintain in trust all such trade secrets or other confidential or proprietary information, as Employer’s property, including, but not limited to, all documents concerning Employer’s business, including Executive’s work papers, telephone directories, customer information and notes, and any and all copies thereof in Executive’s possession or under Executive’s control. Upon the expiration or earlier termination of Executive’s employment with Employer, or upon request by Employer, Executive shall deliver to Employer all such documents belonging to Employer, including any and all copies in Executive’s possession or under Executive’s control.

8. Equitable Remedies; Injunctive Relief. Executive hereby acknowledges and agrees that monetary damages are inadequate to fully compensate Employer for the damages that would result from a breach or threatened breach of Section 7 of this Agreement and, accordingly, that Employer shall be entitled to equitable remedies, including, without limitation, specific performance, temporary restraining orders, and preliminary injunctions and permanent injunctions, to enforce such Section without the necessity of proving actual damages in connection therewith. This provision shall not, however, diminish Employer’s right to claim and recover damages or enforce any other of its legal or equitable rights or defenses.

9. Indemnification; Insurance. Employer and Executive acknowledge that, as the Chief Financial Officer of the Employer, Executive shall be a corporate officer of Employer and, as such, Executive shall be entitled to indemnification to the full extent provided by Employer to its officers, directors and agents under the Employer’s Certificate of Incorporation and Bylaws as in effect as of the date of this Agreement. Employer shall maintain Executive as an additional insured under its current policy of directors and officers liability insurance and shall use commercially reasonable efforts to continue to insure Executive thereunder, or under any replacement policies in effect from time to time, during the Term.

10. Severable Provisions. The provisions of this Agreement are severable and if any one or more provisions is determined to be illegal or otherwise unenforceable, in whole or in part, the remaining provisions, and any partially unenforceable provisions to the extent enforceable, shall nevertheless be binding and enforceable.

11. Successors and Assigns. This Agreement shall inure to the benefit of and shall be binding upon Employer, its successors and assigns and Executive and his heirs and representatives; provided, that this Agreement may be assigned by Employer to a successor (whether direct or indirect, by purchase, merger, consolidation or otherwise) to all or substantially all of the business or assets of Employer.

12. Entire Agreement. This Agreement contains the entire agreement of the parties relating to the subject matter hereof, and the parties hereto have made no agreements, representations or warranties relating to the subject matter of this Agreement that are not set forth otherwise herein. This Agreement supersedes any and all prior or contemporaneous agreements, written or oral, between Executive and Employer relating to the subject matter hereof. Any such prior or contemporaneous agreements are hereby terminated and of no further effect, and Executive, by the execution hereof, agrees that any compensation provided for under any such agreements is specifically superseded and replaced by the provisions of this Agreement.

13. Amendment. No modification of this Agreement shall be valid unless made in writing and signed by the parties hereto and unless such writing is made by an executive officer of Employer (other than Executive). The parties hereto agree that in no event shall an oral modification of this Agreement be enforceable or valid.

14. Governing Law. This Agreement is and shall be governed and construed in accordance with the laws of the State of California without giving effect to California's choice-of-law rules.

15. Notice. All notices and other communications under this Agreement shall be in writing and mailed, telecopied (in case of notice to Employer only) or delivered by hand or by a nationally recognized courier service guaranteeing overnight delivery to a party at the following address (or to such other address as such party may have specified by notice given to the other party pursuant to this provision):

If to Employer:

CytRx Corporation
11726 San Vicente Boulevard, Suite 650
Los Angeles, California 90049
Facsimile: (310) 826-5529
Attention: Chairman of the Board

If to Executive:

John Caloz
9901 Washington Blvd, Ste 512
Culver City, California 90232

16. Survival. Sections 7 through 16, 18 and 19 shall survive the expiration or termination of this Agreement.

17. Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed to be an original and all of which together shall be deemed to be one and the same agreement. A counterpart executed and transmitted by facsimile shall have the same force and effect as an originally executed counterpart.

18. Attorney's Fees. In any action or proceeding to construe or enforce any provision of this Agreement the prevailing party shall be entitled to recover its or his reasonable attorneys' fees and other costs of suit (up to a maximum of \$15,000) in addition to any other recoveries.

19. Section 409A of the Code. The intent of the parties is that the payments and benefits under this Agreement comply with or be exempt from Section 409A of the Code, and accordingly, to the maximum extent permitted, this Agreement shall be interpreted to be in compliance therewith. Notwithstanding anything in this Agreement to the contrary, any compensation or benefits payable under this Agreement that is designated under this Agreement as payable upon the Executive's termination of employment shall be payable only upon the Executive's "separation from service" with Employer within the meaning of Section 409A of the Code. To the extent necessary to comply with Section 409A of the Code, if the period during which the Executive has discretion to execute or to revoke the release of claims straddles two of the Executive's taxable years, then Employer will provide benefits starting in the second of such taxable years, regardless of in which taxable year the Executive actually delivers the executed release to Employer. Further, to the extent that any post-termination payments to which Executive becomes entitled under this Agreement constitute deferred compensation subject to Section 409A of the Code, and Executive is deemed at the time of such termination to be a "specified employee" under Section 409A of the Code, then such payment will not be made or commence until the earliest of (i) the expiration of the six (6) month period measured from the date of Executive's "separation from service" and (ii) the date of Executive's death following such "separation from service". Upon the expiration of the applicable deferral period, any payments which would have otherwise been made during that period (whether in a single sum or installments) in the absence of this Section 19 will be paid to Executive or Executive's beneficiary in one lump sum.

20. No Interpretation of Ambiguities Against Drafting Party. This Agreement has been negotiated at arm's length between persons knowledgeable in the matters dealt with herein. In addition, each party has been represented by experienced and knowledgeable legal counsel. Accordingly, the parties agree that any rule of law, including, but not limited to, California Civil Code Section 1654 or any other statutes, legal decisions, or common law principles of similar effect, that would require interpretation of any ambiguities in this Agreement against the party that has drafted it, is of no application and is hereby expressly waived. The provisions of this Agreement shall be interpreted in a reasonable manner to effect the intentions of the parties hereto.

[Signature Page Follows]

IN WITNESS WHEREOF, this Agreement is executed as of the day and year first above written.

“EMPLOYER”

CytRx Corporation

By:

Steven A. Kriegsman
Chairman of the Board

“EXECUTIVE”

John Caloz

EXHIBIT A

GENERAL RELEASE OF ALL CLAIMS

This General Release of All Claims is made as of _____, 20__ (“**General Release**”), by and between John Caloz (“**Executive**”) and CytRx Corporation, a Delaware corporation (the “**Company**”), with reference to the following facts:

WHEREAS, this General Release is provided for in, and is in furtherance of, the Employment Agreement, dated as of December 16, 2022, between the Company and Executive (the “**Employment Agreement**”);

WHEREAS, Executive desires to execute and deliver to the Company this General Release in consideration of the Company’s providing Executive with certain severance benefits pursuant to Section 4 or Section 6.2, as applicable, of the Employment Agreement; and

WHEREAS, Executive and the Company intend that this General Release shall be in full satisfaction of any and all obligations described in this General Release owed to Executive by the Company, except as expressly provided in this General Release.

NOW, THEREFORE, in consideration of the promises and the mutual covenants and agreements herein contained, Executive and the Company agree as follows:

1. Executive, for himself, his spouse, heirs, administrators, children, representatives, executors, successors, assigns, and all other persons claiming through Executive, if any (collectively, “**Releasers**”), does hereby release, waive, and forever discharge the Company and each of its agents, subsidiaries, parents, affiliates, related organizations, employees, officers, directors, attorneys, successors, and assigns (collectively, the “**Releasees**”) from, and does fully waive any obligations of Releasees to Releasers for, any and all liability, actions, charges, causes of action, obligations, demands, damages, or claims for relief, remuneration, sums of money, accounts or expenses (including attorneys’ fees and costs) of any kind whatsoever, whether known or unknown or contingent or absolute, which heretofore has been or which hereafter may be suffered or sustained, directly or indirectly, by Releasers in consequence of, arising out of, or in any way relating to: (a) Executive’s employment with and services to the Company or any of its affiliates; (b) the termination of Executive’s employment with and services to the Company and any of its affiliates; or (c) any event whatsoever occurring on or prior to the date of this General Release. The foregoing release and discharge, waiver and covenant not to sue includes, but is not limited to, all claims and any obligations or causes of action arising from such claims, under common law including, but not limited to, wrongful or retaliatory discharge, breach of contract (including but not limited to any claims under any employment agreement between Executive, on the one hand, and the Company or its affiliates, on the other hand) and any action arising in tort including, but not limited to, libel, slander, defamation or intentional infliction of emotional distress, and claims under any federal, state or local statute including the Age Discrimination in Employment Act (“**ADEA**”), Title VII of the Civil Rights Act of 1964, the Civil Rights Act of 1866 and 1871 (42 U.S.C. § 1981), the National Labor Relations Act, the Fair Labor Standards Act, the Employee Retirement Income Security Act, the Americans with Disabilities Act of 1990, the Rehabilitation Act of 1973, the California Fair Employment and Housing Act, the Family and Medical Leave Act, the California Family Rights Act or the discrimination or employment laws of any state or municipality, and any claims under any express or implied contract which Releasers may claim existed with Releasees. This also includes, but is not limited to, a release of any claims for wrongful discharge and all claims for alleged physical or personal injury, emotional distress relating to or arising out of Executive’s employment with or services to the Company or any of its affiliates or the termination of that employment or those services; and any claims under the Worker Adjustment and Retraining Notification Act, California Labor Code Section 1400 *et seq.* or any similar law, which requires, among other things, that advance notice be given of certain work force reductions. This release and waiver does not apply to: (i) the Executive’s rights to receive the compensation and benefits provided for in Section 4 or Section 6.2, as applicable, of the Employment Agreement; or (ii) Executive’s rights under any stock option agreement between Executive and the Company.

2. Executive understands and agrees that he is expressly waiving all rights afforded by Section 1542 of the Civil Code of the State of California (“**Section 1542**”) with respect to the Releasees. Section 1542 states as follows:

A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS WHICH THE CREDITOR DOES NOT KNOW OR SUSPECT TO EXIST IN HIS FAVOR AT THE TIME OF EXECUTING THE RELEASE, WHICH IF KNOWN BY HIM MUST HAVE MATERIALLY AFFECTED HIS SETTLEMENT WITH THE DEBTOR.

Notwithstanding the provisions of Section 1542, and for the purpose of implementing a full and complete release, Executive understands and agrees that this General Release is intended to include all claims, if any, which Executive may have and which he does not now know or suspect to exist in his favor against the Releasees and Executive understands and agrees that this Agreement extinguishes those claims.

3. Excluded from this General Release and waiver are any claims which cannot be waived by law, including but not limited to the right to participate in an investigation conducted by certain government agencies. Executive, however, waives Executive’s right to any monetary recovery should any agency (such as the Equal Employment Opportunity Commission or the California Department of Fair Employment and Housing) pursue any claims on Executive’s behalf. Executive represents and warrants that Executive has not filed any complaint, charge or lawsuit against the Releasees with any government agency or any court.

4. Executive agrees never to seek personal recovery from Releasees in any forum for any claim covered by the above waiver and release language, except that Executive may bring a claim under the ADEA to challenge this General Release. Nothing in this General Release is intended to reflect any party’s belief that Executive’s waiver of claims under ADEA is invalid or unenforceable, it being the intent of the parties that such claims are waived.

5. Executive acknowledges and recites that:

(a) Executive has executed this General Release knowingly and voluntarily;

(b) Executive has read and understands this General Release in its entirety;

(c) Executive acknowledges that he has been advised by his own legal counsel and has sought such other advice as he wishes with respect to the terms of this General Release before executing it;

(d) Executive's execution of this General Release has not been forced by any employee or agent of the Company, and Executive has had an opportunity to negotiate about the terms of this General Release; and

(e) Executive has not sold, assigned, transferred or conveyed any claim, demand, right, action, suit, cause of action or other interest that is the subject matter of this General Release.

6. This General Release shall be governed by the internal laws (and not the choice of laws) of the State of California, except for the application of preemptive Federal law.

7. Executive acknowledges that he is waiving his rights under the ADEA and the Older Worker's Benefit Protection Act and therefore, in compliance with those statutes, acknowledges the following:

Executive acknowledges that he has been provided a minimum of twenty-one (21) calendar days after receipt of this Agreement to consider whether to sign it;

Executive acknowledges that he shall have seven days from the date he executes this General Release to revoke his waiver and release of any ADEA claims only (but not his waiver or release hereunder of other claims) by providing written notice of the revocation to the Company, and that, in the event of such revocation, the provisions of Section 4 or clauses (3) through (5) of Section 6.2, as applicable, of the Employment Agreement shall thereupon become null and void and the Company shall be entitled to a return from Executive of all payments to Executive pursuant to such clauses;

Executive acknowledges that this waiver and release does not apply to any rights or claims that may arise under ADEA after the effective date of this Agreement; and

Executive acknowledges that the consideration given in exchange for this waiver and release Agreement is in addition to anything of value to which he was already entitled.

PLEASE READ THIS AGREEMENT CAREFULLY. IT CONTAINS A RELEASE OF ALL KNOWN AND UNKNOWN CLAIMS.

Dated: December 16, 2022

John Caloz

Schedule 1

Description of Duties

The duties of the Chief Financial Officer and Senior Vice President of CytRx Corporation (the "Company") shall include, but not be limited to, the following:

- Accounting and finance departments
- Budgeting
- Cash management
- Accounts payable and aging
- Accounts receivable and aging
- Posting of recurring accounting entries
- Bank reconciliations
- Vendor reconciliations
- Monthly closings of company books of account
- Monthly, quarterly and annual comparisons of actual vs. budgeted results of operations
- Assisting in preparation of press releases regarding financial matters
- Assisting in capital-raising and other financing transactions
- Assisting in in-licensing, business acquisitions and other corporation transactions
- Coding of income and expenditures
- Payroll
- Assisting in establishing and maintaining internal controls and procedures, including financial controls, and complying with the requirements of the Sarbanes-Oxley Act
- Primary responsibility for audits of the company's financial statements and accounting-related disclosure in the company's SEC filings

Schedule 2

Summary of Group Plans

1. See CytRx Corporation Employee Handbook, Part II dated January 2020, which is incorporated herein by reference.

EXHIBIT 21.1

CytRx Corporation

Subsidiaries (all 100% owned)

<u>Subsidiaries of the Registrant</u>	<u>State or Other Jurisdiction of Incorporation</u>
Centurion BioPharma Corporation	Delaware

EXHIBIT 23.1

Consent of Independent Registered Public Accounting Firm

CytRx Corporation
Los Angeles, California

We hereby consent to the incorporation by reference in the Registration Statements on Form S-1 (File No. 333-258453), Form S-3 (File Nos. 333-255431, 333-223808, 333-208803 and 333-215252) and Form S-8 (File Nos. 333-249624, 333-68200, 333-93305, 333-123339, 333-163212 and 333-212934) of CytRx Corporation of our report dated March 23, 2022, relating to the consolidated financial statements for the years ended December 31, 2021 and 2020 (modified for a going concern uncertainty), which appears in this Form 10-K.

/s/ Weinberg & Company

Los Angeles, California
March 23, 2022

Exhibit 31.1**CERTIFICATIONS**

I, Stephen Snowdy, Chief Executive Officer of CytRx Corporation, certify that:

1. I have reviewed this annual report on Form 10-K of CytRx Corporation;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the periods covered by this annual report;

3. Based on my knowledge, the consolidated financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the periods covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 23, 2022

By: /s/ STEPHEN.SNOWDY

Dr. Stephen Snowdy
Chief Executive Officer

Exhibit 31.2**CERTIFICATIONS**

I, John Y. Caloz, Chief Financial Officer of CytRx Corporation, certify that:

1. I have reviewed this annual report on Form 10-K of CytRx Corporation;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the periods covered by this annual report;

3. Based on my knowledge, the consolidated financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the periods covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 23, 2022

By: /s/ JOHN Y. CALOZ

John Y. Caloz
Chief Financial Officer

Exhibit 32.1**Certification of Chief Executive Officer**

Pursuant to 18 U.S.C. 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of CytRx Corporation (the "Company") hereby certifies that:

(i) the accompanying Annual Report on Form 10-K of the Company for the year ended December 31, 2021 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 23, 2022

By: /s/ STEPHEN SNOWDY

Dr. Stephen Snowdy
Chief Executive Officer

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 (Section 906), or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to CytRx Corporation and will be retained by CytRx Corporation and furnished to the Securities and Exchange Commission or its staff upon request.

The foregoing certification is being furnished to the Securities and Exchange Commission as an Exhibit to the Form 10-K and shall not be considered filed as part of the Form 10-K.

Exhibit 32.2**Certification of Chief Financial Officer**

Pursuant to 18 U.S.C. 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of CytRx Corporation (the "Company") hereby certifies that:

(i) the accompanying Annual Report on Form 10-K of the Company for the year ended December 31, 2021 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 23, 2022

By: /s/ JOHN Y. CALOZ

John Y. Caloz
Chief Financial Officer

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 (Section 906), or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to CytRx Corporation and will be retained by CytRx Corporation and furnished to the Securities and Exchange Commission or its staff upon request.

The foregoing certification is being furnished to the Securities and Exchange Commission as an Exhibit to the Form 10-K and shall not be considered filed as part of the Form 10-K.
