CYTRX CORP
Form 10-K
March 29, 2019

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

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

For the fiscal year ended December 31, 2018

or

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

For the transition period from _____ to _____

Commission file number 0-15327

CytRx Corporation

(Exact name of Registrant as specified in its charter)

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

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

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

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

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

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

None

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

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

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

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

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

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

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

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

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

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

CYTRX CORPORATION

2018 ANNUAL REPORT ON FORM 10-K

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NOTE ON FORWARD-LOOKING STATEMENTS

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

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

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

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

INDUSTRY DATA

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

TRADEMARKS

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

PART I

Item 1. *BUSINESS*

COMPANY OVERVIEW

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

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

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

LADR Drug Discovery Platform and Centurion

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

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

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

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

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

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

free active drug is then released into the tumor.

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

Current Business Strategy

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

Aldoxorubicin

Until July 2017, we were focused on the research and clinical development of aldoxorubicin, our modified version of the widely-used chemotherapeutic agent, doxorubicin. Aldoxorubicin combines the chemotherapeutic agent doxorubicin with a novel linker-molecule that binds specifically to albumin in the blood to allow for delivery of higher amounts of doxorubicin (3½ to 4 times) without several of the major dose-limiting toxicities seen with administration of doxorubicin alone.

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

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

Aldoxorubicin has received Orphan Drug Designation (ODD) by the U.S. FDA for the treatment of STS. ODD provides several benefits including seven years of market exclusivity after approval, certain R&D related tax credits, and protocol assistance by the FDA. European regulators granted aldoxorubicin Orphan designation for STS which confers ten years of market exclusivity among other benefits.

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

Disposition of Molecular Chaperone Assets

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

Innovive Acquisition Agreement

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

Research and Development

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

Manufacturing

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

Commercialization and Marketing

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

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

Patents and Proprietary Technology

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

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

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

LICENSE AGREEMENTS

Aldoxorubicin

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

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

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

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

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

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

Competition

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

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

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

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

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

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

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

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

Government Regulation

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

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

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

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

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

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

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

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

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

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

Employees

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

Available Information

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

Potential Strategic Alternatives

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

Item 1A. RISK FACTORS

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

Risks Associated With Our Business

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

We have operated at a loss due to our ongoing expenditures for research and development of our product candidates and for general and administrative purposes, and lack of significant recurring revenues. We incurred a net loss of $12.7 million for the year ended December 31, 2018 and $35.0 million for the year ended December 31, 2017 and had an accumulated deficit as of December 31, 2018 of $456.9 million. We are likely to continue to incur losses unless and until we are able to earn milestones and royalties from our existing licensing agreements and/or conclude a successful strategic partnership for our LADR technology. These losses, among other things, have had and will continue to have an adverse effect on our stockholders’ equity and working capital. Because of the numerous risks and uncertainties associated with our product development efforts, we are unable to predict when we may become profitable, if at all. If we do not become profitable or are unable to maintain future profitability, the market value of our common stock will be adversely affected.

Because we have no source of significant recurring revenue, we must depend on capital raising to sustain our operations, and our ability to raise capital may be severely limited.

Developing products and conducting clinical trials require substantial amounts of capital. To date, we have relied primarily upon proceeds from sales of our equity securities