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, 2024

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

LadRx 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

N/A
(Former name, former address and former fiscal year, if changed since last report)

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**	**LADX**	**OTC Markets**

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 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. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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 the OTC Markets, the aggregate market value of the registrant's common stock held by non-affiliates on June 30, 2024 (the last business day of the registrant's most recently completed second fiscal quarter) was approximately $1.3 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 28, 2025 was 495,092 shares.

LADRX CORPORATION
2024 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 "Annual Report"), the "Company," "LadRx," "we," "us," and "our," except where the context requires otherwise, refer to LadRx Corporation.

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

LadRx, 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

LadRx Corporation ("LadRx" the "Company", "we", "us", or "our") is a biopharmaceutical research and development company specializing in oncology. The Company's focus is on the discovery, research and clinical development of novel anti-cancer drug candidates that employ novel technologies that target chemotherapeutic drugs to solid tumors and reduce off-target toxicities. During 2017, LadRx's discovery laboratory in Freiburg, Germany, synthesized and tested over 75 rationally designed drug conjugates with highly potent anti-cancer 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 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, the Company launched Centurion BioPharma Corporation ("Centurion"), a wholly-owned private subsidiary, and transferred to Centurion all of its assets, liabilities and personnel associated with the laboratory operations in Freiburg, Germany. On December 21, 2018, LadRx announced that Centurion had concluded the pre-clinical phase of development for its four LADR™ (Linker Activated Drug Release) 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 were no longer needed and, accordingly, the lab was closed at the end of January 2019.

On March 9, 2022, Centurion merged with and into LadRx, with LadRx absorbing all of Centurion's assets and continuing after the merger as the surviving entity (the "Merger"). The Merger was implemented through an agreement and plan of merger pursuant to Section 253 of the General Corporation Law of the State of Delaware (the "DGCL") and did not require approval from either our or Centurion's stockholders. The Certificate of Ownership merging Centurion into LadRx was filed with the Secretary of State of Delaware on March 9, 2022.

Effective September 26, 2022, we changed our name from CytRx Corporation to LadRx Corporation pursuant to a Certificate of Amendment to our Restated Certificate of Incorporation (the "Certificate of Incorporation"), as amended, filed with the Secretary of State of Delaware. In accordance with the DGCL, our board of directors (the "Board") approved the name change and the Certificate of Amendment. Pursuant to Section 242(b)(1) of the DGCL, stockholder approval was not required for the name change or the Certificate of Amendment.

2023 Reverse Stock Split

The Company effected a 1-for-100 reverse stock split (the "Reverse Stock Split") of its issued and outstanding shares of common stock on May 17, 2023, pursuant to which every 100 shares of the Company's issued and outstanding shares of common stock were converted into one share of common stock without any change in the par value per share. Any fraction of a share of common stock that would otherwise have resulted from the Reverse Stock Split were rounded up to the nearest whole share. All share and per share amounts in this Annual Report have been adjusted to reflect the reverse stock split as if it had occurred at the beginning of the earliest period presented.

Corporate Information

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.ladrxcorp.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-Based Drugs

The LADR™ Technology offers the opportunity for multiple pipeline drugs. The Company's LADR™ technology platform consists of an organic backbone that is attached to a chemotoxic agent. The purpose of the LADR™ backbone is to first target and deliver the chemotoxic agent to the tumor environment, and then to release the chemotoxic agent within the tumor. By delivering, concentrating, and releasing the chemotoxic agent within the tumor, one expects to reduce the off-target side-effects of the chemotherapeutic, which in turn allows for several-fold higher dosing of the chemotherapeutic to the patient. Being small organic molecules, the Company expects LADR-based drugs to offer the benefits of targeting the tumor without the complexity, side effects, and expense inherent in macromolecules such as antibodies and nanoparticles.

The Company's LADR-based drugs use circulating albumin as the binding target and as the trojan horse to deliver the LADR™ drugs to the tumor. Albumin is the most abundant protein in plasma and accumulates inside tumors due to the aberrant vascular structure that exists within solid tumors. Tumors use albumin as a nutritional source and for transport of signaling and other molecules that are important to the maintenance and growth of the tumor, which makes albumin an excellent target for drugs that are intended for solid tumors.

The Company's LADR™ development efforts are focused on three classes of ultra-high potency albumin-binding drugs. These LADR-based drugs, aldoxorubicin, and LADRs 7, 8, 9, and 10, combine the proprietary LADR™ backbone with novel derivatives of the commonly used chemotherapeutic doxorubicin, in the case of aldoxorubicin, and the auristatin and maytansinoid drug classes, in the cases of LADRs 7-10. Doxorubicin is the most prescribed chemotherapeutic small molecule, but suffers from serious side effects. Auristatin and maytansinoid are highly potent chemotoxins, and require targeting to the tumor for safe administration to humans, as is the case for the U.S. Food and Drug Administration ("FDA")-approved drugs Adcetris (auristatin antibody-drug-conjugate manufactured by Seagen, Inc.) and Kadcyla (maytansine antibody-drug-conjugate manufactured by Genentech, Inc.). We believe that LADR-based drugs may offer the benefits of tumor targeting without the disadvantages of antibodies and other macromolecules, which include expense, complexity, and negative side effects. Additionally, albumin is a very well-characterized drug target, which we believe will reduce clinical and regulatory costs and risks.

The Company's postulated mechanism of action for LADR-based drugs 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, resulting in circulating but inactive drug;

- circulating albumin preferentially accumulates in tumors due to the tumor using albumin as food for growth, and due to a mechanism called "enhanced permeability and retention", which results in lower exposure to the drug in noncancerous tissues of the heart, liver, and other organs;

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

- free active drug is then released within the tumor, causing tumor cell death.

Our first-generation LADR-based drug is called aldoxorubicin. Aldoxorubicin is the well-known drug doxorubicin attached to the first generation LADR™ backbone (LADRs 7-10 employ a next generation LADR™ backbone). Aldoxorubicin has been administered to over 600 human subjects in human clinical trials and has proven the concept of LADR™ in that several-fold more doxorubicin can be administered to patients when the doxorubicin is attached to LADR™ than when administered as native doxorubicin. Aldoxorubicin has received Orphan Drug Designation (ODD) by the FDA for the treatment of soft tissue sarcoma ("STS"), ovarian cancer, pancreatic cancer, and non-small cell lung cancer. 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 also granted orphan designation for aldoxorubicin which confers ten years of market exclusivity among other benefits. LadRx plans to submit aldoxorubicin to the US FDA for marketing approval approximately 2Q or 3Q 2026 following a small number of simple non-clinical studies.

In December 2024, the Company announced that it is restarting a process to seek marketing approval of aldoxorubicin under the provisions of the FDA's Section 505(b)(2). The 505(b)(2) pathway is designed for a new drug composition whose active ingredient is the same active ingredient as a drug previously approved by the FDA. Given that the active component of the tumor-targeted drug aldoxorubicin is the already-marketed drug doxorubicin, the 505(b)(2) pathway is available for aldoxorubicin, and greatly reduces the regulatory burden of getting aldoxorubicin to the market by relying on the non-clinical and clinical data history of doxorubicin and aldoxorubicin to demonstrate equivalence of efficacy and safety. Additionally, the market exclusivity awarded to drugs that have received orphan designation for certain rare diseases, as is the case for aldoxorubicin, is available for drugs approved through the 505(b)(2) process for new drugs. Based on prior discussions with the FDA and input from regulatory experts, the Company does not expect that additional human trials will be necessary to gain approval of aldoxorubicin under Section 505(b)(2). LadRx plans to submit a pre-NDA to the FDA within 3 months of receiving additional funding, and upon agreement with the FDA on a non-clinical path to approval, LadRx plans to submit a full NDA to the FDA. The Company estimates that aldoxorubicin will be ready for submission to the FDA for marketing approval approximately 12 months from receiving additional funding. LadRx expects the capital needed to reach the pre-NDA meeting to be approximately $1.5 million, and the capital needed to reach NDA marketing approval to be an additional $4 million. There can be no certainty that the Company will be successful in its approach to the FDA or in its raising additional capital.

The next generation LADR™ drugs are termed LADR 7, 8, 9, and 10. A great deal of Investigational New Drug ("IND") enabling work has already been accomplished on LADR 7-10, including in-silico modeling, in-vitro efficacy testing in several different cancer models, in-vivo dosing, safety, and efficacy testing in several different cancer models in animals. We have also developed and proven manufacturability, an important step prior to beginning human clinical trials.

The final toxicology studies required for the IND for LADR-7 have been completed. Prior to initiating the first-in-human Phase I studies of LADR-7, LADR-7 must be packaged into clinical trial containers, and the relevant regulatory agencies must be notified. We expect these activities to require approximately six months to complete, once funding has been secured. If the Company fails to meet regulatory agencies' requirements for initiating the first-in-human studies of LADR-7, dosing of the first human patients could be substantially delayed.

Because the LADR™ backbone in future products would be the same as the LADR™ backbone in current product candidates, (i.e. the chemotoxin can be changed without changing the LADR™ backbone), management anticipates that future product candidates beyond LADR7 may enjoy abbreviated pre-clinical pathways to first-in-human. Such abbreviated pathways would be subject to FDA review and agreement.

The Company'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. We have not yet determined whether the use of a companion diagnostic will be necessary or helpful, and plan to continue to investigate this question in parallel to the pre-clinical and clinical development of LADRs 7-10.

The LADR™ backbone and drugs that employ LADR™ are protected by domestic and international patents, and additional patents are pending.

Partnering History of Our Drug Assets

On July 27, 2017, the Company entered into an exclusive worldwide license agreement (the "License Agreement") with ImmunityBio, Inc. (formerly known as NantCell, Inc. ("NantCell, Inc."), and which merged with NantKwest Inc. in March 2021 ("ImmunityBio" and together with NantCell, Inc., "NantCell")), granting to ImmunityBio the exclusive rights to develop, manufacture and commercialize aldoxorubicin in all indications. As part of the License Agreement, ImmunityBio made a strategic investment of $13 million in LadRx's common stock at $660.00 per share (adjusted to reflect the 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 5,000 shares of common stock at $660.00 per share, which such warrant expired on January 26, 2019.

ImmunityBio conducted an open-label, randomized, Phase 2 study of a combination of immunotherapy, aldoxorubicin, and standard-of-care chemotherapy versus standard-of-care chemotherapy alone for the treatment of locally advanced or metastatic pancreatic cancer in patients who have had 1 or 2 lines of treatment (Cohorts A and B) or 3 or greater lines of treatment (Cohort C). In June 2022, ImmunityBio presented data at the American Society of Clinical Oncology meeting showing that patients receiving combination immunotherapy with aldoxorubicin plus standard-of-care chemotherapy experienced overall survival of 5.8 months, compared to 3 months for historical control patients that had received only the standard-of-care chemotherapy (n=78, 95% confidence interval of 4 to 6.9 months). ImmunityBio submitted the results of the Phase 2 study to the FDA for registration. The FDA denied the request and asked for a very large clinical trial with cohorts for each of the test therapies alone, and in permutative combination with the other combination therapies. ImmunityBio chose not to proceed with the FDA's recommended trial, and aldoxorubicin has been returned to LadRx (see below "Mutual Termination and Release Agreement").

Royalty Purchase Agreement with XOMA

On June 21, 2023, the Company, entered into (i) a Royalty Purchase Agreement (the "Royalty Agreement") with XOMA (US) LLC ("XOMA"), for the sale, transfer, assignment and conveyance of the Company's right, title and interest in and to certain royalty payments and milestone payments with respect to aldoxorubicin, and (ii) an Assignment and Assumption Agreement (the "Assignment Agreement") with XOMA for the sale, transfer, assignment and conveyance of the Company's right, title and interest in the Asset Purchase Agreement (the "2011 Arimoclomol Agreement") between the Company and Orphazyme ApS ("Orphazyme"), dated as of May 13, 2011, and assigned to Zevra Denmark A/S ("Zevra Denmark"), effective as of June 1, 2022, which includes certain royalty and milestone payments with respect to arimoclomol. The combined aggregate purchase price paid to the Company for the sale, transfer, assignment and conveyance of the Company's right, title and interest in and to aldoxorubicin and arimoclomol was $5 million, less certain transaction fees and expenses.

The Royalty Agreement and the Assignment Agreement also provide for up to an additional $6 million based on regulatory and commercial milestones related to the development of arimoclomol and aldoxorubicin by their respective sponsors, Zevra, Inc. and Immunity Bio. The $6 million in potential post-closing payments is comprised of $1 million upon acceptance by the FDA of the arimoclomol New Drug Application ("NDA"), $1 million upon first commercial sale of arimoclomol, and $4 million upon FDA approval of aldoxorubicin. All royalty and milestone payments made to XOMA will be net of the existing licensing and milestone obligations owed by LadRx related to arimoclomol and aldoxorubicin. In January 2024, the Company received a payment of $1 million in connection with achieving the milestone relating to the acceptance by the FDA of the arimoclomol NDA, and in November 2024, the Company received $1 million in connection with achieving the milestone relating to the first commercial sale of arimoclomol.

Pursuant to the Royalty Agreement, the Company agreed to sell, transfer, assign and convey to XOMA, among other payments, all royalty payments and regulatory and commercial milestone payments payable to the Company pursuant to the worldwide license agreement, dated July 27, 2017, by and between the Company and Immunity Bio. The Royalty Agreement also provides for the sharing of certain rights with XOMA to bring any action, demand, proceeding or claim as related to receiving such payments.

Management determined that the Royalty Agreement is not considered to be with a customer, and it does not fall within the scope of ASC 606. Instead, the Royalty Agreement represents an in-substance sale of nonfinancial assets, and, therefore, should be accounted for within the scope of ASC 610-20. As such, the Company recognized such net proceeds as other income in the accompanying statement of operations.

First Amendment to Royalty Purchase Agreement

On June 3, 2024, in consideration for the termination of the License Agreement pursuant to the Termination Agreement, the Company and XOMA entered into the First Amendment to the Royalty Agreement (the "First Amendment"). Pursuant to the First Amendment, if the Company decides to commercialize aldoxorubicin itself, prior to the first commercial sale of aldoxorubicin, the Company and XOMA shall enter into a synthetic royalty purchase agreement, pursuant to which the Company shall agree to make quarterly royalty payments to XOMA equal to the amount of all aggregate net sales of aldoxorubicin during each calendar quarter multiplied by 1.5%. If the Company decides not to commercialize aldoxorubicin itself and instead licenses aldoxorubicin to a third party, upon entry of such a new license agreement, XOMA shall be entitled to receive (i) royalty payments with respect to net sales of aldoxorubicin payable to the Company multiplied by 7.5% and (ii) milestone payments of 7.5% of any milestone payable to the Company pursuant to the License Agreement. The First Amendment contains customary covenants and other provisions customary for transactions of this nature.

Mutual Termination and Release Agreement

On June 3, 2024 (the "Effective Date"), we entered into a Mutual Termination and Release Agreement (the "Termination Agreement") with NantCell and its parent company, ImmunityBio and XOMA (as defined below). Pursuant to the Termination Agreement, the License Agreement will terminate automatically on the Effective Date, and neither the Company nor NantCell will have any continuing obligations to each other than as described in the Termination Agreement. Additionally, except that during the 30 day period following the Effective Date (the "Discussion Period"), the Company and NantCell shall engage in good faith discussions regarding the terms of an agreement pursuant to which the Company would have the right to purchase the inventory of aldoxorubicin (including, without limitation, active pharmaceutical ingredient, WPI and finished dose, the "Inventory") and all other materials necessary for the research, development and commercialization, among others, worldwide as of the Effective Date, at the Company's expense. Subsequently, the Company and NantCell have agreed the disposition of the Inventory shall be at NantCell's sole discretion.

The Termination Agreement additionally provides for the release of the Company and NantCell from claims, demands and liabilities, among others, and customary representations and warranties, covenants, and other provisions customary for transactions of this nature.

Transfer of Rights to Molecular Chaperone Assets (Orphayzme)

On May 13, 2011, pursuant to the Asset Purchase Agreement by and between the Company and Orphazyme A/S ("Orphazyme", formerly Orphazyme ApS), LadRx sold the rights to arimoclomol and iroxanadine, based on molecular chaperone regulation technology, 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 (the "2011 Arimoclomol Agreement"). Orphazyme transferred its rights and obligations under the 2011 Arimoclomol Agreement to KemPharm Denmark A/S ("KemPharm"), a wholly owned subsidiary of KemPharm Inc., in May 2022.

In May 2021, Orphazyme announced that the pivotal phase 3 clinical trial for arimoclomol in Amyotrophic Lateral Sclerosis did not meet its primary and secondary endpoints, reducing the maximum amount that LadRx currently has the right to receive under the 2011 Arimoclomol Agreement to approximately $100 million. Orphazyme also tested arimoclomol in Niemann-Pick disease Type C ("NPC") and Gaucher disease, and following a Phase II/III trial submitted to the FDA a NDA for the treatment of NPC with arimoclomol. On June 18, 2021, Orphazyme announced it had received a complete response letter (the "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 had publicly indicated that it intended 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 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.

On May 31, 2022, Orphazyme announced that it had completed the sale of substantially all of its assets and business activities for cash consideration of $12.8 million and assumption of liabilities estimated to equal approximately $5.2 million to KemPharm (the "KemPharm Transaction"). KemPharm is a specialty biopharmaceutical company focused on the discovery and development of novel treatments for rare CNS diseases. As part of the KemPharm Transaction, all of Orphazyme's obligations to LadRx under the 2011 Arimoclomol Agreement, including with regard to milestone payments and royalties on sales, were assumed by KemPharm. KemPharm is expected to continue the early access programs with arimoclomol, and to continue to pursue the potential approval of arimoclomol as a treatment option for NPC. KemPharm resubmitted the NDA for arimoclomol in 2023. It is also identifying a regulatory path forward with the EMA. KemPharm re-branded to Zevra Therapeutics, Inc. in February 2023. In January 2024, the FDA accepted Zevra's NDA for arimoclomol and in September, the FDA approved arimoclomol as an orally-delivered treatment for NPC. In September 2024, Zevra additionally announced that MIPLYFFA™ (arimoclomol) would be commercially available in the United States towards the end of 2024 and in November achieved its first commercial sale.

Assignment and Assumption Agreement with XOMA

On June 21, 2023, the Company entered into the Assignment Agreement with XOMA, pursuant to which, among others, the Company agreed to sell, transfer and assign to XOMA the Company's right, title and interest in the arimoclomol pursuant to the 2011 Arimoclomol Agreement, including the right to receive certain milestone, royalty and other payments from Zevra.

Pursuant to the Assignment Agreement, the Company is entitled to receive (i) a one-time payment of $1 million upon acceptance of a re-submission of a NDA to the FDA for arimoclomol, and (ii) a one-time payment of $1 million upon the first invoiced sale in certain territories of a pharmaceutical product derived from arimoclomol as an active pharmaceutical ingredient, subject to the receipt of the applicable regulatory approval required to sell such a product in such countries. In 2024, both milestones were achieved and the Company received both of the aforementioned milestone payments.

Commercialization and Marketing

We currently have no sales, marketing or commercial product distribution capabilities. A decision will be made at a later time on whether to commercialize aldoxorubicin or to seek a partner for the commercialization of aldoxorubicin.

We are searching for a development and commercialization partner or additional financing for the development of our other LADR drug candidates.

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 January 31, 2025, we have three granted U.S. patents and fifty-two granted foreign patents, and two pending U.S. patent applications and twenty pending foreign patent applications covering our LADR^{TM}-related technology including LADR 7, LADR-8, LADR-9 and LADR-10. The un-extended patent term of patents that issue covering our LADR^{TM}-related technology is between June 2036 and November 2038. We also have four granted foreign patents, one pending US patent application, and eight pending foreign patent applications covering our albumin companion diagnostic (ACDx^{TM}). The un-extended patent term of patents that issue covering our ACDx^{TM} is July 2039. The patents and patent applications covering our LADR^{TM}-related technology, and ACDx^{TM} are assigned to LadRx.

As of January 31, 2025, we have three granted U.S. patents, twenty-three granted foreign patents and three pending foreign patent applications covering aldoxorubicin-related technologies. 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

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 Zevra (formerly KemPharm). As described above in the section "*Assignment and Assumption Agreement with Xoma*," and pursuant to the Assignment Agreement, the Company agreed to sell, transfer and assign to XOMA the Company's right, title and interest in arimoclomol pursuant to the 2011 Arimoclomol Agreement, including the right to receive certain milestone, royalty and other payments from Zevra. Pursuant to the Assignment Agreement, Xoma is responsible for paying Zevra $3.25 million of this milestone payment, which such payment was made in November 2024. LadRx is responsible for the balance of $0.4 million, which is represented as accrued liabilities as of December 31, 2024.

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 tumor-targeting 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 Corp. 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.

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 non-clinical 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 505(b)(2) pathway is designed for a new drug composition whose active ingredient is the same active ingredient as a drug previously approved by the US Food and Drug Administration (FDA). Given that the active component of the tumor-targeted drug aldoxorubicin is the already-marketed drug doxorubicin, the 505(b)(2) pathway is available for aldoxorubicin, and greatly reduces the regulatory burden of getting aldoxorubicin to the market by relying on the non-clinical and clinical data history of doxorubicin to demonstrate efficacy and safety. Additionally, the market exclusivity awarded to drugs that have received orphan designation for certain rare diseases, as is the case for aldoxorubicin, is available for drugs approved through the 505(b)(2) process for new drugs.

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 may also 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 of 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 post-market 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 post-market 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:

- 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 will also 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 products that we may commercialize or promote in the future and our therapeutic candidates from 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 products 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 any products or our development or commercialization partners 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 June 28, 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 first administration, 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 remains 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, on August 16, 2022, the Inflation Reduction Act of 2022 ("IRA") was signed into law and, among other things, requires manufacturers of certain drugs to engage in price negotiations with Medicare beginning in 2026, imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation, and replaces the Part D coverage gap discount program with a new discounting program–which began in 2025. The IRA permits the HHS Secretary to implement many of these provisions through guidance, as opposed to regulation, for the initial years. CMS has published the negotiated prices for the initial ten drugs, which will first be effective in 2026, and has published the list of the subsequent 15 drugs that will be subject to negotiation, although the drug price negotiation program is currently subject to legal challenges. For that and other reasons, it is currently unclear how the IRA will be effectuated. The implementation of cost containment measures, including the prescription drug provisions under the IRA, as well as other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates if approved. Complying with any new legislation and regulatory changes could be time-intensive and expensive, resulting in a material adverse effect on our business.

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 President Trump's second administration will implement in connection with the Health Reform Law or IRA. 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 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 December 31, 2024, we had two full-time employees.

Available Information

We maintain a website at www.ladrxcorp.com and make available there, free of charge, our periodic reports filed with the Securities and Exchange Commission (the "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 financial statements and related notes thereto.

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 following this Risk Factor summary 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. Our independent registered public accounting firm has included an explanatory paragraph in its report as of and for the year ended December 31, 2024, 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.
- 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.

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 rely upon third parties for the manufacture of our clinical product supplies, and we intend to rely on third parties to produce commercial supplies of any approved product candidate, and our commercialization of any product candidates, including aldoxorubicin, could be stopped, delayed or made less profitable if those third parties fail to obtain approval of the FDA, fail to provide us with sufficient quantities of drug product or fail to do so at acceptable quality levels or prices.

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 By-laws 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. For the year ended December 31, 2024, we realized a net loss of $1.6 million and, for the year ended December 31, 2023, had a loss from operations of $3.8 million, , and had total stockholders' deficit as of December 31, 2024 of $1.4 million. We have had no recurring revenue, and we are likely to continue to incur losses unless and until we conclude a successful strategic partnership or financing for our research and development assets. 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, 2024, 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 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. We need to raise additional capital to fund our general and administrative expenses and, if we determine to develop products based on our LADR™ technology platform as well as aldoxorubicin, 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, capital raising has been significantly challenging.

At December 31, 2024, we had cash and cash equivalents of approximately $0.8 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 us. Even if we are 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.

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.

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 ("cGMPs"), and good clinical practices ("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 rely upon third parties for the manufacture of our clinical product supplies, and we intend to rely on third parties to produce commercial supplies of any approved product candidate, and our commercialization of any product candidates, including aldoxorubicin, could be stopped, delayed or made less profitable if those third parties fail to obtain approval of the FDA, fail to provide us with sufficient quantities of drug product or fail to do so at acceptable quality levels or prices.

We do not have the facilities or expertise to manufacture supplies of aldoxorubicin or any of our other product candidates, and we lack the resources and capability to manufacture any of our product candidates on a clinical or commercial scale. Accordingly, we are dependent upon third-party manufacturers, or potential future strategic alliance partners, to manufacture these supplies. We have manufacturing supply arrangements in place with respect to a portion of the clinical supplies needed for the clinical development programs for aldoxorubicin. In September 2015, we entered into an agreement with a supplier to purchase doxorubicin hydrochloride both for clinical and commercial use. However, we have no other supply arrangements for the commercial manufacture of this product candidate or any manufacturing supply arrangements for any other potential product candidates, and we may not be able to secure needed supply arrangements on attractive terms, or at all. Our failure to secure these arrangements as needed could have a materially adverse effect on our ability to complete the development of our products or to commercialize them.

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be completed after we submit our NDA to the FDA. We do not control the manufacturing process of aldoxorubicin and are completely dependent on our contract manufacturing partners for compliance with the FDA's requirements for manufacture of aldoxorubicin. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the FDA's strict regulatory requirements, they will not be able to secure and/or maintain FDA approval for the manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates.

If aldoxorubicin, our lead product candidate, or our other product candidates cannot be manufactured in suitable quantities and in accordance with regulatory standards, our clinical trials, regulatory approvals and marketing efforts for such products may be delayed. Such delays could adversely affect our competitive position and our chances of generating significant recurring revenues. If any of our products that are approved for marketing cannot be manufactured at an acceptable cost, the commercial success of such product candidates may be adversely affected.

We may rely upon third parties in connection with the commercialization of our products.

The marketing and commercialization of aldoxorubicin may require us to enter into strategic alliances or other collaborative arrangements with other pharmaceutical companies under which those companies will be responsible for one or more aspects of the eventual marketing and commercialization of aldoxorubicin, if it is approved for marketing.

Any future product candidate, if approved for marketing, may not have sufficient potential commercial value to enable us to secure strategic arrangements with suitable companies on attractive terms, or at all. If we are unable to enter into such arrangements, we may not have the financial or other resources to commercialize our products and may have to sell our rights in them to a third party or abandon their commercialization altogether.

To the extent we enter into collaborative arrangements, we will be dependent upon the timeliness and effectiveness of the development and marketing efforts of our contractual partners. If these companies do not allocate sufficient personnel and resources to these efforts or encounter difficulties in complying with applicable FDA and other regulatory requirements, we may not obtain regulatory approvals as planned, if at all, and the timing of receipt or the amount of revenue from these arrangements may be materially and adversely affected. By entering into these arrangements rather than completing the development and then marketing these products on our own, the profitability to us of these products may decline.

We may be unable to protect our intellectual property rights, which could adversely affect our ability to compete effectively.

We will be able to protect our technologies from unauthorized use by third parties only to the extent that we have rights to valid and enforceable patents or other proprietary rights that cover them. Although we have rights to patents and patent applications directed to 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.

Moreover, we may be subject to a third-party pre-issuance submission of prior art or become involved in opposition, derivation, re-examination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. The costs of defending our patents or enforcing our proprietary rights in post-issuance administrative proceedings and litigation can be substantial and the outcome can be uncertain. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

We have not pursued or maintained, and may not pursue or maintain in the future, patent protection for our product candidates in every country or territory in which we may sell our products, if approved. The laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from infringing our patents in all countries outside the United States, or from selling or importing products that infringe our patents in and into the United States or other jurisdictions.

Indeed, several companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of some countries do not favor the enforcement of patents and other intellectual property rights, which could make it difficult for us to stop the infringement, misappropriation or other violation of our intellectual property rights generally. Proceedings to enforce our intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful.

Furthermore, the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Moreover, the scope claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Changes in either the patent laws or interpretation of the patent laws may diminish the value of our or our collaborators' patents or narrow the scope of such patent protection and could increase the uncertainties and costs surrounding the prosecution of our or any future collaborators' patent applications and the enforcement or defense of any issued patents. Even if the patent applications we license or own do issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative products in a non-infringing manner.

Some of our technologies and processes do not fulfill the requirements for patent or trademark protection or are not protected by patent or trademark rights for other reasons, e.g., secrecy. We therefore 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.

There is no guarantee, however, that such agreements will not be breached, that they will provide sufficient protection for our business secrets and proprietary information or that adequate remedies will be available in the event of an unauthorized use or disclosure of such information. It cannot be excluded that we do not have, or cannot enforce, legal remedies that are effective at economically acceptable costs. Further, the violation of a non-disclosure agreement might be difficult to prove because business secrets and know- how may be developed independently by, or become otherwise known to, third parties. In addition, it may be difficult to quantify the damages which have occurred and to obtain legal remediation, or to undo the damages caused, by legal remedies. Our failure to effectively protect our business secrets and know-how could have material adverse effects on our business, prospects, financial condition and results of operations.

If our product candidates infringe or otherwise violate 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 commercial success also depends upon our ability, and the ability of any third party with which we may partner, to develop, manufacture, market and sell our product candidates and/or products, if approved, and use our patent-protected technologies without infringing the patents of third parties. There is considerable patent litigation in the biotechnology and pharmaceutical industries. As the biopharmaceutical industry expands and more patents are issued, we face increased risks that there may be patents issued to third parties that relate to our product candidates and technology of which we are not aware or that we must challenge to continue our operations as currently contemplated.

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.

Obtaining and maintaining patent protection depends on compliance with various procedures and other requirements, and our patent protection could be reduced or eliminated in case of non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to the relevant patent agencies in several stages over the lifetime of the patents and /or applications. The relevant patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent application process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which the failure to comply with the relevant requirements can result in the abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to use our technologies and know-how which could have a material adverse effect on our business, prospects, financial condition and results of operation.

If we fail to comply with our obligations under our license agreements, we could lose the rights to intellectual property that is important to our business.

Our current license agreements impose on us various development obligations, payment of royalties and fees based on achieving certain milestones as well as other obligations. If we fail to comply with our obligations under these agreements, the licensor may have the right to terminate the license. In addition, if the licensor fails to enforce its intellectual property, the licensed rights may not be adequately maintained. The termination of any license agreements or failure to adequately protect such license agreements could prevent us from commercializing our product candidates or possible future products covered by the licensed intellectual property. Any of these events could materially adversely affect our business, prospects, financial condition and results of operation.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

Our employees may have been previously employed at other companies in the industry, including our competitors or potential competitors. Although we are not aware of any claims currently pending against us, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of the former employers of our employees. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. If we fail in defending such claims, in addition to paying money claims, we may lose valuable intellectual property rights or personnel. A loss of key personnel or their work product could hamper or prevent our ability to commercialize product(s), which would materially adversely affect our commercial development efforts.

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 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 healthcare 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 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 products we and our development or commercialization partners are currently developing or those that we may commercialize or promote in the future. If reimbursement for 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. 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 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.

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 materialize, it could harm our business and cause our stock price to decline.

We are subject to intense competition, and we may not compete successfully.

Aldoxorubicin is a conjugate of doxorubicin, a widely used anti-cancer drug. Doxorubicin is part of the anthracycline class of chemotherapy agents. Anthracyclines, many of which, including doxorubicin are generic, have been used throughout the world to treat various cancers for several decades. Due to their track record of broad anti-cancer activity, new types of anthracyclines and modified or reformulated versions continue to be developed to overcome toxicities which limit the use of these drugs.

Aldoxorubicin is a chemically modified version of doxorubicin that incorporates an acid sensitive linker technology to improve concentration in the tumor. We believe that the albumin-binding ability of aldoxorubicin will allow the compound to overcome many of the side effect issues typically associated with anthracyclines. We also believe that using albumin as a targeted carrier will allow for higher dosing, greater concentration of the drug in tumors and greater efficacy.

STS patients are typically treated with surgery followed by radiation therapy. For patients ineligible for surgery, radiation or both, chemotherapy is the only option. Doxorubicin is the only approved first-line drug for treating STS patients who are ineligible for surgery and is often used in combination with radiation. The National Comprehensive Cancer Network also includes the use of ifosfamide, epirubicin, gemcitabine, gemcitabine with docetaxel, dacarbazine and liposomal doxorubicin marketed in the United States as Doxil® by Johnson & Johnson. Pazopanib (Votrient®), developed by GlaxoSmithKline and now marketed by Novartis, was approved in the United States and Europe in 2012 for the treatment of certain types of advanced STS following prior chemotherapy. In October 2015, the Janssen unit of Johnson & Johnson received approval for trabectedin (Yondelis®) for the treatment of patients with leiomyosarcoma and liposarcoma,that have previously received an anthracycline-containing regimen. In January 2016, the FDA approved Eisai's eribulin (Halaven®) as a treatment for patients with unresectable or metastatic liposarcoma who have received a prior anthracycline. Eli Lilly is conducting a Phase 3 clinical trial with olaratumab in combination with doxorubicin in first-line STS. Eli Lilly stated in October 2015 that they plan to submit a rolling new drug application based on the Phase 2 clinical trial results in STS. There are other approaches to treating STS in clinical development, including Morphotek's ontuxizumab in combination with chemotherapy, and Tracon Pharmaceuticals' TRC-105 in combination with pazopanib.

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 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 is subject to cybersecurity risks.

Our operations are increasingly dependent on information technologies and services. Threats to information technology systems associated with cybersecurity risks and cyber incidents or attacks continue to grow, and include, among other things, storms and natural disasters, terrorist attacks, utility outages, theft, viruses, phishing, malware, design defects, human error, and complications encountered as existing systems are maintained, repaired, replaced, or upgraded. Risks associated with these threats include, among other things:

- theft or misappropriation of funds
- loss, corruption, or misappropriation of intellectual property, or other proprietary, confidential or personally identifiable information (including supplier, clinical data or employee data);
- disruption or impairment of our and our business operations and safety procedures;
- damage to our reputation with our potential partners, patients and the market;
- exposure to litigation; and
- increased costs to prevent, respond to or mitigate cybersecurity events.

Although we utilize various procedures and controls to mitigate our exposure to such risk, cybersecurity attacks and other cyber events are evolving and unpredictable. Moreover, we have no control over the information technology systems of third parties conducting our clinical trials, our suppliers, and others with which our systems may connect and communicate. As a result, the occurrence of a cyber incident could go unnoticed for a period of time.

We have cybersecurity insurance coverage in the event we become subject to various cybersecurity attacks, however, we cannot ensure that it will be sufficient to cover any particular losses we may experience as a result of such cyberattacks. Any cyber incident could have a material adverse effect on our business, financial condition and results of 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, among others, 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 endemics 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 be subject to inflationary risk

The Company does not believe that inflation has had a material effect on its operations to date, other than the impact of inflation on the general economy. However, there is a risk that the Company's operating costs could become subject to inflationary pressures in the future, which would have the effect of increasing the Company's operating costs, and which would put additional stress on the Company's working capital resources.

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.

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, including but not limited to 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, 2024, we had outstanding stock options to purchase 67,000 shares of our common stock at a weighted-average exercise price of $45.95 per share.

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 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 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 out financial condition.

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

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

We have a classified Board, 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. 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 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.

At the 2022 Annual Meeting of Stockholders, a proposal (the "Declassification Proposal") to declassify the structure of the Board was passed on a precatory basis, which advised the Board that a majority of our stockholders desired to end the classified Board structure in favor of the annual election of directors, in which each director standing for election will only be eligible to be elected for one-year terms.

At the 2023 Annual Meeting of Stockholders, the Board adopted a resolution approving and declaring the advisability of amending our governing documents to the extent necessary to remove provisions that provided for a classified Board. This proposal provides for a rolling declassification of the Board to be completed by the 2026 annual meeting of the stockholders.

Our Bylaws 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 Bylaws 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 DGCL, which may also prevent or delay a takeover of us that may be beneficial to our stockholders.

Our Bylaws, 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 Bylaws 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 DGCL, 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 Bylaws. This choice-of-forum provision may limit our stockholders' ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits. Alternatively, if a court were to find this provision of our amended and restated by-laws inapplicable or unenforceable with respect to one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business and financial condition.

We currently take advantage of reduced disclosure and governance requirements applicable to smaller reporting companies, which could result in our common stock being less attractive to investors.

We have a public float of less than $250 million and therefore qualify as a smaller reporting company under the rules of the SEC. As a smaller reporting company, we are able to take advantage of reduced disclosure requirements, such as simplified executive compensation disclosures and reduced financial statement disclosure requirements in our SEC filings. Decreased disclosures in our SEC filings due to our status as a smaller reporting company may make it harder for investors to analyze our results of operations and financial prospects. We cannot predict if investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of the reporting exemptions applicable to a smaller reporting company until we are no longer a smaller reporting company, which status would end once we have a public float greater than $250 million. In that event, we could still be a smaller reporting company if our annual revenues were below $100 million and we have a public float of less than $700 million.

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 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 $59.3 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 1C. ***CYBERSECURITY***

Risk Management and Strategy

In an effort to protect our business against cybersecurity threats, we have implemented a cybersecurity risk management program that is integrated with our internal risk management processes and designed to identify and protect against cyber threats as well as to respond to and recover from cyber incidents, as applicable. Our cybersecurity risk management program is informed by industry standards, such as the National Institute of Standards and Technology (NIST) Cybersecurity Framework, and is supported by periodic internal and external information security assessments and testing.

We have also established incident response policies and procedures, overseen by our Chief Financial Officer, to review and classify cybersecurity incidents and to define roles and responsibilities for response and remediation in the event of a cyber incident.

In addition, we collaborate with third-party advisory firms to periodically review and evaluate our security measures, which informs our ongoing strategy and execution of our cybersecurity program. We also leverage third-party providers to augment our internal security resources, including to support our ongoing monitoring and threat detection capabilities. We have a process to evaluate certain critical third-party providers before engagement as well as periodically thereafter, which may include a review of available audit reports, security documentation, operating controls, and industry reputation, as well as contractual requirements, as appropriate.

We have not identified any cybersecurity incidents or threats that have materially affected us or are reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition; however, like other companies in our industry, we and our third-party vendors have from time to time experienced threats and security incidents that could affect our information or systems. For more information, please see our Risk Factors.

Item 2. ***PROPERTIES***

We lease storage space in Los Angeles, California, which covers approximately 540 square feet. This lease expires in September 2025, and requires us to make monthly payments of $1,475.

Item 3. LEGAL ***PROCEEDINGS***

We are occasionally involved in legal proceedings and other matters arising from the normal course of business. On November 30, 2022, Jerald Hammann ("Hammann") filed a complaint (the "Complaint") against the Company, Mr. Caloz, and Mr. Kriegsman (together, "Defendants") in the Court of Chancery of the State of Delaware, alleging various violations of a Cooperation Agreement, dated August 21, 2020, by and between the Company and Hammann. The Complaint alleges breaches of a provision limiting the Board's ability to effect discretionary compensation and a non-disparagement provision. The Complaint further alleges a breach of a purported implied obligation that the Company disclose various internal records to Hammann. Defendants believe the Complaint is wholly without merit and have moved to dismiss the Complaint in its entirety. Defendants intend to litigate vigorously against Hammann's claims.

We intend to vigorously defend against any complaint. We have directors' and officers' liability insurance, which will be utilized, after the deductible, 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 "LADX." 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. The stock prices take into account the Reverse Stock Split effectuated in May 2023.

	High	Low
Fiscal Year 2024:		
Fourth Quarter	$ 2.25	$ 0.53
Third Quarter	$ 2.52	$ 1.80
Second Quarter	$ 3.37	$ 2.07
First Quarter	$ 2.42	$ 1.23
Fiscal Year 2023		
Fourth Quarter	$ 1.95	$ 0.63
Third Quarter	$ 3.83	$ 1.49
Second Quarter	$ 12.00	$ 2.30
First Quarter	$ 15.00	$ 7.00

Holders

On March 28, 2025, there were approximately 190 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, 2024, 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	8,298	$ 451.95	—
Equity compensation plans not approved by our security holders:			
2019 Stock Incentive Plan	58,516	$ 1.83	—
Total	66,814	$ 59.44	—

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

There were no sales of unregistered securities during the year ended December 31, 2024.

Repurchase of Shares

We did not repurchase any of our shares during the year ended December 31, 2024.

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 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

LadRx Corporation ("LadRx" the "Company", "we", "us", or "our") is a biopharmaceutical research and development company specializing in oncology. The Company's focus is on the discovery, research and clinical development of novel anti-cancer drug candidates that employ novel technologies that target chemotherapeutic drugs to solid tumors and reduce off-target toxicities. During 2017, LadRx's discovery laboratory in Freiburg, Germany, synthesized and tested over 75 rationally designed drug conjugates with highly potent anti-cancer 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 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, the Company launched Centurion BioPharma Corporation ("Centurion"), a wholly-owned private subsidiary, and transferred to Centurion all of its assets, liabilities and personnel associated with the laboratory operations in Freiburg, Germany. On December 21, 2018, LadRx announced that Centurion had concluded the pre-clinical phase of development for its four LADR™ (Linker Activated Drug Release) 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 were no longer needed and, accordingly, the lab was closed at the end of January 2019.

On March 9, 2022, Centurion merged with and into LadRx, with LadRx absorbing all of Centurion's assets and continuing after the merger as the surviving entity (the "Merger"). The Merger was implemented through an agreement and plan of merger pursuant to Section 253 of the General Corporation Law of the State of Delaware (the "DGCL") and did not require approval from either our or Centurion's stockholders. The Certificate of Ownership merging Centurion into LadRx was filed with the Secretary of State of Delaware on March 9, 2022.

Effective September 26, 2022, we changed our name from CytRx Corporation to LadRx Corporation pursuant to a Certificate of Amendment to our Restated Certificate of Incorporation (the "Certificate of Incorporation"), as amended, filed with the Secretary of State of Delaware. In accordance with the DGCL, our board of directors (the "Board") approved the name change and the Certificate of Amendment. Pursuant to Section 242(b)(1) of the DGCL, stockholder approval was not required for the name change or the Certificate of Amendment.

2023 Reverse Stock Split

We effected a 1-for-100 reverse stock split (the "Reverse Stock Split") of its issued and outstanding shares of common stock on May 17, 2023, pursuant to which every 100 shares of our issued and outstanding common stock were converted into one share of common stock without any change in the par value per share. Any fraction of a share of common stock that would otherwise have resulted from the Reverse Stock Split were rounded up to the nearest whole share. All share and per share amounts in this Annual Report have been adjusted to reflect the reverse stock split as if it had occurred at the beginning of the earliest period presented.

Corporate Information

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.ladrxcorp.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

The LADR™ Technology offers the opportunity for multiple pipeline drugs. The Company's LADR™ technology platform consists of an organic backbone that is attached to a chemotoxic agent. The purpose of the LADR™ backbone is to first target and deliver the chemotoxic agent to the tumor environment, and then to release the chemotoxic agent within the tumor. By delivering, concentrating, and releasing the chemotoxic agent within the tumor, one expects to reduce the off-target side-effects of the chemotherapeutic, which in turn allows for several-fold higher dosing of the chemotherapeutic to the patient. Being small organic molecules, the Company expects LADR-based drugs to offer the benefits of targeting the tumor without the complexity, side effects, and expense inherent in macromolecules such as antibodies and nanoparticles.

The Company's LADR-based drugs use circulating albumin as the binding target and as the trojan horse to deliver the LADR™ drugs to the tumor. Albumin is the most abundant protein in plasma and accumulates inside tumors due to the aberrant vascular structure that exists within solid tumors. Tumors use albumin as a nutritional source and for transport of signaling and other molecules that are important to the maintenance and growth of the tumor, which makes albumin an excellent target for drugs that are intended for solid tumors.

The Company's LADR™ development efforts are focused on three classes of ultra-high potency albumin-binding drugs. These LADR-based drugs, aldoxorubicin, and LADRs 7, 8, 9, and 10, combine the proprietary LADR™ backbone with novel derivatives of the doxorubicin, auristatin, and maytansinoid drug classes. Auristatin and maytansinoid are highly potent chemotoxins, and require targeting to the tumor for safe administration to humans, as is the case for the U.S. Food and Drug Administration ("FDA")-approved drugs Adcetris (auristatin antibody-drug-conjugate manufactured by Seagen, Inc.) and Kadcyla (maytansine antibody-drug-conjugate manufactured by Genentech, Inc.). We believe that LADR-based drugs offer the benefits of tumor targeting without the disadvantages of antibodies and other macromolecules, which include expense, complexity, and negative side effects. Additionally, albumin is a very well-characterized drug target, which we believe will reduce clinical and regulatory costs and risks.

The Company's postulated mechanism of action for LADR-based drugs 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 in tumors due to a mechanism called "enhanced permeability and retention", which results in lower exposure to the drug in noncancerous tissues of the heart, liver, and other organs;
- once localized at the tumor, the acid-sensitive linker of the LADR™ backbone is cleaved due to the specific conditions within the tumor and in the tumor microenvironment; and
- free active drug is then released within the tumor, causing tumor cell death.

The first-generation LADR-based drug is called aldoxorubicin. Aldoxorubicin is the well-known drug doxorubicin attached to the first generation LADR™ backbone (LADRs 7-10 employ a next generation LADR™ backbone). Aldoxorubicin has been administered to over 600 human subjects in human clinical trials and has proven the concept of LADR™ in that several-fold more doxorubicin can be administered to patients when the doxorubicin is attached to LADR™ than when administered as native doxorubicin.

The next generation LADR™ drugs are termed LADR 7, 8, 9, and 10. A great deal of Investigational New Drug ("IND") enabling work has already been accomplished on LADR 7-10, including in-silico modeling, in-vitro efficacy testing in several different cancer models, in-vivo dosing, safety, and efficacy testing in several different cancer models in animals. We have also developed and proven manufacturability, an important step prior to beginning human clinical trials.

The final toxicology studies required for the IND for LADR-7 have been completed. Prior to initiating the first-in-human Phase I studies of LADR-7, LADR-7 must be packaged into clinical trial containers, and the relevant regulatory agencies must be notified. We expect these activities to require approximately six months to complete once funding has been secured. If the Company fails to meet regulatory agencies' requirements for initiating the first-in-human studies of LADR-7, dosing of the first human patients could be substantially delayed.

Because the LADR™ backbone in future products would be the same as the LADR™ backbone in current product candidates, (i.e. the chemotoxin can be changed without changing the LADR™ backbone), management anticipates that future product candidates beyond LADR 7-10 may enjoy abbreviated pre-clinical pathways to first-in-human. Such abbreviated pathways would be subject to FDA review and agreement.

The Company'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. We have not yet determined whether the use of a companion diagnostic will be necessary or helpful, and plan to continue to investigate this question in parallel to the pre-clinical and clinical development of LADRs 7-10.

The LADR™ backbone and drugs that employ LADR™ are protected by domestic and international patents, and additional patents are pending.

Business Strategy for LADR™ Platform

LadRx is now focused on completing the work necessary to gain marketing approval for aldoxorubicin (described below), and on bringing LADR-7 into human clinical trials. The Company recently completed the production of approximately 100 grams of LADR-7 under GMP, which is sufficient to carry out final toxicology studies, and to initiate Phase IA studies in human subjects.

The Company has also completed the Good Laboratory Practices ("GLP") toxicology program that is expected to form the foundation of the regulatory applications necessary to initiate human clinical studies of LADR-7. Management expects to apply for first-in-human approval with the FDA or an international equivalent within 6 months of receiving additional funding.

Management will continue to explore in parallel both partnered and non-partnered funding and development strategies for LADR™ with a goal of obtaining the least costly capital possible to enable value inflection milestones.

Aldoxorubicin

Partnering of Aldoxorubicin

On July 27, 2017, the Company entered into an exclusive worldwide license agreement (the "License Agreement") with ImmunityBio, Inc. (formerly known as NantCell, Inc. ("NantCell, Inc."), and which merged with NantKwest Inc. in March 2021 ("ImmunityBio" and together with NantCell, Inc., "NantCell")), granting to ImmunityBio the exclusive rights to develop, manufacture and commercialize aldoxorubicin in all indications. As a result, we are no longer directly working on the development of aldoxorubicin. As part of the License Agreement, ImmunityBio made a strategic investment of $13 million in LadRx's common stock at $660.00 per share (adjusted to reflect the 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 5,000 shares of common stock at $660.00 per share, which such warrant expired on January 26, 2019.

ImmunityBio conducted an open-label, randomized, Phase 2 study of a combination of immunotherapy, aldoxorubicin, and standard-of-care chemotherapy versus standard-of-care chemotherapy alone for the treatment of locally advanced or metastatic pancreatic cancer in patients who have had 1 or 2 lines of treatment (Cohorts A and B) or 3 or greater lines of treatment (Cohort C). In June 2022, ImmunityBio presented data at the American Society of Clinical Oncology meeting showing that patients receiving combination immunotherapy with aldoxorubicin plus standard-of-care chemotherapy experienced overall survival of 5.8 months, compared to 3 months for historical control patients that had received only the standard-of-care chemotherapy (n=78, 95% confidence interval of 4 to 6.9 months). ImmunityBio submitted the results of the Phase 2 study to the FDA for registration. The FDA denied the request and asked for a very large clinical trial with cohorts for each of the combination therapies alone, and in permutative combination with the other combination therapies. ImmunityBio chose not to proceed with the FDA's recommended trial, and aldoxorubicin has been returned to LadRx (see below "Mutual Termination and Release Agreement").

Aldoxorubicin has received Orphan Drug Designation (ODD) by the FDA for the treatment of soft tissue sarcoma ("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.

Mutual Termination and Release Agreement

On June 3, 2024 (the "Effective Date"), we entered into a Mutual Termination and Release Agreement (the "Termination Agreement") with NantCell and its parent company, ImmunityBio and XOMA (as defined below). Pursuant to the Termination Agreement, the License Agreement will terminate automatically on the Effective Date, and neither the Company nor NantCell will have any continuing obligations to each other than as described in the Termination Agreement. Additionally, except that during the 30 day period following the Effective Date (the "Discussion Period"), the Company and NantCell shall engage in good faith discussions regarding the terms of an agreement pursuant to which the Company would have the right to purchase the inventory of aldoxorubicin (including, without limitation, active pharmaceutical ingredient, WPI and finished dose, the "Inventory") and all other materials necessary for the research, development and commercialization, among others, worldwide as of the Effective Date, at the Company's expense. Subsequently, the Company and NantCell have agreed the disposition of the Inventory shall be at NantCell's sole discretion.

The Termination Agreement additionally provides for the release of the Company and NantCell from claims, demands and liabilities, among others, and customary representations and warranties, covenants, and other provisions customary for transactions of this nature.

Royalty Purchase Agreement with XOMA

On June 21, 2023, the Company, entered into (i) a Royalty Purchase Agreement (the "Royalty Agreement") with XOMA (US) LLC ("XOMA"), for the sale, transfer, assignment and conveyance of the Company's right, title and interest in and to certain royalty payments and milestone payments with respect to aldoxorubicin, and (ii) an Assignment and Assumption Agreement (the "Assignment Agreement") with XOMA for the sale, transfer, assignment and conveyance of the Company's right, title and interest in the Asset Purchase Agreement (the "2011 Arimoclomol Agreement") between the Company and Orphazyme ApS ("Orphazyme"), dated as of May 13, 2011, and assigned to Zevra Denmark A/S ("Zevra Denmark"), effective as of June 1, 2022, which includes certain royalty and milestone payments with respect to arimoclomol. The combined aggregate purchase price paid to the Company for the sale, transfer, assignment and conveyance of the Company's right, title and interest in and to aldoxorubicin and arimoclomol was $5 million, less certain transaction fees and expenses.

The Royalty Agreement and the Assignment Agreement also provide for up to an additional $6 million based on regulatory and commercial milestones related to the development of arimoclomol and aldoxorubicin by their respective sponsors, Zevra, Inc. and Immunity Bio. The $6 million in potential post-closing payments is comprised of $1 million upon acceptance by the FDA of the arimoclomol New Drug Application ("NDA"), $1 million upon first commercial sale of arimoclomol, and $4 million upon FDA approval of aldoxorubicin. All royalty and milestone payments made to XOMA will be net of the existing licensing and milestone obligations owed by LadRx related to arimoclomol and aldoxorubicin. In January 2024, the Company received a payment of $1 million in connection with achieving the milestone relating to the acceptance by the FDA of the arimoclomol NDA and in November 2024, the Company received a payment of $1 million in connection with achieving the milestone relating to the first commercial sale of arimoclomol.

Pursuant to the Royalty Agreement, the Company agreed to sell, transfer, assign and convey to XOMA, among other payments, all royalty payments and regulatory and commercial milestone payments payable to the Company pursuant to the worldwide license agreement, dated July 27, 2017, by and between the Company and Immunity Bio. The Royalty Agreement also provides for the sharing of certain rights with XOMA to bring any action, demand, proceeding or claim as related to receiving such payments.

Management determined that the Royalty Agreement is not considered to be with a customer, and it does not fall within the scope of ASC 606. Instead, the Royalty Agreement represents an in-substance sale of nonfinancial assets, and, therefore, should be accounted for within the scope of ASC 610-20. As such, the Company recognized such net proceeds as other income in the accompanying statement of operations.

First Amendment to Royalty Purchase Agreement

On June 3, 2024, in consideration for the termination of the License Agreement pursuant to the Termination Agreement, the Company and XOMA entered into the First Amendment to the Royalty Agreement (the "First Amendment"). Pursuant to the First Amendment, if the Company decides to commercialize aldoxorubicin itself, prior to the first commercial sale of aldoxorubicin, the Company and XOMA shall enter into a synthetic royalty purchase agreement, pursuant to which the Company shall agree to make quarterly royalty payments to XOMA equal to the amount of all aggregate net sales of aldoxorubicin during each calendar quarter multiplied by 1.5%. If the Company decides not to commercialize aldoxorubicin itself and instead licenses aldoxorubicin to a third party, upon entry of such a new license agreement, XOMA shall be entitled to receive (i) royalty payments with respect to net sales of aldoxorubicin payable to the Company multiplied by 7.5% and (ii) milestone payments of 7.5% of any milestone payable to the Company pursuant to the License Agreement. The First Amendment contains customary covenants and other provisions customary for transactions of this nature.

Mutual Termination and Release Agreement

On June 3, 2024 (the "Effective Date"), we entered into a Mutual Termination and Release Agreement (the "Termination Agreement") with NantCell and its parent company, ImmunityBio and XOMA (as defined below). Pursuant to the Termination Agreement, the License Agreement will terminate automatically on the Effective Date, and neither the Company nor NantCell will have any continuing obligations to each other than as described in the Termination Agreement. Additionally, except that during the 30 day period following the Effective Date (the "Discussion Period"), the Company and NantCell shall engage in good faith discussions regarding the terms of an agreement pursuant to which the Company would have the right to purchase the inventory of aldoxorubicin (including, without limitation, active pharmaceutical ingredient, WPI and finished dose, the "Inventory") and all other materials necessary for the research, development and commercialization, among others, worldwide as of the Effective Date, at the Company's expense. Subsequently, the Company and NantCell have agreed the disposition of the Inventory shall be at NantCell's sole discretion.

The Termination Agreement additionally provides for the release of the Company and NantCell from claims, demands and liabilities, among others, and customary representations and warranties, covenants, and other provisions customary for transactions of this nature.

Business Strategy for Aldoxorubicin

In December 2024, the Company announced that it is restarting a process to seek marketing approval of aldoxorubicin under the provisions of the FDA's Section 505(b)(2). The 505(b)(2) pathway is designed for a new drug composition whose active ingredient is the same active ingredient as a drug previously approved by the FDA. Given that the active component of the tumor-targeted drug aldoxorubicin is the already-marketed drug doxorubicin, the 505(b)(2) pathway is available for aldoxorubicin, and greatly reduces the regulatory burden of getting aldoxorubicin to the market by relying on the non-clinical and clinical data history of doxorubicin and aldoxorubicin to demonstrate equivalence of efficacy and safety. Additionally, the market exclusivity awarded to drugs that have received orphan designation for certain rare diseases, as is the case for aldoxorubicin, is available for drugs approved through the 505(b)(2) process for new drugs. Based on prior discussions with the FDA and input from regulatory experts, the Company does not expect that additional human trials will be necessary to gain approval of aldoxorubicin under Section 505(b)(2). LadRx plans to submit a pre-NDA to the FDA within 3 months of receiving additional funding, and upon agreement with the FDA on a non-clinical path to approval, LadRx plans to submit a full NDA to the FDA. The Company estimates that aldoxorubicin will be ready for submission to the FDA for marketing approval approximately 12 months from receiving additional funding. LadRx expects the capital needed to reach the pre-NDA meeting to be approximately $1.5 million, and the capital needed to reach NDA marketing approval to be an additional $4 million. There can be no certainty that the Company will be successful in its approach to the FDA or in raising additional capital.

Transfer of Rights to Molecular Chaperone Assets (Orphayzme)

On May 13, 2011, pursuant to the Asset Purchase Agreement by and between the Company and Orphazyme A/S ("Orphazyme", formerly Orphazyme ApS), LadRx sold the rights to arimoclomol and iroxanadine, based on molecular chaperone regulation technology, 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 (the "2011 Arimoclomol Agreement"). Orphazyme transferred its rights and obligations under the 2011 Arimoclomol Agreement to KemPharm Denmark A/S ("KemPharm"), a wholly owned subsidiary of KemPharm Inc., in May 2022.

In May 2021, Orphazyme announced that the pivotal phase 3 clinical trial for arimoclomol in Amyotrophic Lateral Sclerosis did not meet its primary and secondary endpoints, reducing the maximum amount that LadRx currently has the right to receive under the 2011 Arimoclomol Agreement to approximately $100 million. Orphazyme also tested arimoclomol in Niemann-Pick disease Type C ("NPC") and Gaucher disease, and following a Phase II/III trial submitted to the FDA a NDA for the treatment of NPC with arimoclomol. On June 18, 2021, Orphazyme announced it had received a complete response letter (the "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 had publicly indicated that it intended 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 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.

On May 31, 2022, Orphazyme announced that it had completed the sale of substantially all of its assets and business activities for cash consideration of $12.8 million and assumption of liabilities estimated to equal approximately $5.2 million to KemPharm (the "KemPharm Transaction"). KemPharm is a specialty biopharmaceutical company focused on the discovery and development of novel treatments for rare CNS diseases. As part of the KemPharm Transaction, all of Orphazyme's obligations to LadRx under the 2011 Arimoclomol Agreement, including with regard to milestone payments and royalties on sales, were assumed by KemPharm. KemPharm is expected to continue the early access programs with arimoclomol, and to continue to pursue the potential approval of arimoclomol as a treatment option for NPC. KemPharm resubmitted the NDA for arimoclomol in 2023. It is also identifying a regulatory path forward with the EMA. KemPharm re-branded to Zevra Therapeutics, Inc. in February 2023. In January 2024, the FDA accepted Zevra's NDA for arimoclomol and in September, the FDA approved arimoclomol as an orally-delivered treatment for NPC. In September 2024, Zevra additionally announced that MIPLYFFA™ (arimoclomol) would be commercially available in the United States towards the end of 2024 and in November achieved its first commercial sale.

Assignment and Assumption Agreement with XOMA

On June 21, 2023, the Company entered into the Assignment Agreement with XOMA, pursuant to which, among others, the Company agreed to sell, transfer and assign to XOMA the Company's right, title and interest in the arimoclomol pursuant to the 2011 Arimoclomol Agreement, including the right to receive certain milestone, royalty and other payments from Zevra.

Pursuant to the Assignment Agreement, the Company is entitled to receive (i) a one-time payment of $1 million upon acceptance of a re-submission of a NDA to the FDA for arimoclomol, and (ii) a one-time payment of $1 million upon the first invoiced sale in certain territories of a pharmaceutical product derived from arimoclomol as an active pharmaceutical ingredient, subject to the receipt of the applicable regulatory approval required to sell such a product in such countries. In 2024, the Company received both of those milestone payments.

Research and Development

In 2024, the Company spent $773,000 on expenditures for research and development activities related to continuing operations as compared to $280,000 in 2023.

The Company plans on restarting a process to seek marketing approval of aldoxorubicin under the provisions of the FDA's Section 505(b)(2). The 505(b)(2) pathway is designed for a new drug composition whose active ingredient is the same active ingredient as a drug previously approved by the FDA. Given that the active component of the tumor-targeted drug aldoxorubicin is the already-marketed drug doxorubicin, the 505(b)(2) pathway is available for aldoxorubicin, and greatly reduces the regulatory burden of getting aldoxorubicin to the market by relying on the non-clinical and clinical data history of doxorubicin to demonstrate efficacy and safety.

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 financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these 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 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 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 ("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 Income (Loss) Per Share of Common Stock

Basic and diluted net income (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 income (loss) per share in the future, and which were excluded from the computation of diluted income (loss) per share, were as follows:

	As of December 31,	
	2024	**2023**
Options to acquire common stock	66,817	14,000
Warrants to acquire common stock	—	42
	66,817	14,042

Liquidity and Capital Resources

Going Concern

The Company has operated at a loss due to its ongoing expenditures for research and development of its product candidates and for general and administrative purposes, and lack of significant recurring revenues. For the year ended December 31, 2024, it incurred a net loss of $1.6 million, had a loss from operations of $3.6 million, and, for the year ended December 31, 2023, the Company had a loss from operations of $3.8 million, and had total stockholders' deficit as of December 31, 2024 of $1.4 million. The Company has had no recurring revenue, and it is likely to continue to incur losses unless and until it concludes a successful strategic partnership or financing for its research and development assets. These losses, among other things, have had and will continue to have an adverse effect on the stockholders' equity and working capital. Because of the numerous risks and uncertainties associated with its product development efforts, they are unable to predict when they may become profitable, if at all. If the Company does not become profitable or are unable to maintain future profitability, the market value of its common stock will be adversely affected. These factors individually and collectively raise a substantial doubt about the Company's ability to continue as a going concern. In addition, our independent registered public accounting firm, in their report on the Company's December 31, 2024, audited financial statements, expressed substantial doubt about the Company's ability to continue as a going concern.

In order to fund its business and operations, the Company has relied primarily upon sales of its equity securities, including proceeds from the exercise of stock options and common stock purchase warrants and long-term loan financing. They have received limited funding from their strategic partners and licensees. The Company will ultimately be required to obtain additional funding in order to execute its long-term business plans, although they do not currently have commitments from any third parties to provide them with long-term debt or capital. The Company cannot assure that additional funding will be available on favorable terms, or at all. If they fail to obtain additional funding when needed, the Company may not be able to execute its business plans and its business may suffer, which would have a material adverse effect on its financial position, results of operations and cash flows. We have approximately $1.0 million of contractual obligations in 2025.

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 for the Years Ended December 31, 2024, and 2023

Cash Flows from Operating Activities

Net cash used in operating activities for the year ended December 31, 2024 was $1.3 million, which was primarily the result of a net loss from operations of $1.6 million, less $0.3 million in net cash outflows associated with changes in assets and liabilities. The net cash outflows associated with changes in assets and liabilities were primarily due to reductions of $0.1 million of prepaid expenses and $0.1 million in accounts payable, offset by an increase in accrued liabilities of $0.2 million.

Net cash provided by operating activities for the year ended December 31, 2023 was $1.0 million, which was primarily the result of the sale of royalty and milestone rights, net of transaction costs of $4.2 million less a net loss from operations of $3.8 million, plus $0.6 million in net cash outflows associated with changes in assets and liabilities. The net cash outflows associated with changes in assets and liabilities were primarily due to reductions of $0.4 million of prepaid expenses and $0.2 million in amortization of right-of-use assets, an increase of $0.2 million in accounts payable, offset by a decrease in lease liabilities of $0.2 million.

Cash Flows from Investing Activities

There were no investing activities in both the years ended December 31, 2024 and December 31, 2023 and do not expect any significant capital spending during the next 12 months.

Cash Flows from Financing Activities

There were no financing activities in 2024. We purchased the preferred investment options for $250,000 and paid dividends of $69,000 on the shares of Series C Preferred Stock in the year ended December 31, 2023.

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.

We do not have any off-balance sheet arrangements.

Results of Operations for the Years Ended December 31, 2024, and 2023

We incurred a net loss from operations of $1.6 million for the year ended December 31, 2024 as compared to a net loss from operations of $3.8 million for the year ended December 31, 2023.

During the years ended December 31, 2024 and 2023, we recognized no service income or licenses fees. We will no longer be entitled to future licensing revenues from our previous licensing agreements, since we transferred the royalty and milestone rights associated with arimoclomol and aldoxorubicin to XOMA, pursuant to the Royalty Agreement and the Assignment Agreement for net proceeds of approximately $4.2 million, along with an aggregate of $6 million in potential post-closing payments, based on achievement of certain future milestones. We recognized the net proceeds in connection with the Royalty Agreement and the Assignment Agreement as Other Income on our statement of operations for the year ended December 31, 2023.

General and Administrative

	Year Ended December 31,	
	2024	2023
	(In thousands)	
General and administrative expenses	$ 2,782	$ 3,532
Employee stock and stock option expense	63	—
Total	$ 2,845	$ 3,532

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 employee stock and stock option exercises, were $2.8 million and $3.5 million in the years ended December 31, 2024 and 2023, respectively.

Research and Development

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 $0.8 million in research and development expenses in the year ended December 31, 2024, as compared to $0.3 million in the comparative 2023 year.

Depreciation and Amortization

Depreciation and amortization expenses for the years ended December 31, 2024 and 2023 were approximately $6,000 and $12,000, respectively. The depreciation expense reflects the depreciation of our equipment and furnishings.

Milestone payments

We received $2 million of milestone payments for the year ended December 31, 2024 relating to the Royalty Purchase Agreement with XOMA. There were no such payments for the year ended December 31, 2023 and there will be no such future payments. In the year ended December 31, 2023, we received a net amount of $4.2 million for the sale of royalty and milestone rights.

Interest Income

Interest income was $33,000 in the year ended December 31, 2024 and $55,000 in the year ended December 31, 2023. 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

Ongoing conflicts in Ukraine and Israel, including related sanctions and countermeasures, are difficult to predict, and could adversely impact geopolitical and macroeconomic conditions, the global economy, and contribute to increased market volatility, which may in turn adversely affect our business and operations. We may not be able to raise sufficient additional capital and may tailor our business and operations based on the amount of funding we are able to raise in the future. Nevertheless, there is no assurance that these initiatives will be successful.

Other than as discussed above and elsewhere in this report, we are not aware of any trends, events or uncertainties that are likely to have a material effect on our financial condition.

Recently Adopted Accounting Pronouncements

Recent authoritative guidance issued by the FASB (including technical corrections to the ASC), the American Institute of Certified Public Accountants, and the SEC did not, or are not expected to, have a material impact on the Company's 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, 2024, 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 financial statements and notes thereto as of December 31, 2024 and 2023, and for the years ended December 31, 2024 and 2023, 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, 2024, 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, 2024, 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, 2024. 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)*. 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, 2024.

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, 2024 that have materially affected, or are reasonably likely to have a material affect, on 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	Age	Class of Director[(2)]	Position
Jennifer K Simpson, Ph.D.	56	III	Chair of the Board[(3)]
Joel Caldwell	69	II	Director[(2)]
Cary Claiborne	64	I	Director[(2) (3)]
Stephen Snowdy, Ph.D.	56	—	Chief Executive Officer
John Y. Caloz	72	—	Chief Financial Officer and Senior Vice-President

(1) Our Class I and Class III directors serve until the 2025 annual meeting of our stockholders and our Class II director serves until the 2026 annual meeting of our stockholders.

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

(3) Members of our Compensation Committee. Mr. Claiborne is Chairman of the Committee.

Jennifer Simpson, Ph.D. joined our Board in July 2021. She was appointed Chair of the Board on July 27, 2022. 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.

Joel Caldwell joined our Board 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'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.

Cary Claiborne joined our Board in July 2022. Mr. Claiborne has served on the Board of Directors of NeuroSense Therapeutics since December 2021, where he also serves as chair of the audit committee. Mr. Claiborne has served as the Chief Executive Officer since August 18, 2022 and prior to that as Chief Operating Officer since December 2021 and a director since November 2021 for Adial Pharmaceuticals Inc. ("Adial") a public biopharmaceutical company. Prior to joining Adial, Mr. Claiborne served as the CEO of Prosperity Capital Management, LLC, a US-based private investment and advisory firm that he founded. From 2014 until 2017, Mr. Claiborne served as the Chief Financial Officer and board member of Indivior PLC. a public global commercial stage pharmaceutical company. Mr. Claiborne was also a director on the Board of Directors of New Generation Biofuels Inc. and MedicAlert Foundation, where he also served as the chair of the audit and finance committees. From 2011 to 2014, Mr. Claiborne was the Chief Financial Officer of Sucampo Pharmaceuticals Inc., a public global biopharmaceutical company focused on drug discovery, development, and commercialization. Mr. Claiborne graduated from Rutgers University with a B.A. in Business Administration. He also holds an M.B.A from Villanova University and was previously a NACD Governance Fellow. His diverse background in the pharmaceutical industry and finance will provide the board with a balanced perspective and 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. In August of 2020 he was named Senior Vice-President and on May 11, 2023, he was named Corporate Secretary. 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.

Involvement in Certain Legal Proceedings

None of our directors or executive officers has been involved in any of the following events during the past ten years:

- any bankruptcy petition filed by or against any business of which such person was a general partner or executive officer either at the time of the bankruptcy or within two years prior to that time;
- any conviction in a criminal proceeding or being subject to a pending criminal proceeding (excluding traffic violations and other minor offences);
- being subject to any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction, permanently or temporarily enjoining, barring, suspending or otherwise limiting his or her involvement in any type of business, securities or banking activities; or
- being found by a court of competent jurisdiction (in a civil action), the SEC or the Commodity Futures Trading Commission to have violated a federal or state securities or commodities law, and the judgment has not been reversed, suspended, or vacated.

Diversity

Our Board 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 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 a complementary mix of individuals with diverse backgrounds and skills reflecting the broad set of challenges that the Board 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 Securities Exchange Act of 1934, as amended (the "Securities Act"), and the Compensation Committee. The Audit Committee consists of Mr. Caldwell and Mr. Claiborne. The Chairman of the Audit Committee is Mr. Caldwell. The Compensation Committee consists of Mr. Claiborne and Dr. Simpson. Mr. Claiborne 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.ladrxcorp.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 has determined that Mr. Claiborne and Mr. Caldwell are "independent" under the current independence standards of both The OTC Market and the SEC.

In the year ended December 31, 2024, the Board met four times, the Audit Committee met four times and the Compensation Committee did not hold any meetings.

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 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 do not believe that there were any delinquent filers, except for the Form 4s filed on January 29, 2024, for each of Stephen Snowdy, Jennifer Simpson, Cary Claiborne, Joel Caldwell and John Caloz. Other than the aforementioned, we believe our directors and executive officers and greater than 10% shareholders for the year ended December 31, 2024 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.ladrxcorp.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.

Insider Trading Policy

We have adopted an insider trading policy governing the purchase, sale, and/or other dispositions of our securities by our directors, officers and employees. The insider trading policy is designed to promote compliance with insider trading laws, rules and regulations. Since the adoption of our insider trading policy, the policy administrator has not granted any such exemptions to the policy's general prohibition on hedging or pledging. While the Company is not subject to the insider trading policy, the company does not trade in its securities when it is in possession of material nonpublic information other than pursuant to previously adopted Rule 10b5-1 trading plans.

Timing and Issuance of Stock Options

There were no equity awards granted to the Named Executive Officers in the period beginning four business days before the filing of a periodic report on Form 10-Q or Form 10-K , or the filing or furnishing of a current report on Form 8-K that discloses material non-public information (other than a current report on Form 8-K disclosing a material new option award grant under Item 5.02(e) of that form), and ending one business day after the filing or furnishing of such report.

Board Structure

Our Certificate of Incorporation and our Bylaws previously provided for the classification of our directors into three classes, which we refer to as Class I, Class II and Class III, with each class to consist as nearly as possible of an equal number of directors.

At the 2022 Annual Meeting, a Declassification Proposal to declassify the structure of the Board was passed on a precatory basis, which advised the Board that a majority of our stockholders desired to end the classified Board structure in favor of the annual election of directors, in which each director standing for election will only be eligible to be elected for one-year terms. At the 2023 Annual Meeting, the stockholders approved the Board's adoption of a resolution approving and declaring the advisability of amending our governing documents to the extent necessary to remove provisions that provide for a classified Board. This resolution provided for a rolling declassification of the Board to be completed by the 2026 annual meeting of the stockholders.

On September 8, 2023, we filed a Certificate of Amendment of Restated Certificate of Incorporation (the "Certificate of Amendment") with the Secretary of State of Delaware to amend and restate in its entirety Section 2 of Article Eighth of our Restated Certificate of Incorporation to effect the declassification of our Board as approved by our stockholders. Our board also amended certain provisions of our Amended and Restated By-Laws (the "By-Laws") consistent with the Certificate of Amendment. Following the filing of the Certificate of Amendment and the amendment of our By-Laws, our Class I and Class II directors will serve until the 2025 annual meeting of our stockholders and our Class III director will serve until the 2026 annual meeting of our stockholders.

Board of Directors Role in Risk Oversight

In connection with its oversight responsibilities, our Board, 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 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, 2024 and 2023 by Stephen Snowdy and John Y. Caloz, who were considered our "Named Executive Officers" for the year ended December 31, 2024.

Summary Compensation Table

Name and Principal Position	Year	Salary ($) (1)	Bonus ($) (2)	Option Awards ($) (3)	All Other Compensation ($)	Total ($)
Stephen Snowdy, Ph.D.						
Chief Executive Officer	2024	535,600	—	42,900	—	578,500
	2023	520,000	25,000	—	—	545,000
John Y. Caloz						
Chief Financial Officer, Treasurer and Senior Vice-President	2024	428,500	—	25,700	—	454,200
	2023	416,000	—	—	—	416,000

(1) The Named Executive Officers received a 3% cost of living adjustment for the 2024 calendar year, and a 4% cost of living adjustment for the 2023 calendar year.

(2) Bonus paid to Dr. Snowdy, the current Chief Executive Officer, was paid in January 2023 and was the last quarterly instalment of his 2022 signing bonus; the other three quarterly instalments were paid in the 2022 calendar year.

(3) In December 2023, the Compensation Committee awarded stock option grants, effective January 15, 2024.

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, 2024 issued under our 2008 Plan and our 2019 Plan:

Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested ($)
Stephen Snowdy, Ph.D. Chief Executive Officer	16,325	8,675	1.83	01/14/34				
John Y. Caloz Chief Financial Officer, Treasurer and Senior Vice-President	9,795	5,205	1.83	01/14/34				
	3,500		26.00	12/14/29				
	583		175.00	12/14/27				
	583		258.00	12/14/26				
	500		1,464.00	12/14/25				

2024 Grants of Plan-Based Awards

In December 2023, the Compensation Committee awarded stock option grants to purchase an aggregate of 55,000 shares of common stock, effective January 15, 2024 to the Company's Named Executive Officers and directors. No stock options or restricted stock were granted in 2023.

2008 Stock Incentive Plan and the 2019 Stock Incentive Plan

The purpose of our 2008 Stock Incentive Plan, (the "2008 Plan"), and our 2019 Stock Incentive Plan (the "2019 Plan"), and together with the 2008 Plan (the "Plans"), 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 on November 21, 2008 and by our stockholders on July 1, 2009 with certain amendments to the 2008 Plan having been subsequently approved by our Board and stockholders. The 2019 Plan was adopted by our Board on November 15, 2019. On September 7, 2023, the Board approved the first amendment (the "Plan Amendment") to the 2019 Plan, effective as of the same date. The Plan Amendment amends the 2019 Plan to (i) reflect the Company's name change from CytRx Corporation to LadRx Corporation in September 2022, and (ii) increase the aggregate number of shares of common stock that may be issued under the 2019 Plan, as set forth in Section 4(a) of the 2019 Plan, by an additional 75,000 shares of common stock.

2008 Plan and the 2019 Plan Descriptions

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 Plans; and
- make all other decisions and determinations that may be required under, or as the Compensation Committee deems necessary or advisable to administer, the Plans.

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 Agreements with Stephen Snowdy

2022 Snowdy Employment Agreement

On January 3, 2022, the Company entered into an employment agreement, effective January 10, 2022 (the "Effective Date"), with Dr. Stephen Snowdy, under which the Company agreed to employ Dr. Snowdy as its Chief Executive Officer through December 31, 2022 (the "Snowdy Employment Agreement"). Pursuant to the Snowdy Employment Agreement, Dr. Snowdy is entitled to a base annual salary of $500,000. Dr. Snowdy also is entitled to receive a signing bonus of $100,000, payable in four quarterly installments, with the first installment to be paid on the date that is 90 days following the Effective Date, and an annual bonus to be determined by the Board in its sole discretion, based on certain performance criteria as established by the Board, with such bonus payable no later than the last regular payroll in 2022. Dr. Snowdy is also eligible to receive a bonus of up to 3.0% of the amount of non-broker assisted funding raised to fund Centurion on terms acceptable to both the Board of Centurion and LadRx. The Snowdy Employment Agreement also entitles Dr. Snowdy to receive customary benefits and reimbursement for ordinary business expenses. In connection with Dr. Snowdy's appointment and as a further inducement to enter into the Snowdy Employment Agreement, the Company granted Dr. Snowdy 300,000 cash-based stock appreciation rights with a base price equal to the closing price of the Company's common stock on the date of grant, subject to the terms and conditions of the Company's form of cash-based stock appreciation rights agreement, which terms shall include vesting in three substantially equal tranches on the first, second and third anniversary of the Effective Date.

Under the Snowdy Employment Agreement, Dr. Snowdy is also eligible to receive nonqualified stock options equal to 2% of the fully diluted common stock of Centurion with an exercise price equal to the fair market value of Centurion on the date of grant, subject to the terms and conditions of a grant agreement. In the event Dr. Snowdy's employment is terminated without "cause" or due to "disability" (each term as defined in the Snowdy Employment Agreement) or death, the Company has agreed to (i) pay Dr. Snowdy or his heirs or personal representatives, as applicable, a lump-sum severance amount equal to six months' base annual salary, or twelve months' base annual salary if Dr. Snowdy's employment is terminated without "cause" following a "change in control" (each term as defined in the Snowdy Employment Agreement), and (ii) continue the participation, at the Company's cost, for a period of six months, or twelve months if the Snowdy Employment Agreement is terminated without "cause" following a "change in control", of Dr. Snowdy and his dependents in the employee benefits plan in which Dr. Snowdy was participating. In the event Dr. Snowdy's employment is terminated without "cause", all of Dr. Snowdy's vested stock options and any other vested equity awards will remain exercisable for their full term notwithstanding the termination of his employment. In the event Dr. Snowdy's employment is terminated due to Dr. Snowdy's "disability" or death, all of Dr. Snowdy's unvested stock options and other equity awards based on the Company's securities will immediately vest in full and all of Dr. Snowdy's stock options and any other equity awards will remain exercisable for their full term notwithstanding the termination of his employment. Dr. Snowdy may also terminate the Employment Agreement for good reason.

2023 Snowdy Employment Agreement

On December 30, 2022, the Company entered into a new employment agreement with Dr. Stephen Snowdy, effective as of January 1, 2023 (the "2023 Snowdy Employment Agreement"), pursuant to which the Company agreed to continue to employ Dr. Snowdy as its Chief Executive Officer through December 31, 2025, unless terminated sooner in accordance with the terms of the 2023 Snowdy Employment Agreement (the "Snowdy Term"). In the event that Dr. Snowdy's employment has not been terminated and the Company has not offered to extend or renew Dr. Snowdy's employment under the 2023 Snowdy Employment Agreement upon expiration of the Snowdy Term, in lieu of any other severance benefits as provided in the 2023 Snowdy Employment Agreement, the Company shall continue to pay Dr. Snowdy his salary commencing on the final date of the Snowdy Term and ending on (a) June 30, 2026, or (b) the date of Dr. Snowdy's re-employment with another employer, whichever is earlier; provided that Dr. Snowdy shall have executed and delivered to the Company a General Release of All Claims. Pursuant to the 2023 Snowdy Employment Agreement, Dr. Snowdy is entitled to receive an annual salary of $520,000, less applicable payroll deductions and tax withholdings. Dr. Snowdy also is eligible for an annual target performance based bonus (the "Snowdy Target Bonus"), equal to 50% of Dr. Snowdy's annual salary during the Snowdy Term, with such bonus dependent in part on the Company's performance and the Compensation Committee's discretion in assessing Dr. Snowdy's individual performance in relation to his objectives as determined by the Company's Board of Directors and the overall performance and status of the Company, payable no later than February 28th of the calendar year following the calendar year in which the Snowdy Target Bonus relates.

The 2023 Snowdy Employment Agreement also entitles Dr. Snowdy to receive customary benefits and reimbursement for ordinary business expenses. In the event Dr. Snowdy's employment is terminated without cause, due to disability or death, or due to good reason by Dr. Snowdy (each term as defined in the 2023 Snowdy Employment Agreement), the Company has agreed to, among other things, (i) pay Dr. Snowdy or his heirs or personal representatives, as applicable, a lump-sum severance amount equal to twelve months' base annual salary and an amount equal to the prorated portion of the Snowdy Target Bonus for the year in which the termination occurred based on the number of days Dr. Snowdy was employed, or an amount equal to eighteen months' annual salary and the full Snowdy Target Bonus amount if such termination occurs within six months prior to or within twelve months following a change in control; and (ii) reimburse Dr. Snowdy and his dependents all premiums associated with Dr. Snowdy's continuation of health insurance pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1986 ("COBRA"), subject to certain conditions. In the event Dr. Snowdy's employment is terminated without cause or by Dr. Snowdy due to good reason, all of Dr. Snowdy's vested stock options and any other vested equity awards will remain exercisable for their full term notwithstanding the termination of his employment. In the event Dr. Snowdy's employment is terminated due to disability or death, all of Dr. Snowdy's unvested stock options and other equity awards based on the Company's securities will immediately vest in full and all of Dr. Snowdy's stock options and any other equity awards will remain exercisable for their full term notwithstanding the termination of his employment.

Employment Agreements with John Y. Caloz

John Y. Caloz is employed as our Chief Financial Officer, Treasurer and Senior Vice-President pursuant to an employment agreement (the "Caloz Employment Agreement") dated as of December 16, 2021 that expired 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 (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 in the Caloz Employment Agreement), 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.

Pursuant to the Caloz Employment Agreement, if the Company does not offer to renew or extend the Caloz Employment Agreement, and that Mr. Caloz's employment had not theretofore been terminated, we will continue to pay him his annual salary thereunder during the period commencing upon expiration of the Caloz Employment Agreement and ending on June 30, 2023.

2023 Caloz Employment Agreement

On December 30, 2022, the Company entered into a new employment agreement with John Y. Caloz, effective January 1, 2023 (the "2023 Caloz Employment Agreement"), pursuant to which the Company agreed to continue to employ Mr. Caloz as its Chief Financial Officer and Senior Vice President through December 31, 2025, unless terminated sooner in accordance with the 2023 Caloz Employment Agreement (the "Caloz Term"). In the event that Mr. Caloz's employment has not been terminated and the Company has not offered to extend or renew Mr. Caloz's employment under the 2023 Caloz Employment Agreement upon expiration of the Caloz Term, in lieu of any other severance benefits as provided in the 2023 Caloz Employment Agreement, the Company shall continue to pay Mr. Caloz his salary commencing on the final date of the Caloz Term and ending on (a) June 30, 2026, or (b) the date of Mr. Caloz's re-employment with another employer, whichever is earlier; provided that Mr. Caloz shall have executed and delivered to the Company a General Release of All Claims. Pursuant to the 2023 Caloz Employment Agreement, Mr. Caloz is entitled to receive an annual salary of $416,000, less applicable payroll deductions and tax withholdings. Mr. Caloz also is eligible for an annual target performance-based bonus (the "Caloz Target Bonus"), equal to 40% of Mr. Caloz's annual salary during the Caloz Term, with such bonus dependent in part on the Company's performance and the Compensation Committee's discretion in assessing Mr. Caloz's individual performance in relation to his objectives as determined by the Board and the overall performance and status of the Company, payable no later than February 28th of the calendar year following the calendar year in which the Caloz Target Bonus relates.

The 2023 Caloz Employment Agreement also entitles Mr. Caloz to receive customary benefits and reimbursement for ordinary business expenses. In the event Mr. Caloz's employment is terminated without cause, due to disability or death, or due to good reason by Mr. Caloz (each term as defined in the 2023 Caloz Employment Agreement), the Company has agreed to, among other things, (i) pay Mr. Caloz or his heirs or personal representatives, as applicable, a lump-sum severance amount equal to twelve months' base annual salary and an amount equal to the prorated portion of the Caloz Target Bonus for the year in which the termination occurred based on the number of days Mr. Caloz was employed, or an amount equal to eighteen months' annual salary and the full Caloz Target Bonus amount if such termination occurs within six months prior to or within twelve months following a change in control; and (ii) reimburse Mr. Caloz and his dependents for all Medicare premiums and premiums associated with Mr. Caloz continuation of health insurance pursuant to COBRA, subject to certain conditions. In the event Mr. Caloz's employment is terminated without cause or by Mr. Caloz due to good reason, all of Mr. Caloz's vested stock options and any other vested equity awards will remain exercisable for their full term notwithstanding the termination of his employment. In the event Mr. Caloz's employment is terminated due to disability or death, all of Mr. Caloz's unvested stock options and other equity awards based on the Company's securities will immediately vest in full and all of Mr. Caloz's stock options and any other equity awards will remain exercisable for their full term notwithstanding the termination of his employment.

Compensation of Directors

We use a combination of cash and stock-based compensation to attract and retain qualified candidates to serve on our Board. 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' annual compensation year begins with the annual election of directors at the annual meeting of stockholders. Periodically, our Board reviews our director compensation policies and, from time to time, makes changes to such policies based on various criteria the board deems relevant. For 2023, the Board implemented an increase of 4 percent in their compensation, with no further increase in 2024.

The non-employee director who serves as Chair of the Board receives a quarterly retainer of $6,500. Our non-employee directors receive a quarterly retainer of $6,240 (plus an additional $5,200 paid to each of the Chairpersons of the Audit and Compensation Committees), a fee of $4,160 for each Board meeting attended (or $750 for Board actions taken by unanimous written consent) and $3,120 for each meeting of the Audit Committee and $2,600 for each meeting of the Compensation Committee attended. Non-employee directors who serve as the Chairperson of a board committee receive an additional $3,120 for each Audit Committee meeting they chair and an additional $4,160 for each Compensation Committee meeting they chair. The non-employee director who serves as Chairperson of the Board receives an additional $4,160 for each meeting attended.

The following table sets forth the compensation paid to our directors for the year ended December 31, 2024:

Director Compensation Table

Name	Fees Earned or Paid in Cash ($) (1)	Total ($)
Cary Claiborne, Director	69,680	87,760
Joel Caldwell, Director	75,920	85,120
Jennifer Simpson, Ph.D., Chair of the Board	74,100	97,240

(1) 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 28, 2025 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 December 31, 2024; 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 28, 2025 (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 495,092 shares of our common stock outstanding as of March 28, 2025. 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 and have an address of 11726 San Vicente Blvd, Ste 650, Los Angeles, CA 90049. An asterisk represents beneficial ownership of less than 1%.

Name and Address of Beneficial Owner (5)	Amount and Nature of Beneficial Ownership (Common Stock)	Percent of Class (Common Stock)
Named Executive Officers and Directors		
Cary Claiborne	3,472	*(1)
Joel Caldwell	6,826	1.4%(2)
Jennifer Simpson, Ph.D.	3,497	*(3)
Stephen Snowdy, Ph.D.	17,361	3.5%(4)
John Y. Caloz	15,591	3.1%(5)
All executive officers and directors as a group (five persons)	46,747	9.4%(6)

(1) Includes 3,472 shares subject to stock options.

(2) Includes 3,472 shares subject to stock options.

(3) Includes 3,472 shares subject to stock options.

(4) Includes 17,361 shares subject to stock options.

(5) Includes 15,583 shares subject to stock options.

(6) Includes 43,960 shares subject to stock options.

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 The Nasdaq Capital Market, our Board has determined that Dr. Simpson, Mr. Caldwell and Mr. Claiborne 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. Our Board has determined that Mr. Claiborne and Mr. Caldwell also are "independent" for purposes of service as the members of our Audit Committee. In making these determinations, our Board 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 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.

Item 14. ***PRINCIPAL ACCOUNTANT FEES AND SERVICES***

Audit Fees

Weinberg & Company ("Weinberg"), served as our independent registered public accounting firm and audited our financial statements for the years ended December 31, 2024 and 2023.

The fees for the year ended December 31, 2024 from Weinberg for professional services rendered in connection with the audit of our annual financial statements and reviews of our unaudited financial statements were approximately $45,600. The fees for the year ended December 31, 2023 from Weinberg for professional services rendered in connection with the audit of our annual financial statements and reviews of our unaudited financial statements and registration statements on Form S-1 were approximately $113,000.

Audit-Related Fees

None.

Tax Fees

The aggregate fees billed by Weinberg for professional services for tax compliance were approximately $21,500 for the year ended December 31, 2024 and approximately $23,000 for 2023.

All Other Fees

No other services were rendered by Weinberg in either year ended December 31, 2024 or 2023.

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, 2024 and 2023.

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 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 financial statements are as follows:

Balance Sheets as of December 31, 2024 and 2023

Statements of Operations for the Years Ended December 31, 2024 and 2023

Statements of Stockholders' Equity for the Years Ended December 31, 2024 and 2023

Statements of Cash Flows for the Years Ended December 31, 2024 and 2023

Notes to 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 financial statements or notes thereto.

(3) Exhibits

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

LadRx 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 and Amendment No. 1 to the Amended and Restated Bylaws of dated May 19, 2022.	8-K	3.3	5/19/2022	
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	
3.10	Certificate of Correction to the Certificate of Amendment of Restated Certificate of Incorporation	8-K	3.3	5/19/2022	
3.11	Certificate of Designation of Series D Preferred Stock	8-K	3.1	5/19/2022	
3.12	Certificate of Amendment of Restated Certificate of Incorporation	8-K	3.1	9/23/2022	
3.13	Certificate of Amendment of Restated Certificate of Incorporation	8-K	3.1	5/11/2023	
3.14	Certificate of Amendment of Restated Certificate of Incorporation	8-K	3.1	9/11/2023	
3.15	Amendments to the By-Laws	8-K	3.2	9/11/2023	
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	
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	

Exhibit Number	Description	Incorporated By Reference to			Filed / Furnished Herewith
		Form	Exhibit	Filing Date	
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	
10.4.1	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	
10.8+	Employment Agreement, dated December 16, 2021, by and between CytRx Corporation and John Y. Caloz	10-K	10.8	3/23/2022	
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, dated 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	
10.15+	Employment Agreement, dated December 30, 2022, by and between LadRx Corporation and Dr. Stephen Snowdy.	10-K	10.15	3/27/2024	
10.16+	Employment Agreement, dated December 30, 2022, by and between LadRx Corporation and John Y. Caloz	10-K	10.16	3/27/2024	
10.17	Royalty Purchase Agreement dated June 21, 2023, by and between LadRx Corporation and XOMA (US) LLC	8-K	10.1	6/26/2023	
10.18#	Assignment and Assumption Agreement, dated June 21, 2023, by and between LadRx Corporation and XOMA (US) LLC	8-K	10.2	6/26/2023	
10.19+	Amendment No. 1 to LadRx Corporation 2019 Stock Incentive Plan	8-K	10.1	9/11/2023	
10.20	Mutual Termination and Release Agreement, dated as of June 3, 2024, by and among LadRx Corporation, NantCell, Inc., ImmunityBio, Inc. and XOMA (US) LLC	8-K	10.1	6/6/2024	
10.20	First Amendment of Royalty Purchase Agreement, dated as of June 3, 2024, by and between LadRx Corporation and XOMA (US) LLC	8-K	10.2	6/6/2024	
19.1	Insider Trading Policy of LadRx 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)				

* Filed herewith.

** Furnished herewith.

\+ Management contract or compensatory plan or arrangement

† Confidential treatment has been requested or granted for certain portions which have been blanked out in the copy of the exhibit filed with the SEC. The omitted information has been filed separately with the SEC.

\# Certain of the schedules (and similar attachments) to this Exhibit have been omitted in accordance with Regulation S-K Item 601(a)(5) of Regulation S-K under the Securities Act because they do not contain information material to an investment or voting decision and that information is not otherwise disclosed in the Exhibit or the disclosure document. The registrant hereby agrees to furnish a copy of all omitted schedules (or similar attachments) to the SEC upon its request.

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.

LADRX CORPORATION

Date: March 28, 2025

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.

Signature	Title	Date
/s/ STEPHEN SNOWDY Stephen Snowdy, Ph.D.	Chief Executive Officer (Principal Executive Officer)	March 28, 2025
/s/ JOHN Y. CALOZ John Y. Caloz	Chief Financial Officer (Principal Financial and Accounting Officer)	March 28, 2025
/s/ CARY CLAIBORNE Cary Claiborne	Director	March 28, 2025
/s/ JENNIFER SIMPSON Jennifer Simpson, Ph.D.	Director and Chair of the Board	March 28, 2025
/s/ JOEL CALDWELL Joel Caldwell	Director	March 28, 2025

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders
LadRx Corporation
Los Angeles, California

Opinion on the Financial Statements

We have audited the accompanying balance sheets of LadRx Corporation (the "Company") and subsidiary as of December 31, 2024 and 2023, the related statements of operations, stockholders' equity (deficit), and cash flows for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company and its subsidiary as of December 31, 2024 and 2023, 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 financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the 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, 2024. 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 financial statements. These financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's 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 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 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 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 financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

Sale of rights to milestone payments

As described in Note 7, the Company entered into an assignment agreement in 2023 for the sale of the Company's interest in certain milestone payments with respect to a license agreement. During 2024, the Company received $2 million in connection with the assignment agreement, and recognized the $2 million as other income.

We identified the recognition of the sale of the Company's interest in certain milestone payments as a critical audit matter. Auditing this transaction required a high degree of audit judgement including evaluating the reasonableness of the significant judgements made by management in determining the appropriate accounting and financial statement presentation.

The following are the primary procedures we performed to address this critical matter:

- We read the assignment agreement and evaluated whether management's accounting position considered the relevant facts and terms included in the agreement.
- We assessed the Company's accounting and disclosure of the transaction was in accordance with relevant accounting guidance.

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

/s/ Weinberg & Company, P.A.
Los Angeles, California
March 28, 2025

LADRX CORPORATION
BALANCE SHEETS

	December 31, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 759,742	$ 2,070,075
Prepaid expenses and other current assets	77,296	191,783
Total current assets	837,038	2,261,858
Equipment and furnishings, net	999	6,711
Other assets	1,475	7,703
Operating lease right-of-use assets	—	31,610
Total assets	$ 839,512	$ 2,307,882
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 1,056,662	$ 1,202,689
Accrued expenses and other current liabilities	1,202,279	964,233
Current portion of operating lease obligations	—	33,606
Total current liabilities	2,258,941	2,200,528
Commitments and contingencies		
Stockholders' equity (deficit):		
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, 2024 and 2023, respectively	—	—
Common stock, $0.001 par value, 62,393,940 shares authorized; 495,092 shares issued and outstanding as at December 31, 2024 and 2023, respectively	495	495
Additional paid-in capital	488,675,792	488,612,890
Accumulated deficit	(490,095,716)	(488,506,031)
Total stockholders' equity (deficit)	(1,419,429)	107,354
Total liabilities and stockholders' equity (deficit)	$ 839,512	$ 2,307,882

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

LADRX CORPORATION
STATEMENTS OF OPERATIONS

	Years Ended December 31,	
	2024	**2023**
Revenue	$ —	$ —
Expenses:		
Research and development	772,702	279,489
General and administrative	2,844,728	3,532,302
Depreciation and amortization	5,712	11,835
	3,623,142	3,823,626
Loss from operations	(3,623,142)	(3,823,626)
Other income (expense):		
Interest income	33,457	55,434
Sale of royalty and milestone rights, net of transaction costs	2,000,000	4,167,219
Other income (expense), net	—	1,416
Net income (loss)	(1,589,685)	400,443
Dividends paid on preferred shares	—	(68,809)
Net income (loss) attributable to common stockholders	$ (1,589,685)	331,634
Basic and diluted income (loss) per share	$ (3.21)	$ 0.68
Basic and diluted weighted average shares outstanding	495,092	488,392

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

LADRX CORPORATION
STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

	Series B Preferred Shares Issued	Preferred Stock Amount	Shares of Common Stock Issued	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Total
Balance at January 1, 2023	—	—	450,374	$ 450	487,519,251	$(488,837,665)	$(1,317,964)
Increase in fractional shares upon reverse stock split			13,191	13	(13)		—
Preferred dividend						(68,809)	(68,809)
Issuance of common stock upon conversion of preferred shares	—	—	31,277	31	1,343,653	—	1,343,684
Issuance of common stock	—	—	250	1	(1)	—	—
Payment to redeem investment option	—	—	—	—	(250,000)		(250,000)
Net income	—	—	—		—	400,443	400,443
Balance at December 31, 2023			495,092	495	488,612,890	(488,506,031)	107,354
Stock compensation on vested options	—	—	—	—	62,902		62,902
Net (loss)	—	—	—	—	—	(1,589,685)	(1,589,685)
Balance at December 31, 2024	—		495,092	$ 495	$488,675,792	$(490,095,716)	$(1,419,429)

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

LADRX CORPORATION
STATEMENTS OF CASH FLOWS

	Years Ended December 31,	
	2024	**2023**
Cash flows from operating activities:		
Net income (loss)	$ (1,589,685)	$ 400,443
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	5,712	11,834
Stock-based compensation expense	62,902	—
Changes in assets and liabilities:		
Prepaid expenses and other current assets	114,487	436,961
Right of-use assets	31,610	185,176
Accounts payable	(146,027)	226,745
Other assets	6,228	—
Lease liabilities	(33,606)	(196,002)
Accrued expenses and other current liabilities	238,046	(51,265)
Net cash provided by (used in) operating activities	(1,310,333)	1,013,892
Cash flows from financing activities:		
Purchase of Investment Option	—	(250,000)
Preferred stock dividend	—	(68,809)
Net cash used in financing activities	—	(318,809)
Net increase (decrease) in cash and cash equivalents	(1,310,333)	695,083
Cash and cash equivalents at beginning of year	2,070,075	1,374,992
Cash and cash equivalents at end of year	$ 759,742	$ 2,070,075
Supplemental disclosures of Cash Flow Information:		
Non-cash investing and financing activities		
Issuance of common stock upon conversion of preferred shares	$ —	$ 1,343,684

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

LADRX CORPORATION
NOTES TO FINANCIAL STATEMENTS
FOR THE YEARS ENDED DECEMBER 31, 2024 AND 2023

1. Nature of Business

LadRx Corporation ("LadRx" the "Company", "we", "us", or "our") is a biopharmaceutical research and development company specializing in oncology. The Company's focus is on the discovery, research and clinical development of novel anti-cancer drug candidates that employ novel technologies that target chemotherapeutic drugs to solid tumors and reduce off-target toxicities. During 2017, LadRx's discovery laboratory in Freiburg, Germany, synthesized and tested over 75 rationally designed drug conjugates with highly potent anti-cancer 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 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, the Company launched Centurion BioPharma Corporation ("Centurion"), a wholly-owned private subsidiary, and transferred to Centurion all of its assets, liabilities and personnel associated with the laboratory operations in Freiburg, Germany. On December 21, 2018, LadRx announced that Centurion had concluded the pre-clinical phase of development for its four LADR™ (Linker Activated Drug Release) 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 were no longer needed and, accordingly, the lab was closed at the end of January 2019.

On March 9, 2022, Centurion merged with and into LadRx, with LadRx absorbing all of Centurion's assets and continuing after the merger as the surviving entity (the "Merger"). The Merger was implemented through an agreement and plan of merger pursuant to Section 253 of the General Corporation Law of the State of Delaware (the "DGCL") and did not require approval from either our or Centurion's stockholders. The Certificate of Ownership merging Centurion into LadRx was filed with the Secretary of State of Delaware on March 9, 2022.

Effective September 26, 2022, we changed our name from CytRx Corporation to LadRx Corporation pursuant to a Certificate of Amendment to our Restated Certificate of Incorporation (the "Certificate of Incorporation"), as amended, filed with the Secretary of State of Delaware. In accordance with the DGCL, our board of directors (the "Board") approved the name change and the Certificate of Amendment. Pursuant to Section 242(b)(1) of the DGCL, stockholder approval was not required for the name change or the Certificate of Amendment.

Aldoxorubicin

On July 27, 2017, the Company entered into an exclusive worldwide license agreement (the "License Agreement") with ImmunityBio, Inc. (formerly known as NantCell, Inc. ("NantCell, Inc."), and which merged with NantKwest Inc. in March 2021 ("ImmunityBio" and together with NantCell, Inc., "NantCell")), granting to ImmunityBio the exclusive rights to develop, manufacture and commercialize aldoxorubicin in all indications. As a result, we are no longer directly working on the development of aldoxorubicin. As part of the License Agreement, ImmunityBio made a strategic investment of $13 million in LadRx's common stock at $660.00 per share (adjusted to reflect the 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 5,000 shares of common stock at $660.00 per share, which such warrant expired on January 26, 2019.

ImmunityBio conducted an open-label, randomized, Phase 2 study of a combination of immunotherapy, aldoxorubicin, and standard-of-care chemotherapy versus standard-of-care chemotherapy alone for the treatment of locally advanced or metastatic pancreatic cancer in patients who have had 1 or 2 lines of treatment (Cohorts A and B) or 3 or greater lines of treatment (Cohort C). In June 2022, Immunity Bio presented data at the American Society of Clinical Oncology meeting showing that patients receiving combination immunotherapy with aldoxorubicin plus standard-of-care chemotherapy experienced overall survival of 5.8 months, compared to 3 months for historical control patients that had received only the standard-of-care chemotherapy (n=78, 95% confidence interval of 4 to 6.9 months). Immunity Bio submitted the results of the Phase 2 study to the FDA for registration. The FDA denied the request and asked for a very large clinical trial with cohorts for each of the combination therapies alone, and in permutative combination with the other combination therapies. Immunity Bio chose not to proceed with the FDA's recommended trial, and aldoxorubicin has been returned to LadRx (see below "Mutual Termination and Release Agreement").

Aldoxorubicin has received Orphan Drug Designation (ODD) by the FDA for the treatment of soft tissue sarcoma ("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.

Mutual Termination and Release Agreement

On June 3, 2024 (the "Effective Date"), we entered into a Mutual Termination and Release Agreement (the "Termination Agreement") with NantCell and its parent company, ImmunityBio and XOMA (as defined below). Pursuant to the Termination Agreement, the License Agreement will terminate automatically on the Effective Date, and neither the Company nor NantCell will have any continuing obligations to each other than as described in the Termination Agreement. Additionally, except that during the 30 day period following the Effective Date (the "Discussion Period"), the Company and NantCell shall engage in good faith discussions regarding the terms of an agreement pursuant to which the Company would have the right to purchase the inventory of aldoxorubicin (including, without limitation, active pharmaceutical ingredient, WPI and finished dose, the "Inventory") and all other materials necessary for the research, development and commercialization, among others, worldwide as of the Effective

Date, at the Company's expense. Subsequently, the Company and NantCell have agreed the disposition of the Inventory shall be at NantCell's sole discretion.

The Termination Agreement additionally provides for the release of the Company and NantCell from claims, demands and liabilities, among others, and customary representations and warranties, covenants, and other provisions customary for transactions of this nature.

In December 2024, the Company announced it is restarting a process to seek marketing approval of aldoxorubicin under the provisions of the FDA's Section 505(b)(2). The 505(b)(2) pathway is designed for a new drug composition whose active ingredient is the same active ingredient as a drug previously approved by the US Food and Drug Administration (FDA). Given that the active component of the tumor-targeted drug aldoxorubicin is the already-marketed drug doxorubicin, the 505(b)(2) pathway is available for aldoxorubicin, and greatly reduces the regulatory burden of getting aldoxorubicin to the market by relying on the non-clinical and clinical data history of doxorubicin to demonstrate efficacy and safety. Additionally, the market exclusivity awarded to drugs that have received orphan designation for certain rare diseases, as is the case for aldoxorubicin, is available for drugs approved through the 505(b)(2) process for new drugs.

2023 Reverse Stock Split

The Company effected a 1-for-100 reverse stock split (the "Reverse Stock Split") of its issued and outstanding shares of common stock on May 17, 2023, pursuant to which every 100 shares of the Company's issued and outstanding shares of common stock were converted into one share of common stock without any change in the par value per share. Any fraction of a share of common stock that would otherwise have resulted from the Reverse Stock Split were rounded up to the nearest whole share. All share and per share amounts in this Annual Report have been adjusted to reflect the reverse stock split as if it had occurred at the beginning of the earliest period presented.

Corporate Information

LadRx is 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.ladrxcorp.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.

Going Concern

The Company has operated at a loss due to its ongoing expenditures for research and development of its product candidates and for general and administrative purposes, and lack of significant recurring revenues. For the year ended December 31, 2024, it incurred a net loss of $1.6 million, had a loss from operations of $3.6 million, incurred a loss from operations of $3.8 million for the year ended December 31, 2023, and had total stockholders' deficit as of December 31, 2024 of $1.4 million. The Company have had no recurring revenue, and it is likely to continue to incur losses unless and until it concludes a successful strategic partnership or financing for its research and development assets. These losses, among other things, have had and will continue to have an adverse effect on the stockholders' equity and working capital. Because of the numerous risks and uncertainties associated with its product development efforts, they are unable to predict when they may become profitable, if at all. If the Company does not become profitable or are unable to maintain future profitability, the market value of its common stock will be adversely affected. These factors individually and collectively raise a substantial doubt about the Company's ability to continue as a going concern.

In order to fund its business and operations, the Company has relied primarily upon sales of its equity securities, including proceeds from the exercise of stock options and common stock purchase warrants and long-term loan financing. They have received limited funding from their strategic partners and licensees. The Company will ultimately be required to obtain additional funding in order to execute its long-term business plans, although they do not currently have commitments from any third parties to provide them with long-term debt or capital. The Company cannot assure that additional funding will be available on favorable terms, or at all. If they fail to obtain additional funding when needed, the Company may not be able to execute its business plans and its business may suffer, which would have a material adverse effect on its financial position, results of operations and cash flows. We have approximately $1.0 million of contractual obligations in 2025.

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.

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation — The accompanying 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").

Revenue Recognition — Revenue consists of license fees from strategic alliances with pharmaceutical companies. During the years ended December 31, 2024 and 2023, 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.

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,	
	2024	**2023**
Options to acquire common stock	66,817	14,000
Warrants to acquire common stock	—	42
	66,817	14,042

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. Recognition of compensation expense for non-employees is in the same period and manner as if the Company had paid cash for the services

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.

Fair Value Measurements - The Company measures the fair value of financial instruments using a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three broad levels:

Level 1—Inputs used to measure fair value are unadjusted quoted prices that are available in active markets for the identical assets or liabilities as of the reporting date.

Level 2— Other significant observable inputs for the assets or liabilities through corroboration with market data at the measurement date.

Level 3—Unobservable inputs that are supported by little or no market activity and reflect the use of significant management judgment are used to measure fair value. These values are generally determined using pricing models for which the assumptions utilize management's estimates of market participant assumptions. The determination of fair value for Level 3 investments and other financial instruments involves the most management judgment and subjectivity.

The carrying amounts of financial assets and liabilities, such as cash, other current assets, accounts payable, and accrued expenses, approximate their fair values because of the short maturity of these instruments.

Segment Information — The Company's Chief Executive Officer and President ("CEO") is our chief operating decision maker ("CODM") and evaluates performance and makes operating decisions about allocating resources based on financial data presented. Because our CODM evaluates financial performance, the Company has determined that it operates as a single reportable segment composed of the financial results of LadRx Corporation (see Note 11).

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 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 financial statements and accompanying notes. The significant estimates in the Company's 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 November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2023-07, "Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosure." The amendments expand a public entity's segment disclosures by requiring disclosure of significant segment expenses that are regularly provided to the chief operating decision maker, requiring other new disclosures, and requiring enhanced interim disclosures. ASU 2023-07 requires public entities with a single reportable segment to provide all the disclosures required by this standard and all existing segment disclosures in Topic 280 on an interim and annual basis. ASU 2023-07 is effective for annual periods beginning after December 15, 2023, and interim periods beginning after December 15, 2024, applied retrospectively with early adoption permitted. As of December 31, 2024, the Company has adopted ASU 2023-07. Adoption of the standard has not impacted our financial statements but has resulted in additional disclosures (See Note 11).

In November 2024, the FASB issued ASU No. 2024-03 "Income Statement – Reporting Comprehensive Income – Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses." This ASU requires public business entities to disclose, for interim and annual reporting periods, additional information about certain income statement expense categories. The requirements are effective for fiscal years beginning after December 15, 2026, and for interim periods beginning after December 15, 2027. Entities are permitted to apply either the prospective or retrospective transition methods. The Company is currently evaluating the impact that the adoption of this ASU will have on its financial statements.

The Company's management has evaluated all other recently issued, but not yet effective, accounting standards and guidance that have been issued or proposed by the FASB or other standards-setting bodies through the filing date of these financial statements and does not believe the future adoption of any such pronouncements will have a material effect on the Company's financial position and results of operations.

3. Equipment and Furnishings

Equipment and furnishings at December 31, 2024 and 2023 consist of the following:

	2024	2023
Equipment and furnishings	$ 18,687	$ 48,742
Less — accumulated depreciation	(17,688)	(42,031)
Equipment and furnishings, net	$ 999	$ 6,711

Depreciation and amortization expense for the years ended December 31, 2024 and 2023 were $5,712 and $11,834, respectively. Fully depreciated assets during 2024 costing approximately $30,000 were written-off during the year ended December 31, 2024.

4. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities at December 31, 2024 and 2023 are summarized below.

	2024	2023
Professional fees	$ 102,785	$ 77,785
Wages, bonuses and employee benefits	262,441	157,024
Royalties and milestones	716,155	716,155
Other	120,898	13,269
Total	$ 1,202,279	$ 964,233

5. Leases

We lease storage space related primarily to the Company's administrative activities. The Company accounts for its leases in accordance with ASC 842, Leases. The Company determines whether a contract is, or contains, a lease at inception. Operating lease right-of-use ("ROU") assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. ROU assets represent the Company's right to use an underlying asset during the lease term, and lease liabilities represent the Company's obligation to make lease payments arising from the lease.

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 was effective March 1, 2020 and extended through February 29, 2024. The monthly rent was $15,361. We did not renew this lease upon its expiration. In February 2020, the Company renewed its additional storage space lease, which requires us to make monthly payments of $1,475. 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 January 1, 2023, the balance of right-of-use assets was $216,786, and the balance of total lease liabilities was $229,607. During the year ended December 31, 2023, the amortization of the right-of-use assets totaled $185,176, and reduction of the lease liabilities totaled $196,001. As of December 31, 2023, the balance of right-of-use assets was $31,610, and the balance of total lease liabilities was $33,606. With the termination of these leases in February 2024, the balance of this right-of-use asset and lease liability obligation was $0 as of December 31, 2024.

6. Stock Compensation

Stock Options

The Company has a 2008 Stock Incentive Plan under which 50,000 shares of common stock are reserved for issuance. As of December 31, 2024, there were 10,500 shares subject to outstanding stock options and approximately 8,000 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 54,000 shares of common stock are reserved for issuance. As of December 31, 2024, there were 3,500 shares subject to outstanding stock options and 250 shares outstanding related to restricted stock grants from the 2019 Plan. This Plan expires on November 14, 2029.

All outstanding options issued to employees, directors and consultants were fully vested in 2020. As such, no further stock compensation expense was recognized during the years ended December 31, 2024 and 2023.

On September 7, 2023, the Board approved the first amendment (the "Plan Amendment") to the 2019 Plan, effective as of the same date. The Plan Amendment amends the 2019 Plan to (i) reflect the Company's recent name change from CytRx Corporation to LadRx Corporation, and (ii) increase the aggregate number of shares of common stock that may be issued under the 2019 Plan, as set forth in Section 4(a) of the 2019 Plan, by an additional 75,000 shares of common stock.

In December 2023, the Compensation Committee awarded stock option grants to purchase an aggregate of 55,000 shares of common stock to the Company's Named Executive Officers and directors, effective January 15, 2024. No stock options or restricted stock were granted in 2023.

During the years ended December 31, 2024 and 2023, there were no options exercised.

The following table sets forth the total stock-based compensation expense resulting from restricted stock included in our Statements of Operations for the years ended December 31, 2024 and 2023:

	Years Ended December 31,	
	2024	**2023**
General and administrative – employees and directors	$ 62,902	$ —
Total employee and director stock-based compensation	$ 62,902	$ —

	Stock Options		Weighted Average Exercise Price	
	2024	**2023**	**2024**	**2023**
Outstanding — beginning of year	10,350	14,001	$ 501.70	$ 768.00
Granted	55,000	—	1.83	—
Exercised	—	—	—	—
Forfeited	—	(2,001)	—	—
Expired	(1,266)	(1,650)	1,290.00	2,796.00
Outstanding — end of year	64,084	10,350	54.39	501.70
Exercisable at end of year	44,995	10,350	$ 76.69	$ 501.70
Weighted average fair value of stock options granted during the year:	$ 1.83	$ —		

Presented below is the Company's non-employee stock option activity:

	Stock Options		Weighted Average Exercise Price	
	2024	2023	2024	2023
Outstanding — beginning of year	3,650	3,650	$ 549.00	$ 549.00
Granted	—	—	—	—
Exercised	—	—	—	—
Expired/Forfeited	(917)	—	1,656.00	—
Outstanding — end of year	2,733	3,650	177.74	549.00
Exercisable at end of year	2,733	3,650	$ 177.74	$ 549.00
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, 2024:

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
$ 1.83 - $25.99	55,000	9.04	$ 1.83	35,914	5.95	$ 1.83
$ 26.00 - $100.00	3,500	4.95	$ 26.00	3,500	3.71	$ 26.00
$ 101.00 - $300.00	6,066	2.71	$ 195.29	6,066	1.83	$ 195.29
$ 300.01 - $1,656.00	2,251	1.31	$ 1,154.35	2,251	0.80	$ 1,154.35
	66,817	7.99	$ 59.44	47,731	7.99	$ 82.47

There was no aggregate intrinsic value of the outstanding options and options vested as of December 31, 2024.

Equity-Classified Warrants

A summary of the Company's warrant activity and related information for the years ended December 31, 2024 and 2023 are shown below.

	Warrants		Weighted Average Exercise Price	
	2024	2023	2024	2023
Outstanding — beginning of year	42	42	$ 3,360.00	$ 3,360.00
Granted	—	—	—	—
Exercised	—	—	—	—
Forfeited	—	—	—	—
Expired	(42)	—	3,360.00	—
Outstanding — end of year	—	42	—	3,360.00
Exercisable at end of year	—	42	$ —	$ 3,360.00
Weighted average fair value of warrants granted during the year:	$ —	$ —		

7. Xoma

Royalty Purchase Agreement with XOMA

On June 21, 2023, the Company, entered into (i) a Royalty Purchase Agreement (the "Royalty Agreement") with XOMA (US) LLC ("XOMA"), for the sale, transfer, assignment and conveyance of the Company's right, title and interest in and to certain royalty payments and milestone payments with respect to aldoxorubicin, and (ii) an Assignment and Assumption Agreement (the "Assignment Agreement") with XOMA for the sale, transfer, assignment and conveyance of the Company's right, title and interest in the Asset Purchase Agreement (the "2011 Arimoclomol Agreement") between the Company and Orphazyme ApS ("Orphazyme"), dated as of May 13, 2011, and assigned to Zevra Denmark A/S ("Zevra Denmark"), effective as of June 1, 2022, which includes certain royalty and milestone payments with respect to arimoclomol. The combined aggregate purchase price paid to the Company for the sale, transfer, assignment and conveyance of the Company's right, title and interest in and to aldoxorubicin and arimoclomol was $5 million, less certain transaction fees and expenses.

The Royalty Agreement and the Assignment Agreement also provide for up to an additional $6 million based on regulatory and commercial milestones related to the development of arimoclomol and aldoxorubicin by their respective sponsors, Zevra, Inc. and Immunity Bio. The $6 million in potential post-closing payments is comprised of $1 million upon acceptance by the FDA of the arimoclomol New Drug Application ("NDA"), $1 million upon first commercial sale of arimoclomol, and $4 million upon FDA approval of aldoxorubicin. All royalty and milestone payments made to XOMA will be net of the existing licensing and milestone obligations owed by LadRx related to arimoclomol and aldoxorubicin.

Pursuant to the Royalty Agreement, the Company agreed to sell, transfer, assign and convey to XOMA, among other payments, all royalty payments and regulatory and commercial milestone payments payable to the Company pursuant to the worldwide license agreement, dated July 27, 2017, by and between the Company and Immunity Bio, Inc.. The Royalty Agreement also provides for the sharing of certain rights with XOMA to bring any action, demand, proceeding or claim as related to receiving such payments.

Management determined that the Royalty Agreement is not considered to be with a customer, and it does not fall within the scope of ASC 606. Instead, the Royalty Agreement represents an in-substance sale of nonfinancial assets, and, therefore, should be accounted for within the scope of ASC 610-20. As such, the Company recognized such net proceeds of $4.2 million as other income in the accompanying statement of operations.

Assignment and Assumption Agreement with XOMA

On June 21, 2023, the Company entered into the Assignment Agreement with XOMA, pursuant to which, among others, the Company agreed to sell, transfer and assign to XOMA the Company's right, title and interest in the arimoclomol pursuant to the 2011 Arimoclomol Agreement, including the right to receive certain milestone, royalty and other payments from Zevra Denmark.

Pursuant to the Assignment Agreement, the Company is entitled to receive (i) a one-time payment of $1 million upon acceptance of a re-submission of an NDA to the FDA for arimoclomol, and (ii) a one-time payment of $1 million upon the first invoiced sale in certain territories of a pharmaceutical product derived from arimoclomol as an active pharmaceutical ingredient, subject to the receipt of the applicable regulatory approval required to sell such a product in such countries. In January 2024, the Company received a payment of $1 million in connection with achieving the milestone relating to the acceptance by the FDA of the arimoclomol NDA, and in November 2024, the Company received $1 million in connection with achieving the milestone relating to the first commercial sale of arimoclomol.

First Amendment to Royalty Purchase Agreement

On June 3, 2024, in consideration for the termination of the License Agreement pursuant to the Termination Agreement (as defined below), the Company and XOMA entered into the First Amendment to the Royalty Agreement (the "First Amendment").

Pursuant to the First Amendment, if the Company decides to commercialize aldoxorubicin itself, prior to the first commercial sale of aldoxorubicin, the Company and XOMA shall enter into a synthetic royalty purchase agreement, pursuant to which the Company shall agree to make quarterly royalty payments to XOMA equal to the amount of all aggregate net sales of aldoxorubicin during each calendar quarter multiplied by 1.5%. If the Company decides not to commercialize aldoxorubicin itself and instead licenses aldoxorubicin to a third party, upon entry of such a new license agreement, XOMA shall be entitled to receive (i) royalty payments with respect to net sales of aldoxorubicin payable to the Company multiplied by 7.5% and (ii) milestone payments of 7.5% of any milestone payable to the Company pursuant to the License Agreement. The First Amendment contains customary covenants and other provisions customary for transactions of this nature.

Mutual Termination and Release Agreement

On June 3, 2024, pursuant to a Mutual Termination and Release Agreement (the "Termination Agreement"), the Company, NantCell, Inc., a Delaware corporation ("NantCell, Inc.," and together with ImmunityBio "NantCell"), and its parent company, ImmunityBio, and XOMA agreed to a mutual termination of the License Agreement, effective as of the same date (the "Effective Date"). Neither the Company nor NantCell will have any continuing obligations to each other than as described in the Termination Agreement. Additionally, except that during the 30 day period following the Effective Date (the "Discussion Period"), the Company and NantCell shall engage in good faith discussions regarding the terms of an agreement pursuant to which the Company would have the right to purchase the inventory of aldoxorubicin (including, without limitation, active pharmaceutical ingredient, WPI and finished dose, the "Inventory") and all other materials necessary for the research, development and commercialization, among others, worldwide as of the Effective Date, at the Company's expense. Subsequently, the Company and NantCell have agreed that the disposition of the Inventory shall be at NantCell's sole discretion.

The Termination Agreement additionally provides for the release of the Company and NantCell from claims, demands and liabilities, among others, and customary representations and warranties, covenants, and other provisions customary for transactions of this nature.

Assignment and Assumption Agreement with XOMA

On June 21, 2023, the Company entered into the Assignment Agreement with XOMA, pursuant to which, among others, the Company agreed to sell, transfer and assign to XOMA the Company's right, title and interest in the arimoclomol pursuant to the 2011 Arimoclomol Agreement, including the right to receive certain milestone, royalty and other payments from Zevra Denmark.

Pursuant to the Assignment Agreement, the Company is entitled to receive (i) a one-time payment of $1 million upon acceptance of a re-submission of an NDA to the FDA for arimoclomol, and (ii) a one-time payment of $1 million upon the first invoiced sale in certain territories of a pharmaceutical product derived from arimoclomol as an active pharmaceutical ingredient, subject to the receipt of the applicable regulatory approval required to sell such a product in such countries. In January 2024, the Company received a payment of $1 million in connection with achieving the milestone relating to the acceptance by the FDA of the arimoclomol NDA, and in November 2024, the Company received $1 million in connection with achieving the milestone relating to the first commercial sale of arimoclomol.

8. 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.

9. Income Taxes

At December 31, 2024, the Company had federal and state net operating loss carryforwards ("NOLs") of $327.6 million and $262.6 million, respectively, available to offset against future taxable income. Of this amount, $309.8 million of federal NOLs expire in 2025 through 2037. The federal operating losses after 2018 totaling $28.6 million carry forward indefinitely but are only able to offset 80% of taxable income in future years. The California NOLs expire in 2029 through 2042.

As a result of a change in-control that occurred in the LadRx shareholder base, approximately $65.2 million in federal net operating loss carryforwards became substantially limited in their annual availability. Management currently believes that the remaining $262.4 million in federal net operating loss carryforwards, and the $262.6 million in state net operating loss carryforwards, are unrestricted.

As of December 31, 2024, LadRx also had research and development tax credits for federal and state purposes of approximately $15.3 million and $15.3 million, respectively, available for offset against future income taxes, which expire in 2024 through 2043. 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,	
	2024	**2023**
Deferred tax assets:		
Net operating loss carryforwards	$ 72,648	$ 74,752
Tax credit carryforwards	30,629	30,721
Equipment, furnishings and other	1,872	7
Total deferred tax assets	105,149	105,480
Deferred tax liabilities	—	—
Net deferred tax assets	105,149	105,480
Valuation allowance	(105,149)	(105,480)
	$ —	$ —

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, 2024 and 2023 was $2.1 million and $6.8 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,	
	2024	2023
Federal benefit at statutory rate	$ (334)	$ 84
State benefit, net of Federal taxes	(29)	35
Capitalized R & D	145	—
Prepaid and accrued expenses	53	—
Other permanent differences	184	(189)
Provision related to change in valuation allowance		(7)
Federal rate adjustment	—	—
NQ Options	—	—
Current year tax credit	—	—
NOL Adjustments	—	—
Termination/Cancellation of Equity Compensation Awards	—	—
Return to provision	(19)	77
Other, net	—	—
	$ —	$ —

There have been no changes to the Company's liability for unrecognized tax benefits during the year ended December 31, 2024.

The Company files income tax returns in the U.S. Federal jurisdiction and various state jurisdictions. As of the year ended December 31, 2024, the tax returns for 2020 through 2024 remain open to examination by the Internal Revenue Service and for 2020 to 2024 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, 2024 and 2023, the Company had accrued no interest or penalties related to uncertain tax positions.

10. Commitments and Contingencies

Commitments

Aldoxorubicin

We have an agreement (the "Vergell Agreement") with Vergell Medical (formerly with KTB Tumorforschungs GmbH) ("Vergell") for the exclusive license of patent rights held by Vergell for the worldwide development and commercialization of aldoxorubicin. Under the agreement, we had to make payments to Vergell upon meeting certain clinical and regulatory milestones up to and including the product's second final marketing approval. However, those payments are no longer required since the intellectual property acquired under the Vergell Agreement expired. We accrued $316,000 that we believe was owed prior to the expiry of the intellectual property. This amount was outstanding at December 31, 2024, and 2023.

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. On May 31, 2022, Orphazyme announced that it had completed the sale of substantially all of its assets and business activities for cash consideration of $12.8 million and assumption of liabilities estimated to equal approximately $5.2 million to KemPharm (the "KemPharm Transaction"). KemPharm is a specialty biopharmaceutical company focused on the discovery and development of novel treatments for rare central nervous system ("CNS") diseases. As part of the KemPharm Transaction, all of Orphazyme's obligations to LadRx under the 2011 Arimoclomol Agreement, including with regard to milestone payments and royalties on sales, were assumed by KemPharm. KemPharm re-branded to Zevra Therapeutics, Inc. in February 2023.

As discussed in Note 7, pursuant to the Assignment Agreement, although all the liabilities and obligations related to arimoclomol remain the responsibility of the Company, XOMA directed an escrow agent appointed by them to pay on behalf of LadRx $3.25 million reflected in the preceding paragraph, as well as all future obligations related to Steven A. Kriegsman, pursuant to the Amended and Restated Employment Agreement, as amended by and between the Company and Mr. Kriegsman, dated March 26, 2019.

Innovive

Under the merger agreement by which we acquired Innovive Pharmaceuticals, Inc. ("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. As of December 31, 2024, there are no longer any further obligations due under this agreement, since the licensed intellectual property rights have expired.

Contractual obligations

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

	Employment Agreements (1)
2025	976
2026	—
Thereafter	—
Total	$ 976

(1) Employment agreements include management contracts which have been revised from time to time. The employment agreements 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.

Contingencies

The Company is occasionally involved in legal proceedings and other matters arising from the normal course of business. On November 30, 2022, Jerald Hammann ("Hammann") filed a complaint (the "Complaint") against the Company, Mr. Caloz, and Mr. Kriegsman (together, "Defendants") in the Court of Chancery of the State of Delaware, alleging various violations of a Cooperation Agreement, dated August 21, 2020, by and between the Company and Hammann. The Complaint alleges breaches of a provision limiting the Board's ability to effect discretionary compensation and a non-disparagement provision. The Complaint further alleges a breach of a purported implied obligation that the Company disclose various internal records to Hammann. Defendants believe the Complaint is wholly without merit and moved to dismiss the Complaint in its entirety. As a result, the Court subsequently dismissed the claims against Mr. Caloz and Mr. Kriegsman and also dismissed one of the claims against the Company. The Company intends to litigate vigorously against Hammann's claims.

The Company intends to vigorously defend against any complaint. We have directors' and officers' liability insurance, which will be utilized, after the deductible, in the defense of any matter involving our directors or officers.

The Company evaluates 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.

11. Segment information

The Company operates and manages its business as one reportable and operating segment dedicated to biopharmaceutical research and development company specializing in oncology. The measure of segment assets is reported on the balance sheet as total assets.

The Company's CODM reviews financial information and decides how to allocate resources based on net income (loss).

Significant segment expenses include research and development, salaries, insurance, and stock-based compensation. Operating expenses include all remaining costs necessary to operate our business, which primarily include external services and other administrative expenses. The following table presents the significant segment expenses and other segment items regularly reviewed by our CODM:

	Year ended December 31,	
	2024	2023
Revenue	$ -	$ -

Less:		
Research and development	(772,702)	(279,489)
Payroll and related	(1,093,327)	(1,174,239)
Insurance	(209,922)	(674,976)
Professional fees primarily related to intellectual property	(895,682)	(963,926)
Operating expenses	(651,509)	(730,996)
Sale of royalty and milestone rights, net of transaction costs	2,000,000	4,167,219
Other income	33,456	56,850
Net income (loss)	$ (1,589,686)	$ 400,443