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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 , 2023

OR

Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

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For the transition period from: to

Commission File Number:

001-35610

ATOSSA THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**26-4753208**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

107 Spring Street
Seattle , WA 98104
(Address of principal executive offices, including zip code)

Registrant's telephone number, including area code: (206) 588-0256

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

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, $0.18 par value	ATOS	The Nasdaq Capital Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. 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 Exchange Act. 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 (or for such shorter period that the registrant was required to file such reports), 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 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 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.

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 Exchange 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 Exchange Act). Yes ☐ No ☒

As of June 30, 2023, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the voting and non-voting common equity held by non-affiliates was $

159,504,497

. Shares of common stock held by each officer and director and by each person who is known by the Company to own 10% or more of the outstanding common stock have been excluded, as such persons may be deemed to be affiliates of the Company. This determination of affiliate status is not necessarily a conclusive determination of affiliate status for other purposes.

The number of shares outstanding of the registrant's common stock, par value $0.18, as of March 15, 2024, was

125,304,064

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NOTE REGARDING FORWARD-LOOKING STATEMENTS

All statements made in this Annual Report on Form 10-K (this Annual Report) that are not statements of historical fact, including statements regarding guidance, industry prospects or future results of operations or financial position, are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act) and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). We have made these statements in reliance on the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements are subject to certain risks and uncertainties, which could cause actual results, outcomes and the timing of results or outcomes to differ materially from those projected or anticipated. Although we believe that our assumptions underlying our forward-looking statements are reasonable as of the date of this Annual Report we cannot assure you that the forward-looking statements set out in this Annual Report will prove to be accurate. We may identify these forward-looking statements by the use of forward-looking words, including, but not limited to, such as “expect,” “potential,” “continue,” “may,” “will,” “should,” “could,” “would,” “seek,” “intend,” “plan,” “estimate,” “anticipate,” “future,” “believe,” “design,” “predict,” “potential” or the negative versions of these words or other similar expressions. Forward-looking statements contained in this Annual Report include, but are not limited to, statements about:

- general macroeconomic conditions, including the impact of inflation, high interest rates, general economic slowdown or a recession, the prospect of a shutdown of the U.S. federal government, foreign exchange rate volatility, financial institution instability, changes in monetary policy and increasing geopolitical instability, including the conflict in Ukraine, the conflict in the Middle East and rising tensions between China and Taiwan, on our business, our ability to access capital markets, our operating costs and our supply chain;
- the effects of natural disasters, pandemics, severe weather conditions and other events beyond our control;
- whether we can obtain approval from the U.S. Food and Drug Administration (FDA), and foreign regulatory bodies, to continue our clinical trials, including our planned (Z)-endoxifen trials, and to sell, market and distribute our therapeutics under development;
- our ability to identify and partner with organizations to commercialize any of our products once they are approved for marketing;
- our ability to successfully initiate and complete clinical trials of our products under development, including our proprietary (Z)-endoxifen (an active metabolite of Tamoxifen);
- the success, costs and timing of our development activities, such as clinical trials, including whether our studies using our (Z)-endoxifen therapies will enroll a sufficient number of subjects in a timely fashion or be completed in a timely fashion or at all;
- whether we will successfully complete our clinical trial of oral (Z)-endoxifen in women with mammographic breast density and our trials of (Z)-endoxifen in women with breast cancer, and whether the studies will meet their objectives;
- our ability to contract with third-party suppliers, manufacturers and service providers, including clinical research organizations, and their ability to perform adequately;
- our ability to successfully develop and commercialize new therapeutics currently in development, or new therapeutics that we might identify in the future, and within the time frames we currently expect;
- our ability to successfully defend litigation and other similar complaints that may be brought in the future, in a timely manner and within the coverage, scope and limits of our insurance policies;
- our ability to establish and maintain intellectual property rights covering our products;
- our increased risk of theft or misappropriation of our intellectual property and other proprietary technology outside of the U.S.;
- our expectations regarding, and our ability to satisfy, federal, state and foreign regulatory requirements, including evolving legal standards and regulations, including those concerning data protection, consumer privacy, sustainability and evolving labor standards;
- our ability to comply with the continued listing requirements of the Nasdaq Capital Market (the Nasdaq);
- the accuracy of our estimates of the size and characteristics of the markets that our products and services may address;
- whether final study results will vary from preliminary study results that we may announce;
- our expectations as to future financial performance, expense levels and capital sources;
- our ability to attract and retain key personnel;

- our ability to execute our share repurchase program as planned; and
- our ability to raise capital.

This Annual Report also contains estimates and other statistical data provided by third-parties and by us relating to market size and growth, and other industry data. These and other forward-looking statements, unless otherwise indicated, are presented as of the date of the filing of this Annual Report. We have included important factors, risks and uncertainties in the cautionary statements included in this Annual Report, particularly in the sections titled "ITEM 1A. RISK FACTORS," "ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS," and elsewhere in this Annual Report that we believe could cause our actual results, events or outcomes, or the timing of these results or outcomes, to differ materially from the anticipated results, events or outcomes, or the anticipated timing of these results or outcomes. Our forward-looking statements do not reflect the potential impact of any new information, future events or circumstances that may affect our business after the date of this Annual Report. Except as required by law, we expressly disclaim any intent to update any forward-looking statements after the date on which the statement is made, whether as a result of new information, future events, future circumstances or otherwise.

CORPORATE INFORMATION

Our corporate website is located at *www.atossatherapeutics.com*. The information contained on or connected to our website is not deemed to be incorporated by reference into this Annual Report or filed with the Securities and Exchange Commission (the SEC) and should not be considered part of this Annual Report. We make available, free of charge through our website or upon written request, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other periodic SEC reports, along with amendments to all of those reports, as soon as reasonably practicable after we file the reports with the SEC.

Unless otherwise noted, the terms "Atossa Therapeutics," "Atossa," the "Company," "we," "us," and "our" refer to Atossa Therapeutics, Inc., a Delaware corporation.

We are regulated by the FDA under the Federal Food Drug and Cosmetics Act, as well as by other U.S. and foreign federal, state and local agencies.

This Annual Report includes trademarks, trade names and service marks of third-parties, which are the property of their respective owners. You are advised to read this Annual Report on Form 10-K in conjunction with other reports and documents that we file from time to time with the SEC.

PART I

ITEM 1. BUSINESS

Overview

We are a clinical-stage biopharmaceutical company developing proprietary innovative medicines in areas of significant unmet medical need in oncology with a focus on women's breast cancer and other breast conditions. Our lead drug candidate under development is oral (Z)-endoxifen, which we are developing for both the prevention and treatment of breast cancer.

Our business strategy is to advance our programs through clinical studies, including potentially with partners, and opportunistically add programs in areas of high unmet medical need through acquisition, minority investment, collaboration or internal development.

(Z)-endoxifen is an active metabolite of tamoxifen, which is an FDA-approved drug to treat and prevent breast cancer. Tamoxifen is a "pro-drug," in that it must be metabolized into active components ("metabolites") to be effective. Despite the success of tamoxifen in treating ER+ breast cancer, its systemic side effects have led to generally low acceptance as a therapy to reduce the risk of breast cancer. These systemic side effects relate to estrogen agonist activity on the endometrium and the activation of coagulation pathways, leading to an increased risk of uterine events and thromboembolism. Hot flashes and vaginal symptoms are additional barriers to tamoxifen being accepted in the prevention setting.

Other limiting aspects of tamoxifen are that some people lack liver enzymes to adequately metabolize it and it can take a long time for many patients to reach therapeutic levels. Up to 50% of breast cancer survivors who take tamoxifen do not achieve therapeutic (Z)-endoxifen levels (meaning they are "refractory") for a number of reasons, including that they, due to their genotype, do not have the requisite liver enzymes. We believe our proprietary oral (Z)-endoxifen, in part because it is not a pro-drug and does not need to be metabolized by the liver, and may overcome some of the shortcomings of tamoxifen.

(Z)-endoxifen is a proprietary, novel Selective Estrogen Receptor Modulator (SERM); which is a class of drugs that blocks estrogen from connecting with breast cancer cells, with the intent of keeping the cells from multiplying. We are developing oral (Z)-endoxifen for the potential prevention and treatment of breast cancer. We have completed four Phase 1 clinical studies (including a study in men) and two Phase 2 clinical studies with our proprietary (Z)-endoxifen (including oral and topical formulations). We have also developed clinical manufacturing capabilities through qualified third parties.

Summary of Leading Programs

(Z)-endoxifen is currently being investigated in four ongoing Phase 2 trials:

EVANGELINE. A Phase 2 randomized study of (Z)-endoxifen as a neoadjuvant treatment for pre-menopausal women with ER+ / Human Epidermal Growth Factor Receptor 2 negative (HER2-) breast cancer. The EVANGELINE study is expected to enroll 180 patients at sites across the U.S.

The EVANGELINE study began enrolling patients in February 2023 as part of a 40mg pharmacokinetic (PK) run-in cohort to assess whether 40mg/day achieved plasma concentrations to optimally target protein kinase C beta (PKC-β) inhibition. The treatment was well tolerated and showed encouraging efficacy but did not reach the desired steady state plasma concentrations. Per the study protocol, an 80mg PK cohort run-in was initiated.

Targeting PKC-β could potentially further enhance (Z)-endoxifen's antitumor mechanism of action. The opportunity is to induce apoptosis, which is programmed cell death where the malignant cells die. Apoptosis is the cellular equivalent of a self-destruct button and would be expected to lead to increased response rates evidenced by reduction or elimination of tumor lesions.

Karisma-Endoxifen.. A Phase 2 study investigating (Z)-endoxifen in premenopausal women with measurable breast density (MBD). Participants in the study are randomized into one of three cohorts to receive a placebo, or 1mg or 2mg of (Z)-endoxifen daily for six months. Mammograms are conducted to measure reduction in breast density over the treatment period and a final mammogram will be conducted at 24 months to assess the durability of density changes. The study fully enrolled in November 2023, and we expect primary data in the second half of 2024.

Almost half of the women in the world over the age of 40 have dense breasts and there are currently no approved treatments to reduce breast density. Elevated breast density can make a mammogram more difficult to interpret because dense breast tissue and some abnormal breast changes, such as calcifications and tumors, both which appear as white areas in the mammogram. In women with the highest density, approximately 50% of breast cancers are missed on a mammogram and diagnosed in the interval between two screening rounds. These are known as "interval cancers," which are often larger, more advanced, and more difficult to treat. Additionally, women with the highest density are four to six times more likely to develop breast cancer in their lifetime compared to women with the least dense breasts.

As of September 10, 2024, the U.S. Food and Drug Administration (FDA) will require mammogram providers to notify patients about the density of their breasts. The notification for patients with dense breasts will include a warning that dense tissue makes it

harder to find breast cancer on a mammogram and raises their risk of developing breast cancer. It will also encourage women with dense breast tissue to discuss the findings with their healthcare provider.

Based on input received in March 2020 from the FDA and Swedish Medical Products Agency, reduction in MBD may not be an approvable indication unless we can demonstrate that (Z)-endoxifen also reduces the incidence of breast cancer. We may therefore conduct additional studies of (Z)-endoxifen to assess its correlation with the risk of breast cancer and/or reduction in the incidence of new breast cancers.

I-SPY 2. A Phase 2 trial investigating (Z)-endoxifen in the neoadjuvant treatment setting, which is the window of time between a diagnosis and the primary treatment. The intent of neoadjuvant therapy is to slow the growth of the cancer or even shrink the cancer prior to surgery. Doing this helps surgery to be more effective and could alter the surgical approach; meaning some breast cancer patients could have a lumpectomy instead of a mastectomy. Neoadjuvant therapy has also been shown to reduce the likelihood that the cancer returns.

The I-Spy 2 trial is being conducted through a partnership with Quantum Leap Healthcare Collaborative, which was established in 2005 by medical researchers at University of California, San Francisco and Silicon Valley entrepreneurs to speed the development of innovative breast cancer therapies like (Z)-endoxifen. The platform trial is enrolling patients with newly diagnosed estrogen receptor-positive (ER+) invasive breast cancer. Participants in the (Z)-endoxifen arm are treated with 10mg daily for up to 24 weeks prior to surgery. Efficacy measures include reduction in Ki-67, a marker for tumor cell proliferation, and objective response rate as measured by MRI. The (Z)-endoxifen treatment cohort of 20 participants completed full enrollment in the first quarter of 2024 with data expected in the second half of 2024.

RECAST DCIS. A Phase 2 platform study investigating (Z)-endoxifen in women diagnosed with Ductal Carcinoma In Situ (DCIS). The goal of the study, which was initiated in October 2023, is to prevent the progression of DCIS to breast cancer. Participants receive six months of treatment with a 10 mg oral dose of (Z)-endoxifen daily with the intent of determining their suitability for long-term active surveillance without surgery. On February 22, 2024, the first patient was dosed with Atossa's proprietary SERM (Z)-endoxifen.

DCIS is the presence of abnormal cells inside a milk duct in the breast. It is considered to be the earliest form of breast cancer and is noninvasive, meaning it has not spread beyond the milk duct. DCIS is usually found during a mammogram done as part of breast cancer screening or to investigate a breast lump. There are approximately 63,000 DCIS diagnoses made each year in the United States alone.

Currently, there is no way to predict which patients diagnosed with DCIS will progress to invasive breast cancer. As a result, aggressive local therapy, identical to the way invasive breast cancer is treated, is the current standard of care. For most patients, this involves mastectomy or lumpectomy, radiation, and hormone therapy for five years. If treatment with (Z)-endoxifen can effectively halt the progression of DCIS, it would potentially spare a significant percentage of patients diagnosed with this disease from aggressive, invasive, or potentially unnecessary treatment.

Other Programs; Immunotherapy/CAR-T Programs

Other Program. On July 6, 2023, Atossa announced a strategic, sponsored research agreement with Weill Cornell Medicine to study the potential of inducing estrogen receptor expression in triple-negative breast cancer (TNBC). The goal of the research is to determine if treating TNBC with extracellular vesicles carrying the estrogen receptor can change the cancer phenotype and turn on the estrogen receptor. Converting the tumor to ER+ would make it sensitive to hormone therapy, including treatment with (Z)-endoxifen. This could potentially fundamentally transform the treatment approach and outlook for patients diagnosed with TNBC.

Investment in CAR-T Company. On December 23, 2022, we closed our investment in DCT, a privately-held, venture-capital backed, developer of CAR-T therapies. DCT is in the pre-clinical phase of developing controllable CAR-T cells to address difficult-to-treat cancers. Its platform technology of dynamic control of engineered T-cells is designed to improve the safety, efficacy, and durability of CAR-T cell therapies. While its initial focus is hematologic malignancies, it's possible that its innovative approach could also have broad applicability in solid tumors and autoimmune diseases.

Much of the recent successes in the field of chimeric antigen receptor therapy, or CAR-T, has relied on the systemic delivery (for example, a needle injection into the blood stream) of the CAR-T which is intended to treat various non-solid tumor cancers, such as blood cancers. One concern with this systemic approach is that it does not target the location of the cancer and it can have adverse effects, including deadly “cytokine storms.” Moreover, CAR-T treatments delivered systemically can be as high as $500,000 per patient.

We have filed patent applications on a novel method to deliver CAR-T cells or other types of immunotherapy into the milk ducts of the breast, the location where most breast cancers originate for the potential targeted treatment of breast cancer. This approach uses targeted intraductal delivery of either T-cells that have been genetically modified to attack breast cancer cells or various other immune-therapies. We believe this intraductal method has several potential advantages, including the reduction of toxicity by limiting systemic exposure of the T-cells or immunotherapy; improved efficacy by placing the T-cells or immunotherapy in direct contact with the target ductal epithelial cells that are undergoing or have undergone malignant transformation; and, lymphatic migration of the

CAR-T cells or immunotherapy potentially extending their cytotoxic actions into the regional lymph system, which could limit tumor cell dissemination or metastasis. Moreover, our approach may be more cost effective if lower doses of therapy can be delivered compared to systemic CAR-T. We have not begun, and may not be successful in completing, pre-clinical and clinical studies of our CAR-T technology.

Markets

Potential Market Opportunities

We believe that, based in part on a study by Defined Health Inc. (now Lumanity), a leading market research firm, the potential U.S. market for our (Z)-endoxifen in the breast cancer treatment and prevention settings is up to $1 billion annually. The American Cancer Society (ACS) estimates that in the U.S. in 2024, 310,720 women will be diagnosed with breast cancer and one in eight women will be diagnosed in their lifetime. Approximately 80% of breast cancers diagnosed are ER+.

Our Capital Resources

We have not yet established an ongoing source of revenue sufficient to cover our operating costs and allow us to continue as a going concern. Our ability to continue as a going concern is dependent on obtaining adequate capital to fund operating losses until we become profitable. We plan to obtain additional capital resources by selling our equity securities and borrowing from stockholders or others when needed. However, we cannot assure you that we will be successful in accomplishing any of these plans and, if we are unable to obtain adequate capital, we could be forced to curtail or suspend our business plans. We do not anticipate any revenue until our pharmaceutical programs are developed, including receipt of all necessary regulatory approvals, and we successfully commercialize these programs.

As of December 31, 2023, we had cash and cash equivalents of approximately $88.5 million.

Potential Uses of Capital Resources

We intend to use our capital resources to execute on our business plan, which may include acquiring or in-licensing additional programs. We may also use our capital resources to invest directly or indirectly in business opportunities in healthcare or other industries including through purchases of equity in other companies. These investments may include investing in special purpose acquisition companies either as a sponsor or as an equity investor. Our business plan may evolve to require more capital resources than currently contemplated either because our existing programs progress more quickly or at a greater cost than currently anticipated or because we may add additional programs.

Research and Development Phase

We are in the research and development phase and are not currently marketing any products or services. We do not anticipate generating revenue unless and until we develop and launch our pharmaceutical programs.

Research and development (R&D) costs are generally expensed as incurred. R&D expenses include, for example, manufacturing expense for our drugs under development, expenses associated with clinical trials and associated salaries and benefits. We have entered into various research and development contracts with research institutions, clinical research organizations, clinical manufacturing organizations and other companies. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and payments made in advance of performance are reflected in the accompanying Consolidated Balance Sheets as prepaid expenses. We accrue for estimated costs incurred for ongoing research and development activities. When evaluating the adequacy of the accrued expenses, we analyze the progress of the services, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates may be made in determining the prepaid expense or accrued expense balances at the end of any reporting period. Actual results could differ from our estimates.

R&D expenses also include an allocation of the CEO's salary and related benefits, including bonus and non-cash stock-based compensation expense based on an estimate of total hours expended on research and development activities. Our CEO is involved in the development of the Company's drug candidates and oversight of the related clinical trial activity.

Research and development expenses for the years ended December 31, 2023 and 2022 were approximately $17.3 million and $15.1 million, respectively.

Intellectual Property

Intellectual property is important to our business and our future income streams will depend, in part, on our ability to obtain and maintain patents. We strive to protect our proprietary technology and innovations that we consider commercially valuable with respect to the development of our business, including by pursuing, maintaining, and defending certain of our U.S. and international patent rights that we have identified as material to our business. We also rely on trade secrets, know-how, continuing technological innovation and licensing of intellectual property from third parties as needed to support and strengthen our position in the field.

Our future commercial success depends, in part, on our ability to obtain and maintain patent and other proprietary protection for our commercially relevant technology, inventions, and know-how related to our business as well as our ability to defend and enforce our intellectual property rights, preserve the confidentiality of our trade secrets, and operate without infringing, misappropriating, or violating the valid and enforceable patents, issued patents and other proprietary rights of third parties.

We own patents directed to (Z)-endoxifen and other therapies as well as patent applications directed to (Z)-endoxifen, immunotherapies such as CAR-T therapies, and other therapies. We commonly seek patent claims directed to compositions of matter, including for (Z)-endoxifen, as well as methods of making and using such compositions. For each of our product candidates, we have filed multiple patent applications and expect to file additional patent applications. As of February 2, 2024, based on a review of our patent portfolio, we own and maintain 11 issued patents (four U.S. patents and seven international patents) and are pursuing 68 pending patent applications (22 U.S. patent applications and 46 international patent applications) directed to our (Z)-endoxifen therapies, immunotherapies such as CAR-T therapies, and other therapies. We continue to evaluate our patent portfolio on an ongoing basis and are no longer pursuing or maintaining patents, patent applications, or technologies that we have determined are no longer core to our business as a result of evolving business goals.

As of February 2, 2024, the following are the estimated number of patents we own related to our programs that we are currently pursuing.

	Issued Patents (1,2,3)		Pending Applications (1, 2, 3)		Estimated
	U.S.	International	U.S.	International	Expiry Date (3)
(Z)-endoxifen programs	3	7	9	30	2038 - 2045
Immunotherapy/CAR-T program	—	—	6	3	2037 - 2044
Other therapy programs	1	—	7	13	2030 - 2044

1. Each patent application includes at least one claim or disclosure directed to a listed therapeutic/program.
2. The patent counts in the table above may differ from the total numbers of the patent applications in our portfolio as the patent counts in the table above reflect that a patent application may have claims directed to more than one type of therapeutic/program.
3. The patent counts and the estimated expiration dates disclosed herein and in our patent estate are subject to change, for example, in the event of changes in the law, post-grant patent challenges, or legal rulings affecting our patents and applications or if we become aware of new information or amend our business goals. The standards that the U.S. Patent and Trademark Office, or USPTO, and foreign patent offices use to grant patents are not always applied predictably or uniformly and can change. Consequently, our pending patent applications may not be allowed and, if allowed, may not contain the type and extent of patent claims that would be adequate to conduct our current or anticipated business. Additionally, any issued patents we currently own or may obtain in the future may have a shorter patent term than expected, may be invalidated or may not contain claims that will permit us to stop competitors from using our technology or methods or similar technology or methods or from copying our products. Finally, if certain patents issued to others are upheld, or if certain patent applications filed by others are issued and upheld, we would likely require additional licenses to continue to develop and commercialize relevant products. Furthermore, there can be no assurance that such licenses, if required, would be available on acceptable or commercially reasonable terms. Our inability to obtain third-party licenses may adversely affect our ability to operate our business and to achieve our revenue goals.

Manufacturing, Clinical Studies and Associated Operations

Our drug development strategy utilizes third-party contractors for the procurement and manufacture, as applicable, of raw materials, active pharmaceutical ingredients and finished drug products, as well as for storage, and distribution of our products and associated supply chain operations. We also rely on third-parties to conduct nonclinical and clinical studies of our drugs under development. As our development programs advance, we expect that our manufacturing, pre-clinical and clinical studies, and related operational requirements will correspondingly increase. We require that each third-party contractor is qualified by Atossa subject matter experts prior to signing any service agreement and initiating any third-party work.

Integral to our development strategy is our quality program, which includes standard operating procedures and specifications with the goal that our work complies with Good Clinical Practices (GCP), Good Laboratory Practices (GLP) and Current Good Manufacturing Practices (cGMP), and other applicable global regulations, when appropriate. We expect and confirm that selected service providers meet or exceed our expectations for compliance with these standards in providing services and products that meet our requirements.

We believe our operational strategy of utilizing qualified contractors and suppliers in the foregoing manner allows us to direct our financial and managerial resources to research and development and commercialization activities, rather than to the establishment and maintenance of manufacturing and clinical infrastructure.

Government Regulation

Drug Regulations

We are subject to extensive regulation by the FDA and other federal, state, and local regulatory agencies. The Federal Food, Drug, and Cosmetic Act, or the FDCA, and its implementing regulations set forth, among other things, regulations for the execution of clinical studies, and the requirements for the testing, development, manufacture, quality control, safety, effectiveness, approval, labeling, storage, record keeping, reporting, distribution, import, export, advertising and promotion of our products. Our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the U.S., although there can be important differences. Additionally, some significant aspects of regulation in the E.U. are addressed in a centralized procedure through the Europe Medicines Agency (EMA) and the European Commission, but country-specific regulation by the competent authorities of the E.U. member states remain essential in many respects. Also see the “Non-U.S. Regulation” section below in connection with the position in the United Kingdom (UK).

U.S. Regulations

In the U.S., the FDA regulates drugs under the FDCA and its implementing regulations, through review and ultimately approval of the New Drug Applications (NDAs). NDAs require extensive studies and submission of a large amount of data by the applicant, which is an amalgamation of data obtained under Investigational New Drug Applications (INDs) and other supporting available information. For a discussion of U.S. privacy laws, see “Privacy and Security of Health Information and Personal Information; Standard Transactions” below.

Drug Development

Nonclinical Testing. Before testing any compound in human subjects in the U.S., extensive nonclinical data are required. Nonclinical testing generally consists of safety, toxicology and pharmacology studies in animals. Many of these studies must be performed in compliance with the FDA’s GLP regulations and the U.S. Department of Agriculture’s Animal Welfare Act.

IND Application. In nearly all cases, human clinical trials in the U.S. cannot commence until an IND is submitted to the FDA for review and a “Safe to Proceed” letter has been provided to the sponsor. The sponsor must prepare a dossier of information that includes the results of nonclinical studies; detailed drug manufacturing information and test results; and proposed clinical studies, design and development strategy. The FDA then evaluates if there is an adequate basis for testing the drug in an initial (human) clinical study. Unless the FDA raises concerns, the IND application becomes effective 30 days following its receipt by the FDA at which time written notification is provided. Once human clinical trials have commenced, the sponsor is obligated to report serious side and unexpected effects to the FDA. The FDA may suspend a clinical trial by placing it on “clinical hold” if the FDA has concerns about the safety of the product being tested, subject risks, investigator actions, related product information or for other reasons.

Clinical Trials. Clinical trials involve the administration of the drug to healthy human volunteers or to patients, under the supervision of a qualified investigator according to a vetted and approved protocol.

The conduct of clinical trials is subject to extensive regulation, including compliance with the FDA’s bioresearch monitoring regulations and GCP requirements, which establish standards for conducting, recording data from and reporting the results of, clinical trials, and are intended to assure that the data and reported results are credible and accurate, and that the rights, safety, and well-being of study participants are protected. Clinical trials must be conducted under written and approved protocols that detail the study objectives, parameters for monitoring safety, and the efficacy criteria, if any, to be evaluated. Each protocol is reviewed by the FDA as part of the IND application. In addition, each clinical trial must be reviewed, approved, and conducted under the auspices of an institutional review board, or IRB. Companies sponsoring the clinical trials, investigators, and IRBs also must comply with regulations and guidelines for obtaining informed consent from the study subjects, complying with the protocol and investigational plan, adequately monitoring the clinical trial and timely reporting adverse events. Foreign studies conducted under an IND application must meet the same requirements that apply to studies being conducted in the U.S. Data from a foreign study not conducted under an IND application may be submitted in support of an NDA if the study was conducted in accordance with GCP and the FDA is able to validate the data from the study through an onsite inspection if it deems such inspection necessary.

A study sponsor is required to submit certain details about applicable active clinical trials and clinical trial results to the National Institutes of Health for public posting on *http://clinicaltrials.gov.* Human clinical trials are typically conducted in three sequential phases, although the phases may overlap with one another:

- Phase 1clinical trials include the initial administration of the investigational drug to humans, typically to a small group of healthy human subjects, but occasionally to a group of patients with the targeted disease or disorder. Phase 1 clinical trials generally are intended to determine the metabolism and pharmacologic actions of the drug, the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness.

- Phase 2 clinical trials generally are controlled studies that involve a relatively small sample of the intended patient population and are designed to develop data regarding the product’s effectiveness, to determine dose response and the optimal dose range and to gather additional information relating to safety and potential adverse effects.

• Phase 3 clinical trials are conducted after preliminary evidence of effectiveness has been obtained and are intended to gather the additional information about safety and effectiveness necessary to evaluate the drug's overall risk-benefit profile, and to provide a basis for physician labeling. Generally, Phase 3 clinical development programs consist of expanded, large-scale studies of patients with the target disease or disorder to obtain statistical evidence of the efficacy and safety of the drug, or the safety, purity, and potency of a biological product, at the proposed dosing regimen.

The sponsoring company, the FDA or the IRB may suspend or terminate a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk. Further, success in early-stage clinical trials does not assure success in later-stage clinical trials. Data obtained from clinical activities are not always conclusive and may be subject to alternative interpretations that could delay, limit, or prevent regulatory approval.

There are regulatory pathways that can accelerate the speed with which a product can be developed, including a Special Protocol Assessment (SPA), break-through therapy designation, among others. The designations are obtained from the FDA on a case-by-case basis and do not guarantee the ultimate approval of a product for commercialization.

Drug Approval

Assuming successful completion of the required clinical testing, the results of the preclinical studies and of the clinical trials, together with other detailed information, including information on the manufacture and composition of the investigational product, are submitted to the FDA in the form of an NDA requesting approval to market the product for one or more indications. The testing and approval process requires substantial time, effort and financial resources. Submission of an NDA requires payment of a review user fee to the FDA, which will be $4.0 million for fiscal year 2024. The FDA will review the application and may deem it to be inadequate to support commercial marketing, and there can be no assurance that any product approval will be granted on a timely basis, if at all. The FDA may also seek the advice of an advisory committee, typically a panel of clinicians practicing in the field for which the product is intended, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendations of the advisory committee.

In addition, the Pediatric Research Equity Act ("PREA") requires a sponsor to conduct pediatric clinical trials for most drugs, including for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs and supplements thereto must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric clinical trials begin.

The FDA has various programs, including break-through therapy, fast track, priority review and accelerated approval that are intended to expedite or simplify the process for reviewing drugs and/or provide for approval on the basis of surrogate endpoints. Generally, drugs that may be eligible for one or more of these programs are those for serious or life-threatening conditions, those with the potential to address unmet medical needs and those that provide meaningful benefit over existing treatments. We cannot be sure that any of our drugs will qualify for any of these programs, or that, if a drug does qualify, the review time will be reduced, or the product will be approved.

Before approving an NDA, the FDA usually inspects the clinical sites with the greatest accrual to confirm the veracity of the clinical data, execution of the clinical study and protection of patient safety. The FDA will inspect the facility or the facilities where the product is manufactured, tested and distributed. Approval is not granted if these inspections raise concerns about the execution of the clinical studies or there is a lack of cGMP compliance. If the FDA evaluates the NDA and determines the clinical trial execution and manufacturing facilities as acceptable, the FDA may issue an approval letter. If the NDA is not approved, the FDA issues a complete response letter which is only issued for applications that are not approved. The approval letter authorizes commercial marketing of the drug for specific indications. As a condition of approval, the FDA may require post-marketing testing and surveillance to monitor the product's safety or efficacy or impose other post-approval commitment conditions.

In some circumstances, post-marketing testing may include post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, which are used primarily to gain additional experience from the treatment of patients in the intended population, particularly for long-term safety follow-up. In addition, the FDA may require a Risk Evaluation and Mitigation Strategy, or REMS, to ensure that the benefits outweigh the risks. A REMS can include medication guides, physician communication plans and elements to assure safe use, such as restricted distribution methods, patient registries or other risk mitigation tools.

After approval, certain changes to the approved product, such as adding new indications, making certain manufacturing changes or making certain additional labeling claims, are subject to further FDA review and approval. Obtaining approval for a new indication generally requires that additional clinical trials be conducted.

Post-Approval Requirements

Holders of an approved NDA are required to, among other things: (i) report certain adverse reactions to the FDA; (ii) comply with certain requirements concerning advertising and promotional labeling for their products; and (iii) continue to have cGMP compliance and all aspects of product manufacturing in a "state of control." The FDA periodically inspects the sponsor's records related to safety reporting and/or manufacturing and distribution facilities; this latter effort includes assessment of compliance with cGMP. Accordingly, manufacturers must continue to expend time, money and effort in the area of production, quality control and distribution to maintain cGMP compliance. Future FDA inspections may identify compliance issues at manufacturing facilities that may disrupt production or distribution or require substantial resources to correct. In addition, discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved NDA, including withdrawal of the product from the market.

Post-approval modifications to the drug product candidate, such as changes in indications, labeling or manufacturing processes or facilities, may require a sponsor to develop additional data or conduct additional preclinical or clinical trials, to be submitted in a new or supplemental NDA, which would require FDA approval.

Marketing of prescription drugs is also subject to significant regulation through federal and state agencies tasked with consumer protection and prevention of medical fraud, waste and abuse. After approval in the U.S., we must comply with FDA's regulation of drug promotion and advertising, including restrictions on off-label promotion, and comply with federal anti-kickback statutes, limitations on gifts and payments to physicians and reporting of payments to certain third-parties, among other requirements.

Failure to comply with applicable U.S. requirements may subject us to administrative or judicial sanctions, such as clinical holds, FDA refusal to approve pending NDAs or supplemental applications, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions and/or criminal prosecution.

Non-U.S. Regulation

Before our products can be marketed outside of the U.S., they are subject to regulatory approval similar to that required in the U.S., although the requirements governing the conduct of clinical trials, including additional clinical trials that may be required, product licensing, pricing and reimbursement vary widely from country to country. No action can be taken to market any product in a country until an appropriate application has been approved by the regulatory authorities in that country. The current approval process varies from country to country, and the time spent in gaining approval varies from that required for FDA approval. In certain countries, the sales price of a product must also be approved. The pricing review period often begins after market approval is granted. Even if a product is approved by a regulatory authority, satisfactory prices may not be approved for such product.

Drug Marketing Authorization. In the E.U., which includes Sweden where our (Z)-endoxifen breast density study is being conducted, and in Iceland, Norway and Liechtenstein (together, the European Economic Area or EEA), after completion of all required clinical testing, medicinal products may only be placed on the market after obtaining a Marketing Authorization (MA). To obtain a MA of a drug under European Union regulatory systems, an applicant can submit a Marketing Authorization Application (MAA), through, amongst others, a centralized or decentralized procedure.

Centralized Authorization Procedure. In the E.U., marketing authorizations for medicinal products can be obtained through several different procedures founded on the same basic regulatory process. The centralized procedure provides for the grant of a single MA that is issued by the European Commission (the EC) following the scientific assessment of the application by the European Medicines Agency (the EMA) that is valid for all E.U. Member States as well as in the three additional EEA Member States. The centralized procedure is mandatory for certain medicinal products, including for medicines developed by means of certain biotechnological processes, products designated as orphan medicinal products, advanced therapy medicinal products (ATMP), and medicinal products with an active substance authorized in the E.U. after May 20, 2004 which is intended for the treatment of certain diseases (e.g., AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases). For medicinal products containing a new active substance not yet authorized in the EEA on May 20, 2004 and indicated for the treatment of other diseases, medicinal products that constitute significant therapeutic, scientific or technical innovations, or for which the grant of a MA through the centralized procedure would be in the interest of public or animal health at the E.U. level, an applicant may voluntarily submit an application for a marketing authorization through the centralized procedure.

Under the centralized procedure, the Committee for Medicinal Products for Human Use (the CHMP), established at the EMA, is responsible for conducting the initial assessment of a drug. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing marketing authorization. Under the centralized procedure, the timeframe for the evaluation of an MAA by the EMA's CHMP is, in principle, 210 days from receipt of a valid MAA. However, this timeline excludes clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP, so the overall process typically takes a year or more, unless the application is eligible for an accelerated assessment. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, particularly from the point of view of therapeutic innovation. Upon request, the CHMP can reduce the time frame to 150 days if the applicant provides sufficient justification for an accelerated assessment. The CHMP will provide a positive opinion regarding the application only if it meets certain quality, safety and efficacy requirements. This

opinion is then transmitted to the EC, which has the ultimate authority for granting MA within 67 days after receipt of the CHMP opinion.

Decentralized Authorization Procedure. Medicines that fall outside the mandatory scope of the centralized procedure have three routes to authorization: (i) they can be authorized under the centralized procedure if they concern a significant therapeutic, scientific or technical innovation, or if their authorization would be in the interest of public health; (ii) they can be authorized under a decentralized procedure where an applicant applies for simultaneous authorization in more than one E.U. member state; or (iii) they can be authorized in an E.U. member state in accordance with that state's national procedures and then be authorized in other E.U. countries by a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization (mutual recognition procedure).

The decentralized procedure permits companies to file identical MA applications for a medicinal product to the competent authorities in various E.U. Member States simultaneously if such medicinal product has not received marketing approval in any E.U. Member State before. This procedure is available for medicinal products not falling within the mandatory scope of the centralized procedure. The competent authority of a single E.U. Member State, known as the reference E.U. Member State, is appointed to review the application and provide an assessment report. Under this procedure, an applicant submits an application based on identical dossiers and related materials, including a draft summary of product characteristics, and draft labeling and package leaflet, to the reference E.U. Member State and concerned E.U. Member States. The reference E.U. Member State prepares a draft assessment report and drafts of the related materials within 120 days after receipt of a valid application. Subsequently each concerned E.U. Member State must decide whether to approve the assessment report and related materials. If an E.U. Member State cannot approve the assessment report and related materials on the grounds of potential serious risk to public health, the disputed points are subject to a dispute resolution mechanism and may eventually be referred to the EC, whose decision is binding for all E.U. Member States.

Risk Management Plan. All new MAAs must include a Risk Management Plan (RMP), describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. RMPs are continually modified and updated throughout the lifetime of the medicine as new information becomes available. We need to submit an updated RMP: (i) at the request of EMA or a national competent authority, or (ii) whenever the risk-management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit-risk profile or as a result of an important pharmacovigilance or risk-minimization milestone being reached. The regulatory authorities may also impose specific obligations as a condition of the MA. Since October 20, 2023, all RMPs for centrally authorized products are published by the EMA, subject to only limited redactions.

MA Validity Period. Marketing Authorizations have an initial duration of five years. After these five years, the authorization may subsequently be renewed on the basis of a reevaluation of the risk-benefit balance. Once renewed, the MA is valid for an unlimited period unless the EC or the national competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with only one additional five-year renewal. Applications for renewal must be made to the EMA at least nine months before the five-year period expires.

Exceptional Circumstances/Conditional Approval. Similar to accelerated approval regulations in the U.S., conditional marketing authorizations can be granted in the E.U. by the European Commission in exceptional circumstances. A conditional marketing authorization can be granted for medicinal products where, although comprehensive clinical data referring to the safety and efficacy of the medicinal product have not been supplied, a number of criteria are fulfilled, including: (i) the benefit/risk balance of the product is positive, (ii) it is likely that the applicant will be in a position to provide the comprehensive clinical data, (iii) unmet medical needs will be fulfilled by the grant of the MA and (iv) the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required. A conditional marketing authorization must be renewed annually.

Pricing and Reimbursement Environment. Even if a medicinal product obtains a marketing authorization in the E.U., there can be no assurance that reimbursement for such product will be secured on a timely basis or at all. Individual countries comprising the E.U. member states, rather than the E.U., have jurisdiction across the region over patient reimbursement or pricing matters. Therefore, we will need to expend significant effort and expense to establish and maintain reimbursement arrangements in the various countries comprising the E.U. and may never succeed in obtaining widespread reimbursement arrangements therein.

The national authorities of the individual E.U. Member States are free to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices and/or reimbursement of medicinal products for human use. Some E.U. Member States adopt policies according to which a specific price or level of reimbursement is approved for the medicinal product. Other E.U. Member States adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market, including volume-based arrangements, caps and reference pricing mechanisms.

Reference pricing used by various E.U. Member States and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries, we may be required to conduct a clinical study or other studies that compare the cost-effectiveness of our product candidates, if any, to other available therapies in order to obtain or maintain reimbursement or pricing approval. There can be no assurance that any country that has price controls or reimbursement limitations for medicinal products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, medicinal

products launched in the E.U. do not follow price structures of the U.S. and generally published and actual prices tend to be significantly lower. Publication of discounts by third party payers or authorities and public tenders may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries.

Health Technology Assessment (HTA) of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some E.U. Member States, including France, Germany, Ireland, Italy and Sweden. The HTA process, which is governed by the national laws of these countries, is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product vary between E.U. Member States. The HTA generally focuses on the clinical efficacy and effectiveness, safety, cost and cost-effectiveness of individual medicinal products as well as their potential implications for the healthcare system. Those elements of medicinal products are compared with other treatment options available on the market. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to medicinal products by the regulatory authorities of individual E.U. Member States. A negative HTA of one of our products by a leading and recognized HTA body could not only undermine our ability to obtain reimbursement for such product in the E.U. Member State in which such negative assessment was issued, but also in other E.U. Member States. For example, E.U. Member States that have not yet developed HTA mechanisms could rely to some extent on the HTA performed in other countries with a developed HTA framework, when adopting decisions concerning the pricing and reimbursement of a specific medicinal product.

On January 31, 2018, the European Commission adopted a proposal for a regulation on health technology assessment. This legislative proposal is intended to boost E.U. level cooperation among E.U. Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at the E.U. level for joint clinical assessments in these areas. The proposal provides that E.U. Member States will be able to use common HTA tools, methodologies and procedures across the European Union, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual E.U. Member States will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement. While E.U. Member States could choose to delay participation in the joint work until three years after the rules enter into force, it will become mandatory after six years. The European Commission has stated that the role of the HTA regulation is not to influence pricing and reimbursement decisions in the individual E.U. Member States, but there can be no assurance that the HTA regulation will not have effects on pricing and reimbursement decisions. The HTA entered into force on January 11, 2022 and applies as of January 2025 followed by a further three-year transitional period during which E.U. member states must fully adapt to the new system.

To obtain, reimbursement or pricing approval in some countries, including the E.U. Member States, we may be required to conduct studies that compare the cost-effectiveness of our product candidates to other therapies that are considered the local standard of care. There can be no assurance that any country will allow favorable pricing, reimbursement and market access conditions for any of our products, or that we will be feasible to conduct additional cost-effectiveness studies, if required.

In certain of the E.U. Member States, medicinal products that are designated as orphan medicinal products may be exempted or waived from having to provide certain clinical, cost-effectiveness and other economic data in connection with their filings for pricing/reimbursement approval.

Post-Approval Regulation

Similarly, to the U.S., both marketing authorization holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the EC and/or the competent regulatory authorities of the individual E.U. Member States. This oversight applies both before and after grant of the manufacturing licenses and marketing authorizations. It includes control of compliance with E.U. good manufacturing practices rules, manufacturing authorizations, pharmacovigilance rules and requirements governing advertising, promotion, sale, and distribution, recordkeeping, importing and exporting of medicinal products.

Failure by us or by any of our third-party partners, including suppliers, manufacturers and distributors to comply with E.U. laws and the related national laws of individual E.U. Member States governing the conduct of clinical trials, manufacturing approval, marketing authorization of medicinal products and marketing of such products, both before and after grant of marketing authorization, statutory health insurance, bribery and anti-corruption or other applicable regulatory requirements may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials or to grant marketing authorization, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the marketing authorization, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

The holder of an E.U. marketing authorization for a medicinal product must also comply with E.U. pharmacovigilance legislation and its related regulations and guidelines, which entail many requirements for conducting pharmacovigilance, or the assessment and monitoring of the safety of medicinal products.

These pharmacovigilance rules can impose on central marketing authorization holders for medicinal products the obligation to conduct a labor-intensive collection of data regarding the risks and benefits of marketed products and to engage in ongoing assessments of those risks and benefits, including the possible requirement to conduct additional clinical studies or post-authorization safety studies to obtain further information on a medicine's safety, or to measure the effectiveness of risk-management measures, which may be time consuming and expensive and could impact our profitability. MA holders must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance, who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of Periodic Safety Update Reports (PSURs) in relation to medicinal products for which they hold MAs. The EMA reviews PSURs for medicinal products authorized through the centralized procedure. If the EMA has concerns that the risk benefit profile of a product has varied, it can adopt an opinion advising that the existing MA for the product be suspended, withdrawn or varied. The agency can advise that the MA holder be obliged to conduct post-authorization Phase IV safety studies. If the EC agrees with the opinion, it can adopt a decision varying the existing MA. Failure by the MA holder to fulfill the obligations for which the EC's decision provides can undermine the ongoing validity of the MA.

More generally, non-compliance with pharmacovigilance obligations can lead to the variation, suspension or withdrawal of the marketing authorization for the product or imposition of financial penalties or other enforcement.

The manufacturing process for medicinal products in the E.U. is highly regulated: regulators may shut down manufacturing facilities that they believe do not comply with regulations. Manufacturing requires a manufacturing authorization, and the manufacturing authorization holder must comply with various requirements set out in the applicable E.U. laws, regulations and guidance, including Directive 2001/83/EC, Directive 2003/94/EC, Regulation (EC) No 726/2004 and the European Commission Guidelines for Good Manufacturing Practice (GMP). These requirements include compliance with E.U. GMP standards when manufacturing medicinal products and active pharmaceutical ingredients, including the manufacture of active pharmaceutical ingredients outside of the E.U. with the intention to import the active pharmaceutical ingredients into the E.U. Similarly, the distribution of medicinal products into and within the E.U. is subject to compliance with the applicable E.U. laws, regulations and guidelines, including the requirement to hold appropriate authorizations for distribution granted by the competent authorities of the E.U. Member States. The manufacturer or importer must have a qualified person who is responsible for certifying that each batch of product has been manufactured in accordance with GMP, before releasing the product for commercial distribution in the E.U. or for use in a clinical trial. Manufacturing facilities are subject to periodic inspections by the competent authorities for compliance with GMP.

Sales and Marketing Regulations

In the E.U., the advertising and promotion of our products are subject to E.U. and E.U. Member States' laws governing promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. In addition, other legislation adopted by individual E.U. Member States may apply to the advertising and promotion of medicinal products and may differ from one country to another. These laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics (SmPC) as approved by the competent authorities. The SmPC is the document that provides information to physicians concerning the safe and effective use of the medicinal product. It forms an intrinsic and integral part of the marketing authorization granted for the medicinal product. Promotion of a medicinal product that does not comply with the SmPC is considered to constitute off-label promotion. All advertising and promotional activities for the product must be consistent with the approved SmPC and therefore all off-label promotion of medicinal products is prohibited. Direct-to-consumer advertising of prescription-only medicinal products is also prohibited in the E.U. Violations of the rules governing the promotion of medicinal products in the E.U. could be penalized by administrative measures, fines and imprisonment. These laws may further limit or restrict the advertising and promotion of our products to the general public and may also impose limitations on our promotional activities with health care professionals.

Anti-Corruption Legislation

Our business activities outside of the U.S. are subject to anti-bribery or anti-corruption laws, regulations, industry self-regulation codes of conduct, and physicians' codes of professional conduct or rules of other countries in which we operate, including the U.K. Bribery Act of 2010.

Interactions between pharmaceutical companies and physicians are also governed by strict laws, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct developed at both the E.U. level and in the individual E.U. Member States. The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the E.U. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of the E.U. Member States. Violation of these laws could result in substantial fines and imprisonment. Payments made to physicians in certain E.U. Member States also must be publicly disclosed. Moreover, agreements with physicians must often be the subject of prior notification and approval by the physician's employer, his/her competent professional organization, and/or the competent authorities of the individual E.U. Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the individual E.U.

Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Data Privacy and Protection

Data protection laws and regulations have been adopted at the E.U. level, with related implementing laws in individual E.U. Member States which impose significant compliance obligations. The E.U. has adopted a comprehensive overhaul of its data protection regime from an E.U. Data Protection Directive with national legislative approaches to a single European Economic Area Privacy Regulation, the General Data Protection Regulation 2016/679/E.U. (GDPR), which came into effect on May 25, 2018. The GDPR extends the scope of the E.U. data protection law to the processing of personal data carried out by companies not established in the E.U., where such processing relates to (a) the offering of goods or services to data subjects who are in the E.U., or (b) the monitoring of the behavior of data subjects who are in the E.U. It imposes a strict data protection compliance regime with severe penalties of up to the greater of 4% of total worldwide annual turnover of the preceding financial year and €20 million, and it provides for new rights (such as the “right to be forgotten” and “portability” of personal data), obligations related to the implementation of appropriate security measures, personal data breach notification requirements, as well as restrictions on the processing of health data. E.U. Member States may also impose additional requirements in relation to health, genetic and biometric data through their national implementing legislation.

Furthermore, there is a growth towards the public disclosure of clinical trial data in the E.U. which also adds to the complexity of processing health data from clinical trials. Such public disclosure obligations are provided in the new E.U. Clinical Trials Regulation, EMA disclosure initiatives, and voluntary commitments by industry. Data protection authorities from the different E.U. Member States may interpret the GDPR differently, which adds to the complexity of processing personal data in the E.U., and guidance on implementation and compliance practices are often updated or otherwise revised.

In addition, the GDPR imposes specific restrictions on transfer of personal data to countries outside of the EEA that are not considered by the European Commission to provide an adequate level of data protection. Appropriate safeguards are required to enable such transfers. Among the appropriate safeguards that can be used, the data exporter may use standard contractual clauses (SCCs). When relying on SCCs, the data exporters are also required to conduct a transfer risk assessment to verify if anything in the law and/or practices of the third country may impinge on the effectiveness of the SCCs in the context of the transfer at stake and, if so, to identify and adopt supplementary measures that are necessary to bring the level of protection of the data transferred to the E.U. standard of essential equivalence. Where no supplementary measure is suitable, the data exporter should avoid, suspend or terminate the transfer. With respect to transfers to the U.S., on July 10, 2023, the European Commission adopted its adequacy decision for the EU-U.S. Data Privacy Framework. This decision concludes that the U.S. provides an adequate level of protection for personal data transferred from the EEA to U.S. entities which have self-certified their compliance with the new EU-U.S. Data Privacy Framework. On the basis of the new adequacy decision, personal data can flow from the EEA to U.S. companies participating in the framework.

United Kingdom (UK)

The UK formally left the E.U. on January 31, 2020 (Brexit). E.U. laws now only apply to the UK with respect to Northern Ireland as laid out in the Protocol on Ireland and Northern Ireland, as amended by the Windsor Framework, agreed to by the UK and the E.U. on February 27, 2023.

The E.U. and the UK have also agreed to a trade and cooperation agreement (TCA), which includes provisions affecting the life sciences industry (including regarding customs and tariffs). It includes certain provisions concerning pharmaceuticals, including the mutual recognition of GMP, inspections of manufacturing facilities for medicinal products and issued GMP documents. The TCA does not, however, contain wholesale mutual recognition of UK and E.U. pharmaceutical regulations and product standards.

Medicines are approved and licensed in the UK (excluding Northern Ireland) by the UK’s Medicines and Healthcare products Regulatory Agency (MHRA). Under the Windsor Framework, from January 1, 2025, the EMA will no longer have a role in approving or licensing new drugs for provision in Northern Ireland; medicines will need to be approved and licensed on a UK-wide basis by the MHRA, with medicines using the same packaging and labelling across the UK.

The UK government has adopted the Medicines and Medical Devices Act 2021 (MMDA) to enable the UK’s regulatory frameworks to be updated following the UK’s departure from the E.U. The MMDA introduces regulation-making, delegated powers covering the fields of human medicines, clinical trials of human medicines, veterinary medicines and medical devices. The MHRA has since been consulting on future regulations for medicines and medical devices in the UK.

Additionally, following Brexit, companies also have to comply with the UK’s data protection laws, including the UK GDPR, which is based on the GDPR.

Privacy and Security of Health Information and Personal Information; Standard Transactions

We are subject to state and federal laws and implementing regulations relating to the privacy and security of the medical information of the patients we treat. The principal federal legislation is the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (collectively, HIPAA).

Pursuant to HIPAA, the Secretary of the Department of Health and Human Services (HHS), has issued final regulations designed to improve the efficiency and effectiveness of the healthcare system by facilitating the electronic exchange of information in certain financial and administrative transactions, while protecting the privacy and security of the patient information exchanged.

State statutes and regulations also regulate the privacy and security of patients' medical and health information, that is not regulated by HIPAA. These laws vary from state to state, and impose a range of obligations. For instance, the California Consumer Privacy Act of 2018 (CCPA), as amended by the California Privacy Rights Act of 2020 (CPRA), applies to personal data of consumers, business representatives, and employees, and imposes obligations on certain businesses that do business in California, including to provide specific disclosures in privacy notices, rights to California residents in relation to their personal information. Health information falls under the CCPA/CPRA's definition of personal information where it identifies, relates to, describes, or is reasonably capable of being associated with or could reasonably be linked with a particular consumer or household—unless it is subject to HIPAA—and is included under a new category of personal information, "sensitive personal information," which is offered greater protection. A similar law in Virginia went into effect on January 1, 2023 and in Colorado and Connecticut on July 1, 2023, and similar laws also have passed in other states, including in Delaware, Indiana, Iowa, Montana, Oregon, Tennessee, Texas and Utah. Comprehensive privacy laws also have been proposed in other states and at the federal level, reflecting a trend toward more stringent privacy legislation in the U.S. Some of these laws and regulations impose different, and in certain instances, more stringent requirements than HIPAA.

International regulations (such as the GDPR and UK GDPR) also provide privacy protection to clinical trial participants of their personal health care information. We intend to take appropriate steps to protect the privacy of our clinical study participants. However, the documentation and process requirements of applicable privacy and security regulations are complex and subject to interpretation. Failure to comply with applicable privacy and security regulations could subject us to sanctions or penalties, loss of business and negative publicity.

Federal and State Fraud and Abuse Laws

The federal healthcare Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce referrals or in return for purchasing, leasing, ordering, or arranging for the purchase, lease, or order of any healthcare item or service reimbursable under a governmental payor program. The definition of "remuneration" has been broadly interpreted to include anything of value, including gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payments, ownership interests, opportunity to earn income, and providing anything at less than its fair market value. The Anti-Kickback Statute is broad, and it prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Recognizing that the Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements within the healthcare industry, HHS has issued a series of regulatory "safe harbors." These safe harbor regulations set forth certain provisions that, if met, will provide healthcare providers and other parties with an affirmative defense against prosecution under the federal Anti-Kickback Statute. Although full compliance with these provisions provides a defense against prosecution under the federal Anti-Kickback Statute, the failure of a transaction or arrangement to fit within a specific safe harbor does not necessarily mean that the transaction or arrangement is illegal or that prosecution under the federal Anti-Kickback Statute will be pursued.

Other Healthcare Laws

Our products are subject to various other healthcare-related laws regulating fraud and abuse, R&D, pricing, sales and marketing practices, and the privacy and security of health information. Among other things, these laws and others generally (a) prohibit the provision of anything of value in exchange for the referral of patients or for the purchase, order, or recommendation of any item or service reimbursed by a federal healthcare program, including Medicare and Medicaid; (b) require that claims for payment submitted to federal healthcare programs be truthful; and (c) require the maintenance of certain government licenses and permits. Specific health-care laws and regulations that we are subject to include:

- the federal Physician Self-Referral Law, which prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship, and prohibits the entity from presenting or causing to be presented claims to Medicare for those referred services;

- the federal civil and criminal false claims laws, including the False Claims Act ("FCA"), which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other federal healthcare programs that are false or fraudulent. Moreover, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA;

- the federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier;

- the federal Physician Payments Sunshine Act which requires certain applicable manufacturers of drugs, devices, biologics and medical supplies for which payment is available under certain federal healthcare programs, to monitor and report to CMS, certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors); certain other healthcare providers, including physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, certified nurse-midwives, and teaching hospitals; as well as ownership and investment interests held by physicians and their immediate family members;

- U.S. federal consumer protection and unfair competition laws, which broadly regulate marketplace activities that potentially harm customers; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to item or services reimbursed by any third-party payor, including commercial insurers; state laws requiring device companies to comply with specific compliance standards, restrict payments made to healthcare providers and other potential referral sources, and report information related to payments and other transfers of value to healthcare providers or marketing expenditures and state laws related to insurance fraud in the case of claims involving private insurers.

Compliance

Compliance with government rules and regulations is a significant concern throughout the industry, in part due to evolving interpretations of these rules and regulations. We seek to conduct our business in compliance with all statutes and regulations applicable to our operations. Failure to comply with applicable requirements may subject us to administrative or judicial sanctions, such as clinical holds, refusal of regulatory authorities to approve or authorize pending product applications, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, monetary penalties, injunctions and/or criminal prosecution.

Employees

As of the date of filing this Annual Report, we employ two executive officers and ten full-time employees. We expect that we will hire more employees as we develop our current and future programs.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, and incentivizing our management team and our clinical, scientific and other employees and consultants. The principal purposes of our equity and bonus plans are to attract, retain and motivate personnel through the granting of stock-based and cash-based compensation awards, to align our interests and the interests of our stockholders with those of our employees. The Compensation Committee of our Board of Directors approves associated merit increases and annual incentive bonus payments to our executives during the first quarter annually.

When needed, we augment our employee base with outside consultants who specialize in various fields.

Insurance

We currently maintain director’s and officer’s insurance, commercial general and office premises liability insurance, insurance on our clinical studies, and product errors and omissions liability insurance for our products.

ITEM 1A. RISK FACTORS

Summary of Risk Factors

Our business is subject to a number of risks, including risks that may prevent us from achieving our business objectives or may adversely affect our business, clinical and commercialization activities, the manufacturing of our product candidates, intellectual property, third party relationships, competitive environment, product and environmental liabilities, and our common stock. These risks are discussed more fully below and include, but are not limited to, risks related to:

Risks Relating to our Business

- We have a history of operating losses, and, as such, an investor cannot assess our profitability or performance based on past results.
- We have not established sources of ongoing revenue to cover operating costs and allow us to continue as a going concern.
- We will need to raise substantial additional capital in the future to fund our operations and we may be unable to raise such funds when needed and on acceptable terms.
- We may expend our capital resources in ways that you do not agree or that do not produce stockholder value.
- We have a history of operating losses, and we expect to continue to incur losses in the future.
- Any products we may develop may never achieve significant commercial market acceptance.
- We may be unable to establish sales, marketing and commercial supply capabilities.
- The loss of the services of our Chief Executive Officer could adversely affect our business.
- Our acquisitions of, collaborations with, licenses with and investments in, other businesses may not yield expected benefits and our inability to successfully integrate these transactions may negatively impact our business, financial condition, and results of operations. We may experience difficulty in locating, attracting and retaining experienced and qualified personnel, which could adversely affect our business.
- Compounds and methods that appear promising in research and development may fail to reach later stages of development for a number of reasons, including, among others, that clinical trials may take longer to complete than expected or may not be completed at all, and interim, top-line or preliminary clinical trial data reports may ultimately differ from actual results once data are more fully evaluated.
- We may not obtain or maintain the regulatory approvals required to develop or commercialize some or all of our products.
- We are developing our products for patients who are severely ill, and patient deaths that occur in our clinical trials could negatively impact our business even if such deaths are not shown to be related to our drugs.
- We are dependent on third party service providers for a number of critical operational activities including, in particular, for the manufacture and testing of our products and associated supply chain operations, as well as for clinical trial activities. Any failure or delay in these undertakings by third parties could harm our business.
- We may encounter delays in our clinical trials or may not be able to conduct our trials in a timely manner.
- Our clinical trials may fail to demonstrate adequately the efficacy and safety of our product candidates, which would prevent or delay regulatory approval and commercialization.
- Our products and services may expose us to possible litigation and product liability claims.
- Business disruptions, including natural disasters, severe weather, and pandemics, could seriously harm our future revenue and financial condition and increase our costs and expenses.
- We maintain our cash at financial institutions, often in balances that exceed federally-insured limits. The failure of financial institutions could adversely affect our ability to pay our operational expenses or make other payments.
- Our ability to use net operating loss carryforwards and research tax credits to reduce future tax payments may be limited or restricted.
- If we, or our wholly-owned subsidiary, lose our ability to operate in Australia, or if our subsidiary is unable to benefit from the past or future R&D rebates available under current Australian regulations, our business and results of operations could be harmed.

Risks Related to our Intellectual Property

- If we are not able to protect our proprietary technology, others could compete against us more directly, which would harm our business.
- Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.
- Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.
- We may not be able to protect our intellectual property rights throughout the world.

- Our current patent portfolio may not include all patent rights needed for the full development and commercialization of our products. We cannot be sure that patent rights we may need in the future will be available for license on commercially reasonable terms, or at all.
- Third party claims alleging intellectual property infringement may prevent or delay our drug discovery and development efforts.
- We cannot assure you that our current or future products will not infringe on existing or future patents.
- We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.
- We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

Risks Related to Our Industry

- Legislative or regulatory reforms may make it more difficult and costly for us to obtain regulatory approval of our product candidates and to manufacture, market and distribute our products after approval is obtained.
- Our inadvertent or unintentional failure to comply with the complex government regulations concerning patients' privacy, data subjects, and of medical records could subject us to fines and adversely affect our reputation.
- If we **e**xperience incidents in our information technology systems, and if we experience a significant disruption in our information technology systems or breaches of data security, our business could be adversely affected.
- The failure to comply with complex federal and state laws and regulations related to submission of claims for services could result in significant monetary damages and penalties and exclusion from the Medicare and Medicaid programs.
- We face significant competition from other biotechnology and pharmaceutical companies.
- Our employees and third party partners may engage in misconduct or other improper activities.
- Our business involves risk associated with handling hazardous and other dangerous materials.

Risks Related to the Securities Markets and Investment in our Securities.

- Our shares of common stock are listed on the Nasdaq Capital Market, but we cannot guarantee that we will be able to comply with the continued listing standards or satisfy the continued listing standards going forward.
- The sale of a substantial number of shares of our common stock into the market may cause substantial dilution to our existing stockholders and the sale, actual or anticipated, of a substantial number of shares of common stock could cause the price of our common stock to decline.
- The trading price of our common stock has been and is likely to continue to be volatile.
- We have never paid dividends and we do not anticipate paying dividends in the future.
- The ownership of our common stock may become concentrated among a small number of stockholders.
- If we are unable to implement and maintain effective internal control over financial reporting in the future, investors may lose confidence in the accuracy and completeness of our financial reports and the trading price of our common stock may be negatively affected.
- The requirements of being a public company may strain our resources, result in litigation, and divert management's attention.
- Our Stockholder Rights Agreement, the anti-takeover provisions in our governing documents and Delaware law could delay or prevent a change in control which could reduce the market price of our common stock.
- Our Amended and Restated Certificate of Incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders.
- If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, the price of our common stock and trading volume could decline.

Purchasing shares of common stock is an investment in our securities and involves a high degree of risk and uncertainty. You should carefully consider the following information about these risks and uncertainties, together with the other information contained in this Annual Report on Form 10-K for the year ended December 31, 2023, before purchasing our securities. If any of the following risks and uncertainties actually occur, our business, financial condition and results of operations may suffer. In that case, the market price of our common stock could decline, and you may lose part or all of your investment in our Company. Additional risks and uncertainties of which we are not presently aware or that we currently believe are immaterial may also harm our business and results of operations.

Risks Relating to our Business

We have a history of operating losses, and, as such, an investor cannot assess our profitability or performance based on past results.

Since December 2015, our business has primarily focused on the development of novel therapeutics for the treatment of breast cancer and other breast conditions. Because of our limited operating history, particularly in the area of pharmaceutical development, our revenue and income potential is uncertain and cannot be based on prior results. Any evaluation of our business and prospects must be considered in light of these factors and the risks and uncertainties often encountered by companies in the development stage. Some of these risks and uncertainties include our ability to:

- commence, execute and obtain successful results from our clinical studies;
- obtain regulatory approvals in the U.S. and elsewhere for our pharmaceuticals we are developing;
- work with contract manufacturers to produce our pharmaceuticals under development in clinical and commercial quantities on acceptable terms and in accordance with required standards;
- respond effectively to competition;
- manage our growth in operations;
- respond to changes in applicable government regulations and legislation;
- access additional capital when required;
- execute and successfully integrate strategic transactions, including potential acquisitions or investments; and
- attract and retain key personnel.

We have not established sources of ongoing revenue to cover operating costs and allow us to continue as a going concern.

Although we believe we have sufficient capital resources to fund our operations for at least the next 12 months based on our current business plan, our business plan may change and may require greater expenditures of capital than currently anticipated, in particular, due to expenditures relating to strategic transactions. We have not yet established an ongoing source of revenue sufficient to cover operating costs and allow us to continue as a going concern. Our ability to continue as a going concern is dependent on obtaining adequate capital to fund operating losses until we become profitable. If we are unable to obtain adequate capital on reasonable terms, if at all, including due to macroeconomic factors, such as high interest rates, the inflationary environment, recessionary fears and instability in financial institutions, we may be unable to develop and commercialize our product offerings or increase our geographic reach and we could be forced to cease operations.

We will need to raise substantial additional capital in the future to fund our operations and we may be unable to raise such funds when needed and on acceptable terms.

For the year ended December 31, 2023, we incurred a net loss of approximately $30.1 million, and we had an accumulated deficit of approximately $186.3 million since inception. As of December 31, 2023, we had cash and cash equivalents of approximately $88.5 million. Because we have no current sources of revenue, we expect that we will need to raise capital again in the future to continue to fund our operations. When we elect to raise additional funds or when additional funds are required, we may raise such funds through public or private equity offerings, debt financings, corporate collaboration and licensing arrangements or other financing alternatives. These financing arrangements may not be available on acceptable terms, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may be prevented from developing our pharmaceutical candidates, pursuing acquisitions, and investing in other companies, including as a sponsor or investor in special purpose acquisition companies, licensing, development and commercialization efforts, and our ability to continue our operations, generate revenues, and achieve or sustain profitability may be substantially harmed. We currently have fewer than five million shares of common stock authorized that are not reserved for specific purposes. Although we proposed to our stockholders, at our 2021 and 2022 annual stockholders' meetings and at a special meeting of stockholders held in September 2021, that our amended and restated certificate of incorporation, as amended, be further amended to add additional authorized shares for various potential purposes, including potential capital raising transactions, our stockholders did not approve such proposals and may not approve a similar proposal in the future. A lack of authorized shares may limit our ability to raise capital when needed.

If we raise additional funds by issuing equity securities, our stockholders will experience dilution. Debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any debt

financing or additional equity, including securities convertible into or exercisable for equity securities, that we raise may contain terms, such as liquidation, conversion and other preferences, that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary for us to relinquish valuable rights to our technologies, future revenue streams or product candidates or to grant licenses on terms that may not be favorable to us. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, our business, operating results, financial condition and prospects could be materially and adversely affected, and we may be unable to continue our operations.

We may expend our capital resources in ways that you do not agree or that do not produce stockholder value.

We intend to use our capital resources to execute on our business plan, which may include acquiring or in-licensing programs and may also include the internal development of additional programs that may or may not be related to oncology. We may also use our capital resources to invest directly or indirectly in business opportunities in healthcare or other industries, including through purchases of equity in other companies, such as our investment in Dynamic Cell Therapies, Inc. (DCT). These investments may be in special purpose acquisition companies, including either as a sponsor or as an equity investor. Our business plan may evolve to require more capital resources than currently contemplated either because our existing programs progress more quickly or at a greater cost than currently anticipated or because we may add additional programs. Stockholders may not agree with the ways in which we expend our capital resources and our capital deployment activities may not lead to increases in stockholder value.

We have a history of operating losses, and we expect to continue to incur losses in the future.

We have a limited operating history and have incurred net losses each year. Our net operating loss for the year ended December 31, 2023, was approximately $30.1 million. We will continue to incur further losses in connection with research and development costs for development of our programs, including ongoing and additional clinical studies.

Any products we may develop may never achieve significant commercial market acceptance.

We may not succeed in achieving commercial market acceptance of any of our products. In order to gain market acceptance for the drugs under development, we will need to demonstrate to physicians and other healthcare professionals the benefits of these therapies, including the clinical and economic application for their particular practice, the efficacy and safety and potential advantages compared to alternative therapies. Many physicians and healthcare professionals may be hesitant to introduce new services or techniques into their practice for many reasons, including lack of time and resources, the learning curve associated with the adoption of such new services or techniques into already established procedures, the product's cost, convenience and ease of administration, the then-current standard of care, the strength of marketing and distribution support and the uncertainty of the applicability or reliability of the results of a new product. In addition, the availability of full or even partial payment for our products, whether by third party payors (e.g., insurance companies), by government payors or the patients themselves, will likely heavily influence physicians' decisions to recommend or use our products.

We may be unable to establish sales, marketing and commercial supply capabilities.

We do not currently have, nor have we ever had, commercial pharmaceutical sales and marketing capabilities. If any of our product candidates become approved, we would need to build these capabilities in order to commercialize our approved product candidates. The process of establishing commercial capabilities will be expensive and time consuming, and may not be successful. Even if we are successful in building these capabilities, we may not be successful in commercializing any of our product candidates.

The loss of the services of our Chief Executive Officer could adversely affect our business.

Our success is dependent in large part upon our ability to execute our business plan, manufacture our pharmaceutical drugs and attract and retain highly skilled professional personnel. In particular, due to the relatively early stage of our business, our future success is highly dependent on the services of Steven C. Quay, our Chief Executive Officer and founder, who provides much of the necessary experience to execute our business plan.

Our acquisitions of, collaborations with, licenses with and investments in, other businesses may not yield expected benefits and our inability to successfully integrate these transactions may negatively impact our business, financial condition, and results of operations.

We anticipate that we will make acquisitions of, collaborations with, licenses with or investments in businesses in the future. We may not realize the anticipated benefits, or any benefits, from these transactions. If we fail to properly evaluate, complete and execute acquisitions, our business may be seriously harmed and our stock price may decline. For us to realize the benefits of future transactions, we must successfully integrate the acquired businesses with ours. Some of the challenges to successful integration include:

- unanticipated costs or liabilities resulting from our acquisitions;

- inability to retain key employees from acquired businesses;
- difficulties integrating acquired operations, personnel, and technologies;
- diversion of management attention from existing business operations and strategy;
- diversion of resources that are needed in other parts of our business;
- potential write-offs of acquired assets;
- inability to maintain relationship partners of the acquired business;
- potential financial and credit risks associated with the acquired business;
- the need to implement controls, procedures, and policies at the acquired company;
- the need to comply with additional laws and regulations applicable to the acquired business; and
- the indirect tax of any such acquisitions.

Our failure to address these risks or other problems encountered in connection with our past or future acquisitions and other transactions, including our investment in DCT, have in the past and could in the future cause us to fail to realize the anticipated benefits of such acquisitions and transactions, and result in higher than expected costs, the recording of asset impairment or restructuring charges and other actions which could negatively impact our business, financial condition, results of operations and our ability to execute on our strategic plan. For example, we incurred a $3.0 million impairment charge for the year ended December 31, 2023 in connection with our investment in DCT.

We may experience difficulty in locating, attracting and retaining experienced and qualified personnel, which could adversely affect our business.

We will need to attract, retain, and motivate experienced clinical development and other personnel, particularly in the greater Seattle area as we expand our pharmaceutical development activities. Personnel with the required skills and experience may be scarce or may not be available at all in this geographic region. In addition, competition for these skilled personnel is intense and recruiting and retaining skilled employees is difficult, particularly for a development-stage Company such as ours. If we are unable to attract and retain qualified personnel, our development activities may be adversely affected. Even if we are successful in identifying and attracting qualified employees, recent market changes, including the labor shortage, and high inflation have increased employee-related costs substantially. As a result, our operating expenses may continue to increase in the current market environment.

Compounds and methods that appear promising in research and development may fail to reach later stages of development for a number of reasons, including, among others, that clinical trials may take longer to complete than expected or may not be completed at all, and interim, top-line or preliminary clinical trial data reports may ultimately differ from actual results once data are more fully evaluated.

Successful development of pharmaceutical products is highly uncertain and obtaining regulatory approval to market drugs is expensive, difficult, and speculative. Compounds that appear promising in research and development may fail to reach later stages of development for several reasons, including, but not limited to:

- an unacceptable safety profile;
- lack of efficacy;
- delay or failure in obtaining necessary U.S. and international regulatory approvals, or the imposition of a partial or full regulatory hold on a clinical trial;
- difficulties in formulating a compound, scaling the manufacturing process, timely attaining process validation for particular drug products, and completing manufacturing to support clinical studies;
- pricing or reimbursement issues or other factors that may make the product uneconomical to commercialize;
- production problems, such as the inability to obtain raw materials or supplies satisfying acceptable standards for the manufacture of our products;
- equipment obsolescence, malfunctions or failures, product quality/contamination problems or changes in regulations requiring manufacturing modifications;
- inefficient cost structure of a compound, finished drug, or device compared to alternative treatments;
- obstacles resulting from proprietary rights held by others, such as patent rights for a particular compound;

- lower than anticipated rates of patient enrollment as a result of factors, such as the number of patients with the relevant conditions, the proximity of patients to clinical testing centers, perceived cost/benefit of participating in the study, eligibility criteria for tests, patient insurance approvals of trial participation, and competition with other clinical testing programs;
- nonclinical or clinical testing requiring significantly more time than expected resources or expertise than originally expected and inadequate financing, which could cause clinical trials to be delayed or terminated;
- failure of clinical testing to show potential products to be safe and efficacious, and failure to demonstrate desired safety and efficacy characteristics in human clinical trials;
- suspension of a clinical trial at any time by us, an applicable collaboration partner or a regulatory authority on the basis that the participants are being exposed to unacceptable health risks or for other reasons;
- delays in reaching or failing to reach agreement on acceptable terms with manufacturers or prospective Contract Research Organizations (CROs) and trial sites; and
- failure of third parties, such as CROs, academic institutions, collaborators, cooperative groups, and/or investigator sponsors, to conduct, oversee, and monitor clinical trials and results.

In addition, from time to time we expect to report interim, top-line or "preliminary" data for clinical trials, including for example the results reported in 2021 for our neoadjuvant or "window of opportunity" Phase 2 study of (Z)-endoxifen. Such data are based on a preliminary analysis of then-available efficacy and safety data, and such findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. Interim, top-line or preliminary data are based on important assumptions, estimations, calculations and information then available to us to the extent we have had, at the time of such reporting, an opportunity to fully and carefully evaluate such information in light of all surrounding facts, circumstances, recommendations and analyses. As a result, interim, top-line or "preliminary" results may differ from future/final results, or different conclusions or considerations may qualify such results once existing data have been more fully evaluated. In addition, third parties, including regulatory agencies, may not accept or agree with our assumptions, estimations, calculations or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular compound and our business generally.

If the development of our products is delayed or fails, or if top-line or preliminary clinical trial data reported differ from actual results, our development costs may increase and our ability to commercialize our products may be harmed, which could harm our business, financial condition, operating results or prospects.

We may not obtain or maintain the regulatory approvals required to develop or commercialize some or all of our products.

We are subject to rigorous and extensive regulation by the FDA in the U.S. and by comparable agencies in other jurisdictions, including the Europe Medicines Agency (EMA) in the European Union (E.U.), the United Kingdom's Medicines and Healthcare products Regulatory Agency and the Therapeutic Goods Administration (TGA) in Australia.

Our product candidates are currently in research or development, and we have not received marketing approval for our products. Our products may not be marketed in the U.S. until they have been approved by the FDA and may not be marketed in other jurisdictions until they have received approval from the appropriate foreign regulatory agencies. Each product candidate requires significant research, development and pre-clinical testing and extensive clinical investigation before submission of any regulatory application for marketing approval. As a result, the regulatory pathway for these products may be more complex and obtaining regulatory approvals may be more difficult.

Obtaining regulatory approval requires substantial time, effort and financial resources, and we may not be able to obtain approval of any of our products on a timely basis, or at all. The number, size, design, and focus of pre-clinical and clinical trials that will be required for approval by the FDA, the EMA, or any other foreign regulatory agency varies depending on the compound, the disease or condition that the products are designed to address and the regulations applicable to any particular products. Pre-clinical and clinical data can be interpreted in different ways, which could delay, limit or preclude regulatory approval. The FDA, the EMA, and other foreign regulatory agencies can delay, limit, or deny approval of a product for many reasons, including, but not limited to:
a product may not be shown to be safe or effective;

- the clinical and other benefits of a product may not outweigh its safety risks;
- clinical trial results may be negative or inconclusive, or adverse medical events may occur during a clinical trial;
- the results of clinical trials may not meet the level of statistical significance required by regulatory agencies for approval;
- regulatory agencies may interpret data from pre-clinical and clinical trials in different ways than we do;
- regulatory agencies may not approve the manufacturing process or determine that the manufacturing is not in accordance with current good manufacturing practices;

- a product may fail to comply with regulatory requirements; or
- regulatory agencies might change their approval policies or adopt new regulations.

If our products are not approved at all or quickly enough to provide net revenues to defray our operating expenses, our business, financial condition, operating results and prospects could be harmed.

We are developing our products for patients who are severely ill, and patient deaths that occur in our clinical trials could negatively impact our business even if such deaths are not shown to be related to our drugs.

We have enrolled patients in studies of our drug candidates who may die while enrolled in our studies. Patients in our clinical trials may also experience adverse outcomes following treatment with our drug candidates, including patient death. These adverse outcomes, even if unrelated to our drugs, could expose us to lawsuits and liabilities and could diminish our ability to obtain regulatory approval and/or achieve commercial acceptance for the related drug and our business could be materially harmed.

We are dependent on third party service providers for a number of critical operational activities including, in particular, for the manufacture and testing of our products and associated supply chain operations, as well as for clinical trial activities. Any failure or delay in these undertakings by third parties could harm our business.

Our business is dependent on the performance by third parties of their responsibilities under contractual relationships. In particular, we heavily rely on third parties for the manufacture and testing of our products. We do not have an internal analytical laboratory or manufacturing facilities to allow the testing or production of products in compliance with Good Manufacturing Practices (cGMP). As a result, we rely on third parties to supply us in a timely manner with manufactured product candidates. We may not be able to adequately manage and oversee the manufacturers we choose; they may not perform as agreed or they may terminate their agreements with us. In particular, we depend on third party manufacturers to conduct their operations in compliance with applicable requirements under current Good Laboratory Practices (GLP), cGMP, GCP or similar standards imposed by the U.S. and/or applicable foreign regulatory authorities, including the FDA and EMA. Any of these regulatory authorities may take action against a contract manufacturer who violates cGMP. Failure of our manufacturers to comply with FDA, EMA or other applicable regulations may cause us to curtail or stop the manufacture of such products until we obtain regulatory compliance.

We may not be able to obtain sufficient quantities of our products if we are unable to secure manufacturers when needed, or if our designated manufacturers do not have the capacity or otherwise fail to manufacture compounds according to our schedule and specifications or fail to comply with cGMP regulations. Furthermore, in order to ultimately obtain and maintain applicable regulatory approvals, any manufacturers we utilize are required to consistently produce the respective products in commercial quantities and of specified quality or execute fill-finish services on a repeated basis and document their ability to do so, which is referred to as process validation. In order to obtain and maintain regulatory approval of a compound, the applicable regulatory authority must consider the result of the applicable process validation to be satisfactory and must otherwise approve of the manufacturing process. Even if our compound manufacturing processes obtain regulatory approval and sufficient supply is available to complete clinical trials necessary for regulatory approval, there are no guarantees we will be able to supply the quantities necessary to affect a commercial launch of the applicable drug, or once launched, to satisfy ongoing demand. Any product shortage could also impair our ability to deliver contractually required supply quantities to applicable collaborators, as well as to complete any additional planned clinical trials.

We also rely on third party service providers for certain warehousing and transportation. With regard to the distribution of our drugs, we depend on third party distributors to act in accordance with Good Distribution Practice (GDP), and the distribution process and facilities are subject to continuing regulation by applicable regulatory authorities with respect to the distribution and storage of products.

In addition, we depend on medical institutions and CROs (together with their respective agents) to conduct clinical trials and associated activities in compliance with Good Clinical Practices (GCP) and data privacy standards such as defined under the Health Insurance Portability and Accountability Act (HIPAA), General Data Protection Regulation (GDPR) and UK GDPR, and in accordance with our timelines, expectations and requirements. We are substantially dependent on the organizations conducting our clinical trials. To the extent any such third parties are delayed in achieving or fail to meet our clinical trial enrollment expectations, fail to conduct our trials in accordance with GCP, patient and data privacy standards such as HIPAA or study protocol or otherwise take actions outside of our control or without our consent, our business may be harmed. Furthermore, we conduct clinical trials in foreign countries, subjecting us to additional risks and challenges, including, patient and data privacy standards, such as GDPR and UK GDPR and in particular, as a result of the engagement of foreign medical institutions and foreign CROs, who may be less experienced with regard to regulatory matters applicable to us and may have different standards of medical care.

With regard to certain of the foregoing clinical trial operations and stages in the manufacturing and distribution chain of our compounds, we rely on vendors. In most cases we use a primary vendor and have identified, in some cases, secondary vendors. In particular, our current business structure contemplates, at least in the foreseeable future, use of a primary commercial supplier for the (Z)-endoxifen drug substance. The use of primary vendors for core operational activities, such as, manufacturing, and the resulting

lack of diversification, exposes us to the risk of a material interruption in service related to these primary, outside vendors. As a result, our exposure to this concentration risk could harm our business.

We also rely on a third-party information technology vendor to oversee our information technology systems, including our mechanisms, controls, technologies, systems, and other processes designed to prevent or mitigate data loss, theft, misuse, or other security incidents or vulnerabilities affecting our data and to maintain a stable information technology environment. As a result, our cybersecurity systems and processes are dependent upon the performance of our information technology vendor.

Although we monitor the compliance of our third party service providers performing the aforementioned services, we cannot be certain that such service providers will consistently comply with applicable regulatory requirements or that they will otherwise timely satisfy their obligations to us. We and our third party service providers may be subject to inspections by FDA and other regulatory authorities. Any such failure by us or by our third party service providers to comply with applicable legal or regulatory requirements and/or any failure by us to monitor their services or to plan for and manage our short- and long-term requirements underlying such services could result in shortage of the required compound, delays in or cessation of clinical trials, failure to obtain or revocation of product approvals or authorizations, product recalls, withdrawal, administrative detention, seizure of products, suspension of an applicable wholesale distribution authorization, and/or distribution of products, operating restrictions, injunctions, suspension of licenses, other administrative or judicial sanctions (including warning or untitled letters, import alerts, civil penalties and/or criminal prosecution), and/or unanticipated related expenditures to resolve shortcomings.

Such consequences could have a significant impact on our business, financial condition, operating results, or prospects.

We may encounter delays in our clinical trials or may not be able to conduct our trials in a timely manner.

Clinical trials are expensive and subject to regulatory approvals. Potential trial delays may arise from, but are not limited to:

- supply chain disruptions, or lack of availability or increased costs of materials for our product candidates;
- outbreaks of disease, pandemics or epidemics, which could limit access to clinical trial sites, divert healthcare resources and limit the availability of medical facilities for our clinical trials;
- failure to obtain on a timely basis, or at all, approval from the applicable institutional review board or ethics committee to open a clinical study;
- lower than anticipated patient enrollment or delays in patient enrollment, including due to the size and nature of the patient population, existing conditions, patient eligibility criteria defined in the protocol, proximity of patients to trial sites, the design of the trial, our ability to recruit clinical trial investigators with the appropriate competencies and expertise, competing clinical trials for similar or alternate therapeutic treatments, clinicians' and patients' perception of a lack of benefit to enroll in the study for whatever reason, our ability to obtain and maintain patient consents and patients dropping out of the trial;
- delays in reaching agreements on acceptable terms with prospective CRO or vendors;
- failure of CROs or other third parties to effectively and timely monitor, oversee, and maintain the clinical trials;
- the imposition of partial or full clinical holds by FDA, or the pausing or termination of our clinical trials by institutional review boards or ethics committees;
- complying with design protocols of any applicable special protocol assessment we receive from the FDA;
- severe or unexpected drug-related side effects experienced by patients in clinical trials;
- availability of materials provided by third parties necessary to manufacture our product candidates; and
- changes in regulatory requirements, or additional regulatory requirements.

Our clinical trials may fail to demonstrate adequately the efficacy and safety of our product candidates, which would prevent or delay regulatory approval and commercialization.

Even if our clinical trials are completed as planned, we cannot be certain that their results will support our product candidate claims or that the FDA or foreign authorities will agree with our conclusions. Success in pre-clinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior trials and pre-clinical studies. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for the proposed indicated uses. If the FDA concludes that our clinical trials have failed to demonstrate safety and effectiveness, we would not receive FDA approval to market that product candidate in the U.S. for the indications sought. In addition, it could cause us to abandon the product candidate and might delay development of other product candidates. Any delay or termination of our clinical trials would delay or preclude the filing of any submissions with the FDA and, ultimately, our ability to commercialize our product

candidates and generate revenues. It is also possible that patients enrolled in clinical trials could experience adverse side effects that are not currently part of a product candidate's profile.

Our products and services may expose us to possible litigation and product liability claims.

Our business may expose us to potential product liability risks inherent in the testing, marketing, and processing personalized medical products, particularly those products and services we offered prior to shifting our focus on pharmaceutical development. Product liability risks may arise from, but are not limited to:

- death of severely ill patients participating in our studies; and
- adverse events related to drugs and therapies we are developing.

A successful product liability claim, or the costs and time commitment involved in defending against a product liability claim, could have a material adverse effect on our business. Regardless of the merit or outcome of a claim, it may result in decreased demand for our product candidates, reputational harm, withdrawal of clinical trial participants, investigations by regulators, withdrawal of prior governmental approvals, substantial monetary awards to patients, loss of revenue and the inability to commercialize our product candidates. Although we currently carry clinical trial insurance and product liability insurance which we believe to be reasonable, it may not be adequate to cover all liability that we may incur. An inability to renew our policies or to obtain sufficient insurance at an acceptable cost and on commercially desirable or reasonable terms, if at all, including due to a successful product liability claim, could prevent or inhibit the commercialization of our products.

Business disruptions, including natural disasters, severe weather and pandemics, could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations are based primarily in Seattle, Washington. These operations could be subject to power shortages, telecommunications failures, water shortages, floods, earthquakes, fires, extreme weather conditions, pandemics or epidemics and other natural or man-made disasters or business interruptions, for which we maintain customary insurance policies that we believe are appropriate. In addition, outbreaks of viruses, infectious diseases or pandemics, terrorist acts or acts of war, or geopolitical tensions, could cause damage or cause disruptions to us, our employees, facilities, contractors and collaborators, which could have a material adverse effect on our business, financial condition and results of operations. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. Our ability to manufacture clinical supplies of our product candidates could be disrupted if our suppliers are affected by any of the above events. We may have limited recourse against third parties if the non-compliance is due to factors outside of the manufacturer's control.

We maintain our cash at financial institutions, often in balances that exceed federally-insured limits. The failure of financial institutions could adversely affect our ability to pay our operational expenses or make other payments.

Our cash is held at banking institutions in non-interest-bearing and interest-bearing accounts in amounts that exceed the Federal Deposit Insurance Corporation (FDIC) insurance limits. If such banking institutions were to fail, we could lose all or a portion of those amounts held in excess of such insurance limitations. For example, the FDIC took control of Silicon Valley Bank on March 10, 2023. Although we did not have cash, cash equivalents or investments at SVB and the Federal Reserve subsequently announced that account holders would be made whole, the FDIC may not make all account holders whole in the event of future bank failures. In addition, even if account holders are ultimately made whole with respect to a future bank failure, account holders' access to their accounts and assets held in their accounts may be substantially delayed. Any material loss that we may experience in the future or inability for a material time period to access our cash and cash equivalents could have an adverse effect on our ability to pay our operational expenses or make other payments, which could adversely affect our business.

Our ability to use net operating loss carryforwards and research tax credits to reduce future tax payments may be limited or restricted.

We have generated significant net operating loss carryforwards (NOLs), and research and development tax credits (R&D credits) as a result of our incurrence of losses and our conduct of research activities since inception. We generally are able to carry NOLs and R&D credits forward to reduce our tax liability in future years. However, our ability to utilize the NOLs and R&D credits is subject to the rules of Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the Code), respectively. Those sections generally restrict the use of NOLs and R&D credits after an "ownership change." An ownership change occurs if, among other things, the stockholders (or specified groups of stockholders) who own or have owned, directly or indirectly, 5% or more of a corporation's common stock or are otherwise treated as 5% stockholders under Section 382 of the Code and the U.S. Treasury Department regulations promulgated thereunder increase their aggregate percentage ownership of that corporation's stock by more than 50 percentage points over the lowest percentage of the stock owned by these stockholders over the applicable testing period. In the event of an ownership change, Section 382 of the Code imposes an annual limitation on the amount of taxable income a

corporation may offset with NOL carry forwards and Section 383 of the Code imposes an annual limitation on the amount of tax a corporation may offset with business credit (including R&D credits) carryforwards.

We have experienced ownership changes in the past, and there can be no assurance that we will not experience ownership changes in the future. As a result, our NOLs and business credits (including R&D credits) may be subject to limitations, and we may be required to pay taxes earlier and in larger amounts than would be the case if our NOLs or R&D credits were freely usable.

If we, or our wholly-owned subsidiary, lose our ability to operate in Australia, or if our subsidiary is unable to benefit from the past or future R&D rebates available under current Australian regulations, our business and results of operations could be harmed.

Through our wholly-owned subsidiary in Australia, Atossa Genetics AUS Pty Ltd., we conduct certain R&D activities, including some of our clinical trials. Current Australian tax regulations provide for a R&D cash rebate on qualified R&D activities incurred in the country. The Australian R&D tax incentive program is a self-assessment program, and as such, the Australian Taxation Office (ATO) has the right to review our program and our related expenditures for a period of four years following the tax return filing date. If we are ineligible or unable to receive the anticipated cash rebate, if past rebates are determined to be ineligible upon an audit by the ATO, or if the Australian government significantly reduces or eliminates the rebate, our business and results of operations would be adversely affected.

Based on our evaluation of the ATO's taxpayer alert published in the fourth quarter of 2023, we believe that it is no longer reasonably assured that our full tax position would be sustained under an audit. Accordingly, we recorded a change in estimate that represents our estimate of the amount (inclusive of potential penalties) that no longer meets the reasonably assured threshold. We recorded an estimated accrued current liability of $1.8 million in our Consolidated Balance Sheet for the year ended December 31, 2023. The change in estimate also increased our R&D expenses by $1.4 million and G&A expenses by $0.4 million in the Consolidated Statement of Operations, for the year ended December 31, 2023. We may in the future be required to record additional changes in estimates, which could further increase our expenses and adversely affect our business and results of operations.

Additionally, due to the geographic distance from our headquarters, we may not be able to successfully monitor or conduct our clinical trials and R&D activities in Australia and develop or commercialize our drug candidates. We can provide no assurance that the results of any clinical trials that we conduct in Australia will be accepted by the FDA or other foreign authority. Furthermore, if we lose our ability to operate our subsidiary in Australia, our business and results of operations may be adversely affected.

Risks Related to our Intellectual Property

If we are not able to protect our proprietary technology, others could compete against us more directly, which would harm our business.

Our commercial success will depend, in part, on our ability to obtain additional patents and licenses and to protect our existing patent position, both in the U.S. and in other countries, for therapeutics and related technologies, processes, methods, compositions, and other inventions that we believe are patentable, all of which provide limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. As of February 2, 2024, we own or exclusively in-license and are pursuing 68 pending provisional and non-provisional patent applications (22 U.S. patent applications and 46 international patent applications) and 11 issued patents (four U.S. patents and seven international patents). We continue to evaluate the full range of our technologies and file new patent applications consistent with our evolving business goals.

Our ability to preserve our trade secrets, trademarks and other intellectual property rights is also important to our long-term success. Our success depends in part on obtaining patent protection for our products and processes, preserving trade secrets, patents, copyrights and trademarks, operating without infringing the proprietary rights of third parties, and acquiring licenses for technology or products. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and ability to establish or maintain profitability. Patents may also be issued to third parties, which could interfere with our ability to bring our therapeutics to market. As the patent landscape for products for breast disorders, including breast cancers, grows more crowded and becomes more complex we may find it more difficult to obtain patent protection for our products, including those related to (Z)-endoxifen.

The laws of some foreign countries do not protect our proprietary rights to the same extent as U.S. laws, and we may encounter significant problems in protecting our proprietary rights in these countries. Even in the U.S., the patent positions of diagnostic companies and pharmaceutical and biotechnology companies, including our patent position, are generally highly uncertain, particularly after the Supreme Court decisions *Mayo Collaborative Services v. Prometheus Laboratories*, 132 S. Ct. 1289 (2012), *Association for Molecular Pathology v. Myriad Therapeutics, Inc.*, 133 S. Ct. 2107 (2013), *Alice Corp. v. CLS Bank International*, 134 S. Ct. 2347 (2014), and *Amgen Inc. v. Sanofi,* 598 U.S. 594 (2023), and the Federal Circuit Court decisions *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 915 F.3d 743 (Fed. Cir. 2019). Our patent positions also involve complex legal and factual questions, for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in pharmaceutical and biotechnology companies' patents has emerged to date in the U.S. Furthermore, in the biotechnology and

pharmaceutical fields, courts frequently render opinions that may affect the patentability of certain inventions or discoveries, including opinions that may affect the patentability of methods for diagnostics, personalized medicine, and analysis and comparison of DNA and, therefore, any patents issued to us may be challenged and potentially invalidated or found ineligible. We will be able to protect our proprietary rights from unauthorized use by third-parties only to the extent that our proprietary technologies and any future tests and products are covered by valid and enforceable patents or are effectively maintained as trade secrets. In addition, our patent applications may never issue as patents, and the claims of any issued patents may not afford meaningful protection for our products, technology or tests.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- we or others were the first to make the inventions covered by each of our patent applications;
- we or others were the first to file patent applications for our claimed inventions;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies;
- any of our patent applications will result in issued patents;
- other parties will not challenge any patents issued to us;
- any of our patents will be valid or enforceable;
- any patents issued to us and collaborators will provide a basis for commercially viable therapeutics, will provide us with any competitive advantages or will not be challenged by third parties; or
- the patents of others will not have an adverse effect on our business.

If a third party files a patent application with claims to a drug we have discovered or developed, a derivation proceeding may be initiated regarding competing patent applications. If a derivation proceeding is initiated, we may not prevail in the derivation proceeding. If the other party prevails in the derivation proceeding, we may be precluded from commercializing our products, or may be required to seek a license. A license may not be available to us on commercially acceptable terms, if at all.

On August 30, 2023, we announced that Intas Pharmaceuticals LTD. (the "Petitioner") had filed a Petition for Post Grant Review ("PGR") with the U.S. Patent and Trademark Office (the "PGR Petition") relating to one of our issued patents (U.S. Patent No. 11,572,334), titled, "Methods for Making and Using Endoxifen," (the "Patent"). We are actively contesting the PGR Petition and believe that the Patent was properly granted and is valid and enforceable. However, there can be no assurance that we will prevail in contesting the PGR Petition. If we do prevail in contesting the PGR Petition, the Petitioner will be estopped from raising arguments in subsequent litigation that were raised, or reasonably could have been raised, during the PGR proceedings.

On September 28, 2023, the Indian Pharmaceutical Alliance (the “Opponent”) filed a Pre-Grant Opposition (the “Opposition”) against our pending Indian Patent Application No. 202017009369, titled, “Methods of Making and Using Endoxifen,” (the “Patent Application”). We intend to assess the value of the Patent Application to our current and future business opportunities, and if of sufficient value, we will consider contesting the Opposition. However, there can be no assurance that we will contest the Opposition and that if we choose to do so, that we would prevail in contesting the Opposition.

Any litigation proceedings relating to our proprietary technology may result in unsuccessful outcomes for us and, even if such proceedings result in successful outcomes for us, the proceedings may result in substantial costs and distract our management and other employees. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Finally, we may not be able to prevent, alone or with the support of our licensors, if any, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the U.S.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

United States Patent and Trademark Office (USPTO) and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent process. Periodic maintenance fees, renewal fees, annuity fees, and various other governmental fees on any issued patents and/or applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ outside firms and rely on our outside counsel to pay these fees. While an inadvertent lapse

may sometimes be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in 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 enter the market earlier than should otherwise have been the case, which would have a material adverse effect on our business.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on our intellectual property, particularly on obtaining and enforcing patents. Obtaining and enforcing patents in the biotechnology and pharmaceutical industries involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. For the past several years, the U.S. has conducted proceedings involving post-issuance patent review procedures, such as *inter partes* review (IPR), and post-grant review and covered business methods. These proceedings are conducted before the Patent Trial and Appeal Board (PTAB), of the USPTO. Each proceeding has different eligibility criteria and different patentability challenges that can be raised. In this regard, the IPR process permits any person (except a party who has been litigating the patent for more than a year) to challenge the validity of a U.S. patent on the grounds that it was anticipated or made obvious by prior art consisting of patents or printed publications. As a result, non-practicing entities associated with hedge funds, pharmaceutical companies who may be our competitors and others have challenged certain valuable pharmaceutical U.S. patents based on prior art through the IPR process. A decision in such a proceeding adverse to our interests could result in the loss of valuable patent rights, which would have a material adverse effect on our business, financial condition, results of operations and growth prospects. For example, there is a PGR Petition relating to one of our issued patents, see Note 13. Any potential future changes to the U.S. patent system could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and growth prospects. Further, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In particular, on March 20, 2012, the U.S. Supreme Court issued the *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* decision, holding that several claims drawn to measuring drug metabolite levels from patient samples were not patentable subject matter. The full impact of the *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* decision on diagnostic and certain method claims is uncertain. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. The standards that courts use to interpret patents are not always applied predictably or uniformly and may evolve, particularly as new technologies develop. In addition, changes to patent laws in the U.S. or other countries may be applied retroactively to affect the validity, enforceability, or term of our patent. For example, the U.S. Supreme Court has modified some legal standards applied by the USPTO in examination of U.S. patent applications, which may decrease the likelihood that we will be able to obtain patents and may increase the likelihood of challenges to patents we obtain or license.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our products in all countries throughout the world would be prohibitively expensive. In addition, the laws of some foreign countries do not protect intellectual property rights in the same manner and to the same extent as laws in the U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S. For example, the Indian Pharmaceutical Alliance filed a Pre-Grant Opposition against our pending Indian Patent Application. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement of such patent protection is not as strong as that in the U.S. These products may compete with our products and services, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing with our products.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products and services in violation of our proprietary rights generally. Proceedings to enforce our patent 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 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. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop.

Our current patent portfolio may not include all patent rights needed for the full development and commercialization of our products. We cannot be sure that patent rights we may need in the future will be available for license on commercially reasonable terms, or at all.

We may be unable to obtain any licenses or other rights to patents, technology, or know-how from third parties necessary to conduct our business and such licenses, if available at all, may not be available on commercially reasonable terms. Others may seek licenses from us for other technology we use or intend to use. Any failure to obtain such licenses could delay or prevent us from developing or commercializing our proposed products, which would harm our business. We may not be able to secure such a license on acceptable terms. Litigation or patent derivation proceedings may need to be brought against third parties, as discussed below, to enforce any of our patents or other proprietary rights, or to determine the scope and validity or enforceability of the proprietary rights of such third parties.

Third party claims alleging intellectual property infringement may prevent or delay our drug discovery and development efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties, including the intellectual property rights of competitors. There is a substantial amount of litigation, both within and outside the U.S., involving patents and other intellectual property rights in the medical device and pharmaceutical fields, as well as administrative proceedings for challenging patents, including *inter partes* review, post-grant review, derivation, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in various foreign jurisdictions, for example, the PGR Petition and the Indian Pharmaceutical Alliance Pre-Grant Opposition. These procedures bring uncertainty to the possibility of challenges to our patents in the future, including those patents perceived by our competitors as blocking entry into the market for their products, and the outcome of such challenges. Any such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our drug product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art and that prior art that was cited during prosecution, but not relied on by the patent examiner, will not be revisited. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our products. As the medical device, biotechnology, and pharmaceutical industries expand and more patents are issued, the risk increases that our activities related to our products may give rise to claims of infringement of the patent rights of others.

We cannot assure you that our current or future products will not infringe on existing or future patents. We may not be aware of patents that have already been issued that a third party might assert are infringed by one of our current or future products.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture, or methods for treatment related to the use or manufacture of our products. Because patent applications can take many years to issue and may be confidential for eighteen months or more after filing, there may be currently pending third party patent applications which may later result in issued patents that our products may infringe, or which such third parties claim are infringed by our products and services.

Parties making claims against us for infringement or misappropriation of their intellectual property rights may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our products. Defense of these claims, regardless of their merit, would involve substantial expenses and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us by a third party, we may have to (i) pay substantial damages, including treble damages and attorneys' fees if we are found to have willfully infringed the third party's patents; (ii) obtain one or more licenses from the third-party; (iii) pay royalties to the third party; or (iv) redesign any infringing products. Redesigning any infringing products may be impossible or require substantial time and monetary expenditure. Further, we cannot predict whether any required license would be available at all or whether it would be available on commercially reasonable terms. In the event that we could not obtain a license, we may be unable to further develop and commercialize our products, which could harm our business significantly. Even if we were able to obtain a license, the rights may be nonexclusive, which would give our competitors access to the same intellectual property.

In addition to infringement claims against us, if third parties have prepared and filed patent applications in the U.S. that also claim technology related to our products, we may have to participate in derivation proceedings in the USPTO to determine the priority of invention. We may also become involved in similar proceedings in the patent offices in other jurisdictions regarding our intellectual property rights with respect to our products and technology.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other diagnostic, medical device or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise improperly used or disclosed confidential information of these third parties or our employees' former employers. Further, we may be subject to ownership disputes in the future

arising, for example, from conflicting obligations of consultants or others who are involved in developing our products. We may also be subject to claims that former employees, consultants, independent contractors, collaborators or other third parties have an ownership interest in our patents or other intellectual property. Litigation may be necessary to defend against these and other claims challenging our right to and use of confidential and proprietary information. If we fail in defending any such claims, in addition to paying monetary damages, we may lose our rights therein. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

We rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce, and any other elements of our discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect. We require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology, to enter into confidentiality agreements. However, we cannot be certain that all such confidentiality agreements have been duly executed, that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret.

Risks Related to Our Industry

Legislative or regulatory reforms may make it more difficult and costly for us to obtain regulatory approval of our product candidates and to manufacture, market and distribute our products after approval is obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory approval, manufacture and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of future products. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be. Similar changes and revisions can also occur in foreign countries.

For example, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which, may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently cleared products on a timely basis. Any change in the laws or regulations that govern the clearance and approval processes relating to our current and future products could make it more difficult and costly to obtain clearance or approval for new products, or to produce, market and distribute existing products. Significant delays in receiving clearance or approval, or the failure to receive clearance or approval for our new products would have an adverse effect on our ability to expand our business.

Our inadvertent or unintentional failure to comply with the complex government regulations concerning patients' privacy, data subjects, and of medical records could subject us to fines and adversely affect our reputation.

Federal privacy regulations, among other things, restrict our ability to use or disclose protected health information in the form of patient-identifiable laboratory data, without written patient authorization, for purposes other than payment, treatment, or healthcare operations as defined under HIPAA, except for disclosures for various public policy purposes and other permitted purposes outlined in the privacy regulations. Applicable privacy regulations provide for significant fines and other penalties for wrongful use or disclosure of protected health information, including potential civil and criminal fines and penalties.

We intend to implement policies and practices that we believe will make us compliant with applicable privacy regulations. However, the documentation and process requirements of applicable privacy regulations are complex and subject to interpretation. Failure to comply with applicable privacy regulations could subject us to sanctions or penalties, loss of business, and negative publicity.

The HIPAA privacy regulations establish a “floor” of minimum protection for patients as to their medical information and do not supersede state laws that are more stringent. Therefore, we are required to comply with both HIPAA privacy regulations and state privacy laws, which vary from state to state, impose a range of obligations, and are often more restrictive than HIPAA. The failure to comply with applicable privacy laws could subject us to regulatory actions, including significant fines or penalties, and to private actions by patients, as well as to adverse publicity and possible loss of business. In addition, federal and state laws and judicial

decisions provide individuals with various rights for violating the privacy of their medical information by healthcare providers such as us.

In addition to HIPAA, failing to take appropriate steps to keep consumers' personal information secure may result in the Federal Trade Commission (FTC) bringing a claim that a company has engaged in unfair or deceptive acts or practices in or affecting commerce, in violation of Section 5(a) of the Federal Trade Commission Act, (FTCA). The FTC requires companies to have reasonable and appropriate security measures, based on factors such as data sensitivity and volume, complexity of the business and available resources. Health information is considered sensitive data that merits stronger safeguards. There are also state consumer protection laws, which may be modeled on the FTCA, that can provide state-law causes of action for allegedly unfair or deceptive acts or practices, among other things.

While we may not be presently subject to any comprehensive state privacy laws (e.g., the California Consumer Privacy Act as amended by the California Privacy Rights Act) as a covered entity due to applicability and exemption considerations, the legal landscape is rapidly changing. If we were to become subject to these laws, we would be required to comply with the demanding obligations they impose with respect to personal information. Furthermore, if our service providers or partners are subject to such laws, we may have contractual obligations relating to these requirements.

The collection and processing of personal data, including personal health data related to individuals in the E.U. regardless of citizenship or residence is governed by the provisions of the General Data Protection Regulation 2016/679 (GDPR) which provides for significant penalties for noncompliance. GDPR supersedes the Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995. The GDPR regulates (i) the processing of personal data carried out in the context of the activities of a company established in the E.U.; and (ii) the processing of personal data carried out by a company not established in the E.U. where such processing relates to (a) the offering of goods or services to data subjects who are in the E.U. or (b) the monitoring of the behavior of data subjects who are in the E.U. The GDPR imposes a number of requirements, including an obligation to rely on a legal basis (such as the consent of individuals to whom the personal data relates), the information that must be provided to the individuals, notification obligations to the competent national data protection authorities, and the security and confidentiality of the personal data. E.U. Member States may also impose additional requirements in relation to health, genetic and biometric data through their national implementing legislation.

Further, from January 1, 2021, in addition to the GDPR, companies have to comply with the UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR, i.e., fines up to the greater of £17.5 million or 4% of global turnover. The European Commission has adopted an adequacy decision in favor of the UK, enabling personal data transfers from E.U. member states to the UK without additional safeguards. However, the UK adequacy decision will automatically expire in June 2025 unless the European Commission re-assesses and renews/ extends that decision and remains under review (and may be modified or revoked) by the Commission during this period. In addition, transfers of personal data from the UK to other countries, including the EEA, are subject to specific transfer rules under the UK regime. Personal data may freely flow from the UK to the EEA, since the EEA is deemed to have an adequate data protection level for purposes of the UK regime. These UK international transfer rules broadly mirror the E.U. GDPR rules. With regard to the transfer of personal data from the UK to the U.S., from October 12, 2023, businesses in the UK can start to transfer personal data to U.S. organizations certified to the "UK Extension to the EU-US Data Privacy Framework" (UK Extension) under the UK GDPR, without the need for further safeguards. On March 21, 2022, the international data transfer agreement (IDTA) and the international data transfer addendum to the EC's standard contractual clauses for international data transfers (Addendum), and a document setting out transitional provisions, came into force and replaced the prior EU SCCs for purposes of the UK regime. However, the transitional provisions, adopted with the IDTA and the Addendum, provide that contracts concluded on or before September 21, 2022 on the basis of any prior EU SCCs continue to provide appropriate safeguards for the purpose of the UK's regime until March 21, 2024, provided that the processing operations that are the subject matter of the contract remain unchanged and appropriate safeguards can be ensured. The relationship between the UK and other jurisdictions in relation to certain aspects of data protection law remains unclear, and it is unclear how UK data protection laws and regulations will develop in the medium to longer term, and how personal data transfers to and from the UK will be regulated in the long term. These changes may lead to additional costs and increase our overall risk exposure.

Failure to comply with the requirements of GDPR and/or UK GDPR, and the related national data protection laws of the E.U. Member States or the UK may result in fines and other administrative penalties, litigation, government enforcement actions (which could include civil and/or criminal penalties), and harm our business. Moreover, patients about whom we or our partners obtain information, as well as the providers who share this information with us, may have contractual rights that may limit our ability to use this information. Claims that we have violated patient's or any individual's rights or breached our contractual obligations, even if ultimately we are not found liable, could be expensive and time-consuming to defend, and could result in adverse publicity and harm our business.

If we experience incidents in our information technology systems, and if we experience a significant disruption in our information technology systems or breaches of data security, our business could be adversely affected.

We rely on information technology systems to keep financial records, maintain corporate records, communicate with staff and external parties and operate other critical functions. Our information technology systems are potentially vulnerable to disruption due to

breakdown, malicious intrusion and computer viruses or other disruptive events, including, but not limited to, natural disasters, terrorist attacks, utility outages, theft, viruses, phishing, malware, design defects, human error and complications encountered as existing systems are maintained, repaired, replace or upgraded. If we were to experience a prolonged system disruption in our information technology systems or those of certain of our vendors, it could negatively impact our ability to serve our customers, which could adversely impact our business. Although we maintain offsite back-ups of our data, if operations at our facilities were disrupted, it may cause a material disruption in our business if we are not capable of restoring function on an acceptable time frame. In addition, our information technology systems are potentially vulnerable to data security breaches — whether by employees or others — which may expose data (including sensitive data) to unauthorized persons. Such data security breaches could lead to the loss of trade secrets or other intellectual property or could lead to the public exposure of personal data (including sensitive personal data) of our employees, customers and others, any of which could have a material adverse effect on our business, reputation, financial condition and results of operations. In addition, because we collect, store and transmit confidential information in digital form, we, and third parties who we work with, are or may become subject to numerous domestic and foreign laws, regulations, and standards relating to privacy, data protection, and data security, the scope of which is changing, subject to differing applications and interpretations, and may be inconsistent among countries, or conflict with other rules. Any data breaches disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, including state data protection regulations (including data breach notification statutes and the California Consumer Privacy Act), the E.U. GDPR and the UK GDPR, and other regulations, the violation of which could result in significant penalties. In addition, these breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above.

Additionally, we are or may become subject to contractual obligations related to privacy, data protection, and data security. Our obligations may also change or expand as our business grows. The actual or perceived failure by us or third parties related to us to comply with such laws, regulations and obligations could increase our compliance and operational costs, expose us to regulatory scrutiny, actions, fines and penalties, result in reputational harm, lead to a loss of customers, result in litigation and liability, and otherwise cause a material adverse effect on our business, financial condition, and results of operations.

Although we utilize various procedures and controls to mitigate our exposure to these risks, cyber attacks and other cyber events are evolving, unpredictable and increasing in sophistication. Moreover, the information technology systems of our third-party partners, including suppliers, manufacturers, service providers and others on which we rely, may be subject to similar risks. We have cybersecurity insurance coverage in the event we become subject to various cyber attacks, however, we cannot ensure that it will be sufficient to cover any particular losses we may experience. Any cyber incident could have a material adverse effect on our business, financial condition and results of operations.

The failure to comply with complex federal and state laws and regulations related to submission of claims for services could result in significant monetary damages and penalties and exclusion from the Medicare and Medicaid programs.

We are subject to extensive federal and state laws and regulations relating to the submission of claims for payment for services, including those that relate to coverage of services under Medicare, Medicaid, and other governmental healthcare programs, the amounts that may be billed for services, and to whom claims for services may be submitted, such as billing Medicare as the secondary, rather than the primary, payor. The failure to comply with applicable laws and regulations, for example, enrollment in the Medicare Provider Enrollment, Chain and Ownership System, could result in our inability to receive payment for our services or attempts by third party payors, such as Medicare and Medicaid, to recover payments from us that we have already received. Submission of claims in violation of certain statutory or regulatory requirements can result in penalties, including civil money penalties of up to $10,000 for each item or service billed to Medicare in violation of the legal requirement, and exclusion from participation in Medicare and Medicaid. Government authorities may also assert that violations of laws and regulations related to submission of claims violate the federal False Claims Act or other laws related to fraud and abuse, including submission of claims for services that were not medically necessary. The Company will be generally dependent on independent physicians to determine when its services are medically necessary for a particular patient. Nevertheless, we could be adversely affected if it were determined that the services we provided were not medically necessary and not reimbursable, particularly if it were asserted that we contributed to the physician's referrals of unnecessary services. It is also possible that the government could attempt to hold us liable under fraud and abuse laws for improper claims submitted by us if it were found that we knowingly participated in the arrangement that resulted in submission of the improper claims.

In addition to the Patient Protection and Affordable Care Act (the PPACA), the effect of which cannot presently be quantified, various healthcare reform proposals have also emerged from federal and state governments. Changes in healthcare policy could adversely affect our business.

We cannot predict whether future healthcare initiatives will be implemented at the federal or state level or in countries outside of the U.S. in which we may do business, or the effect any future legislation or regulation will have on us. The taxes imposed by any new federal legislation and the expansion in government's effect on the U.S. healthcare industry, including the Inflation Reduction Act enacted in August 2022, may result in decreased profits to us, lower reimbursements by payors for our products or reduced medical procedure volumes, all of which may adversely affect our business, financial condition and results of operations.

We face significant competition from other biotechnology and pharmaceutical companies.

Our product candidates face, and will continue to face, intense competition from large pharmaceutical and biotechnology companies, as well as academic and research institutions. We compete in an industry that is characterized by (i) rapid technological change, (ii) evolving industry standards, (iii) emerging competition and (iv) new product introductions. Our competitors have existing products that compete with our product candidates and they may develop and commercialize additional products that will compete with our product candidates. Because competing companies and institutions may have greater financial resources than us, they may be able to provide broader services and product lines, make greater investments in research and development or carry on broader R&D initiatives. Our competitors also have greater development capabilities than we do and have substantially greater experience in undertaking preclinical and clinical testing of product candidates, obtaining regulatory approvals and manufacturing and marketing pharmaceutical products.

Even if we obtain regulatory approval for our products, we may not be the first to market and that may affect the price or demand for our potential products. Existing or future competing products may provide greater therapeutic convenience or clinical or other benefits for a specific indication, or fewer side effects, than our potential products or may offer comparable performance at a lower cost. Additionally, the availability and price of our competitors' products could limit the demand and the price we are able to charge for our potential products thereby reducing or eliminating our commercial opportunity. We may not be able to implement our business plan if the acceptance of our potential products is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to our potential products, or if physicians switch to other new products or choose to reserve our potential products. Additionally, a competitor could obtain orphan product exclusivity from the FDA with respect to such competitor's product, which may prevent us from obtaining approval from the FDA for such potential products for the same indication for a period of time. If our potential products fail to capture and maintain market share, we may not achieve sufficient product revenues and our business will suffer.

Our employees and third party partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employees' or our third party partners' fraud or other misconduct. Misconduct by our employees or partners could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. Employee and third party misconduct could involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our business and our reputation. It is not always possible to identify and deter such misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a material adverse effect on our business, financial condition and results of operations, and result in the imposition of significant fines or other sanctions against us.

Our business involves risk associated with handling hazardous and other dangerous materials.

Our research and development activities involve the controlled use of hazardous materials, chemicals, human blood and tissue, animal blood and blood products, animal tissue, and biological waste. The risk of accidental contamination or injury from these materials cannot be completely eliminated. The failure to comply with current or future regulations could result in the imposition of substantial fines against the Company, suspension of production, alteration of our manufacturing processes or cessation of operations.

Risks Related to the Securities Markets and Investment in our Securities.

Our shares of common stock are listed on the Nasdaq Capital Market, but we cannot guarantee that we will be able to comply with the continued listing standards or satisfy the continued listing standards going forward, which could make it more difficult for our stockholders to sell their shares.

Our shares of common stock are listed on the Nasdaq Capital Market (Nasdaq), and as such, we are required to satisfy the continued listing standards of Nasdaq to maintain our listing. However, we cannot assure you that we will be able to comply with the continued listing standards of Nasdaq, including its minimum closing bid price requirement, or satisfy the continued listing standards of Nasdaq going forward. For example, on September 26, 2023, we were notified by Nasdaq that we were not in compliance with Nasdaq Listing Rule 5550(a)(2) because our common stock failed to maintain a minimum closing bid price of $1.00 per share for 30 consecutive business days. To regain compliance, we were required to maintain a minimum closing bid price of $1.00 per share for at least 10 consecutive business days. On March 15, 2024, we received written notice from Nasdaq that we had regained compliance with the minimum closing bid price requirement.

If we are unable to comply with the continued listing standards of Nasdaq, including Nasdaq Listing Rule 5550(a)(2), Nasdaq may commence delisting procedures against us, which could result in our stock being removed from listing on Nasdaq and we could face significant material adverse consequences, including:

- stock price volatility;
- limited availability of market quotations for our common stock;
- reduce liquidity with respect to our common stock;
- a determination that our shares are "penny stock," which will require brokers trading in our shares to adhere to more stringent requirements, and which may limit demand for our common stock among certain investors;
- limited news and analyst coverage on the Company; and
- decrease ability to issue additional securities or obtain additional financing in the future.

The sale of a substantial number of shares of our common stock into the market may cause substantial dilution to our existing stockholders and the sale, actual or anticipated, of a substantial number of shares of common stock could cause the price of our common stock to decline.

We have offered and sold a considerable amount of our common stock in past financings. Any additional or anticipated sales of shares by us, holders of our warrants to purchase common stock or other stockholders may cause the trading price of our common stock to decline. Additional issuances of shares by us may result in dilution to the interests of other holders of our common stock. The sale of a substantial number of shares of our common stock by us, our warrant holders or other stockholders or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales.

The trading price of our common stock has been and is likely to continue to be volatile.

Our stock price is highly volatile. In addition to the factors discussed in this Quarterly Report, the trading price of our common stock may fluctuate significantly in response to numerous factors, many of which are beyond our control including:

- price and volume fluctuations in the overall stock market;
- changes in operating results and performance and stock market valuations of other biopharmaceutical companies generally;
- macroeconomic industry, geopolitical and market conditions, including, but not limited to, high interest rates, the inflationary environment, recessionary fears, rising geopolitical instability including the ongoing conflict in Ukraine, the conflict in the Middle East, and rising tensions between China and Taiwan and the prospect of a shutdown of the U.S. federal government;
- financial or operational projections we may provide to the public, any changes in these projections or our failure to meet these projections;
- changes in government regulations;
- our inclusion or removal from certain stock indices;
- developments in patent or other proprietary rights;
- new products by our competitors;
- announcements of changes in our senior management or directors;
- other events, including those resulting from war, incidents of terrorism, natural disasters, severe weather, pandemics, or responses to these events;
- public statements made by third parties, including trial participants and clinical investigators, regarding our current or future clinical trials that may harm our reputation;
- changes in accounting principles;
- results of clinical studies;
- regulatory and FDA actions, including inspections and warning letters;

- coverage of us, and changes in financial estimates by any securities analysts who follow our Company, or our failure to meet these estimates or the expectations of investors;
- any ongoing litigation that we are currently involved in or litigation that we may become involved in the future;
- additional shares of our common stock being sold into the market by us or our existing stockholders or warrant holders or the anticipation of such sales;
- our ability to execute on our Share Repurchase Program as planned, including failure to meet internal or external expectation around the timing or price of share repurchases, and any reductions or discontinuances of repurchases thereunder; and
- media coverage of our business and financial performance.

In addition, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many healthcare companies. Stock prices of many healthcare companies have fluctuated in a manner unrelated or disproportionate to the operating performance of those companies. As a result, an investment in our common stock may decrease in value.

We have never paid dividends and we do not anticipate paying dividends in the future.

We have never declared or paid dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth, development, operation and expansion of our business, and we do not anticipate declaring or paying any dividends for the foreseeable future. As a result, capital appreciation, if any, of our common stock will be stockholders' sole source of gain for the foreseeable future.

The ownership of our common stock may become concentrated among a small number of stockholders, and if our principal stockholders, directors and officers choose to act together, they may be able to significantly influence management and operations, which may prevent us from taking actions that may be favorable to stockholders.

Our ownership may become concentrated among a small number of stockholders. These stockholders, acting together, could have the ability to exert substantial influence over all matters requiring approval by our stockholders, including the election and removal of directors and any proposed merger, consolidation or sale of all or substantially all of our assets. This concentration of ownership could also have the effect of delaying, deferring, or preventing a change in control of the Company or impeding a merger or consolidation, takeover or other business combination that could be favorable to stockholders.

If we are unable to implement and maintain effective internal control over financial reporting in the future, investors may lose confidence in the accuracy and completeness of our financial reports and the trading price of our common stock may be negatively affected.

We are required to maintain internal controls over financial reporting and to report any material weaknesses in such internal controls. If we identify material weaknesses in our internal control over financial reporting, or if we are unable to comply with the requirements of the Sarbanes-Oxley Act in a timely manner or assert that our internal control over financial reporting is effective, investors may lose confidence in the accuracy and completeness of our financial reports and the trading price of our common stock could be negatively affected, and we could become subject to investigations by the stock exchange on which our securities are listed, the SEC, or other regulatory authorities, which could require additional financial and management resources.

The requirements of being a public company may strain our resources, result in litigation, and divert management's attention.

As a public company, we are subject to certain reporting requirements, listing requirements, and other applicable securities rules and regulations. Complying with these rules and regulations has increased and will continue to increase our legal and financial compliance costs, make some activities more difficult, time consuming or costly and increase demand on our systems and resources. As a result, management's attention may be diverted from other business concerns, which could materially and adversely affect our business and operating results. In addition, a change in our filer status could trigger a requirement to begin complying with Section 404(b) of the Sarbanes-Oxley Act of 2002, and our independent registered public accounting firm would have to evaluate and report on the effectiveness of internal control over financial reporting, increasing our costs. We may also need to hire additional employees or engage outside consultants to comply with these requirements, which will also increase our costs and expenses.
By disclosing information in this and in future filings required of a public company, our business and financial condition will become more visible, which has resulted in, and may in the future result in, threatened or actual litigation, including by competitors and other third parties. If those claims are successful, our business could be seriously harmed. Even if the claims do not result in litigation or are resolved in our favor, the time and resources needed to resolve them could divert our management's resources and seriously harm our business.

Our Stockholder Rights Agreement, the anti-takeover provisions in our governing documents and Delaware law could delay or prevent a change in control which could reduce the market price of our common stock and could prevent or frustrate attempts by our stockholders to replace or remove our current management and the current Board.

Our Stockholder Rights Agreement, which we adopted in May 2014, our amended and restated certificate of incorporation, as amended, and our amended and restated bylaws contain provisions that could delay or prevent a change in control or changes in our Board that our stockholders might consider favorable. These provisions include a staggered Board, which divides the Board into three classes, with directors in each class serving staggered three-year terms. The existence of a staggered board can make it more difficult for a third party to effect a takeover of our Company if the incumbent Board does not support the transaction. These and other provisions in our corporate documents, including our Shareholder Rights Plan and Delaware law might discourage, delay or prevent a change in control or changes in our Board. These provisions could also discourage proxy contests and make it more difficult for activist investors and other stockholders to elect directors not nominated by our Board. Furthermore, the existence of these provisions, together with certain provisions of Delaware law, might hinder or delay an attempted takeover other than through negotiations with our Board.

Our Amended and Restated Certificate of Incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes.

Our Amended and Restated Certificate of Incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for certain actions. The exclusive forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes, which may discourage lawsuits. In addition, there is uncertainty as to whether a court would enforce such a provision. If a court were to find these types of provisions to be inapplicable or unenforceable, and if a court were to find the exclusive forum provision in our Amended and Restated Certificate of Incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could materially and adversely affect our business.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, the price of our common stock and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. Multiple securities and industry analysts currently cover us. If one or more of the analysts downgrade our common stock or publish inaccurate or unfavorable research about our business, the price of our common stock would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our common stock could decrease, which could cause the price of our common stock and trading volume to decline.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 1C. CYBERSECURITY

In the ordinary course of our business, we use, store, and transmit digitally confidential, sensitive, proprietary, personal, and health-related information. The secure maintenance of this information and our information technology systems is important to our operations and business strategy. To this end, we have implemented processes designed to assess, identify, and manage risks from potential unauthorized occurrences on or through our information technology systems that may result in adverse effects on the confidentiality, integrity, and availability of these systems and the data residing therein. These processes are managed and monitored by a third-party information technology vendor, which is overseen by our Senior Vice President of Administration, and include mechanisms, controls, technologies, systems, and other processes designed to prevent or mitigate data loss, theft, misuse, or other security incidents or vulnerabilities affecting the data and maintain a stable information technology environment. For example, we conduct vulnerability and data penetration testing, regularly review third party audits of our cloud-based technology vendors and perform ongoing regular risk assessments. We also conduct periodic employee training on cyber and information security, among other topics. In addition, to our third-party information technology vendor, we also consult with outside advisors and experts, when appropriate, to assist with assessing, identifying, and managing cybersecurity risks, including to anticipate future threats and trends, and their impact on the Company's risk environment.

Our Senior Vice President of Administration who reports directly to the Chief Executive Officer and has over seven years of experience managing information technology and cybersecurity matters, together with our senior leadership team, is responsible for assessing and managing cybersecurity risks. We consider cybersecurity, along with other significant risks that we face, within our overall enterprise risk management framework. In the last fiscal year, we have not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected us, but we face certain ongoing cybersecurity risks threats that, if realized, are reasonably likely to materially affect us. Additional information on cybersecurity risks we face is

discussed in “PART I, ITEM 1A, RISK FACTORS,” under the heading “If we experience a significant disruption in our information technology systems or breaches of data security, our business could be adversely affected.”

The Board of Directors, as a whole, has oversight for the most significant risks facing us and for our processes to identify, prioritize, assess, manage, and mitigate those risks. The Board receives at least quarterly updates on cybersecurity and information technology matters and related risk exposures from our Senior Vice President, Administration as well as other members of the senior leadership team.

ITEM 2. PROPERTIES

As of December 31, 2023, we leased a total of approximately 200 square feet of office space in one location in Seattle, Washington, from WW 107 Spring Street LLC. We believe that our current facilities will be adequate to meet our needs for the next 12 months, and we anticipate that additional space will be available, when needed, on commercially reasonable terms. The information set forth in “PART II, ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS – Commercial Lease Agreement” is incorporated herein by reference.

ITEM 3. LEGAL PROCEEDINGS

We are, and from time to time we may become, involved in legal proceedings or be subject to claims arising in the ordinary course of our business. For a discussion of our legal proceedings, see Note 13 to the Consolidated Financial Statements. We are not presently a party to any other legal proceedings that in the opinion of our management, if determined adversely to us, would individually or taken together have a material adverse effect on our consolidated results of operations, financial condition or cash flows.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Market Information

Our common stock, par value $0.18 per share, trades on the Nasdaq Capital Market under the symbol "ATOS."

Stockholders

As of March 15, 2024, there were approximately 41 stockholders of record of our common stock, one of which is Cede & Co., a nominee for Depository Trust Company (DTC). All of the shares of common stock held by brokerage firms, banks and other financial institutions as nominees for beneficial owners are deposited into participant accounts at DTC and are therefore considered to be held of record by Cede & Co. as one stockholder.

Dividends

We have never declared or paid any cash dividends on our common stock and do not currently anticipate declaring or paying cash dividends on our common stock in the foreseeable future. We currently intend to retain any future earnings to finance the growth and development of our business. Any future determination relating to our dividend policy will be made at the discretion of our Board of Directors and depends on a number of factors, including future earnings, capital requirements, financial conditions, future prospects, contractual restrictions and other factors that our Board of Directors may deem relevant.

Issuer Purchases of Securities

We did not repurchase any of our equity securities during the fourth quarter of fiscal 2023.

Unregistered Sales of Equity Securities and Use of Proceeds

None.

ITEM 6. RESERVED

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

Overview

The following discussion of the financial condition and results of operations should be read in conjunction with the Consolidated Financial Statements and the related notes included elsewhere in this Annual Report. This discussion contains forward-looking statements, which are based on assumptions about the future of our business. Actual results and outcomes could differ materially from those contained in the forward-looking statements. Please read "Forward-Looking Statements" included elsewhere in this Annual Report for additional information regarding forward-looking statements.

Company Overview

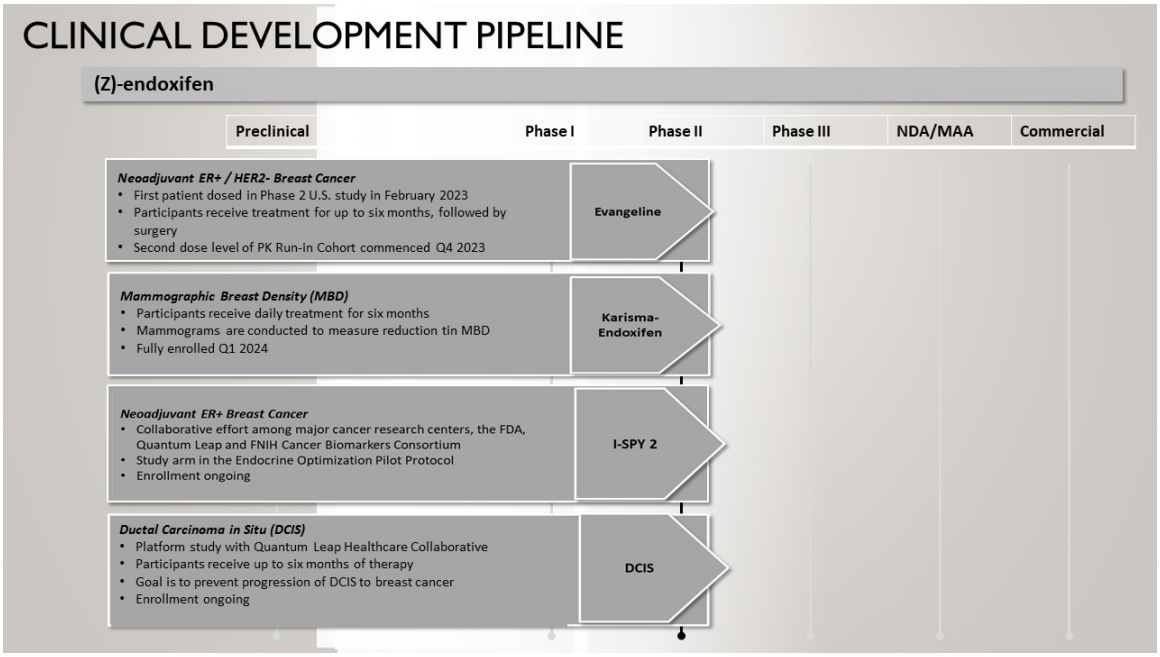
We are a clinical-stage biopharmaceutical company developing proprietary innovative medicines in areas of significant unmet medical need in oncology, with a focus on women's breast cancer and other breast conditions. Our lead drug candidate under development is oral (Z)-endoxifen, which we are developing for both the prevention and treatment of breast cancer.

We have been granted three U.S. patents and one international patent covering our proprietary (Z)-endoxifen, and we have numerous applications pending in the U.S. and in other major countries. We have patent protection covering our proprietary (Z)-endoxifen through November 17, 2038.

Our business strategy is to advance our programs through clinical studies, including potentially with partners, and opportunistically add programs in areas of high unmet medical need through acquisition, minority investment, collaboration or internal development.

Summary of Our Leading Programs

The following is a summary of the status of our major clinical development programs as of the date of this Annual Report:



(Z)-endoxifen. (Z)-endoxifen is an active metabolite of tamoxifen, which is an FDA-approved drug to treat and prevent breast cancer in high-risk women. It is also referred to as a Selective Estrogen Receptor Modulator (SERM). We are developing a proprietary form of (Z)-endoxifen which is administered orally for the potential treatment of breast cancer and reduction of breast density. We have completed four Phase 1 clinical studies (including a study in men) and two Phase 2 clinical studies with our proprietary (Z)-endoxifen (including oral and topical formulations). We have also completed significant pre-clinical development and have developed clinical manufacturing capabilities through qualified third parties.

(Z)-endoxifen for Neoadjuvant Treatment of Breast Cancer. We are also developing (Z)-endoxifen to treat ER+ HER2- breast cancer in the neoadjuvant setting, which is the administration of a therapy before the main treatment, which is usually surgery. Although there are neoadjuvant treatments for breast cancers that are not ER+, there are few neoadjuvant treatments for ER+ breast cancer which comprises about 78% of all breast cancers.

In October 2022, we received authorization from the U.S. FDA for our Investigational New Drug (IND) application for oral (Z)-endoxifen. The study, "A Randomized Phase 2 Noninferiority Trial of (Z)-endoxifen and Exemestane + Goserelin as Neoadjuvant Treatment in Premenopausal Women with ER+/HER2-Breast Cancer," also known as "EVANGELINE." The study is an open-label, randomized, Phase 2 study designed to investigate (Z)-endoxifen for the neoadjuvant treatment of premenopausal women ages 18 and older with early stage (Grade 1 or 2) ER+/HER2- breast cancer.

The study is expected to enroll approximately 180 patients at up to 25 sites. EVANGELINE is a two-part study consisting of a PK Run-in Cohort and a Treatment Cohort. The primary objective of the Treatment Cohort is to evaluate the endocrine sensitive disease (ESD) rate, measured by Ki-67 (a proliferation marker prognostic for disease free survival), after four weeks of treatment with (Z)-endoxifen compared to treatment with current standard of care, exemestane + goserelin. Exemestane is an aromatase inhibitor designed to block the synthesis of estrogen and slow the growth of ER+ cancers. Goserelin is a medication given to block the ovaries from making estrogen, also called ovarian function suppression.

In March 2023, a second Phase 2 trial investigating oral (Z)-endoxifen as a neoadjuvant treatment for women diagnosed with locally advanced ER+ breast cancer was initiated. This trial is a study arm in the ongoing I-SPY 2 clinical trial. The I-SPY 2 TRIAL is a collaborative effort among academic investigators from major cancer research centers across the U.S., Quantum Leap Healthcare Collaborative, the U.S. FDA, and the Foundation for the National Institutes of Health (FNIH) Cancer Biomarkers Consortium. Approximately 20 patients are being treated with (Z)-endoxifen for up to 24 weeks prior to surgery. Enrollment was completed in January of 2024 for the Phase 2 I-SPY clinical trial.

(Z)-endoxifen for Women with Breast Density. Mammographic breast density (MBD) is an emerging public health issue affecting over 10 million women in the U.S. alone. Dense breast tissue makes mammography less effective. When women with MBD are diagnosed with breast cancer, it is often later stage, which makes treatment outcomes suboptimal. Studies conducted by others have also shown that MBD increases the risk of developing breast cancer and that reducing MBD may reduce the incidence of breast cancer.

In December 2021, we commenced a Phase 2 study of our proprietary oral (Z)-endoxifen. The study, known as the Karisma-(Z)-endoxifen study, is a Phase 2, randomized, double-blind, placebo-controlled, dose-response study of our proprietary oral (Z)-endoxifen in healthy premenopausal women with measurable breast density. The primary objective of the study is to determine the dose-response relationship of daily (Z)-endoxifen on breast density reduction. Secondary endpoints will assess safety and tolerability. The study also includes an exploratory endpoint to assess durability of the breast density changes. The study is being conducted in Stockholm, Sweden and includes approximately 240 participants, at full enrollment, who receive daily doses of oral (Z)-endoxifen or placebo for six months after they enroll. The study fully enrolled in November 2023 and we expect primary data in the second half of 2024.

Based on input from the FDA and Swedish Medical Products Agency, reduction in MBD may not be an approvable indication unless we can demonstrate that our (Z)-endoxifen also reduces the incidence of breast cancer. We may therefore conduct additional studies of (Z)-endoxifen to assess its correlation with the risk of breast cancer and/or reduction in the incidence of new breast cancers.

(Z)-endoxifen for Ductal Carcinoma In Situ. Ductal carcinoma in situ (DCIS) is a pre-cancerous lesion of the breast. It rarely produces symptoms, or a breast lump one can feel, typically being detected through screening mammography. In some cases, DCIS may become invasive and spread to other tissues, but there is no way of determining which lesions will remain stable without treatment, and which will go on to become invasive. This uncertainty can result in aggressive and unnecessary treatment approaches that can have harmful side effects without significant benefit.

In October 2023, Quantum Leap Healthcare Collaborative announced the initiation of the Phase 2 DCIS: Re-Evaluating Conditions for Active Surveillance Suitability as Treatment (RECAST) study. (Z)-endoxifen is being investigated as part of this platform trial, which offers women with DCIS six months of neoadjuvant treatment with the intent of determining their suitability for long-term active surveillance without surgery. Approximately 100 patients will be treated with (Z)-endoxifen. The study incorporates both a neoadjuvant therapy phase, with patients at high risk for progression to invasive disease proceeding to surgery, followed by an extended surveillance phase for low-risk patients.

Investment in CAR-T Company. In December 2022, we closed our investment in Dynamic Cell Therapies, Inc. (DCT), a privately-held, venture capital-backed, developer of CAR-T therapies. DCT is in the pre-clinical phase of developing controllable CAR-T cells to address difficult-to-treat cancers. Its platform technology of dynamic control of engineered T-cells is designed to improve the safety, efficacy, and durability of CAR-T cell therapies. While its initial focus is hematologic malignancies, its innovative approach could also have broad applicability in solid tumors and autoimmune diseases.

Research and Development Phase

We are in the research and development phase and are not currently marketing any products. We do not anticipate generating revenue unless and until we develop and launch our pharmaceutical programs.

Commercial Lease Agreement

On November 22, 2022, we entered into an operating lease with WW 107 Spring Street LLC for office space in Seattle, Washington. We agreed to pay monthly rent of $2 thousand for a term of 12 months beginning January 1, 2023. On June 26, 2023, we terminated the existing lease without additional cost and entered a new operating lease for monthly rent of $3 thousand for a term of 12 months commencing July 1, 2023, for a larger office space at the same location.

Critical Accounting Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our Consolidated Financial Statements, which have been prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP). The preparation of these Consolidated Financial Statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. We base our estimates on our historical experience, known trends and events, and on various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making our judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions.

We believe that the following are the most critical accounting estimates used in the preparation of our Consolidated Financial Statements.

Investments in Equity Securities

Our investment in DCT Series Seed Preferred Stock does not have a readily determinable fair value, so we have elected to measure the investment at cost less impairment, adjusted to fair value if there are observable price changes in orderly transactions for an identical or similar investment of the same issuer. As part of preparing our Consolidated Financial Statements, we considered qualitative impairment factors in determining if an impairment analysis is required. Specifically, during 2023, we considered the adverse change in the general market condition of the industry in which DCT operates and concerns about the investee's ability to continue as a going concern, due to negative cash flows from operations. Based on these impairment indicators, we performed a fair value measurement using a dynamic options approach and an adjusted book value approach, giving each a weighting of 50% probability.

We used the dynamic options approach, which requires assumptions regarding the expected average volatility of comparable companies, the expected term of our investment, and an estimation of an appropriate risk-free interest rate over the expected term of our investment. The expected stock price volatility assumption is based upon the average historic volatility of comparable public clinical stage immunotherapy or CAR-T companies. The expected term of our investment is 3.5 years and the risk-free interest rate used is based upon prevailing short-term interest rates over the expected term of the investment.

An adjusted book value approach was also considered due to DCT's limited cash on hand, status of current fundraising efforts and the estimated timing of a deemed liquidation event occurring. This approach requires an adjustment to each balance sheet account to estimate the value upon liquidation.

Our resulting valuation concluded that the investment was impaired, and accordingly, an impairment charge of $3.0 million was recorded in the Consolidated Statements of Operations for the year ended December 31, 2023. No impairment was recorded for the year ended December 31, 2022.

While assumptions used to calculate and account for the investment in non-marketable equity securities represent management's best estimates, these estimates involve inherent uncertainties and the application of management's judgment. If underlying assumptions and estimates change, our investment may be impaired further in future periods.

Research and Development Expenses

As part of the process of preparing our Consolidated Financial Statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and work orders, communicating with our applicable personnel to identify services that have been performed on our behalf, and estimating the associated cost incurred for the services, including, in some cases, when we have not yet been invoiced or otherwise notified of actual costs. R&D costs are generally expensed as incurred. R&D expenses include, for example, manufacturing expense for our drugs under development, expenses associated with preclinical studies, clinical trials and associated salaries, bonuses, stock-based compensation and benefits. R&D expenses also include an allocation of the CEO's salary and related benefits, including bonus and non-cash stock-based compensation expense, based on an estimate of his total hours spent on research and development activities.

We have entered into various research and development contracts with CROs, contract manufacturing organizations (CMOs) and other companies. The majority of our service providers invoice us monthly for services performed, however, payments under some of these contracts may be required in advance of the services being performed, for example when a contract requires an initial

payment at the outset of the contract. Payments made in advance of performance of services are reflected in the Consolidated Balance Sheets as prepaid expenses.

We base our expenses related to preclinical studies and clinical trials on our estimates of the services received and efforts expended pursuant to quotes and contracts with CROs and other companies that conduct and manage preclinical studies and clinical trials on our behalf. The financial terms of these vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors exceed the level of services provided and result in a prepayment of the expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or prepaid expense accordingly. We estimate our accrued expenses as of each balance sheet date in the Consolidated Financial Statements based on facts and circumstances known to us at that time. However, additional information may become available to us, which may allow us to make a more accurate estimate in future periods. There have not been material adjustments to our estimates in the past but, if we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates.

Stock-Based Compensation

We measure all stock option awards granted to employees, non-employee directors and consultants based on the fair value on the date of grant, and we recognize compensation expense over the requisite service period, which is generally the vesting period of the award. The straight-line method of expense recognition is applied to all awards with service-only conditions. We account for forfeitures as they occur.

The fair value of each option grant is estimated using the Black-Scholes option-pricing model, which requires assumptions regarding the expected volatility of the price of our common stock, the expected life of the options, an expectation regarding future dividends on our common stock, an estimate of the appropriate risk-free interest rate and the expected term. Our expected common stock price volatility assumption is based upon the historic volatility of our stock price. The expected life for stock option grants is based on an average of the contractual term of the options of 10 years with the average vesting term of one to four years. The dividend yield assumption of zero is based upon the fact that we have never paid cash dividends and presently have no intention of paying cash dividends in the future. The risk-free interest is based upon prevailing short-term interest rates over the expected lives of the options.

While assumptions used to calculate and account for stock-based compensation awards represent management's best estimates, these estimates involve inherent uncertainties and the application of management's judgment.

Results of Operations

Comparison of Years Ended December 31, 2023 and 2022

Revenue and Cost of Revenue. For the years ended December 31, 2023 and 2022, we had no source of revenue and no associated cost of revenue.

Operating Expenses. Total operating expenses were $31.4 million for the year ended December 31, 2023, which was an increase of $3.7 million, from the year ended December 31, 2022 of $27.7 million. As (Z)-endoxifen is our only product candidate for which we currently incur R&D expense we have not further disaggregated R&D expenses. Factors contributing to the increased operating expenses in the year ended December 31, 2023 are explained below.

The following table provides a breakdown of major categories within R&D expense for the years ended December 31, 2023 and 2022, together with the dollar change in those categories (in thousands):

		Year Ended December 31, 2023	Year Ended December 31, 2022	Increase (decrease)
Research and Development Expense				
	Clinical and non-clinical trials	$ 12,722	$ 10,225	$ 2,497
	Compensation	3,474	4,268	(794)
	Professional fees and other	1,138	590	548
	Research and Development Expense Total	$ 17,334	$ 15,083	$ 2,251

R&D Expenses. R&D expenses for the year ended December 31, 2023, were $17.3 million, an increase of $2.3 million from total R&D expenses for the year ended December 31, 2022 of $15.1 million. Key changes were as follows:

- The increase in R&D expense was in part due to increased spending on clinical and non-clinical trials of $1.1 million compared to the prior year due to increased spending on (Z)-endoxifen trials, including drug development costs. The additional increase of $1.4 million was due to a change in estimate of the amount of tax rebates that no longer met the reasonably assured

threshold to be sustained under a potential ATO audit related to R&D expenditures under the Australian R&D tax incentive program as a result of recent ATO guidance (for more information, see Note 6 of the Consolidated Financial Statements).

- The decrease in R&D compensation expense for the year ended December 31, 2023 compared to the prior year was primarily due to a decrease in non-cash stock-based compensation of $0.8 million. Non-cash stock-based compensation decreased compared to the prior year due to the weighted average fair value of options amortizing in the year ended December 31, 2023 being lower year over year.

- The increase in R&D professional fees and other was due in part to the refund in the prior year of $1.0 million from a research institution with which we had an exclusive right to negotiate for the acquisition of worldwide rights of two oncology programs. No exclusivity payments were made or refunded during the year ended December 31, 2023.

The following table provides a breakdown of major categories within General and Administrative (G&A) expenses for the years ended December 31, 2023 and 2022, together with the dollar change in those categories (in thousands):

		Year Ended December 31, 2023	Year Ended December 31, 2022	Increase (decrease)
General and Administrative Expense				
	Compensation	$ 7,388	$ 7,429	$ (41)
	Professional fees and other	5,367	3,539	1,828
	Insurance	1,288	1,640	(352)
	General and Administrative Expense Total	$ 14,043	$ 12,608	$ 1,435

G&A Expenses. G&A expenses for the year ended December 31, 2023 were $14.0 million an increase of $1.4 million from total G&A expenses for year ended December 31, 2022 of $12.6 million. Key changes were as follows:

- The decrease in G&A compensation expense of $41 thousand for the year ended December 31, 2023 compared to the prior year was partially due to an increase in cash compensation expense of $1.3 million, offset by a decrease in non-cash stock-based compensation of $1.4 million. The increase in cash compensation expense compared to the prior year was primarily driven by salary and bonus severance costs for former executives of $0.6 million, an increase of $0.4 million due to compensation for new employees as well as an overall increase in salaries, bonuses and benefits of $0.3 million. Non-cash stock-based compensation decreased by $1.4 million due to the weighted average fair value of options amortizing in 2023 being lower year over year.

- The increase in G&A professional fees of $1.8 million for the year ended December 31, 2023 compared to the prior year was primarily due to an increase in legal fees for higher patent-related activity of $0.7 million and an increase in professional fees of $0.6 million primarily due to higher investor relations costs and accounting fees. The additional increase of $0.4 million was due to a change in estimate related to the Australian R&D tax incentive program (for more information see Note 6 to the Consolidated Financial Statements).

- The decrease in G&A insurance expense of $0.4 million for the year ended December 31, 2023 compared to the prior year was due to lower negotiated insurance premiums for the same or better coverage year over year.

Impairment Charge on Investment in Equity Securities. For the year ended December 31, 2023, we wrote down our investment in DCT by $3.0 million due to an impairment charge. For the year ended December 31, 2022 there were no impairment charges related to our equity securities. Refer to Note 4 to the Consolidated Financial Statements in Item 8 of this Annual Report.

Interest Income. Interest income was $4.3 million for the year ended December 31, 2023, an increase of $3.5 million from interest income of $0.9 million for the year ended December 31, 2022. The increase was due to the higher average balance invested in money market funds of $26.5 million and higher average interest rates for the year ended December 31, 2023 compared to the prior year.

Income Taxes. We did not record an income tax expense or benefit for the years ended December 31, 2023 and 2022 due to uncertainty regarding utilization of our net operating loss carryforwards and our history of losses.

Liquidity and Capital Resources

We have incurred net losses and negative operating cash flows since inception. For the year ended December 31, 2023, we recorded a net loss of $30.1 million and used $20.9 million of cash in operating activities. As of December 31, 2023, we had $88.5

million in unrestricted cash and cash equivalents and working capital of $87.0 million. We believe we have sufficient cash on hand to fund our projected operating requirements for at least the next 12 months.

As of December 31, 2023, we had cash, cash equivalents and restricted cash of $88.6 million.

Net Cash Flows from Operating Activities. Net cash used in operating activities was $20.9 million for the year ended December 31, 2023, compared to net cash used of $20.8 million for the same period in 2022, an increase of $0.1 million. Cash used in operating activities for the year ended December 31, 2023 primarily related our net loss of $30.1 million, adjusted for non-cash items such as non-cash stock-based compensation expense of $4.6 million, non-cash impairment charge on investment in equity securities of $3.0 million and net cash inflows from a change in our operating assets and liabilities of $1.5 million. Cash used in operating activities for the year ended December 31, 2022 primarily related to our net loss of $27.0 million, adjusted for non-cash share-based compensation expense of $6.8 million and net cash outflows from a change in our operating assets and liabilities of $0.6 million.

Net Cash Flows from Investing Activities. Net cash used in investing activities was $14 thousand for the year ended December 31, 2023, compared to net cash used in investing activities of $4.7 million for the year ended December 31, 2022. Current period cash used in investing activities was primarily related to purchases of new computers while prior period cash used in investing activities was primarily related to the investment in equity securities of $4.7 million.

Net Cash Flows from Financing Activities. Net cash used in financing activities was $1.5 million for the repurchase of common stock under the Share Repurchase Program for the year ended December 31, 2023. No cash was used in financing activities during the year ended December 31, 2022.

Funding Requirements

We expect to incur ongoing operating losses for the foreseeable future as we continue to develop our planned therapeutic programs, including related clinical studies and other programs in the pipeline. Our future funding requirements will depend on many factors, including:

- the costs of manufacturing drugs under development, the costs associated with clinical and non-clinical trials and associated salaries and benefits;
- the extent to which we enter into contracts or invest in third parties in order to further develop our drug candidates;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending other intellectual property-related claims; and
- the costs and fees associated with the discovery, acquisition or license of additional product candidates or technologies.

If we are unable to raise additional capital when needed on reasonable terms, if at all, we could be forced to curtail or cease our operations. Our future capital uses and requirements will depend on the time and expenses needed to begin and continue clinical trials for our new drug developments.

Additional funding may not be available to us on acceptable terms or at all. Continued uncertain market and macroeconomic conditions, including due to inflationary pressures, high interest rates, general economic slowdown or a recession, the prospect of a shutdown of the U.S. federal government, foreign exchange rate volatility, financial institution instability, changes in monetary policy and increasing geopolitical instability, may limit our ability to access capital. In addition, the terms of any financing may adversely affect the holdings or the rights of our stockholders. For example, we may raise additional funds by issuing equity securities or by equity offerings, collaboration agreements, debt financings or licensing arrangements.

If adequate funds are not available, we may be required to terminate, significantly modify or delay our development programs, reduce our planned commercialization efforts, or obtain funds through collaborators that may require us to relinquish rights to our technologies or product candidates that we might otherwise seek to develop or commercialize independently. Further, we may elect to raise additional funds even before we need them if we believe the conditions for raising capital are favorable.

Although we submitted a proposal to our stockholders to amend our amended and restated certificate of incorporation to increase the number of authorized shares of our common stock for various potential purposes, including potential capital raising transactions, our stockholders did not approve the proposal at our 2021 and 2022 annual meetings of stockholders nor did they approve it at a special meeting of stockholders held in September 2021. A lack of authorized shares may limit our ability to raise capital when needed.

On September 26, 2023, we were notified by Nasdaq that we were not in compliance with Nasdaq Listing Rule 5550(a)(2) because our common stock failed to maintain a minimum closing bid price of $1.00 per share for 30 consecutive business days. To regain compliance, we were required to maintain a minimum closing bid price of $1.00 per share for a minimum of 10 consecutive business days. On March 15, 2024, we received written notice from Nasdaq that we had regained compliance with the minimum closing bid price requirement under Nasdaq Listing Rule 5550(a)(2).

Contractual Obligations

Our contractual obligations represent our future cash commitments and liabilities under agreements with third party clinical trial service providers. Apart from contracts with a third party clinical trial service provider, such agreements are cancellable upon written notice by us. The non-cancellable contracts expire upon completion of the clinical trial and release of the final report, or the contract may be terminated by the clinical trial service provider, by the FDA or another governmental agency. As of December 31, 2023, our estimated non-cancellable commitment was $6.1 million which will be paid over the term of the clinical trials which are expected to be complete in 2025.

Share Repurchase Program

In June 2023, our Board of Directors (the Board) authorized a program to repurchase up to $10.0 million of our common stock (the Share Repurchase Program). The Share Repurchase Program does not obligate us to acquire any specific number of shares. Under the Share Repurchase Program, shares of common stock may be repurchased using a variety of methods, including privately negotiated and/or open market transactions, including under plans complying with Rule 10b5-1 under the Exchange Act, as part of accelerated share repurchases and other methods. The timing, manner, price and amount of any repurchases are determined by the Board in its discretion and depend on a variety of factors, including legal requirements, price and economic and market conditions. The program was originally set to expire on December 31, 2023, however, on December 18, 2023 the Board authorized an extension of the program through December 31, 2024. During the year ended December 31, 2023, 1,320,046 shares were repurchased under the Share Repurchase Program for a total cost of $1.5 million. As of December 31, 2023, $8.5 million remained available for future stock repurchases under the Share Repurchase Program.

Off-Balance Sheet Arrangements

We do not currently have, nor have we ever had, any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we do not engage in trading activities involving non-exchange traded contracts.

Recently Issued Accounting Pronouncements

In November 2023, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2023-07, Segment Reporting (Topic 280): *Improvements to Reportable Segment Disclosures*. This standard requires disclosure of significant segment expenses and other segment items by reportable segment. The ASU becomes effective for annual periods beginning in 2024 and interim periods in 2025. We are currently assessing the potential impact of this ASU.

In December 2023, the FASB issued ASU No. 2023-09, Income Taxes (Topic 740): *Improvements to Income Tax Disclosures*. This standard enhances disclosures related to income taxes, including the rate reconciliation and information on income taxes paid. The ASU becomes effective January 1, 2025. We are currently assessing the potential impact of this ASU.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As a smaller reporting company, we are not required to provide the information required by this item pursuant to Item 305(e) of Regulation S-K.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements required by this item are set forth beginning on page 64 of this Annual Report and are incorporated herein by reference.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Principal Executive Officer and Principal Financial Officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures as of December 31, 2023, pursuant to Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act).

Our disclosure controls and procedures are designed to ensure that information required to be disclosed in our reports that are filed or furnished under the Exchange Act are recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. Disclosure controls and procedures include, without limitation, controls and procedures designed to

ensure that information required to be disclosed in our reports filed or furnished under the Exchange Act is accumulated and communicated to our management, including our Principal Executive Officer and Principal Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Based on the evaluation of our disclosure controls and procedures as of December 31, 2023, our Principal Executive Officer and Principal Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Controls Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (pursuant to Rules 13a-15(f) and 15d-15(f) under the Exchange Act). Our internal control over financial reporting includes policies and procedures designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external reporting purposes in accordance with generally accepted accounting principles in the United States.

Under the supervision and with the participation of our management, including our Principal Executive Officer and Principal Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2023, based on the Framework in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under this framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2023. Because we are a non-accelerated filer, our independent registered public accounting firm is not required to attest to or issue a report on the effectiveness of our internal control over financial reporting.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during the quarter ended December 31, 2023, that have materially affected or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

(a) Announcement of 2024 Annual Stockholders' Meeting Date and Related Information

We intend to hold our 2024 Annual Meeting of Stockholders (the "2024 Annual Meeting") on June 27, 2024. Because the date of the 2024 Annual Meeting has been changed by more than 30 days from the anniversary of our 2023 Annual Meeting of Stockholders, the deadline for the submission of stockholder proposals for inclusion in our proxy materials relating to the 2024 Annual Meeting in accordance with Rule 14a-8 under the Exchange Act will be the close of business (6:00 p.m. Pacific Time) on April 15, 2024, which we believe is a reasonable time before we expect to begin to print and send our proxy materials. Any proposal received after such date will be considered untimely.

(b) Trading Plans

During the quarter ended December 31, 2023, no director or Section 16 officer adopted or terminated any Rule 10b5-1 trading arrangements or non-Rule 10b5-1 trading arrangements (in each case, as defined in Item 408(a) of Regulation S-K).

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

We have adopted a Code of Business Conduct and Ethics (the "Code of Conduct") that applies to all of our directors, officers and employees, including our principal executive, principal financial and principal accounting officers, or persons performing similar functions. Our Code of Conduct is posted on our website located at *https://atossatherapeutics.com/investors/* under "Governance." We intend to disclose future amendments to certain provisions of the Code of Conduct, and waivers of the Code of Conduct granted to executive officers and directors, on the website within four business days following the date of the amendment or waiver.

DIRECTORS

The Amended and Restated Certificate of Incorporation of the Company provides that our Board is to be divided into three classes nearly equal in number as reasonably possible, with directors in each class serving three-year terms. The total Board size is currently fixed at seven directors. The Class I directors (whose terms expire at the 2025 Annual Meeting of Stockholders) are Steven C. Quay, M.D., Ph.D. and Jonathan Finn, C.F.A. The Class II directors (whose terms expire at the 2026 Annual Meeting of Stockholders) are Stephen J. Galli, M.D., Richard I. Steinhart and Tessa Cigler, M.D., M.P.H. The Class III directors (whose terms expire at the 2024 Annual Meeting of Stockholders) are Shu-Chih Chen, Ph.D. and H. Lawrence Remmel, Esq.

There are no family relationships among any of our directors or executive officers, except for Dr. Chen, who is married to Dr. Quay.

Director Name and Year Director Joined the Board	Age[(1)]	Position(s) with the Company	Year Current Term Expires	Current Director Class
Steven C. Quay, M.D., Ph.D. (2009)	73	Chairman of the Board of Directors, President, and Chief Executive Officer	2025	I
Jonathan Finn, C.F.A. (2023)	50	Director	2025	I
Stephen J. Galli, M.D. (2011)	77	Director	2026	II
Richard I. Steinhart (2014)	66	Director	2026	II
Tessa Cigler, M.D., M.P.H. (2024)	50	Director	2026	II
Shu-Chih Chen, Ph.D. (2009)	62	Director	2024	III
H. Lawrence Remmel, Esq. (2012)	72	Director	2024	III

(1) As of April 1, 2024

Class I Directors

Steven C. Quay, MD., Ph.D. Steven C. Quay, M.D., Ph.D. has served as Chief Executive Officer, President and Chairman of the Board of Directors of the Company since the Company was incorporated in April 2009. Dr. Quay is certified in Anatomic Pathology with the American Board of Pathology, completed both an internship and residency in anatomic pathology at Massachusetts General Hospital, a Harvard Medical School teaching hospital, and is a former faculty member of the Department of Pathology, Stanford University School of Medicine. Dr. Quay is a named inventor on 90 U.S. patents, 862 published US and international patent applications, and is named inventor on patents covering seven pharmaceutical products that have been approved by the U.S. Food and Drug Administration. Dr. Quay received an M.D. in 1977 and a Ph.D. in 1975 from the University of Michigan. He received his B.A. degree in biology, chemistry and mathematics from Western Michigan University in 1971. He is a director and the Chair of the Governance Committee, of the Taipei-American School in Taipei, Taiwan. He was selected to serve on the Company's Board of Directors because of his role as a founder of the Company, as well as his qualifications as a physician and the principal researcher overseeing the research, preclinical, clinical and regulatory development of the Company's pharmaceutical programs.

Jonathan Finn, C.F.A. Jonathan Finn has served as a director of the Company since November 2023. Mr. Finn has worked at Vantage Consulting Group, an investment advisory firm, since 1995 and served as Executive Vice President and Chief Investment Officer at Vantage since 2005. In this role, he directs investment strategy, asset allocation, manager selection and portfolio construction. Mr. Finn is also a Founding Partner of Scientia Ventures, a manager of venture capital funds that invest in companies targeting computational biology and chemistry, the digitization of medicine, digital therapies, and traditional drug development businesses at the cutting edge of the life sciences industry and has served in this role since 2006. Earlier in his career, Mr. Finn was a portfolio manager for the Lindner family of mutual funds, serving as co-manager for the Small Cap and Asset Allocation funds from 2000 to 2001. He currently serves as director of Verigraft AB, a regenerative medicine venture, Rose Pharma LLC, a development stage specialty pain company, and Solör Bioenergy Holdings AB, a bioenergy business. Mr. Finn has a B.A. in Economics from the University of Virginia and holds the Chartered Financial Analyst designation. Mr. Finn has been selected to serve on the Company's Board of Directors because of his qualifications as a business executive and his familiarity with investment strategy in the biotechnology sector.

Class II Directors

Stephen J. Galli, M.D. Dr. Galli has served as a director of the Company since July 2011. Dr. Galli has been a Professor of Pathology and of Microbiology & Immunology and the Mary Hewitt Loveless, M.D., Professor, Stanford University School of Medicine, Stanford, California since February 1999. He served as Chair of the Department of Pathology at Stanford University School of Medicine from 1999 to 2016. Before joining Stanford, he was on the faculty of Harvard Medical School. He holds 16 U.S. patents and has over 490 publications. He is past president of the American Society for Investigative Pathology, past president of the Collegium Internationale Allergologicum, and past president of the Pluto Club (Association of University Pathologists). In addition to receiving several awards for his research, and being elected to the National Academy of Medicine (USA), the Accademia Nazionale de Lincei (Rome, Italy), and the American Clinical and Climatological Association, he was recognized with the 2010 Stanford University President's Award for Excellence through Diversity for his recruitment and support of women and underrepresented minorities at Stanford University. He received his B.A. degree in biology, *magna cum laude*, from Harvard College in 1968 and his M.D. degree from Harvard Medical School in 1973 and completed a residency in anatomic pathology at the Massachusetts General Hospital in 1977. Dr. Galli has been selected to serve on the Company's Board of Directors because of his qualifications as a professor and physician, and his specialized expertise as a pathologist.

Richard I. Steinhart. Mr. Steinhart has served as a director of the Company since March 2014. Mr. Steinhart is currently the Senior Vice President and Chief Financial Officer of BioXcel Therapeutics, Inc., a clinical-stage biopharmaceutical company, which he joined in October 2017. From October 2015 to June 2017, he was Vice President and Chief Financial Officer of Remedy Pharmaceuticals, Inc., a privately held pharmaceuticals company. From January 2014 until he joined Remedy Pharmaceuticals, Mr. Steinhart acted as an independent financial consultant to various companies in the biotechnology and medical device industries. From April 2006 to December 2013, Mr. Steinhart was an executive at MELA Sciences, Inc., serving as its Senior Vice President, Chief Financial Officer, Treasurer and Secretary. From 1992 to 2006, Mr. Steinhart was Managing Director at Forest St. Capital/SAE Ventures. Earlier, he served as Vice President and Chief Financial Officer at Emisphere Technologies from 1991 to 1992 and as General Partner and Chief Financial Officer of CW Group Inc. Mr. Steinhart is a Member of the Board of Directors of Actinium Pharmaceuticals where he is Chairman of the Audit Committee. From 2004 to 2012, Mr. Steinhart was a Member of the Board of Directors of Manhattan Pharmaceuticals and was Chairman of the Audit Committee. Mr. Steinhart received his B.B.A. and M.B.A. degrees from Pace University. Mr. Steinhart has been selected to serve on the Company's Board of Directors because of his qualifications as a business executive and audit committee financial expert, and his prior experience as a Chief Financial Officer, director and committee member of public companies.

Tessa Cigler, M.D., M.P.H. Dr. Cigler joined the Company as a director in March 2024. Dr. Cigler is a medical oncologist whose work is dedicated to the treatment and prevention of breast cancer. Dr. Cigler joined the Cornell faculty in August 2007 as a medical oncologist and clinical investigator at the Weill Cornell Breast Center. As a member of the Weill Cornell Breast Center research team, she heads several clinical trials. Dr. Cigler received her undergraduate degree from Harvard College, and her M.D. from Duke University School of Medicine. She also holds a Master's in Public Health from the Harvard School of Public Health. She completed her residency in Internal Medicine at New York Presbyterian Hospital Weill Cornell Medical Center, followed by a fellowship in Medical Oncology and Hematology at the Dana-Farber Harvard Cancer Center.

Class III Directors

Shu-Chih Chen, Ph.D. Dr. Chen has served as a director since April 2009. She was a founder of the Company and served as Chief Scientific Officer of the Company since it was incorporated in April 2009 through August 2014. Prior to joining the Company, she was an Associate Professor at National Yang Ming University, Taipei, Taiwan, and served as the principal investigator of an NIH RO1 grant, studying tumor suppression by gap junction protein connexin 43, at the Department of Molecular Medicine at Northwest Hospital, Seattle, WA. She has two issued U.S. patents and 20 pending U.S. patent applications related to cancer therapeutics. Dr. Chen received her Ph.D. degree in microbiology and public health from Michigan State University in 1992 and has published extensively on molecular oncology. She received her B.S. degree in medical technology from National Yang Ming University, Taipei, Taiwan in 1984. Dr. Chen has been selected to serve on the Company's Board of Directors because of her role as a founder of the Company and her qualifications in medical technology and as a professor and researcher in the field of cancer therapeutics.

H. Lawrence Remmel, Esq. Mr. Remmel has served as a director of the Company since February 2012. He is currently a partner of the law firm Pryor Cashman LLP, located in New York City, where he chairs the Banking and Finance practice group. Mr. Remmel joined Pryor Cashman in 1988. His practice includes corporate and banking financings, issues relating to the Investment Company Act of 1940, and intellectual property and licensing issues, in particular in the biotechnology and biocosmeceutical areas. Mr. Remmel previously served on the Board of Advisors of CytoDel, LLC, an early-stage bio-pharmaceutical company developing products for bio-defense, neuronal drug delivery, and musculoskeletal and aesthetic medicine. In February 2018, he became a director of CytoDel, Inc., the successor to CytoDel LLC. In March 2019 he became a director of Aufbau Holdings Limited, an Irish limited company, developing therapeutics in ophthalmology and other areas. He was an associate of the law firm Reboul, MacMurray, Hewitt, Maynard & Kristol from 1984 to 1988, and began his legal career at Carter, Ledyard & Milburn, where he was an associate from 1979 to 1984. He was admitted to the New York bar in 1980 and is a member of the New York State Bar Association. He received his J.D. from the Washington & Lee University School of Law in 1979 and his B.A. from Princeton University in 1975. He currently is a doctoral candidate in the Graduate School of Life Sciences of the University of Utrecht, in the Department of Clinical and Translational Oncology, with a thesis project in hyperplasia and early-stage breast cancer. Mr. Remmel has been selected to serve on the Company's

Board of Directors because of his substantial experience as a corporate attorney advising biotechnology companies and his familiarity with the fiduciary duties and the regulatory requirements affecting publicly traded companies.

Board of Directors Transition

On October 5, 2023, Greg Weaver resigned from his role as our Executive Vice President and Chief Financial Officer and as a member of our Board and Heather Rees succeeded Greg Weaver as SVP, Finance and Accounting and Principal Financial and Accounting Officer. On November 8, 2023, Jonathan Finn was appointed by the Board to succeed Greg Weaver to serve as a Class I director until the Company's 2025 Annual Meeting of Stockholders. On March 9, 2024, the Board expanded its size and appointed Dr. Tessa Cigler to the Board to serve as a Class II director until the Company's 2026 Annual Meeting of Stockholders.

Compensation Committee Interlocks

None of the members of our Compensation Committee has at any time during the prior three years been one of our officers or employees. None of our executive officers currently serves, or in the past fiscal year has served, as a member of the board or compensation committee of any entity that has one or more executive officers serving on our Board or Compensation Committee.

EXECUTIVE OFFICERS

Our current executive officers and their respective ages and positions are set forth in the following table.

Name	Age[1]	Position
Executive Officers:		
Steven C. Quay, M.D., Ph.D.[2]	73	Chairman of the Board, President and Chief Executive Officer
Heather Rees, CPA (inactive)	51	SVP, Finance and Principal Accounting Officer

(1) As of April 1, 2024
(2) For Dr. Quay's biographical information, see "Directors" above.

Heather Rees., CPA (inactive). Heather Rees has served as the Company's Senior Vice President, Finance and Principal Accounting Officer since 2023. Prior to that time, Ms. Rees served as the Company's Vice President of Finance & Accounting since 2021 and controller since 2017. Ms. Rees previously spent ten years working as an independent financial consultant serving public and private companies. She began her career with Deloitte & Touche and worked for nine years in the audit practice. Ms. Rees earned a Bachelor of Business Administration in Accounting from Gonzaga University.

Audit Committee and Audit Committee Financial Expert

Our Board has a separately designated Audit Committee comprised solely of independent directors. Mr. Steinhart qualifies as an "audit committee financial expert," as that term is defined in the rules and regulations established by the SEC, and all members of the Audit Committee are "financially literate" under Nasdaq listing rules.

ITEM 11. EXECUTIVE COMPENSATION

DIRECTOR COMPENSATION

Non-employee director compensation is generally reviewed and set annually at the Board meeting held in connection with the Annual Stockholder Meeting. The non-employee directors of the Company received the following for service on the Board from May 2023 through May 2024:

- upon joining the Board, an initial fee of $50,000 in cash;
- an annual cash payment of $50,000 for each board member; and
- an annual grant of options exercisable for 125,000 shares.

The Compensation Committee has engaged Aon Consulting Inc. to provide advice regarding the amount and form of director compensation. Based on their compensation analysis, and to more closely align with our peers, the annual grant of options was increased in May 2023 from 50,000 shares to 125,000 shares. All other Board compensation was unchanged.

In addition to the above, annual compensation for service on the Audit Committee is $20,000 for the Chair and $15,000 for each committee member, paid in cash quarterly. Annual compensation for service on the Compensation Committee and Nominating and Governance Committee is $15,000 for the Chair and $10,000 for each committee member, paid in cash quarterly. The independent board members are also reimbursed on a case-by-case basis up to a pre-set amount for actual out of pocket expenses for graduate level course work in fields related to the business of the Company, though no such reimbursements were made with respect to 2023.

The employee directors receive no compensation for their board service. Pursuant to the policies of Pryor Cashman, the law firm of which Mr. Remmel is a partner, the compensation Mr. Remmel receives for his services as a director (other than expense reimbursement) is paid to the firm directly. All directors receive reimbursement for reasonable travel expenses. The following table sets forth information regarding compensation earned by our non-employee directors during the fiscal year ended December 31, 2023:

Name	Fees Earned or Paid in Cash	Option Awards Dollar Amount[1]	Options Awards Number of Shares	All Other Compensation	Total	Outstanding Option Awards[2]
Shu-Chih Chen, Ph.D.	$ 50,000	$ 66,169	125,000	$ —	$ 116,169	366,555
Stephen Galli, M.D.	$ 78,750	$ 66,169	125,000	$ —	$ 144,919	366,658
H. Lawrence Remmel, Esq.[3]	$ 78,750	$ 66,169	125,000	$ —	$ 144,919	—
Richard Steinhart	$ 80,000	$ 66,169	125,000	$ —	$ 146,169	364,926
Jonathan Finn[4]	$ 60,834	$ 33,146	62,500	$ —	$ 93,980	62,500

(1) The value of the awards has been computed in accordance with Accounting Standards Codification Topic 718, *Compensation - Stock Compensation* (ASC 718). Assumptions used in the calculations for these amounts are included in the notes to our financial statements included in our Annual Report for the fiscal year ended December 31, 2023. Except for Mr. Finn, option awards consist of 2023 annual option grants, to purchase shares of Common Stock with an exercise price of $0.66, which was the fair value of our common shares at the time of grant. Options vest quarterly over a year. Mr. Finn's Option awards were granted when he commenced service on the Board with an exercise price of $0.65, which was the fair value of our common shares at the time of grant.

(2) The shares reported in this column represent the aggregate number of option awards outstanding as of December 31, 2023.

(3) The compensation Mr. Remmel receives for his services as a director in the form of an option grant is assigned to the Pryor Cashman law firm of which Mr. Remmel is a partner.

(4) Mr. Finn was added to the Board on November 8, 2023.

EXECUTIVE COMPENSATION

Remuneration of Officers

Our Compensation Committee is responsible for reviewing and evaluating key executive employee base salaries, setting goals and objectives for executive bonuses and administering benefit plans. The Compensation Committee provides advice and recommendations to our Board of Directors on such matters.

Summary Compensation Table

The following table sets forth the compensation earned by our President and Chief Executive Officer and Senior Vice President of Finance and Accounting, and our two former Chief Financial Officers (together, the "2023 *Named Executive Officers*") for fiscal year 2023 and, in the case of Dr. Quay and Mr. Guse, fiscal year 2022:

Name and Position		Year	Salary	Bonus	Option Awards[1]	Non-equity Incentive Plan Compensation[2]	All Other Compensation[3]	Total
Steven C. Quay	President and Chief Executive Officer	2023	$ 705,910	$ —	$ 1,143,927	$ 469,783	$ 36,600	$ 2,356,220
		2022	$ 705,910	$ —	$ 2,019,697	$ 402,369	$ 32,900	$ 3,160,876
Heather Rees	Senior Vice President Finance and Accounting	2023	$ 331,585	$ —	$ 166,818	$ 152,460	$ 36,600	$ 687,463
Kyle Guse	Former Chief Financial Officer, General Counsel and Secretary	2023	$ 248,358	$ —	$ 342,790	$ —	$ 580,483	$ 1,171,631
		2022	$ 466,658	$ —	$ 788,918	$ 239,395	$ 32,900	$ 1,527,871
Greg Weaver	Former Chief Financial Officer	2023	$ 197,756 [4]	$ 43,493 [5]	$ 2,116,394	$ —	$ 21,783	$ 2,379,426

(1) The value of the option awards has been computed in accordance with ASC 718. Assumptions used in the calculations for these amounts are included in the notes to our financial statements included in our Annual Report.

The options vest quarterly over two years from the date of grant, except for 125,000 options with a grant date fair value of $66,169 that were granted to Mr. Weaver in connection with his service as a non-employee director prior to commencing service as Chief Financial Officer, which options were scheduled to vest quarterly over one year from the date of grant, and 2,600,000 options with a grant date fair value of $2,050,225 that were granted to Mr. Weaver in connection with his appointment as Chief Financial Officer, which options were scheduled to vest 25% on the one-year anniversary of the date of grant with the remainder scheduled to vest in equal quarterly installments over the following three years. In connection with his termination of service as Chief Financial Officer and a member of the Board, however, all of Mr. Weaver's unvested options were terminated.

(2) Amounts represent the annual performance bonus.

(3) Amounts represent the 401(k) match made by the Company on behalf of the Named Executive Officer and reimbursements under our wellness program. For Mr. Guse the amounts also include a $553,533 severance payment.

(4) Includes $33,333 paid to Mr. Weaver in connection with his service as a non-employee director prior to becoming Chief Financial Officer.

(5) Mr. Weaver received a sign on bonus of $125,000, but upon his resignation from the Company, he was required to return $81,507 to the Company per his employment agreement.

Outstanding Equity Awards at Fiscal Year-End

The following table shows information regarding our outstanding equity awards at December 31, 2023 for the 2023 Named Executive Officers under the Company's Incentive Plans:

Name		Grant Date	Number of Securities Underlying Unexercised Options Exercisable		Number of Securities Underlying Unexercised Options Unexercisable	Option Exercise Price	Option Expiration Date
Steven Quay	President and Chief Executive Officer	5/6/2014	1,389		—	$ 219.60	5/6/2024
		3/16/2015	1,528		—	$ 338.40	3/16/2025
		5/18/2016	3,163		—	$ 47.34	5/18/2026
		5/24/2017	47,992		—	$ 5.64	5/24/2027
		5/17/2019	2,300,000		—	$ 1.36	5/17/2029
		4/9/2020	195,000		—	$ 1.48	4/9/2030
		5/15/2020	1,305,000		—	$ 1.48	5/15/2030
		5/14/2021	1,900,000		—	$ 2.90	5/14/2031
		2/24/2022	1,662,500	(1)	237,500	$ 1.25	2/24/2032
		3/2/2023	702,415	(1)	1,170,685	$ 0.72	3/2/2033
Heather Rees	Senior Vice President Finance and Accounting	4/9/2020	32,500		—	$ 1.48	4/9/2030
		7/3/2020	23,500		—	$ 3.18	7/3/2030
		5/14/2021	129,700		—	$ 2.90	5/21/2031
		8/11/2021	100,000		—	$ 3.18	8/11/2031
		5/13/2022	112,500	(1)	37,500	$ 0.93	5/13/2032
		6/12/2023	56,500	(1)	169,500	$ 0.92	6/12/2033
Kyle Guse	Former Chief Financial Officer, General Counsel and Secretary	1/8/2014	778		—	$ 396.00	1/8/2024
		5/6/2014	1,112		—	$ 219.60	5/6/2024
		3/16/2015	1,056		—	$ 338.40	3/16/2025
		5/18/2016	6,056		—	$ 47.34	5/18/2026
		5/24/2017	41,280		—	$ 5.64	5/24/2027
		5/17/2019	800,000		—	$ 1.36	5/17/2029
		4/9/2020	195,000		—	$ 1.48	4/9/2030
		5/15/2020	395,000		—	$ 1.48	5/15/2030
		5/14/2021	850,000		—	$ 2.90	5/14/2031
		2/24/2022	606,669	(2)	—	$ 1.25	2/24/2032
		3/2/2023	278,953	(2)	—	$ 0.72	3/2/2033
Greg Weaver[3]	Former Chief Financial Officer	5/6/2014	84		—	$ 219.60	4/05/2024
		5/12/2015	223		—	$ 246.60	4/05/2024
		5/18/2016	624		—	$ 47.34	4/05/2024
		5/14/2021	50,000		—	$ 2.90	4/05/2024
		5/13/2022	50,000		—	$ 0.93	4/05/2024
		5/4/2023	31,250		—	$ 0.66	4/05/2024

(1) Option vests quarterly over two years from the date of grant.
(2) Option accelerated upon termination per Mr. Guse's employment agreement.
(3) Mr. Weaver's vested options expire six months following his October 5, 2023 termination date.

Employment Agreements

Employment Agreement with Steven Quay, M.D., Ph.D.

The Company entered into an employment agreement with Dr. Quay on September 27, 2010, to act as the Company's Chief Executive Officer. The agreement provided for an initial base salary of $250,000, which was amended over the years and has been subsequently increased to $705,910 for 2023, with an annual target bonus of up to 55% of Dr. Quay's then-current base salary, payable upon the achievement of performance goals to be established annually by the Compensation Committee.

The goals for fiscal 2023 included (1) completion of enrollment in the Endoxifen Phase 2 clinical study in women with mammographic breast density, (2) completion of the PK run-in cohort for the Evangeline Phase 2 neoadjuvant trial; (3) acquisition or development of additional programs; (4) commencement of one or more additional studies, and (5) accomplishment of one or more specified "stretch goals." On January 16, 2024, the Compensation Committee reviewed the performance of Dr. Quay for 2023 against these goals and determined that his bonus for 2023 was 121% of potential, or $469,783.

During the employment term, the Company will make available to Dr. Quay employee benefits provided to other key employees and officers of the Company. To the extent these benefits are based on length of service with the Company, Dr. Quay will receive full credit for prior service with the Company. Dr Quay is entitled to participation in health, hospitalization, disability, dental and other insurance plans that the Company may have in effect for other executives, all of which shall be paid for by the Company with contribution by Dr. Quay as set for the other executives, as and if appropriate.

Dr. Quay has also agreed that, for the period commencing on the date of his employment agreement with the Company and during the term of his employment and for a period of 12 months following termination of his employment with the Company that he will not compete with the Company in the United States. The employment agreement also contains provisions relating to confidential information and assignment of inventions, which require Dr. Quay to refrain from disclosing any proprietary information and to assign to the Company any inventions, or future products, research, or development, or which result from work they perform for the Company or using its facilities.

Employment Letter with Heather Rees

The Company is party to an employment letter with Heather Rees dated as of October 6, 2023, pursuant to which she was promoted to act as the Company's Senior Vice President, Finance and Principal Accounting Officer. The agreement provided for an initial base salary of $360,000, with an annual target bonus of up to 35% of Ms. Rees' then-current base salary, payable upon the achievement of performance goals to be established annually by the Compensation Committee.

The goals for fiscal 2023 included (1) completion of enrollment in the Endoxifen Phase 2 clinical study in women with mammographic breast density, (2) completion of the PK run-in cohort for the Evangeline Phase 2 neoadjuvant trial (3) acquisition or development of additional programs (4) commencement of one or more additional studies, and (5) accomplishment of one or more specified "stretch goals." On January 16, 2024, the Compensation Committee reviewed the performance of Ms. Rees for 2023 against these goals and determined that her bonus for 2023 was 121% of potential, or $152,460.

Employment Agreement with Kyle Guse

The Company entered into an employment agreement with Mr. Guse to act as the Company's Chief Financial Officer, General Counsel and Secretary. The agreement was amended on May 18, 2016 and provided for a base salary of $364,000, which was amended over the years and was increased to $466,658 for 2023, with an annual target bonus of up to 45% of Mr. Guse's then-current base salary, payable upon the achievement of performance goals to be established annually by the Compensation Committee.

The goals for fiscal 2023 included (1) completion of enrollment in the Endoxifen Phase 2 clinical study in women with mammographic breast density, (2) completion of the PK run-in cohort for the Evangeline Phase 2 neoadjuvant trial; (3) acquisition or development of additional programs; (4) commencement of one or more additional studies, and (5) accomplishment of one or more specified "stretch goals." In accordance with his severance agreement, Mr. Guse was paid his pro-rata share of his bonus for 2023. Refer below for severance benefits paid to Mr. Guse.

During the employment term, the Company was required to make available to Mr. Guse employee benefits provided to other key employees and officers of the Company. To the extent these benefits were based on length of service with the Company, Mr. Guse was entitled to full credit for prior service with the Company. Mr. Guse was entitled to participation in health, hospitalization, disability, dental and other insurance plans that the Company may have had in effect for other executives, all of which were to be paid for by the Company with contribution by Mr. Guse as set for the other executives, as and if appropriate.

Mr. Guse has also agreed that, for the period commencing on the date of his employment agreement with the Company and during the term of his employment and for a period of six months following termination of his employment with the Company that he will not compete with the Company in the United States. The employment agreement also contains provisions relating to confidential information and assignment of inventions, which require Mr. Guse to refrain from disclosing any proprietary information and to assign to the Company any inventions, or future products, research, or development, or which result from work they perform for the Company or using its facilities.

Employment Agreement with Greg Weaver

The Company entered into an employment agreement with Mr. Weaver on June 1, 2023, to act as the Company's Executive Vice President and Chief Financial Officer. The agreement provided for an initial base salary of $450,000, with an annual target bonus of up to 45% of Mr. Weaver's then-current base salary, payable upon the achievement of performance goals to be established annually by the Compensation Committee.

The goals for fiscal 2023 included (1) completion of enrollment in the Endoxifen Phase 2 clinical study in women with mammographic breast density, (2) completion of the PK run-in cohort for the Evangeline Phase 2 neoadjuvant trial, (3) acquisition or development of additional programs, (4) commencement of one or more additional studies, and (5) accomplishment of one or more specified "stretch goals." Mr. Weaver did not become eligible for payment of a bonus for 2023 in connection with his termination of employment.

The agreement also provided for payment of a one-time signing bonus of $125,000, which was subject to pro-rata repayment in connection with his termination of employment.

During the employment term, Mr. Weaver was eligible to participate in the Company's employee benefit plans as in effect from time to time on the same basis as other senior executives.

Mr. Weaver also entered into an agreement with the Company relating to confidential information and assignment of inventions, which requires Mr. Weaver to refrain from disclosing any proprietary information and to assign to the Company any inventions, or future products, research, or development, or which result from work they perform for the Company or using its facilities.

Severance Benefits and Change in Control Arrangements

The Company has agreed to provide the severance benefits and change in control arrangements described below to its named executive officers.

Dr. Steven Quay

Pursuant to his employment agreement, if (i) the Company terminates the employment of Dr. Quay without cause, or (ii) Dr. Quay terminates his employment for good reason, then Dr. Quay will be entitled to receive all accrued but unpaid compensation including pro-rated bonus, plus a severance payment equal to 12 months of base salary. In addition, upon such event, the vesting of all shares of Common Stock underlying unvested options then held by Dr. Quay will accelerate, and the options will remain exercisable for the remainder of their terms. The cash severance payment is required to be paid in substantially equal installments over a period of six months beginning on the Company's first payroll date that occurs following the 30th day after the effective date of termination of Dr. Quay's employment, subject to certain conditions. The Company will not be required, however, to pay any severance pay for any period following the termination date if Dr. Quay materially violates certain provisions of his employment agreement and the violation is not cured within 30 days following receipt of written notice from the Company containing a description of the violation and a demand for immediate cure.

In addition, under the terms of his employment agreement, in the event of a "change in control" of the Company (as defined in the employment agreement) during Dr. Quay's employment term, Dr. Quay will be entitled to receive a one-time payment equal to 2.9 times his base salary, and the vesting of all outstanding equity awards then held by Dr. Quay will accelerate such that they are fully vested as of the date of the change in control.

Heather Rees

Pursuant to her employment agreement, if (i) the Company terminates the employment of Ms Rees without cause, or (ii) Ms. Rees terminates her employment for good reason, in either event not within 30 days before or 12 months after a change in control, she will be entitled to receive (a) a pro rata portion of the actual bonus that would have been earned for the year of termination, based on the days employed during such year, payable on the date when bonuses are otherwise paid to company employees and (b) full acceleration of the vesting of all outstanding equity awards.

Kyle Guse

Mr. Guse, ceased to serve as the Company's General Counsel and Chief Financial Officer as of May 26, 2023. Pursuant to his employment agreement, Mr. Guse became entitled to receive all accrued but unpaid compensation including a pro-rated bonus, plus a severance payment equal to 12 months of base salary. In addition, the vesting of 50% of shares of common stock underlying his unvested options accelerated, and the options will remain exercisable for the remainder of their terms. The cash severance payment was required to be paid in substantially equal installments over a period of six months beginning on the Company's first payroll date that occurred following the 30th day after the effective date of termination of Mr. Guse's employment, subject to certain conditions. The Company was not required, however, to pay any severance pay for any period following the termination date if Mr. Guse materially violated certain provisions of his employment agreement and the violation was not cured within 30 days following receipt of written notice from the Company containing a description of the violation and a demand for immediate cure. Subject to, and in accordance with, the terms of his employment agreement, upon Mr. Guse's termination without cause, he became entitled to receive the severance benefits payable of $554,000.

Greg Weaver

In connection with Mr. Weaver's voluntary resignation, he was not entitled to any severance benefits.

Other Benefits

The Company offers health, dental, disability and life insurance to its full-time employees. A 401(k) Plan with matching up to 4% of salary is also offered to its full and part-time employees.

Prohibition on Hedging and Pledging

Under our Insider Trading Policy and procedures pursuant to which, among other things, our directors, officers, and employees, and their respective family members and controlled entities, are prohibited from (i) engaging in short sales, (ii) unless approved by the Audit Committee, buying or selling puts, calls, other derivative securities of the Company or any derivative securities that provide the economic equivalent of ownership of any of the Company's securities or an opportunity, direct or indirect, to profit from any change in the value of the Company's securities, (iii) using the Company's securities as collateral in a margin account, and (iv) unless approved by the Audit Committee, pledging Company securities as collateral for a loan (or modifying an existing pledge).

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

Based on information available to us and filings with the SEC, the following table sets forth certain information regarding the beneficial ownership (as defined by Rule 13d-3 under the Exchange Act) of our outstanding Common Stock for (i) each of our directors and nominees, (ii) each of our "named executive officers," as defined in "Executive Compensation" above, (iii) all of our current directors and executive officers as a group, and (iv) persons known to us to beneficially hold more than 5% of our outstanding Common Stock. The following information is presented as of March 15, 2024 or such other date as may be reflected below.

Beneficial ownership and percentage ownership are determined in accordance with the rules of the SEC and include voting or investment power with respect to shares of stock. This information does not necessarily indicate beneficial ownership for any other purpose. Under these rules, shares of Common Stock issuable pursuant to stock options or warrants that are exercisable within 60 days of March 15, 2024, as well as convertible preferred stock, are deemed outstanding for the purpose of computing the percentage ownership of the person holding the options, warrants or convertible preferred stock, but are not deemed outstanding for the purpose of computing the percentage ownership of any other person. To our knowledge and subject to applicable community property rules, and except as otherwise indicated below, the persons and entities named in the table have sole voting and sole investment power with respect to all shares beneficially owned. Unless otherwise noted, the address of each person listed on the table is c/o Atossa Therapeutics, Inc., 107 Spring Street, Seattle, Washington 98104.

	Shares Beneficially Owned	
Name of Beneficial Owner	**Number**	**Percent of Class [1]**
Steven C. Quay, M.D. Ph.D.[2]	8,616,421	6.4%
Shu-Chih Chen, Ph.D.[3]	390,387	*
Jonathan Finn[4]	31,250	*
Stephen J. Galli, M.D.[5]	366,673	*
Heather Rees[6]	520,450	*
H. Lawrence Remmel, Esq.[7]	257	*
Richard I. Steinhart[8]	364,750	*
Tessa Cigler, M.D., M.P.H.	—	—
Kyle Guse, Esq., CPA[9]	3,177,120	2.5%
Gregory L. Weaver[10]	56	*
All current executive officers and directors as a group (8 persons)[11]	10,267,934	7.6%
Other 5% Beneficial Owners:		
CVI Investments, Inc. and Heights Capital Management, Inc.[12]	7,762,500	6.2%

* Less than one percent.

(1) Based on 125,469,405 shares of Common Stock and Preferred Stock, on an as converted basis, issued and outstanding as of March 15, 2024.

(2) Consists of (i) 2,659 shares of Common Stock directly owned by Dr. Quay, (ii) 22,254 shares of Common Stock owned by Ensisheim Partners LLC (Ensisheim), (iii) 8,589,235 shares of Common Stock issuable upon the exercise of stock options held by Dr. Quay and exercisable within 60 days of March 15, 2024 and (iv) 8 shares of Preferred B Stock convertible into 2,273 shares of Common Stock. Drs. Quay and Chen share voting and investment power over the securities held by Ensisheim. Ensisheim is solely owned and controlled by Drs. Quay and Chen, and, as a result, Drs. Quay and Chen are deemed to be beneficial owners of the shares held by this entity.

(3) Consists of (i) 22,254 shares of Common Stock owned by Ensisheim, (ii) 365,860 shares of Common Stock issuable upon the exercise of stock options held by Dr. Chen and exercisable within 60 days of March 15, 2024 and (iii) 8 shares of Preferred B Stock, convertible into 2,273 shares of Common Stock. Drs. Quay and Chen share voting and

investment power over the securities held by Ensisheim. Ensisheim is solely owned and controlled by Drs. Quay and Chen, and, as a result, Drs. Quay and Chen are deemed to be beneficial owners of the shares held by this entity.

(4) Consists of 31,250 shares of Common Stock issuable upon the exercise of stock options held by Mr. Finn and exercisable within 60 days of March 15, 2024.

(5) Consists of (i) 99 shares of Common Stock held by Dr. Galli, and (ii) 366,574 shares of Common Stock issuable upon the exercise of stock options held by Dr. Galli and exercisable within 60 days of March 15, 2024.

(6) Consists of 520,450 shares of Common Stock issuable upon the exercise of stock options held by Ms. Rees and exercisable within 60 days of March 15, 2024.

(7) Consists of 257 shares of Common Stock held by Mr. Remmel. Mr. Remmel disclaims beneficial ownership of the 11 shares of Common Stock held by his spouse.

(8) Consists of 364,750 shares of Common Stock issuable upon the exercise of stock options held by Mr. Steinhart and exercisable within 60 days of March 15, 2024.

(9) Consists of (i) 3,174,014 shares of Common Stock issuable upon the exercise of stock options held by Mr. Guse and exercisable within 60 days of March 15, 2024, (ii) 833 shares of Common Stock held by Mr. Guse and (iii) 8 shares of Preferred B Stock convertible into 2,273 shares of Common Stock.

(10) Consists of 56 shares of Common Stock held by Mr. Weaver.

(11) Consists of (i) 25,269 shares of Common Stock, (ii) 10,238,119 shares of Common Stock issuable upon the exercise of stock options exercisable within 60 days of March 15, 2024 and (iii) 16 shares of Preferred B Stock convertible into 4,546 shares of Common Stock

(12) Based on information set forth in a Schedule 13G/A filed with the SEC on February 14, 2022, by CVI Investments, Inc. (CVI) and Heights Capital Management, Inc. (Heights Capital). Consists of (i) no shares for which CVI and Heights Capital have sole dispositive power, (ii) 7,762,500 shares for which CVI and Heights Capital have shared dispositive power, (iii) no shares for which CVI and Heights Capital have sole voting power, and (iv) 7,762,500 shares for which CVI and Heights Capital have shared voting power. CVI's business address is P.O. Box 309GT, Ugland House, South Church Street, George Town, Grand Cayman, KY1-1104, Cayman Islands. Heights Capital's business address is 101 California Street, Suite 3250, San Francisco, California 94111. and the address of Heights Capital is 101 California Street, Suite 3250, San Francisco, California 94111.

Equity Compensation Plan Information

The following table sets forth certain information, as of December 31, 2023, regarding the Company's Incentive Plans, as well as other stock options and warrants previously issued by the Company as compensation for services.

Plan category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in First Column)
Equity compensation plans approved by security holders	17,506,345	$ 1.79	4,646,686
Equity compensation plans not approved by security holders	—	—	—
Total	17,506,345	$ 1.79	4,646,686

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Transactions with Related Parties

Other than compensation arrangements described above under the captions “Director Compensation” and “Executive Compensation,” since January 1, 2022, we have not been a party to any related party transactions within the meaning of SEC rules.

Related-Party Transaction Review and Approval

Related party transactions that the Company is required to disclose publicly under the federal securities laws require prior approval by the Company’s independent directors without the participation of any director who may have a direct or indirect interest in the transaction in question. Related parties include directors, nominees for director, principal stockholders (that is, any person who beneficially owns five percent or more of any class of the Company’s voting securities), executive officers and members of their immediate families. For these purposes, a “transaction” includes all financial transactions, arrangements or relationships, ranging from extending credit to the provision of goods and services for value. The Company’s policies and procedures regarding related party transactions are not part of a formal written policy, but rather, represent a course of practice determined to be appropriate by the Board of Directors of the Company.

Director Independence

We believe that the Company benefits from having a strong and independent Board. For a director to be considered independent, the Board must determine, in accordance with the Nasdaq listing rules, that the director does not have any direct or indirect material relationship with the Company that would affect his or her exercise of independent judgment. On an annual basis, the Board reviews the independence of all directors under guidelines established by Nasdaq and in light of each director’s background, employment and affiliations with the Company and members of management, as well as significant holdings of Company securities. This review considers all known relevant facts and circumstances in making an independence determination. Based on this review, the Board has made an affirmative determination that all directors, other than Drs. Quay and Chen, are “independent directors” as defined by the Nasdaq listing rules. The Board determined that Dr. Quay is not independent because of his status as the Company’s President and Chief Executive Officer and that Dr. Chen is not independent because of her marriage to Dr. Quay. Former director, Greg Weaver, was not independent during the period he served on the Board because he also served as our Executive Vice President and Chief Financial Officer at that time. The independent board members meet regularly in executive sessions without the non-independent members and without management.

Our Board also determined that each of the directors currently serving on the Audit Committee and the Compensation Committee satisfy the heightened independence standards for audit committees and compensation committees, as applicable, as established by the SEC and Nasdaq listing rules.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Ernst & Young LLP (“EY”) has served as our independent auditor for the year ended December 31, 2023 (on or after May 17, 2023 (the “Effective Date”)). BDO USA, LLP (“BDO”) served as our independent auditor prior to the Effective Date.

Fees for Independent Registered Public Accounting Firm

The following is a summary of the audit fees billed and expected to be billed to the Company by EY and BDO for the fiscal year ended December 31, 2023 and 2022, respectively, and the fees billed to the Company by EY and BDO for all other services rendered during the fiscal year ended December 31, 2023 and 2022, respectively. All services associated with such fees were pre-approved by our Audit Committee in accordance with the “Pre-Approval Policies and Procedures” described below.

	2023	2022
Audit Fees:		
Consists of fees billed for the audit of our annual financial statements and the review of the financial statements included in our quarterly reports on Form 10-Q, and services that are normally provided by the independent auditors in connection with statutory and regulatory filings or engagements for that fiscal year, including consents and expenses.	$ 610,000	$ 219,750
Audit-Related Fees: Consists of fees billed for assurance services reasonably related to the performance of the audit or review of our financial statements.	—	20,000
Tax Fees	—	—
All Other Fees	—	—
Total Fees	$ 610,000	$ 239,750

Pre-Approval Policies and Procedures

The Audit Committee reviews and pre-approves all audit and non-audit services performed by the Company's independent registered public accounting firm, as well as the fees charged for such services, in order to assure that these services do not impair the auditor’s independence. This generally involves approval of the performance of specific services subject to a cost limit for all such services. This general approval is reviewed, and if necessary modified, at least annually. Management must obtain the specific prior

approval of the committee for each engagement of our auditor to perform other audit-related or other non-audit services. The committee does not delegate its responsibility to approve services performed by our auditor to any member of management. The committee has delegated authority to the committee chair to pre-approve certain audit or non-audit services to be provided to us by our auditor. Any approval of services by the committee chair pursuant to this delegated authority is reported to the committee at its next regularly scheduled meeting.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as a part of this Annual Report:

1. Financial Statements

2. Financial Statement Schedules

All financial statement schedules are omitted because they are not required or the required information is included in the consolidated financial statements or notes thereto.

3. Exhibits

See the Exhibit Index on page 80 of this report.

ITEM 16. FORM 10-K SUMMARY

None.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of Atossa Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Atossa Therapeutics, Inc. (the Company) as of December 31, 2023, the related consolidated statements of operations, shareholders' equity and cash flows for the year then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2023, and the results of its operations and its cash flows for the year ended December 31, 2023 in conformity with U.S. generally accepted accounting principles.

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 audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audit 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 audit 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 audit provides a reasonable basis for our opinion.

Critical Audit Matter

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

Valuation of Investment in Equity Securities

Description of the Matter	As described in Note 4 to the consolidated financial statements, the Company recorded an impairment charge of $3.0 million on its equity investment in Dynamic Cell Therapies, Inc. (DCT) for the year ended December 31, 2023. The Company previously elected to measure its investment in DCT at cost less impairment and identified indicators of impairment during the year. Auditing the impairment charge was complex due to the significant estimation uncertainty and judgment involved in determining the fair value of the investment in DCT, a private company without a readily determinable fair value. In particular, the fair value estimate was sensitive to significant assumptions, such as weighting of a non-liquidation scenario and a liquidation scenario, expected average volatility based on comparable companies, and expected percentage adjustment to book value in a hypothetical liquidation scenario. These significant assumptions are highly judgmental and could be affected by future market conditions and the investee's operational decisions.
How We Addressed the Matter in Our Audit	To test the fair value of the Company's equity investment in DCT and the related impairment charge, our audit procedures included, among others, evaluating methodologies and testing the significant assumptions discussed above and the underlying data used by the Company in its analysis with the assistance of our internal valuation specialists. For example, we compared the significant assumptions used by management to industry trends and DCT's financial status. We evaluated the reasonableness of the comparable companies used to estimate expected volatility based on their industry and business stage and recomputed the volatility inputs used based on the historical data of the comparable companies. We also performed sensitivity analysis of the expected percentage adjustment to book value in a hypothetical liquidation scenario to evaluate the changes in the fair value that would result from changes in this assumption.

/s/ Ernst & Young LLP
We have served as the Company's auditor since 2023.
Seattle, Washington
April 1, 2024

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Shareholders and Board of Directors
Atossa Therapeutics, Inc.
Seattle, Washington

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheet of Atossa Therapeutics, Inc. (the "Company") as of December 31, 2022, the related consolidated statements of operations, stockholders' equity, and cash flows for the year then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2022, and the results of its operations and its cash flows for the year then ended**,** in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

/s/ BDO USA, LLP

We served as the Company's auditor from 2014 to 2023.

Seattle, Washington
March 22, 2023

ATOSSA THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(amounts in thousands, except share and per share data)

	As of December 31, 2023	2022
Assets		
Current assets		
Cash and cash equivalents	$ 88,460	$ 110,890
Restricted cash	110	110
Prepaid materials	1,487	5,247
Prepaid expenses and other current assets	2,162	1,207
Research and development tax rebate receivable	—	743
Total current assets	92,219	118,197
Investment in equity securities	1,710	4,700
Other assets	2,323	635
Total assets	$ 96,252	$ 123,532
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 806	$ 2,965
Accrued expenses	973	1,059
Payroll liabilities	1,654	1,525
Other current liabilities	1,803	19
Total current liabilities	5,236	5,568
Total liabilities	5,236	5,568
Commitments and contingencies (Note 13)		
Stockholders' equity		

Convertible preferred stock - $ 0.001 par value; 10,000,000 shares authorized; 582 shares issued and outstanding as of December 31, 2023 and 2022	—	—
Common stock - $ 0.18 par value; 175,000,000 shares authorized; 125,304,064 and 126,624,110 shares issued and outstanding as of December 31, 2023 and 2022, respectively	22,792	22,792
Additional paid-in capital	255,987	251,366
Treasury stock, at cost; 1,320,046 and 0 shares of common stock at December 31, 2023 and 2022, respectively	(1,475)	—
Accumulated deficit	(186,288)	(156,194)
Total stockholders' equity	91,016	117,964
Total liabilities and stockholders' equity	$ 96,252	$ 123,532

The accompanying notes are an integral part of these Consolidated Financial Statements.

ATOSSA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(amounts in thousands, except share and per share data)

	For the Year Ended December 31, 2023	2022
Operating expenses		
Research and development	$ 17,334	$ 15,083
General and administrative	14,043	12,608
Total operating expenses	31,377	27,691
Operating loss	(31,377)	(27,691)
Impairment charge on investment in equity securities	(2,990)	—
Interest income	4,343	877
Other expense, net	(70)	(146)
Loss before income taxes	(30,094)	(26,960)
Income tax benefit	—	—
Net loss	(30,094)	(26,960)
Net loss per share of common stock - basic and diluted	$ (0.24)	$ (0.21)
Weighted average shares outstanding used to compute net loss per share - basic and diluted	126,081,602	126,624,110

The accompanying notes are an integral part of these Consolidated Financial Statements.

ATOSSA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(amounts in thousands, except share data)

	Convertible Preferred Stock		Common Stock			Treasury Stock		
	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Amount	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2021	582	$ —	126,624,110	$ 22,792	$ 244,578	$ —	$ (129,234)	$ 138,136
Stock-based compensation	—	—	—	—	6,788	—	—	6,788
Net loss	—	—	—	—	—	—	(26,960)	(26,960)
Balance at December 31, 2022	582	$ —	126,624,110	$ 22,792	$ 251,366	$ —	$ (156,194)	$ 117,964
Common stock repurchased	—	—	(1,320,046)	—	—	(1,475)	—	(1,475)
Stock-based compensation	—	—	—	—	4,621	—	—	4,621
Net loss	—	—	—	—	—	—	(30,094)	(30,094)
Balance at December 31, 2023	582	$ —	125,304,064	$ 22,792	$ 255,987	$ (1,475)	$ (186,288)	$ 91,016

The accompanying notes are an integral part of these Consolidated Financial Statements.

ATOSSA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	For the Year Ended December 31, 2023	2022
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (30,094)	$ (26,960)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation	4,621	6,788
Impairment charge on investment in equity securities	2,990	—
Depreciation	23	8
Disposal of assets	—	3
Changes in operating assets and liabilities:		
Prepaid materials	2,544	(2,953)
Research and development tax rebate receivable	743	329
Prepaid expenses and other current assets	261	180
Other assets	(1,697)	(597)
Accounts payable	(2,159)	1,248
Accrued expenses	(86)	855
Payroll liabilities	129	341
Other current liabilities	1,784	(2)
Net cash used in operating activities	(20,941)	(20,760)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of investment in equity securities	—	(4,700)
Purchase of property and equipment	(14)	(27)
Net cash used in investing activities	(14)	(4,727)

CASH FLOWS FROM FINANCING ACTIVITIES		
Common stock repurchased	(1,475)	—
Net cash used in financing activities	(1,475)	—
NET DECREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	(22,430)	(25,487)
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, BEGINNING BALANCE	111,000	136,487
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, ENDING BALANCE	$ 88,570	$ 111,000
RECONCILIATION OF CASH AND CASH EQUIVALENTS AND RESTRICTED CASH		
Cash and cash equivalents	$ 88,460	$ 110,890
Restricted cash	110	110
Total cash, cash equivalents and restricted cash	$ 88,570	$ 111,000

The accompanying notes are an integral part of these Consolidated Financial Statements.

ATOSSA THERAPEUTICS, INC.
NOTES TO CONSLIDATED FINANCIAL STATEMENTS

NOTE 1: NATURE OF OPERATIONS

Atossa Therapeutics, Inc. (the Company) was incorporated on April 30, 2009, in the State of Delaware to develop and market medical devices, laboratory tests and therapeutics to address breast health conditions. The Company is focused on developing proprietary innovative medicines in areas of significant unmet medical need in oncology, with a focus on breast cancer and other breast conditions.

NOTE 2: LIQUIDITY AND CAPITAL RESOURCES

The Company has incurred net losses and negative operating cash flows since inception. For the year ended December 31, 2023, the Company recorded a net loss of $

30.1
million and used $

20.9
million of cash in operating activities. As of December 31, 2023, the Company had $

88.5
million in unrestricted cash and cash equivalents and working capital of $

87.0
million. The Company has not yet established an ongoing source of revenue sufficient to cover its operating costs, and it believes it will need to continue to raise substantial additional capital to accomplish its business plan over the next several years. Management believes its currently available cash and cash equivalents will be sufficient to finance the Company's operations for at least one year from the date these Consolidated Financial Statements are issued. The Company plans to continue to fund its losses from operations and capital funding needs through a combination of public or private equity offerings, debt financings or other sources, including potential corporate collaborations, licenses and other similar arrangements. There can be no assurance as to the availability or terms upon which such financing and capital might be available in the future. If the Company is unable to secure additional funding, it may be forced to curtail or suspend its business plans.

NOTE 3: SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

These Consolidated Financial Statements have been prepared pursuant to the rules of the Securities and Exchange Commission (SEC) and in accordance with the accounting principles generally accepted in the U.S. (GAAP). The accompanying Consolidated Financial Statements include the financial statements of Atossa Therapeutics, Inc. and its wholly-owned subsidiaries. All significant intercompany transactions and balances have been eliminated in consolidation.

Reclassification

Certain reclassifications have been made to prior period financial information to conform to the current year presentation.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Significant estimates and assumptions reflected in these financial statements include the valuation of the investment in non-marketable equity securities, stock-based compensation expense, and prepaid or accrued clinical trial balances at the end of any reporting period. Actual results could differ materially from the Company's estimates.

Segments

The Company operates as a single segment. Operating segments are identified as the components of an enterprise of which separate discrete financial information is available for evaluation by the chief operating decision maker in making decisions regarding resource allocation and in assessing performance. To date, the Company's chief operating decision maker has made such decisions and assessed performance at the Company-level as a single segment.

Cash and Cash Equivalents

Cash and cash equivalents include unrestricted cash and all highly liquid instruments with original maturities of three months or less at the date of purchase. Cash equivalents consist primarily of amounts invested in money market accounts.

Restricted Cash

The Company's restricted cash balance as of December 31, 2023 and 2022, consisted entirely of cash pledged as security for the Company's issued commercial credit cards.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist primarily of deposits of cash and cash equivalents, including those deposited in money market deposit accounts. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any material losses in such accounts and believes it is not exposed to significant risk. The Company has invested its excess cash primarily in money market funds.

Prepaid Materials

We capitalize the purchase of certain raw materials, active pharmaceutical ingredient and related supplies for use in the manufacturing of drug products for use in our preclinical and clinical development programs, as we have determined that these materials have alternative future use. We can use these raw materials and related supplies in multiple clinical drug products, and therefore have future use independent of the development status of any particular drug program until it is utilized in the manufacturing process. We expense the cost of materials when used. We periodically review these capitalized materials for continued alternative future use and write down the asset to its net realizable value in the period in which an impairment is identified. Prepaid materials not expected to be used within 12 months of the balance sheet date are presented in Other assets on the Consolidated Balance Sheets.

Research and Development Tax Rebate Receivable

The Company uses the grant accounting model by analogy to International Accounting Standards (IAS) 20 *Accounting for Government Grants and Disclosure of Government Assistance* to account for the cash rebates received from the Australian government. The Company records the research and development rebate credit in the period when it incurs the associated research and development costs as a reduction to the research and development expenses in the Consolidated Statements of Operations.

Variable Interest Entities

The Company reviews agreements it enters into with third-party entities, pursuant to which the Company may have a variable interest in the entity, in order to determine if the entity is a variable interest entity (VIE). If the entity is a VIE, the Company assesses whether or not it is the primary beneficiary of that entity. In determining whether the Company is the primary beneficiary of an entity, the Company applies a qualitative approach that determines whether it has both (i) the power to direct the economically significant activities of the entity and (ii) the obligation to absorb losses of, or the right to receive benefits from, the entity that could potentially be significant to that entity. If the Company determines it is the primary beneficiary of a VIE, it consolidates that VIE into the Company's consolidated financial statements. The Company's determination about whether it should consolidate such VIEs is made continuously as changes to existing relationships or future transactions may result in a consolidation or deconsolidation event. The Company currently does not consolidate any VIEs.

Investments in Equity Securities

The Company has one investment in non-marketable equity securities. This investment does not have a readily determinable fair value, so the Company has elected to measure the investment at cost less any impairment, adjusted to fair value if there are observable price changes in orderly transactions for an identical or similar investment of the same issuer, in accordance with Accounting Standards Codification (ASC) *321, Investments – Equity Securities*. At each reporting period, the Company performs an assessment to determine if it still qualifies for this measurement alternative.

At each reporting period, the Company makes a qualitative assessment considering impairment indicators to evaluate whether the investment is impaired. If a qualitative assessment indicates the investment is impaired, the Company estimates the investment's fair value. If the fair value is less than the investment's carrying value, an impairment charge is recorded in the Consolidated Statements of Operations equal to the difference between the carrying value and fair value and a new basis in the investment is established. Refer to Note 4.

Other Assets

Other assets consist of property and equipment, prepaid materials and clinical deposits.

Fair Value Measurements

The Company has certain financial assets and liabilities recorded at fair value which have been classified as Level 1, 2 or 3 within the fair value hierarchy as described in the accounting standards for fair value measurements.

The fair value hierarchy is broken down into the three input levels summarized below:

- Level 1: Quoted market prices in active markets for identical assets or liabilities;

- Level 2: Other observable market-based inputs or unobservable inputs that are corroborated by market data; and

• Level 3: Unobservable inputs that cannot be corroborated by market data that reflects the reporting entity's own assumptions.

The carrying amounts reflected in the accompanying Consolidated Balance Sheets for cash and cash equivalents, restricted cash, research and development tax rebate receivable, and accounts payable approximate their fair values due to their short-term nature. Refer to Note 9.

Research and Development

Research and development (R&D) costs are generally expensed as incurred. R&D expenses include, for example, manufacturing expenses for the Company's drugs under development, expenses associated with preclinical studies, clinical trials and associated salaries, bonuses, stock-based compensation and benefits. The Company has entered into various research and development contracts with research institutions, clinical research organizations (CROs), clinical manufacturing organizations (CMOs) and other third parties. Payments for these activities are based on the terms of the individual agreements, which may differ from the timing of costs incurred. The Company records accruals for estimated costs incurred for ongoing research and development activities as reflected in the consolidated balance sheets as accrued expenses. Payments made in advance of incurring costs are reflected in the Consolidated Balance Sheets as prepaid expenses. When evaluating the adequacy of the accrued expenses and prepaid expenses, the Company analyzes progress of the services, including the phase or completion of events, invoices received and contracted costs.

R&D expenses also include an allocation of the CEO's salary and related benefits, including bonus and non-cash stock-based compensation expense, based on an estimate of his total hours spent on R&D activities. The Company's CEO is involved in the development of the Company's drug candidates and oversight of the related clinical trial activities and also acts as the Company's chief medical officer.

Stock-based Compensation

The Company measures and recognizes compensation expense for all stock-based awards made to employees, officers, non-employee directors, and other key persons providing services to the Company, currently limited to stock options. Stock-based compensation is measured using the estimated grant date fair value and is recognized as an expense over the requisite service period, generally the vesting period. The Company has made a policy election to recognize forfeitures when they occur.

The fair value of each stock option grant is estimated using the Black-Scholes option-pricing model, which requires assumptions regarding the expected volatility of the price of the Company's common stock, the expected life of the options, an expectation regarding future dividends on the Company's common stock, and a risk-free interest rate. The Company's expected common stock price volatility assumption is based upon the historical volatility of its stock price. The Company has elected the simplified method for the expected life assumption for stock option grants, which averages the contractual term of the options of 10 years with the vesting term, typically one to four years , as the Company does not have sufficient option exercise experience. The dividend yield assumption of

zero

is based upon the fact that the Company has never paid cash dividends and presently has no intention of paying cash dividends in the future. The risk-free interest rate assumption is based upon prevailing short-term interest rates over the expected life of the options as of the grant date.

Income Taxes

The Company accounts for income taxes under the asset and liability method. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax bases of assets and liabilities and are measured using enacted tax rates and laws that are expected to be in effect when the differences are expected to be recovered or settled. Realization of deferred tax assets is dependent upon future taxable income. A valuation allowance is recognized if it is more likely than not that some portion or all of a deferred tax asset will not be realized based on the weight of available evidence, including expected future earnings. The Company recognizes an uncertain tax position in its financial statements when it concludes that a tax position is more likely than not to be sustained upon examination based solely on its technical merits. Only after a tax position passes the first step of recognition will measurement be required. Under the measurement step, the tax benefit is measured as the largest amount of benefit that is more likely than not to be realized upon effective settlement. This is determined on a cumulative probability basis. The full impact of any change in recognition or measurement is reflected in the period in which such change occurs. The Company records any interest or penalties related to income taxes in income tax benefit in the Consolidated Statements of Operations.

Recently Issued Accounting Pronouncements

In November 2023, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*. This standard requires disclosure of

significant segment expenses and other segment items by reportable segment. This ASU becomes effective for annual periods beginning in 2024 and interim periods in 2025. The Company is assessing the potential impact of this ASU.

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures.* This standard enhances disclosures related to income taxes, including the rate reconciliation and information on income taxes paid. This ASU becomes effective on January 1, 2025. The Company is currently assessing the potential impact of this ASU.

The Company does not expect adoption of any other recently issued accounting pronouncements to have a material impact on its financial statements.

NOTE 4: INVESTMENT IN EQUITY SECURITIES

On December 23, 2022, the Company completed its investment in Dynamic Cell Therapies, Inc. (DCT), a U.S. private company that is in the pre-clinical stage of developing novel Chimeric Antigen Receptor (CAR) T-cell therapies based on technology licensed from a leading U.S. cancer treatment and research institution. The Company's determined that DCT is a variable interest entity. The Company does not consolidate DCT because it does not have the power to direct economically significant activities. The Company has no obligation to provide any future funding to DCT and its maximum exposure to loss is its investment value. In total, the Company paid $

4.7

million during the year ended December 31, 2022 to DCT in exchange for Series Seed Preferred Shares representing approximately

19

% of the post-investment outstanding shares of DCT as of December 31, 2022.

During 2023, the Company considered the additional adverse changes in the general market condition of the industry in which DCT operates and continued concerns about the investee's ability to continue as a going concern, due to negative cash flows from operations. Based on these impairment indicators, the Company performed a quantitative fair value measurement in the second quarter of 2023.

The assumptions and estimates used to estimate the fair value of the investment include the following information from DCT:

- Unaudited financial statements;
- Projected technological developments of DCT;
- Then-current fundraising transactions;
- The-current ability of DCT to raise additional financing when needed;
- Changes in the economic environment which may have a material impact on the operating results of DCT; and
- Timing of a deemed liquidation event occurring.

The impairment of the Company's investment in equity securities required the estimation of fair value using unobservable inputs (a Level 3 fair value measurement). The Company used the dynamic options approach, which requires assumptions regarding the expected average volatility of comparable companies, the expected term of the investment, and the risk-free interest rate over the expected term of the investment. The expected stock price volatility assumption is based upon the average historic volatility of comparable public clinical stage immunotherapy or CAR-T companies. The expected term of the Company's investment is

3.5

years and the risk-free interest rate used is based upon prevailing short-term interest rates over the expected term of the investment. The dynamic options approach was weighted at a

50

% outcome probability. An adjusted book value approach was also considered and also weighted at a

50

% probability due to DCT's limited cash on hand, status of current fundraising efforts and the estimated timing of a deemed liquidation event occurring. The Company recorded an impairment charge of $

3.0

million for the year ended December 31, 2023.

No

impairment was recorded during the year ended December 31, 2022 as a result of the Company's qualitative impairment analysis.

NOTE 5: PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consisted of the following (in thousands):

	As of December 31, 2023	As of December 31, 2022
Prepaid clinical trial deposits	$ 805	$ 611
Prepaid insurance	794	387
Prepaid professional services	501	130

Other	62	79
Total prepaid expenses and other current assets	$ 2,162	$ 1,207

NOTE 6: RESEARCH AND DEVELOPMENT TAX REBATE RECEIVABLE

On May 23, 2017, the Company formed a wholly owned subsidiary in Australia called Atossa Genetics AUS Pty Ltd. The purpose of this subsidiary is to perform R&D activities, including some of the Company's clinical trials. Australia offers R&D cash rebates on qualified R&D activities incurred in the country. During the years ended December 31, 2023 and 2022, the Company collected R&D cash rebates of $

0.7
million and $

1.0
million, respectively. The Company did

no
t recognize any rebates during the year ended December 31, 2023 and recognized rebates of $

0.7
million for the year ended December 31, 2022.

The Australian R&D tax incentive program is a self-assessment program, and as such, the Australian Taxation Office (ATO) has the right to review the Company’s program and related expenditures for a period of four years following the tax return filing date. If a review were to occur, a qualified program and related expenditures could be disqualified by the ATO with interest and penalties. Based on the Company's evaluation of the ATO's taxpayer alert in December 2023, the Company believes that it is no longer reasonably assured that the full tax position would be sustained under audit. Accordingly, a change in estimate was recorded during the three-month period ended December 31, 2023 that represents the Company's estimate of the amount plus penalties that no longer meets the reasonably assured threshold. The Company accrued a liability of $

1.8
million, which is included in other current liabilities in the Consolidated Balance Sheet for the year ended December 31, 2023. The change in estimate also increased the Company's R&D expenses by $

1.4
million and G&A expenses by $

0.4
million, for the year ended December 31, 2023.

NOTE 7: ACCRUED EXPENSES

Accrued expenses consisted of the following (in thousands):

	As of December 31, 2023	As of December 31, 2022
Accrued clinical trial costs	$ 608	$ 1,038
Accrued professional services and other	365	21
Total accrued expenses	$ 973	$ 1,059

NOTE 8: PAYROLL LIABILITIES

Payroll liabilities consisted of the following (in thousands):

	As of December 31, 2023	As of December 31, 2022
Accrued bonuses	$ 1,134	$ 1,060
Accrued vacation	236	224
Accrued payroll and benefits	284	241
Total payroll liabilities	$ 1,654	$ 1,525

NOTE 9: FAIR VALUE OF FINANCIAL INSTRUMENTS

The following tables present the Company's fair value hierarchy for all its financial assets and liabilities, by major security type, measured at fair value on a recurring basis (in thousands):

December 31, 2023	Estimated Fair Value	Level 1	Level 2	Level 3
Assets:				
Money market fund	$ 88,029	$ 88,029	$ —	$ —

December 31, 2022	Estimated Fair Value	Level 1	Level 2	Level 3
Assets:				
Money market fund	$ 102,681	$ 102,681	$ —	$ —

NOTE 10: STOCKHOLDERS' EQUITY

Common Stock

The Company is authorized to issue a total of

185,000,000
shares of stock, consisting of

175,000,000
shares of common stock, par value $

0.18
per share, and

10,000,000
shares of preferred stock, par value $

0.001
per share.

On May 19, 2014, the Company adopted a stockholder rights agreement, pursuant to which all stockholders of record on May 26, 2014 received a non-taxable distribution of

one
preferred stock purchase right for each share of the Company's common stock held by such stockholder. Each right is attached to and trades with the associated share of common stock. The rights will become exercisable only if one of the following occurs: (1) a person becomes an "Acquiring Person" by acquiring beneficial ownership of

15
% or more of the Company's common stock (or, in the case of a person who beneficially owned

15
% or more of the Company's common stock on the date the stockholder rights agreement was executed, by acquiring beneficial ownership of additional shares representing

2.0
% of the Company's common stock then outstanding (excluding compensatory arrangements)), or (2) a person commences a tender offer that, if consummated, would result in such person becoming an Acquiring Person. If a person becomes an Acquiring Person, each right will entitle the holder, other than the Acquiring Person and certain related parties, to purchase a number of shares of the Company's common stock with a market value that equals twice the exercise price of the right. The initial exercise price of each right is $

15.00
, so each holder (other than the Acquiring Person and certain related parties) exercising a right would be entitled to receive $

30.00
worth of the Company's common stock. If the Company is acquired in a merger or similar business combination transaction at any time after a person has become an Acquiring Person, each holder of a right (other than the Acquiring Person and certain related parties) will be entitled to purchase a similar amount of stock of the acquiring entity.

Share Repurchases

On June 27, 2023, the Board of Directors (the Board) authorized a program to repurchase common stock, par value $

0.18
per share, up to an aggregate market value of $

10.0
million. During the year ended December 31, 2023,

1,320,046
shares were repurchased pursuant to the program for a total cost of $

1.5
million. The share repurchase program was originally set to expire on December 31, 2023, however, on December 18, 2023 the Board authorized an extension through December 31, 2024. The Board may suspend, modify, or terminate the share repurchase program at any time.

Series Convertible Preferred Stock

The Company has designated

750,000
shares of Series A junior participating preferred stock, par value $

0.001
per share,

4,000
shares of Series A convertible preferred stock, par value $

0.001
per share,

25,000
shares of Series B convertible preferred stock, par value $

0.001
per share, and

20,000
shares of Series C convertible preferred stock, par value $

0.001
per share, through the filings of certificates of designation with the Delaware Secretary of State.

No

shares of Series A junior participating preferred stock, Series A convertible preferred stock, or Series C convertible preferred stock, were outstanding as of December 31, 2023 or 2022.

Series B Convertible Preferred Stock

Conversion. Each share of Series B convertible preferred stock is convertible at the Company's option at any time, or at the option of the holder at any time, into the number of shares of the Company's common stock determined by dividing the $

1,000
stated value per share of the Series B convertible preferred stock by a conversion price of $

3.52
per share. In addition, the conversion price per share is subject to adjustment for stock dividends, distributions, subdivisions, combinations, or reclassifications. Subject to limited exceptions, a holder of the Series B convertible preferred stock will not have the right to convert any portion of the Series B convertible preferred stock to the extent that, after giving effect to the conversion, the holder, together with its affiliates, would beneficially own in excess of

9.99
% of the number of shares of our common stock outstanding immediately after giving effect to its conversion.

During the years ended December 31, 2023 and 2022, there were no conversions of Series B convertible preferred stock**.**

Fundamental Transactions. In the event the Company effects certain mergers, consolidations, sales of substantially all of its assets, tender or exchange offers, reclassifications, or share exchanges in which its common stock is effectively converted into or exchanged for other securities, cash or property, the Company consummates a business combination in which another person acquires

50
% of the outstanding shares of its common stock, or any person or group becomes the beneficial owner of

50
% of the aggregate ordinary voting power represented by its issued and outstanding common stock, then, upon any subsequent conversion of the Series B convertible preferred stock, the holders of the Series B convertible preferred stock will have the right to receive any shares of the acquiring corporation or other consideration it would have been entitled to receive if it had been a holder of the number of shares of common stock then issuable upon conversion in full of the Series B convertible preferred stock.

Dividends. Holders of Series B convertible preferred stock shall be entitled to receive dividends (on an as-if-converted-to-common-stock basis) in the same form as dividends actually paid on shares of the common stock when, as and if such dividends are paid on shares of common stock. The Company's preferred stock contractually entitles the holders of such securities to participate in dividends but do not contractually require the holders of such securities to participate in losses of the Company.

Voting Rights. Except as otherwise provided in the certificate of designation or as otherwise required by law, the Series B convertible preferred stock has no voting rights.

Liquidation Preference. Upon the Company's liquidation, dissolution or winding-up, whether voluntary or involuntary, holders of Series B convertible preferred stock will be entitled to receive out of the Company's assets, whether capital or surplus, the same amount that a holder of common stock would receive if the Series B convertible preferred stock were fully converted (disregarding for such purpose any conversion limitations under the certificate of designation) to common stock, which amounts shall be paid *pari passu* with all holders of common stock.

Redemption Rights. The Company is not obligated to redeem or repurchase any shares of Series B convertible preferred stock. Shares of Series B convertible preferred stock are not otherwise entitled to any redemption rights, or mandatory sinking fund or analogous provisions.

2021 and 2020 Warrants

The warrants were issued to institutional and accredited investors as a part of the financing transactions, which closed on December 11, 2020, December 21, 2020, December 28, 2020, January 8, 2021, and March 23, 2021. The terms and conditions of the warrants are as follows:

Exercisability. Each warrant is exercisable at any time and will expire between 4 and 4.5 years from the date of issuance. The warrants are exercisable, at the option of each holder, in whole or in part by delivering to the Company a duly executed exercise notice and payment in full for the number of shares of the Company's common stock purchased upon such exercise, except in the case of a cashless exercise as discussed below. The number of shares of common stock issuable upon exercise of the warrants is subject to adjustment in certain circumstances, including a stock split or, stock dividend on, or a subdivision, combination or recapitalization of the common stock. Upon the merger, consolidation, sale of substantially all of the Company's assets, or other similar transaction, the holders of warrants shall, at the option of the Company, be required to exercise the warrants immediately prior to the closing of the transaction, or such warrants shall automatically expire. Upon such exercise, the holders of warrants shall participate on the same basis as the holders of common stock in connection with the transaction.

Cashless Exercise. If at any time there is no effective registration statement registering, or the prospectus contained therein is not available for issuance of, the shares issuable upon exercise of the warrant, the holder may exercise the warrant on a cashless basis. When exercised on a cashless basis, a portion of the warrant is cancelled in payment of the purchase price payable in respect of the number of shares of the Company's common stock purchasable upon such exercise.

Exercise Price. Each warrant represents the right to purchase

one

share of common stock. In addition, the exercise price per share is subject to adjustment for stock dividends, distributions, subdivisions, combinations or reclassifications, and for certain dilutive issuances. Subject to limited exceptions, a holder of warrants will not have the right to exercise any portion of the warrant to the extent that, after giving effect to the exercise, the holder, together with its affiliates, and any other person acting as a group together with the holder or any of its affiliates, would beneficially own in excess of

4.99

% of the number of shares of the Company's common stock outstanding immediately after giving effect to its exercise. The holder, upon notice to the Company, may increase or decrease the beneficial ownership limitation provisions of the warrant, provided that in no event shall the limitation exceed

9.99

% of the number of shares of the Company's common stock outstanding immediately after giving effect to the exercise of the warrant.

Transferability. Subject to applicable laws and restrictions, a holder may transfer a warrant upon surrender of the warrant to us with a completed and signed assignment in the form attached to the warrant. The transferring holder will be responsible for any tax liability that may arise as a result of the transfer.

Exchange Listing. The Company does not intend to apply to list the warrants on any securities exchange or recognized trading system.

Rights as Stockholder. Except as set forth in the warrant, the holder of a warrant, solely in such holder's capacity as a holder of a warrant, will not be entitled to vote, to receive dividends or to any of the other rights of the Company's stockholders. The Company's warrants contractually entitles the holders of such securities to participate in dividends but do not contractually require the holders of such securities to participate in losses of the Company.

Warrants Outstanding

As of December 31, 2023, the following warrants to purchase shares of common stock were outstanding:

	Outstanding Warrants to Purchase Shares	Exercise Price Per Warrant	Expiration Date
December 2020 warrants	6,489,500	$ 1.00	December 11, 2024-June 21, 2025
January 2021 warrants	4,500,000	$ 1.055	July 8, 2025
March 2021 warrants	10,525,000	$ 2.88	September 22, 2025
	21,514,500		

Warrant Activity

There were

no

warrant exercises during the years ended December 31, 2023 or 2022. On May 30, 2022, all

762,000

of the warrants issued in May 2018 expired, unexercised, with an exercise price of $

4.05

per share.

NOTE 11: NET LOSS PER SHARE

Basic net loss per share of common stock is computed by dividing net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding. Diluted net loss per share of common stock is computed by dividing net loss attributable to common stockholders by the weighted average number of shares of common stock that would have been outstanding during the period assuming the issuance of shares of common stock for all potentially dilutive shares of common stock outstanding. Potentially dilutive shares of common stock consist of future exercises of outstanding stock options, convertible preferred stock and common stock warrants. Because the inclusion of potential shares of common stock would be anti-dilutive for all periods presented, they have been excluded from the calculation.

The following table sets forth the weighted average number of common shares excluded from the calculation of diluted net loss per share, because including them would be anti-dilutive:

	Year Ended December 31,	
	2023	2022
Options to purchase common stock	17,547,573	12,989,635
Series B convertible preferred stock	165,338	165,338
Warrants to purchase common stock	21,514,500	21,825,703
	39,227,411	34,980,676

NOTE 12: INCOME TAXES

A reconciliation of the income tax benefit calculated at the federal statutory rate to total income tax provision is as follows (in thousands):

	Year Ended December 31,	
	2023	2022

Expected federal income tax benefit	$ (6,320)	$ (5,662)
Disallowed R&D expenses	9	351
Non-taxable R&D rebate	(7)	(156)
Other permanent items	738	214
Return to provision	47	862
Stock-based compensation	682	213
Foreign rate differential	(453)	(270)
Other	(2)	27
Effect of change in valuation allowance	5,306	4,421
Income tax benefit	$ —	$ —

The following table summarizes the significant components of the Company's deferred tax assets and liabilities (in thousands):

	As of December 31,	
	2023	2022
Deferred tax assets		
Accrued bonus	$ 238	$ 222
Accrued vacation	50	47
Stock-based compensation	4,203	4,067
Capitalized R&D expenses	5,788	3,155
Rebate reserve	303	—
Intangible assets, net	248	315
Investment in equity securities	628	—
Net operating loss carryforwards	13,276	11,522
Other	6	—
Total gross deferred tax asset	24,740	19,328
Valuation allowance	(24,646)	(19,327)
Net deferred tax assets	94	1
Deferred tax liabilities		
Section 481(a) adjustment - bonus compensation	(94)	—
Fixed assets	—	(1)
Net deferred tax assets	$ —	$ —

As of December 31, 2023 and 2022, a valuation allowance was established against the Company's net deferred tax assets due to the uncertainty regarding the realization of such assets and evidenced by the cumulative losses from operations through December 31, 2023 and 2022. The total valuation allowance increased by $

5.4
million for the year ended December 31, 2023.

The Company has incurred net operating losses since inception. At December 31, 2023, the Company had domestic federal net operating loss carryforwards of $

106.7
million and foreign net operating loss carryforwards of $

1.6
million. Federal net operating loss carryforwards generated through December 31, 2017 expire at various dates beginning 2029 through 2038 , while Federal net operating loss carryforwards generated during or after 2018 do not expire. Foreign net operating losses do not expire.

The future utilization of the Federal net operating loss carryforwards to offset future taxable income, may be subject to an annual limitation as a result of ownership changes that may have occurred previously or may occur in the future. The Tax Reform Act of 1986 (the Act) limits a Company's ability to utilize certain net operating loss carry forwards in the event of a cumulative change in ownership in excess of 50% (by value) defined in the act. The Company has not completed a study to assess whether an ownership change, as defined by the Act, had occurred from the Company's formation through December 31, 2023.

In previous years, the Company completed public offerings, which it believes triggered ownership changes under Section 382 of the Act. The Company believes that as of December 31, 2023, the gross net operating loss carryforward is limited to $

60.9
million, which are available to reduce future taxable income.

The Company files income tax returns in the U.S. and Australia. The Company has not been audited for any open taxation years. The Company is subject to federal tax examinations for 2017 and beyond for the U.S. operations and 2019 and beyond for Australia operations.

The Company has

no

unrecognized tax positions as of December 31, 2023 or 2022 and does not believe there will be any material changes in its unrecognized tax positions over the next 12 months. The Company has

no

t incurred any interest or penalties related to unrecognized tax positions for the years ended December 31, 2023 or 2022.

NOTE 13: COMMITMENTS AND CONTINGENCIES

Litigation and Contingencies

On August 18, 2023, Intas Pharmaceuticals LTD. filed a Petition for Post Grant Review (PGR) with the U.S. Patent and Trademark Office (the PGR Petition), seeking to invalidate one of the Company's issued patents (U.S. Patent No. 11,572,334) titled “Methods for Making and Using Endoxifen” (the Patent) on the grounds of anticipation and obviousness. The Company is actively contesting the PGR Petition and believes that the Patent was properly granted and is valid and enforceable. However, there can be no assurance that the Company will prevail in contesting the PGR Petition.

The Company is subject to other legal proceedings and claims that arise in the ordinary course of its business. The Company believes that these matters do not have a material effect, individually or in the aggregate, on its financial position, results of operations or cash flows.

Contractual Obligations

Contractual obligations represent the Company's future cash commitments and liabilities under agreements with third party clinical trial service providers. Apart from contracts with a third party clinical trial service provider, such agreements are cancellable upon written notice by the Company. The non-cancellable contracts expire upon completion of the clinical trial and release of the final report, or the contracts may be terminated by the clinical trial service provider, by the FDA or another governmental agency. As of December 31, 2023, the Company's estimated non-cancellable commitment was $

6.1
million.

NOTE 14: STOCK BASED COMPENSATION

On May 15, 2020, the stockholders of the Company approved the 2020 Stock Incentive Plan (the 2020 Plan) to provide for the grants of equity-based awards to employees, officers, non-employee directors and other key persons providing services to the Company. No awards may be granted under the 2020 Plan after May 15, 2030. An aggregate of

3,000,000
shares of common stock was initially reserved for issuance in connection with awards granted under the 2020 Plan. On May 14, 2021, the stockholders approved an additional

15,000,000
shares available for issuance under the 2020 Plan. As of December 31, 2023,

4,646,686
shares were available for future grants under the 2020 Plan.

The Company granted

6,828,600
and

4,079,667
options to purchase shares of common stock to employees and directors during the years ended December 31, 2023 and 2022, respectively. The weighted average grant date fair value of options granted during 2023 and 2022 was $

0.69
and $

0.96
, respectively.

No

options were exercised during the years ended December 31, 2023 or 2022.

The fair values of stock options granted were calculated using the Black-Scholes option-pricing model applying the following assumptions:

	Year Ended December 31,	
	2023	2022
Risk-free interest rate		
	3.27% - 4.48%	1.86% - 3.56%
Expected term (in years)		
	5.31 - 6.16	5.19 - 6.11
Dividend yield	—	—
Expected volatility		
	103% - 129%	103% - 128%

The Company recognized stock-based compensation expense in the Consolidated Statements of Operations as follows (in thousands):

	Year Ended December 31,	
	2023	2022

General and administrative	$ 3,038	$ 4,395
Research and development	1,583	2,393
Total stock-based compensation expense	$ 4,621	$ 6,788

The following table shows a summary of all stock option activity for the year ended December 31, 2023:

	Number of Underlying Shares	Weighted-Average Exercise Price Per Share	Weighted-Average Contractual Life Remaining in Years	Aggregate Intrinsic Value
Outstanding as of January 1, 2023	13,906,358	$ 2.35		—
Granted	6,828,600	0.82		
Forfeited	(3,223,874)	0.92		
Exercised	—	—		
Expired	(4,739)	836.63		
Outstanding as of December 31, 2023	17,506,345	$ 1.79	7.34	$ 554,525
Exercisable as of December 31, 2023	14,568,342	$ 1.97	6.99	$ 233,076
Vested and expected to vest	17,506,345	$ 1.79	7.34	$ 554,525

As of December 31, 2023, there were

2,938,003
unvested options outstanding, and the related unrecognized total compensation cost associated with these options was $

1.7
million. This expense is expected to be recognized over a weighted-average period of 1.21 years.

NOTE 15: DEFINED CONTRIBUTION PLAN

The Company has a defined contribution plan to which employees of the Company may defer contributions for income tax purposes. Participants are eligible to receive employer matching contributions up to

6
% of deferrals. Employees may also be eligible for a discretionary match over

6
%. Defined contribution plan employer matching contributions for the years ended December 31, 2023 and 2022 were $

0.3
million and $

0.2
million, respectively.

SIGNATURES

Pursuant to the requirements Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant, a corporation organized and existing under the laws of the State of Delaware, has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized in the City of Seattle, State of Washington, on April 1, 2024.

Atossa Therapeutics, Inc.

By: /s/ Steven C. Quay
Steven C. Quay, M.D., Ph.D.
Chairman, President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Steven C. Quay and Heather Rees and each of them acting individually, as his or her true and lawful attorneys-in-fact and agents, each with full power of substitution, for him or her in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, with full power of each to act alone, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully for all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or his, her or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Annual Report on Form 10-K has been signed by the following persons in the capacities and on the dates indicated.

Signature	Office(s)	Date
/s/ Steven C. Quay **Steven C. Quay, M.D., Ph.D.**	Chairman, President and Chief Executive Officer (Principal Executive Officer)	April 1, 2024
/s/ Heather Rees **Heather Rees**	Senior Vice President, Finance and Accounting (Principal Financial and Accounting Officer)	April 1, 2024
/s/ Richard I. Steinhart **Richard I. Steinhart**	Director	April 1, 2024
/s/ Shu-Chih Chen **Shu-Chih Chen, Ph.D.**	Director	April 1, 2024
/s/ Jonathan Finn **Jonathan Finn**	Director	April 1, 2024
/s/ Stephen J. Galli **Stephen J. Galli, M.D.**	Director	April 1, 2024
/s/ H. Lawrence Remmel **H. Lawrence Remmel**	Director	April 1, 2024
/s/ Tessa Cigler **Tessa Cigler, M.D., M.P.H.**	Director	April 1, 2024

EXHIBIT INDEX

Exhibit No.	Description	Incorporated by Reference Herein or Filed or Furnished Herewith	
		Form	Date
3.1	Amended and Restated Certificate of Incorporation	Amendment No. 3 to Registration Statement on Form S-1, as Exhibit 3.2	June 11, 2012
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation	Current Report on Form 8-K, as Exhibit 4.1	August 26, 2016
3.3	Certificate of Amendment to Amended and Restated Certificate of Incorporation	Current Report on Form 8-K, as Exhibit 4.1	April 23, 2018
3.4	Certificate of Amendment to Amended and Restated Certificate of Incorporation	Current Report on Form 8-K, as Exhibit 3.1	January 7, 2020
3.5	Amended and Restated Bylaws	Current Report on Form 8-K, as Exhibit 3.2	April 26, 2023
3.6	Certificate of Designation Preferences, and Rights of Series A Junior Participating Preferred Stock	Current Report on Form 8-K, as Exhibit 3.1	May 22, 2014
3.7	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock	Quarterly Report on Form 10-Q, as Exhibit 3.1	May 11, 2017
3.8	Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock	Current Report on Form 8-K, as Exhibit 3.1	May 31, 2018
3.9	Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock	Current Report on Form 8-K, as Exhibit 3.1	December 14, 2020
4.1	Specimen Common Stock Certificate	Amendment No. 2 to Registration Statement on Form S-1, as Exhibit 4.1	May 21, 2012
4.2	Form of Warrant	Amendment No. 1 to Registration Statement on Form S-1 as Exhibit 4.3	April 23, 2018
4.3	Form of Warrant	Current Report on Form 8-K, as Exhibit 4.1	December 14, 2020

4.4	Form of Warrant	Current Report on Form 8-K, as Exhibit 4.1	December 21, 2020
4.5	Form of Warrant	Current Report on Form 8-K, as Exhibit 4.1	January 8, 2021
4.6	Form of Warrant	Current Report on Form 8-K, as Exhibit 4.1	March 23, 2021
4.7	Form of Senior Indenture	Registration Statement on Form S-3, as Exhibit 4.1	September 2, 2020
4.8	Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934	Annual Report on Form 10-K, as Exhibit 4.16	March 26, 2020
10.1#	Restated and Amended Employment Agreement with Steven Quay dated September 27, 2010	Registration Statement on Form S-1, as Exhibit 10.3	February 14, 2012
10.2#	Amended and Restated Employment Agreement with Kyle Guse dated May 18, 2016	Current Report on Form 8-K, as Exhibit 10.1	May 20, 2016
10.3#	Form of Indemnification Agreement	Annual Report on Form 10-K, as Exhibit 10.3	March 22, 2023
10.4#	2010 Stock Option and incentive Plan, as amended	Current Report on Form 8-K, as Exhibit 4.2	January 15, 2019
10.5#	Form of Non-Qualified Stock Option Agreement for Employees	Amendment No. 3 to Registration Statement on Form S-1, as Exhibit 10.8	June 11, 2012
10.6#	Form of Non-Qualified Stock Option Agreement for Non-Employee Directors	Amendment No. 3 to Registration Statement on Form S-1, as Exhibit 10.9	June 11, 2012
10.7#	Form of Restricted Stock Award Agreement	Amendment No.3 Registration Statement on Form S-1, as Exhibit 10.13	June 11, 2012
10.8#	Form of 2019 Option Award Agreement	Current Report on Form 8-K, as Exhibit 4.1	January 15, 2019
10.9#	2020 Stock Incentive Plan, as amended	Registration Statement on Form S-8, as Exhibit 99.1	March 31, 2021

10.10#	Form of ISO Option Award Agreement	Quarterly Report on Form 10-Q, as Exhibit 4.1	May 13, 2020
10.11#	Form of Option Award Agreement	Current Report on Form 8-K, as Exhibit 4.1	April 13, 2020
10.12#	Employment Agreement with Greg Weaver Dated June 1, 2023	Filed herewith	
10.13#†	Employment Letter with Heather Rees Dated October 6, 2023	Filed herewith	
16.1	Letter from BDO USA, LLP, dated May 22, 2023	Current Report on Form 8-K, as Exhibit 16.1	May 22, 2023
21.1	List of Subsidiaries	Filed herewith	
23.1	Consent of Ernst & Young, LLP	Filed herewith	
23.2	Consent of BDO USA, P.C.	Filed herewith	
24.1	Powers of Attorney (included in signature page of this Form 10-K)	Filed herewith	
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act	Filed herewith	
31.2	Certification Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act	Filed herewith	
32.1	Certification of Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act	Furnished herewith	
32.2	Certification of Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act	Furnished herewith	
97.1	Incentive Compensation Clawback Policy	Filed herewith	
101.INS	Inline XBRL Instance Document		
101.SCH	Inline XBRL Taxonomy Extension Schema Document With Embedded Linkbase Documents		
104	Cover Page Interactive Data File (embedded within the Inline XBRL and contained in Exhibit 101)		

# Indicates management contract or compensatory plan, contract or agreement.
† Portions of this exhibit have been omitted as the Registrant has determined that (i) the omitted information is not material and (ii) the omitted material is of the type that the Registrant treats as private or confidential.

Exhibit 10.12

EMPLOYMENT AGREEMENT

This **EMPLOYMENT AGREEMENT** (the "Agreement") is entered into as of June 1, 2023 (the "Effective Date"), by and between Atossa Therapeutics Inc. (the "Company") and Gregory Weaver ("Executive").

WHEREAS, the Company wishes to employ Executive as the Executive Vice President and Chief Financial Officer of the Company and Executive wishes to work in such capacity; and

WHEREAS, the Company and Executive wish to enter into this Agreement on the terms and conditions set forth below.

NOW, **THEREFORE**, it is hereby agreed as follows

1. Employment. The Company agrees to employ Executive, and Executive hereby accepts such employment, upon the terms and subject to the conditions set forth herein, for a period commencing on the Effective Date and ending on the date that this Agreement is terminated in accordance with Section 7 below (the "Employment Term").

2.Position; Duties. During the Employment Term, Executive shall serve as the Executive Vice President and Chief Financial Officer of the Company. In such position, Executive shall report directly to the Company's Chief Executive Officer and shall have such duties and authority as are customary to such position and as otherwise determined from time to time by the Company. During the Employment Term, Executive agrees to devote Executive's full time and reasonable best efforts to the performance of Executive's duties to the Company. The foregoing shall not be construed to prohibit Executive from engaging in activities relating to serving on civic and charitable boards or committees, approved boards of directors, as set forth on Appendix A (which may be updated after the date hereof by mutual agreement), and managing personal investments, provided that such activities do not significantly interfere or conflict with the performance by Executive of Executive's duties, responsibilities, or authorities hereunder.

3.Base Salary. During the Employment Term, the Company shall pay Executive an initial base salary at the annualized rate of $450,000, payable in regular installments in accordance with the Company's usual payment practices. Executive's base salary may be adjusted in the sole discretion of the Compensation Committee of the Board of Directors (the "Committee"). Executive's annual base salary, as in effect from time to time, is hereinafter referred to as the "Base Salary."

4.Incentive Compensation.

(a) Annual Bonus. During the Employment Term, Executive shall be eligible to receive an annual cash bonus based on performance objectives established by the Committee each year (the "Annual Bonus"). Executive's target Annual Bonus amount will be the percentage of Base Salary designated as the target by the Committee, which annual target amount shall equal 45% of

the Base Salary then in effect (the "Target Annual Bonus"). Notwithstanding the preceding, the Annual Bonus, if any, may be below (including zero), at, or above the target based upon the achievement of the performance objectives.

(b) Sign-on Bonus. Additionally, within 30 days from the Effective Date, the Company shall pay a one-time signing bonus in the amount of $125,000 (the "Sign-on Bonus"). In the event that Executive resigns his employment within 12 months from the Effective Date (other than for Good Reason) or if Executive is removed for Cause within 12 months from the Effective Date, then Executive shall repay a ratable portion of the Sign-on Bonus equal to the shortfall of such initial one-year service period (e.g., if resigning without Good Reason after 10 months, then repaying 16.7% of the Sign-on Bonus).

5. Employee Benefits. During the Employment Term, Executive shall be entitled to participate in the Company's employee benefit plans as in effect from time to time (collectively "Employee Benefits"), on the same basis as those benefits are generally made available to other senior executives of the Company, in each case to the extent that Executive is eligible under the terms of such plans or programs.

6.Business Expenses. During the Employment Term, reasonable business expenses incurred by Executive in the performance of Executive's duties hereunder shall be advanced or promptly reimbursed by the Company in accordance with Company policies.

7.Termination. The Employment Term and Executive's employment shall be at-will and may be terminated by the Company at any time and for any reason upon Notice to Executive and by Executive upon at least 30 days' advance Notice of any such resignation of Executive's employment. Notwithstanding any other provision of this Agreement, the provisions of this Section 7 shall exclusively govern Executive's rights to payment of compensation, severance, Employee Benefits and business expenses upon termination of employment with the Company.

(a)By the Company for Cause; By Executive without Good Reason.

(i)The Employment Term and Executive's employment may be terminated by the Company for Cause and shall terminate automatically upon the effective date of Executive's resignation without Good Reason. For purposes of this Agreement, "Cause" shall mean (A) indictment for, conviction of, or a plea of *nolo contendere* to, (x) a felony (other than traffic-related) under the laws of the United States or any state thereof or any similar criminal act in a jurisdiction outside the United States or (y) a crime involving moral turpitude that could be injurious to the Company or its reputation, (B) Executive's willful malfeasance or willful misconduct which is materially and demonstrably injurious to the Company, (C) any act of fraud by Executive in the performance of Executive's duties or (D) Executive's material breach of any Agreement with the Company or any of the Company's material policies. The determination of Cause shall be made by the Board of Directors or the Committee, in its good faith discretion. For purposes of this Agreement, "Good Reason" shall mean the occurrence of any of the following events, without Executive's written consent, provided, in each case, that such event is not cured within 30 days after the Company receives notice from Executive specifying in reasonable detail

the event which constitutes Good Reason: (1) any failure by the Company to pay Executive's Base Salary or Annual Bonus (if any) when due; (2) a reduction in Executive's Base Salary or Target Annual Bonus (excluding any change in value of equity incentives); or (3) any diminution in Executive's title or any substantial and sustained diminution in Executive's duties. "Good Reason" shall cease to exist for an event on the 90th day following Executive's knowledge thereof, unless Executive has given the Company Notice thereof prior to such date.

(ii) If Executive's employment is terminated by the Company for Cause, or if Executive resigns without Good Reason, Executive shall be entitled to receive:

a. the Base Salary accrued through the date of termination, payable as soon as practicable following the date of such termination or as otherwise required by applicable law;

b. any Annual Bonus earned, but unpaid, as of the date of termination for the year immediately preceding the year in which such termination occurs, paid on the date when bonuses are otherwise paid to Company executives, and in all events by March 15th of the calendar year following the year in which such termination occurs;

c. reimbursement, within 60 days following submission by Executive to the Company of appropriate supporting documentation, for any unreimbursed business expenses properly incurred by Executive in accordance with Company policy prior to the date of Executive's termination; provided, that claims for such reimbursement (accompanied by appropriate supporting documentation) are submitted to the Company within 90 days following the date of Executive's termination of employment; and

d. such Employee Benefits, if any, as to which Executive may be entitled under the employee benefit plans of the Company, which shall be paid in accordance with the terms of the applicable plans (the amounts described in clauses (A) through (D) hereof, the "Accrued Rights").

Following such termination of Executive's employment by the Company for Cause or resignation by Executive without Good Reason, except as set forth in this Section 7(a)(ii), Executive shall have no further rights to any compensation or any other benefits under this Agreement.

(b) Disability or Death.

(i) The Employment Term and Executive's employment shall terminate automatically upon Executive's death and may be terminated by the Company upon Executive's Disability. For purposes of this Agreement, a "Disability" shall be deemed to have occurred if Executive has for 120 consecutive days or 180 non-consecutive days in any 12-month period been disabled in a manner which has rendered Executive unable to perform the essential functions of

Executive's job duties with or without reasonable accommodation.

(ii) Upon termination of Executive's employment for either Disability or death, Executive or Executive's estate (as the case may be) shall be entitled to receive (A) the Accrued Rights and (B) a pro rata portion of the actual Annual Bonus earned for the year of termination, based on the days employed during such year, payable on the date when bonuses are otherwise paid to Company executives and in all events by March 15th of the calendar year following the year in which such termination occurs.

Following Executive's termination of employment due to death or Disability, except as set forth in this Section 7(b)(ii), Executive shall have no further rights to any compensation or any other benefits under this Agreement.

(c) By the Company without Cause; By Executive with Good Reason.

(i) The Employment Term and Executive's employment may be terminated by the Company without Cause or by Executive with Good Reason.

(ii) If Executive's employment is terminated by the Company without Cause (other than by reason of death or Disability) or if Executive resigns with Good Reason, in either event not within 30 days before or 12 months after a Change in Control, Executive shall be entitled to receive:

(A) the Accrued Rights; and

(B) subject to Executive's execution and non-revocation of a release of claims in the form provided by the Company and within the time period specified therein and Executive's continued compliance with the provisions of the DCNN Agreement:

(1) payment of an amount equal to 50% of the Executive's annual Base Salary at the time of termination, which shall be payable to Executive in equal installments in accordance with the Company's normal payroll practices, for six months following the date that the release of claims becomes effective and irrevocable (provided, however, that if the period during which the release could become effective and irrevocable spans two calendar years, payments of such installments shall not commence until the first normal payroll date in the second calendar year); and

(2) subject to Executive's timely election of continuation coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA"), and subject to Executive's copayment of premium amounts at the active employees' rate, the Company shall pay the remainder of the premiums for Executive's participation in the Company's group health plans pursuant to COBRA for a period ending on the earlier of (i)

the six-month anniversary of the date of termination; (ii) Executive becoming eligible for other group health benefits, or (iii) the expiration of Executive's rights under COBRA; provided, however, that in the event that the benefits provided herein would subject the Company or any of its affiliates to any tax or penalty under the Patient Protection and Affordable Care Act or Section 105(h) of the Internal Revenue Code of 1986, as amended (the "Code"), Executive and the Company agree to work together in good faith to restructure the foregoing benefit.

Following Executive's termination of employment by the Company without Cause (other than by reason of Executive's death or Disability) or Executive's resignation with Good Reason not within 30 days before or 12 months after a Change in Control, except as set forth in this Section 7(c)(ii), Executive shall have no further rights to any compensation or any other benefits under this Agreement.

(iii) If Executive's employment is terminated by the Company without Cause (other than by reason of death or Disability) or if Executive resigns with Good Reason, in either event within 30 days before or 12 months after a Change in Control, Executive shall be entitled to receive in lieu of the benefits set forth in Section 7(c)(ii):

(A) the Accrued Rights; and

(B) subject to Executive's execution and non-revocation of a release of claims in the form provided by the Company and within the time period specified therein and Executive's continued compliance with the provisions of the DCNN Agreement:

(1) a pro rata portion of the actual Annual Bonus that would have been earned for the year of termination, based on the days employed during such year, payable on the date when bonuses are otherwise paid to Company executives and in all events by March 15th of the calendar year following the year in which such termination occurs;

(2) payment of an amount equal to 1.0 times the sum of Executive's annual Base Salary plus Executive's Target Annual Bonus amount for the year of termination, which shall be payable to Executive in a single lump sum within 10 days following the date that the release of claims becomes effective and irrevocable;

(3) full acceleration of the vesting of all outstanding equity awards; and

(4) subject to Executive's timely election of continuation coverage under COBRA, and subject to Executive's copayment of premium amounts at the active employees' rate, the Company shall pay the remainder of the premiums for Executive's participation in the Company's group health plans pursuant to COBRA for a period ending on the earlier of (i) the 12-month anniversary of the date of termination; (ii) Executive becoming

eligible for other group health benefits, or (iii) the expiration of Executive's rights under COBRA; provided, however, that in the event that the benefits provided herein would subject the Company or any of its affiliates to any tax or penalty under the Patient Protection and Affordable Care Act or Section 105(h) of the Code, Executive and the Company agree to work together in good faith to restructure the foregoing benefit.

For purposes of this Agreement, "Change in Control" means the occurrence of one or more of the following events: (i) any "person" (as such term is used in Sections 3(a)(9) and 13(d) of the Securities Exchange Act of 1934, as amended (the "Act")) or "group" (as such term is used in Section 13(d)(3) of the Act), other than the Company or its subsidiaries or any benefit plan of the Company or its subsidiaries is or becomes a "beneficial owner" (as such term is used in Rule 13d-3 promulgated under the Act) of more than 50% of the Voting Stock of the Company; (ii) the Company transfers all or substantially all of its assets (unless the shareholders of the Company immediately prior to such transaction beneficially own, directly or indirectly, in substantially the same proportion as they owned the Voting Stock of the Company, all of the Voting Stock or other ownership interests of the entity or entities, if any, that succeed to the business of the Company or the Company's ultimate parent company if the Company is a subsidiary of another corporation); or (iii) any merger, reorganization, consolidation or similar transaction unless, immediately after consummation of such transaction, the shareholders of the Company immediately prior to the transaction hold, directly or indirectly, more than 50% of the Voting Stock of the Company or the Company's ultimate parent company if the Company is a subsidiary of another corporation. For purposes of this Change in Control definition, "Voting Stock" means securities or ownership interests of any class or classes having general voting power under ordinary circumstances, in the absence of contingencies, to elect the directors of a corporation, including securities that are convertible into voting stock (e.g., warrants and convertible preferred stock), even if subject to beneficial ownership blockers or other limits on the ability to acquire such securities. Following Executive's termination of employment by the Company without Cause (other than by reason of Executive's death or Disability) or by Executive with Good Reason within 30 days before or 12 months after a Change in Control, except as set forth in this Section 7(c)(iii), Executive shall have no further rights to any compensation or any other benefits under this Agreement.

(d) Notice of Termination. Any termination of employment by the Company or by Executive (other than due to Executive's death) shall be communicated by Notice of Termination to the other party hereto in accordance with Section 9(k) hereof. For purposes of this Agreement, a "Notice of Termination" shall mean a Notice that indicates the specific termination provision in this Agreement relied upon and sets forth in reasonable detail the facts and circumstances claimed to provide a basis for termination of employment under the provision so indicated.

(e) Termination and Offices Held. Upon termination of Executive's employment for any reason, Executive shall be deemed to have resigned, and hereby agrees to resign, from all positions that Executive may then hold as an employee, officer or director of the Company or any affiliate of the Company. Executive shall promptly deliver to the Company any additional documents reasonably required by the Company to confirm such resignations.

8.Proprietary Information and Inventions Assignment Agreement. As a condition to Executive's employment with the Company, Executive shall execute and deliver to the Company as of the Effective Date, the Company's standard Development, Confidentiality, Nondisclosure and Noncompetition Agreement (the "DCNN Agreement"), a copy of which has been provided under separate cover. The provisions of the DCNN Agreement shall survive the termination of Executive's employment for any reason.

9.Miscellaneous.

(a) Arbitration. For the avoidance of doubt, the arbitration and equitable relief provisions of the DCNN Agreement shall apply to any dispute concerning Executive's employment with the Company or arising under or in any way related to this Agreement.

(b)Governing Law; Consent to Personal Jurisdiction. THIS AGREEMENT WILL BE GOVERNED BY THE LAWS OF THE STATE OF WASHINGTON WITHOUT REGARD FOR CONFLICTS OF LAWS PRINCIPLES. SUBJECT TO THE ARBITRATION PROVISION IN THE DCNN AGREEMENT, EXECUTIVE HEREBY EXPRESSLY CONSENTS TO THE PERSONAL JURISDICTION OF THE STATE AND FEDERAL COURTS LOCATED IN SEATTLE, WASHINGTON FOR ANY LAWSUIT FILED THERE AGAINST EXECUTIVE BY THE COMPANY CONCERNING EXECUTIVE'S EMPLOYMENT OR THE TERMINATION OF EXECUTIVE'S EMPLOYMENT OR ARISING FROM OR RELATING TO THIS AGREEMENT.

(c)Entire Agreement/Amendments. This Agreement, together with the DCNN Agreement, contains the entire understanding of the parties with respect to the employment of Executive by the Company. There are no restrictions, agreements, promises, warranties, covenants or undertakings between the parties with respect to the subject matter herein other than those expressly set forth herein or as may be set forth from time to time in the Company's employee benefit plans and policies applicable to Executive. This Agreement may not be altered, modified, or amended except by written instrument signed by the parties hereto. In the event of any inconsistency between this Agreement and any other plan, program, practice or agreement of which Executive is a participant or a party, this Agreement shall control unless such other plan, program, practice or agreement specifically refers to the provisions of this sentence.

(d)No Waiver. The failure of a party to insist upon strict adherence to any term of this Agreement on any occasion shall not be considered a waiver of such party's rights or deprive such party of the right thereafter to insist upon strict adherence to that term or any other term of this Agreement.

(e)Severability. In the event that any one or more of the provisions of this Agreement shall be or become invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions of this Agreement shall not be affected thereby.

(f)Assignment. This Agreement, and all of Executive's rights and duties

hereunder, shall not be assignable or delegable by Executive. Any purported assignment or delegation by Executive in violation of the foregoing shall be null and *void ab initio* and of no force and effect. This Agreement may be assigned by the Company to a person or entity which is an affiliate or a successor in interest to substantially all of the business operations of the Company. Upon such assignment, the rights and obligations of the Company hereunder shall become the rights and obligations of such affiliate or successor person or entity.

(g) Counterclaim; No Mitigation. The Company's obligation to pay Executive the amounts provided and to make the arrangements provided hereunder shall be subject to counterclaim and to seek recoupment of amounts owed by Executive to the Company or its affiliates. Executive shall not be required to mitigate the amount of any payment provided for pursuant to this Agreement by seeking other employment, and such payments shall not be reduced by any compensation or benefits received from any subsequent employer or other endeavor.

(h) Compliance with Code Section 409A. Notwithstanding anything herein to the contrary, (i) if at the time of Executive's termination of employment, Executive is a "specified employee" as defined in Section 409A of the Code and the deferral of the commencement of any payments or benefits otherwise payable hereunder as a result of such termination of employment is necessary in order to prevent any accelerated or additional tax under Section 409A of the Code, then the Company will defer the commencement of the payment of any such payments or benefits hereunder (without any reduction in such payments or benefits ultimately paid or provided to Executive) until the date that is six months following Executive's termination of employment with the Company (or the earliest date as is permitted under Section 409A of the Code) and (ii) if any other payments of money or other benefits due to Executive hereunder could cause the application of an accelerated or additional tax under Section 409A of the Code, such payments or other benefits shall be deferred if deferral will make such payment or other benefits compliant under Section 409A of the Code, or otherwise such payment or other benefits shall be restructured, to the extent possible, in a manner, determined by the Board of Directors or the Committee, that does not cause such an accelerated or additional tax. For purposes of Section 409A of the Code, each payment made under this Agreement shall be designated as a "separate payment" within the meaning of the Section 409A of the Code, and references herein to Executive's "termination of employment" shall refer to Executive's separation from service with the Company within the meaning of Section 409A. To the extent any reimbursements or in-kind benefits due to Executive under this Agreement constitute "deferred compensation" under Section 409A of the Code, any such reimbursements or in-kind benefits shall be paid to Executive in a manner consistent with Treas. Reg. Section 1.409A-3(i)(1)(iv). The Company shall consult with Executive in good faith regarding the implementation of the provisions of this Section 9(h); provided that neither the Company nor any of its employees or representatives shall have any liability to Executive with respect to thereto or any tax imposed under Section 409A.

(i) Code Section 280G. Notwithstanding anything in this Agreement to the contrary, if any payment or distribution Executive would receive pursuant to this Agreement or otherwise ("Payment") would (a) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (b) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), then such Payment shall either be (i) delivered in full, or (ii)

delivered as to such lesser extent which would result in no portion of such Payment being subject to the Excise Tax, whichever of the foregoing amounts, taking into account the applicable federal, state and local income taxes and the Excise Tax, results in the receipt by Executive on an after-tax basis, of the largest payment, notwithstanding that all or some portion the Payment may be taxable under Section 4999 of the Code. The accounting firm engaged by the Company for general audit purposes as of the day prior to the effective date of the Change in Control shall perform the foregoing calculations. The Company shall bear all expenses with respect to the determinations by such accounting firm required to be made hereunder. The accounting firm shall provide its calculations to the Company and Executive within 15 calendar days after the date on which Executive's right to a Payment is triggered (if requested at that time by the Company or Executive) or such other time as requested by the Company or Executive. Any good faith determinations of the accounting firm made hereunder shall be final, binding and conclusive upon the Company and Executive. Any reduction in payments and/or benefits hereunder will occur in the following order: (1) reduction of cash payments; (2) cancellation of accelerated vesting of equity awards other than stock options; (3) cancellation of accelerated vesting of stock options; and (4) reduction of other benefits payable to Executive.

(j) Successors; Binding Agreement. This Agreement shall inure to the benefit of and be binding upon personal or legal representatives, executors, administrators, successors, heirs, distributees, devisees and legatees. In the event of Executive's death prior to receipt of all amounts payable to Executive (including any unpaid amounts due under Section 7), such amounts shall be paid to Executive's beneficiary designated in a Notice provided to and accepted by the Company or, in the absence of such designation, to Executive's estate.

(k) Notice. For the purpose of this Agreement, notices and all other communications provided for in the Agreement shall be in writing and shall be deemed to have been duly given when delivered by hand or overnight courier or three postal delivery days after it has been mailed by United States registered mail, return receipt requested, postage prepaid, addressed to the respective addresses set forth below in this Agreement, or to such other address as either party may have furnished to the other in writing in accordance herewith, except that Notice of change of address shall be effective only upon receipt (each such communication, "Notice").

If to the Company, addressed to:

Atossa Therapeutics Inc.
Attn: Chief Executive Officer
107 Spring Street
Seattle, WA 98104

If to Executive, to the address listed in the Company's payroll records from time to time.

(l) Executive Representation. Executive hereby represents to the Company that the execution and delivery of this Agreement by Executive and the Company and the performance by Executive of Executive's duties hereunder shall not constitute a breach of, or

otherwise contravene, the terms of any employment agreement or other agreement or policy to which Executive is a party or otherwise bound.

(m) Prior Agreements. This Agreement supersedes all prior agreements and understandings (including verbal agreements) between Executive and the Company and/or its affiliates regarding the terms and conditions of Executive's employment with the Company and/or its affiliates.

(n)Cooperation. Executive shall provide Executive's reasonable cooperation in connection with any action or proceeding (or any appeal from any action or proceeding) which relates to events occurring during Executive's employment hereunder, provided, that, following termination of Executive's employment, the Company shall pay all reasonable expenses incurred by Executive in providing such cooperation. This provision shall survive any termination of this Agreement.

(o)Withholding Taxes. The Company may withhold from any amounts payable under this Agreement such federal, state and local taxes as may be required to be withheld pursuant to any applicable law or regulation.

(p)Counterparts. This Agreement may be signed in counterparts, each of which shall be an original, with the same effect as if the signatures thereto and hereto were upon the same instrument.

[Signature Page Follows this Page]

IN WITNESS WHEREOF, the parties hereto have duly executed this Employment Agreement as of the Effective Date.

ATOSSA THERAPEUTICS INC.

/s/ Steven C. Quay
By: Steven C. Quay

Title: Chief Executive Officer

EXECUTIVE

/s/ Gregory Weaver
Gregory Weaver

Chief Financial Officer

Appendix A

- Rejuveron - longevity biotech
- BioIntelliSense - medtech device
- HarborPath - not for profit patient assistance program

EXHIBIT 10.13

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) is the type that the registrant treats as private or confidential.

October 6, 2023

Heather Rees
[*]

*Delivered via email

Dear Heather,

A significant factor in our success at Atossa Therapeutics is our people and the effort and talent they bring to the workplace. In recognition of this importance, we are pleased to inform you that effective October 6, 2023, you will be promoted to Senior Vice President, Finance and Principal Accounting Officer reporting to me. Your new annual salary will be $360,000 and your targeted bonus potential will also increase to 35% of your annual base pay.

In addition, if your employment is terminated by the Company without Cause (other than by reason of death or disability) or if you resign with Good Reason, in either event not within 30 days before or 12 months after a Change in Control, you will be entitled to receive the following.

- a pro rata portion of the actual bonus that would have been earned for the year of termination, based on the days employed during such year, payable on the date when bonuses are otherwise paid to company employees.
- full acceleration of the vesting of all outstanding equity awards

“Cause” shall mean (A) indictment for, conviction of, or a plea of *nolo contendere* to, (x) a felony (other than traffic-related) under the laws of the United States or any state thereof or any similar criminal act in a jurisdiction outside the United States or (y) a crime involving moral turpitude that could be injurious to the Company or its reputation, (B) Employee’s willful malfeasance or willful misconduct which is materially and demonstrably injurious to the Company, (C) any act of fraud by Employee in the performance of Employee’s duties or (D) Employee’s material breach of any Agreement with the Company or any of the Company’s material policies. The determination of Cause shall be made by the Board of Directors or the Committee, in its good faith discretion. For purposes of this Agreement, “Good Reason” shall mean the occurrence of any of the following events, without Employee’s written consent, provided, in each case, that such event is not cured within 30 days after the Company receives notice from Employee specifying in reasonable detail the event which constitutes Good Reason: (1) any failure by the Company to pay Employee’s Base Salary or Annual Bonus (if any) when due; (2) a reduction in Employee’s Base Salary or Target Annual Bonus (excluding any change in value of equity incentives); or (3) any diminution in Employee’s title or any substantial and
sustained diminution in Employee’s duties. “Good Reason” shall cease to exist for an event on the 90th day following Employee’s knowledge thereof, unless Employee has given the Company Notice thereof prior to such date.

In your time with Atossa, you have demonstrated your work ethic, dedication, and your superb qualifications. We have faith that you will continue to excel in your new position and hope that you continue to develop your potential here at Atossa.

Congratulations on this promotion, and we look forward to your contributions in your new position.

Thank you for being such an asset to Atossa Therapeutics and for your loyal service.

Sincerely,

/s/ Steve Quay
Steven Quay
CEO & President

/s/ Heather Rees 10/6/2023
Acknowledgement of receipt – Heather Rees Date

Exhibit 21.1

LIST OF SUBSIDIARIES

Atossa Genetics UK Ltd.
Atossa Genetics AUS Pty Ltd.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-3 No. 333-255411 and 333-252335) of Atossa Therapeutics, Inc.,

(2) Registration Statement (Form S-8 No. 333-185625) pertaining to the 2010 Stock Option and Incentive Plan, as amended, of Atossa Genetics, Inc.;

(3) Registration Statement (Form S-8 No. 333-193952) pertaining to the 2010 Stock Option Incentive Plan, as amended, and inducement option grants outside of a plan of Atossa Genetics Inc.; and

(4) Registration Statement (Form S-8 No. 333-254905) pertaining to the 2020 Stock Incentive Plan, as amended, of Atossa Therapeutics, Inc. and the 2010 Stock Option and Incentive Plan, as amended, of Atossa Genetics, Inc.;

of our report dated April 1, 2024, with respect to the consolidated financial statements of Atossa Therapeutics, Inc. included in this Annual Report (Form 10-K) of Atossa Therapeutics, Inc. for the year ended December 31, 2023.

/s/ Ernst & Young LLP

Seattle, Washington
April 1, 2024

Exhibit 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-255411 and 333-252335), and Form S-8 (No. 333-254905, 333-185625 and 333-193952) of Atossa Therapeutics, Inc. of our report dated March 22, 2023, relating to the consolidated financial statements as of and for the year ended December 31, 2022, which appears in this Annual Report on Form 10-K.

/s/ BDO USA, P.C.

Seattle, Washington
April 1, 2024

Exhibit 31.1

**CERTIFICATION PURSUANT TO RULES 13a-14(a) AND 15d-14(a)
OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED,
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Steven C. Quay, certify that:

1. I have reviewed this Annual Report on Form 10-K of Atossa Therapeutics, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: April 1, 2024

/s/ Steven C. Quay
Steven C. Quay, M.D., Ph D.
Chairman, President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

**CERTIFICATION PURSUANT TO RULES 13a-14(a) and 15d-14(2)
OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED,
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Heather Rees, certify that:

1. I have reviewed this Annual Report on Form 10-K of Atossa Therapeutics, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: April 1, 2024

/s/ Heather Rees
Heather Rees
Senior Vice President, Finance and Accounting
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Atossa Therapeutics, Inc. (the "Company") for the fiscal year ended December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Steven C. Quay, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: April 1, 2024

/s/ Steven C. Quay

Steven C. Quay, M.D., Ph D.
Chairman, President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Atossa Therapeutics, Inc. (the "Company") for the fiscal year ended December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Heather Rees, Senior Vice President, Finance and Accounting of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: April 1, 2024

/s/ Heather Rees
Heather Rees
Senior Vice President, Finance and Accounting
(Principal Financial and Accounting Officer)

Exhibit 97.1

INCENTIVE COMPENSATION CLAWBACK POLICY

Recoupment of Incentive-Based Compensation

It is the policy of Atossa Therapeutics, Inc. (the "Company") that, in the event the Company is required to prepare an accounting restatement of the Company's financial statements due to material non-compliance with any financial reporting requirement under the federal securities laws (including any such correction that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period), the Company will recover on a reasonably prompt basis the amount of any Incentive-Based Compensation Received by a Covered Executive during the Recovery Period that exceeds the amount that otherwise would have been Received had it been determined based on the restated financial statements (each as defined below). This Incentive Compensation Clawback Policy (this "Policy") has been adopted by the Company's Board of Directors (the "Board") effective November 8, 2023 (the "Effective Date"). The Board may amend or change the terms of this Policy at any time for any reason, including as required to comply with any laws, rules, regulations and listing standards that may be applicable to the Company.

Policy Administration and Definitions

This Policy is administered by the Compensation Committee of the Board (the "Committee"), subject to ratification by the independent directors (as directed by the Board) with respect to final determinations related to Covered Executive compensation. The Policy is intended to comply with, and as applicable to be administered and interpreted consistent with, and subject to the exceptions set forth in, Listing Rule 5608 adopted by the Nasdaq Stock Market ("Nasdaq") to implement Rule 10D-1 under the Securities Exchange Act of 1934, as amended (collectively, "Rule 10D-1").

For purposes of this Policy:

- "Covered Executive" means any "executive officer" of the Company as defined under Rule 10D-1.

• A "Financial Reporting Measure" is (i) any measure that is determined and presented in accordance with the accounting principles used in preparing the Company's financial statements and any measure derived wholly or in part from such a measure, and (ii) any measure based in whole or in part on the Company's stock price or total shareholder return.

• "Incentive-Based Compensation" means any compensation granted, earned or vested based in whole or in part on the Company's attainment of a Financial Reporting Measure that was Received by a person (i) on or after the Effective Date and after the person began service as a Covered Executive, and (ii) who served as a Covered Executive at any time during the performance period for the Incentive-Based Compensation.

• Incentive-Based Compensation is deemed to be "Received" in the fiscal period during which the relevant Financial Reporting Measure is attained, regardless of when the compensation is actually paid or awarded.

• "Recovery Period" means the three completed fiscal years immediately preceding the date that the Company is required to prepare the accounting restatement described in this Policy and any transition period of less than nine months that is within or immediately following such three fiscal years, all as determined pursuant to Rule 10D-1.

Determination by the Committee

If the Committee determines the amount of Incentive-Based Compensation Received by a Covered Executive during a Recovery Period exceeds the amount that would have been Received if determined or calculated based on the Company's restated financial results, such excess amount of Incentive-Based Compensation shall be subject to recoupment by the Company pursuant to this Policy. For Incentive-Based Compensation based on stock price or total shareholder return, where the amount of erroneously awarded compensation is not subject to mathematical recalculation directly from the information in an accounting restatement, the Committee will determine the amount based on a reasonable estimate of the effect of the accounting restatement on the relevant stock price or total shareholder return. In all cases, the calculation of the excess amount of Incentive-Based Compensation to be recovered will be determined on a pre-tax basis (*i.e.*, without regard to any taxes paid with respect to such compensation). The Company will maintain and will provide to Nasdaq documentation of all determinations and actions taken in complying with this Policy. All determinations made by the Committee or the Board under this Policy shall be final and binding on all affected individuals.

Methods of Clawback

The Company may effect any recovery pursuant to this Policy in any manner consistent with applicable law, including by requiring payment of such amount(s) to the Company, by set-off, by reducing future compensation, or by such other means or combination of means as the Committee determines to be appropriate. The Company need not recover the excess amount of Incentive-Based Compensation if and to the extent that the Committee determines that such

recovery is impracticable, subject to and in accordance with any applicable exceptions under the Nasdaq listing rules and not required under Rule 10D-1, including if the Committee determines that the direct expense paid to a third party to assist in enforcing this Policy would exceed the amount to be recovered after making a reasonable attempt to recover such amounts. The Company is authorized to take appropriate steps to implement this Policy with respect to Incentive-Based Compensation arrangements with Covered Executives.

Not Exclusive Remedy

Any right of recoupment or recovery pursuant to this Policy is in addition to, and not in lieu of, any other remedies or rights of recoupment that may be available to the Company pursuant to the terms of any other policy, any employment agreement or plan or award terms, and any other legal remedies available to the Company (including, but not limited to, Section 304 of the Sarbanes-Oxley Act of 2002); provided that the Company shall not recoup amounts pursuant to such other policy, terms or remedies to the extent it is recovered pursuant to this Policy. The Company shall not indemnify any Covered Executive against (i) any liability or loss (including without limitation the loss of any Incentive-Based Compensation pursuant to this Policy, including any payment or reimbursement for the cost of third-party insurance purchased by any Covered Executives to fund potential recovery obligations under this Policy, any judgments, fines, taxes, penalties or amounts paid in settlement by or on behalf of any Covered Executive) incurred by such Covered Executive in connection with or as a result of any action taken by the Company to enforce this Policy (a "Clawback Proceeding") or (ii) any indemnification or advancement of expenses (including attorneys' fees) incurred by such Covered Executive in connection with any such Clawback Proceeding.

Certification

All Covered Executives subject to this Policy will be required to certify their understanding of and intent to comply with this Policy periodically.

ACKNOWLEDGMENT AND CERTIFICATION

By signing below, the undersigned covered executive (the "Covered Executive") acknowledges and confirms that the Covered Executive has received and reviewed a copy of the Atossa Therapeutics, Inc. (the "Company") Incentive Compensation Clawback Policy (the "Policy"), and in addition, the Covered Executive acknowledges and agrees that, for good and valid consideration, including continuing participation in the Company's incentive compensation programs, the receipt and sufficiency of which the Covered Executive hereby acknowledges, the Covered Executive will be bound by and abide by the Policy as follows:

(a) the Covered Executive is and will continue to be subject to the Policy and the Policy will apply both during and after the Covered Executive's employment with the Company;

(b) to the extent necessary to comply with the Policy, the Company hereby amends any employment agreement, equity award agreement or similar agreement that the Covered Executive is a party to with the Company;

(c) the Covered Executive shall abide by the terms of the Policy, including, without limitation, by returning any compensation to the Company to the extent required by, and in a manner permitted by, the Policy, and understands and agrees that the Company is not permitted to, and will not, indemnify the Covered Executive for any liability, loss, including loss of any compensation that is subject to recovery by the Company, or expenses nor will the Company advance any expenses (including attorneys' fees) incurred as a result of any action by or on behalf of the Company pursuant to the Policy and the Covered Executive hereby knowingly and intentionally waives and agrees not to assert any claim for indemnification or advancement of expenses against the Company or any subsidiary of the Company to which the Covered Executive is now or may become entitled notwithstanding any other agreement or provision therefor;

(d) any amounts payable to the Covered Executive shall be subject to the Policy as may be in effect and interpreted or modified from time to time in the discretion of the Company's Board of Directors or Compensation Committee (the "Committee") or as required by applicable law or the requirements of any securities exchange on which the Company's securities are listed, and that such interpretation or modification will be covered by this acknowledgment;

(e) the Company may recover compensation paid to the Covered Executive through any method of recovery the Committee or its delegate deems appropriate, including without limitation by reducing any amount that is or may become payable to the Covered Executive, and the Covered Executive agrees to comply with any request or demand for repayment by the Company in order to comply with the Policy; and

(f) the Company is not responsible for and shall not make the Covered Executive whole for any effect under any tax law or regulation of the recovery of any compensation pursuant to the

Policy, or for any taxes paid by the Covered Executive on compensation that is subject to recovery or is recovered pursuant to the Policy.