UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark one)

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

For the fiscal year ended December 31, 2024

OR

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

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.)**

10202 Fifth Avenue NE, Suite 200
Seattle, WA 98125
(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 28, 2024, 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 $149,586,095. 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 17, 2025, was 129,170,004 .

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the registrant's Definitive Proxy Statement for the registrant's 2025 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report. Such Definitive Proxy Statement will be filed with the Securities and Exchange Commission within 120 days after the end of the registrant's fiscal year ended December 31, 2024.

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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, "expect," "potential," "continue," "may," "will," "should," "could," "would," "seek," "intend," "plan," "estimate," "anticipate," "future," "believe," "design," "predict," 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:

- the impact of general macroeconomic conditions, including the impact of inflation, high interest rates, general economic slowdown or a recession, foreign exchange rate volatility, financial institution instability, changes in monetary policy, changes in trade policies, including tariffs or other trade restrictions or the threat of such actions, 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 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 deploy artificial intelligence "AI" in our or our collaborators' product candidates;
- 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, including our ability to obtain patent coverage for our product candidates;
- 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 regain compliance with the continued listing requirements of the Nasdaq Capital Market (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; 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 made in this Annual Report, unless otherwise indicated, are presented as of the date of the filing of this Annual Report. We have discussed certain 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 our anticipated results, events or outcomes, or the anticipated timing of these results or outcomes, including any variation between interim or preliminary and final clinical results or analysis. 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 and other therapeutic areas.

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 or metabolites to be effective. Despite the success of tamoxifen in treating Estrogen Receptor Positive (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, may overcome some of the shortcomings of tamoxifen.

(Z)-endoxifen is a proprietary, novel Selective Estrogen Receptor Modulator (SERM), which is a class of drug 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 Phase 2 trials:

EVANGELINE: EVANGELINE is a Phase 2 randomized study evaluating (Z)-endoxifen as neoadjuvant therapy for premenopausal women with primary ER+, HER2– breast cancer. The trial will enroll approximately 190 patients across up to 25 U.S. sites and is divided into two parts:

Part 1: Pharmacokinetic (PK) Run-In Cohort: A 40 mg/day cohort was opened in February 2023 to assess if plasma steady state concentrations (Css) of 500 to 1000 ng/mL, which is required for optimal PKC-β inhibition, could be achieved. Subsequently, an 80 mg/day PK cohort was initiated and fully enrolled in July 2024.

Data from both the 40 mg and 80 mg cohorts, which included 12-week and 24-week Magnetic Resonance Imaging (MRI) and safety assessments, showed that no patients in the 40 mg cohort achieved the target plasma Css. In the 80 mg cohort, approximately 50% of patients receiving (Z)-endoxifen with Ovarian Function Suppression (OFS or goserelin) and 38% of patients receiving (Z)-endoxifen alone reached the target plasma Css, with an average plasma Css of 484 ng/mL. We believe that targeting PKC-β may further enhance (Z)-endoxifen's antitumor activity.

As part of a previously amended protocol, tumor Css levels were assessed in the 80 mg cohort and were found to be more than double the plasma levels, exceeding 500 ng/g in 90% of patients. Substantial tumor suppression was also observed, with 85% of patients exhibiting a 4-week Ki-67 response (≤10%), regardless of ovarian function suppression.

(Z)-endoxifen was well tolerated overall. No significant Grade 3 or 4 toxicities were observed, although four gynecologic events were reported in the 80 mg group, including one Grade 3 hemorrhagic ovarian cyst.

In January 2025, based on an analysis of Part 1 of the study, which included the PK, efficacy and safety data, we further revised the study protocol to focus on the 40 mg per day dose, a dose we believe to be sufficient to achieve tumor Css levels >500 ng/g for effective PKC-β1 targeting.

Part 2: The Treatment Cohort: This cohort is expected to be initiated in the first half of 2025 and compares two treatment arms: Part 2a, which assesses (Z)-endoxifen plus goserelin for patients with baseline Ki-67 >10%, and Part 2b, which assesses (Z)-endoxifen on its own for patients with baseline Ki-67 ≤10%.

The primary objective of Part 2a is to determine if the endocrine sensitive disease rate (ESDR), which is defined as the percentage of patients with Ki-67 ≤10% after 4 weeks of treatment in patients given (Z)-endoxifen plus goserelin is non-inferior to the ESDR in patients given exemestane plus goserelin, in patients with baseline Ki-67 ≥10%.

The primary objective of Part 2b is to evaluate the 24-week ESDR in patients with baseline Ki-67 ≤10%.

Secondary endpoints for both cohorts include pathologic complete response (pCR) at surgery, the Preoperative Endocrine Prognostic Index (PEPI), residual cancer burden (class 0–1), as well as safety and laboratory assessments.

Karisma-(Z)-endoxifen: Karisma-(Z)-endoxifen is a Phase 2 study of our proprietary oral (Z)-endoxifen in healthy premenopausal women with measurable mammographic breast density (MBD). In November 2024, the Karisma-(Z)-Endoxifen study reported data which showed the potential of low-dose (Z)-endoxifen to significantly reduce MBD, a key risk factor for breast cancer, while showing a favorable safety profile. The randomized, double-blind, placebo-controlled study enrolled 240 premenopausal women aged 40-55, randomized to one of three arms: placebo, 1 mg, or 2 mg of daily oral (Z)-endoxifen for six months. The study aimed to evaluate reductions in MBD and assess safety and tolerability. Mammograms were conducted to measure the 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.

Results showed that the 1 mg dose of (Z)-endoxifen reduced MBD by 17.3% ($p<0.01$), while the 2 mg dose achieved a reduction of 23.5% ($p<0.01$), compared to a minimal change in the placebo group of 0.27 percentage points. Plasma concentrations for (Z)-endoxifen were measured at 4.8 ng/mL and 9.7 ng/mL for the 1 mg and 2 mg arms, respectively, which showed the effectiveness of the lower dose in achieving significant reductions. Importantly, no significant differences in adverse events were observed between the 1 mg dose and the placebo. The 2 mg dose was associated with higher rates of hot flashes, night sweats and vaginal discharge.

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, appear as white areas in a mammogram. Women with the highest density are four to six times more likely to develop breast cancer in their lifetime and more likely to develop cancer between mammograms compared to those with low breast density. The latter are sometimes referred to as "interval cancers," which are often larger, more advanced, and more difficult to treat.

As of September 10, 2024, the FDA required mammogram providers to notify patients about the density of their breasts. The notification for patients with dense breasts includes a warning that dense breast tissue makes it harder to find breast cancer with a mammogram and raises their risk of developing breast cancer. It also encourages 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 Endocrine optimization Pilot (EOP): I-SPY 2 EOP is 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. We believe that 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 of the cancer returning.

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

On October 31, 2024, a preliminary data analysis was released which showed that (Z)-endoxifen met the primary endpoint with 95% (19/20 patients) receiving >75% of the planned treatment. The data also showed (Z)-endoxifen activity in rapidly reducing key biomarkers, such as Ki-67, by 69% from baseline and a 30.4 % reduction in functional tumor volume (FTV) from baseline after three weeks of treatment. Ki-67 is a protein that helps measure how quickly cancer cells in a tumor are dividing, and FTV is a quantitative measurement of tumor burden that can be used to assess treatment response for breast cancer.

(Z)-endoxifen was well tolerated in this study with the most common side effects being mild, including hot flashes, insomnia and fatigue. No dose reductions or discontinuations due to treatment related adverse events were observed in this study. Surgical Ki-67 values and 24-week imaging will be analyzed in the future.

On April 15, 2024, we announced our participation in a new study arm of I-SPY 2 EOP which was initiated to evaluate our proprietary (Z)-endoxifen in combination with abemaciclib (VERZENIO®), a cyclin-dependent kinase (CDK) 4/6 inhibitor marketed by Eli Lilly and Company, in women with ER+/HER2- breast cancer. On June 28, 2024, we announced that the study was expanded to include 80 women with newly diagnosed ER+ / HER2- invasive breast cancer.

Participants in this trial were initially intended to receive 80 mg of (Z)-endoxifen once daily alongside 150 mg of abemaciclib twice daily for 24 weeks prior to surgery. However, while no ovarian cysts have been reported, the I-SPY 2 EOP protocol has been updated, out of an abundance of caution, to align with recent updates to the EVANGELINE trial protocol. As a result, current and newly enrolled participants will now transition to or begin treatment with 40 mg per day of (Z)-endoxifen. Enrollment in this study is ongoing.

RECAST DCIS. RECAST DCIS is 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 our 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 non-invasive, 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.

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, we believe it could potentially spare a significant percentage of patients diagnosed with this disease from aggressive, invasive, or potentially unnecessary treatment.

Other Programs

Forthcoming Programs. On March 11, 2025 we announced our strategic decision to pursue a metastatic breast cancer indication for (Z)-endoxifen. Atossa believes that pursuing a metastatic indication may offer a more efficient regulatory pathway to deliver (Z)-endoxifen to women in urgent need and simultaneously plans to work with the FDA to advance additional indications, such as breast cancer prevention and neoadjuvant therapy, that often require larger and longer clinical trials.

Pre-Clinical Program. We sponsor strategic research, and have agreements with, with Weill Cornell Medicine, with the goal of making TNBC more treatable.

Investment in CAR-T Company. During the fourth quarter of 2024, Dynamic Cell Therapies, Inc. (DCT), a U.S. private company previously focused on Chimeric Antigen Receptor (CAR) T-cell therapies, laid off all employees and ceased operations. We have recorded impairment charges related to our investment in DCT. Refer to Note 4 to the Consolidated Financial Statements.

Markets

Potential Market Opportunities

The American Cancer Society (ACS) estimates that in the U.S. in 2025, 316,950 women will be diagnosed with breast cancer and one in eight women will be diagnosed with breast cancer in their lifetime. Approximately 80% of breast cancers diagnosed are estrogen receptor positive (ER+). The global ER+ breast cancer treatment market is anticipated to reach $33.7 billion by 2030 and is projected to grow at a compound annual growth rate (CAGR) of 7.89% from 2024 to 2030, according to a 2024 report by Grand View Research, Inc. 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 (Z)-endoxifen in each indication in breast cancer treatment and prevention settings could be up to $1 billion or more, annually.

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, 2024, we had cash and cash equivalents of approximately $71.1 million.

On November 19, 2024, we entered into an Open Market Sale Agreement, (the Sale Agreement), with Jefferies LLC (Jefferies) to sell shares of our common stock. Under the prospectus supplement and in accordance with the terms of the Sale Agreement, we may offer and sell shares of our common stock up to an aggregate offering price of $100,000,000. We did not sell any shares of our common stock under the Sale Agreement during 2024.

Warrant Activity

During the year ended December 31, 2024, we received $3.7 million from the exercise of warrants, resulting in the issuance of 3,672,500 shares of common stock.

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, 2024 and 2023 were approximately $14.1 million and $17.3 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 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 3, 2025, based on a review of our patent portfolio, we own and maintain 13 issued patents (five U.S. patents and eight international patents) and are pursuing 119 pending patent applications (28 U.S. patent applications and 91 international patent applications, including two allowed U.S. applications and three

allowed international applications) directed to our (Z)-endoxifen therapies, immunotherapies, such as CAR-T therapies, and other therapies. We continue to evaluate our patent portfolio on a regular 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 3, 2025, 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	4	8	15	70	2038 - 2046
Immunotherapy/CAR-T program	—	—	3	3	2037 - 2044
Other therapy programs	1	—	10	18	2030 - 2045

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 non-clinical 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 and unexpected side effects to the FDA. The FDA may suspend a clinical trial by placing it on a "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 (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 1 clinical 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, Fast Track Designation, Accelerated Approval, and Priority Review. These 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 is $4.3 million for fiscal year 2025. 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 designation, fast track, priority review and accelerated approval that are intended to expedite the process for reviewing drugs, to provide sponsors additional opportunities for FDA interaction, and in the case of accelerated approval, 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. Eligible drugs must also meet other requirements specific to each program. 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. In addition, some of these programs, such as accelerated approval, may include post-approval requirements. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. Under the Food and Drug Omnibus Reform Act of 2022, the FDA may require, as appropriate, that such studies be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. Products receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required post-marketing studies or if such studies fail to verify the predicted clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

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.

Abbreviated New Drug Applications for Generic Drugs

In 1984, with passage of the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly referred to as the "Hatch-Waxman Amendments") amending the Federal Food, Drug, and Cosmetic Act (FDCA), Congress authorized the FDA to approve generic drugs that are the same as drugs previously approved by the FDA under the NDA provisions of the statute. To obtain approval of a generic drug, an applicant must submit an abbreviated new drug application (ANDA) to the agency. Upon approval of an ANDA, the FDA indicates that the generic product is "therapeutically equivalent" to the drug product previously approved under an NDA, known as the reference listed drug (RLD), and it assigns a therapeutic equivalence rating to the approved generic drug in its publication "Approved Drug Products with Therapeutic Equivalence Evaluations," also referred to as the "Orange Book". Physicians and pharmacists consider the therapeutic equivalence rating to mean that a generic drug is fully substitutable for the RLD. In addition, by operation of certain state laws and numerous health insurance programs, the FDA's designation of a therapeutic equivalence rating often results in substitution of the generic drug without the knowledge or consent of either the prescribing physician or patient.

Under the Hatch-Waxman Amendments, the FDA may not approve an ANDA until any applicable period of nonpatent exclusivity for the RLD has expired. The FDCA provides a period of five years of data exclusivity for NDAs containing a new chemical entity. In cases where such exclusivity has been granted, an ANDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification (discussed further below), in which case the applicant may submit its application four years following the original product approval. The FDCA also provides for a period of three years of exclusivity if the NDA includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted by or for the applicant and are essential to the approval of the application. This three-year exclusivity period often protects changes to a previously approved drug product, such as a new dosage form, route of administration, combination or indication.

Hatch-Waxman Patent Certification and the 30 Month Stay

Upon approval of an NDA or a supplement thereto, NDA sponsors are required to list with the FDA each patent with claims that cover the applicant's product or a method of using the product. When an ANDA applicant files its application with the FDA, the applicant is required to certify to the FDA concerning any patents listed for the reference product in the Orange Book, except for patents covering methods of use for which the ANDA applicant is not seeking approval.

A certification that the new product will not infringe the already approved product's listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the applicant does not challenge the listed patents or indicate that it is not seeking approval of a patented method of use, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the ANDA applicant.

505(b)(2) New Drug Applications

As an alternative path to FDA approval for modifications to formulations or uses of products previously approved by the FDA pursuant to an NDA, an applicant may submit an NDA under Section 505(b)(2) of the FDCA. Section 505(b)(2) was enacted as part of the Hatch-Waxman Amendments and permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by, or for, the applicant, and for which the applicant has not obtained a right of reference. If the 505(b)(2) applicant can establish that reliance on the FDA's previous findings of safety and effectiveness is scientifically and legally appropriate, it may eliminate the need to conduct certain preclinical studies or clinical trials of the new product. The FDA may also require companies to perform additional bridging studies or measurements, including clinical trials, to support the change from the previously approved reference drug. The FDA may then approve the new drug candidate for all, or some, of the label indications for which the reference drug has been approved, as well as for any new indication sought by the 505(b)(2) applicant.

To the extent that a Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would. As a result, approval of a 505(b)(2) NDA can be stalled until all the listed patents claiming the referenced product have expired, until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired, and, in the case of a Paragraph IV certification and subsequent patent infringement suit, until the earlier of 30 months, settlement of the lawsuit or a decision in the infringement case that is favorable to the Section 505(b)(2) applicant.

Patent Term Extension

In the U.S., after an NDA is approved, owners of relevant drug patents may apply for up to a five-year patent extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory process. The allowable patent term extension is typically calculated as one-half the time between, the latter of the effective date of an IND and issue date of the patent for which extension is sought, and the submission date of an NDA, plus the time between NDA submission date and the NDA approval

date up to a maximum of five years. The time can be shortened if the FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed 14 years from the date of product approval. Only one patent applicable to an approved drug is eligible for extension and only those claims covering the product, a method for using it, or a method for manufacturing it may be extended and the application for the extension must be submitted prior to the expiration of the patent in question. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Some, but not all, foreign jurisdictions possess patent term extension or other additional patent exclusivity mechanisms that may be more or less stringent and comprehensive than those of the U.S.

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, among other things, 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, which may need to be submitted in a new or supplemental NDA, which would require FDA approval.

Advertising, marketing and promotion of prescription drugs is also subject to significant regulation under federal and state laws and regulations, including those administered by FDA and other federal and state regulatory bodies through federal and state agencies tasked with consumer protection and prevention of medical fraud, waste and abuse. After receiving approval in the U.S., we must comply with the FDA's regulation of drug promotion and advertising, including requirements that communications be consistent with the FDA-approved labeling, truthful and non-misleading, and present a fair balance of risk and benefit information, and compliance with federal anti-kickback statutes, limitations on gifts and payments to physicians and reporting of payments to certain third parties, among other requirements. The FDA actively monitors promotional activities and may take enforcement actions, including issuing warning letters, imposing fines, or pursuing criminal penalties in cases of noncompliance. Federal and state laws may impose further restrictions on promotional practices, including limitations on interactions with health care professionals and transparency requirements for marketing expenditures. Noncompliance with these provisions could result in significant legal and financial consequences, including civil and criminal penalties, reputational harm, and increased scrutiny from regulatory authorities.

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 or untitled letters, product recalls, product seizures, import alerts, 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 and process governing the conduct of clinical trials, including additional clinical trials that may be required, product licensing, safety reporting, post-authorization requirements, marketing and promotion, interactions with healthcare professionals, 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, which would make launch of such products commercially unfeasible in such countries.

Drug Marketing Authorization. In the E.U., 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 and, after respective national implementing decisions which must be rendered within 30 days in the three additional EEA Member States. The centralized procedure is compulsory for specific

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 a new active substance indicated for the treatment of certain diseases (e.g., HIV/AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases). For medicinal products containing a new active substance not yet authorized in the EEA before 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 MA 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 MA. 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 MA (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 MAs can be granted in the E.U. by the EC in exceptional circumstances. A conditional MA 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 conditional 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. Once a conditional MA has been granted, the MA holder must fulfill specific obligations within defined timelines. A conditional MA is valid for one year and must be renewed annually, but it can be converted

into a standard MA, initially valid for five years with the possibility of an indefinite extension once the MA holder fulfills the obligations imposed and the complete data confirms that the medicine's benefits continue to outweigh its risks.

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 Regulation (EU) 2021/2282 (HTAR), a regulation on health technology assessment. HTAR entered into force on January 11, 2022 and applies from January 12, 2025 onwards, followed by a further three-year transitional period during which EU member states must fully adapt to the new system. It 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. HTAR provides that E.U. Member States will be able to use common HTA tools, methodologies and procedures across the E.U., 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 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. On February 3, 2025, the first request submission period for joint scientific consultations under HTAR was opened by the EC.

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

Similar to the U.S., both MA 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 MAs. 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, MA of medicinal products and marketing of such products, both before and after grant of MA, 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 MA, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the MA, 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. MA 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 MA 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 MA for the product or imposition of financial penalties or other enforcement measures.

The manufacturing process for medicinal products in the E.U. is highly regulated and 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 (repealed by Directive 2017/1572 on January 31, 2022), 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. Amendments or replacements of at least Directive 2001/83/EC and Regulation (EC) No 726/2004 are part of the reform proposal for European pharmaceutical legislation. 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 national 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 regulatory 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 MA 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.

In the E.U., 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 regulatory 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 and mandatory sharing 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 European Health Data Space Regulation 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 labeling across the UK. The MHRA has introduced new regulatory pathways, including the International Recognition Procedure (IRP), which allows reliance on approvals from select global regulators, such as the FDA and EMA, to accelerate the authorization process. Additionally, the Innovative Licensing and Access Pathway (ILAP) facilitates faster access to innovative medicines by providing early regulatory and payer engagement.

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 broadly 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, as amended by the California Privacy Rights Act of 2020 (collectively, CCPA), 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, and affords rights to California residents in relation to their personal information. Health information falls under the CCPA's definition of personal information where it identifies, relates to, describes, or is reasonably capable of being associated with or could reasonably be linked, directly or indirectly, 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. Numerous other comprehensive privacy laws have passed or are being considered in other states, as well as at the federal and local levels, which also exempt some data processed in the context of clinical trials; but others exempt covered entities and business associates subject to HIPAA altogether, further complicating compliance efforts, and increasing legal risk and compliance costs for us and the third parties upon whom we rely.

Additionally, our use of artificial intelligence and machine learning may be subject to laws and evolving regulations regarding the use of artificial intelligence and machine learning, controlling for data bias, and antidiscrimination.

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 can result in the imposition of significant civil and/or criminal penalties, private litigation, loss of business and negative publicity. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Federal and State Fraud and Abuse Laws

The federal healthcare Anti-Kickback Statute prohibits, among other things, persons and entities from 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. HHS and the Office of Inspector General (OIG) assess arrangements on a case-by-case basis, considering factors such as potential overutilization and potential effects on clinical decision-making, patient safety, and quality of care.

Violations of the Anti-Kickback Statute can result in significant penalties, including criminal fines, imprisonment, exclusion from federal healthcare programs, and civil monetary penalties. In addition, violations may serve as the basis for liability under the False Claims Act, exposing companies to lawsuits brought by the federal government or private whistleblowers, and exposing companies to treble damages and per-violation civil penalties. Sustained enforcement efforts and evolving interpretations of the statute continue to shape the compliance landscape within the healthcare industry.

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 Anti-Kickback Statute, which prohibits knowingly and willfully paying, offering, soliciting, or receiving remuneration to induce referrals or the purchase of items or services covered by federal healthcare programs;
- 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 or private whistleblowers 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.

Additionally, federal and state privacy and security laws, including HIPAA and state consumer data protection laws, regulate the collection, storage, and use of personal health information, requiring strict safeguards and reporting obligations for data breaches.

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. Regulatory scrutiny continues to increase, with expanded enforcement efforts and potential changes in legislation that could impact our business operations and compliance obligations.

Employees

As of the date of filing this Annual Report, we employ two executive officers and thirteen 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 and uncertainties, including risks and uncertainties 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. 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, 2024, 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. These risks and uncertainties are discussed more fully below and include, but are not limited to, risks related to:

Risks Related to our Business

- We have a history of operating losses and 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.
- 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.
- 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.
- 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 as well as for clinical trial activities.
- 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.
- The deployment of artificial intelligence (AI) in our or our collaborators' product candidates could adversely affect our business, reputation or financial results.
- 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.
- Our ability to use net operating loss carryforwards and research tax credits to reduce future tax payments may be limited or restricted.
- We, or our wholly-owned subsidiary, could lose our ability to operate in Australia, or our subsidiary may be unable to benefit from the past or future R&D tax rebates available under current Australian regulations.

Risks Related to our Intellectual Property

- We may not be able to protect our proprietary technology.
- Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies.
- Changes in U.S. patent law could diminish the value of patents in general.
- 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.
- Significant disruptions in our information technology systems or breaches of data security could adversely affect our business.
- 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 regain compliance 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.
- 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.
- We may be unable to implement and maintain effective internal control over financial reporting.
- The requirements of being a public company may strain our resources, result in litigation, and divert management's attention.
- 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.

In evaluating our business, you should carefully consider the following discussion of material risks, events and uncertainties that make an investment in us speculative or risky in addition to the other information included in this Annual Report. A manifestation of any of the following risks and uncertainties could, in circumstances we may or may not be able to accurately predict, materially and adversely affect our business and operations, growth, reputation, prospects, operating and financial results, financial condition, cash flows, liquidity and stock price. Some of the factors, events and contingencies discussed below may have occurred in the past, but the disclosures below are not representations as to whether or not the factors, events or contingencies have occurred in the past, and instead reflect our beliefs and opinions as to the factors, events, or contingencies that could materially and adversely affect us in the future. The risks and uncertainties described below are not the only ones we face. Our operations could also be affected by factors, events or uncertainties that are not presently known to us or that we currently do not consider to present significant risks to our business. Therefore, you should not consider the following risks to be a complete statement of all the potential risks or uncertainties that we face.

Risks Related 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, foreign exchange rate volatility, instability in financial institutions, changes in monetary policy, changes in trade policies including tariffs and other trade restrictions or the threat of such actions, and rising geopolitical instability 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 years ended December 31, 2024 and 2023, we incurred net losses of approximately $25.5 million and $30.1 million, respectively, and we had an accumulated deficit of approximately $211.8 million since inception. As of December 31, 2024 and 2023, we had cash and cash equivalents of approximately $71.1 million and $88.5 million, respectively. 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.

For example, our ability to raise capital in the public capital markets, including through "at the market" offerings pursuant to our Open Market Sale Agreement℠ (the Sale Agreement) with Jefferies LLC (Jefferies), may be limited by, among other things, SEC rules and regulations impacting the eligibility of smaller companies to use Form S-3 for primary offerings of securities. Although alternative public and private transaction structures may be available, these may require additional time and cost, may impose operational restrictions on us, and may not be available on attractive terms.

If we raise additional funds by selling or issuing equity securities or equity-linked securities, including through our Sale Agreement, our stockholders will experience dilution and it may have an adverse effect on the price of our common stock. 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 and as a sponsor or as an equity investor in special purpose acquisition companies, and we may not be able to realize the expected business or financial benefits of these investments. For example, in the fourth quarter of 2024, Dynamic Cell Therapies, Inc. (DCT), a U.S. private company previously focused on Chimeric Antigen Receptor (CAR) T-cell therapies, laid off all employees and ceased operations, and we incurred a $1.7 million and $3.0 million impairment charge for the years ended December 31, 2024 and 2023, respectively.

In addition, 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 loss for the year ended December 31, 2024 was approximately $25.5 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 Chairman, President, 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 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 $1.7 million and $3.0 million impairment charge for the years ended December 31, 2024 and 2023, respectively, 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 2024 for our EVANGELINE study, 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. Such data is 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.

In addition, our employees and personnel or our vendors or partners may use AI, including generative AI, technologies to perform their work or in their operations, and the disclosure and use of personal information in AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating AI, controlling for data bias and antidiscrimination. Any use of this technology could result in additional compliance costs, regulatory investigations and actions, and consumer lawsuits.

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 help prevent or mitigate data loss, theft, misuse, or other security incidents or vulnerabilities affecting our data and to help 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.

The deployment of AI in our or our collaborators' product candidates could adversely affect our business, reputation or financial results.

We or our collaborators may integrate AI, including generative AI, and machine learning in our drug discovery efforts and efforts to develop our product candidates. As a new and rapidly evolving technology, the use of AI is subject to numerous risks and uncertainties, including operational, technical, legal, compliance, privacy, data security, ethical, competitive and reputational risks. Machine learning and predictive analytics may produce flawed, biased, incomplete, overbroad or inaccurate results, which could negatively impact the development of our or our collaborators' product candidates and expose us to competitive and reputational harm. Developing, testing and deploying resource-intensive AI systems, or supporting our collaborator's development of such systems, including our sponsorship of the Phase 2 SMART study that seeks to validate an AI-driven breast cancer risk assessment model, requires significant investment and may increase our costs, and there is no guarantee that our investment in such systems will lead to discovery of new product candidates or eventual regulatory approval or commercialization of any product candidates or accelerate or reduce costs associated with the drug discovery, development or approval timeline. Our inability to successfully deploy AI in the discovery or development of our or our collaborators' product candidates, or the public's lack of acceptance of such products, could adversely affect our business, reputation and financial results.

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 and wildfires, 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 tax 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 $1.5 million and $1.8 million in our Consolidated Balance Sheets as of December 31, 2024 and 2023, respectively. 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.

If the estimates we make, or the assumptions on which we rely, in preparing our consolidated financial statements prove inaccurate, our actual results may vary from those reflected in our accruals.

Our consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, revenues and expenses, the amounts of charges accrued by us and related disclosure of contingent assets and liabilities. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. We cannot assure you, however, that our estimates, or the assumptions underlying them, will be correct.

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 3, 2025, we own and are pursuing 119 pending provisional and non-provisional patent applications (28 U.S. patent applications and 91 international patent applications, including two allowed U.S. applications and three allowed international applications) and 13 issued patents (five U.S. patents and eight 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 or drug candidate 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.

For example, on August 18, 2023, Intas Pharmaceuticals LTD. filed a Petition for Post Grant Review (PGR) with the Patent Trial and Appeal Board (PTAB) of the U.S. Patent and Trademark Office, the (PGR Petition), seeking to invalidate all claims related to one of our issued patents (U.S. Patent No. 11,572,334) titled "Methods for Making and Using Endoxifen," (the Patent). We actively contested the PGR Petition and believed that the Patent was properly granted and was valid and enforceable.

On January 29, 2025, the PTAB issued a final written decision that found that all claims under the Patent were unpatentable.

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 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 to the Consolidated Financial Statements. 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 the 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. State health information privacy laws, such as California's Confidentiality of Medical Information Act and Washington's My Health My Data Act, govern the privacy and security of health-related information and may apply even when HIPAA does not and impose additional requirements. 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 requirements related to the legal basis of the processing (such as consent of the individuals to whom the personal data relates), the information provided to the individuals prior to processing their personal data, the personal data breaches which may have to be notified to the national data protection authorities and data subjects, the measures to be taken when engaging processors, 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

European Commission's standard contractual clauses (SCCs) 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. 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.

Significant disruptions in our information technology systems or breaches of data security could adversely affect our business.

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. Sensitive data could also be leaked, disclosed, or revealed as a result of or in connection with our employee's, personnel's, vendors' or partners' use of AI technologies. 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 help mitigate our exposure to these risks, cyber attacks and other cyber events are evolving, unpredictable and increasing in sophistication, including through the use of increasingly sophisticated and evolving AI technologies. 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 certain 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 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.

We also compete with a substantial number of other companies that are working to develop novel drugs using emerging AI technologies that compete directly or indirectly with us. Companies implementing generative AI, for example, have been devoting resources to create large and high-quality training datasets in order to accelerate drug discovery processes. This includes using AI tools to create novel drug molecules, streamline disease target identification, and construct AI-based prediction models for clinical trial outcomes. As a result of these dynamics, we may not be able to secure the technologies we desire or to otherwise effectively compete. Furthermore, should any commercial undertaking by us prove to be successful, there can be no assurance competitors with greater financial resources will not offer competitive products and/or technologies.

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 regain compliance 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 regain compliance with the continued listing standards of Nasdaq, including its minimum closing bid price requirement, or satisfy the continued listing standards of Nasdaq going forward.

On February 21, 2025, we received a letter from Nasdaq informing us that we are not in compliance with Nasdaq Listing Rule 5550(a)(2) for continued listing on Nasdaq, because our common stock failed to maintain a minimum closing bid price of $1.00 per share for 30 consecutive business days. We have until August 20, 2025 to regain compliance with Nasdaq Listing Rule 5550(a)(2). In the event we do not regain compliance by then, we may be eligible an additional 180 calendar day compliance period, subject to certain conditions. To regain compliance, the closing bid price of our common stock must be at least $1.00 per share for a minimum of 10 consecutive business days.

The Nasdaq notice has no immediate effect on the listing or trading of our common stock on Nasdaq. However, if we are unable to regain compliance with Nasdaq Listing Rule 5550(a)(2) or if we are unable to comply with other continued listing standards of Nasdaq, going forward, 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, including through “at the market” offerings pursuant to our Sale Agreement with Jefferies, sales by holders of our warrants to purchase common stock or sales by 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 Annual Report on Form 10-K, 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, general economic slowdown or a recession, foreign exchange rate volatility, financial institution instability, changes in monetary policy, changes in trade policies including tariffs and other trade restrictions or the threat of such actions, and rising geopolitical instability, including the ongoing conflict in Ukraine, the conflict in the Middle East, and rising tensions between China and Taiwan;
- 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; 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.

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 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, 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, as amended, 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, as amended, 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 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 help 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 Business Operations, and include mechanisms, controls, technologies, systems, and other processes designed to help prevent or mitigate data loss, theft, misuse, or other security incidents or vulnerabilities affecting the data and help 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 help anticipate future threats and trends, and their impact on the Company's risk environment.

Our Senior Vice President of Business Operations who reports directly to the Chief Executive Officer and has over eight 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. Since the beginning of 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 help 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 of Business Operations as well as other members of the senior leadership team.

ITEM 2. PROPERTIES

We have an operating lease with Regus International Workplace Group for office space in Seattle, Washington. The lease commencement date was June 1, 2024, and we agreed to pay monthly rent of $1 thousand per month for 12 months. On December 20, 2024, we entered into an additional operating lease with Regus International Workplace Group for additional office space in Seattle, Washington.

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, refer to 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 17, 2025, there were approximately 43 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 2024.

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 our 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, outcomes and the timing of results or outcomes could differ materially from those contained in the forward-looking statements. Please read "*Note Regarding *Forward-Looking Statements" included elsewhere in this Annual Report for additional information regarding forward-looking statements.*

Company Overview

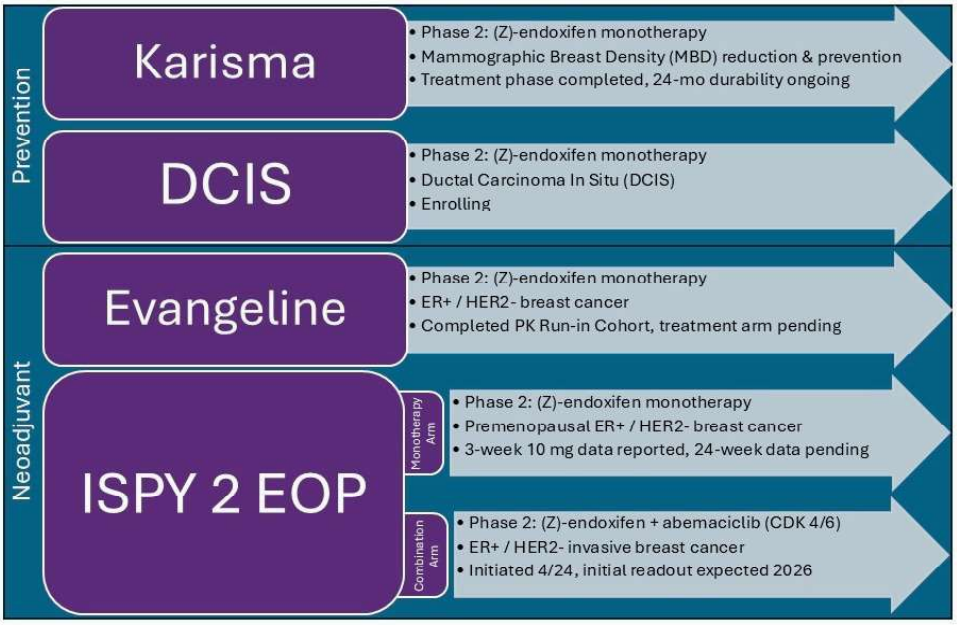
We are a clinical-stage biopharmaceutical company developing proprietary innovative medicines in areas of significant unmet medical need in oncology, with a focus on women's breast cancer and other breast conditions. Our lead drug candidate under development is oral (Z)-endoxifen, which we are developing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

We have been granted four U.S. and eight international patents 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 at least 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 the 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 Women with Mammographic Breast Density. Mammographic breast density (MBD) is an emerging public health issue. 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, appear as white areas in a mammogram. Women with the highest density are four to six times more likely to develop breast cancer in their lifetime and more likely to develop cancer between mammograms compared to those with low breast density. The latter are sometimes referred to as "interval cancers," which are often larger, more advanced, and more difficult to treat.

In December 2021, we commenced a Phase 2 study of our proprietary oral (Z)-endoxifen. The study, known as the Karisma-(Z)-endoxifen study, was a Phase 2, randomized, double-blind, placebo-controlled, dose-response study of our proprietary oral (Z)-endoxifen in healthy premenopausal women with measurable mammographic breast density. The primary objective of the study was to determine the dose-response relationship of daily (Z)-endoxifen on breast density reduction. Secondary endpoints assessed safety and tolerability. The study was conducted in Stockholm, Sweden and included approximately 240 participants who received daily doses of oral (Z)-endoxifen or placebo for six months after enrollment, randomized to one of three arms: placebo, 1 mg, or 2 mg of (Z)-endoxifen. The study also included an exploratory endpoint to assess durability of the breast density changes.

The study fully enrolled in November 2023 and in September 2024, the study concluded. The data showed the potential of low-dose (Z)-endoxifen to significantly reduce MBD, a key risk factor for breast cancer, while showing a favorable safety profile.

Results showed that the 1 mg dose of (Z)-endoxifen reduced MBD by 17.3% ($p<0.01$), while the 2 mg dose achieved a reduction of 23.5% ($p<0.01$), compared to a minimal change in the placebo group of 0.27%. Plasma concentrations for (Z)-endoxifen were measured at 4.8 ng/mL and 9.7 ng/mL for the 1 mg and 2 mg arms, respectively, which showed the effectiveness of the lower dose in achieving significant reductions. Importantly, no significant differences in adverse events were observed between the 1 mg dose and the placebo. The 2 mg dose was associated with higher rates of hot flashes, night sweats and vaginal discharge.

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 the presence of abnormal cells inside a milk duct in 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 (the QLHC) announced the initiation of the Phase 2 DCIS: Re-Evaluating Conditions for Active Surveillance Suitability as Treatment (the 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 are expected to 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. Enrollment in this study is ongoing.

(Z)-endoxifen for Neoadjuvant Treatment of Breast Cancer. We are also developing (Z)-endoxifen to treat estrogen receptor positive (ER+) / human epidermal growth factor receptor 2 negative (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 approximately 240,000 new cases or 78% of all breast cancers.

In October 2022, we received authorization from the FDA for our Investigational New Drug (IND) application for oral (Z)-endoxifen. The study, known as "EVANGELINE" is a Phase 2 randomized study assessing (Z)-endoxifen as neoadjuvant therapy in premenopausal women with primary ER+, HER2– breast cancer. The study will enroll approximately 190 patients across up to 25 U.S. sites, and is structured in two parts.

In Part 1, a Pharmacokinetic (PK) Run-In Cohort evaluated two dosage levels. A 40 mg per day cohort was initiated in February 2023 to assess if a plasma steady state concentration (Css) of 500 to1000 ng/mL, which is required for optimal PKC-β inhibition, could be achieved. However, data showed that none of the patients in the 40 mg cohort reached the target Css. Subsequently, an 80 mg per day cohort was initiated and fully enrolled in July 2024. In this higher dose group, about 50% of patients receiving (Z)-endoxifen with goserelin and 38% of patients receiving (Z)-endoxifen alone attained the target plasma Css, with an average of 484 ng/mL.

Importantly, tumor Css levels were found to be more than double the plasma levels, exceeding 500 ng/g in 90% of patients, and 85% of patients exhibited a 4-week Ki-67 response (≤10%), indicating substantial tumor suppression. (Z)-endoxifen was generally well tolerated, with no significant Grade 3 or 4 toxicities, though four gynecologic events (including one Grade 3 hemorrhagic ovarian cyst) were noted in the 80 mg group.

In January 2025, based on the PK, efficacy, and safety data, the protocol was revised to focus on the 40 mg per day dose. Part 2 is expected to compare two treatment arms based on baseline Ki-67 levels, and the aim is to evaluate the endocrine sensitive disease rate, pathologic complete response, and other key endpoints. The initiation of the Treatment Cohort is planned for the first half of 2025.

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 Endocrine Optimization Pilot (I-SPY 2 EOP). The I-SPY 2 EOP is a collaborative effort among academic investigators from major cancer research centers across the U.S., QLHC, the FDA, and the Foundation for the National Institutes of Health (FNIH) Cancer Biomarkers Consortium. 20 patients were treated with (Z)-endoxifen for up to 24 weeks prior to surgery. Enrollment was completed in January 2024.

A preliminary data analysis from this study, which included 20 women with ER+/HER2- breast cancer who received 10 mg of (Z)-endoxifen orally once daily for six cycles (each cycle = 28 days), showed that (Z)-endoxifen met the primary endpoint with 95% (19/20 patients) receiving > 75 % of planned treatment. The data also showed (Z)-endoxifen activity in rapidly reducing key biomarkers, such as Ki-67, by 69% from baseline and a 30.4% reduction in functional tumor volume (FTV) from baseline after three weeks of treatment. FTV is a quantitative measurement of tumor burden that can be used to assess treatment response for breast cancer. (Z)-endoxifen was well tolerated in this study with the most common side effects being mild, including hot flashes, insomnia, and fatigue. No dose reductions or discontinuations due to treatment related adverse events were observed in this study. Surgical Ki-67 values and 24-week imaging will be analyzed in the future.

On April 15, 2024, we announced our participation in a new study arm of the I-SPY 2 EOP which was initiated to evaluate our proprietary (Z)-endoxifen in combination with abemaciclib (VERZENIO®), a cyclin-dependent kinase (CDK) 4/6 inhibitor marketed by Eli Lilly and Company, in women with ER+/HER2- breast cancer. On June 28, 2024, we announced that the study had been expanded to include 80 women with newly diagnosed ER+ / HER2- invasive breast cancer. Currently enrolled and newly enrolled participants are expected to transition to or be initiated on 40 mg of (Z)-endoxifen (from 80 mg) once daily in combination with 150 mg of abemaciclib twice daily for a total of 24 weeks prior to surgery. The transition to the 40 mg dose from an 80 mg dose is the result of a protocol amendment approved in January 2025. Enrollment in this study is ongoing.

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

We had an operating lease for office space in Seattle, Washington with WW 107 Spring Street LLC. Rent was $2 thousand a month, and this lease terminated on June 30, 2024. On February 29, 2024, we entered into an operating lease with Regus International Workplace Group for office space in Seattle, Washington. The lease commencement date was June 1, 2024, and we agreed to pay monthly rent of $1 thousand per month for 12 months. On December 20, 2024, we entered into an additional operating lease with Regus International Workplace Group for additional office space in Seattle, Washington for 12 months.

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.

Research and Development Expenses

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 Contract Research Organizations (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.

Clinical Trial and Preclinical Study Accruals

We make estimates of our accrued expenses for clinical trial and preclinical study activities based on the facts and circumstances known to us at the time. These accruals are based upon estimates of costs incurred and fees that may be associated with services provided by clinical trial investigational sites and CROs, CMOs and for other clinical trial-related activities. In accruing for these services, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If possible, we obtain information regarding unbilled services directly from these service providers. However, we may be required to estimate these services based on other information available to us by reviewing contracts, vendor agreements and through discussions with internal clinical and preclinical personnel and external service providers as to the progress or stage of completion of services and the agreed-upon fee to be paid for such services. If we underestimate or overestimate the activities or fees associated with a study or service at a given point in time, adjustments to research and development expenses may be necessary in future periods. Historically, our estimated accrued liabilities have approximated actual expense incurred. Subsequent changes in estimates may result in a material change in our accruals.

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.

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, 2024 and 2023

Revenue and Cost of Revenue. For the years ended December 31, 2024 and 2023, we had no source of revenue and no associated cost of revenue.

Operating Expenses. Total operating expenses were $27.6 million for the year ended December 31, 2024, which was a decrease of $3.8 million, from the year ended December 31, 2023 of $31.4 million. Factors contributing to the decreased operating expenses in the year ended December 31, 2024 are explained below.

Research & Development (R&D) Expenses. The following table provides a breakdown of major categories within R&D expenses for the years ended December 31, 2024 and 2023, together with the dollar change in those categories (dollars in thousands):

		Year Ended December 31, 2024	Year Ended December 31, 2023	Increase (Decrease)	% Increase (Decrease)
Research and Development Expense					
	Clinical and pre-clinical trials	$ 10,107	$ 12,722	$ (2,615)	(21)%
	Compensation	2,928	3,474	(546)	(16)%
	Professional fees and other	1,082	1,138	(56)	(5)%
	Research and Development Expense Total	$ 14,117	$ 17,334	$ (3,217)	(19)%

As (Z)-endoxifen is our only product candidate for which we currently incur R&D expense, we have not further disaggregated R&D expenses by product candidate:

- Clinical and pre-clinical trial expense decreased $2.6 million for the year ended December 31, 2024 compared to the prior year due to a decrease in spending for the (Z)-endoxifen trials, including a decrease in drug development costs.

- The decrease in R&D compensation expense of $0.5 million for the year ended December 31, 2024 compared to the prior year was primarily due to a decrease in non-cash stock-based compensation expense of $0.9 million. Non-cash stock-based compensation expense decreased compared to the prior year due to the weighted average fair value of stock options amortizing in 2024 being lower than 2023. The decrease in compensation expense was partially offset by an increase in cash compensation expense of $0.4 million due to the hiring in early 2024 of additional R&D employees.

General and Administrative (G&A) Expenses. The following table provides a breakdown of major categories within G&A expenses for the years ended December 31, 2024 and 2023, together with the dollar change in those categories (dollars in thousands):

		Year Ended December 31, 2024	Year Ended December 31, 2023	Increase (Decrease)	% Increase (Decrease)
General and Administrative Expense					
	Compensation	$ 5,458	$ 7,388	$ (1,930)	(26)%
	Professional fees and other	7,164	5,367	1,797	33%
	Insurance	882	1,288	(406)	(32)%
	General and Administrative Expense Total	$ 13,504	$ 14,043	$ (539)	(4)%

- The decrease in G&A compensation expense of $1.9 million for the year ended December 31, 2024 compared to the prior year was due to a decrease in both cash compensation and non-cash stock-based compensation expense. Non-cash stock-based compensation expense decreased by $1.4 million for the year ended December 31, 2024 compared to the prior year due to the weighted average fair value of stock options amortizing in 2024 being lower than in 2023. Cash compensation decreased by $0.5 million for the year ended December 31, 2024 compared to the prior year primarily due to salary and bonus severance expense of $0.6 million related to the departure of our former Chief Financial Officer in 2023.

- G&A professional fees and other expense increased by $1.8 million for the year ended December 31, 2024 compared to the prior year primarily due to the increase in legal fees of $1.1 million for the year ended December 31, 2024. Legal costs for the PGR litigation and patent defense in 2024 increased $0.7 million, and we also incurred legal costs associated with the filing of our Registration Statement on Form S-3 and the establishment of our ATM facility of $0.4 million. Investor relations expense increased by $0.3 million for the year ended December 31, 2024 compared to the prior year due to an increase in investor

outreach costs. Accounting fees also increased by $0.3 million for the year ended December 31, 2024 compared to the prior year due to procedures needed from both current and former auditors related to the Registration Statement on Form S-3 and our ATM facility.

- The decrease in G&A insurance expense of $0.4 million for the year ended December 31, 2024 compared to the prior year was due to lower negotiated insurance premiums for the same or better coverage in 2024.

Interest Income. Interest income of $4.1 million for the year ended December 31, 2024 represented a decrease of $0.2 million compared to the prior year, and was primarily due to a decrease in funds invested in the money market account.

Impairment Charge on Investment in Equity Securities. For the year ended December 31, 2024 and 2023, we wrote down our Investment in equity securities by $1.7 million and $3.0 million, respectively, due to impairment of our investment in DCT. Refer to Note 4 "Investment in Equity Securities" to the Consolidated Financial Statements.

Income Taxes. We did not record an income tax expense or benefit for the years ended December 31, 2024 and 2023 due to uncertainty regarding utilization of our net operating loss carryforwards and our history of losses.

Liquidity and Capital Resources

On June 27, 2024, our stockholders approved an amendment to our Amended and Restated Certificate of Incorporation to increase the number of authorized shares of our common stock, par value $0.18 per share, from 175,000,000 to 350,000,000. As of December 31, 2024, we are authorized to issue 350,000,000 shares of common stock, par value $0.18 per share. On November 19, 2024, we entered into an Open Market Sale Agreement℠ with Jefferies LLC. We may offer, from time to time, to sell, in an "at the market offering", shares of our common stock up to an aggregate offering price of up to $100.0 million. We did not make any sales under the at the market offering facility during the year ended December 31, 2024.

During the year ended December 31, 2024, we received $3.7 million from the exercise of warrants resulting in the issuance of 3,672,500 shares of common stock.

We have incurred net losses and negative operating cash flows since inception. For the year ended December 31, 2024, we recorded a net loss of $25.5 million and used $21.0 million of cash in operating activities. As of December 31, 2024, we had $71.1 million in unrestricted cash and cash equivalents and working capital of $69.5 million. We believe we have sufficient cash on hand to fund our projected operating requirements for at least the next 12 months.

Net Cash Flows from Operating Activities. Net cash used in operating activities was $21.0 million for the year ended December 31, 2024, compared to net cash used in operating activities of $20.9 million in 2023, an increase of $0.1 million. Cash used in operating activities for the year ended December 31, 2024 primarily consisted of our net loss of $25.5 million, adjusted for non-cash items such as non-cash stock-based compensation expense of $2.3 million, non-cash impairment charge on investment in equity securities of $1.7 million and net cash inflows from a change in our operating assets and liabilities of $1.1 million. Cash used in operating activities for the year ended December 31, 2023 primarily consisted of to our net loss of $30.1 million, adjusted for non-cash items such as stock-based compensation expense of $4.6 million, non-cash impairment charge on investment in equity securities of $3.0 million and net cash outflows from a change in our operating assets and liabilities of $0.9 million.

Net Cash Flows from Investing Activities. Net cash used in investing activities was $19 thousand for the year ended December 31, 2024, compared to net cash used in investing activities of $14 thousand for the year ended December 31, 2023. Current and prior year cash used in investing activities was primarily related to purchases of new computers.

Net Cash Flows from Financing Activities. Net cash provided by financing activities for the year ended December 31, 2024 was $3.7 million compared to net cash used in financing activities of $1.5 million for 2023. The $3.7 million net cash provided by financing activities for the year ended December 31, 2024 primarily consisted of the receipt of proceeds from the exercise of warrants. Net cash used in financing activities for the year ended December 31, 2023 consisted of $1.5 million for the repurchase of common stock under the Share Repurchase Program.

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, foreign exchange rate volatility, financial institution instability, changes in monetary policy, changes in trade policies including tariffs and other trade restrictions or the threat of such actions, 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.

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 one 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, 2024, our estimated non-cancellable commitment was $10.2 million which will be paid over the term of the clinical trials.

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 did not obligate us to acquire any specific number of shares. Under the Share Repurchase Program, shares of common stock could have been 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 were determined by the Board in its discretion and depended on a variety of factors, including legal requirements, price and economic and market conditions. The Share Repurchase Program expired on December 31, 2024, and there were no shares repurchased under the program during the year ended 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.

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 Adopted Accounting Pronouncements

Refer to Note 3 to these Consolidated Financial Statements.

Recently Issued Accounting Pronouncements

Refer to Note 3 to these Consolidated Financial Statements.

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 56 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, 2024, 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, 2024, 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 Control 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, 2024, 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, 2024. 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, 2024, that have materially affected or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

(a) Trading Plans

During the quarter ended December 31, 2024, 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

Except as indicated below, the other information required by this item is incorporated by reference to the sections entitled "Election of Directors," "Executive Officers," "Board Committees," "Insider Trading Policy," and, as applicable, "Delinquent Section 16(a) Reports" in our Definitive Proxy Statement for our 2025 Annual Meeting of Stockholders (the Proxy Statement).

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://investors.atossatherapeutics.com/ under "Corporate 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.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference to the sections entitled "Executive Compensation," "Director Compensation" and "Compensation Committee Interlocks" in our Proxy Statement.

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

The information required by this item is incorporated by reference to the sections entitled "Executive Compensation- Equity Compensation Plan Information" and "Security Ownership of Beneficial Owners and Management" in our Proxy Statement.

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

The information required by this item is incorporated by reference to the sections entitled "Certain Relationships and Related Party Transactions" and "Corporate Governance" in our Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item is incorporated by reference to the section entitled "Ratification of the Selection of the Independent Registered Public Accounting Firm" in our Proxy Statement.

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 72 of this Annual Report.

ITEM 16. FORM 10-K SUMMARY

None.

Report of Independent Registered Public Accounting Firm

To the Stockholders 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, 2024 and 2023, the related consolidated statements of operations, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2024, 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, 2024 and 2023, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2024, 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 audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

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

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

Critical Audit Matter

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.

Accrued and prepaid research and development expenses

Description of the Matter	As of December 31, 2024, the Company accrued $700 thousand for estimated costs incurred for research and development activities and recorded $350 thousand as prepaid expenses for payments made in advance of incurring such costs. As described in Note 3, 5 and 6 to the consolidated financial statements, the Company has entered into various research and development contracts for which payments may differ from the timing of costs incurred. The Company analyzes progress of the services, including the phase or completion of events, invoices received and contracted costs to determine the appropriate amount to record at period-end. Auditing management's accounting for accrued and prepaid research and development expenses, including clinical trial and preclinical study activities, is especially challenging as evaluating the progress or stage of completion of the

activities under the Company's research and development agreements includes subjective and qualitative aspects and is dependent on information from third-party service providers and internal clinical personnel.

How We Addressed the Matter in Our Audit

We obtained an understanding of the Company's clinical trials, its research and development contracts, and management's process for estimating the accrued and prepaid research and development expenses.

To test the Company's accrued and prepaid research and development expenses, our procedures included, among others, obtaining supporting evidence of the research and development activities performed for significant clinical trials and preclinical studies, meeting with project managers to corroborate progress of activities, and inspecting vendor contracts. We compared the costs for a sample of research and development transactions against the related invoices. We confirmed with vendors the activity and amounts invoiced to-date and recalculated the amount recorded at period-end based on the contractual terms. We also tested a sample of subsequent invoices and compared them to amounts recorded at period-end.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2023.

Seattle, Washington
March 25, 2025

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

	As of December 31,	
	2024	2023
Assets		
Current assets		
Cash and cash equivalents	$ 71,084	$ 88,460
Restricted cash	110	110
Prepaid materials	2,098	1,487
Prepaid expenses and other current assets	1,165	2,162
Total current assets	74,457	92,219
Investment in equity securities	—	1,710
Other assets	1,987	2,323
Total assets	$ 76,444	$ 96,252
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 679	$ 806
Accrued expenses	919	973
Payroll liabilities	1,862	1,654
Other current liabilities	1,507	1,803
Total current liabilities	4,967	5,236
Total liabilities	4,967	5,236
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, 2024 and 2023	—	—
Common stock - $0.18 par value; 350,000,000 and 175,000,000 shares authorized as of December 31, 2024 and 2023, respectively; 129,170,004 and 125,304,064 shares issued and outstanding as of December 31, 2024 and 2023, respectively	23,488	22,792
Additional paid-in capital	261,256	255,987
Treasury stock, at cost; 1,320,046 shares of common stock at December 31, 2024 and 2023	(1,475)	(1,475)
Accumulated deficit	(211,792)	(186,288)
Total stockholders' equity	71,477	91,016
Total liabilities and stockholders' equity	$ 76,444	$ 96,252

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,	
	2024	2023
Operating expenses		
Research and development	$ 14,117	$ 17,334
General and administrative	13,504	14,043
Total operating expenses	27,621	31,377
Operating loss	(27,621)	(31,377)
Impairment charge on investment in equity securities	(1,710)	(2,990)
Interest income	4,050	4,343
Other expense, net	(223)	(70)
Loss before income taxes	(25,504)	(30,094)
Income tax benefit	—	—
Net loss	(25,504)	(30,094)
Net loss per share of common stock - basic and diluted	$ (0.20)	$ (0.24)
Weighted average shares outstanding used to compute net loss per share - basic and diluted	125,859,276	126,081,602

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, 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
Issuance of common stock upon warrant exercise	—	—	3,672,500	661	3,012	—	—	3,673
Issuance of common stock upon option exercise	—	—	343,998	62	211	—	—	273
Shares withheld related to cashless exercise of options and taxes	—	—	(150,558)	(27)	(246)	—	—	(273)
Stock-based compensation	—	—	—	—	2,292	—	—	2,292
Net loss	—	—	—	—	—	—	(25,504)	(25,504)
Balance at December 31, 2024	582	$ —	129,170,004	$ 23,488	$ 261,256	$ (1,475)	$ (211,792)	$ 71,477

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,	
	2024	2023
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (25,504)	$ (30,094)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation	2,292	4,621
Impairment charge on investment in equity securities	1,710	2,990
Depreciation	17	23
Loss on disposal of assets	7	—
Changes in operating assets and liabilities:		
Prepaid materials	(611)	2,544
Prepaid expenses and other current assets	997	1,004
Other assets	331	(1,697)
Accounts payable	(127)	(2,159)
Accrued expenses	(54)	(86)
Payroll liabilities	208	129
Other current liabilities	(296)	1,784
Net cash used in operating activities	(21,030)	(20,941)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property and equipment	(19)	(14)
Net cash used in investing activities	(19)	(14)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from exercise of warrants	3,673	—
Common stock repurchased	—	(1,475)
Net cash provided by (used in) financing activities	3,673	(1,475)
NET DECREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	(17,376)	(22,430)
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, BEGINNING BALANCE	88,570	111,000
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, ENDING BALANCE	$ 71,194	$ 88,570
RECONCILIATION OF CASH AND CASH EQUIVALENTS AND RESTRICTED CASH		
Cash and cash equivalents	71,084	$ 88,460
Restricted cash	110	110
Total cash, cash equivalents and restricted cash	$ 71,194	$ 88,570
NON-CASH INVESTING AND FINANCING ACTIVITIES		
Common stock issued upon cashless exercise of stock options	$ 273	$ —

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

ATOSSA THERAPEUTICS, INC.
NOTES TO CONSOLIDATED 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, 2024, the Company recorded a net loss of $25.5 million and used $21.0 million of cash in operating activities. As of December 31, 2024, the Company had $71.1 million in unrestricted cash and cash equivalents and working capital of $69.5 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 (the 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.

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, 2024 and 2023, 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 and a prime money market fund 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 invests its excess cash in a highly rated prime money market fund that management believes protects the Company from risk of default and impairment.

Clinical Trial and Preclinical Study Accruals

The Company makes estimates of its accrued expenses for clinical trial and preclinical study activities as of each balance sheet date in its financial statements based on the facts and circumstances known to the Company at that time. These accruals are based upon estimates of costs incurred and fees that may be associated with services provided by clinical trial investigational sites and Contract Research Organizations (CROs), and for other clinical trial-related activities. Payments under certain contracts with such parties depend on factors such as successful enrollment of patients, site initiation and progression through the various stages of the Company's clinical trials. In accruing for these services, the Company estimates the time period over which services will be performed and the level of effort to be expended in each period. If possible, the Company obtains information regarding unbilled services directly from these service providers. However, the Company may be required to estimate these services based on other information available to it. If the Company underestimates or overestimates the activities or fees associated with a study or service at a given point in time, adjustments to research and development expenses may be necessary in future periods. Historically, the Company's estimated accrued liabilities have approximated actual expense incurred. Subsequent changes in estimates may result in a material change in the Company's accruals.

Prepaid Materials

The Company capitalizes the purchase of certain raw materials, active pharmaceutical ingredients and related supplies for use in the manufacturing of drug products for use in its preclinical and clinical development programs, as it has determined that these materials have alternative future use. The Company can use these raw materials and related supplies in multiple clinical drug products, and therefore has future use independent of the development status of any particular drug program until it is utilized in the manufacturing process. The Company expenses the cost of materials when used. The Company periodically reviews 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.

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 had one investment in non-marketable equity securities. This investment did not have a readily determinable fair value, so the Company elected to measure the investment at cost less any impairment, adjusted to fair value if there were 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 performed an assessment to determine if it qualified for this measurement alternative.

At each reporting period, the Company made a qualitative assessment considering impairment indicators to evaluate whether the investment was impaired. If a qualitative assessment indicated the investment was impaired, the Company estimated the investment's fair value. If the fair value was less than the investment's carrying value, an impairment charge was 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 was established. Refer to Note 4 to these Consolidated Financial Statements.

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, and accounts payable approximate their fair values due to their short-term nature. Refer to Note 9 to these Consolidated Financial Statements.

Research and Development

Research and development (R&D) costs are expensed as incurred and consist of costs associated with research activities. 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.

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 Adopted Accounting Pronouncements

For the year ended December 31, 2024, the Company adopted 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 adoption of this guidance did not have a material financial impact on the Company's Consolidated Financial Statements, see Note 16 to these Consolidated Financial Statements.

Recently Issued Accounting Pronouncements

In November 2024, the Financial Accounting Standards Board (FASB) issued ASU No. 2024-03, *Disaggregation of Income Statement Expenses (Topic 220-40)*. This standard requires business entities to disclose in a tabular format, on an annual and interim basis, purchases of inventory, employee compensation, depreciation, intangible asset amortization and depletion for each income statement line item that contains those expenses. The guidance is effective for fiscal years beginning after December 15, 2025, and interim periods within fiscal years beginning after December 15, 2027. Entities may apply the guidance prospectively or retrospectively. The Company is currently assessing the potential impact of this ASU.

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

The Company held an investment in Dynamic Cell Therapies, Inc. (DCT), a U.S. private company that was 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 determined that DCT was a VIE however, the Company did not consolidate DCT because it did not have the power to direct economically significant activities. The Company had no obligation to provide any future funding to DCT and its maximum exposure to loss was its investment value, which was recorded in the Consolidated Balance Sheets as an Investment in equity securities.

The Company considered qualitative and quantitative impairment factors in determining if there were indicators of impairment of this investment as of September 30, 2024. Specifically, the Company considered concerns about the investee's ability to continue as a going concern due to negative cash flows from operations and its inability to raise additional funding during the three and nine months ended September 30, 2024. Based on these impairment indicators, the Company performed a quantitative fair value measurement as of September 30, 2024. 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 required the assumptions regarding the expected average volatility of comparable companies, the expected term of the Company's investment, and an estimation of an appropriate risk-free interest rate over the term of the Company's investment. The expected stock price volatility assumption was based upon the average historic volatility of comparable public clinical stage immunotherapy or CAR-T companies. The expected term of the Company's investment was 3.0 years and the risk-free interest rate used was based upon prevailing short term interest rates over the expected term of the investment. The dynamic options approach was weighted at a 5% outcome probability. An adjusted book value approach was also considered and weighted at a 95% probability due to DCT's limited cash on hand, status of current fundraising efforts and the subsequent decision by DCT to lay off all employees and wind down operations. Based on the valuation, the Company concluded that the investment was impaired, and accordingly, an impairment charge of $1.7 million was recorded in the Consolidated Statements of Operations for the year ended December 31, 2024.

On June 30, 2023, the Company considered adverse changes in the general market condition of the industry in which DCT operates and concerns about DCT's ability to continue as a going concern. Based on these impairment indicators, the Company performed a quantitative fair value measurement in the second quarter of 2023. 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 required assumptions regarding the expected average volatility of comparable companies, the expected term of the Company's investment, and an estimation of an appropriate risk-free interest rate over the term of the Company's investment. The expected stock price volatility assumption was based upon the average historic volatility of comparable public clinical stage immunotherapy or CAR-T companies. The expected term of the Company's investment as of June 30, 2023 was 3.5 years and the risk-free interest rate used was 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 then-current fundraising efforts and the estimated timing of a deemed liquidation event occurring as of June 30, 2023. The Company recorded an impairment charge of $3.0 million for the year ended December 31, 2023.

The following table summarizes the changes in the Company's fair value estimate of its Investment in equity securities (in thousands):

Balance as of January 1, 2023 of Investment in equity securities	$ 4,700
Impairment charge on Investment in equity securities	(2,990)
Balance as of December 31, 2023 Investment in equity securities	1,710
Impairment charge on Investment in equity securities	(1,710)
Balance as of December 31, 2024 Investment in equity securities	$ -

NOTE 5: PREPAID EXPENSES AND OTHER CURRENT ASSETS

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

	As of December 31, 2024	As of December 31, 2023
Prepaid pre-clinical and clinical trial deposits	$ 350	$ 805
Prepaid insurance	628	794
Prepaid professional services	68	501
Other	119	62
Total prepaid expenses and other current assets	$ 1,165	$ 2,162

NOTE 6: ACCRUED EXPENSES

Accrued expenses consisted of the following (in thousands):

	As of December 31, 2024	As of December 31, 2023
Accrued pre-clinical and clinical trial costs	$ 700	$ 608
Accrued professional services and other	219	365
Total accrued expenses	$ 919	$ 973

NOTE 7: PAYROLL LIABILITIES

Payroll liabilities consisted of the following (in thousands):

	As of December 31, 2024	As of December 31, 2023
Accrued bonuses	$ 1,305	$ 1,134
Accrued vacation	226	236
Accrued payroll and benefits	331	284
Total payroll liabilities	$ 1,862	$ 1,654

NOTE 8: RESEARCH AND DEVELOPMENT TAX REBATE LIABILITY

In 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. 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 not reasonably assured that the full tax position would be sustained under audit. Accordingly, as of December 31, 2024 and 2023, a liability of $1.5 million and $1.8 million, respectively, was included in Other current liabilities in the Consolidated Balance Sheets.

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, 2024	Estimated Fair Value	Level 1	Level 2	Level 3
Assets:				
Money market fund	$ 68,543	$ 68,543	$ —	$ —

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

NOTE 10: STOCKHOLDERS' EQUITY

Common Stock

On June 27, 2024, the Company's stockholders approved an amendment of the Company's Amended and Restated Certificate of Incorporation to increase the number of authorized shares of the Company's common stock, par value $0.18 per share, from 175,000,000 to 350,000,000. As of December 31, 2024, the Company was authorized to issue 350,000,000 shares of common stock, par value $0.18 per share.

Share Repurchases

On June 27, 2023, the Board of Directors (the Board) authorized a program to repurchase the Company's 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. No shares were repurchased during the year ended December 31, 2024 and the program expired on December 31, 2024.

Preferred Stock

The Company is authorized to issue a total of 10,000,000 shares of preferred stock, par value $0.001 per share. 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, 2024 and 2023.

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 the Company's common stock outstanding immediately after giving effect to its conversion.

During the years ended December 31, 2024 and 2023, 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 entitle 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, 2024, the following warrants to purchase shares of the Company's common stock were outstanding:

	Outstanding Warrants to Purchase Shares	Exercise Price Per Warrant	Expiration Date
December 2020 warrants	2,812,500	$ 1.00	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
	17,837,500		

Warrant Activity

During the year ended December 31, 2024, the Company received $3.7 million from the exercises of warrants resulting in the issuance of 3,672,500 shares of common stock. There were no warrant exercises during the year ended December 31, 2023.

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,	
	2024	2023
Options to purchase common stock	18,787,743	17,547,573
Series B convertible preferred stock	165,338	165,338
Warrants to purchase common stock	21,081,655	21,514,500
	40,034,736	39,227,411

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,	
	2024	2023
Expected federal income tax benefit at statutory rate	$ (5,356)	$ (6,320)
Disallowed R&D expenses	3	9
Non-taxable R&D rebate	—	(7)
Other permanent items	235	738
Return to provision	57	47
Stock-based compensation	246	682
Foreign rate differential	(76)	(453)
Other	21	(2)
Effect of change in valuation allowance	4,870	5,306
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,	
	2024	2023
Deferred tax assets		
Accrued bonus	$ 274	$ 238
Accrued vacation	47	50
Stock-based compensation	4,265	4,203
Capitalized R&D expenses	7,825	5,788
Rebate reserve	220	303
Intangible assets, net	181	248
Investment in equity securities	987	628
Net operating loss carryforwards	15,716	13,276
Other	48	6
Total gross deferred tax asset	29,563	24,740
Valuation allowance	(29,516)	(24,646)
Net deferred tax assets	47	94
Deferred tax liabilities		
Section 481(a) adjustment - bonus compensation	(47)	(94)
Net deferred tax assets	$ —	$ —

As of December 31, 2024 and 2023, 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, 2024 and 2023. The total valuation allowance increased by $4.9 million for the year ended December 31, 2024 as a result of an increase in net operating loss carryforwards.

The Company has incurred net operating losses since inception. At December 31, 2024, the Company had domestic federal net operating loss carryforwards of $118.4 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, 2024.

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, 2024, the gross net operating loss carryforward is limited to $72.5 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 2018 and beyond for the U.S. operations and 2020 and beyond for Australia operations.

The Company has no unrecognized tax positions as of December 31, 2024 or 2023 and does not believe there will be any material changes in its unrecognized tax positions over the next 12 months. The Company has not incurred any interest or penalties related to unrecognized tax positions for the years ended December 31, 2024 or 2023.

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 Patent Trial and Appeal Board (PTAB) of the U.S. Patent and Trademark Office, the (PGR Petition), seeking to invalidate all claims related to 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 matter is captioned *Intas Pharmaceuticals Ltd. v. Atossa Therapeutics, Inc.*, PGR 2023-00043.

On January 29, 2025, the PTAB issued a Final Written Decision (the PTAB Decision) finding all challenged claims under the Patent unpatentable. While the Company disagrees with the decision and believes there are appealable issues, the Company will not be pursuing an appeal from the PTAB decision, given the cost and time involved. As of December 31, 2024, there was no material impact to the consolidated financial statements related to this decision.

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 one 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, 2024, the Company's estimated non-cancellable commitment was $10.2 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. 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. On June 27, 2024, the stockholders of the Company approved an amendment and restatement of the 2020 Plan which increased the shares available for issuance by 12,000,000 shares, to a total of 30,000,000 shares available for grant. The 2020 Plan was also extended through June 27, 2034. As of December 31, 2024, 12,991,925 shares were available for future grants under the 2020 Plan.

The Company granted 4,701,334 and 6,828,600 options to purchase shares of common stock to employees and directors during the years ended December 31, 2024 and 2023, respectively. The weighted average grant date fair value of options granted during the years ended December 31, 2024 and 2023 was $0.88 and $0.69, respectively. There were 343,998 options exercised during the year ended December 31, 2024. No options were exercised during the year ended December 31, 2023.

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

	Year Ended December 31,	
	2024	2023
Risk-free interest rate	4.01% - 4.24%	3.27% - 4.48%
Expected term (in years)	5.31 - 6.11	5.31 - 6.16
Dividend yield	—	—
Expected volatility	97% - 120%	103% - 129%

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

	Year Ended December 31,	
	2024	2023
General and administrative	$ 1,647	$ 3,038
Research and development	645	1,583
Total stock-based compensation expense	$ 2,292	$ 4,621

The following table shows a summary of all stock option activity for the year ended December 31, 2024:

	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, 2024	17,506,345	$ 1.79		
Granted	4,701,334	1.11		
Forfeited	(1,167,504)	1.60		
Exercised	(343,998)	0.79		
Expired	(4,606)	258.08		
Outstanding as of December 31, 2024	20,691,571	$ 1.60	6.95	$ 657,814
Exercisable as of December 31, 2024	16,978,976	$ 1.71	6.42	$ 594,188
Vested and expected to vest	20,691,571	$ 1.60	6.95	$ 657,814

As of December 31, 2024, there were 3,712,595 unvested options outstanding, and the related unrecognized total compensation cost associated with these options was $3.0 million. This expense is expected to be recognized over a weighted-average period of 1.83 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, 2024 and 2023 were $0.3 million and $0.3 million, respectively.

NOTE 16: 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 (the CODM) in making decisions regarding resource allocation and in assessing performance. To date, the Company's CODM has made such decisions and assessed performance at the Company-level as a single segment using information at the consolidated financial statement level.

The CODM is Steven C. Quay, M.D., Ph D. Chairman, President and CEO. The CODM utilizes Net Loss from the Consolidated Statement of Operations for the measure of segment profit or loss.

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	Certificate of Amendment to Amended and Restated Certificate of Incorporation	Current Report on Form 8-K, as Exhibit 3.1	July 2, 2024
3.6	Amended and Restated Bylaws	Current Report on Form 8-K, as Exhibit 3.2	April 26, 2023
3.7	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
3.8	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
3.9	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
3.10	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	Current Report on Form 8-K, as Exhibit 4.1	January 8, 2021
4.3	Form of Warrant	Current Report on Form 8-K, as Exhibit 4.1	March 23, 2021

4.4	Form of Senior Indenture	Registration Statement on Form S-3, as Exhibit 4.1	September 2, 2020
4.5	Form of Senior Indenture	Registration Statement on Form S-3, as Exhibit 4.1	May 13, 2024
4.6	Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.	Filed herewith	
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#	Form of Indemnification Agreement	Annual Report on Form 10-K, as Exhibit 10.3	March 22, 2023
10.3#	2010 Stock Option and Incentive Plan, as Amended	Current Report on Form 8-K, as Exhibit 4.2	January 15, 2019
10.4#	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
10.5#	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
10.6#	Form of Restricted Stock Award Agreement	Amendment No. 3 Registration Statement on Form S-1, as Exhibit 10.13	June 11, 2012
10.7#	Form of 2019 Option Award Agreement	Current Report on Form 8-K, as Exhibit 4.1	January 15, 2019
10.8#	2020 Stock Incentive Plan, as Amended	Current Report on Form 8-K, as Exhibit 10.1	July 2, 2024
10.9#	Form of ISO Option Award Agreement	Quarterly Report on Form 10-Q, as Exhibit 4.1	May 13, 2020
10.10#	Form of Option Award Agreement	Current Report on Form 8-K, as Exhibit 4.1	April 13, 2020
10.11#	Employment Agreement with Heather Rees Dated July 1, 2024	Quarterly Report on Form 10-Q, As Exhibit 10.2	August 12, 2024
10.12	Open Market Sale Agreement SM, dated November 19, 2024, by and between Atossa Therapeutics, Inc. and Jefferies LLC	Current Report on Form 8-K, as Exhibit	November 19, 2024

		1.1	
19.1	Insider Trading Policy	Filed herewith	
21.1	List of Subsidiaries	Filed herewith	
23.1	Consent of Ernst & Young, LLP	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 of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act	Filed herewith	
32.1 (1)	Certification of Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act	Furnished herewith	
32.2 (1)	Certification of Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act	Furnished herewith	
97.1	Incentive Compensation Clawback Policy	Annual Report on Form 10-K as Exhibit 97.1	April 1, 2024
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.
(1) The certification that accompanies this Annual Report on Form 10-K is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Annual Report on Form 10-K, irrespective of any general incorporation language contained in such filing.

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 March 25, 2025.

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, 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)	March 25, 2025
/s/ Heather Rees **Heather Rees**	Chief Financial Officer (Principal Financial and Accounting Officer)	March 25, 2025
/s/ Richard I. Steinhart **Richard I. Steinhart**	Director	March 25, 2025
/s/ Shu-Chih Chen **Shu-Chih Chen, Ph.D.**	Director	March 25, 2025
/s/ Jonathan Finn **Jonathan Finn**	Director	March 25, 2025
/s/ Stephen J. Galli **Stephen J. Galli, M.D.**	Director	March 25, 2025
/s/ H. Lawrence Remmel **H. Lawrence Remmel**	Director	March 25, 2025
/s/ Tessa Cigler **Tessa Cigler, M.D., M.P.H.**	Director	March 25, 2025