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, 2025

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.)**

1448 NW Market Street, Suite 500
Seattle, WA 98107
(Address of principal executive offices, including zip code)

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

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

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

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒ Smaller reporting company ☒

Emerging growth company ☐

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

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

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

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

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

As of June 30, 2025, 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 $107,145,637. 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, 2026, was 8,611,361.

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the registrant's Definitive Proxy Statement for the registrant's 2026 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, 2025.

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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:

- our ability to shorten our clinical development timelines and reduce future clinical development costs through an accelerated path to filing a New Drug Application, which is dependent on the timing and outcomes of submissions to and other interactions with the U.S. Food and Drug Administration (FDA);
- 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 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);
- our ability to pursue a Duchenne muscular dystrophy (DMD) indication or other indications for our lead program, (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;
- our ability to continue as a going concern;
- 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 eligibility for the Rare Pediatric Disease Priority Review Voucher (PRV) program and the value of a future PRV;
- our ability to receive orphan-drug exclusivity for (Z)-endoxifen for DMD;
- our ability to maintain 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
- our ability to raise capital; and
- other risks and uncertainties, including those incorporated by reference in the section titled "Risk Factors."

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, 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 breast cancer and other breast conditions. Our lead drug candidate is oral (Z)-endoxifen, a selective estrogen receptor modulator (SERM)/ selective estrogen receptor degrader (SERM/D) currently in Phase 2 clinical development. The Company is evaluating potential indications for (Z)-endoxifen based on its pharmacologic profile, including its potential for both reducing the risk of and for the treatment of breast cancer, as well as in other therapeutic areas.

We have been granted U.S. and international patents covering our proprietary (Z)-endoxifen, and we have numerous applications pending in the U.S. and in other major countries. We expect to 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 with potential partners, and opportunistically add programs in areas of high unmet medical need through acquisition, minority investment, collaboration, or internal development.

(Z)-endoxifen is the most active metabolite of Tamoxifen and is substantially more potent as an estrogen receptor antagonist than Tamoxifen and other approved SERMs. Unlike Tamoxifen, which requires metabolic activation through CYP2D6 and other liver enzymes, (Z)-endoxifen does not require first-pass metabolism to achieve therapeutic concentrations. As a result, its activity is not dependent on patient-specific metabolic variability.

(Z)-endoxifen is a small-molecule oral agent designed to directly inhibit estrogen receptor signaling, induce estrogen receptor degradation, and promote apoptosis in estrogen receptor positive (ER+) breast cancer cells. Preclinical and clinical data suggest that (Z)-endoxifen may inhibit clinically relevant ESR1 mutations associated with resistance to aromatase inhibitors and may also inhibit protein kinase C beta one (PKCβ1), resulting in downregulation of the AKT signaling pathway. We are evaluating (Z)-endoxifen across multiple settings within the ER+/human epidermal growth factor receptor 2 negative (HER2-) breast cancer treatment continuum, including neoadjuvant, adjuvant and breast density reduction indications.

In an ongoing neoadjuvant clinical study, (Z)-endoxifen has demonstrated early signs of anti-tumor activity. Reported results include one complete response and multiple partial responses, as well as substantial reductions in Ki-67 proliferation across dose levels. Tumor shrinkage was observed by MRI imaging, which is atypical for endocrine therapies that are generally cytostatic.

We are also supporting multiple collaborative and investigator-sponsored clinical studies evaluating (Z)-endoxifen in additional breast cancer settings. These studies are not fully funded by us and are intended to further characterize clinical activity, optimize endocrine therapy strategies, and inform future regulatory pathways.

Based on its mechanism of action, we are exploring the potential application of (Z)-endoxifen beyond breast cancer, including gynecological cancers, endocrine resistance driven by ESR1 mutations, as well as applications in other rare disease indications, including Duchenne Muscular Dystrophy (DMD), women carriers of DMD, and McCune-Albright Syndrome (MAS) in girls. In preclinical models of DMD, (Z)-endoxifen demonstrated muscle-protective, anti-inflammatory, and anti-fibrotic effects. We believe similar efficacy could potentially apply to women carriers of DMD. For MAS, we believe (Z)-endoxifen could potentially be an effective hormone blocker, significantly reducing the effects of early onset puberty in young girls. We have developed a proprietary manufacturing process for (Z)-endoxifen, including defined processes for the active pharmaceutical ingredient and drug product. The drug product is available in multiple dosage strengths and is supported by qualified suppliers and manufacturing redundancies.

Summary of Leading Oncology Programs

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

Karisma-(Z)-endoxifen: We are developing our proprietary oral (Z)-endoxifen as a potential therapy to help reduce mammographic breast density (MBD). In December 2021, we initiated the Karisma-(Z)-endoxifen study, a Phase 2, randomized, double-blind, placebo-controlled, dose-response study evaluating the effect of low-dose (Z)-endoxifen on MBD in healthy premenopausal women with measurable MBD.

The study was conducted in Stockholm, Sweden and enrolled 240 participants who were randomized to receive daily oral dosing for six months of either placebo, 1 mg of (Z)-endoxifen, or 2 mg of (Z)-endoxifen. The primary endpoint was dose-response reduction in MBD. Secondary endpoints included safety and tolerability, and an exploratory endpoint assessed durability of MBD changes over 24 months. The study fully enrolled in November 2023 and concluded in June 2024 with database lock in September 2024. The follow up 24-month mammographic record review of participants is expected to conclude by the end of the first quarter in 2026. Durability data is expected to be received at the end of Q2.

The initial study data demonstrated that low-dose (Z)-endoxifen significantly reduced MBD compared to placebo. The 1 mg

dose showed a mean MBD reduction of 17.3% ($p<0.01$) and the 2 mg dose showed a mean reduction of 23.5% ($p<0.01$), compared to a 0.27% change in the placebo group. Mean plasma concentrations were 4.8 ng/mL and 9.7 ng/mL in the 1 mg and 2 mg dose groups, respectively, indicating that substantial MBD reductions were achieved at relatively low systemic exposure. (Z)-endoxifen was generally well tolerated. No meaningful differences in adverse events were observed between the 1 mg dose group and placebo. The 2 mg dose group experienced higher rates of certain adverse events, including hot flashes, night sweats, and vaginal discharge.

We expect to report top-line data from the Karisma-(Z)-endoxifen study in the first half of 2026. Further development will depend on regulatory guidance, study outcomes, and available resources.

I-SPY 2 Endocrine Optimization Pilot (I-SPY): (Z)-endoxifen is being evaluated as a neoadjuvant therapy in patients with ER+/HER2- early breast cancer as well as in combination with other partner drugs such as CDK4/6 inhibitors and ovarian function suppression medications.

Results from the daily 10 mg dose demonstrated excellent tolerability, with approximately 95% of patients completing at least 75% of planned therapy and showing predominantly low-grade adverse events. Biologic activity was observed across multiple measures, including reductions in the Ki-67 proliferation index, median MRI functional tumor volume reduction of approximately 72%, and the clearance of circulating tumor DNA (ctDNA) in a majority of patients who were ctDNA-positive at baseline.

(Z)-endoxifen was well tolerated in this study with the most common side effects being mild, including hot flashes, insomnia and fatigue. At baseline, the average Ki-67% was 16% with a minimum of 2% and a maximum of 60%. At week 3, this decreased to an average of 10% with a minimum of 0% and a maximum of 35%. Ki-67 decreased below 10% in a majority of participants, including some patients with Ki-67 levels below 3%. At the time of surgery, the average Ki-67% remained at 10% and the majority of patients maintained Ki-67 levels below 10%, including certain patients with Ki-67 levels that remained below 3%. Results were similar in the postmenopausal and premenopausal groups.

Based on these findings, the study is being expanded to a 40 mg daily dose of (Z)-endoxifen in premenopausal and postmenopausal patients, targeting enhanced ERα antagonism and PKCβ1 inhibition, with or without combination therapy. For the expanded arms of this study, (Z)-endoxifen is being used in combination with two FDA approved drugs: 1) abemaciclib (VERZENIO®), a cyclin-dependent kinase (CDK) 4/6 inhibitor marketed by Eli Lilly and Company, and 2) elagolix (ORILISSA®), a prescription medicine used to treat moderate to severe pain associated with endometriosis marketed by AbbVie, Inc. More specifically, (Z)-endoxifen is being used in combination with abemaciclib in postmenopausal patients and in combination with elagolix for certain premenopausal patients where ovarian function suppression (OFS) treatment is required. Enrollment for the two primary arms of this expanded study using (Z)-endoxifen as a combination therapy is nearly complete and we expect to begin receiving data early in the second half of 2026. For the ongoing arms of the study involving premenopausal women, (Z)-endoxifen is being used combination with elagolix or GnRH Agonist. Enrollment is nearly complete for these arms, and we expect to begin receiving data in the second half of 2026.

RECAST DCIS (RECAST). We are participating in RECAST, a multicenter platform study evaluating whether short-term endocrine therapy combined with MRI response assessment can identify patients with low-risk ductal carcinoma in situ (DCIS) who may safely avoid surgery and pursue long-term active surveillance.

(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. Early findings from RECAST suggest that this “window of opportunity” approach is feasible and well tolerated. 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, and a substantial proportion of patients have elected to continue active surveillance following initial treatment and imaging assessment. These early observations support the potential of the therapy and assessment to reduce the risk of overtreatment in selected DCIS patients while maintaining oncologic safety.

Future efforts within RECAST are expected to focus on integrating advanced imaging modalities with molecular and transcriptomic biomarkers to help better predict progression risk, refine patient selection, and evaluate long-term outcomes, including invasive recurrence rates, durability of active surveillance, patient experience, and quality of life.

EVANGELINE: EVANGELINE is a Phase 2 study evaluating (Z)-endoxifen plus OFS compared to exemestane plus OFS as a neoadjuvant therapy in premenopausal women with ER+/HER2- breast cancer.

We believe this study addresses a significant unmet need among premenopausal patients who experience poor tolerability with aromatase inhibitor-based regimens combined with OFS. Pharmacodynamic run-in data demonstrated strong early biologic activity, with approximately 86% of patients achieving a Ki-67 value of 10% or less at Week 4. These early data results supported the selection of 40 mg (Z)-endoxifen with OFS for the randomized Phase 2 portion of the study.

The EVANGELINE study utilizes a Simon two-stage design to assess whether the regimen meets or exceeds a predefined Ki-67 response threshold of 65%. Secondary endpoints include safety and tolerability, residual cancer burden (RCB), preoperative endocrine prognostic index (PEPI) score, and MRI-based tumor response.

(Z)-Endoxifen in rare diseases

In addition to the oncology related indications, we believe that (Z)-endoxifen has potentially broader utility as a therapeutic platform in serious and rare diseases, many of which have significant unmet medical need. The following underscore the growing scientific evidence supporting the potential role of estrogen signaling modulation in muscle preservation and inflammation and highlight the potential versatility of our proprietary molecule beyond oncology.

Duchenne muscular dystrophy: DMD is a serious, progressive neuromuscular disease that primarily affects boys, leading to loss of muscle function, loss of ambulation, and life-threatening heart and respiratory complications. We believe that (Z)-endoxifen's direct estrogen-receptor modulation, PKC inhibition, and effects on key signaling pathways could be relevant in addressing various pathologies associated with DMD, including inflammation, fibrosis, and cardiomyopathy. Through its potential ability to upregulate utrophin, (Z)-endoxifen may help stabilize muscle health, including muscle growth, repair, and fibrosis. FDA engagement commenced in Q4 2025.

In December 2025 and early in 2026, we received two FDA designations for (Z)-endoxifen for the treatment of DMD: 1) Rare Pediatric Disease Designation and 2) Orphan Drug Designation. We believe these designations provide us with several potential strategic benefits, including incentives, such as a potential Priority Review Voucher (PRV) for future FDA applications, other regulatory support, and potential market exclusivity for a period of time. PRVs, which were recently reauthorized by legislation, could create significant value to the Company and could represent meaningful, non-dilutive value opportunities, either through use in another program or monetization through sale to third parties.

Women carriers of DMD: (Z)-endoxifen has also shown potential relevance in symptomatic female Duchenne and Becker muscular dystrophy carriers, an under-recognized population in which a subset may experience skeletal-muscle symptoms or develop dilated cardiomyopathy in adult life. The work done in 2025, including our manuscript entitled, "(Z)-Endoxifen as a Modulator of Utrophin Pathways in Duchenne Muscular Dystrophy," will continue to inform our hypotheses and potential clinical trial protocols in 2026. Additionally, we believe this condition meets the requirements of and could qualify for Orphan Drug Designation, and we intend to pursue this designation in the first half of 2026.

McCune-Albright Syndrome: MAS is a rare, non-inherited genetic disorder caused by a postzygotic GNAS mutation, affecting bones, skin, and the endocrine system, with symptoms typically appearing in early childhood. In young girls (as early as 2 years old), early onset puberty can occur (Precocious Puberty) which can have a very significant effect on quality of life and limit growth. We believe that (Z)-endoxifen could prove to be an effective hormone blocker and potentially significantly reduce the effects of Precocious Puberty until young girls reach a more typical age for the onset of puberty and related developmental changes. Given the age of impacted girls and the relatively small size of this impacted population, we expect to seek both Rare Pediatric Disease and Orphan Drug designations for MAS in the first half of 2026.

Potential Market Opportunities

The American Cancer Society (ACS) estimates that in the U.S. in 2026 approximately 321,910 new cases of invasive breast cancer will be diagnosed in women, approximately 60,730 new cases of DCIS will be diagnosed, and approximately 42,140 women will die from breast cancer. According to the National Breast Cancer Foundation, Inc, 2,670 men will be diagnosed with invasive breast cancer and one in eight women will be diagnosed with breast cancer in their lifetime. Approximately 70% of diagnosed breast cancers are ER+. According to a 2025 report by Strategic Market Research, the global ER+ breast cancer treatment market is anticipated to reach approximately $30 billion by 2030 and is projected to grow at a compound annual growth rate (CAGR) of approximately 7% through 2030. 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.

Duchenne muscular dystrophy, DMD, is a rare, X-linked genetic neuromuscular disease characterized by progressive muscle degeneration and weakness, primarily affecting boys. Globally, it is estimated that more than 200,000 boys are affected by DMD with approximately 15,000 of those impacted located in the United States. The global therapeutics market for DMD treatment is estimated to be approximately $3 billion in 2025, and is projected to grow to potentially $10 billion by 2030.

Duchenne and Becker muscular dystrophies share genetic etiologies, and a proportion of female carriers may develop skeletal-muscle symptoms or dilated cardiomyopathy over their lifetimes. Carrier frequency estimates for dystrophin gene mutations in women are estimated to be approximately 1 in 1,000 women with up to 200,000 carriers in the United States. Carrier identification and reproductive risk assessment are typically conducted through expanded genetic carrier screening, which is part of a broader carrier screening market that was valued at more than $1 billion globally in 2025 and is projected to grow to multiple billions by the early 2030s.

McCune-Albright Syndrome (MAS) is a rare mosaic genetic disorder involving bone (fibrous dysplasia), café-au-lait skin pigmentation, and endocrine abnormalities, including precocious puberty, caused by somatic mutations in the GNAS gene. Prevalence estimates range from approximately 1 in 100,000 to 1 in 1,000,000 individuals, resulting in up to 80,000 patients worldwide and up to approximately 3,500 individuals in the United States annually. Treatment options for MAS are limited, with significant unmet medical need, and are estimated at as much as $1 billion annually within broader rare bone and endocrinology therapeutic markets.

Nasdaq Notice

On February 21, 2025, we received a letter from Nasdaq informing us that were 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. To regain compliance, we were required to maintain a minimum closing bid price of our common stock of $1.00 per share for a minimum of 10 consecutive business days.

In order to regain compliance with Nasdaq Listing Rule 5550(a)(2), on February 2, 2026, we effected a 1-for-15 reverse stock split of our common stock. Our common stock began trading on a split-adjusted basis (above $1 per share) at the opening of the market on Monday, February 2, 2026. Subsequently, we were able to maintain a minimum closing bid price of $1.00 per share for the required 10 consecutive trading days, and we were notified by Nasdaq that we regained compliance with Nasdaq Listing Rule 5550(a)(2) on February 17, 2026.

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 as well as short-term borrowing from banks, stockholders or other related parties, if 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 cease operations or substantially curtail our activities. 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. These conditions raise substantial doubt as to our ability to continue as a going concern. As of the date of filing this Annual Report, we expect our existing resources will be sufficient to fund our planned operations for the next 12 months; additional capital resources will be needed to fund operations longer-term.

As of December 31, 2025, we had cash and cash equivalents of approximately $41.3 million.

On November 19, 2024, we entered into an Open Market Sale Agreement℠ (the Prior Agreement), with Jefferies LLC (Jefferies) to sell shares of our common stock. We did not sell any shares of our common stock under the Prior Agreement during 2024 or 2025.

On February 19, 2026, we delivered written notice to Jefferies terminating the Prior Agreement effective as of February 19, 2026. We were not subject to any termination penalties related to the termination of the Prior Agreement. On February 20, 2026, we entered into an At the Market Offering Agreement, dated February 20, 2026 (the Sales Agreement), with Rodman & Renshaw LLC (the "Sales Agent"), pursuant to which the we may offer and sell from time to time up to $50,000,000 of shares of our common stock through the Sales Agent as agent or principal.

Warrant Activity

During the year ended December 31, 2025, warrants granted in prior years expired as follows: 187,500 warrants granted in December 2020 expired on June 21, 2025; 300,000 warrants granted in January 2021 expired on July 8, 2025; and 701,667 warrants granted in March 2021 expired on September 22, 2025. No warrants were outstanding at December 31, 2025 and no warrants were exercised during 2025. During the year ended December 31, 2024, we received $3.7 million from the exercise of warrants, resulting in the issuance of 244,833 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, 2025 and 2024 were approximately $21.2 million and $14.1 million, respectively.

Intellectual Property

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

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

We own patents directed to (Z)-endoxifen and other therapies as well as patent applications directed to (Z)-endoxifen, immunotherapies 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, 2026, based on a review of our patent portfolio, we own and maintain 24 issued patents (8 U.S. patents and 16 international patents) and are pursuing 141 pending patent applications (30 U.S. patent applications and 111 international patent applications, including one allowed U.S. application and two 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 2, 2026, 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	7	16	18	83	2038 - 2047
Immunotherapy/CAR-T program	—	—	—	3	2037 - 2038
Other therapy programs	1	—	12	25	2030 - 2047

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. In April 2025, the FDA published a roadmap to reduce animal testing in preclinical safety studies, including those required in INDs, with scientifically validated new approach methodologies (NAMs).

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 $4.682 million for fiscal year 2026. 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.

Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted, except that the PREA will apply to an original NDA for a new active ingredient that is orphan-designated if the drug is a molecularly targeted cancer product intended for the treatment of an adult cancer and is directed at a molecular target that the FDA determines to be substantially relevant to the growth or progression of a pediatric cancer. A drug can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

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.

Orphan Drug Designation and Exclusivity

On January 16, 2026, we announced that FDA had granted orphan drug designation to Z-endoxifen for the treatment of Duchenne muscular dystrophy. Under the Orphan Drug Act of 1983, the FDA may grant orphan drug designation to a product candidate intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or 200,000 or more individuals in the United States for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that product candidate. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusive approval (or exclusivity), which means that the FDA may not approve any other applications, including a full NDA, to market the same product for the same approved use or indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity by means of greater effectiveness, greater safety or providing a major contribution to patient care or if the holder of the orphan drug exclusivity cannot assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the same use or indication for which the already-approved or licensed product was approved or licensed. Orphan drug exclusivity does not prevent the FDA from

approving a different drug for the same disease or condition, or the same drug for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA application fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan drug designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Rare Pediatric Disease Designation and Priority Review Vouchers

Under the FDCA, as amended, the FDA incentivizes the development of drugs and biologics intended to treat conditions that meet the definition of a "rare pediatric disease," defined to mean a serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years and the disease affects fewer than 200,000 individuals in the U.S. or affects more than 200,000 in the U.S. and for which there is no reasonable expectation that the cost of developing and making in the U.S. a drug for such disease or condition will be received from sales in the U.S. of such drug. On December 11, 2025, we announced that the FDA had granted rare pediatric disease designation to (Z)-endoxifen for DMD. The sponsor of a product candidate for a rare pediatric disease may be eligible for a voucher that can be used to obtain a priority review for a subsequent human drug or biologic application after the date of approval of the rare pediatric disease drug product, referred to as a PRV. A sponsor may request rare pediatric disease designation from the FDA prior to the submission of its biologics license application (BLA). A rare pediatric disease designation does not guarantee that a sponsor will receive a PRV upon approval of its BLA. Moreover, a sponsor who chooses not to submit a rare pediatric disease designation request may nonetheless receive a PRV upon approval of their marketing application if they request such a voucher in their original marketing application and meet all of the eligibility criteria. If a PRV is received, it may be sold or transferred an unlimited number of times. A rare pediatric disease PRV may only be granted if a designated drug is approved or licensed by September 30, 2029, unless Congress further extends the program.

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.

Clinical Trials. The conduct of clinical trials for medicinal products in the E.U. is governed by Regulation (EU) No. 536/2014 (the Clinical Trials Regulation, or CTR), which became fully applicable on January 31, 2025 following the end of the transition period from the prior Clinical Trials Directive. Under the CTR, clinical trial applications and related information and data are submitted through the Clinical Trials Information System (CTIS), which now supports submission, assessment and oversight of all clinical trials in the E.U.

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 December 15, 2021, the European Parliament and the Council 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, requiring, among other things, joint clinical assessments of certain new medicines for the treatment of cancer and advanced therapy medicinal products. This is followed by a further three-year transitional period during which EU member states must fully adapt to the new system, until eventually all medicinal products fall within the scope of HTAR as of 2030. 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. 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 EC opened the first request submission period for joint scientific consultations under HTAR.

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 it 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. In April 2023, the EC published proposals to revise the E.U.'s general pharmaceutical legislation (including Directive 2001/83/EC and Regulation (EC) No 726/2004), and, on December 11, 2025, the Council of the European Union and the European Parliament reached a provisional agreement on the so-called "pharma package"; the final content and timing of any changes, and their impact on the regulatory framework applicable to medicinal products, remain uncertain. 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 (as applicable in the E.U., and in Iceland, Norway and Liechtenstein (together, the European Economic Area or EEA)), with related implementing laws in individual E.U. Member States which impose significant compliance obligations. The processing of personal data is mainly governed by the General Data Protection Regulation 2016/679/E.U. (GDPR), which came into effect on May 25, 2018. The GDPR applies to the processing of personal data

carried out by companies not established in the EEA, where such processing relates to (a) the offering of goods or services to data subjects who are in the EEA, or (b) the monitoring of the behavior of data subjects who are in the EEA. It imposes a strict data protection compliance regime with severe monetary fines for noncompliance of up to the greater of 4% of total worldwide annual turnover of the preceding financial year or €20 million, and it provides data subjects with specific rights (such as the "right to be forgotten" and "portability" of personal data), obligations related to the legal basis of the processing, information provided to data subjects, implementation of appropriate security measures, personal data breach notification requirements, as well as restrictions on the processing of health data. E.U. Member States and EEA countries 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 EEA which also adds to the complexity of processing health data from clinical trials. Such public disclosure obligations are provided in the 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 and EEA countries may interpret the GDPR differently, which adds to the complexity of processing personal data in the EEA, 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 the appropriate safeguards (including the SCCs), the data exporters with the assistance of the data importers, 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 safeguards 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.

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 and other personal information we process. 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. In January 2025, HHS proposed updates to the HIPAA Security Rule intended to enhance and clarify cybersecurity and safeguard requirements for electronic health information, which, if finalized, could increase compliance obligations.

A growing number of 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, the CCPA), applies to personal information 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 to honor certain rights afforded to California residents in relation to their personal information. Among various other information, personal health information falls under the CCPA's definition of personal information unless it is subject to HIPAA and in certain cases is also considered "sensitive personal information," a category of personal information that is subject to additional protections. Numerous other similar privacy laws have passed or are being considered in other states, as well as at the federal and local levels, some of which provide exemptions for health information that is subject to HIPAA, while others provide exemptions in certain circumstances to covered entities and business associates subject to HIPAA, further complicating compliance efforts and increasing legal risk and compliance costs for us and the third parties upon whom we rely.

Additionally, the use of artificial intelligence and machine learning tools by us and the third parties upon which we rely may be subject to rapidly evolving and sometimes conflicting global artificial intelligence, privacy, and consumer protection laws, regulations and guidance, including related to transparency, governance, bias, and discrimination.

International regulations, such as the GDPR and UK GDPR, also provide privacy protection to clinical trial participants of their personal health care information, as described herein. 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 accurate; 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, ordering, or recommendation 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 federally reimbursable health services 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 government health care programs 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 and which imposes treble damages and per-violation penalties and empowers private whistleblowers to sue in the name of the government and share in any recoveries. 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 14 full-time employees. We may hire additional 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, our ability to continue as a going concern 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, 2025, 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 expect to continue to incur losses in the future.
- We have not established sources of ongoing revenue to cover operating costs and allow us to continue as a going concern.
- We will need to raise substantial additional capital in the future to fund our operations and we may be unable to raise such funds when needed and on acceptable terms.
- We may expend our capital resources in ways that you do not agree or that do not produce stockholder value.
- 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.
- Rare pediatric disease designation for any of our product candidates does not guarantee that the NDA for the product will qualify for a priority review voucher upon approval, and it does not lead to a faster development or regulatory review process, or increase the likelihood that our product candidates will receive marketing approval.
- We may not enjoy the market exclusivity benefits of our orphan drug designations.
- 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.
- Our products and services may expose us to possible litigation and product liability claims.
- The deployment of artificial intelligence (AI) in our or our collaborators' product candidates could adversely affect our business, reputation or 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.
- 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.
- Disruptions at the FDA and other government agencies could negatively affect the review of our regulatory submissions, which could negatively impact 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.
- 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 maintain 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. References to past events are provided by way of example only and are not intended to be a complete listing or a representation as to whether or not such factors have occurred in the past. 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 expect to continue to incur losses in the future, 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. We have a limited operating history and have incurred net losses each year. Our net losses for the years ended December 31, 2025 and 2024 were $34.8 million and $25.5 million, respectively. We will continue to incur further losses in connection with costs for development of our programs, including ongoing and additional clinical studies.

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:

- continue as a going concern;
- 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.

If we do not raise additional capital, we anticipate liquidity issues after the next twelve months and we may not continue as a going concern.

For the year ended December 31, 2025, we incurred a net loss of $34.8 million, and we had an accumulated deficit of $246.6 million. As of the date of filing this Annual Report, we expect that our existing resources should be sufficient to fund our planned operations for at least the next 12 months, however, additional capital resources will be needed to fund operations longer-term. 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 as well as short-term borrowing from banks, stockholders or other related parties, if 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 on reasonable terms, if at all, we may be unable to develop and commercialize our product offerings or increase our geographic reach, and we could be forced to cease operations or substantially curtail our activities. 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. These conditions raise substantial doubt as to our ability to continue as a going concern.

Macroeconomic factors could adversely impact our business and our ability to raise additional capital.

Our business and our ability to obtain adequate capital on reasonable terms, if at all, can be impacted by macroeconomic factors, such as high interest rates, the inflationary environment, recessionary fears, foreign exchange rate volatility, instability in financial institutions, government shutdowns, changes in monetary policy, changes in trade policies, including tariffs and other trade restrictions or the threat of such actions, and rising geopolitical instability. The United States has announced tariffs on imports from most countries, including significant tariffs on imports from Canada, Mexico and China, leading to increasing trade and political tensions. In response to tariffs, other countries have implemented retaliatory tariffs on U.S. goods. In addition, in September 2025, the United States announced plans to impose up to 100% tariffs on imported branded or patented pharmaceuticals, subject to certain exceptions (the Pharmaceutical Tariffs). There remains substantial uncertainty as to when such tariffs may go into effect, the level of such tariffs and whether such tariffs would apply to the importation of active pharmaceutical ingredients or bulk drug products that are intended for use in clinical trials and, more generally, about the duration of existing tariffs, tariff levels, implementation of announced tariffs, litigation challenging tariffs and whether additional tariffs or other retaliatory actions may be imposed, modified or suspended. For example, the U.S. Supreme Court ruled in February 2026 that certain tariffs imposed by the U.S. federal government under the

International Emergency Economic Powers Act exceeded presidential authority and therefore are invalid. However, tariffs imposed under different statutes (including the Pharmaceutical Tariffs, if implemented) were not directly impacted by the decision and therefore remain in place. These actions and the related rising political tensions could negatively impact global macroeconomic conditions and the stability of global financial markets, which could have a material adverse effect on our business, financial condition and results of operations, including through increased supply chain costs.

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, 2025 and 2024, we incurred a net loss of $34.8 million and $25.5 million, respectively, and we had an accumulated deficit of $246.6 million since inception. As of December 31, 2025 and 2024, we had cash and cash equivalents of approximately $41.3 million and $71.1 million, respectively. Because we have no current sources of revenue, substantial doubt exists about our ability to continue as a going concern, and 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 Sales Agreement with the Sales Agent, 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 Sales 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, for the year ended December 31, 2024, we wrote down our Investment in equity securities by $1.7 million due to the impairment of our investment in Dynamic Cell Therapies, Inc. (DCT), a U.S. private company previously focused on Chimeric Antigen Receptor (CAR) T-cell therapies, which laid off all employees and ceased operations.

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.

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 impairment charge for the year ended December 31, 2024 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 premenopausal women with estrogen receptor positive (ER+) / human epidermal growth factor receptor 2 negative (HER2-) breast cancer, and in 2025, for our Phase 2 Endocrine Optimization Pilot sub‑study within the I‑SPY 2 TRIAL evaluating low‑dose oral (Z)‑endoxifen as a neoadjuvant treatment in women with stage II/III ER+/HER2‑negative breast cancer. Such data are based on a preliminary analysis of then-available efficacy and safety data, and such findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. Interim, top-line or preliminary data are based on important assumptions, estimations, calculations and information then available to us to the extent we have had, at the time of such reporting, an opportunity to fully and carefully evaluate such information in light of all surrounding facts, circumstances, recommendations and analyses. As a result, interim, top-line or "preliminary" results may differ from future/final results, or different conclusions or considerations may qualify such results once existing data have been more fully evaluated. In addition, third parties, including regulatory agencies, may not accept or agree with our assumptions, estimations, calculations or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the ability to obtain approvals, 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 have received Rare Pediatric Disease designation by the FDA for (Z)-Endoxifen for Duchenne Muscular Dystrophy. However, Rare Pediatric Disease designation for any of our product candidates does not guarantee that the NDA for the product will qualify for a priority review voucher upon approval, and it does not lead to a faster development or regulatory review process, or increase the likelihood that our product candidates will receive marketing approval.

Under the Rare Pediatric Disease Priority Review Voucher program, upon the approval of a qualifying NDA for the treatment of a rare pediatric disease, the sponsor of such an application would be eligible for a rare pediatric disease PRV that can be used to obtain priority review for a subsequent BLA or NDA. Currently, a rare pediatric disease PRV may be issued only if the FDA approves the BLA or NDA on or before September 30, 2029. Designation of a drug for a rare pediatric disease does not guarantee that an NDA will meet the eligibility criteria for a rare pediatric disease PRV at the time the application is approved. A rare pediatric disease PRV may only be granted if a designated drug is approved or licensed by September 30, 2029, unless Congress further extends the program. If Congress does not extend this program, we may not meet the deadline for PRVs to be granted for our current programs given the expected timeline of development. Additionally, a rare pediatric disease designation does not lead to faster development or regulatory review of the product or increase the likelihood that it will receive marketing approval.

We may not enjoy the market exclusivity benefits of our orphan drug designations.

Although we may obtain orphan designations in the treatment of certain diseases our products are intended to treat, the designation may not be applicable to any particular product we might get approved and that product may not be the first product to receive approval for that indication. Under the Orphan Drug Act, the first approved product with an orphan designation receives market exclusivity, which prohibits the FDA from approving the "same" drug for the same indication. The FDA has stated that drugs can be the "same" even when they are not identical. It is possible that another drug that the FDA considers to be the "same" as (Z)-endoxifen could be approved for the treatment of a disease that one of our orphan products is intended to treat before our product is approved, which means that we may not obtain orphan drug exclusivity and could also potentially be blocked from approval until the first product's orphan drug exclusivity period expires or we demonstrate, if we can, that our product is superior. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved and granted orphan drug exclusivity, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is safer, more effective or makes a major contribution to patient care. Further, orphan drug exclusivity can be lost if the FDA later determines that the request for designation was materially defective or if the applicant is unable to assure the availability of sufficient quantities of the

drug to meet the needs of patients with the same approved indication or use for which the drug was approved. Orphan Drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

We do not know if, when, or how the FDA, Congress, or future judicial challenges may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted. In view of the overturn of the *Chevron* doctrine in *Loper Bright Enterprises v. Raimondo*, this landmark Supreme Court decision may invite various stakeholders to bring lawsuits against the FDA to challenge longstanding decisions and policies, including regulatory exclusivities, which could lead to uncertainties in the industry. Further, changes in the leadership of the FDA and other federal agencies under the Trump administration may lead to new policies and changes in the regulations and operations of the FDA, which may impact our clinical development plans.

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, Good Clinical Practices (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 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 anti-discrimination. 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, including as a result of changes in trade policies, including tariffs or other trade restrictions or the threat of such actions;
- 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 Regulatory Agencies, 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 tools in connection with drug discovery efforts and the development of our product candidates. As a 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 seeking to validate an AI-driven breast cancer risk assessment model, may require significant investment and increase our costs, and there is no guarantee that any such investment will lead to the discovery of new product candidates, eventual regulatory approval or commercialization of any product candidates, or acceleration of, or reduction in, costs associated with the drug discovery, development or approval timeline. Our inability, or our collaborators' inability, to successfully use AI-enabled tools in the discovery or development of product candidates, or lack of public 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 $1.1 million and $1.5 million in our Consolidated Balance Sheets as of December 31, 2025 and December 31, 2024, 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.

Risks Related to our Intellectual Property

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

Our commercial success will depend, in part, on our ability to obtain additional patents and licenses and to protect our existing patent position, both in the U.S. and in other countries, for therapeutics and related technologies, processes, methods, compositions, and other inventions that we believe are patentable, all of which provide limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. As of February 2, 2026, we owned and were pursuing 141 pending provisional and non-provisional patent applications (30 U.S. patent applications and 111 international patent applications, including one allowed U.S. application and two allowed international applications) and 24 issued patents (8 U.S. patents and 16 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.

If third parties successfully challenge the validity of one or more of our patent applications, we may lose certain patent rights, even if previously granted by a patent office. For example, on August 18, 2023, Intas Pharmaceuticals Ltd. (Intas) filed a Petition for Post Grant Review with the Patent Trial and Appeal Board (PTAB) of the U.S. Patent and Trademark Office (USPTO), 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", and on January 29, 2025, the PTAB issued a final written decision finding all claims of U.S. Patent No. 11,572,334 were unpatentable. In addition, on April 3, 2025, Intas filed two separate petitions with the PTAB seeking to invalidate two additional patents. For more information regarding our legal proceedings, including these additional petitions, refer to Note 13 "Commitments and Contingencies" to the Consolidated Financial Statements.

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.

The 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 (PGR) 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, we are currently contesting the 391 PGR Petition and the 151 IPR Petition. Refer to Note 13 “Commitments and Contingencies” 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. 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 IPR, PGR, derivation, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in various foreign jurisdictions. For example, we are currently contesting the 391 PGR Petition and the 151 IPR Petition. 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 use PTAB proceedings to challenge the validity of third-party intellectual property.

We actively manage risks and opportunities associated with third-party intellectual property rights. From time to time, we may identify patents or other IP held by third parties that we believe could impact our business operations, competitive position, or future commercial opportunities. In response, we may elect to challenge the validity of such third-party intellectual property by initiating proceedings before the United States Patent and Trademark Office's Patent Trial and Appeal Board (PTAB), such as IPR or PGR.

We may pursue these PTAB challenges for strategic business reasons, including but not limited to: (i) reducing the risk of future litigation involving third-party intellectual property; (ii) improving our negotiating position in connection with licenses, partnerships, or acquisitions; (iii) removing perceived barriers to the development, commercialization, or sale of our products or services; and (iv) promoting freedom to operate in key technology areas.

Importantly, we may initiate PTAB proceedings regardless of whether the Company has been accused of infringement or whether we believe it currently infringes any such third-party intellectual property. The decision to challenge third-party intellectual property may be based on a variety of strategic considerations, including the potential impact of the intellectual property on our business, legal developments in relevant technology fields, or competitive dynamics within the industry.

There can be no assurance as to the outcome of any such PTAB proceedings. Adverse decisions in these or other proceedings could result in us having to seek licenses, modify our products or services, or cease certain activities, which could have a material adverse effect on our business, financial condition, or results of operations.

For more information regarding our legal proceedings, including these additional petitions, refer to Note 13 "Commitments and Contingencies" to the Consolidated Financial Statements.

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.

In January 2025, an executive order entitled “Unleashing Prosperity Through Deregulation”, was issued which calls for at least 10 existing regulations to be repealed whenever an executive department or agency publicly proposes for notice and comment or otherwise promulgates a new regulation. Recent developments at the FDA include announcement of a plan to phase out animal testing for monoclonal antibodies and certain other drugs, the proposed rare disease evidence principles (RDEP) program to facilitate approval of drugs to treat rare diseases with very small patient populations with significant unmet medical need and with a known genetic defect that is the major driver of the pathophysiology, and the announcement of a new Commissioner’s National Priority Voucher program for companies supporting certain U.S. national health priorities and interests. To the extent our competitors are selected for this new voucher pilot program, or are otherwise able to participate in any of these initiatives intended to accelerate drug development and application review, and obtain approval faster, our competitive position may be harmed, which could have a material adverse effect on our business. FDA has also increased its scrutiny of foreign drug manufacturing facilities and other contractors based in China, especially with respect to the transfer of biological materials, genetic data, and other sensitive data of American patients to parties located in China. It is unclear how the industry and our clinical programs will be impacted by policies and regulations implemented under the current administration and FDA leadership, or other executive orders.

As we work to align with the FDA on development paths for combination therapies using (Z)-endoxifen in high-risk breast cancer and in other rare disease indications with significant unmet need, the scope, size, endpoints, or sequencing of required studies may change. Such changes could increase costs, extend timelines, or require modifications to our regulatory strategy. There can be no assurance that the FDA will agree with any of our proposed paths that any expedited program will be available or granted or that we will be able to successfully complete the required studies on a timely basis or at all, which could have a material adverse effect on our business.

Disruptions at the FDA and other government agencies could negatively affect the review of our regulatory submissions, which could negatively impact our business.

The ability of the FDA to review and approve regulatory submissions can be affected by a variety of factors, including statutory, regulatory and policy changes, inadequate government budget funding levels or a reduction in the FDA’s workforce and its ability to hire and retain key personnel, disruptions caused by government shutdowns, public health crises, the FDA’s ability to accept the payment of user fees, and other events that may otherwise affect the FDA’s ability to perform routine functions. There have been mass layoffs of federal employees and reorganizations since the start of the current presidential administration in January 2025, the full impact of which is unclear at this time. Such disruptions could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. In addition, the presidential administration has made and is expected to continue to make changes in the leadership of various U.S. federal regulatory agencies and changes to U.S. federal government policy that have led to, in some cases, legal challenges and uncertainty around the funding, functioning and policy priorities of the U.S. federal regulatory agencies, including the FDA.

We are unable to predict the extent to which the presidential administration may impose or seek to impose leadership or policy changes at the FDA or changes to rules and policies impacting our business and operations. It is unclear how these executive actions or other potential actions by the federal government will impact the FDA or other regulatory authorities that oversee our business. Government proposals to reduce or eliminate budgetary deficits may include reduced allocations to the FDA and other related government agencies. These budgetary pressures may reduce the FDA’s ability to perform its responsibilities, which could result in delays in our clinical trial timelines. If a significant reduction in the FDA’s workforce occurs, the FDA’s budget is significantly reduced or the current government shutdown is prolonged, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions or take other actions critical to the development or approval of our product candidates, which could have a material adverse effect on our business.

Our inadvertent or unintentional failure to comply with the complex government regulations concerning patients' privacy, other 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, including patient-identifiable laboratory data, without written patient authorization, for purposes other than payment, treatment, or healthcare operations as defined under HIPAA, except as otherwise permitted for various public policy purposes and other authorized uses under privacy regulations. Applicable privacy regulations provide for significant fines and other penalties for the wrongful use or disclosure of protected health information, including potential civil and criminal fines and penalties.

We seek to implement policies and practices designed to support compliance with applicable privacy regulations. However, the documentation and process requirements of applicable privacy regulations are complex, evolving, and subject to interpretation. Failure to comply with applicable privacy regulations could subject us to sanctions or penalties, loss of business, and negative publicity. State privacy laws may also restrict our ability to use or process personal information (including information not covered by HIPAA), and require us to adhere to additional obligations and honor additional data rights.

The HIPAA Privacy Rule establishes a “floor” of minimum protection for patients' medical information and does not supersede state privacy 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 or different requirements. Therefore, we may be required to comply with both HIPAA and state privacy laws, which vary from state to state, impose a range of obligations, and in some cases are more restrictive than HIPAA. The failure to comply with applicable privacy laws could subject us to regulatory actions, including significant fines or penalties, private actions by patients, adverse publicity and 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 protect consumers’ personal information 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 (FTC Act). The FTC expects companies to have reasonable and appropriate data security measures based on factors such as data sensitivity and volume, the 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 FTC Act, that can also provide state-law causes of action for allegedly unfair or deceptive acts or practices, among other things.

While we may not currently be subject to any comprehensive state privacy laws (e.g., the CCPA) due to applicability or 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, partners or collaborators 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 EEA regardless of citizenship or residence, is governed by the provisions of the General Data Protection Regulation 2016/679 (GDPR) which provides for significant monetary fines for noncompliance. The GDPR regulates (i) the processing of personal data carried out in the context of the activities of a company established in the EEA; and (ii) the processing of personal data carried out by a company not established in the EEA where such processing relates to (a) the offering of goods or services to data subjects who are in the EEA 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 and EEA countries 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. Furthermore, the passage of the Data (Use and Access) Act 2025 (DUAA), which received Royal Assent in June 2025, introduced new obligations. These include mandatory internal complaint mechanisms, and aligning the maximum fines of the Privacy and Electronic Communications Regulations (PECR) with UK GDPR levels. Notably for our operations, the DUAA provides a more expansive statutory definition of scientific research that explicitly includes commercial and privately funded activities, and it permits the use of "broad consent" for future research purposes where specific goals cannot be fully identified at the outset.These changes may lead to additional costs and increase our overall risk exposure. 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. The European Commission renewed the UK adequacy decision on December 19, 2025 for a period of six years until December 27, 2031, with the possibility to be renewed after 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.

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, replaced or upgraded. If we were to experience a prolonged disruption in our information technology systems or those of our vendors or other third parties upon whom we rely, it could negatively impact our ability to operate our business and serve our customers, which could adversely impact our business. Although we maintain offsite back-ups of our data, if our operations were disrupted, it may cause a material disruption to our business if we are unable to restore systems, data and functions in 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 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 compromised, disclosed, or revealed in connection with the use or misuse of AI or other automated tools by our employees, personnel, vendors or partners. In addition, because we collect, store and transmit confidential information in digital form, we, and third parties with whom we work, 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 these requirements is evolving, subject to differing applications and interpretations, and may be inconsistent among jurisdictions or conflict with one another. Any data breaches, security incidents or other loss of information could result in legal claims or proceedings, regulatory investigations, liability under laws that protect personal information, including state data privacy and breach notification laws, the E.U. GDPR and the UK GDPR, which could result in significant penalties. In addition, these breaches and other unauthorized access can be difficult to detect, and as threat actors increasingly leverage AI and other advanced technologies, cyber attacks and security incidents may become more frequent, sophisticated and harder to identify, and it may take considerable time for us to investigate and evaluate the full impact of cyber attacks, particularly for sophisticated attacks, which may inhibit our ability to provide prompt, full, and reliable information about cybersecurity incidents to our customers, regulators, and the public. Any delay in identifying or responding to cyberattacks and security incidents may lead to increased harm of the type described above.

Additionally, we are or may become subject to contractual obligations related to data privacy, protection and security, and such obligations may change or expand as our business grows. The actual or perceived failure by us, or by 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 business, 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 designed to help mitigate these risks, cyber attacks and other cyber events are evolving, unpredictable and increasing in sophistication, including through the use of advanced and evolving technologies, such as AI. 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. While we maintain cybersecurity insurance coverage for certain security incidents, we cannot ensure that it will be sufficient in type or amount to cover any particular losses we may experience. Any significant security 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, damages and exclusion from participation in Medicare and Medicaid. Government authorities and private whistleblowers 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 maintain 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 maintain 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.

For example, on February 21, 2025, we were notified by Nasdaq that we were not in compliance with Nasdaq Listing Rule 5550(a)(2), because our common stock failed to maintain a minimum closing bid price of $1.00 per share for 30 consecutive business days. On February 2, 2026, we effected a 1-for-15 reverse stock split, and our common stock began trading on a split-adjusted basis (above $1 per share) at the opening of the market on February 2, 2026. To regain compliance, we were required to maintain a minimum closing bid price of $1.00 per share for at least 10 consecutive trading days. This requirement was met as of the close of trading on February 13, 2026.

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

- stock price volatility;
- limited availability of market quotations for our common stock;
- reduced 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
- decreased 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 Sales Agreement with the Sales Agent, sales by holders of our warrants to purchase our 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, 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, government shutdowns, 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 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 our Chief Executive Officer and has over nine 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 "Significant disruptions in our information technology systems or breaches of data security could adversely affect our business".

The Board of Directors (the Board), 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 1448 NW Market Street Tenant LLC for office space in Seattle, Washington. The lease commencement date was November 1, 2025 and we agreed to pay $3 thousand per month for 13 months.

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, 2026, there were approximately 33 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 and depends on a number of factors, including future earnings, capital requirements, financial conditions, future prospects, contractual restrictions and other factors that our Board may deem relevant.

Issuer Purchases of Securities

We did not repurchase any of our equity securities during the fourth quarter of fiscal 2025.

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

*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 breast cancer and other breast conditions, as well as certain rare diseases. Our lead drug candidate is oral (Z)-endoxifen, a selective estrogen receptor modulator (SERM)/ selective estrogen receptor degrader (SERM/D) currently in Phase 2 clinical development. The Company is evaluating potential indications for (Z)-endoxifen based on its pharmacologic profile, including its potential for both reducing the risk of and for the treatment of breast cancer, as well as in other therapeutic areas.

We have been granted seven U.S. and 16 international patents covering our proprietary (Z)-endoxifen, and we have numerous applications pending in the U.S. and in other major countries. We expect to 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 with potential partners, and opportunistically add programs in areas of high unmet medical need through acquisition, minority investment, collaboration or internal development.

(Z) endoxifen. (Z)-endoxifen is the most active metabolite of Tamoxifen, a U.S. Food and Drug Administration (FDA) approved drug to treat and prevent breast cancer in high-risk women, and it is substantially more potent as an estrogen receptor antagonist than Tamoxifen and other approved SERMs. Unlike Tamoxifen, which requires metabolic activation through CYP2D6 and other liver enzymes, (Z)-endoxifen does not require first-pass metabolism to achieve therapeutic concentrations. As a result, its activity is not dependent on patient-specific metabolic variability.

(Z)-endoxifen is a small-molecule oral agent designed to directly inhibit estrogen receptor signaling, induce estrogen receptor degradation, and promote apoptosis in estrogen receptor positive (ER+) breast cancer cells. Preclinical and clinical data suggest that (Z)-endoxifen may inhibit clinically relevant ESR1 mutations associated with resistance to aromatase inhibitors and may also inhibit protein kinase C beta one (PKCβ1), resulting in downregulation of the AKT signaling pathway. We are evaluating (Z)-endoxifen across multiple settings within the ER+/human epidermal growth factor receptor 2 negative (HER2-) breast cancer treatment continuum, including neoadjuvant, adjuvant and breast density reduction indications.

In an ongoing neoadjuvant clinical study, (Z)-endoxifen has demonstrated early signs of anti-tumor activity. Reported results include one complete response and multiple partial responses, as well as substantial reductions in Ki-67 proliferation across dose levels. Tumor shrinkage was observed by MRI imaging, which is atypical for endocrine therapies that are generally cytostatic.

We are also supporting multiple collaborative and investigator-sponsored clinical studies evaluating (Z)-endoxifen in additional breast cancer settings. These studies are not fully funded by us and are intended to further characterize clinical activity, optimize endocrine therapy strategies, and inform future regulatory pathways.

Based on its mechanism of action, we are exploring the potential application of (Z)-endoxifen beyond breast cancer, including gynecological cancers, endocrine resistance driven by ESR1 mutations, as well as applications in other rare disease indications, including Duchenne Muscular Dystrophy (DMD), women carriers of DMD, and McCune-Albright Syndrome (MAS) in girls. In preclinical models of DMD, (Z)-endoxifen demonstrated muscle-protective, anti-inflammatory, and anti-fibrotic effects. We believe similar efficacy could potentially apply to women carriers of DMD. For MAS, we believe (Z)-endoxifen could potentially be an effective hormone blocker, significantly reducing the effects of early onset puberty in young girls. We have developed a proprietary manufacturing process for (Z)-endoxifen, including defined processes for the active pharmaceutical ingredient and drug product. The drug product is available in multiple dosage strengths and is supported by qualified suppliers and manufacturing redundancies.

Summary of Our Leading Programs

We are developing a proprietary form of (Z)-endoxifen which is administered orally for the potential treatment of high-risk breast cancer and the reduction of mammographic breast density (MBD). As part of this development, we are also evaluating the potential for (Z)-endoxifen to work in combination with other cancer treatment therapies for premenopausal and postmenopausal women with high-risk breast cancer.

In addition to oncology related indications, we believe (Z)-endoxifen has potentially broader utility as a therapeutic platform in serious and rare diseases, many of which have significant unmet medical need. There is growing scientific evidence supporting the

potential role of estrogen signaling modulation in muscle preservation and inflammation associated with conditions, such as DMD and MAS, among others.

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

Oncology/Breast Cancer

In support of our breast cancer risk reduction and treatment indications, 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.

Karisma Study

(Z)-endoxifen for Women with 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 MBD. 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 of (Z)-endoxifen, or 2 mgs of (Z)-endoxifen. The study also included an exploratory endpoint to assess twenty-four month durability of the breast density changes. Top line data for this study measuring both MBD reduction after six months of treatment and data regarding twenty-four month durability is expected in the first quarter of 2026.

The study fully enrolled in November 2023 and in September 2024, the primary objective measuring MBD after six months of treatment, was concluded. The data showed the potential of low-dose (Z)-endoxifen to significantly reduce MBD with a favorable safety profile.

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, demonstrating the effectiveness of the lower dose in achieving significant MBD 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.

We expect to report top-line data from the Karisma (Z)-endoxifen study in the first half of 2026. Further development will depend on regulatory guidance, study outcomes, and available resources.

RECAST DCIS Study

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, and is typically 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, the 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.

EVANGELINE Study

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 approximately 80% of all breast cancers each year.

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 designed to assess (Z)-endoxifen as neoadjuvant therapy in premenopausal women with primary ER+/HER2– breast cancer. As originally designed, the study was to consist of two parts: Part 1 was a Pharmacokinetic (PK) Run-In Cohort evaluating daily dosing of 40 mg and 80 mg to assess if a plasma steady state concentration (Css) of 500 to 1000 ng/mL, which is required for optimal PKC-β inhibition, could be achieved; and Part 2 was expected to compare the two treatment arms based on baseline Ki-67 levels, with the aim of evaluating the endocrine sensitive disease rate, pathologic complete response, and other key endpoints.

Data showed that none of the patients in the 40 mg cohort reached the target Css. However, in the 80 mg cohort, approximately 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, although four gynecologic events (including one Grade 3 hemorrhagic ovarian cyst) were noted in the 80 mg group.

Based on preliminary results from the 40 mg and 80 mg cohorts, the EVANGELINE study design and treatment protocol were amended in 2025. The study design has been updated to a single-arm, open-label, Phase 2 in premenopausal women with ER+/HER2– breast cancer in the pre-surgical setting. The study includes two Cohorts: Cohort A (signal-seeking), a two-stage futility design assessing the Week-4 Ki-67 ≤10% rate to allow early stop if not promising, and Cohort B (estimation), assessing Week-24 objective response (RECIST 1.1, central review). The amended design will focus on objective, short-interval endpoints to inform development decisions efficiently while working to preserve patient safeguards.

The initial EVANGELINE study design included enrollment estimates for 214 patients and has been amended to reduce enrollment totals to 40-65 patients. Enrollment in this study is ongoing, and it is expected to be complete in the second quarter of 2026.

I-SPY 2 Endocrine Optimization Pilot Study

In March 2023, a second neoadjuvant Phase 2 trial investigating oral (Z)-endoxifen as a treatment for women diagnosed with locally advanced ER+/HER2- breast cancer was initiated. This trial is a study arm in the ongoing I‑SPY 2 Endocrine Optimization Pilot (I-SPY 2 EOP) which 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. This study included twenty women who received 10 mg of (Z)-endoxifen (monotherapy) orally once daily for six cycles (each cycle = 28 days) or up to 24 weeks prior to surgery.

For the monotherapy arm of I-SPY 2 EOP, enrollment was completed in January 2024 and 3-week preliminary data results were reported in October 2024. In May 2025, we reported updated results from this study which found that (i) 95% of participants (19/20 participants) completed at least 75% of planned dosing, (ii) median Ki-67 fell from 10.5% at baseline to 5% by Week 3, (iii) 65% of patients achieved Ki-67< 10% at Week 3 with suppression maintained at surgery, (iv) median functional tumor volume measurement (performed at baseline, Week 3, Week 12 and at surgery) decreased 77.7% from baseline to surgery, and (v) the longest tumor diameter in the participants from baseline to preoperative MRI was reduced by 36.8%. (Z)-endoxifen was well tolerated in this study with the most common side effects being relatively mild, consisting of hot flashes, insomnia, and fatigue. No dose reductions or discontinuations due to treatment related adverse events occurred during this study.

In April and June of 2024, we announced our participation in two new study arms of the I-SPY 2 EOP which were initiated to evaluate our proprietary (Z)-endoxifen in combination with two FDA approved drugs: 1) abemaciclib (VERZENIO®), a cyclin-dependent kinase (CDK) 4/6 inhibitor marketed by Eli Lilly and Company, and 2) elagolix (ORILISSA®), a prescription medicine used to treat moderate to severe pain associated with endometriosis marketed by AbbVie, Inc. Total enrollment across the combination therapy arms of this study is expected to be approximately 90 enrollees. Preliminary data has not been made available related to the ongoing combination therapy arms of I-SPY 2 EOP. Enrollment in the combination therapy arms of this nearly complete, and we expect to begin receiving data in the second half of 2026.

Rare Pediatric Disease and Orphan Designations

Duchenne Muscular Dystrophy

DMD is a serious and progressive neuromuscular disease that primarily affects boys, leading to loss of muscle function, loss of ambulation, and life-threatening heart and respiratory complications. We believe that (Z)-endoxifen's direct estrogen-receptor modulation, PKC inhibition, and effects on key signaling pathways could be relevant in addressing various pathologies associated with DMD, including inflammation, fibrosis, and cardiomyopathy. Through its potential ability to upregulate utrophin, (Z)-endoxifen may help stabilize muscle health, including muscle growth, repair, and fibrosis. FDA engagement commenced in Q4 2025.

In December 2025 and early in 2026, we received two FDA designations for (Z)-endoxifen for the treatment of DMD: 1) Rare Pediatric Disease Designation and 2) Orphan Drug Designation. We believe these designations provide us with several potential strategic benefits, including incentives, such as a potential Priority Review Voucher (PRV) for future FDA applications, other

regulatory support, and potential market exclusivity for a period of time. PRVs, which were recently reauthorized by legislation, could create significant value and could represent a meaningful source of non-dilutive value opportunities, either through use in another program or monetization through sale to third parties.

Women Carriers of DMD

(Z)-endoxifen has also shown potential relevance in symptomatic female Duchenne and Becker muscular dystrophy carriers, an under-recognized population in which a subset may experience skeletal-muscle symptoms or develop dilated cardiomyopathy in adult life. The work done in 2025, including our manuscript entitled, "(Z)-Endoxifen as a Modulator of Utrophin Pathways in Duchenne Muscular Dystrophy," will continue to inform our hypotheses and potential clinical trial protocols in 2026. Additionally, we believe this condition meets the requirements of and could qualify for Orphan Drug Designation, and we intend to pursue this designation in the first half of 2026.

McCune-Albright Syndrome:

MAS is a rare, non-inherited genetic disorder caused by a postzygotic GNAS mutation, affecting bones, skin, and the endocrine system, with symptoms typically appearing in early childhood. In young girls (as early as 2 years old), early onset puberty can occur (Precocious Puberty) which can have a very significant effect on quality of life and limit growth. We believe that (Z)-endoxifen could prove to be an effective hormone blocker and potentially significantly reduce the effects of Precocious Puberty until young girls reach a more typical age for the onset of puberty and related developmental changes. Given the age of impacted girls and the relatively small size of this impacted population, we expect to seek both Rare Pediatric Disease and Orphan Drug designations for MAS in the first half of 2026.

Research and Development Phase

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

Commercial Lease Agreement

On September 22, 2025, we entered into an operating lease with 1448 NW Market Street Tenant LLC for additional office space in Seattle, Washington. We agreed to pay $3 thousand per month for 13 months commencing on November 1, 2025.

Reverse Stock Split

On February 2, 2026, the Company effected a 1-for-15 reverse stock split of its issued and outstanding common stock (the Reverse Stock Split). As a result of the Reverse Stock Split, each 15 shares of common stock issued and outstanding immediately prior to February 2, 2026 were automatically converted into one new share of common stock.

The Reverse Stock Split did not change the par value of the common stock or the authorized number of shares of common stock. Proportionate adjustments were made (i) in accordance with the terms of the Company's equity plans, to the number of shares subject to outstanding equity awards, the per share exercise price, if any, with respect to those awards and the number of shares of common stock reserved for future issuance under such plans, and (ii) in accordance with the Certificate of Designation of Preferences, Rights and Limitation of the Series B Convertible Preferred Stock (Preferred Stock), to the conversion price of the Preferred Stock and the number of shares of common stock reserved for issuance pursuant to the Preferred Stock. All applicable common stock and per share amounts have been retrospectively restated to reflect the effect of the reverse stock split.

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

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 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 rate 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, 2025 and 2024

Revenue and Cost of Revenue. For the years ended December 31, 2025 and 2024, we had no source of revenue and no associated cost of revenue.

Operating Expenses. Total operating expenses were $37.1 million for the year ended December 31, 2025, which was an increase of $9.5 million, from the year ended December 31, 2024 of $27.6 million. Factors contributing to the increased operating expenses in the year ended December 31, 2025 are explained below.

Research & Development Expenses. The following table provides a breakdown of major categories within R&D expenses for the years ended December 31, 2025 and 2024, together with the dollar change in those categories (dollars in thousands):

		Year Ended December 31, 2025	Year Ended December 31, 2024	Increase	% Increase
Research and Development Expense					
	Clinical and pre-clinical trials	$ 16,204	$ 10,107	$ 6,097	60%
	Compensation	3,206	2,928	278	9%
	Professional fees and other	1,775	1,082	693	64%
	Research and Development Expense Total	$ 21,185	$ 14,117	$ 7,068	50%

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 increased $6.1 million for the year ended December 31, 2025 compared to the prior year due to an increase in spending for the (Z)-endoxifen trials, including an increase in drug development costs.

- The increase in R&D compensation expense of $0.3 million for the year ended December 31, 2025 compared to the prior year was due primarily to an increase in cash compensation expense of $0.4 million resulting from an increase in headcount. This increase was partially offset by a non-cash stock-based compensation expense decrease of $0.1 million compared to the prior year due to the weighted average fair value of stock options amortizing in 2025 being lower than 2024.

- The increase in R&D professional fees and other of $0.7 million for the year ended December 31, 2025 compared to the prior year was primarily attributable to higher regulatory consulting fees in 2025 related to our (Z)-endoxifen program.

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, 2025 and 2024, together with the dollar change in those categories (dollars in thousands):

		Year Ended December 31, 2025	Year Ended December 31, 2024	Increase (Decrease)	% Increase (Decrease)
General and Administrative Expense					
	Compensation	$ 6,062	$ 5,458	$ 604	11%
	Professional fees and other	9,191	7,164	2,027	28%
	Insurance	703	882	(179)	(20)%
	General and Administrative Expense Total	$ 15,956	$ 13,504	$ 2,452	18%

- The increase in G&A compensation expense of $0.6 million for the year ended December 31, 2025 compared to the prior year was due to an increase in both cash compensation expense of $0.2 million and non-cash stock-based compensation expense of $0.4 million. The increase in cash compensation expense compared to the prior year was primarily driven by salary, bonus and severance costs for a former executive of $0.4 million, partially offset by a decrease in cash bonus related to terminations and reductions in expected bonus payouts in 2025. The non-cash stock-based compensation expense increase was driven by an increase in the fair value of grants to members of our Board of Directors (the Board) which amortize over one year.

- G&A professional fees and other expenses increased by $2.0 million for the year ended December 31, 2025 compared to the prior year due primarily to an increase in legal fees of $1.8 million for the year ended December 31, 2025 driven by the costs for

our ongoing litigation and patent defense which increased by $1.6 million compared to the prior year. Investor relations expense increased by $0.3 million for the year ended December 31, 2025 compared to the prior year due to changes in investor outreach and broader investor relations strategy. Partially offsetting the increases, our accounting fees decreased by $0.3 million for the year ended December 31, 2025 compared to the prior year due to the inclusion of higher auditor fees associated with our 2024 Registration Statement on Form S-3 and our at the market offering facility.

- The decrease in G&A insurance expense of $0.2 million for the year ended December 31, 2025 compared to the prior year was due primarily to lower negotiated insurance premiums associated with our Director's and Officer's insurance and other key insurance policies in 2025.

Interest Income. Interest income of $2.4 million for the year ended December 31, 2025 represented a decrease of $1.7 million compared to the prior year, and was due primarily to a decrease in the average funds invested in our money market account.

Impairment Charge on Investment in Equity Securities. For the year ended December 31, 2024, we wrote down our Investment in equity securities by $1.7 million due to impairment of our investment in Dynamic Cell Therapies, Inc. Refer to Note 4 "Investment in Equity Securities" to the Consolidated Financial Statements for more information.

Income Taxes. We did not record an income tax expense or benefit for the years ended December 31, 2025 and 2024 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, 2025, 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[SM] with Jefferies LLC (the Prior ATM Facility), pursuant to which we were able to 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 Prior ATM Facility during the year ended December 31, 2025, and the Prior ATM Facility was cancelled on February 19, 2026.

On February 20, 2026, we entered into the At the Market Offering Agreement, dated February 20, 2026 (the Sales Agreement), with Rodman & Renshaw LLC. Pursuant to the Sales Agreement, 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 $50.0 million.

During the year ended December 31, 2024, we received $3.7 million from the exercise of warrants resulting in the issuance of 244,833 shares of common stock. No warrants were outstanding as of December 31, 2025.

Cash Flows

The following table shows a summary of our cash flows for the years indicated (in thousands):

	For the Year Ended December 31,	
	2025	2024
Net cash used in operating activities	$ (29,762)	$ (21,030)
Net cash used in investing activities	(23)	(19)
Net cash provided by financing activities	—	3,673
Net decrease in cash, cash equivalents and restricted cash	$ (29,785)	$ (17,376)

We have incurred net losses and negative operating cash flows since inception. For the year ended December 31, 2025, we recorded a net loss of $34.8 million and used $29.8 million of cash in operating activities. As of December 31, 2025, we had $41.3 million in unrestricted cash and cash equivalents and working capital of $37.4 million. 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 as well as short-term borrowing from banks, stockholders or other related parties, if 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 cease operations or substantially curtail our activities. 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. These conditions raise substantial doubt as to our ability to continue as a going concern. As of the date of filing this Annual Report, we expect our existing resources to be sufficient to fund our planned operations for the next 12 months; however, additional capital resources will be needed to fund operations longer.

Net Cash Flows from Operating Activities. Net cash used in operating activities was $29.8 million for the year ended December 31, 2025, compared to net cash used in operating activities of $21.0 million in 2024, an increase of $8.8 million. Cash used in operating activities for the year ended December 31, 2025 consisted primarily of our net loss of $34.8 million, adjusted for non-cash items such as non-cash stock-based compensation expense of $2.6 million and partially offset by net cash inflows from a change in our operating assets and liabilities of $1.9 million. Cash used in operating activities was $21.0 million for the year ended December 31, 2024 and consisted primarily of our net loss of $25.5 million, adjusted for non-cash items such as stock-based compensation expense of $2.3 million, non-cash impairment charge on investment in equity securities of $1.7 million and net cash outflows from a change in our operating assets and liabilities of $1.1 million.

Net Cash Flows from Investing Activities. Net cash used in investing activities was $23 thousand for the year ended December 31, 2025, compared to net cash used in investing activities of $19 thousand for the year ended December 31, 2024. Current and prior year cash used in investing activities was related primarily to purchases of new computers.

Net Cash Flows from Financing Activities. We received no net cash flows from financing activities for the year ended December 31, 2025 compared to net cash provided by financing activities of $3.7 million for 2024. The $3.7 million net cash provided by financing activities for the year ended December 31, 2024 consisted primarily of cash proceeds from the exercise of warrants.

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.

Substantial doubt exists about our ability to continue as a going concern. If we are unable to raise additional capital when needed on reasonable terms, if at all, we could be forced to cease operations or substantially curtail our activities. 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, 2025, our estimated non-cancellable commitment was $7.0 million, which will be paid over the term of the clinical trials.

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 61 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, 2025, 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, 2025, 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, 2025, 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, 2025. 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, 2025, 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, 2025, 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 2026 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 77 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, 2025 and 2024, the related consolidated statements of operations, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2025, 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, 2025 and 2024, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2025, in conformity with U.S. generally accepted accounting principles.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has suffered recurring losses from operations and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

Critical Audit Matter

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, 2025, the Company accrued $661 thousand for estimated costs incurred for research and development activities and recorded $410 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 prepaid or accrued amounts at period-end and recalculated such amounts based on the contractual terms and activity to date. 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, 2026

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

	As of December 31,	
	2025	2024
Assets		
Current assets		
Cash and cash equivalents	$ 41,299	$ 71,084
Restricted cash	110	110
Prepaid materials	3,081	2,098
Prepaid expenses and other current assets	1,128	1,165
Total current assets	45,618	74,457
Other assets	1,990	1,987
Total assets	$ 47,608	$ 76,444
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 4,293	$ 679
Accrued expenses	1,307	919
Payroll liabilities	1,558	1,862
Other current liabilities	1,097	1,507
Total current liabilities	8,255	4,967
Total liabilities	8,255	4,967
Commitments and contingencies (Note 13)	—	—
Stockholders' equity		
Series B convertible preferred stock - $0.001 par value; 10,000,000 shares authorized; 577 and 582 shares issued and outstanding as of December 31, 2025 and 2024, respectively	—	—
Common stock - $0.18 par value; 350,000,000 shares authorized 8,611,361 and 8,611,266 shares issued and outstanding as of December 31, 2025 and 2024, respectively	1,550	1,550
Additional paid-in capital	285,840	283,194
Treasury stock, at cost; 88,003 shares of common stock at December 31, 2025 and 2024, respectively	(1,475)	(1,475)
Accumulated deficit	(246,562)	(211,792)
Total stockholders' equity	39,353	71,477
Total liabilities and stockholders' equity	$ 47,608	$ 76,444

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,	
	2025	**2024**
Operating expenses		
Research and development	$ 21,185	$ 14,117
General and administrative	15,956	13,504
Total operating expenses	37,141	27,621
Operating loss	(37,141)	(27,621)
Impairment charge on investment in equity securities	—	(1,710)
Interest income	2,377	4,050
Other expense, net	(6)	(223)
Loss before income taxes	(34,770)	(25,504)
Income tax benefit	—	—
Net loss	(34,770)	(25,504)
Net loss per share of common stock - basic and diluted	$ (4.04)	$ (3.04)
Weighted average shares outstanding used to compute net loss per share - basic and diluted	8,611,321	8,390,618

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, 2023	582	$ —	8,353,537	$ 1,504	$ 277,275	$ (1,475)	$ (186,288)	$ 91,016
Issuance of common stock upon warrant exercise	—	—	244,832	44	3,629	—	—	3,673
Issuance of common stock upon option exercise	—	—	22,934	4	269	—	—	273
Shares withheld related to cashless exercise of options and taxes	—	—	(10,037)	(2)	(271)	—	—	(273)
Stock-based compensation	—	—	—	—	2,292	—	—	2,292
Net loss	—	—	—	—	—	—	(25,504)	(25,504)
Balance at December 31, 2024	582	$ —	8,611,266	$ 1,550	$ 283,194	$ (1,475)	$ (211,792)	$ 71,477
Issuance of common stock upon Series B preferred stock conversion	(5)	—	95	—	—	—	—	—
Stock-based compensation	—	—	—	—	2,646	—	—	2,646
Net loss	—	—	—	—	—	—	(34,770)	(34,770)
Balance at December 31, 2025	577	$ —	8,611,361	$ 1,550	$ 285,840	$ (1,475)	$ (246,562)	$ 39,353

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,	
	2025	**2024**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (34,770)	$ (25,504)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation	2,646	2,292
Impairment charge on investment in equity securities	—	1,710
Depreciation	16	17
Loss on disposal of assets	—	7
Changes in operating assets and liabilities:		
Prepaid materials	(983)	(611)
Prepaid expenses and other current assets	37	997
Other assets	4	331
Accounts payable	3,614	(127)
Accrued expenses	388	(54)
Payroll liabilities	(304)	208
Other current liabilities	(410)	(296)
Net cash used in operating activities	(29,762)	(21,030)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property and equipment	(23)	(19)
Net cash used in investing activities	(23)	(19)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from exercise of warrants	—	3,673
Net cash provided by financing activities	—	3,673
NET DECREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	(29,785)	(17,376)
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, BEGINNING BALANCE	71,194	88,570
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, ENDING BALANCE	$ 41,409	$ 71,194
RECONCILIATION OF CASH AND CASH EQUIVALENTS AND RESTRICTED CASH		
Cash and cash equivalents	41,299	71,084
Restricted cash	110	110
Total cash, cash equivalents and restricted cash	$ 41,409	$ 71,194
NON-CASH INVESTING AND FINANCING ACTIVITIES		
Common stock issued upon cashless exercise of stock options	$ —	$ 273
Conversion of Series B convertible preferred stock to common stock	$ 5	$ —

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, as well as other rare diseases.

NOTE 2: GOING CONCERN

The Company's consolidated financial statements are prepared under the going concern basis of accounting, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company has incurred net losses and negative operating cash flows since inception. For the year ended December 31, 2025, the Company recorded a net loss of $34.8 million and used $29.8 million of cash in operating activities. As of December 31, 2025, the Company had $41.3 million in unrestricted cash and cash equivalents and working capital of $37.4 million. The Company has not yet established an ongoing source of revenue sufficient to cover its operating costs and allow it to continue as a going concern. The ability of the Company to continue as a going concern is dependent on the Company obtaining adequate capital to fund operating losses until it becomes profitable. These conditions raise substantial doubt as to the Company's ability to continue as a going concern. The accompanying consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts and classification of liabilities should the Company be unable to continue as a going concern.

In order to alleviate the conditions that raise substantial doubt, the Company will need, among other things, additional capital resources. Management plans to obtain such resources for the Company include obtaining capital from the sale of its equity securities as well as short-term borrowings from banks, stockholders or other related parties if needed. However, management cannot provide any assurance that the Company will be successful in accomplishing any of its plans.

The ability of the Company to continue as a going concern is dependent upon its ability to successfully accomplish the plans described in the preceding paragraphs and eventually to secure other sources of financing and attain profitable operations.

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 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.

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.

Reverse Stock Split

On February 2, 2026, the Company effected a 1-for-15 reverse stock split of its issued and outstanding common stock (the Reverse Stock Split). As a result of the Reverse Stock Split, each 15 shares of common stock issued and outstanding immediately prior to February 2, 2026 was automatically converted into one share of common stock. The Reverse Stock Split affected all common stockholders uniformly and did not alter any stockholders' percentage interest in the Company's equity, except to the extent that the Reverse Stock Split would result in a stockholder owning a fractional share. No fractional shares were issued in connection with the Reverse Stock Split. Stockholders who otherwise would be entitled to receive a fractional share instead were entitled to receive cash in lieu of such fractional share.

The Reverse Stock Split did not change the par value of the common stock or the authorized shares of common stock. The shares of common stock retain a par value of $0.18 per share. Accordingly, an amount equal to the par value of the decreased shares resulting from the reverse stock split was reclassified from “Common stock” to “Additional paid-in capital”.

All common stock and per-share amounts in this Form 10-K have been retroactively restated to reflect the effect of the Reverse Stock Split.

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, 2025 and 2024, 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 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 writes 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 are observable price changes in orderly transactions for an identical or similar investment of the same issuer, in accordance with Accounting

Standards Codification (ASC) *321, Investments – Equity Securities*. At each reporting period, the Company performed an assessment to determine if it still 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 that 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 is recorded in the Consolidated Statements of Operations equal to the difference between the carrying value and fair value and a new basis in the investment was established. Refer to Note 4 “Investment in Equity Securities” to the 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 limited exercise history and 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. 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, 2025, the Company adopted Accounting Standards Update (ASU) No. 2023-09, *Income Taxes: Improvements to Income Tax Disclosures (Topic 740)*. This standard enhances disclosures related to income taxes, including the rate reconciliation and information on income taxes paid. See Note 12 to these Consolidated Financial Statements.

Recently Issued Accounting Pronouncements

In November 2024, the Financial Accounting Standards Board (the 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 public business entities in annual reporting periods beginning after December 15, 2026, and in interim periods within annual reporting periods beginning after December 15, 2027. Entities may apply the guidance prospectively or retrospectively. The Company is currently assessing the potential impact of this ASU.

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 DCT’s economically significant activities. The Company had no obligation to provide any future funding to DCT.

The Company considered qualitative and quantitative impairment factors in determining if there were any signs of impairment of this investment as of September 30, 2024. Specifically, the Company considered continued 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 assumptions regarding (i) the expected average volatility of comparable companies, (ii) the expected term of the Company's investment, and (iii) 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 (i) DCT's limited cash on hand at the time, (ii) the status of fundraising efforts and (iii) 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.

NOTE 5: PREPAID EXPENSES AND OTHER CURRENT ASSETS

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

	As of December 31, 2025	As of December 31, 2024
Prepaid pre-clinical and clinical trial deposits	$ 410	$ 350
Prepaid insurance	517	628
Prepaid professional services	68	68
Other	133	119
Total prepaid expenses and other current assets	$ 1,128	$ 1,165

NOTE 6: ACCRUED EXPENSES

Accrued expenses consisted of the following (in thousands):

	As of December 31, 2025	As of December 31, 2024
Accrued pre-clinical and clinical trial costs	$ 661	$ 700
Accrued professional services and other	646	219
Total accrued expenses	$ 1,307	$ 919

NOTE 7: PAYROLL LIABILITIES

Payroll liabilities consisted of the following (in thousands):

	As of December 31, 2025	As of December 31, 2024
Accrued bonuses	$ 680	$ 1,305
Accrued vacation	213	226
Accrued payroll and benefits	665	331
Total payroll liabilities	$ 1,558	$ 1,862

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, 2025 and 2024, a liability of $1.1 million and $1.5 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, 2025	Estimated Fair Value	Level 1	Level 2	Level 3
Assets:				
Money market fund	$ 40,367	$ 40,367	$ —	$ —

December 31, 2024	Estimated Fair Value	Level 1	Level 2	Level 3
Assets:				
Money market fund	$ 68,543	$ 68,543	$ —	$ —

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.

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, 2025 and 2024.

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 $52.80 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 year ended December 31, 2025, certain holders of the Series B convertible preferred stock exercised their conversion option and converted an aggregate of 5 shares of Series B convertible preferred stock into 95 shares of the Company's common stock. No cash was exchanged in connection with the conversion. During the year ended December 31, 2024, 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 does 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.

Warrants

There were no warrant exercises during the year ended December 31, 2025. During the year ended December 31, 2025, warrants granted in prior years expired as follows: 187,500 warrants granted in December 2020 expired on June 21, 2025; 300,000 warrants granted in January 2021 expired on July 8, 2025; and 701,667 warrants granted in March 2021 expired on September 22, 2025. No warrants remain outstanding at December 31, 2025.

During the year ended December 31, 2024, the Company received $3.7 million from the exercises of warrants resulting in the issuance of 244,833 shares of common stock.

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 shares of common stock excluded from the calculation of diluted net loss per share, because including them would be anti-dilutive:

	Year Ended December 31,	
	2025	2024
Options to purchase common stock	1,520,347	1,252,516
Series B convertible preferred stock	10,968	11,023
Warrants to purchase common stock	—	1,405,461
	1,531,315	2,669,000

NOTE 12: INCOME TAXES

The Company adopted ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, on a prospective basis effective January 1, 2025. A reconciliation of the income tax benefit calculated at the U.S. federal statutory rate to the recognized income tax benefit and effective income tax rate is as follows (in thousands, except percentages):

	As of December 31, 2025	
	Amount	Percent
Income tax benefit at the U.S. federal statutory rate	$ (7,302)	21.0%
State income taxes, net of federal income tax effect	—	0.0%
Foreign tax effects		
Australia		
Statutory tax rate difference between Australia and U.S.	(31)	0.1%
Change in valuation allowance	22	-0.1%
Other	85	-0.2%
Effect of changes in tax laws or rates enacted in the current period	—	0.0%
Effect of cross border tax laws	(76)	0.2%
Tax credits	—	0.0%
Change in valuation allowance	7,278	-20.9%
Non taxable or non deductible items		
Other non-taxable income & disallowed expenses	173	-0.5%
Other	(149)	0.4%
Changes in unrecognized tax benefits	—	0.0%
Income tax benefit	$ —	0.0%

	As of December 31, 2024
Expected federal income tax benefit at statutory rate	$ (5,356)
Disallowed R&D expenses	3
Non-taxable R&D rebate	—
Other permanent items	235
Return to provision	57
Stock-based compensation	246
Foreign rate differential	(76)
Other	21
Effect of change in valuation allowance	4,870
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,	
	2025	2024
Deferred tax assets		
Accrued bonus	$ 143	$ 274
Accrued vacation	45	47
Stock-based compensation	4,887	4,265
Capitalized R&D expenses	300	7,825
Rebate reserve	153	220
Intangible assets, net	113	181
Investment in equity securities	987	987
Net operating loss carryforwards	30,091	15,716
Other	98	48
Total gross deferred tax asset	36,817	29,563
Valuation allowance	(36,817)	(29,516)
Net deferred tax assets	—	47
Deferred tax liabilities		
Bonus compensation	—	(47)
Net deferred tax assets	$ —	$ —

As of December 31, 2025 and 2024, a valuation allowance was established against the Company's net deferred tax assets due to the uncertainty regarding the realization of such assets as evidenced by the cumulative losses from operations through December 31, 2025 and 2024. The total valuation allowance increased by $7.3 million for the year ended December 31, 2025 primarily as a result of an increase in net operating loss carryforwards, partially offset by a reduction in deferred tax assets related to previously capitalized R&D expenses.

The Company has incurred net operating losses since inception. At December 31, 2025, the Company had domestic federal net operating loss (NOL) carryforwards of $186.7 million and foreign NOL carryforwards of $1.7 million. The 2017 Tax Cut and Jobs Act (the Act) generally allows federal losses generated after 2017 to be carried forward indefinitely, but also limits the NOL deduction to the lesser of the NOL carryover or 80% of a corporation's taxable income (subject to Section 382 of the Internal Revenue Code of 1986, as amended (the IRC). Additionally, there is no carryback for losses generated after 2017. Losses generated prior to 2018 are deductible using the lesser of a corporation's NOL carryover or 100% of a corporation's taxable income and have a 20 year carryforward period. Federal NOL carryforwards generated prior to 2018 expire at various dates beginning 2029 through 2037. Foreign NOLs do not expire.

The future utilization of the federal NOL 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 IRC limits a Company's ability to utilize certain NOL carry forwards in the event of a cumulative change in ownership in excess of 50% (by value) defined in the IRC. The Company has not completed a study to assess whether an ownership change, as defined by the IRC, had occurred since its inception.

The Company has no unrecognized tax positions as of December 31, 2025 or 2024 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, 2025 or 2024.

The Company files income tax returns in the U.S. and Australia. The Company has incurred net losses since inception and has not been audited for any open taxation years. As such, all tax years remain open for federal tax examinations in the U.S. For Australia, tax years from 2020 to present remain open and subject to audit.

NOTE 13: COMMITMENTS AND CONTINGENCIES

Litigation and Contingencies

On April 3, 2025, Intas Pharmaceuticals Ltd. (Intas) filed a Petition for Post Grant Review (PGR) with the U.S. Patent and Trademark Office’s (USPTO) Patent Trial and Appeal Board (PTAB) (the 391 PGR Petition) seeking to invalidate one of the

Company's issued patents (U.S. Patent No. 12,071,391) titled "Methods for Making and Using Endoxifen," on the alleged grounds of anticipation, obviousness, lack of written description, and lack of enablement.

On April 3, 2025, Intas also filed a Petition for Inter Partes Review (IPR) with the USPTO's PTAB (the 151 IPR Petition) seeking to invalidate one of the Company's issued patents (U.S. Patent No. 11,261,151) titled "Methods for Making and Using Endoxifen" (together with U.S. Patent No. 12,071,391, the Patents) on the alleged grounds of anticipation and obviousness.

On November 3, 2025, the PTAB released a Decision Granting Institution of PGR for U.S. Patent No. 12,071,391 and a Decision Granting Institution of IPR for U.S. Patent No. 11,261,151. On January 26, 2026, the Company submitted responses to the 391 PGR Petition and the 151 IPR Petition. Final written decisions are expected for the PGR and IPR proceedings by November 3, 2026.

The Company intends to continue to vigorously contest the 391 PGR Petition and the 151 IPR Petition and believes that the Patents were properly granted and include valid and enforceable claims and that the risk of experiencing financial loss related to the Petitions is remote. However, there can be no assurance that the Company will prevail in contesting either the 391 PGR Petition or the 151 IPR Petition.

From time to time, 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, 2025, the Company's estimated non-cancellable commitment was $7.0 million.

NOTE 14: STOCK BASED COMPENSATION

On May 15, 2020, the stockholders of the Company approved the 2020 Stock Incentive Plan (the 2020 Plan) to provide for the grants of equity-based awards to employees, officers, non-employee directors and other key persons providing services to the Company. No awards may be granted under the 2020 Plan after June 27, 2034. An aggregate of 2,000,000 shares of common stock is reserved for issuance in connection with awards granted under the 2020 Plan. As of December 31, 2025, 679,462 shares were available for future grants under the 2020 Plan.

The Company granted 344,548 and 313,419 options to purchase shares of common stock to employees and directors during the years ended December 31, 2025 and 2024, respectively. The weighted average grant date fair value of options granted during the years ended December 31, 2025 and 2024 was $14.72 and $13.20, respectively. No options were exercised during the year ended December 31, 2025. There were 22,933 options exercised during the year ended December 31, 2024.

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

	Year Ended December 31,	
	2025	2024
Risk-free interest rate	4.03% - 4.11%	4.01% - 4.24%
Expected term (in years)	5.18 - 6.09	5.31 - 6.11
Dividend yield	—	—
Expected volatility	89% - 105%	97% - 120%

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

	Year Ended December 31,	
	2025	2024
General and administrative	$ 2,081	$ 1,647
Research and development	565	645
Total stock-based compensation expense	$ 2,646	$ 2,292

The following table shows a summary of all stock option activity for the year ended December 31, 2025:

	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, 2025	1,379,437	$ 24.06		
Granted	344,548	14.72		
Forfeited	(158,484)	18.64		
Exercised	—			
Expired	(229)	4,710.97		
Outstanding as of December 31, 2025	1,565,272	$ 21.86	5.85	$ 120
Exercisable as of December 31, 2025	1,326,076	$ 23.12	5.22	$ 83
Vested and expected to vest	1,565,272		5.85	$ 120

As of December 31, 2025, there were 239,196 unvested options outstanding, and the related unrecognized total compensation cost associated with these options was $2.2 million. This expense is expected to be recognized over a weighted-average period of 1.74 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, 2025 and 2024 were $0.4 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.

NOTE 17: SUBSEQUENT EVENT

On February 20, 2026, the Company entered into the At the Market Offering Agreement (the Sales Agreement), with Rodman & Renshaw LLC (the Sales Agent), pursuant to which the Company may offer and sell from time to time up to $50,000,000 of shares of the Company’s common stock, par value $0.18 per share (the Shares), through the Sales Agent as agent or principal. On February 19, 2026, the Company delivered written notice to Jefferies LLC indicating that it was terminating the Open Market Sale Agreement℠ (the Prior Agreement) by and between the Company and Jefferies LLC, dated November 19, 2024, effective as of February 19, 2026. The Company is not subject to any termination penalties related to the termination of the Prior Agreement. The Company did not undertake any sales of its common stock pursuant to the Prior Agreement.

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	Certificate of Amendment to the Amended and Restated Certificate of Incorporation	Current Report on Form 8-K, as Exhibit 3.1	January 26, 2026
3.7	Amended and Restated Bylaws	Current Report on Form 8-K as Exhibit 3.2	April 26, 2023
3.8	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
3.9	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
3.10	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
3.11	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 Senior Indenture	Registration Statement on Form S-3, as Exhibit 4.1	May 13, 2024
4.3	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#	Separation Agreement with Heather Rees Dated November 15, 2025	Filed herewith	
10.12#	Employment Agreement by and between Atossa Therapeutics, Inc. and Mark J. Daniel, effective October 14, 2025	Current Report on Form 8-K, as Exhibit 10.1	October 14, 2025

10.13	At the Market Offering Agreement, dated February 20, 2026, by and between Atossa Therapeutics, Inc. and Rodman & Renshaw LLC	Current Report on Form 8-K, as Exhibit 1.1	February 20, 2026
19.1	Insider Trading Policy	Annual Report on Form 10-K, as Exhibit 19.1	March 25, 2025
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, 2026.

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 Mark J. Daniel, 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 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, 2026
/s/ Mark J. Daniel **Mark J. Daniel**	Chief Financial Officer (Principal Financial and Accounting Officer)	March 25, 2026
/s/ Richard I. Steinhart **Richard I. Steinhart**	Director	March 25, 2026
/s/ Shu-Chih Chen **Shu-Chih Chen, Ph.D.**	Director	March 25, 2026
/s/ Jonathan F. Finn **Jonathan F. Finn**	Director	March 25, 2026
/s/ Stephen J. Galli **Stephen J. Galli, M.D.**	Director	March 25, 2026
/s/ H. Lawrence Remmel **H. Lawrence Remmel**	Director	March 25, 2026
/s/ Tessa Cigler **Tessa Cigler, M.D., M.P.H.**	Director	March 25, 2026

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Atossa Therapeutics, Inc.
1448 NW Market Street, Suite 500
Seattle, Washington 98107

NOTICE OF THE ANNUAL MEETING OF STOCKHOLDERS
To Be Held on Thursday May 7, 2026 at 9:00 A.M. Pacific Time
Virtual Meeting to be Held Live via the Internet at: the unique link that will be emailed to you after you register in advance at https://web.viewproxy.com/AtossaTherapeutics/2026

You must register by 11:59 P.M. Eastern Time on May 5, 2026 in order to attend the Annual Meeting
Technical Support Contact: VirtualMeeting@viewproxy.com or call 1-866-612-8937

Dear Stockholder:

You are cordially invited to attend the Annual Meeting of Stockholders (the "***Annual Meeting***") of Atossa Therapeutics, Inc., a Delaware corporation (the "***Company***"), which will be held virtually on Thursday, May 7, 2026, at 9:00 A.M. Pacific Time. The Annual Meeting will be held in a virtual only meeting format via live audio webcast. You will need to register in advance to attend the Annual Meeting virtually. For more information, see "General Information—About the Meeting – What do I need to do to virtually attend the Annual Meeting via live audio webcast?" Only stockholders of record who held the Company's common stock at the close of business on the record date, March 19, 2026 (the "***Record Date***"), may attend virtually, and vote online at the Annual Meeting, including at any adjournment or postponement thereof.

At the Annual Meeting, you will be asked to consider and vote upon: (1) the election of the three Class II director nominees named in the Proxy Statement ("***Proposal 1***"); (2) the ratification of the selection of Ernst & Young LLP ("***EY***") as the Company's independent registered public accounting firm for the fiscal year ending December 31, 2026 ("***Proposal 2***"); (3) the approval of an amendment of the Company's Certificate of Incorporation to effect, within 12 months following the date of stockholder approval and solely if the Board determines that it is necessary and advisable to maintain* compliance with the minimum bid price requirements of Nasdaq, a reverse stock split of the Company's common stock at a reverse stock split ratio ranging from 2:1 to 20:1, with the exact ratio to be set within that range but the Board ("***Proposal 3***"); (4) the approval, on a non-binding, advisory basis, of the compensation of the Company's named executive officers ("***Proposal 4***"); (5) the approval of an adjournment of the Annual Meeting, if necessary or appropriate, to solicit additional proxies ("***Proposal 5***"); and (6) the transaction of any other matters that may properly come before the Annual Meeting or any adjournments or postponements thereof.

No other items of business are expected to be considered at the Annual Meeting and, pursuant to the Company's Bylaws, no other director nominees will be entertained. The enclosed Proxy Statement more fully describes the details of the business to be conducted at the Annual Meeting. After careful consideration, our Board of Directors has unanimously approved the proposals and recommends that you vote "FOR" each director nominee and "FOR" each of the other proposals. After reading the Proxy Statement and our other proxy materials, please vote online, by telephone or by returning your proxy card or your voting instruction form. YOUR SHARES WILL NOT BE VOTED UNLESS YOU VOTE IN ONE OF THE WAYS DESCRIBED OR IF YOU ATTEND AND VOTE AT THE VIRTUAL ANNUAL MEETING.

Instructions for accessing the virtual Annual Meeting are provided in the Proxy Statement. To attend the virtual Annual Meeting, stockholders must register by 11:59 P.M. Eastern Time on May 5, 2026. In the event of a technical malfunction or other situation that the meeting chair determines may affect the ability of the Annual Meeting to satisfy the requirements for a meeting of stockholders to be held by means of remote communication under the Delaware General Corporation Law, or that otherwise makes it advisable to adjourn the Annual Meeting, the meeting chair or secretary will convene the meeting at 10:00 A.M. Pacific Time on the date specified above and at the Company's address specified above solely for the purpose of adjourning the meeting to reconvene at a date, time and physical or virtual location announced by the meeting chair or secretary. Under either of the foregoing circumstances, we will post information regarding the announcement on the Investors page of the Company's website at https://investors.atossatherapeutics.com.

** The Company is currently in compliance with the minimum bid price requirements of Nasdaq and is submitting this Proposal 3 for stockholder vote as a precautionary measure to provide additional flexibility to address any potential future deficiency with respect to the Nasdaq minimum bid price requirements.*

A copy of the Company's 2025 Annual Report has been mailed with this Proxy Statement to all stockholders entitled to notice of and to vote at the virtual Annual Meeting.

We look forward to seeing you at the Annual Meeting.

Sincerely,

Steven C. Quay, M.D., Ph.D.
Chairman of the Board, President and Chief Executive Officer
March 30, 2026

WHETHER OR NOT YOU EXPECT TO ATTEND THE ANNUAL MEETING, PLEASE MARK, DATE AND SIGN THE ENCLOSED PROXY OR YOUR VOTING INSTRUCTION FORM AND RETURN IT AT YOUR EARLIEST CONVENIENCE, OR PLEASE VOTE IN ONE OF THE OTHER WAYS DESCRIBED IN THE PROXY STATEMENT. EVEN IF YOU HAVE VOTED BY PROXY, YOU MAY REVOKE YOUR PROXY AT ANY TIME BEFORE THE FINAL VOTE AT THE ANNUAL MEETING. YOUR LAST SUBMITTED VOTE IS THE ONE THAT WILL BE COUNTED. PLEASE NOTE THAT IF YOUR SHARES ARE HELD OF RECORD BY A BROKER, BANK OR OTHER NOMINEE AND YOU WISH TO VOTE AT THE VIRTUAL MEETING, YOU MUST OBTAIN A LEGAL PROXY ISSUED IN YOUR NAME FROM YOUR BROKER, BANK OR OTHER NOMINEE (PREFERABLY AT LEAST FIVE DAYS BEFORE THE ANNUAL MEETING).

LEGAL MATTERS

IMPORTANT NOTICE REGARDING THE AVAILABILITY OF PROXY MATERIALS FOR THE ANNUAL MEETING OF STOCKHOLDERS TO BE HELD VIRTUALLY ON MAY 7, 2026: THIS PROXY STATEMENT, THE NOTICE OF ANNUAL MEETING OF STOCKHOLDERS AND THE ANNUAL REPORT ARE AVAILABLE AT HTTPS://WEB.VIEWPROXY.COM/ATOSSATHERAPEUTICS/2026. WE ENCOURAGE YOU TO REVIEW ALL OF THE IMPORTANT INFORMATION CONTAINED IN THE PROXY MATERIALS BEFORE VOTING.

Forward-Looking Statements. The Proxy Statement may contain "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, which statements are subject to substantial risks and uncertainties and are based on estimates and assumptions. All statements other than statements of historical fact included in the Proxy Statement are forward-looking statements, including statements about the reverse stock split, the Company's Board of Directors, corporate governance practices, executive compensation program and equity compensation utilization. In some cases, you can identify forward-looking statements by terms such as "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "design," "estimate," "predict," "potential," "plan" or the negative of these terms, and similar expressions intended to identify forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors that could cause our actual results or outcomes to differ materially from the forward-looking statements expressed or implied in the Proxy Statement. Such risks, uncertainties and other factors include those risks described in "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in the Company's most recent Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission ("SEC") and other subsequent documents we file with the SEC. The Company expressly disclaims any obligation to update or alter any statements whether as a result of new information, future events or otherwise, except as required by law.

Website References. Website references throughout this document are inactive textual references and provided for convenience only, and the content on the referenced websites is not incorporated herein by reference and does not constitute a part of the Proxy Statement.

Use of Trademarks. Atossa Therapeutics is the trademark of Atossa Therapeutics, Inc. Other names and brands may be claimed as the property of others.

Reverse Stock Split. Effective February 2, 2026, the Company effected a reverse stock split of all outstanding shares of the Company's common stock at a ratio of 15:1. Unless otherwise specified, all share amounts and related figures (as applicable) reported in this Proxy Statement are presented on a post-split basis.

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1448 NW Market Street, Suite 500
Seattle, Washington 98107

PROXY STATEMENT FOR
2026 ANNUAL MEETING OF STOCKHOLDERS
TO BE HELD ON MAY 7, 2026 AT 9:00 A.M. PACIFIC TIME

VIRTUAL MEETING
TO BE HELD LIVE VIA THE INTERNET AT: THE UNIQUE LINK THAT WILL BE EMAILED TO YOU AFTER YOU REGISTER IN ADVANCE AT HTTPS://WEB.VIEWPROXY.COM/ATOSSATHERAPEUTICS/2026

This Proxy Statement is furnished in connection with the solicitation of proxies by the Board of Directors (the "***Board***") of Atossa Therapeutics, Inc. ("***Atossa***" or the "***Company***") for use at the Company's 2026 Annual Meeting of Stockholders (the "***Annual Meeting***"). This year's Annual Meeting will be held in a virtual only meeting format via live audio webcast. You will need to register in advance to attend the Annual Meeting virtually. For more information, see "General Information— About the Meeting - What do I need to do to virtually attend the Annual Meeting via live audio webcast?" This Proxy Statement and the accompanying form of proxy will be mailed to our stockholders on or about March 30, 2026.

For a proxy to be effective, it must be properly executed and received prior to the Annual Meeting. Each proxy properly executed and tendered will, unless otherwise directed by the stockholder (in which case, such proxies will be voted as directed), be voted "FOR" each of the director nominees, "FOR" each of the other proposals described in this Proxy Statement and at the discretion of the proxy holder(s) with respect to all other matters that may properly come before the Annual Meeting or any adjournments or postponements thereof.

The Company will pay all costs of soliciting proxies. We will provide copies of this Proxy Statement, Notice of Annual Meeting and accompanying materials to brokerage firms, fiduciaries, and custodians for forwarding to beneficial owners and may reimburse these parties for their costs of forwarding these materials. Our directors, officers and employees may also solicit proxies by telephone, facsimile, or personal solicitation; however, we will not pay them additional compensation for any of these services. We have retained Alliance Advisors, a proxy solicitation firm, at an estimated cost of approximately $20,000.

Only holders of record of our common stock, par value $0.18 per share (the "c***ommon stock***"), at the close of business on March 19, 2026 (the "***Record Date***") are entitled to notice of and to vote at the Annual Meeting. On the Record Date, there were a total of 8,611,361 shares of common stock issued and outstanding. Each share of common stock is entitled to one vote on all matters to be voted upon at the Annual Meeting. Holders of common stock do not have the right to cumulative voting in the election of directors. The presence, virtually or by proxy, of the holders of one-third of the outstanding shares of common stock on the Record Date will constitute a quorum for the transaction of business at the Annual Meeting. If there is no quorum, the meeting chair or the holders of a majority of shares of common stock present at the Annual Meeting, either in person or by proxy, may adjourn the meeting to another time or date.

Persons who hold shares of common stock directly on the Record Date and not through a broker, bank or other financial institution (e.g., your shares of common stock are registered directly in your name with our transfer agent) ("***record holders***") may vote by the following methods:

- Vote by proxy - You may complete, sign and return a proxy card;
- Proxy Vote by Internet - Go to www.FCRvote.com/ATOS to complete an electronic proxy card. Have your proxy card available when you access the website. Your vote must be received by 11:59 P.M. Eastern Time on May 6, 2026 to be counted;
- Proxy Vote by Phone - You may use any touch-tone telephone to transmit your voting instructions up until 11:59 P.M. Eastern Time on May 6, 2026 by calling the toll-free number 1-866-402-3905. Have your proxy card in hand when you call and then follow the instructions; or

- Vote at the Annual Meeting - If you registered in advance to attend the Annual Meeting, you may attend the Annual Meeting and vote online during the meeting.

Persons who hold shares of common stock indirectly on the Record Date through a brokerage firm, bank, or other financial institution ("***beneficial holders***") must return a voting instruction form to have their shares voted on their behalf (or obtain a "legal proxy" to register to attend the Annual Meeting and vote during the Annual Meeting as described under "General Information—About the Meeting—What do I need to do to virtually attend the Annual Meeting via live audio webcast?"). Brokerage firms, banks or other financial institutions that do not receive voting instructions from beneficial holders will only be able to vote shares on behalf of the beneficial holders with respect to proposals considered to be "routine" and are not entitled to vote shares on behalf of beneficial holders with respect to "non-routine" proposals (referred to as a "***broker non-vote***"). Whether a proposal is considered routine or non-routine is subject to stock exchange rules and final determination by the stock exchange. Even with respect to routine matters, some brokerage firms, banks or other financial institutions are choosing not to exercise discretionary voting authority. As a result, beneficial holders are urged to direct their brokerage firm, bank or other financial institution how to vote their shares on all proposals to ensure that their votes are counted.

Abstentions and broker non-votes, if any, will be counted for the purpose of determining the presence or absence of a quorum. The required vote for each of the proposals expected to be acted upon at the Annual Meeting is described below:

Proposal No. 1 — Election of Class II directors. Directors are elected by a plurality of the votes cast, with the nominees obtaining the most votes cast being elected. Votes that are withheld and broker non-votes, if any, are not counted as votes cast and will have no effect on the outcome of the proposal.

Proposal No. 2 — Ratification of the selection of the independent registered public accounting firm. This proposal must be approved by a majority of the votes cast on the matter. As a result, abstentions and broker non-votes, if any, will have no effect on the outcome of the proposal.

Proposal No. 3 — Approval of an amendment of the Company's Certificate of Incorporation to effect, within 12 months following the date of stockholder approval and solely if the Board determines that it is necessary and advisable to maintain compliance with the minimum bid price requirements of Nasdaq, a reverse stock split of the Company's common stock at a reverse stock split ratio ranging from 2:1 to 20:1, with the exact ratio to be set within that range by the Board (**the "Reverse Stock Split Proposal"**).* This proposal must be approved by a majority of the votes cast on the matter. As a result, abstentions and broker non-votes, if any, will have no effect on the outcome of the proposal.

Proposal No. 4 — Approval, on a non-binding, advisory basis, of the compensation of the Company's named executive officers. This non-binding, advisory proposal must be approved by a majority of the votes cast on the matter. As a result, abstentions and broker non-votes, if any, will have no effect on the outcome of the proposal.

Proposal No. 5 — Approval of an adjournment of the Annual Meeting. This proposal must be approved by a majority of the votes cast on the matter. As a result, abstentions and broker non-votes, if any, will have no effect on the outcome of the proposal.

We encourage you to vote by returning your proxy or voting instruction form or if you are a record holder by voting on-line or via phone prior to the meeting. Voting in advance of the meeting helps ensure that your shares will be voted and reduces the likelihood that the Company will be forced to incur additional expenses to solicit proxies for the Annual Meeting. Any record holder of our common stock may revoke their proxy at any time prior to the closing of the polls at the Annual Meeting by:

- Executing and submitting a later-dated proxy;
- Submitting new proxy instructions via phone or the Internet;
- Delivering a written revocation to the Corporate Secretary at the address set forth above; or
- Voting online during the virtual Annual Meeting. However, your virtual attendance at the Annual Meeting will not, by itself, revoke your proxy.

**The Company is currently in compliance with the minimum bid price requirements of Nasdaq and is submitting this Proposal 3 for stockholder vote as a precautionary measure to provide additional flexibility to address any potential future deficiency with respect to the Nasdaq minimum bid price requirements.*

Your last submitted vote is the one that will be counted.

Beneficial holders of our common stock who wish to change or revoke their voting instructions should contact their brokerage firm, bank or other financial institution for information on how to do so. Beneficial holders who wish to attend the Annual Meeting virtually and vote during the virtual meeting should contact their brokerage firm, bank or other financial institution holding shares of common stock on their behalf in order to obtain a "legal proxy" (preferably at least five days before the Annual Meeting), which will allow them to register to attend the Annual Meeting and to vote during the virtual meeting. Without a legal proxy, beneficial holders cannot vote at the virtual Annual Meeting because their brokerage firm, bank or other financial institution may have already voted or returned a broker non-vote on their behalf.

FOR TECHNICAL SUPPORT PRIOR TO OR DURING THE ANNUAL MEETING, PLEASE CONTACT:
VirtualMeeting@viewproxy.com or call 1-866-612-8937

PROPOSAL NO. 1

ELECTION OF DIRECTORS

The Amended and Restated Certificate of Incorporation of the Company provides that the Board is to be divided into three classes nearly equal in number as reasonably possible, with directors in each class serving three-year terms. The total Board size is currently fixed at seven directors. Currently, the Class II directors (whose terms expire at this Annual Meeting) are Stephen J. Galli, M.D., Richard I. Steinhart and Tessa Cigler, M.D., M.P.H. If elected at the Annual Meeting, the Class II directors will hold office until the 2029 Annual Meeting of Stockholders and until their successors are duly elected and qualified, or until their earlier resignation, death or removal. The Class III Directors (whose terms expire at the 2027 Annual Meeting of Stockholders) are Shu-Chih Chen, Ph.D. and H. Lawrence Remmel, Esq. The Class I directors (whose terms expire at the 2028 Annual Meeting of Stockholders) are Steven C. Quay, M.D., Ph.D. and Jonathan F. Finn, C.F.A.

As described below, the Board has nominated Dr. Galli, Mr. Steinhart, and Dr. Cigler for election as Class II directors at the Annual Meeting. Dr. Galli and Mr. Steinhart were most recently elected by stockholders at the 2023 Annual Meeting of Stockholders. Dr. Cigler was appointed to the Board in March 2024 upon the recommendation of a member of the Nominating Committee. All the nominees have indicated their willingness and ability to serve if elected. Should any of the nominees become unavailable for election at the Annual Meeting, unable to serve or, for good cause, unwilling to serve, the persons named on the enclosed proxy as proxy holders may vote all proxies given in response to this solicitation for the election of a substitute nominee chosen by the Board, or the Board may decrease the size of the Board.

Nomination of Directors

The Nominating and Governance Committee reviews and recommends to the Board potential nominees for election to the Board. In reviewing potential nominees, the Nominating and Governance Committee considers the qualifications of each potential nominee in light of the Board's existing and desired mix of experience and expertise. Specifically, the Nominating and Governance Committee considers each potential nominee's personal and professional ethics, integrity and values, business acumen, interest in the Company, commitment to representing the long-term interests of the stockholders, leadership experience, financial expertise and industry knowledge. The Nominating and Governance Committee also seeks to have a Board that encompasses a range of talents, ages, skills, perspective, backgrounds, and expertise sufficient to provide sound and prudent oversight with respect to the operations and interests of the business.

After reviewing the qualifications of potential Board candidates, the Nominating and Governance Committee presents its recommendations to the Board, which selects the final director nominees. Upon the recommendation of the Nominating and Governance Committee, the Board nominated for election Dr. Galli, Mr. Steinhart, and Dr. Cigler as the Company's Class II directors. The Company did not pay any fees to any third parties to identify or assist in identifying or evaluating nominees for the Annual Meeting.

It is the Nominating and Governance Committee's policy to consider written recommendations from stockholders for director candidates. The Nominating and Governance Committee considers stockholder nominees in the same manner and using the same criteria as nominees recommended by other sources. Any such recommendations should be submitted to the committee as described under "Stockholder Communications" and should include the same information required under our Bylaws for nominating a director, as described under "Stockholder Proposals."

The Board and the Nominating and Corporate Governance Committee generally consider a potential director candidate's ability to contribute to the diversity of occupations, perspectives and backgrounds on the Board. As part of the search process for new directors, the Nominating and Corporate Governance Committee seeks to include, and instructs any search firm it engages to seek to include, qualified candidates with diverse backgrounds in the pool from which the Committee selects the nominees with the skills, experience and qualifications that it believes best support the Company in the context of the Board as a whole. The Nominating and Governance Committee assesses its effectiveness in balancing these considerations in connection with its annual evaluation of the composition of the Board. For example, our current Board of seven directors includes two directors who self-identify as female (28%) and 2 directors who self-identify as racially/ethnically diverse (28%).

Nominees and Incumbent Directors

The Nominating and Governance Committee has recommended, and the Board has nominated, Dr. Galli, Mr. Steinhart, and Dr. Cigler to be elected as Class II directors at the Annual Meeting. The following table sets forth the following information for these nominees and the Company's continuing directors: the year each was first elected or appointed as a director of the Company; their respective ages as of the date of this Proxy Statement; the positions currently held with the Company; the year their current terms will expire; and their current class.

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

Nominee/Director Name and Year First Became a Director	Age	Position(s) with the Company	Year Current Term Expires	Current Director Class
Nominees for Class II Directors:				
Stephen J. Galli, M.D. (2011).....	79	Director	2026	II
Richard I. Steinhart (2014)	68	Director	2026	II
Tessa Cigler, M.D., M.P.H. (2024)	52	Director	2026	II
Continuing Directors				
Shu-Chih Chen, Ph.D. (2009).....	64	Director	2027	III
H. Lawrence Remmel, Esq. (2012)	74	Lead Independent Director	2027	III
Steven C. Quay, M.D., Ph.D. (2009).....	75	Chairman of the Board, President, and Chief Executive Officer	2028	I
Jonathan F. Finn, C.F.A. (2023).....	52	Director	2028	I

Class II Director Nominees

Stephen J. Galli, M.D. Dr. Galli has served as a director of the Company since July 2011. Dr. Galli has been a Professor of Pathology and of Microbiology & Immunology and the Mary Hewitt Loveless, M.D., Professor, at Stanford University School of Medicine, Stanford, California since February 1999. He served as Chair of the Department of Pathology at Stanford University School of Medicine from 1999 to 2016. Before joining Stanford, he was on the faculty of Harvard Medical School. He holds 17 U.S. patents, has over 505 publications, and in 2025 was ranked by ScholarGPS (ID:71074738968163) as a Highly Ranked Scholar – Lifetime, in Medicine. He is the past president of the American Society for Investigative Pathology, the past president of the Collegium Internationale Allergologicum, and the past president of the Pluto Club (Association of University Pathologists). In addition to receiving several awards for his research, and being elected to the National Academy of Medicine (USA), the Accademia Nazionale de Lincei (Rome, Italy), and the American Clinical and Climatological Association, he was recognized with the 2010 Stanford University President's Award for Excellence through Diversity for his recruitment and support of women and underrepresented minorities at Stanford University. He received his B.A. degree in biology, magna cum laude, from Harvard College in 1968 and his M.D. degree from Harvard Medical School in 1973 and completed a residency in anatomic pathology at the Massachusetts General Hospital in 1977. Dr. Galli has been selected to serve on the Company's Board of Directors because of his qualifications as a professor and physician, and his specialized expertise as a pathologist.

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

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

Class III Directors Continuing in Office Until 2027

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

H. Lawrence Remmel, Esq. Mr. Remmel has served as a director of the Company since February 2012, and as our Lead Independent Director since 2024. He is currently a partner of the law firm Pryor Cashman LLP, located in New York City, where he chairs the Banking and Finance practice group. Mr. Remmel joined Pryor Cashman in 1988. His practice includes corporate and banking financings, issues relating to the Investment Company Act of 1940, and intellectual property and licensing issues, in particular in the biotechnology and biocosmeceutical areas. Mr. Remmel previously served on the Board of Advisors of CytoDel, LLC, an early-stage bio-pharmaceutical company developing products for bio-defense, neuronal drug delivery, and musculoskeletal and aesthetic medicine. In February 2018, he became a director of CytoDel, Inc., the successor to CytoDel LLC. In March 2019, he became a director of Aufbau Holdings Limited, an Irish limited company, developing therapeutics in ophthalmology and other areas. He was an associate of the law firm Reboul, MacMurray, Hewitt, Maynard & Kristol from 1984 to 1988, and began his legal career at Carter, Ledyard & Milburn, where he was an associate from 1979 to 1984. He was admitted to the New York bar in 1980 and is a member of the New York State Bar Association. He received his J.D. from the Washington & Lee University School of Law in 1979 and his B.A. from Princeton University in 1975. He currently is a doctoral candidate in the Graduate School of Life Sciences of the University of Utrecht, in the Department of Clinical and Translational Oncology, with a thesis project in novel diagnostics and therapies for early-stage breast cancer. Mr. Remmel has been selected to serve on the Company's Board of Directors because of his substantial experience as a corporate attorney advising biotechnology companies and his familiarity with the fiduciary duties and the regulatory requirements affecting publicly traded companies.

Class I Directors Continuing in Office Until 2028

Steven C. Quay, M.D., Ph.D. Dr. Quay has served as Chairman of the Board, President and Chief Executive Officer since the Company was incorporated in April 2009. Dr. Quay is certified in Anatomic Pathology with the American Board of Pathology, has completed both an internship and residency in anatomic pathology at Massachusetts General Hospital, a Harvard Medical School teaching hospital, and is a former faculty member of the Department of Pathology, Stanford University School of Medicine. Dr. Quay is a named inventor on 91 U.S. patents, 907 published US and international patent applications, and is a named inventor on patents covering seven pharmaceutical products that have been approved by the U.S. Food and Drug Administration. Dr. Quay received an M.D. in 1977 and a Ph.D. in 1975 from the University of Michigan. He received his B.A. degree in biology, chemistry and mathematics from Western Michigan University in 1971. He is a director and the Chair of the Governance Committee, of the Taipei-American School in Taipei, Taiwan. He was selected to serve on the Company's Board of Directors because of his role as a founder of the Company, as well as his qualifications as a physician and the principal researcher overseeing the research, preclinical, clinical and regulatory development of the Company's pharmaceutical programs.

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

Vote Required

Directors are elected by a plurality of the votes cast. The three director nominees who receive the highest number of affirmative votes cast will be elected as Class II directors. Votes that are withheld and broker non-votes, if any, are not counted as votes cast and will have no effect on the outcome of the matter.

Holders of proxies solicited by this Proxy Statement will vote the proxies received by them as directed on the proxy card or, if no direction is made but the card is signed, "FOR" the election of each of the director nominees named in this Proxy Statement.

THE BOARD OF DIRECTORS RECOMMENDS A VOTE "FOR" EACH OF THE DIRECTOR NOMINEES IDENTIFIED ABOVE.

PROPOSAL NO. 2

RATIFICATION OF THE SELECTION OF THE INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Our Audit Committee has selected Ernst & Young LLP ("***EY***") as our independent registered public accounting firm for the fiscal year ending December 31, 2026.

The Company is not required to submit the selection of our independent registered public accounting firm for stockholder approval but is doing so as a matter of good corporate practice. However, if the stockholders do not ratify this selection, the Audit Committee will reconsider its selection of EY. Even if the selection is ratified, our Audit Committee may direct the appointment of a different independent registered public accounting firm at any time during the year if the Audit Committee determines that the change would be in the best interests of the Company and our stockholders.

Pre-Approval Policies and Procedures

The Audit Committee reviews and pre-approves all audit and non-audit services performed by the Company's independent registered public accounting firm, as well as the fees charged for such services, in order to confirm that these services do not impair the auditor's independence. This generally involves the pre-approval of the performance of specific services subject to a cost limit for all such services. This general pre-approval is reviewed, and if necessary modified, at least annually. Management must obtain the specific prior approval of the committee for each engagement of our auditor to perform other audit-related or other non-audit services. The committee does not delegate its responsibility to approve services performed by our auditor to any member of management. The committee has delegated authority to the committee chair to pre-approve certain audit or non-audit services to be provided to us by our auditor. Any approval of services by the committee chair pursuant to this delegated authority is reported to the committee at its next regularly scheduled meeting.

EY has served as our independent auditor since May 2023. Representatives of EY are expected to be present virtually or by telephone at the Annual Meeting, will have the opportunity to make a statement if they desire to do so and are expected to be available to respond to appropriate stockholder questions.

Fees for Independent Registered Public Accounting Firm

The following is a summary of the audit fees billed and expected to be billed to the Company by EY for the fiscal years ended December 31, 2025 and 2024, and the fees billed to the Company by EY for all other services rendered during the fiscal years ended December 31, 2025 and 2024. All services associated with such fees were pre-approved by our Audit Committee in accordance with the "Pre-Approval Policies and Procedures" described above. In its review of non-audit service fees, the Audit Committee considers, among other things, the possible impact of the performance of such services on the auditor's independence. The Audit Committee has determined that the services described below were compatible with maintaining the auditor's independence. Additional information concerning the Audit Committee and its activities can be found in the following sections of this Proxy Statement: "Board Committees" and "Report of the Audit Committee."

	2025	2024
Audit Fees:		
Consists of fees billed for the audit of our annual financial statements and the review of the financial statements included in our quarterly reports on Form 10-Q, and services that are normally provided by the independent auditors in connection with statutory and regulatory filings or engagements for that fiscal year, including consents and expenses.	$ 691,854	$ 779,600
Audit-Related Fees	—	—
Tax Fees	—	—
All Other Fees:		
Consists of fees billed for the EY Atlas Subscription Fee	5,200	5,000
Total Fees	$ 697,054	$ 784,600

Vote Required

Ratification of the selection of the independent registered public accounting firm requires the affirmative vote of a majority of the votes cast on the matter. Abstentions and broker non-votes, if any, are not counted as votes cast, and they will have no effect on the outcome of the proposal.

THE BOARD OF DIRECTORS RECOMMENDS A VOTE "FOR" PROPOSAL NO. 2.

PROPOSAL NO. 3
APPROVAL OF A REVERSE STOCK SPLIT IF THE BOARD DETERMINES TO BE NECESSARY OR APPROPRIATE

We are asking our stockholders to approve an amendment to our Amended and Restated Certificate of Incorporation, as amended (the "***Certificate of Incorporation***"), which the Board has approved and declared advisable, to effect a reverse stock split (the "***Reverse Stock Split***") of all issued and outstanding shares of our common stock, at a ratio ranging from 2:1 to 20:1, inclusive, if determined necessary or appropriate by the Board ("***Proposal 3***"). Approval of this Proposal 3 gives the Board discretion, without further action by our stockholders, to determine whether to implement a Reverse Stock Split at any time within one year after the date of stockholder approval, with the specific Reverse Stock Split ratio and timing to be determined at the discretion of our Board (within the range specified above). Even if stockholders approve this Proposal 3, our Board may determine in its discretion to not effectuate any Reverse Stock Split.

The Board does not currently anticipate effectuating a Reverse Stock Split. The purpose of Proposal 3 is to give the Board the flexibility to do so in the event it is necessary or appropriate to maintain the Company's listing on the Nasdaq Stock Market ("***Nasdaq***"), and without the delay and expense of having to call a special stockholder meeting, as the Company's common stock potentially could face an immediate delisting without the benefit of a six-month grace period if the Company falls out of compliance with certain Nasdaq listing rules, as discussed below.

Background

The primary purpose of any Reverse Stock Split would be to raise the per share trading price of our common stock by reducing the number of outstanding shares in order to maintain our listing on Nasdaq. The continued listing requirements of Nasdaq provide, among other things, that our common stock must maintain a minimum closing bid price of $1.00 per share, as set forth in Nasdaq Listing Rule 5550(a)(2) (the "***Bid Price Rule***"). While we are currently in compliance with the Bid Price Rule, we have in the past, and may in the future, fail to maintain the minimum closing bid price required under the Bid Price Rule. As of the Record Date, the closing price of the Company's common stock was $5.13 per share.

Because the Company completed a reverse stock split on February 2, 2026, if the Company is determined to be non-compliant with the Bid Price Rule during the following twelve months, the Company likely would not have the benefit of a six-month grace period to regain compliance, and the Company's common stock would likely face immediate suspension and delisting, unless appealed, in accordance with Nasdaq Listing Rule 5810(c)(3)(A)(iv).

Reasons for a Reverse Stock Split (if the Board determines to be necessary or appropriate)

To maintain compliance with Nasdaq rules and maintain our stock listing. As discussed above, the primary purpose of the Reverse Stock Split is to raise the per share trading price of the Company's common stock in order to maintain its listing on Nasdaq. The Board believes that delisting from Nasdaq would adversely affect the Company's ability to raise additional financing through the public or private sale of equity securities, would significantly affect the ability of investors to trade in the Company's securities and would negatively affect the value and liquidity of the Company's common stock. Delisting may also have other negative impacts, including potential loss of employee confidence, the loss of institutional investors or interest in business development opportunities.

To potentially improve the marketability and liquidity of our common stock. The Board believes that an increased stock price may also improve the marketability and liquidity of our common stock. For example, many brokerages, institutional investors and funds have internal policies that either prohibit them from investing in low-priced stocks or tend to discourage individual brokers from recommending low-priced stocks to their customers by restricting or limiting the ability to purchase such stocks on margin. Additionally, investors may be dissuaded from purchasing stocks below certain prices because brokers' commissions, as a percentage of the total transaction value, can be higher for low-priced stocks.

To decrease the risk of market manipulation of our common stock. The Board believes that the potential increase in stock price may reduce the risk of market manipulation of our common stock, which we believe is enhanced when our stock trades below $1.00 per share. By reducing market manipulation risk, we may also thereby potentially decrease the volatility of our stock price.

To provide us with flexibility with respect to our authorized common stock. A Reverse Stock Split is expected to increase the number of authorized, but unissued and unreserved, shares of our common stock. These additional shares would provide flexibility to the Company for raising capital; repurchasing debt; providing equity incentives to employees, officers,

directors, consultants and advisors (including pursuant to our equity compensation plans); expanding our business through the acquisition of other businesses and for other purposes. However, we currently do not have any specific plans, arrangements, understandings or commitments for the additional shares that would become available.

Accordingly, for these and other reasons, the Board believes that approval of this proposal is in the best interests of the Company and our stockholders.

Criteria to be Used for Determining Whether to Implement a Reverse Stock Split

Proposal 3 gives the Board discretion to select a Reverse Stock Split ratio from within a range between and including 2:1 and 20:1 based on the Board's then-current assessment of the best interests of the Company and stockholders. In determining whether to implement the Reverse Stock Split, and which ratio to implement, if any, the Board may consider, among other factors:

- the historical trading price and trading volume of our common stock;
- the then-prevailing trading price and trading volume of our common stock and the expected impact of the Reverse Stock Split on the trading market in the short- and long-term;
- the continued listing requirements for our common stock on Nasdaq or other applicable exchanges;
- the number of shares of common stock outstanding;
- administrative costs to the Company; and
- prevailing industry, market and economic conditions.

Certain Risks and Potential Disadvantages Associated with a Reverse Stock Split

We cannot assure stockholders that any Reverse Stock Split will sufficiently increase our stock price to maintain compliance with Nasdaq's Bid Price Rule or be completed before Nasdaq commences delisting procedures. The effect of a Reverse Stock Split on our stock price cannot be predicted with any certainty, and the history of reverse stock splits for other companies in our industry is varied, particularly since some investors may view a reverse stock split negatively. It is possible that our stock price after a Reverse Stock Split will not increase in the same proportion as the reduction in the number of shares outstanding, causing a reduction in the Company's overall market capitalization. Further, even if we implement a Reverse Stock Split, our stock price may decline due to various factors, including our future performance and general industry and market or economic conditions. This percentage decline, as an absolute number and as a percentage of our overall market capitalization, may be greater than would occur in the absence of a Reverse Stock Split. If we fail to meet any of Nasdaq's listing requirements, Nasdaq may suspend trading and commence delisting proceedings.

The proposed Reverse Stock Split may decrease the liquidity of our common stock and result in higher transaction costs. The liquidity of our common stock may be negatively affected by the reduced number of shares outstanding after the Reverse Stock Split, which would be exacerbated if the stock price does not increase following the split. In addition, a Reverse Stock Split would increase the number of stockholders owning "odd lots" of fewer than 100 shares, trading in which generally results in higher transaction costs. Accordingly, a Reverse Stock Split may not achieve the desired results of increasing marketability and liquidity as described above.

The implementation of a Reverse Stock Split would result in an effective increase in the authorized number of shares of common stock available for issuance, which could, under certain circumstances, have anti-takeover implications. The additional shares of common stock available for issuance could be used by the Company to oppose a hostile takeover attempt or to delay or prevent changes in control or in our management. Although the Reverse Stock Split has been prompted by business and financial considerations, and not by the threat of any hostile takeover attempt (nor is the Board currently aware of any such attempts directed at us), stockholders should be aware that approval of the Reverse Stock Split could facilitate future efforts by us to deter or prevent changes in control, including transactions in which stockholders might otherwise receive a premium for their shares over then-current market prices.

Stockholders should also keep in mind that the implementation of a Reverse Stock Split does not have an effect on the actual or intrinsic value of our business or a stockholder's proportional ownership interest (subject to the treatment of fractional shares). However, should the overall value of our common stock decline after a Reverse Stock Split, then the

actual or intrinsic value of shares held by stockholders will also proportionately decrease as a result of the overall decline in value.

Effects of a Reverse Stock Split

As of the Effective Date (as defined below):

- each 2 to 20 shares of common stock outstanding (depending on the Reverse Stock Split ratio selected by the Board) will be combined, automatically and without any action on the part of the Company or its stockholders, into one new share of common stock;
- no fractional shares of common stock will be issued; instead, stockholders who would otherwise receive a fractional share will receive cash in lieu of the fractional share (as detailed below);
- proportionate adjustments will be made to the number of shares issuable upon the exercise of all then-outstanding stock options, which will result in a proportional decrease in the number of shares of common stock reserved for issuance upon exercise of such stock options and a proportional increase in the exercise price of all such stock options;
- the number of shares of common stock then reserved for issuance under our equity compensation plans will be reduced proportionately; and
- the number of shares of common stock then reserved for issuance pursuant to the Company's Series B Convertible Preferred Stock will be reduced proportionately and the conversion price will be increased proportionately.

The following table summarizes, for illustrative purposes only, the anticipated effects of a Reverse Stock Split on our shares available for issuance based on information as of March 1, 2026 and without giving effect to the treatment of fractional shares:

Status	Number of Shares of Common Stock Authorized	Number of Shares of Common Stock Issued and Outstanding	Number of Shares of Common Stock Reserved for Future Issuance	Number of Shares of Common Stock Authorized but Unissued and Unreserved
Pre-Reverse Stock Split	350,000,000	8,611,361	2,255,684	339,132,955
Post-Reverse Stock Split 2:1	350,000,000	4,305,681	1,127,842	344,566,478
Post-Reverse Stock Split 10:1	350,000,000	861,136	225,568	348,913,296
Post-Reverse Stock Split 20:1	350,000,000	430,568	112,784	349,456,648

A Reverse Stock Split would affect all stockholders uniformly. As of the Effective Date, each stockholder would own a reduced number of shares of common stock. Percentage ownership interests, voting rights and other rights and preferences would not be affected, except to the extent that the Reverse Stock Split would result in fractional shares (as described below).

A Reverse Stock Split would not affect the registration of our common stock under Section 12(b) of the Securities Exchange Act of 1934, as amended (the "***Exchange Act***"), and we would continue to be subject to the periodic reporting and other requirements of the Exchange Act. Barring delisting by Nasdaq, our common stock would continue to be listed on Nasdaq under the symbol "ATOS," but would have a new Committee on Uniform Securities Identification Procedures (CUSIP) number after the Effective Date.

Cash Payment In Lieu of Fractional Shares

The Company will not issue any fractional shares of common stock as a result of the Reverse Stock Split. In lieu of any fractional shares to which a stockholder of record would otherwise be entitled, the Company will pay cash (without interest and subject to withholding taxes, as applicable) equal to such fraction multiplied by the closing price of our common stock on Nasdaq on the first business day immediately preceding the Effective Date (as adjusted in good faith by the Company to

account for the Reverse Stock Split ratio). After the Effective Date, a stockholder otherwise entitled to a fractional interest will not have any voting, dividend or other rights with respect to such fractional interest, except to receive such cash payment.

Additionally, under the escheat laws of the various jurisdictions where stockholders may reside, where the Company is domiciled or where the cash payment may be deposited, sums due for fractional interests that are not timely claimed after the Effective Date may be required to be paid to the designated agent for such jurisdiction, unless correspondence has been received by us or the transfer agent concerning ownership of such funds within the specified time period. Thereafter, stockholders otherwise entitled to receive such payments would need to seek them directly from the state to which they were paid.

As of March 1, 2026, there were 33 common stockholders of record. After the Effective Date, stockholders owning less than a whole share will no longer be stockholders. We do not intend for this transaction to be the first step in a series of plans or proposals of a "going private transaction" within the meaning of Rule 13e-3 of the Exchange Act.

Procedure for Effecting a Reverse Stock Split

Beneficial holders of common stock. Stockholders who hold their shares through a bank, broker or other nominee will be treated in the same manner as registered stockholders (who hold their shares in their names). Banks, brokers and other nominees will be instructed to effect the Reverse Stock Split for beneficial owners of such shares. However, banks, brokers or other nominees may implement different procedures than those to be followed by registered stockholders for processing the Reverse Stock Split, particularly with respect to the treatment of fractional shares. Stockholders whose shares of common stock are held in the name of a bank, broker or other nominee are encouraged to contact their bank, broker or other nominee with any questions regarding the procedures for implementing the Reverse Stock Split with respect to their shares.

Registered holders of common stock. Registered stockholders who hold shares electronically in book-entry form under the direct registration system (i.e., do not have stock certificates evidencing their share ownership but instead have a statement reflecting the number of shares registered in their accounts) do not need to take any action to receive post-split shares. If they are entitled to receive post-split shares, they will automatically receive, at their address of record, a transaction statement indicating the number of post-split shares held following the Effective Date. Registered stockholders who hold their shares in certificated form should contact the Company's transfer agent, VStock Transfer, LLC, via telephone at: (212) 828-8436 or by email at: action@vstocktransfer.com to receive instructions on how to receive an updated certificate.

U.S. Federal Income Tax Considerations

The following discussion is a summary of U.S. federal income tax considerations to U.S. Holders (as defined below) of our common stock of the Reverse Stock Split. The discussion does not purport to be a complete analysis of all potential tax considerations. The considerations of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local or non-U.S. tax laws, are not discussed. This discussion is based on the U.S. Internal Revenue Code of 1986, as amended (the "***Code***"), Treasury Regulations promulgated under the Code, judicial decisions and published rulings and administrative pronouncements of the Internal Revenue Service (the "***IRS***"), in each case in effect as of the date of this filing. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a U.S. Holder. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position to that discussed below regarding the tax considerations of the Reverse Stock Split.

This discussion is limited to a U.S. Holder that holds our common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax considerations relevant to a U.S. Holder's particular circumstances, including without limitation the effect of the Medicare contribution tax on net investment income, the alternative minimum tax or the special tax accounting rules under Section 451(b) of the Code. In addition, it does not address considerations relevant to U.S. Holders subject to special rules, such as:

- U.S. expatriates and former citizens or long-term residents of the United States;
- U.S. Holders whose functional currency is not the U.S. dollar;
- persons holding our common stock as part of a hedge, straddle or other risk-reduction strategy or as part of a conversion transaction or other integrated investment;

- banks, insurance companies and other financial institutions;
- real estate investment trusts or regulated investment companies;
- brokers, dealers or traders in securities or other persons that elect to use a mark-to-market method of accounting for their holdings in our common stock;
- partnerships or other entities or arrangements classified as partnerships, disregarded entities for U.S. federal income tax purposes (and investors therein), S corporations or other passthrough entities (including hybrid entities);
- tax-exempt organizations or governmental organizations;
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- tax-qualified retirement plans; and
- persons that own, or have owned, actually or constructively, more than 5% of our common stock.

If an entity or arrangement classified as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner in the partnership will depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. Accordingly, a partnership holding our common stock and each partner in such partnership is urged to consult its tax advisor regarding the U.S. federal income tax considerations to it of the Reverse Stock Split.

For purpose of this discussion, a "U.S. Holder" is any beneficial owner of our common stock that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized under the laws of the United States, any state thereof or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that: (i) is subject to the primary supervision of a U.S. court and the control of one or more "United States persons" (within the meaning of Section 7701(a)(30) of the Code); or (ii) has a valid election in effect to be treated as a U.S. person for U.S. federal income tax purposes.

This discussion is for informational purposes only and is not tax advice. Each U.S. Holder is urged to consult its tax advisor with respect to the application of the U.S. federal income tax laws to its particular situation as well as any tax considerations of the Reverse Stock Split arising under U.S. federal estate or gift tax laws, the laws of any state, local or non-U.S. taxing jurisdiction or any applicable income tax treaty.

Tax Consequences of the Reverse Stock Split

The Reverse Stock Split is intended to qualify as a "recapitalization" for U.S. federal income tax purposes pursuant to Section 368(a)(1)(E) of the Code. As a result, assuming the Reverse Stock Split qualifies as a recapitalization, a U.S. Holder generally should not recognize gain or loss upon the Reverse Stock Split, except with respect to cash received in lieu of a fractional share of our common stock, as discussed below. A U.S. Holder's aggregate adjusted tax basis in the shares of our common stock received pursuant to the Reverse Stock Split should equal the aggregate adjusted tax basis of the shares of our common stock surrendered (excluding any portion of such basis that is allocated to any fractional share of our common stock), and such U.S. Holder's holding period in the shares of our common stock received should include the holding period in the shares of our common stock surrendered. U.S. Treasury Regulations provide detailed rules for allocating the tax basis and holding period of the shares of our common stock surrendered to the shares of our common stock received in a recapitalization pursuant to the Reverse Stock Split.

Each U.S. Holder of shares of our common stock acquired on different dates and at different prices is urged to consult its tax advisor regarding the allocation of the tax basis and holding period of such shares.

Cash in Lieu of Fractional Shares

A U.S. Holder that receives cash in lieu of a fractional share of our common stock pursuant to the Reverse Stock Split should recognize capital gain or loss in an amount equal to the difference between the amount of cash received and the U.S. Holder's tax basis in the shares of our common stock surrendered that is allocated to such fractional share of our common stock. Such capital gain or loss should be long-term capital gain or loss if the U.S. Holder's holding period for our common stock surrendered exceeded one year on the Effective Date. The deductibility of net capital losses by individuals and corporations is subject to limitations. Depending on a U.S. Holder's individual facts and circumstances, it is possible that the receipt of cash in lieu of a fractional share by such U.S. Holder may instead be treated as a distribution under Section 301 of the Code. Each U.S. Holder is urged to consult its tax advisor regarding that possibility and the considerations of the receipt of cash in lieu of a fractional share being treated as a distribution under Section 301 of the Code.

Tax Reporting Regarding the Reverse Stock Split

Assuming the Reverse Stock Split qualifies as a recapitalization within the meaning of Section 368(a) of the Code, each U.S. Holder who receives shares of our common stock in the Reverse Stock Split is required to retain permanent records pertaining to the Reverse Stock Split and make such records available to any authorized IRS officers and employees. Such records should specifically include information regarding the amount, basis and fair market value of all transferred property and relevant facts regarding any liabilities assumed or extinguished as part of such reorganization. Each U.S. Holder who owned at least 5% of our outstanding common stock or who owned our securities with a basis of $1,000,000 or more as of immediately prior to the Effective Date are required to attach a statement to such U.S. Holder's tax returns for the year in which the Reverse Stock Split is consummated that contains the information listed in Treasury Regulations Section 1.368-3(b). Such statement must include the U.S. Holder's tax basis in the U.S. Holder's common stock and the fair market value of such stock. Each U.S. Holder is urged to consult with its tax advisor regarding its compliance with these rules.

Information Reporting and Backup Withholding

Payments of cash in lieu of a fractional share of our common stock may, under certain circumstances, be subject to information reporting and backup withholding. To avoid backup withholding, each stockholder that does not otherwise establish an exemption should furnish its taxpayer identification number to the applicable withholding agent and comply with the applicable certification procedures. Backup withholding is not an additional tax. Any amounts withheld will be allowed as a credit against the stockholder's U.S. federal income tax liability and may entitle such stockholder to a refund, provided the required information is timely furnished to the IRS. Each stockholder is urged to consult its tax advisor regarding such stockholder's qualification for an exemption from backup withholding and the procedures for obtaining such an exemption.

Accounting Consequences

The par value per share of our common stock will remain unchanged at $0.18 per share following a Reverse Stock Split. As a result, as of the Effective Date, the stated capital on the Company's balance sheets attributable to common stock will be reduced proportionally based on the Reverse Stock Split ratio, and the additional paid-in capital will be credited with the amount by which the capital is reduced. The net income or loss per share of common stock will be increased as a result of the fewer shares of common stock outstanding. The Reverse Stock Split will be reflected retroactively in our consolidated financial statements.

Effectiveness of Amendment

If approved by stockholders and implemented by the Board, the Reverse Stock Split will become effective upon the filing of the Certificate of Amendment with the Secretary of State of the State of Delaware, or such later date as is chosen by the Board and set forth in the Certificate of Amendment (the "***Effective Date***"). We will publicly announce the Reverse Stock Split ratio chosen by the Board prior to the Effective Date. The effectiveness of this amendment or the abandonment thereof, notwithstanding stockholder approval, will be determined by the Board, at its sole option, at any time within the one year period following stockholder approval at the Annual Meeting. The text of the proposed form of Certificate of Amendment to our Certificate of Incorporation (the "***Certificate of Amendment***") is attached hereto as Appendix A.

No Dissenter's or Appraisal Rights

Under the Delaware General Corporation Law, stockholders are not entitled to dissenter's or appraisal rights with respect to Proposal 3, or the corresponding amendment to our Certificate of Incorporation.

Interest of Certain Persons in Matter to be Acted Upon

No officer or director has any substantial interest, direct or indirect, by security holdings or otherwise, in Proposal 3 that is not shared by all other stockholders.

Vote Required

The approval of this proposal requires the affirmative vote of a majority of the votes cast on the matter. Abstentions and broker non-votes, if any, are not counted as votes cast, and they will have no effect on the outcome of the proposal.

THE BOARD OF DIRECTORS RECOMMENDS A VOTE "FOR" PROPOSAL NO. 3.

PROPOSAL NO. 4
APPROVAL, ON A NON-BINDING ADVISORY BASIS, OF EXECUTIVE COMPENSATION

Background

In accordance with the requirements of the Dodd-Frank Wall Street Reform and Consumer Protection Act (the "***Dodd-Frank Act***") and Section 14A of the Exchange Act, we are providing our stockholders with the opportunity to cast a non-binding, advisory vote to approve the compensation of our named executive officers (the "***say-on-pay***" vote).

The say-on-pay vote is a non-binding, advisory vote on the compensation of the Company's "named executive officers," as described in this Proxy Statement under the caption "Executive Compensation," including in the tabular disclosure regarding such compensation and in the accompanying narrative disclosure. The say-on-pay vote is not a vote on the Company's general compensation policies or the compensation of the Company's Board.

Our philosophy in setting compensation policies for executive officers has two fundamental objectives: (1) to attract and retain a highly skilled team of executives and (2) to align our executives' interests with those of our stockholders by rewarding short-term and long-term performance and tying compensation to increases in stockholder value. The Compensation Committee believes in a pay-for-performance culture, meaning that executive compensation should be directly linked both to improvements in corporate performance and accomplishments that are expected to increase stockholder value.

The vote under this Proposal No. 4 is advisory, and therefore not binding on the Company, the Board or our Compensation Committee. However, our Board, including our Compensation Committee, values the opinions of our stockholders and, to the extent there is any significant vote against the executive officer compensation as disclosed in this Proxy Statement, we will consider the outcome of the vote when making future compensation decisions for our named executive officers.

We are required to hold a say-on-pay vote at least once every three years, and our Board's current policy is to hold a say-on-pay vote on an annual basis. Unless the Board modifies its policy on the frequency of holding say-on-pay advisory votes, after the Annual Meeting, the next say-on-pay vote is expected to occur at our 2027 Annual Meeting of Stockholders.

Vote Required

The non-binding, advisory approval of this proposal requires the affirmative vote of a majority of the votes cast on the matter. Abstentions and broker non-votes, if any, are not counted as votes cast, and they will have no effect on the outcome of the proposal.

THE BOARD OF DIRECTORS RECOMMENDS AN ADVISORY VOTE "FOR" PROPOSAL NO.4

PROPOSAL NO. 5

APPROVAL OF THE ADJOURNMENT OF THE ANNUAL MEETING, IF NECESSARY OR APPROPRIATE, TO SOLICIT ADDITIONAL PROXIES

General

We may ask stockholders to vote on a proposal to adjourn the Annual Meeting, if necessary or appropriate, to solicit additional proxies if there are insufficient votes at the time of the Annual Meeting to adopt the other proposals. In that event, stockholders will be asked to vote only upon this proposal and not on any other matter. If this proposal is approved, the Board may in its discretion, if necessary or appropriate, adjourn the Annual Meeting to use the additional time to solicit additional proxies in favor of the other proposals.

Vote Required

The approval of this proposal requires the affirmative vote of a majority of the votes cast on the matter. Abstentions and broker non-votes, if any, are not counted as votes cast, and they will have no effect on the outcome of the proposal.

THE BOARD OF DIRECTORS RECOMMENDS A VOTE "FOR" PROPOSAL NO. 5.

CORPORATE GOVERNANCE

Our business affairs are managed under the direction of our Board. Our Board has adopted a set of Principles of Corporate Governance as a framework for the governance of the Company, which is posted on our website located at *https://atossatherapeutics.com/investors/* under "Governance."

Director Independence

We believe that the Company benefits from having a strong and independent Board. For a director to be considered independent, the Board must determine, in accordance with the Nasdaq listing rules, that the director does not have any direct or indirect material relationship with the Company that would affect his or her exercise of independent judgment. On an annual basis, the Board reviews the independence of all directors under guidelines established by Nasdaq and in light of each director's background, employment and affiliations with the Company and members of management, as well as significant holdings of Company securities considering all known relevant facts and circumstances. Based on this review, the Board has made an affirmative determination that all current directors, other than Drs. Quay and Chen, are "independent directors" as defined under the Nasdaq listing rules. The Board determined that Dr. Quay is not independent because of his service as the Company's President and Chief Executive Officer and that Dr. Chen is not independent because of her marriage to Dr. Quay. The independent board members meet regularly in executive sessions without the non-independent members and without management present.

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

Corporate Code of Business Conduct and Ethics

We believe that our Board and committees, led by a group of strong and independent directors, provide the necessary leadership, wisdom and experience that the Company needs in making sound business decisions. We have adopted a Code of Business Conduct and Ethics (the "Code of Conduct") that applies to all of our officers, directors and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. Our Code of Conduct helps clarify the operating standards and ethics that we expect of all of our officers, directors and employees. Our Code of Conduct is posted on our website located at *https://atossatherapeutics.com/investors/* under "Governance." We intend to disclose future amendments to certain provisions of the Code of Conduct, and waivers of the Code of Conduct granted to executive officers and directors, on the website within four business days following the date of the amendment or waiver.

Stockholder Communications

Generally, stockholders and other interested parties who have questions or concerns regarding the Company should contact our Corporate Secretary at IR@atossainc.com. However, any party who wishes to address questions regarding the business or affairs of the Company directly with the Board, or any individual director, should direct his or her questions in writing to the Corporate Secretary, Atossa Therapeutics, Inc., 1448 NW Market Street, Suite 500, Seattle, WA 98107. Upon receipt of any such communications, the correspondence will be reviewed by our Corporate Secretary, who will determine whether the communication is appropriate for presentation to the Board or the individual director, and if so determined by our Corporate Secretary, will be directed to the appropriate person, including individual directors. The purpose of this screening is to allow the Board to avoid having to consider irrelevant or inappropriate communications (such as advertisements, solicitations and hostile communications).

BOARD OF DIRECTORS AND COMMITTEES

Director Attendance

During fiscal 2025, our Board met eight times and each director attended at least 75% of the aggregate number of meetings of the Board and of the committees on which he or she was a member (during the period in which he or she was on the Board or committee). Directors attended, on average, 96% of the meetings.

The Company encourages all directors to attend Annual Meetings of Stockholders, absent unusual circumstances. All members of the Board were present virtually or by telephone at the 2025 Annual Meeting of Stockholders.

Board Leadership Structure

We do not have a policy regarding whether the roles of Chairman of the Board and the Chief Executive Officer should be separate or combined, and our Board believes that the Company should maintain its flexibility to determine the appropriate leadership structure, from time to time, based on criteria that are in the Company's best interests and the best interests of the Company's stockholders. As such, the Board periodically reviews its leadership structure to evaluate whether the structure remains appropriate for the Company, and may modify this structure from time to time as and when appropriate to best address the Company's unique circumstances and advance the best interests of all stockholders. At any time when the Chairman is not independent, the independent directors of the Board will designate an independent director to serve as lead independent director for a period of at least one year.

The Board currently combines the role of Chairman of the Board with the role of Chief Executive Officer, and the independent directors have appointed Mr. Remmel to serve as our Lead Independent Director. The Board believes this leadership model, together with five of the other six Board members being independent, all key committees of the Board being comprised solely of, and chaired by, independent directors, and the Company's established Principles of Corporate Governance, provides an effective leadership structure for the Company. Combining the Chairman and Chief Executive Officer roles fosters clear accountability, effective decision-making, and aligns corporate strategy with the Company's day-to-day operations, while our Lead Independent Director provides independent Board oversight of management. Dr. Quay has served as Chairman, President, and Chief Executive Officer since the Company was incorporated in April 2009. The independent directors believe that because Dr. Quay manages the Company on a day-to-day basis as Chief Executive Officer and President, his direct involvement in the Company's operations makes him uniquely qualified to lead the Board in effective decision-making and to efficiently align the Company's day-to-day operations with the Board's objectives. In addition, to further foster effective independent oversight of the Company, the Board holds executive sessions of the independent directors of the Board at every meeting.

The Lead Independent Director's responsibilities include: (a) presiding at meetings of the Board at which the Chairman of the Board is not present, including executive sessions of the independent directors; (b) approving information sent to the Board; (c) approving the agenda and schedule for Board meetings so that there is sufficient time for discussion of all agenda items; (d) serving as a liaison between the Chairman of the Board and the independent directors; and (e) being available for consultation and communication with major stockholders upon request. The Lead Independent Director also has the authority to call executive sessions of the independent directors.

The Board believes that its programs for overseeing risks, as described below, would be effective under a variety of leadership frameworks. Accordingly, the Board's risk oversight function did not significantly impact its selection of the current leadership structure.

Board Risk Oversight

The Board has overall responsibility for the oversight of the Company's risk management process, which is designed to support the achievement of organizational objectives, including strategic objectives, to improve long-term organizational performance and enhance stockholder value. Risk management includes not only understanding Company-specific risks and the steps management implements to manage those risks, but also what level of risk is acceptable and appropriate for the Company. Management is responsible for establishing our business strategy, identifying, and assessing the related risks and implementing appropriate risk management practices. The Board periodically reviews our business strategy and management's assessment of the related risks, including risks related to cybersecurity and information technology matters, and discusses with management the appropriate level of risk for the Company. The Board also delegates oversight to Board committees to oversee selected elements of risk as set forth below.

Board Committees

Our Board has a separately designated Audit Committee, Compensation Committee and Nominating and Governance Committee. Members serve on these committees until their resignation or until otherwise determined by our Board. Each of these committees is comprised solely of independent directors, is empowered to retain outside advisors as it deems appropriate and regularly reports its activities to the full Board.

Audit Committee. The Audit Committee is comprised of Mr. Steinhart (Chairman), Mr. Finn, Mr. Remmel and Dr. Galli. The Audit Committee selects the Company's independent registered public accounting firm, approves its compensation, oversees and evaluates the performance of the independent registered public accounting firm, oversees the accounting and financial reporting policies and internal control systems of the Company, reviews the Company's interim and annual financial statements, independent registered public accounting firm reports and management letters and performs other duties, as specified in the Audit Committee Charter, a copy of which is available on the Company's website at *www.atossatherapeutics.com.* Additionally, the Audit Committee is involved in the oversight of the Company's risk management through its review of the Company's practices relating to risk assessment and management, and in particular, its oversight of risks related to the Company's financial statements and financial reporting process, compliance and information technology and cybersecurity. The Audit Committee met four times in fiscal 2025. All members of the Audit Committee satisfy the heightened independence standards under the Nasdaq listing rules and the rules and regulations established by the SEC applicable to directors serving on audit committees. The Board has determined that Mr. Steinhart qualifies as an "audit committee financial expert," as that term is defined in the rules and regulations established by the SEC, and all members of the Audit Committee are "financially literate" under Nasdaq listing rules.

Compensation Committee. The Compensation Committee is comprised of Mr. Remmel (Chairman), Mr. Steinhart and Dr. Galli. The Compensation Committee reviews and recommends the compensation arrangements for management or approves such arrangements if so directed by the Board, establishes and reviews general compensation policies, administers the Company's equity compensation plans and reviews and recommends to the Board the compensation paid to non-employee directors for their service on the Board. Our Chief Executive Officer makes recommendations to the Compensation Committee regarding corporate and individual performance goals and objectives relevant to executive compensation and executives' performance in light of such goals and objectives and recommends other executives' compensation levels to the Compensation Committee based on such evaluations. The Compensation Committee may delegate authority to grant awards under our equity compensation plan to the Chief Executive Officer, but it has not historically done so. The Compensation Committee considers these recommendations and then makes an independent decision regarding officer compensation levels and awards. The Chief Executive Officer is not present when his compensation is evaluated. The Compensation Committee has the authority to engage outside advisors, such as compensation consultants, to assist it in carrying out its responsibilities. The Compensation Committee engaged Aon Consulting Inc. ("Aon") (the "***Compensation Consultant***") in 2025 to provide advice regarding the amount and form of executive and director compensation. The Compensation Committee met five times in fiscal 2025. A copy of the Compensation Committee Charter is available on the Company's website at *www.atossatherapeutics.com*. All members of the Compensation Committee satisfy the heightened independence standards under the Nasdaq listing rules and the rules and regulations established by the SEC applicable to directors serving on compensation committees.

Compensation Committee Interlocks

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

Nominating and Governance Committee. The Nominating and Governance Committee is comprised of Dr. Galli (Chairman), Dr. Cigler, Mr. Finn and Mr. Remmel. The Nominating and Governance Committee identifies and nominates candidates for election to the Board, establishes procedures under which stockholders may recommend a candidate for consideration for nomination as a director, annually reviews and evaluates the performance, size, structure, composition and functioning of the Board and periodically assesses and reviews the Company's Principles of Corporate Governance and recommends any appropriate changes to the Board. The Nominating and Governance Committee met one time in fiscal 2025. A copy of the Nominating and Governance Committee Charter is available on our website at *www.atossatherapeutics.com*. All members of the Nominating and Governance Committee satisfy the independence standards under the Nasdaq listing rules.

EXECUTIVE OFFICERS

Our current executive officers and their respective ages and positions as of the date of this Proxy Statement are set forth in the following table. Biographical information for Dr. Quay is set forth above under Proposal No. 1 (Election of Directors).

Name	Age	Position
Executive Officers:		
Steven C. Quay, M.D., Ph.D [(1)]	75	Chairman of the Board, President and Chief Executive Officer
Mark J. Daniel	50	Chief Financial Officer

(1) For Dr. Quay's biographical information, see "Nominees and Incumbent Directors" above

Mark J. Daniel. Mr. Daniel has served as the Company's Chief Financial Officer since October 2025. Mr. Daniel is a senior finance leader with more than 25 years of experience building the forecasting cadence, systems, and public-company discipline that support revenue scale in global life-science businesses. Most recently, from 2017 until 2025, Mr. Daniel served as Senior Vice President, Finance at Bruker Spatial Biology, Inc. (formerly Nanostring Technologies, Inc.), a provider of gene expression profiling and spatial multiomics solutions. From 2014 until 2016, Mr. Daniel served as Chief Financial Officer of Newyu, Inc. Mr. Daniel serves as an independent member of the Board of National Fiduciary Trust, Inc., a trust services company in the State of Washington. Mr. Daniel has more than 20 years of experience working at publicly listed companies (NASDAQ and LSE) with oversight responsibility for all areas of accounting, finance, tax, treasury and risk management for operations in the United States as well as Europe, Asia and South America. Mr. Daniel earned a B.S. degree in Business Administration, Accounting Emphasis from Washington State University.

SECURITY OWNERSHIP OF BENEFICIAL OWNERS AND MANAGEMENT

Based on information available to us and filings with the SEC, the following table sets forth certain information regarding the beneficial ownership (as defined by Rule 13d-3 under the Exchange Act) of our outstanding common stock for (i) each of our directors and nominees, (ii) each of our "named executive officers," as defined in the "Executive Compensation" section below and (iii) all of our current directors and executive officers as a group. As of March 1, 2026, there are no persons known to us to beneficially hold more than 5% of our outstanding common stock. The following information is presented as of March 1, 2026 or such other date as may be reflected below.

Beneficial ownership and percentage ownership are determined in accordance with the rules of the SEC and include voting or investment power with respect to shares of common stock. This information does not necessarily indicate beneficial ownership for any other purpose. Under these rules, shares of common stock issuable pursuant to stock options that are exercisable within 60 days of March 1, 2026, as well as convertible preferred stock, are deemed outstanding for the purpose of computing the percentage ownership of the person holding the options or convertible preferred stock, but are not deemed outstanding for the purpose of computing the percentage ownership of any other person. To our knowledge and subject to applicable community property rules, and except as otherwise indicated below, the persons and entities named in the table have sole voting and sole investment power with respect to all shares beneficially owned. Unless otherwise noted, the address of each person listed on the table is c/o Atossa Therapeutics, Inc., 1448 NW Market Street, Suite 500, Seattle, Washington 98107.

	Shares Beneficially Owned	
Name of Beneficial Owner	**Number**	**Percent of Class [1]**
Steven C. Quay, M.D., Ph.D.[2]	776,380	8.3%
Shu-Chih Chen, Ph.D.[3]	40,608	*
Tessa Cigler, M.D., M.P.H. [4]	15,972	*
Mark J. Daniel	—	—
Jonathan F. Finn, C.F.A.[5]	20,417	*
Stephen J. Galli, M.D.[6]	39,012	*
Heather Rees, CPA (inactive)[7]	—	—
H. Lawrence Remmel, Esq.[8]	681	*
Richard I. Steinhart[9]	38,884	*
All current executive officers and directors as a group (8 persons)[10]	930,470	9.8%

* Less than one percent.

(1) Based on 8,611,361 shares of common stock issued and outstanding as of March 1, 2026.
(2) Consists of (i) 927 shares of common stock directly owned by Dr. Quay, (ii) 1,484 shares of common stock owned by Ensisheim Partners LLC ("Ensisheim"), (iii) 773,817 shares of common stock issuable upon the exercise of stock options held by Dr. Quay and exercisable within 60 days of March 1, 2026 and (iv) 8 shares of Series B Convertible Preferred Stock convertible into 152 shares of common stock. Drs. Quay and Chen share voting and investment power over the securities held by Ensisheim. Ensisheim is solely owned and controlled by Drs. Quay and Chen, and, as a result, Drs. Quay and Chen are deemed to be beneficial owners of the shares held by this entity.
(3) Consists of (i) 1,484 shares of common stock owned by Ensisheim, (ii) 38,972 shares of common stock issuable upon the exercise of stock options held by Dr. Chen and exercisable within 60 days of March 1, 2026 and (iii) 8 shares of Series B Convertible Preferred Stock convertible into 152 shares of common stock. Drs. Quay and Chen share voting and investment power over the securities held by Ensisheim. Ensisheim is solely owned and controlled by Drs. Quay and Chen, and, as a result, Drs. Quay and Chen are deemed to be beneficial owners of the shares held by this entity.
(4) Consists of 15,972 shares of common stock issuable upon the exercise of stock options held by Dr. Cigler and exercisable within 60 days of March 1, 2026.
(5) Consists of (i) 1,667 shares of common stock and (ii) 18,750 shares of common stock issuable upon the exercise of stock options held by Mr. Finn and exercisable within 60 days of March 1, 2026.
(6) Consists of (i) 7 shares of common stock and (ii) 39,005 shares of common stock issuable upon the exercise of stock options held by Dr. Galli and exercisable within 60 days of March 1, 2026.
(7) Ms. Rees stepped down as our Chief Financial Officer on October 14, 2025. Her stock options expired as of March 31, 2026.
(8) Consists of 681 shares of common stock held by Mr. Remmel.
(9) Consists of 38,884 shares of common stock issuable upon the exercise of stock options held by Mr. Steinhart and exercisable within 60 days of March 1, 2026.

(10) Consists of (i) 4,766 shares of common stock, (ii) 925,400 shares of common stock issuable upon the exercise of stock options exercisable within 60 days of March 1, 2026 and (iii) 8 shares of Series B Convertible Preferred Stock convertible into 304 shares of common stock.

DELINQUENT SECTION 16(A) REPORTS

Section 16(a) of the Exchange Act requires our directors, officers and persons who beneficially own more than 10% of a registered class of our equity securities to file with the SEC initial reports of ownership and reports of changes in ownership of our common stock and other equity securities. To our knowledge, based solely on our review of Forms 3, 4 and 5 filed with the SEC or written representations that no Form 5 was required, during the year ended December 31, 2025, we believe that our directors, officers and persons who beneficially own more than 10% of a registered class of our equity securities timely filed all reports required under Section 16(a) of the Exchange Act, except that, due to administrative delays in receiving EDGAR filer codes, one Form 4 to report a grant of stock options was filed late with respect to Mark J. Daniel.

CERTAIN RELATIONSHIPS AND RELATED-PARTY TRANSACTIONS

Transactions with Related Parties

Other than compensation arrangements described below under the captions "Director Compensation" and "Executive Compensation," since January 1, 2024, we have not been a party to any related party transactions within the meaning of the SEC rules.

Related-Party Transaction Review and Approval

Related party transactions that the Company is required to disclose publicly under the federal securities laws require prior approval by the Company's independent directors without the participation of any director who may have a direct or indirect interest in the transaction in question. Related parties include directors, nominees for director, principal stockholders (that is, any person who beneficially owns five percent or more of any class of the Company's voting securities), executive officers and members of their immediate families. For these purposes, a "transaction" includes all financial transactions, arrangements or relationships, ranging from extending credit to the provision of goods and services for value. The Company's policies and procedures regarding related party transactions are not part of a formal written policy, but rather, represent a course of practice determined to be appropriate by the Audit Committee. In determining to approve or ratify any such transaction, our Audit Committee is expected to take into account, among other factors it deems appropriate, whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third-party under the same or similar circumstances and the extent of the related person's interest in the transaction.

DIRECTOR COMPENSATION

Non-employee director compensation is generally reviewed and set annually at the Board meeting held in connection with the Annual Meeting of Stockholders. The non-employee directors of the Company received the following for service on the Board from May 2025 through May 2026:

- upon joining the Board, an initial fee of $50,000 in cash;
- an annual cash payment of $50,000 for each board member; and
- an annual grant of options exercisable for 8,333 shares that vests quarterly over the one-year period following the date of grant, subject to continued service through each such date.

In addition to the above, annual compensation for service as the Lead Independent Director is $30,000 and annual compensation for service on the Audit Committee is $20,000 for the Chair and $15,000 for each committee member, paid in cash quarterly. Annual compensation for service on the Compensation Committee and Nominating and Governance Committee is $15,000 for the Chair and $10,000 for each committee member, paid in cash quarterly. The independent board members are also reimbursed on a case-by-case basis up to a pre-set amount for actual out of pocket expenses for graduate level course work in fields related to the business of the Company, though no such reimbursements were made with respect to 2025. The employee directors receive no compensation for their board service.

Pursuant to the policies of Pryor Cashman, the law firm of which Mr. Remmel is a partner, the compensation Mr. Remmel receives for his services as a director (other than expense reimbursement) is paid to the firm directly. All directors receive reimbursement for reasonable travel and other out of pocket expenses. The following table sets forth information regarding compensation earned by our non-employee directors during the fiscal year ended December 31, 2025:

Name	Fees Earned or Paid in Cash	Option Awards Dollar Amount[1]	Option Awards Number of Shares	All Other Compensation	Total	Outstanding Option Awards[2]
Shu-Chih Chen, Ph.D.	$ 37,500	$ 107,563	8,333	$ —	$ 145,063	41,055
Tessa Cigler, M.D., M.P.H.	$ 45,000	$ 110,839	8,333	$ —	$ 155,839	18,055
Jonathan F. Finn, C.F.A.	$ 56,250	$ 107,563	8,333	$ —	$ 163,813	20,833
Stephen Galli, M.D.	$ 67,500	$ 107,563	8,333	$ —	$ 175,063	41,088
H. Lawrence Remmel, Esq.[3]	$ 90,000	$ 107,405	8,333	$ —	$ 197,405	41,034
Richard Steinhart	$ 60,000	$ 107,563	8,333	$ —	$ 167,563	40,967

(1) The value of the awards has been computed in accordance with Accounting Standards Codification Topic 718, Compensation - Stock Compensation (ASC 718). Assumptions used in the calculations for these amounts are included in the notes to our financial statements included in our Annual Report for the fiscal year ended December 31, 2025.

(2) The shares reported in this column represent the aggregate number of option awards outstanding as of December 31, 2025.

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

EXECUTIVE COMPENSATION

Remuneration of Officers

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

Summary Compensation Table

The following table sets forth the compensation earned by our Chairman, President and Chief Executive Officer, Dr. Quay, our Chief Financial Officer, Mr. Daniel and our former Chief Financial Officer, Ms. Rees (together, the "***Named Executive Officers***") for fiscal years 2025 and 2024:

Name and Position		Year	Salary	Option Awards [1]	Non-equity Incentive Plan Compensation [2]	All Other Compensation [3]	Total
Steven C. Quay, M.D., Ph. D.	Chairman, President and Chief Executive Officer	2025	$ 730,961	$ 1,482,695	$ 250,000	$ 39,200	$ 2,502,856
		2024	$ 705,910	$ 1,490,639	$ 529,433	$ 38,100	$ 2,764,082
Mark J. Daniel [4]	Chief Financial Officer	2025	$ 72,516	$ 456,109	$ —	$ 7,864	$ 536,489
Heather Rees, CPA (Inactive) [5]	Former Chief Financial Officer	2025	$ 482,217	$ 415,918	$ —	$ 83,589	$ 981,724
		2024	$ 402,487	$ 489,237	$ 219,850	$ 38,100	$ 1,149,674

(1) The value of the option awards has been computed in accordance with ASC 718. Assumptions used in the calculations for these amounts are included in the notes to our financial statements included in our Annual Report for the fiscal year ended December 31, 2025.

(2) Amounts represent the annual performance bonus.

(3) Amounts represent the 401(k) match made by the Company on behalf of the Named Executive Officers and reimbursements under our wellness program and an internet stipend, and with respect to Ms. Rees, $44,539 in respect of severance payments and COBRA reimbursements made during 2025 in connection with her termination of employment.

(4) Mr. Daniel joined the Company effective October 14, 2025.

(5) Ms. Rees stepped down as our Chief Financial Officer on October 14, 2025.

Outstanding Equity Awards at Fiscal Year-End

The following table shows information regarding our outstanding equity awards at December 31, 2025 for the Named Executive Officers under the Company's equity incentive plans:

Name		Grant Date	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable [1]	Option Exercise Price	Option Expiration Date
Steven C. Quay, M.D., Ph.D.	President and Chief Executive Officer	5/18/2016	211	—	$ 710.10	5/18/2026
		5/24/2017	3,200	—	$ 84.60	5/24/2027
		5/17/2019	153,334	—	$ 20.40	5/17/2029
		4/9/2020	13,000	—	$ 22.20	4/9/2030
		5/15/2020	87,000	—	$ 22.20	5/15/2030
		5/14/2021	126,667	—	$ 43.50	5/14/2031
		2/24/2022	126,666	—	$ 18.75	2/24/2032
		3/2/2023	124,873	—	$ 10.80	3/2/2033
		6/27/2024	89,755	29,918	$ 15.75	6/27/2034
		5/15/2025	22,768	68,303	$ 14.85	5/15/2035
Mark J. Daniel [2]	Chief Financial Officer	10/14/2025	—	38,533	$ 15.45	10/14/2035
Heather Rees, CPA (Inactive) [3]	former Chief Financial Officer	4/9/2020	2,167	—	$ 22.20	3/31/2026
		7/3/2020	1,566	—	$ 47.70	3/31/2026
		5/14/2021	8,646	—	$ 43.50	3/31/2026
		8/11/2021	6,667	—	$ 47.70	3/31/2026
		5/13/2022	10,000	—	$ 13.95	3/31/2026
		6/12/2023	15,067	—	$ 13.80	3/31/2026
		6/27/2024	24,071	—	$ 15.75	3/31/2026
		5/15/2025	9,063	—	$ 14.85	3/31/2026

(1) Except as set forth in footnote (2) below, options vest quarterly over two years from the date of grant.

(2) Mr. Daniel's new hire grant vests with respect to 25% of the shares on the one-year anniversary of the date of grant and the remaining shares vest quarterly over the subsequent three years.

(3) Ms. Rees terminated employment on November 15, 2025. Her vested shares remained exercisable until March 31,2026 and unvested shares were forfeited upon the termination date.

Equity Award Grant Practices

We do not have any program, plan or obligation that requires us to grant equity awards on specified dates. We also do not have any program, plan or practice to time award dates of stock option grants to our executive officers in coordination with the release of material nonpublic information and typically aim to make equity grants during an open trading window. Equity awards may occasionally be granted following a significant change in job responsibilities or to meet special retention or performance objectives. During 2025, the Compensation Committee did not take material nonpublic information into account when determining the timing and terms of equity-based awards, including stock options, and the Company did not time the disclosure of material nonpublic information for the purpose of affecting the value of executive compensation. During 2025, the Compensation Committee did grant stock option awards to one of our NEOs within the period beginning four business days before our filing of a periodic report on Form 10-K or Form 10-Q or the filing or furnishing of a current report on Form 8-K that disclosed material nonpublic information (other than a current report on Form 8-K disclosing a material new stock option award under Item 5.02(e) of such Form 8-K), and ending one business day after the filing or furnishing of such report because the Compensation Committee granted a new hire award to Mr. Daniel on the same day the Company filed a Form 8-K announcing his appointment and the departure of Ms. Rees. The following information regarding such option grant is provided in accordance with SEC rules:

Name and Position	Grant Date	Number of Securities Underlying Award	Exercise Price	Grant Date Fair Value	Percentage Change in Closing Market Price of Securities Underlying the Award Between the Trading Day Ending Immediately Prior to the Disclosure of Material Nonpublic Information and the Trading Day Beginning Immediately Following the Disclosure of Material Nonpublic Information
Mark J. Daniel	10/14/2025	38,533	$ 15.45	$ 456,109	0%

PAY VERSUS PERFORMANCE

As required by the Dodd-Frank Act and Item 402(v) of SEC Regulation S-K, we are providing the following specified disclosures regarding the relationship between the compensation actually paid to our executive officers and certain measures of financial performance. The following table reports the compensation of Dr. Steven C. Quay, our Chairman, President and CEO (our Principal Executive Officer, or "**PEO**") and the average compensation of the other Named Executive Officers (our "**Non-PEO NEOs**") as reported in the Summary Compensation Table for the past three fiscal years, as well as their "compensation actually paid" as calculated pursuant to the SEC rules (referred to as "**CAP**").

Year	Summary Compensation Table Total for PEO [1]	Compensation Actually Paid to PEO [1][2]	Summary Compensation Table Total for Non-PEO NEOs [1]	Compensation Actually Paid to Non-PEO NEOs [1][3]	Value of Initial Fixed $100 Investment Based On Total Shareholder Return[4]	Net Loss
2025	$ 2,502,856	$ 2,198,059	$ 759,107	$ 594,114	$ 12	$ (34,770,000)
2024	$ 2,764,082	$ 3,018,458	$ 1,149,674	$ 1,238,488	$ 79	$ (25,504,000)
2023	$ 2,356,220	$ 2,653,763	$ 1,412,840	$ 715,616	$ 67	$ (30,094,000)

(1) Dr. Quay is our PEO for 2025, 2024 and 2023. Mr. Daniel and Ms. Rees, our Former Chief Financial Officer, are the Non-PEO NEOs for 2025. Ms. Rees is the only Non-PEO NEO for 2024. Kyle Guse, Former Chief Financial Officer, Greg Weaver, Former Chief Financial Officer, and Ms. Rees are the Non-PEO NEOs for 2023.

(2) The table below shows the amount of CAP to our PEO, as computed in accordance with Item 402(v) of SEC regulation S-K. The dollar amounts reported do not reflect actual amount of compensation earned by or paid to our PEO during the applicable year, and the Compensation Committee did not consider CAP in making any executive compensation decisions with respect to our PEO. In accordance with SEC rules, these amounts reflect the "Total" compensation as set forth in the Summary Compensation Table for the applicable year, adjusted as shown below. Equity values are calculated in accordance with FASB ASC Topic 718, and the valuation assumptions used to calculate fair values did not materially differ from those disclosed at the time of grant.

Year	Summary Compensation Table Total for PEO	Equity Awards in SCT (A)	Equity Award Adjustments (B)	Compensation Actually Paid to PEO
2025	$ 2,502,856	$ (1,482,695)	$ 1,177,898	$ 2,198,059
2024	$ 2,764,082	$ (1,490,639)	$ 1,745,015	$ 3,018,458
2023	$ 2,356,220	$ (1,143,927)	$ 1,441,470	$ 2,653,763

(A) Represents the amounts reported in the Option Awards column in the Summary Compensation Table ("**SCT**") for the applicable year.

(B) Represents the equity award adjustments (deductions and additions) for PEO equity awards for each applicable year calculated as follows:

Year	Year-End Fair Value of Outstanding and Unvested Equity Awards Granted During the Year	Year-over-Year Change in Fair Value of Outstanding and Unvested Equity Awards Granted in Prior Years	Fair Value as of Vesting Date of Equity Awards Granted and Vested in the Year	Change in the Fair Value from Prior Fiscal Year End to Vesting Date of Equity Awards Granted in Prior Years that Vested in the Year	Total Equity Award Adjustments
2025	$ 1,015,137	$ (63,742)	$ 260,011	$ (33,508)	$ 1,177,898
2024	$ 1,418,914	$ (8,325)	$ 370,608	$ (36,182)	$ 1,745,015
2023	$ 1,093,739	$ (15,321)	$ 428,413	$ (65,361)	$ 1,441,470

(3) The table below shows CAP for the Non-PEO NEOs, as computed in accordance with Item 402(v) of SEC Regulation S-K. The dollar amounts reported do not reflect the actual amount of compensation earned by or paid to our Non-PEO NEOs during the applicable year, and the Compensation Committee did not consider CAP in making any executive compensation decisions with respect to our Non-PEO NEOs. In accordance with SEC rules, these amounts reflect the "Total" compensation as set forth in the Summary Compensation Table for the applicable year, on average, adjusted as shown below. Equity values are calculated in accordance with FASB ASC Topic 718, and the valuation assumptions used to calculate fair values did not materially differ from those disclosed at the time of grant.

Year	Summary Compensation Table Total for Non-PEO NEOs	Equity Awards in SCT (A)	Equity Award Adjustments (B)	Compensation Actually Paid to Non-PEO NEOs
2025	$ 759,107	$ (436,014)	$ 271,021	$ 594,114
2024	$ 1,149,674	$ (489,237)	$ 578,051	$ 1,238,488
2023	$ 1,412,840	$ (875,334)	$ 178,110	$ 715,616

(A) Represents the average of the amounts reported in the Option Awards column in the Summary Compensation Table for the applicable year.

(B) Represents the equity average award adjustments (deductions and additions) for our Non-PEO NEOs equity awards for the applicable year calculated as follows:

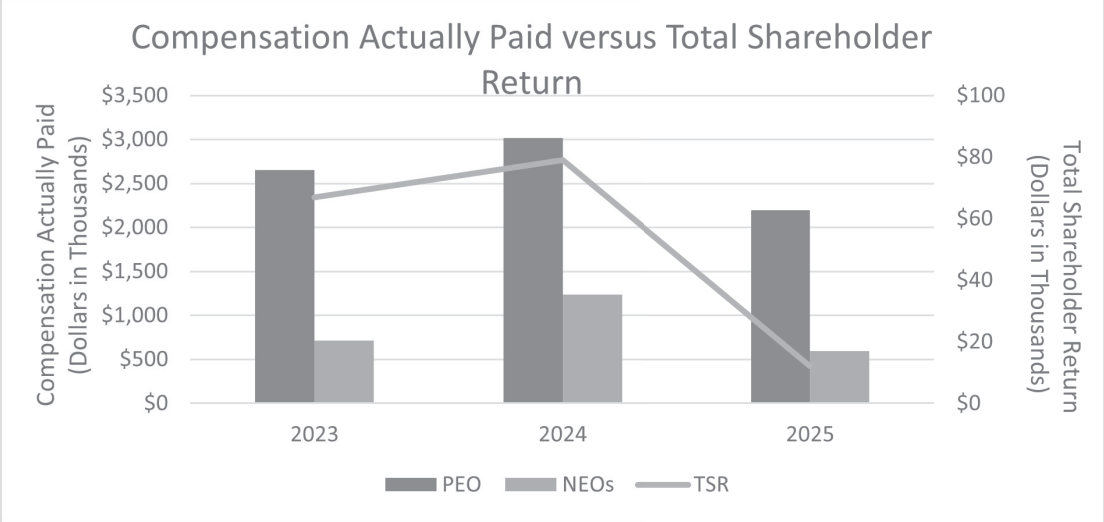
Year	Year-End Fair Value of Outstanding and Unvested Equity Awards Granted During the Year	Year-over-Year Change in Fair Value of Outstanding and Unvested Equity Awards Granted in Prior Years	Fair Value as of Vesting Date of Equity Awards Granted and Vested in the Year	Change in the Fair Value from Prior Fiscal Year End to Vesting Date of Equity Awards Granted in Prior Years that Vested in the Year	Prior Year End Fair Value for Equity Awards Granted in Prior Years that were Forfeited During the Year	Total Equity Award Adjustments
2025	$ 295,381	$ —	$ 56,583	$ 8,477	$ (89,420)	$ 271,021
2024	$ 466,599	$ (2,558)	$ 119,271	$ (5,261)	-	$ 578,051
2023	$ 113,935	$ (536)	$ 76,474	$ (8,675)	$ (3,088)	$ 178,110

(4) Total Shareholder Return ("***TSR***") is calculated by dividing (a) the sum of (i) the cumulative amount of dividends for the measurement period, assuming dividend reinvestment, and (ii) the difference between the Company's share price at the end of each fiscal year shown and the beginning of the measurement period, by (b) the Company's share price at the beginning of the measurement period. The beginning of the measurement period for each year in the table is December 31, 2022.

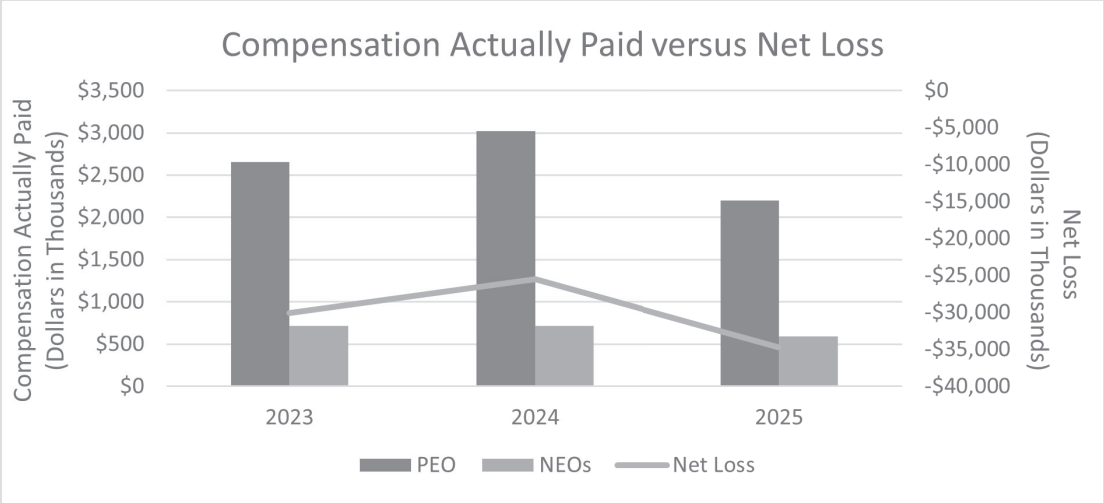
Description of Certain Relationships between Information Presented in the Pay versus Performance Table

While the Company utilizes several performance measures to align executive compensation with Company performance, all of those Company measures are not presented in the Pay versus Performance table. Moreover, the Company generally seeks to incentivize long-term performance, and therefore does not specifically align the Company's performance measures with compensation that is actually paid (as computed in accordance with SEC rules) for a particular year. In accordance with SEC rules, the Company is providing the following descriptions of the relationships between information presented in the Pay versus Performance table.

Compensation Actually Paid and Cumulative TSR



Compensation Actually Paid and Net Loss



Employment Agreements

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

The Company entered into an employment agreement with Dr. Quay on September 27, 2010, to act as the Company's Chief Executive Officer. The agreement provided for an initial base salary of $250,000, which was amended over the years and has been subsequently increased to $730,961 for 2025, with an annual target bonus of up to 60% of Dr. Quay's then-current base salary, payable upon the achievement of performance goals to be established annually by the Compensation Committee.

The goals for fiscal 2025 related to the advancement of the Company's (Z)-endoxifen program and included (1) obtaining U.S. Food and Drug Administration ("***FDA***") feedback on potential accelerated pathways for (Z)-endoxifen in multiple settings, including risk reduction, adjuvant, and metastatic indications, (2) advancing clinical studies of (Z)-endoxifen for mammographic breast density and neoadjuvant treatment, (3) advancing (Z)-endoxifen manufacturing capabilities and supply sourcing, and initiation of drug stability studies, (4) initiating nonclinical toxicity studies for (Z)-endoxifen, (5)

evaluating the efficacy of (Z)-endoxifen in selected rare disease mouse models, and (6) achieving one or more specified stretch objectives.

On January 20, 2026, the Compensation Committee reviewed Dr. Quay's performance against these objectives and determined that his 2025 performance was consistent with target achievement. In reaching this conclusion, the Compensation Committee considered progress made during the year across the Company's regulatory, clinical, manufacturing, nonclinical, and exploratory rare disease initiatives, including progress in obtaining and assessing FDA feedback, advancing key clinical and development activities, and supporting longer-term pipeline opportunities. Based on this review, the Compensation Committee approved a payout at target, consisting of a $250,000 cash bonus and a restricted stock award with a grant-date value of $200,000. The Compensation Committee determined to deliver a significant portion of the award in equity to reinforce alignment with long-term stockholder value creation.

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

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

Employment Agreement with Mark Daniel

The Company entered into an employment agreement with Mr. Daniel on October 14, 2025, to act as the Company's Chief Financial Officer. The agreement provides for an initial base salary of $415,900 and an annual target bonus of up to 40% of Mr. Daniel's then-current base salary, payable upon the achievement of performance goals to be established annually by the Compensation Committee, commencing with fiscal year 2026.

The employment agreement also provided for the grant of a stock option award with respect to 38,533 shares of the Company's common stock, vesting 25% on October 14, 2026 and, with respect to the remaining 75% of the award, in equal quarterly installments over the subsequent three-year period, subject, in each case, to continued service on each such vesting date.

During the employment term, Mr. Daniel is entitled to participate in the Company's employee benefit plans as in effect from time to time on the same basis as those benefits are generally made available to other senior executives of the Company, in each case to the extent that he is eligible under the terms of such plans or programs.

In connection with his commencement of employment, Mr. Daniel also entered into the Company's standard form of Development, Confidentiality, Nondisclosure and Noncompetition Agreement.

Employment Agreement with Heather Rees, CPA (inactive)

The Company was party to an employment agreement with Ms. Rees dated as of July 1, 2024, pursuant to which she was promoted to act as the Company's Chief Financial Officer. The agreement provided for an initial base salary of $439,700, with an annual target bonus of up to 40% of Ms. Rees' then-current base salary, payable upon the achievement of performance goals to be established annually by the Compensation Committee.

During the employment term, Ms. Rees was entitled to participate in the Company's employee benefit plans as in effect from time to time on the same basis as those benefits are generally made available to other senior executives of the Company, in each case to the extent that she is eligible under the terms of such plans or programs.

In connection with her termination of employment, we entered into a separation agreement with Ms. Rees (the "***Rees Agreement***") in exchange for a release of claims and her continued compliance with certain restrictive covenants, which provided for her continued employment following the appointment of Mr. Daniel to assist with certain transitional duties until November 15, 2025, and, thereafter, severance payments equal to nine months of base salary and continued payment of the employer portion of premiums under COBRA.

Severance Benefits and Change in Control Arrangements

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

Dr. Steven C. Quay, M.D. Ph.D.

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

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

Mark Daniel

Pursuant to his employment agreement, (i) if Mr. Daniel terminates employment due to death or disability, he will be entitled to receive, in addition to accrued benefits, a pro rata portion of the actual bonus that would have been earned for the year of termination, based on the days employed during such year, payable on the date when bonuses are otherwise paid to Company employees, and (ii) if the Company terminates the employment of Mr. Daniel without Cause or Mr. Daniel terminates his employment for Good Reason, in either event not within 30 days before or 12 months after a Change in Control (with "Cause," "Good Reason," and "Change in Control" each as defined in the employment agreement), he will be entitled to receive, in addition to accrued benefits, subject to his execution and non-revocation of a release of claims in favor of the Company and continued compliance with certain restrictive covenants, (a) payment of 50% of his base salary over six months and (b) up to six months of COBRA benefits.

In addition, under the terms of the employment agreement, in the event of a termination without Cause or for Good Reason within the period 30 days prior to or within 12 months after a Change in Control of the Company, Mr. Daniel will be entitled to receive, in addition to accrued benefits and subject to his execution and non-revocation of a release of claims in favor of the Company and continued compliance with certain restrictive covenants, (a) a pro rata portion of the actual bonus that would have been earned for the year of termination, based on the days employed during such year, payable on the date when bonuses are otherwise paid to Company employees, (b) a one-time payment equal to 1.0 times his base salary plus target annual bonus, payable in a lump sum, (c) acceleration of the vesting of all outstanding equity awards then held by Mr. Daniel, and (d) up to twelve months of COBRA benefits.

Heather Rees, CPA (inactive)

Pursuant to the Rees Agreement, in exchange for a release of claims and continued compliance with certain restrictive covenants, she will receive payment of nine months of her base salary over the nine month period following her termination of employment and, subject to her timely election of continuation of group health coverage under the Company's group health plan pursuant to COBRA, the Company will continue to pay the employer portion of the premiums required for such coverage for a period of nine months.

Other Benefits

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

Insider Trading Policy and Prohibition on Hedging and Pledging

We have adopted insider trading policies and procedures governing the purchase, sale and other transactions in Company securities by the Company's directors, officers and employees, as well as the Company itself, that we believe are reasonably designed to promote compliance with insider trading laws, rules and regulations and Nasdaq listing standards.

Under our insider trading policies and procedures, our directors, officers and certain employees are prohibited from (i) engaging in short sales, (ii) buying or selling puts, calls, other derivative securities of the Company or any derivative securities that provide the economic equivalent of ownership of any of the Company's securities or an opportunity, direct or indirect, to profit from any change in the value of the Company's securities, (iii) using the Company's securities as collateral in a margin account, (iv) unless approved by the Audit Committee, pledging Company securities as collateral for a loan (or modifying an existing pledge) and (v) short-term trading (generally defined as selling Company securities within six months following a purchase).

Incentive Compensation Clawback Policy

We have adopted an Incentive Compensation Clawback Policy, which is intended to comply with the requirements of Nasdaq Listing Standard 5608 implementing Rule 10D-1 under the Exchange Act. In the event the Company is required to prepare an accounting restatement of the Company's financial statements due to material non-compliance with any financial reporting requirement under the federal securities laws, the Company will recover, on a reasonably prompt basis, the excess incentive-based compensation received by any covered executive during the prior three fiscal years that exceeds the amount that the executive otherwise would have received had the incentive-based compensation been determined based on the restated financial statements.

Equity Compensation Plan Information

The following table sets forth certain information, as of December 31, 2025, regarding the Company's equity incentive plans, as well as other stock options and warrants previously issued by the Company as compensation for services.

Plan category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in First Column)
Equity compensation plans approved by security holders	1,565,272	$ 21.86	679,463
Equity compensation plans not approved by security holders			
Total	1,565,272	$ 21.86	679,463

REPORT OF THE AUDIT COMMITTEE

No member of the Audit Committee is a professional accountant or auditor. The members' functions are not intended to duplicate or to certify the activities of management and the independent registered public accounting firm. The Audit Committee serves a board-level oversight role in which it provides advice, counsel and direction to management and the auditors on the basis of the information it receives, discussions with management and the auditors, and the experience of the Audit Committee's members in business, financial and accounting matters.

The Audit Committee oversees the Company's financial reporting process on behalf of the Board. The Company's management has the primary responsibility for the financial statements and reporting process, including the Company's system of internal controls. In fulfilling its oversight responsibilities, the Audit Committee reviewed and discussed with management and the independent auditor the audited financial statements included in the Annual Report on Form 10-K for the fiscal year ended December 31, 2025. This review included a discussion of the quality and the acceptability of the Company's financial reporting, including the nature and extent of disclosures in the financial statements and the accompanying notes. The Audit Committee also reviewed the progress and results of management's evaluation of the design and effectiveness of its internal controls over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act of 2002. The Audit Committee also reviewed with the Company's independent registered public accounting firm, which is responsible for expressing an opinion on the conformity of the audited financial statements with accounting principles generally accepted in the United States, its judgment as to the quality and the acceptability of the Company's financial reporting and discussed with the auditor the matters required to be discussed by the applicable requirements of the Public Company Accounting Oversight Board ("***PCAOB***") and the SEC. The Audit Committee has received from the independent auditor the written disclosures and the letter required by the applicable requirements of the PCAOB regarding the auditor's communications with the Audit Committee concerning independence, and has discussed with the independent auditor the independent auditor's independence.

In addition to the matters specified above, the Audit Committee discussed with the Company's independent registered public accounting firm the overall scope, plans and estimated costs of its audit. The Audit Committee met with the independent registered public accounting firm periodically, with and without management present, to discuss the results of the independent registered public accounting firm's examinations, the overall quality of the Company's financial reporting and the independent registered public accounting firm's reviews of the quarterly financial statements, and drafts of the Company's quarterly and annual reports.

In reliance on the reviews and discussions referred to above, the Audit Committee recommended to the Board of Directors that the Company's audited financial statements be included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2025 for filing with the SEC.

Submitted by the Audit Committee of the Board of Directors

Richard I. Steinhart, Chairman
Jonathan F. Finn, C.F.A.
Stephen J. Galli, M.D.
H. Lawrence Remmel, Esq.

GENERAL INFORMATION

"About the Meeting - What do I need to do to virtually attend the Annual Meeting via live audio webcast?"

In order to attend and participate in the Annual Meeting live via the Internet, you must register at https://web.viewproxy.com/AtossaTherapeutics/2026 by 11:59 P.M. Eastern Time on May 5, 2026. If you are a registered holder, you must register using the Virtual Control Number included in your proxy card which will be mailed on or about March 30, 2026 to stockholders of record at the close of business on the Record Date, March 19, 2026. If you hold your shares beneficially through a bank, broker or other financial institution, you must provide a legal proxy from your bank, broker or other financial institution during registration and you will be assigned a Virtual Control Number in order to attend and vote your shares during the Annual Meeting. If you are unable to obtain a legal proxy to vote your shares, you will still be able to virtually attend the Annual Meeting (but will not be able to vote your shares) so long as you demonstrate proof of stock ownership. Instructions on how to connect and participate via the Internet, including how to demonstrate proof of stock ownership, are posted at https://web.viewproxy.com/AtossaTherapeutics/2026.

"About the Meeting – Meeting Conduct"

We will endeavor to answer as many stockholder-submitted questions as time permits that comply with the Annual Meeting rules of conduct. We reserve the right to edit profanity or other inappropriate language and to exclude questions regarding topics that are not pertinent to meeting matters or Company business. If we receive substantially similar questions, we may group such questions together and provide a single response to avoid repetition.

The meeting webcast will begin promptly at 9:00 A.M. Pacific Time. Online check-in will begin approximately 15 minutes before then, and we encourage you to allow ample time for check-in procedures. If you experience technical difficulties during the check-in process or during the meeting, please refer to the contact information below. Additional information regarding the rules and procedures for participating in the Annual Meeting will be set forth in our meeting rules of conduct, which stockholders can view during the meeting at the meeting website.

"About the Meeting – Who do I contact if I am having technical problems voting or attending the meeting?"

If you have any questions about attending the virtual meeting, or otherwise require technical assistance prior to or during the meeting, please contact: VirtualMeeting@viewproxy.com or call 1-866-612-8937.

OTHER BUSINESS

We know of no other matters to be submitted to a vote of stockholders at the Annual Meeting. If any other matter is properly brought before the Annual Meeting or any adjournments or postponements thereof, it is the intention of the proxies named in the enclosed proxy card to vote the shares they represent in their discretion. In order for any stockholder to nominate a candidate for director election or to submit a proposal for other business to be acted upon at any given annual meeting of stockholders, he or she must provide timely written notice to our Corporate Secretary in the form prescribed by our Bylaws, as described below.

STOCKHOLDER PROPOSALS

Pursuant to Rule 14a-8 of the Exchange Act, stockholder proposals intended to be included in the proxy statement for the 2027 Annual Meeting of Stockholders must be received by our Corporate Secretary at the address set forth below no later than the close of business (6:00 p.m. Pacific Time) on November 30, 2026. The form and substance of such proposals must satisfy the requirements established by the SEC, including Rule 14a-8 of the Exchange Act. The submission of a stockholder proposal does not guarantee that it will be included in the proxy statement.

Additionally, stockholders who intend to present a stockholder proposal, other than pursuant to Rule 14a-8 under the Exchange Act, or nominate director nominees for election at the 2027 Annual Meeting of Stockholders must provide the Corporate Secretary with written notice of the proposal or nomination in accordance with our Bylaws. Such notice must be received by the Corporate Secretary at the address set forth below not later the close of business on the 90th day nor earlier than the close of business on the 120th day prior to the one-year anniversary date of the Annual Meeting; *provided, however*, that if the date of the 2027 Annual Meeting of Stockholders is advanced by more than 30 days before or delayed by more than 60 days after the one-year anniversary date of the Annual Meeting, then stockholders must provide notice not later than the close of business on the later of the 90th day prior to the scheduled date of such meeting or the 10th day following the day on which public announcement of the date of such meeting is first made. Therefore, unless the date of the 2027 Annual Meeting of Stockholders is advanced by more than 30 days before or delayed by more than 60 days after the one-year anniversary of the Annual Meeting, notice of proposed nominations or proposals (other than pursuant to Rule 14a-8 of the Exchange Act) must be received by our Corporate Secretary not earlier than January 7, 2027 and not later than the close of business (6:00 p.m. Pacific Time) on February 6, 2027. If a stockholder fails to meet these deadlines or fails to satisfy the requirements of Rule 14a-4 of the Exchange Act, we may exercise discretionary voting authority under proxies we solicit to vote on any such proposal as we determine appropriate. In addition to satisfying the deadlines in the advance notice provisions of our Bylaws, a stockholder who intends to solicit proxies pursuant to Rule 14a-19 of the Exchange Act in support of nominees submitted under these advance notice provisions for the 2027 Annual Meeting of Stockholders must provide the notice required under Rule 14a-19 of the Exchange Act to our Corporate Secretary in writing not later than the close of business (6:00 p.m. Pacific Time) on March 8, 2027.

Notice must be tendered in the proper form prescribed by our Bylaws. Proposals or nominations not meeting the requirements set forth in our Bylaws will not be entertained at the meeting. We reserve the right to reject, rule out of order or take other appropriate action with respect to any nomination or proposal that does not comply with these and other applicable requirements.

DELIVERY OF PROXY MATERIALS

Our Annual Report on Form 10-K for the fiscal year ended December 31, 2025, including our audited financial statements, accompanies this Proxy Statement. We will provide a copy of our Annual Report on Form 10-K, free of charge, upon the written or oral request of a stockholder. Please send a written request to our Corporate Secretary at the address set forth below or call the number below. Copies of these materials are also available online through the SEC at *www.sec.gov*.

The Company may satisfy SEC rules regarding delivery of proxy materials by delivering a single copy of the proxy materials, including the Proxy Statement and Annual Report to an address shared by two or more Company stockholders. This delivery method can result in meaningful cost savings for the Company. In order to take advantage of this opportunity, the Company may deliver only one copy of the proxy materials to multiple stockholders who share an address, unless contrary instructions are received prior to the mailing date. Similarly, if you share an address with another stockholder and have received multiple copies of our proxy materials, you may write or call us at the address and phone number below to request delivery of a single copy of these materials in the future. We will deliver promptly upon written or oral request, a separate copy of the proxy materials to a stockholder at a shared address to which a single copy of these documents was delivered. If you hold stock as a record stockholder and prefer to receive separate copies of the proxy materials either now or in the future, please contact the Company's Corporate Secretary at 1448 NW Market Street, Suite 500, Seattle, Washington 98107 or by telephone at (866) 893-4927. If your stock is held through a brokerage firm, bank or other financial institution and you prefer to receive separate copies of the proxy materials, or if you received multiple copies of these materials and would prefer to receive a single copy, either now or in the future, please contact your brokerage firm, bank or other financial institution.

APPENDIX A

CERTIFICATE OF AMENDMENT TO THE AMENDED AND RESTATED CERTIFICATE OF INCORPORATION OF ATOSSA THERAPEUTICS, INC.

Atossa Therapeutics, Inc., a corporation organized and existing under the laws of the State of Delaware (the "Corporation"), hereby certifies as follows:

FIRST: That the current name of the Corporation is Atossa Therapeutics, Inc., and the Corporation was originally incorporated pursuant to the General Corporation Law of the State of Delaware (the "DGCL") on April 30, 2009 under the name Atossa Genetics Inc.

SECOND: That the Corporation's Amended and Restated Certificate of Incorporation was filed with the Secretary of State of the State of Delaware on November 8, 2012 (as subsequently amended, the "Certificate of Incorporation").

THIRD: That pursuant to and in accordance with Section 242 of the DGCL, this Certificate of Amendment hereby further amends the provisions of the Certificate of Incorporation as follows:

Article IV is hereby amended to delete Section C of such article in its entirety and to substitute in its place the following:

"C. REVERSE STOCK SPLIT

Effective as of 12:01 A.M. Eastern Time on _____ (the "Effective Time"), each _____ shares of the Corporation's Common Stock issued and outstanding immediately prior to the Effective Time shall, automatically and without any action on the part of the Corporation or the respective holders thereof, be combined and converted into one share of Common Stock without increasing or decreasing the par value of each share of Common Stock (the "Reverse Stock Split"). No fractional shares of Common Stock shall be issued as a result of the Reverse Stock Split and, in lieu thereof, upon surrender after the Effective Time of a certificate or book entry position which formerly represented shares of Common Stock that were issued and outstanding immediately prior to the Effective Time, any person who would otherwise be entitled to a fractional share of Common Stock as a result of the Reverse Stock Split, following the Effective Time, shall be entitled to receive a cash payment (without interest and subject to withholding taxes, as applicable) equal to the fraction of a share of Common Stock to which such holder would otherwise be entitled multiplied by the closing price of Common Stock on the Nasdaq Stock Market on the first business day immediately preceding the Effective Time (as adjusted in good faith by the Corporation to account for the reverse stock split ratio). The Reverse Stock Split shall occur whether or not the certificates representing such shares of Common Stock are surrendered to the Corporation or its transfer agent. Each certificate or book entry position that immediately prior to the Effective Time represented shares of Common Stock shall thereafter represent the number of shares of Common Stock into which the shares of Common Stock represented by such certificate or book entry position has been combined, subject to the elimination of fractional interests set forth above."

FOURTH: This Certificate of Amendment to the Certificate of Incorporation was duly authorized and adopted by the Corporation's Board of Directors (the "Board") and stockholders in accordance with the provisions of Section 242 of the DGCL.

FIFTH: This Certificate of Amendment to the Certificate of Incorporation shall be effective as of 12:01 A.M. Eastern Time on _____.

IN WITNESS WHEREOF, the Corporation has caused this Certificate of Amendment to the Certificate of Incorporation to be executed by Steven C. Quay, M.D., Ph.D., its Chairman of the Board, President and Chief Executive Officer, this _____ day of _____.

ATOSSA THERAPEUTICS, INC.

By: _____

Name: Steven C. Quay, M.D., Ph.D.
Title: Chairman of the Board, President and Chief Executive Officer

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