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

FORM 10-K

(Mark one)

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

For the fiscal year ended December 31, 2021

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.)**

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

Registrant's telephone number, including area code: **(206) 325-6068**

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 X

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (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 X 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 X 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 X 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 13a of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assertion 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 X

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

As of June 30, 2021, 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 $795,626,162. Shares of common stock held by each officer and director and by each person who is known to own 10% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates of the Company. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of shares outstanding of the registrant's common stock, par value $0.18, as of February 18, 2022, was 126,624,110.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information required to be disclosed in Part III of this report is incorporated by reference from the registrant’s Definitive Proxy Statement for the 2022 Annual Meeting of Stockholders, which proxy statement is expected to be filed no later than 120 days after the end of the fiscal year covered by this report.

ATOSSA THERAPEUTICS, INC.
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Explanatory Note: Based on the value of the non-affiliate float for our common stock as of June 30, 2021, we have transitioned from a "Non-Accelerated Filer" and "Smaller Reporting Company" for 2021 to a "Large Accelerated Filer" for 2022. As this Annual Report on Form 10-K is our first filing following our transition from being a Smaller Reporting Company to a Large Accelerated Filer, we are permitted to continue to provide scaled disclosures under Regulations S-K and S-X for this Annual Report on Form 10-K and in our definitive proxy statement on Schedule 14A for our 2022 Annual Meeting of Stockholders. We have elected to make such scaled disclosures in this report, where we are permitted to do so. Commencing with our Quarterly Report on Form 10-Q for the quarter ending March 31, 2022, we will no longer be permitted to report under the Smaller Reporting Company scaled disclosure regime for our periodic reports.

NOTE REGARDING FORWARD-LOOKING STATEMENTS

Statements made in this report on Form 10-K that are not statements of historical information 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 to differ materially from those projected or anticipated. Although we believe our assumptions underlying our forward-looking statements are reasonable as of the date of this report we cannot assure you that the forward-looking statements set out in this report will prove to be accurate. We typically identify these forward-looking statements by the use of forward-looking words such as "expect," "potential," "continue," "may," "will," "should," "could," "would," "seek," "intend," "plan," "estimate," "anticipate" or the negative version of those words or other comparable words. Forward-looking statements contained in this report include, but are not limited to, statements about:

- the impact of the ongoing COVID-19 pandemic and the degree to which the pandemic negatively impacts our supply chain, clinical trial enrollment and timing and our ability to access capital markets;
- whether we can obtain approval from the U.S. Food and Drug Administration (FDA), and foreign regulatory bodies, to commence our clinical trials, including our planned COVID-19 and Endoxifen trials, and to sell, market and distribute our therapeutics under development;
- our ability to identify and partner with organizations able to commercialize any of our products once they are approved for marketing;
- our ability to successfully initiate and complete clinical trials of our pharmaceutical candidates under development, including our proprietary Endoxifen (an active metabolite of Tamoxifen);
- the success, cost and timing of our product and drug development activities and clinical trials, including whether our studies using our Endoxifen and COVID-19 therapies will enroll a sufficient number of subjects or be completed in a timely fashion or at all;
- whether we will successfully complete our clinical trial of oral Endoxifen in women with mammographic breast density and whether the study will meet its 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 that we might identify in the future and in the time frames currently expected;
- 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;
- 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;
- the accuracy of our estimates of the size and characteristics of the markets that our products and services may address;
- whether final study results will vary from preliminary study results that we may announce;
- our expectations as to future financial performance, expense levels and capital sources;
- our ability to attract and retain key personnel; and
- our ability to raise capital.

This Annual Report also contains estimates and other statistical data provided by third parties and by us relating to market size and growth and other industry data. These and other forward-looking statements are presented as of the date on which the statements are made. We have included important factors in the cautionary statements included in this Annual Report, particularly in the section titled "ITEM 1A. RISK FACTORS," that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. 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 do not intend to update any forward-looking statements after the date on which the statement is made, whether as a result of new information, future events, circumstances or otherwise.

CORPORATE INFORMATION

Our corporate website is located at *www.atossatherapeutics.com*. Information contained on, or that can be accessed through, our website is not a part of this report. We make available, free of charge through our website or upon written request, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other periodic SEC reports, along with amendments to all of those reports, as soon as reasonably practicable after we file the reports with the SEC.

Unless otherwise noted, the term "Atossa Therapeutics", "Atossa," the "Company," "we," "us," and "our" refers 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 report includes additional 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 Securities and Exchange Commission (the SEC). In particular, please read our definitive proxy statement, which will be filed with the SEC in connection with our 2022 Annual Meeting of Stockholders, our Quarterly Reports on 10-Q and any Current Reports on Form 8-K, and any amendments thereto, that we may file from time to time. You may obtain copies of these reports after the date of this annual report from the SEC at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. In addition, the SEC maintains information for electronic filers (including Atossa) at its website www.sec.gov. The public may obtain information regarding the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330.

PART I

ITEM 1. BUSINESS

Overview

We are a clinical-stage biopharmaceutical company seeking to develop proprietary innovative medicines in areas of significant unmet medical need in oncology and infectious diseases, with a current focus on breast cancer, other breast conditions and COVID-19. Our drug under development for breast cancer and other breast conditions is Endoxifen which is being developed primarily in two settings: one to reduce tumor cell activity in breast cancer patients in the neoadjuvant setting, meaning prior to surgery; and another to reduce dense breast tissue in women. Our two COVID-19 drugs under development are AT-H201, an inhalation therapy to improve lung function of moderate to severely ill, hospitalized COVID-19 patients; and AT-301, a nasal spray for COVID-19 patients for at-home use. A key feature of the original SARS-CoV-2 virus that is retained in both the Delta and Omicron variants, is the furin cleavage site found on the spike protein which facilitates viral infection. Our COVID-19 programs under development are designed to interact with this cleavage site so they are expected to be effective against both current and future COVID-19 variants that continue to contain a furin cleavage site.

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

Summary of Leading Programs

Endoxifen. Endoxifen is an active metabolite of tamoxifen which is an FDA-approved drug to treat and prevent breast cancer in high-risk women. We are developing a proprietary form of Endoxifen which is administered orally for the potential treatment of breast cancer and women with breast density. We have successfully completed three Phase 1 clinical studies (including a study in men) and two Phase 2 clinical studies with our proprietary Endoxifen (one with our oral Endoxifen and one with our topical Endoxifen). We have also completed significant pre-clinical development and have developed clinical manufacturing capabilities through qualified third parties.

Endoxifen for Women with Breast Density. Mammographic breast density (MBD) is an emerging public health issue affecting over 10 million women in the U.S. Studies conducted by others have shown that MBD increases the risk of developing breast cancer and that reducing MBD can reduce the incidence of breast cancer.

In December 2021, we commenced a Phase 2 study of our proprietary oral Endoxifen. The study, known as the Karisma-Endoxifen study, is a Phase 2, randomized, double-blind, placebo-controlled, dose-response study of our proprietary oral Endoxifen in healthy premenopausal women with measurable breast density. The primary objective of the study is to determine the dose-response relationship of daily Endoxifen on breast density reduction. Secondary endpoints will assess safety and tolerability, and the trial includes an exploratory endpoint to assess durability of the breast density changes. The study is being conducted at the South General Hospital in Stockholm and will include approximately 240 participants who will receive daily doses of Endoxifen or placebo for six months. The study is being led by principal investigator Per Hall, M.D., Ph.D., Department of Medical Epidemiology and Biostatistics at Karolinska Institutet.

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

Endoxifen for Neoadjuvant Treatment of Breast Cancer. We are also developing Endoxifen to treat breast cancer in the neoadjuvant setting, which is the administration of a therapy before the surgical treatment, with a current focus on breast cancers that are classified as estrogen receptor positive (ER+). Although there are numerous neoadjuvant treatments for breast cancers that are not ER+, there are few neoadjuvant treatments for ER+ breast cancer which comprises about 78% of all breast cancers. We believe there is a compelling need for therapy with our Endoxifen in this setting.

In December 2021, we completed a pre-investigational new drug (PIND) meeting with the FDA. The purpose of the meeting was to obtain input from the FDA on pre-clinical, clinical, manufacturing and regulatory matters in the U.S. for our proprietary Endoxifen to treat breast cancer. Based in part on the feedback from the FDA, we plan to open an investigational new drug (IND) application for a multi-center Phase 2 study to further advance our Endoxifen in the neoadjuvant setting. We plan to focus our development on pre-menopausal women with ER+, human epidermal growth factor receptor negative (HER2-) breast cancer for whom the current treatment options typically includes drugs that suppress ovarian function and essentially force the patient into menopause.

We recently completed a Phase 2 study in Australia which enrolled 7 newly diagnosed patients with ER+ and stage 1 or 2 invasive breast cancer, requiring mastectomy or lumpectomy. In February 2021, we concluded that the study produced positive results and that continuing enrollment in the study would not be necessary in advancing the program. We therefore discontinued the study based in part on results from the first six patients. In June 2021, we reported final results from the study of all 7 patients which showed that tumor cell proliferation in study participants was reduced by an average of 65%, as measured by Ki-67 expression, which is a common measure of tumor cell activity in breast cancer.

AT-301 for COVID-19. AT-301 is our proprietary drug formulation candidate intended for nasal administration in patients immediately following diagnosis of COVID-19 but who have not yet exhibited symptoms severe enough to require hospitalization. It is intended for at-home use to reduce symptoms of COVID-19 and to slow the infection rate so that a person's immune system can more effectively fight COVID-19.

AT-301 is being developed with a nasal spray delivery mechanism because many COVID-19 patients are infected via the nasal passage. Our nasal spray formulation AT-301 is being designed to contain ingredients that can potentially block SARS-CoV-2 viral entry gene proteins in nasal epithelial cells by interfering with spike protein activation by host proteases, by masking receptor binding domains via electrostatic mechanisms, and by providing a generalized mucoadhesive epithelial barrier.

In October 2020, we completed enrollment in a Phase 1 study of AT-301 which was a double-blinded, randomized, and placebo-controlled safety study of AT-301 nasal spray in 32 healthy adult subjects. An evaluation of the data indicated that there were no serious adverse events, no discontinuations, and only one of the subjects in the study experienced adverse events that were considered related to the study drug and moderate in severity. We concluded that our AT-301 nasal spray was safe and well tolerated in this study. We received input from the FDA on this program in 2021 and based in part on that input, we are now preparing to conduct additional pre-clinical studies. Following that, we expect to apply to the FDA to commence a Phase 2 study in the United States.

We may also seek to develop our AT-301 nasal spray to potentially help prevent COVID-19 infection — particularly for people in high-risk environments, such as people living with an infected patient, people living and working in healthcare facilities, emergency responders or teachers.

AT-H201 for COVID-19. AT-H201 is a proprietary combination of two drugs previously approved by the FDA to treat other diseases. It is intended to improve compromised lung function for moderate to severely ill, hospitalized COVID-19 patients by inhalation. We received input from the FDA on potential pathways to develop AT-H201 and the FDA requested that we provide, among other things, additional pre-clinical results and other information on AT-H201.

In September 2021 we began enrollment in Australia in a Phase 1/2a study of AT-H201 and in February 2022, we began enrollment in the second of four parts of the study. The study plans to enroll 60 healthy participants and moderately ill hospitalized COVID-19 patients. The Australian regulatory authority will review data after each part of the study before we may proceed with subsequent parts of the study. Because the final part of the study in COVID-19 infected patients may require that we use additional study sites, approval of that part of the study, and additional sites will depend on COVID-19 infections and may therefore be delayed.

Impact of the Novel Coronavirus

The continued spread of the COVID-19 pandemic is affecting the U.S. and global economies and may affect the Company's operations and those of third parties on which the Company relies, including causing possible disruptions in the supply of the Company's Endoxifen, AT-H201, AT-301, the pace of enrollment in our clinical trials and the conduct of current and future clinical trials. In addition, the COVID-19 pandemic may affect the operations of the U.S. FDA and other health authorities including similar entities/agencies in Sweden and Australia, which could result in delays in meetings, reviews and approvals. Additionally, while the potential economic impact brought by, and the duration of, the COVID-19 pandemic is difficult to assess or predict, the impact of the COVID-19 pandemic on the global financial markets may reduce the Company's ability to access capital, which could negatively impact the Company's short-term and long-term liquidity. The ultimate impact of the COVID-19 pandemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, financing or clinical trial activities or on healthcare systems or the global economy; however, we have not experienced a significant delay in the enrollment or the drug supply for our ongoing and planned clinical studies, including studies of Endoxifen, AT-301 and AT-H201. In recent weeks the number of reported cases of COVID-19 has declined in many countries. If this trend continues it may be difficult to enroll in our COVID-19 clinical studies. We will continue to monitor future enrollment in studies for potential restrictions on site visits, mammograms or the impositions of new restrictions on trials as a result of the COVID-19 pandemic.

We were incorporated in 2009 and our common stock is currently quoted on The Nasdaq Capital Market under the symbol "ATOS."

Our Programs Under Development

Endoxifen Programs

Background

Endoxifen is one of the metabolites of an FDA-approved drug called tamoxifen, which has been FDA-approved and widely used for over 40 years to both treat and prevent breast cancer. Tamoxifen is a "pro-drug", in that it must be metabolized into active components ("metabolites") in order to be effective. Despite the success of tamoxifen in treating ER+ breast cancer, its systemic side effects have led to generally low acceptance as a therapy to reduce the risk of breast cancer. These systemic side effects relate to estrogen agonist activity on the endometrium and the activation of coagulation pathways, leading to an increased risk of uterine events and thromboembolism. Hot flashes and vaginal symptoms are additional barriers to tamoxifen being accepted in the prevention setting.

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

We estimate that approximately ten million women in the U.S. have MBD, for which there is no FDA-approved treatment. MBD is an emerging public health issue and studies conducted by others have shown that MBD increases the risk of developing breast cancer and that reducing MBD can reduce the incidence of breast cancer. Although oral tamoxifen is approved to prevent breast cancer in "high-risk" women (typically based on responses to a questionnaire), it is used by less than 5% of women with an increased risk of developing breast cancer because of the actual or perceived side effects and risks of tamoxifen. We believe our Endoxifen may provide an option for women to proactively reduce the density of their breasts. Moreover, our Endoxifen may improve mammography accuracy and patient care by unmasking cancerous tumors that are otherwise hidden by breast density.

U.S. federal and state legislation requires that women be notified if they have MBD. These notifications typically state that women with MBD have a higher risk of developing breast cancer, and that mammography may not be as effective in detecting breast cancer because the MBD can "mask" the detection of cancers.

Our Phase 1 Studies

In September 2019, we completed additional Phase 1 work using our capsule Endoxifen and a new modified-release tablet form of our oral Endoxifen. Study results showed that the capsule and tablet were safe and well-tolerated. Because the pharmacokinetic profile of the tablet did not meet the desired pharmacokinetic profile, we do not expect to further develop the tablet.

In 2017 we completed a comprehensive Phase 1 study in 48 healthy women in Australia using both the topical and oral forms of our proprietary Endoxifen. The objectives of this double-blinded, placebo-controlled, Phase 1 study were to assess the pharmacokinetics of our proprietary Endoxifen dosage forms as single (oral) and repeat (oral and topical) doses, as well as to assess safety and tolerability. The study was conducted in two parts based on route of administration.

There were no clinically significant safety signals and no clinically significant adverse events: both the oral and topical Endoxifen were well tolerated. In the topical arm of the study, there were low but detectable Endoxifen levels in the blood in a dose-dependent fashion and in the oral arm of the study participants exhibited dose-dependent Endoxifen levels consistent with published reports of the therapeutic range. The median time for patients in the study to reach the steady-state serum levels of Endoxifen while taking daily doses of oral Endoxifen was approximately seven days. Published literature indicates that it takes approximately 50-200 days for patients to reach steady-state Endoxifen levels when taking daily doses of oral tamoxifen. Finally, the median time for patients in the study to reach the maximum serum level of Endoxifen after taking Atossa's oral Endoxifen ranged from 4 to 8 hours (depending on dose). The 4 mg dose of Endoxifen produced a maximum serum level of Endoxifen in 4 to 8 hours at levels above the generally accepted threshold for a therapeutic effect on estrogen-dependent breast cancer.

We have also completed a double-blinded, placebo controlled, three arm Phase 1 study of our topical Endoxifen in men which showed that various dose levels of our topical Endoxifen were safe and well tolerated by the 24 study participants over 28 days of dosing.

Our Phase 2 Studies

In December 2021, we completed a pre-investigational new drug meeting with the FDA. The purpose of the meeting was to obtain input from the FDA on pre-clinical, clinical, manufacturing and regulatory matters in the U.S. for our proprietary Endoxifen to treat breast cancer. Based in part on the feedback from the FDA, we plan to open an IND for a multi-center Phase 2 study to further advance our proprietary oral proprietary Endoxifen in the neoadjuvant setting. We plan to focus our development on pre-menopausal women with ER+, HER2- breast cancer for whom the current treatment options typically include aromatase inhibitors combined with drugs that suppress ovarian function and essentially force the patient into menopause.

In December 2021, we began to enroll participants in a Phase 2 clinical study of oral Endoxifen in women with increased MBD. The study, known as the Karisma-Endoxifen study, is a Phase 2, randomized, double-blind, placebo-controlled, dose-response study of our proprietary Endoxifen in healthy pre-menopausal women with increased breast density. The primary objective of the study is to determine the dose-response relationship of daily oral Endoxifen on MBD reduction, with secondary endpoints to assess safety and tolerability, and an exploratory endpoint to assess durability of the MBD changes after the study drug has been discontinued. It is being conducted by South General Hospital in Stockholm and includes approximately 240 participants who will receive daily doses of oral Endoxifen or placebo for six months. The study is being led by principal investigator Per Hall, M.D., Ph.D., Department of Medical Epidemiology and Biostatistics at Karolinska Institutet.

In February 2021, we concluded a Phase 2 study of our oral Endoxifen in Australia. The study enrolled patients newly-diagnosed with ER+ and HER2- stage 1 or 2 invasive breast cancer, requiring mastectomy or lumpectomy. Patients received our proprietary oral Endoxifen for at least 14 days from the time of diagnosis up to the day of surgery. The primary endpoint was to determine if the administration of oral Endoxifen reduces the tumor activity as measured by Ki-67 (a measure of cellular proliferation that correlates with tumor growth). The secondary endpoints were safety and tolerability and assessment of the study drug on expression levels of both estrogen and progesterone receptors. In June 2021, we concluded that the study produced substantially positive results and that continuing enrollment in the study would not be useful in advancing the program. The final results from the 7 women in the study indicated that six of the 7 patients had 65% reduction in Ki-67 and 7/7 had Ki-67<25% at the time of surgery. There were no adverse safety signals or laboratory findings.

In April 2019, Stockholm South General Hospital in Sweden completed a randomized, double-blinded placebo-controlled Phase 2 study of our topical Endoxifen in women with measurable MBD. The study was led by principal investigator Dr. Per Hall, MD, Ph.D., Department of Medical Epidemiology and Biostatistics at Karolinska Institutet. The primary endpoint of this pilot study was to determine if topical Endoxifen reduces individual MBD as measured by mammography. Secondary endpoints included demonstrating safety and tolerability. The primary objective was to determine if topical Endoxifen reduces MBD, and if so by how much, in order to calculate the sample size for statistical significance in a future trial. The study enrolled 90 participants who were equally randomized to three different groups (30 per group): placebo; 10 mg topical Endoxifen; and 20 mg topical Endoxifen. Participants applied the study drug to each breast daily for a maximum of six months. Each participant received a baseline (pre-treatment) mammogram, and additional mammograms at month 3 and 6, or at the time of study exit. Once the study was completed, all mammograms were interpreted and MBD determined and any changes that occurred per participant recorded.

In June 2019, we reported preliminary analysis from our Phase 2 study of proprietary daily topical Endoxifen to reduce MBD, showing significant (p=0.02) and rapid reduction in MBD at the 20 mg daily dose level. MBD was reduced by an average of 14.3% in the group applying 20 mg daily topical Endoxifen, which was statistically significant (p = 0.02). In the 10 mg dose group, MBD was reduced by an average of 9.0%, but was not statistically significant. Approximately 70% of participants receiving 20 mg topical Endoxifen experienced a reduction in MBD, and of those, the mean reduction in MBD was 27%. There were no differences in systemic endocrine or vascular side effects (for example, hot flashes) in the placebo versus active groups. Systemic side effects were measured using a modified validated symptom questionnaire. Approximately 72 participants eventually developed skin rashes and local irritation and did not complete a full six months of dosing. However, these results which are based on MBD measurements at the time of enrollment in the study and again at the time dosing ended, show that even in those participants who dropped out of the study due to skin reactions, Endoxifen reduced MBD in a mean of 55 and 88 days for the 20 mg and 10 mg groups, respectively. Our initial evaluation indicates that the skin reactions are due to the active pharmaceutical ingredient. We are not currently planning to further develop our topical Endoxifen.

AT-H201 Inhalation Therapy for COVID-19

AT-H201 uses a novel combination of two drugs that have been previously approved by the FDA for other diseases. It is intended to improve compromised lung function for moderate to severely ill, hospitalized COVID-19 patients by inhalation. We also intend to study AT-H201 to potentially treat long haul COVID-19 survivors.

In May 2020, we completed in vitro testing of AT-H201 that showed that the components of AT-H201 inhibit SARS-CoV-2 infectivity of VERO cells, which is a standard cell type being used to study infectivity of the coronavirus. The AT-H201 components were found to be at least four times more potent than Remdesivir and at least 20 times more potent than Hydroxychloroquine. Potency was measured by microscopic examination of the cytopathic effect caused by SARS-CoV-2 in VERO cells. We received input from the FDA on potential pathways to develop AT-H201 and the FDA requested that we provide, among other things, additional pre-clinical and other information on AT-H201.

In September 2021 we began enrollment in Australia in a Phase 1/2a study of AT-H201. In December 2021 we completed enrollment in the first of four parts of the study and in February 2022 we started enrollment in the second part. The study plans to enroll 60 healthy participants and moderately ill hospitalized COVID-19 patients. The Australian regulatory authority will review data after each part of the study before we proceed to subsequent parts of the study. Because the final part of the study in COVID-19 infected patients may require that we use additional study sites, approval of that part of the study, and additional sites may be at a later date depending on COVID-19 infections.

AT-301 Nasal Spray for COVID-19

AT-301 is our proprietary drug candidate intended for nasal administration in patients immediately following diagnosis of COVID-19 but who have not yet exhibited symptoms severe enough to require hospitalization. It is intended for at-home use to reduce symptoms of COVID-19 and to slow the infection rate so that a person's immune system can more effectively fight COVID-19.

AT-301 is being developed with a nasal spray delivery mechanism because many COVID-19 patients are infected via the nasal passage. Our nasal spray formulation AT-301 is being designed to contain ingredients that can potentially block SARS-CoV-2 viral entry gene proteins in nasal epithelial cells by interfering with spike protein activation by host proteases, by masking receptor binding domains via electrostatic mechanisms, and by providing a generalized mucoadhesive epithelial barrier. In July 2020, we completed in vitro testing of AT-301 which showed that AT-301 inhibits SARS-CoV-2 infectivity of VERO cells in a laboratory culture.

We may also develop our AT-301 nasal spray to potentially help prevent COVID-19 infection — particularly for people in high-risk environments, such as people living with an infected patient, people living and working in healthcare facilities, emergency responders or teachers.

While the traditional vaccines have reduced the spread of COVID-19 infections, it is also clear to us that therapies such as AT-301 nasal spray will also play an important role, particularly as the COVID-19 virus variants have necessitated booster vaccines and potentially the development of vaccines that are variant-specific. Deadlier and/or more transmissible variants of COVID-19 continue to develop and reach the U.S. and in many other countries, questions continue to remain regarding how effective current and future vaccines may be against these and future variants. Additionally, none of the currently available vaccines are 100% effective, they may have side effects in selected populations and effectiveness is expected to diminish over time. For these reasons, we believe therapies like ours will provide valuable protection even as vaccines continue to be developed and deployed.

We have completed a Phase 1, double-blinded, randomized, and placebo-controlled safety study of AT-301 nasal spray in 32 healthy adult subjects who were divided into two study groups. Part A consisted of two single-dose cohorts receiving either active therapy, AT-301B, or the placebo comparator AT-301, at two different doses. Part B was a multiple dose arm with cohorts receiving either AT-301A or AT-301B for 14 days at two different doses. The primary objectives of the study were to evaluate the safety and tolerability of single and multiple doses of AT-301 administered via nasal instillation to healthy volunteers. Secondary objectives were to assess the incidence and severity of local irritation and bronchospasm following administration of AT-301 via nasal instillation. The study was conducted in Australia.

Final analysis of the data from the study indicates that there were no serious adverse events, no discontinuations, no bronchospasms, and only one subject of the 32 subjects in the study experienced adverse events that were considered moderate in severity and all other adverse events were considered mild. Our assessment is that AT-301 nasal spray was safe and well tolerated in this study. The most common treatment-related adverse events observed with AT-301 treatment with either single or multiple doses were nasal discomfort and sneezing.

In January 2021, we received input from the FDA on the AT-301 program and based in part on that input, we are now preparing to conduct an additional pre-clinical study, and following that, we expect to apply to the FDA to commence a Phase 2 study in the United States.

Other Programs; Immunotherapy/CAR-T Programs

Our immunotherapy/CAR-T programs are in early stage of development. On November 26, 2020, we entered into a sponsored research agreement with Dana-Farber Cancer Institute, Inc. The agreement provides that Atossa will support research of cytokine-coated nanoparticles for the potential treatment of breast cancer in research being conducted by Carl Novina, MD, Ph.D.

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

We have filed patent applications on a novel method to deliver CAR-T cells or other types of immunotherapy into the milk ducts of the breast, the location where most breast cancers originate for the potential targeted treatment of breast cancer. This approach uses targeted intraductal delivery of either T-cells that have been genetically modified to attack breast cancer cells or various other immune-therapies. We believe this intraductal method has several potential advantages including the reduction of toxicity by limiting systemic exposure of the T-cells or immunotherapy; improved efficacy by placing the T-cells or immunotherapy in direct contact with the target ductal epithelial cells that are undergoing or have undergone malignant transformation; and, lymphatic migration of the CAR-T cells or immunotherapy potentially extending their cytotoxic actions into the regional lymph system, which could limit tumor cell dissemination or metastasis. Moreover, our approach may be more cost effective if lower doses of therapy can be delivered compared to systemic CAR-T. We have not begun, and may not be successful in completing, pre-clinical and clinical studies of our CAR-T technology.

We paid a fee of $1,000,000 in June 2021 to a U.S. leading research institution for the exclusive right to negotiate for the period of six months for the acquisition of the world-wide rights to two oncology R&D programs. This agreement was amended on December 3, 2021, which extended the negotiation term through April 18, 2022. Those negotiations concluded in February 2022 without reaching a definitive agreement and the research institution agreed to return the $1,000,000 million fee as they did not honor their obligation and cancelled the agreement.

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Markets

Potential Breast Cancer Market Opportunities

We believe that, based in part on a January 2017 study by Defined Health Inc. (now called Cello Health Bioconsulting), a leading market research firm, the potential U.S. market for our Endoxifen in the breast cancer treatment and prevention settings is up to $1 billion annually. The American Cancer Society (ACS) estimates that in the U.S. in 2022, 287,850 women will be diagnosed with breast cancer, 47,550 of which will be under the age of 50 and 43,250 of which will die from the disease. Approximately 80% of breast cancers are ER+.

Although about 100 times less common than in women, breast cancer also affects men. The ACS estimates that in the U.S. in 2022, 2,710 new cases of invasive breast cancer will be diagnosed in men, and 530 men will die from breast cancer.

Potential COVID-19 Market Opportunities

According to the COVID-19 Dashboard by the Center for Systems Science and Engineering at Johns Hopkins University, as of the date of this report, more than 390 million cases of COVID-19 have been reported world-wide and over 5.7 million people have died from the disease. We believe the potential market for an at-home therapy like AT-301 is large given that most COVID-19 patients are not hospitalized and instead recover at home. Furthermore, our products could provide benefit to those who are infected with new variants that may escape vaccine protection or individuals who are vaccinated with break-through infections.

Vaccines have been approved for the prevention of COVID-19; however, their effectiveness may decrease over time and may not be effective against all variants of the novel coronavirus. Currently, the only FDA approved treatment for COVID-19 is Remdesivir for certain COVID-19 patients. In addition, emergency use authorization has been granted for two new oral antiviral agents, several monoclonal antibodies, and the use of convalescent plasma for certain COVID-19 patients. The impact of these on the development of our COVID-19 programs is unknown. There remains a significant unmet medical need for therapies to be approved for the treatment of all individuals infected with the virus.

A key feature of the original SARS-CoV-2 virus, and that is retained in both the Delta and Omicron variants, is the furin cleavage site found on the spike protein which facilitates viral infection. Our COVID-19 programs under development are designed to interact with this cleavage site so they are expected to be effective against both current and future COVID-19 variants that continue to contain a furin cleavage site.

Our Capital Resources

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

As of December 31, 2021, we had cash and cash equivalents of $136,377,000. Our capital raising activity in the past fiscal year consisted of the following:

On January 6, 2021, the Company entered into a securities purchase agreement with certain institutional and accredited investors relating to the offering and sale of 23,850,000 shares of Company common stock, par value $0.18 per share and warrants to purchase 17,887,500 shares of common stock. The combined purchase price for one share of common stock and a warrant to purchase 0.75 shares of common stock was $1.055. Subject to certain ownership limitations, the warrants are exercisable upon issuance. The warrants will expire on the 4.5-year anniversary of the date of issuance and have an exercise price of $1.055 per share. The common stock and warrants have been registered under the Securities Act of 1933, as amended. The offering closed on January 8, 2021, with net proceeds to the Company from the offering of approximately $23.3 million, after deducting fees and expenses.

On March 22, 2021, the Company entered into a securities purchase agreement with certain institutional and accredited investors relating to the offering and sale of 17,361,100 shares of our common stock, par value $0.18 per share. Concurrently with the offering, and pursuant to the purchase agreement, the Company also commenced a private placement whereby it issued and sold warrants exercisable for an aggregate of up to 13,020,825 shares of common stock. The combined purchase price for one share of common stock and a purchase warrant to purchase 0.75 shares of common stock is $2.88. Subject to certain ownership limitations, the warrants are exercisable upon issuance. The warrants will expire on the 4.5-year anniversary of the date of issuance. Subsequent to the issuance of the warrants, the Company filed a registration statement on Form S-3 (File No. 333-255411) to cover the sale of an aggregate of 13,020,825 shares of common stock issuable upon exercise of the warrants which was declared effective by the SEC on April 29, 2021. The net proceeds to the Company from the offering and the private placement are approximately $46.4 million, after deducting fees and expenses.

Warrant Activity

During 2021, the Company received $43.8 million from the exercises of warrants. The 2021 warrant exercises resulted in the reduction of approximately 37.5 million warrants, and the issuance of approximately 37.5 million shares of common stock. There were no warrant exercises during 2020.

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 be 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 expense than currently anticipated or because we add additional programs.

Research and Development Phase

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 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 or accrued 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, 2021 and 2020 were approximately $9,210,000 and $6,608,000, respectively.

Intellectual Property

We own patent applications directed to Endoxifen, treatments for COVID-19, and immunotherapies such as CAR-T therapies. We commonly seek patent claims directed to compositions of matter to therapeutics, including Endoxifen as well as methods of using such compositions. For each of our products, we have filed and expect to file multiple additional patent applications. As of January 15, 2022, based on a review of our patent estate, we own and are pursuing 83 pending patent applications (11 U.S. applications, including 1 allowed U.S. application, and 72 international applications) directed to our Endoxifen, immunotherapies such as CAR-T therapeutics and COVID-19 therapeutics programs. As a company focused on therapies in oncology and infectious diseases, we are not developing or commercializing any of our medical devices, including our breast aspirator devices, transportation kits, tools for breast surgeons, and nipple aspirate fluid (NAF) cytology tests or methods of using such devices, kits or tests – nor do we maintain an inventory of our medical devices. We continue to evaluate our patent portfolio on an ongoing basis and, as a clinical-stage pharmaceutical company, no longer file, prosecute, maintain, or defend our patents and patent applications directed to any of our medical devices, kits, tests, and compositions not core to our business or to methods of using the foregoing due to short patent terms remaining on them and changed business goals.

As of January 15, 2022, the following are the estimated number of patents (2) related to our programs that we are currently pursuing.

	Pending Applications (1, 2, 4)		Approximate Expiry Date (3)
	U.S.	International	
Endoxifen Programs	6	45	2038 - 2043
COVID-19 Programs	2	4	2041 - 2042
Immunotherapy/CAR-T Program	3	23	2037 - 2039

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 the Atossa 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 approximate expiry 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 will be adequate to conduct our business as planned. Additionally, any issued patents we currently own or obtain in the future may have a shorter patent term than expected or may not contain claims that will permit us to stop competitors from using our technology or similar technology or from copying our products.

4. The standards that the 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 scope, type and extent of patent claims that will be adequate to conduct our business as planned. Additionally, any issued patents we currently own or obtain in the future may have a shorter patent term than expected or may not contain claims that will permit us to stop competitors from using our technology or similar technology or from copying our product.

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 plan to rely on third parties to conduct nonclinical and clinical studies of our drugs under development. As our development programs advance, we expect that our manufacturing, pre-clinical and clinical studies, and related operational requirements will correspondingly increase. Each third-party contractor undergoes a qualification process 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 (GCP), Good Laboratory (GLP) and Good Manufacturing Practices (cGMP), and other applicable global regulations. 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 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.

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.

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 toxicological and pharmacological studies in animals. Studies must be performed in compliance with the FDA's GLP regulations and the U.S. Department of Agriculture's Animal Welfare Act.

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

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

The conduct of clinical trials is subject to extensive regulation, including compliance with the FDA's bioresearch monitoring regulations and GCP requirements, which establish standards for conducting, recording data from and reporting the results of, clinical trials, and are intended to assure that the data and reported results are credible and accurate, and that the rights, safety, and well-being of study participants are protected. Clinical trials must be conducted under written and approved protocols that detail the study objectives, parameters for monitoring safety, and the efficacy criteria, if any, to be evaluated. Each protocol is reviewed by the FDA as part of the IND application. In addition, each clinical trial must be reviewed, approved, and conducted under the auspices of an institutional review board, or IRB, at the institution conducting the clinical trial. 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.

A study sponsor is required to submit certain details about 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, etc. The designations are obtained from the FDA on a case-by-case basis and do not guarantee the ultimate approval of a product for commercialization.

Drug Approval

Assuming successful completion of the required clinical testing, the results of the preclinical studies and of the clinical trials, together with other detailed information, including information on the manufacture and composition of the investigational product, are submitted to the FDA in the form of an NDA requesting approval to market the product for one or more indications. The testing and approval process requires substantial time, effort and financial resources. Submission of an NDA requires payment of a review user fee to the FDA, which will be $3,177,218 for fiscal year 2022. 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.

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

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

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

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

Post-Approval Requirements

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

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

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

Non-U.S. Regulation

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

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 is mandatory for certain medicinal products, including orphan medicinal products, medicinal products derived from certain biotechnological processes, advanced therapy medicinal products and certain other new medicinal products containing a new active substance for the treatment of certain diseases. It is optional for certain other products, including medicinal products that are significant therapeutic, scientific or technical innovations, or whose authorization would be in the interest of public or animal health. The centralized procedure allows a company to submit a single application to the EMA which will provide a positive opinion regarding the application if it meets certain quality, safety, and efficacy requirements. Based on the opinion of the EMA, the European Commission makes a final decision to grant a centralized marketing authorization which is valid in all 27 E.U. Member States and three of the four European Free Trade Association states (Iceland, Liechtenstein and Norway). Cancer products are usually required to go through the centralized procedure.

Unlike the centralized authorization procedure, the decentralized marketing authorization procedure requires a separate application to, and leads to separate approval by, the competent authorities of each E.U. Member State in which the product is to be marketed. One national competent authority selected by the applicant, the Reference Member State, assesses the application for marketing authorization. Following a positive opinion by the competent authority of the Reference Member State the competent authorities of the other E.U. Member States, Concerned Member States are subsequently required to grant marketing authorization for their territory on the basis of this assessment except where grounds of potential serious risk to public health require this authorization to be refused. The mutual recognition procedure is similarly based on the acceptance by the competent authorities of the Concerned Member States of the marketing authorization of a medicinal product by the competent authorities of other Reference Member States. The holder of a national marketing authorization granted by a Reference Member State may submit an application to the competent authority of a Concerned Member State requesting that this authority mutually recognize the marketing authorization delivered by the competent authority of the Reference Member State.

Similar to accelerated approval regulations in the U.S., conditional marketing authorizations can be granted in the E.U. by the European Commission in exceptional circumstances. A conditional marketing authorization can be granted for medicinal products where a number of criteria are fulfilled: i) although comprehensive clinical data referring to the safety and efficacy of the medicinal product have not been supplied, 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 and iv) the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required. A conditional marketing authorization must be renewed annually.

Even if a product receives 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 and reference pricing mechanisms.

Health Technology Assessment, or HTA, of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some E.U. Member States. These E.U. Member States include the U.K, France, Germany 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.

Post-Approval Regulation

Similarly, to the U.S., both marketing authorization holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA and the competent authorities of the individual E.U. Member States both before and after grant of the manufacturing and marketing authorizations. Failure by us or by any of our third-party partners, including suppliers, manufacturers and distributors to comply with E.U. laws and the related national laws of individual E.U. Member States governing the conduct of clinical trials, manufacturing approval, marketing authorization of medicinal products and marketing of such products, both before and after grant of marketing authorization, may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials or to grant marketing authorization, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the marketing authorization, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

The holder of an E.U. marketing authorization for a medicinal product must also comply with E.U. pharmacovigilance legislation and its related regulations and guidelines, which entail many requirements for conducting pharmacovigilance, or the assessment and monitoring of the safety of medicinal products. These rules can impose on central marketing authorization holders for medicinal products the obligation to conduct a labor-intensive collection of data regarding the risks and benefits of marketed products and to engage in ongoing assessments of those risks and benefits, including the possible requirement to conduct additional clinical studies, which may be time consuming and expensive and could impact our profitability. Non-compliance with such obligations can lead to the variation, suspension, or withdrawal of the marketing authorization 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: regulators may shut down manufacturing facilities that they believe do not comply with regulations. Manufacturing requires a manufacturing authorization, and the manufacturing authorization holder must comply with various requirements set out in the applicable E.U. laws, regulations and guidance, including Directive 2001/83/EC, Directive 2003/94/EC, Regulation (EC) No 726/2004 and the European Commission Guidelines for Good Manufacturing Practice. These requirements include compliance with E.U. cGMP standards when manufacturing medicinal products and active pharmaceutical ingredients, including the manufacture of active pharmaceutical ingredients outside of the E.U. with the intention to import the active pharmaceutical ingredients into the E.U. Similarly, the distribution of medicinal products into and within the E.U. is subject to compliance with the applicable E.U. laws, regulations and guidelines, including the requirement to hold appropriate authorizations for distribution granted by the competent authorities of the E.U. Member States.

We and our third-party manufacturers are subject to cGMP, which are extensive regulations governing manufacturing processes, stability testing, record keeping, and quality standards as defined by the EMA, the competent authorities of E.U. Member States and other regulatory authorities. The EMA reviews Periodic Safety Update Reports for medicinal products authorized in the E.U. If the EMA has concerns that the risk benefit profile of a product has varied, it can adopt an opinion advising that the existing marketing authorization for the product be suspended or varied and can advise that the marketing authorization holder be obliged to conduct post-authorization safety studies. The EMA opinion is submitted for approval by the European Commission. Failure by the marketing authorization holder to fulfill the obligations for which the approved opinion provides can undermine the on-going validity of the marketing authorization.

Sales and Marketing Regulations

In the E.U., the advertising and promotion of our products are subject to E.U. Member States' laws governing promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. In addition, other legislation adopted by individual E.U. Member States may apply to the advertising and promotion of medicinal products. These laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics, or SmPC, as approved by the competent authorities. Promotion of a medicinal product that does not comply with the SmPC is considered to constitute off-label promotion. The off-label promotion of medicinal products is prohibited in the E.U. The applicable laws at E.U. level and in the individual E.U. Member States also prohibit the direct-to-consumer advertising of prescription-only medicinal products. Violations of the rules governing the promotion of medicinal products in the E.U. could be penalized by administrative measures, fines and imprisonment. These laws may further limit or restrict the advertising and promotion of our products to the general public and may also impose limitations on our promotional activities with health care professionals.

Anti-Corruption Legislation

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

Interactions between pharmaceutical companies and physicians are also governed by strict laws, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct developed at both 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. Violation of these laws could result in substantial fines and imprisonment. Payments made to physicians in certain E.U. Member States also must be publicly disclosed. Moreover, agreements with physicians must often be the subject of prior notification and approval by the physician's employer, his/her competent professional organization, and/or the competent authorities of the individual E.U. Member States. 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 E.U. level with related implementing laws in individual E.U. Member States which impose significant compliance obligations. For example, the E.U. Data Protection Directive, as implemented into national laws by the E.U. Member States, imposes strict obligations and restrictions on the ability to collect, analyze, and transfer personal data, including health data from clinical trials and adverse event reporting. Furthermore, there is a growth towards the public disclosure of clinical trial data in the E.U. which also adds to the complexity of processing health data from clinical trials. Such public disclosure obligations are provided in the new E.U. Clinical Trials Regulation, EMA disclosure initiatives, and voluntary commitments by industry. Data protection authorities from the different E.U. Member States may interpret the E.U. Data Protection Directive and national laws differently, which adds to the complexity of processing personal data in the E.U., and guidance on implementation and compliance practices are often updated or otherwise revised. Apart from exceptional circumstances, the E.U. Data Protection Directive prohibits the transfer of personal data to countries outside of the European Economic Area that are not considered by the European Commission to provide an adequate level of data protection including the U.S.

Further, the E.U. has recently adopted a comprehensive overhaul of its data protection regime from the current national legislative approach to a single European Economic Area Privacy Regulation, the General Data Protection Regulation 2016/679/EU (GDPR), which came into effect on May 25, 2018. The GDPR extends the scope of the E.U. data protection law to all foreign companies controlling, processing, and/or using data of E.U. residents. It imposes a strict data protection compliance regime with severe penalties of up to the greater of 4% of worldwide turnover and €20 million and includes new rights such as the "right to be forgotten" and "portability" of personal data, with more onerous requirements related to pseudo-anonymization and anonymization of personal data. Further, the scope of "personal data" has been expanded to include genetic data, and data concerning health and adverse event reporting from clinical trials.

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 it treats. The principal federal legislation is part of HIPAA. Pursuant to HIPAA, the Secretary of the Department of Health and Human Services, or 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. International regulations (such as the current Directive 95/46/EC and the GDPR and their implementing regulations) also provide privacy protection to clinical trial participants of their personal health care information. We take appropriate steps to protect the privacy of our clinical study participants.

Federal and State Fraud and Abuse Laws

The federal healthcare Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce referrals or in return for purchasing, leasing, ordering, or arranging for the purchase, lease, or order of any healthcare item or service reimbursable under a governmental payor program. The definition of "remuneration" has been broadly interpreted to include anything of value, including gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payments, ownership interests, opportunity to earn income, and providing anything at less than its fair market value. The Anti-Kickback Statute is broad, and it prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Recognizing that the Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements within the healthcare industry, HHS has issued a series of regulatory "safe harbors." These safe harbor regulations set forth certain provisions that, if met, will provide healthcare providers and other parties with an affirmative defense against prosecution under the federal Anti-Kickback Statute. Although full compliance with these provisions ensures 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.

From time to time, the Office of Inspector General, or OIG, issues alerts and other guidance on certain practices in the healthcare industry. In October 1994, the OIG issued a Special Fraud Alert on arrangements for the provision of clinical laboratory services. The Fraud Alert set forth a number of practices allegedly engaged in by some clinical laboratories and healthcare providers that raise issues under the "fraud and abuse" laws, including the Anti-Kickback Statute.

Compliance Program

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. To this end, we have established a compliance program that reviews for regulatory compliance procedures, policies, and facilities throughout our business. Failure to comply with applicable requirements may subject us to administrative or judicial sanctions, such as clinical holds, refusal of regulatory authorities to approve or authorize pending product applications, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, monetary penalties, injunctions and/or criminal prosecution.

Employees

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

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, and incentivizing our management team and our clinical, scientific and other employees and consultants. The principal purposes of our equity and bonus plans are to attract, retain and motivate personnel through the granting of stock-based and cash-based compensation awards, to align our interests and the interests of our stockholders with those of our employees and consultants. Our compensation committee approves associated merit increases and annual incentive bonus payments during the first quarter annually. When needed, we augment our employee base with outside consultants who specialize in various fields.

On March 29, 2021, the Board of Directors approved an amendment to the 2020 Stock Incentive Plan to increase the plan by 15 million shares. This amendment was approved by the stockholders on May 14, 2021.

Executive officers

The names of our executive officers and their ages as of December 31, 2021, are as follows:

Name	Age	Position
Executive Officers:		
Steven C. Quay, M.D., Ph.D.	71	Chairman of the Board, President and Chief Executive Officer
Kyle Guse, Esq., CPA (inactive)	58	Chief Financial Officer, General Counsel and Secretary

Steven C. Quay, M.D., Ph.D. Dr. Quay has served as Chief Executive Officer, President and Chairman of the Board of Directors of the Company since the Company was incorporated in April 2009. Dr. Quay is certified in Anatomic Pathology with the American Board of Pathology and completed both an internship and residency in anatomic pathology at Massachusetts General Hospital, a Harvard Medical School teaching hospital. He is a former faculty member of the Department of Pathology, Stanford University School of Medicine. Dr. Quay is an inventor, with 87 U.S. patents, 139 pending patent applications and is a named inventor on patents covering five 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 Medical School. He also received his B.A. degree in biology, chemistry and mathematics from Western Michigan University in 1971.

Kyle Guse, Esq., CPA (inactive). Mr. Guse has served as Chief Financial Officer, General Counsel and Secretary since January 2013. His experience includes more than 25 years of counseling life sciences and other rapid growth companies through all aspects of finance, corporate governance, securities laws and commercialization. Mr. Guse has practiced law at several of the largest international law firms, including from January 2012 through January 2013 as a partner at Baker Botts LLP and, prior to that, from October 2007 to January 2012, as a partner at McDermott Will & Emery LLP. Before working at McDermott Will & Emery, Mr. Guse previously served as a partner at Heller Ehrman LLP. Mr. Guse began his career as an accountant at Deloitte & Touche and he is a licensed Certified Public Accountant (inactive) and member of the Bar in the State of California. Mr. Guse earned a B.S. in business administration and an M.B.A. from California State University, Sacramento, and a J.D. from Santa Clara University School of Law.

Insurance

We currently maintain director's and officer's insurance, key-man life insurance for our Chief Executive Officer, commercial general and office premises liability insurance, insurance on our clinical studies, and product errors and omissions liability insurance for our products and services.

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.

ITEM 1A. RISK FACTORS

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

Risks Relating to our Business

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

Since December 2015, our business has focused on the development of novel therapeutics and delivery methods for the treatment of breast cancer and other breast conditions. In the first quarter of 2020, we began development of a novel potential therapy for hospitalized COVID-19 patients and in the second quarter 2020 we launched a second COVID-19 program for patients who do not require hospitalization. However, this is a departure from our historical focus on breast cancer and we have no operating history as a company in developing treatments for infectious diseases. Because of our limited operating history, particularly in the area of pharmaceutical development, our revenue and income potential is uncertain and cannot be based on prior results. Any evaluation of our business and prospects must be considered in light of these factors and the risks and uncertainties often encountered by companies in the development stage. Some of these risks and uncertainties include our ability to:

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

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

Although we have sufficient capital resources to fund our operations for at least the next 12 months based on our current business plan, our business plan may change and may require greater expenditures of capital than currently anticipated. We have not yet established an ongoing source of revenue sufficient to cover operating costs and allow us to continue as a going concern. Our ability to continue as a going concern is dependent on obtaining adequate capital to fund operating losses until we become profitable. If we are unable to obtain adequate capital, we may be unable to develop and commercialize our product offerings or geographic reach and we could be forced to cease operations.

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

For the year ended December 31, 2021, we incurred a net loss of $20,606,000 and we had an accumulated deficit of $129,234,000 since inception. As of December 31, 2021, we had cash and cash equivalents of $136,377,000. Because we have no current sources of revenue, we expect that we will need to raise capital again in the future to continue to fund our operations. When we elect to raise additional funds or when additional funds are required, we may raise such funds from time to time 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 will be prevented from developing our pharmaceutical candidates, pursuing acquisitions, invest in other companies including as a sponsor or investor in special purpose acquisition companies, licensing, development and commercialization efforts, and our ability to continue operations, generate revenues, and achieve or sustain profitability will be substantially harmed. We currently have fewer than 4 million shares of common stock authorized that are not reserved for specific purposes. Although we have proposed to our stockholders that our charter be amended to add additional authorized shares for various potential purposes, including potential capital raising transactions, to date our stockholders have not approved such a proposal and may not approve such a proposal in the future. A lack of authorized shares may limit our ability to raise capital when needed.

If we raise additional funds by issuing equity securities, our stockholders will experience dilution. Debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any debt financing or additional equity, including securities convertible into or exercisable for equity securities, that we raise may contain terms, such as liquidation, conversion and other preferences, that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary 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 don't agree or that don't produce stockholder value

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 be 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 expense than currently anticipated or because we add additional programs. You may not agree with the ways in which we expend our capital resources and we may not produce stockholder value from the ways we deploy our capital.

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

We have a limited operating history and have incurred net losses each year. Our net loss for the year ended December 31, 2021, was $20,606,000. We will continue to incur further losses in connection with research and development costs for development of our programs, including ongoing and additional clinical studies.

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

We may not succeed in achieving commercial market acceptance of any of our products. In order to gain market acceptance for the drugs under development, we will need to demonstrate to physicians and other healthcare professionals the benefits of these therapies including the clinical and economic application for their particular practice. 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, 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), or the patients themselves, will likely heavily influence physicians' decisions to recommend or use our products.

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

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

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. These employees may not be available in this geographic region. In addition, competition for these employees is intense and recruiting and retaining skilled employees is difficult, particularly for a development-stage organization 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 have made employment costs substantially higher. As a result, our operating expenses may go up 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 anti-cancer and other pharmaceutical products is highly uncertain and obtaining regulatory approval to market drugs to treat cancer and other breast conditions 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, 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 clinical research organizations (CROs), and trial sites;
- availability of vaccines or approved therapeutics developed by others may reduce the demand and commercial opportunities for our COVID-19 drug candidates; and
- failure of third-parties, such as clinical research organizations, 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 interim results reported in May 2020 for our Phase 2 study of Endoxifen in Australia. 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 results, or different conclusions or considerations may qualify such results once existing data have been more fully evaluated. In addition, third parties, including regulatory agencies, may not accept or agree with our assumptions, estimations, calculations or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular compound and our business in general.

For example, some participants in the Phase 2 MBD study we conducted in Stockholm, Sweden despite showing reduced MBD as a result of using our topical Endoxifen exited the study before completing a full six months of dosing because of skin irritation and rashes.

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 the 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.) 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 preclinical 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 preclinical 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. Preclinical 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.

Regulatory agencies may also fail to grant approvals to commence studies for any number of reasons. For example, in May 2020, the FDA asked for additional pre-clinical data and other information for a proposed study of AT-H201. If we cannot provide the requested data and information the FDA may not authorize us to commence this study.

Another example is that Hunan Research Ethics Committee (HREC) provided approval to commence the study but has not approved the final part of the study involving COVID-19 infected patients because it is unclear if that part of the study will be conducted at the site in Australia. The addition of new sites will require additional approvals and we will have to conduct this part of the study where COVID-19 infections allow.

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

We are developing our products, including AT-H201 drug to treat COVID-19 patients and Endoxifen to treat patients with breast cancer, 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 intend to enroll patients in studies of our drug candidates for patients who may die while enrolled in our studies. For example, we are developing AT-H201for COVID patients who may be severely ill, including patients on ventilators. COVID patients on ventilators are very sick and many do not recover either because of COVID-19 or other illnesses. Patients in our Endoxifen studies may have breast cancer which could cause death. As a result, it is likely that we will observe severe adverse outcomes of some patients in our clinical trials for our drugs, 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 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 Good Laboratory Practices (GLP) 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 effect a commercial launch of the applicable drug, or once launched, to satisfy ongoing demand. Any product shortage could also impair our ability to deliver contractually required supply quantities to applicable collaborators, as well as to complete any additional planned clinical trials.

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

In addition, we depend on medical institutions and CROs (together with their respective agents) to conduct clinical trials and associated activities in compliance with Good Clinical Practices (GCP) and data privacy standards such as defined under the Health Insurance Portability and Accountability Act (HIPAA), California Consumer Privacy Acts (CCPA), and General Data Protection Regulation (GDPR) and in accordance with our timelines, expectations and requirements. We are substantially dependent on the organizations conducting the clinical trials of our proprietary Endoxifen. 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 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 Endoxifen drug substance. The use of primary vendors for core operational activities, such as, manufacturing, the resulting lack of diversification, expose 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.

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. Any such failure 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 compound, delays in or cessation of clinical trials, failure to obtain or revocation of product approvals or authorizations, product recalls, withdrawal or 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 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:

- the effects of the ongoing coronavirus pandemic, including access to clinical trial sites both by study participants and our clinical research organizations;
- failure to obtain on a timely basis, or at all, approval from the applicable institutional review board or ethics committee to open a clinical study;
- lower than anticipated patient enrollment for reasons such as existing conditions, eligibility criteria or if patients perceive a lack of benefit to enroll in the study for whatever reason;
- delays in reaching agreements on acceptable terms with prospective CROs; and
- failure of CROs or other third parties to effectively and timely monitor, oversee, and maintain the clinical trials.

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. Any successful product liability claim may prevent us from obtaining adequate product liability insurance in the future on commercially desirable or reasonable terms. An inability to obtain sufficient insurance coverage at an acceptable cost, or otherwise, to protect against potential product liability claims could prevent or inhibit the commercialization of our products.

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 January 15, 2022, we own and are pursuing 83 (11 U.S. and 72 international applications) pending provisional and non-provisional patent applications. We continue to evaluate the full range of our technologies and file new patent applications.

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 and 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 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. The patent positions of diagnostic companies and pharmaceutical and biotechnology companies, including our patent position, are generally highly uncertain and 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 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 such 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, deemed unenforceable, invalidated or circumvented. 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 or 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;
- the patents of others will not have an adverse effect on our business; or
- our patents and patent applications or patents and patent applications that we license from others, if any will survive legal challenges, and remain valid and enforceable.

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

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

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

United States Patent and Trademark Office (USPTO) and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent process. Periodic maintenance fees, renewal fees, annuity fees, and various other governmental fees on any issued patents and/or applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ outside firms and rely on our outside counsel to pay these fees. While an inadvertent lapse may sometimes be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market earlier than should otherwise have been the case, which would have a material adverse effect on our business.

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

As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly on obtaining and enforcing patents. Obtaining and enforcing patents in the biotechnology and pharmaceutical industries involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. For the past several years, the U.S. has conducted proceedings involving post-issuance patent review procedures, such as *inter partes* review (IPR), and post-grant review and covered business methods. These proceedings are conducted before the Patent Trial and Appeal Board (PTAB), of the USPTO. Each proceeding has different eligibility criteria and different patentability challenges that can be raised. In this regard, the IPR process permits any person (except a party who has been litigating the patent for more than a year) to challenge the validity of U.S. patents on the grounds that it was anticipated or made obvious by prior art. 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. 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 Prometheus and Alice decision, holding that several claims drawn to measuring drug metabolite levels from patient samples were not patentable subject matter. The full impact of the Prometheus and Alice 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 *inter partes* review, post-grant review, derivation, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in various foreign jurisdictions. 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. 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 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. Third parties may also attempt to initiate reexamination, post-grant review or *inter partes* review of our patents in the USPTO. We may also become involved in similar proceedings in the patent offices in other jurisdictions regarding our intellectual property rights with respect to our products and technology.

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

We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other diagnostic, medical device or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise improperly used or disclosed confidential information of these third parties or our employees' former employers. Further, we may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our products. We may also be subject to claims that former employees, consultants, independent contractors, collaborators or other third parties have an ownership interest in our patents or other intellectual property. Litigation may be necessary to defend against these and other claims challenging our right to and use of confidential and proprietary information. If we fail in defending any such claims, in addition to paying monetary damages, we may lose our rights therein. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

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

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

Risks Related to Our Industry

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

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

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

The FDA recently announced the Coronavirus Treatment Acceleration Program. That program may not, however, lead to a faster review or approval of our FDA submissions including for our COVID-19 studies.

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

Federal privacy regulations, among other things, restrict our ability to use or disclose protected health information in the form of patient-identifiable laboratory data, without written patient authorization, for purposes other than payment, treatment, or healthcare operations as defined under HIPAA, except for disclosures for various public policy purposes and other permitted purposes outlined in the privacy regulations. The privacy regulations provide for significant fines and other penalties for wrongful use or disclosure of protected health information, including potential civil and criminal fines and penalties. Although the HIPAA statute and regulations do not expressly provide for a private right of damages, we could incur damages under state laws, for example, California Consumer Privacy Act, to private parties for the wrongful use or disclosure of confidential health information or other private personal information.

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

The HIPAA privacy regulations establish a “floor” of minimum protection for patients as to their medical information and do not supersede state laws that are more stringent. Therefore, we are required to comply with both HIPAA privacy regulations and various state privacy laws. The failure to do so could subject us to regulatory actions, including significant fines or penalties, and to private actions by patients, as well as to adverse publicity and possible loss of business. In addition, federal and state laws and judicial decisions provide individuals with various rights for violation of the privacy of their medical information by healthcare providers such as us.

The collection and use of personal data including personal health data of individuals in the E.U. regardless of citizenship or residence is governed by the provisions of the General Data Protection Regulation 2016/679 (commonly known as GDPR) which came into effect on May 25, 2018 with no transition period, and which has penalties for noncompliance. GDPR supersedes the Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995. GDPR regulates the protection of individuals in E.U. with regard to the processing of personal data and on the free movement of such data within E.U. and outside the E.U. and European Economic Area ("EEA") areas. GDPR imposes a number of requirements including an obligation to seek the consent of individuals to whom the personal data relates, the information that must be provided to the individuals, notification of data processing obligations to the competent national data protection authorities of individual E.U. Member States, and the security and confidentiality of the personal data. No personal data may be processed unless this processing is done under one of six lawful bases specified by the regulation (consent, contract, public task, vital interest, legitimate interest or legal requirement). When the processing is based on consent the data subject has the right to revoke it at any time.

Failure to comply with the requirements of GDPR, and the related national data protection laws of the E.U. Member States 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.

Further, from January 1, 2021, companies have to comply with the GDPR and also the United Kingdom GDPR, or UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR, i.e., fines up to the greater of £17.5 million or 4% of global turnover. The European Commission has adopted an adequacy decision in favor of the UK, enabling data transfers from EU member states to the UK without additional safeguards. However, the UK adequacy decision will automatically expire in June 2025 unless the European Commission re-assesses and renews/ extends that decision, and remains under review by the Commission during this period. The relationship between the UK and the EU in relation to certain aspects of data protection law remains unclear, and it is unclear how UK data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the UK will be regulated in the long term. These changes may lead to additional costs and increase our overall risk exposure

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

We rely on information technology systems to keep financial records, manage our manufacturing operations, fulfill customer orders, capture laboratory data, 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 disaster. If we were to experience a prolonged system disruption in our information technology systems or those of certain of our vendors, it could negatively impact our ability to serve our customers, which could adversely impact our business. Although we maintain offsite back-ups of our data, if operations at our facilities were disrupted, it may cause a material disruption in our business if we are not capable of restoring function on an acceptable timeframe. In addition, our information technology systems are potentially vulnerable to data security breaches — whether by employees or others — which may expose sensitive data to unauthorized persons. Such data security breaches could lead to the loss of trade secrets or other intellectual property, or could lead to the public exposure of personal information (including sensitive personal information) of our employees, customers and others, any of which could have a material adverse effect on our business, reputation, financial condition and results of operations. In addition, any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, including state data protection regulations and the E.U. GDPR, and other regulations, the breach of which could result in significant penalties. In addition, these breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above.

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

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

In addition to the 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 the new federal legislation and the expansion in government's effect on the U.S. healthcare industry 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.

Other Risks

The continued spread of coronavirus globally could adversely impact our operations and clinical trials.

Public health pandemics, epidemics or outbreaks could adversely impact our business. The ongoing COVID-19 pandemic and related supply-chain disruptions are affecting the United States and global economies and may affect our operations and those of third parties on which we rely, including causing possible disruptions in the supply of the Company's Endoxifen, AT-H201, AT-301 and the conduct of current and future clinical trials. In addition, the COVID-19 pandemic may affect the operations of the U.S. FDA and other health authorities including similar entities/agencies in Sweden and Australia, which could result in delays in meetings, reviews and approvals. The evolving COVID-19 pandemic could also directly or indirectly impact the pace of enrollment in our clinical trials for at least the next several months and possibly longer as patients may avoid or may not be able to travel to healthcare facilities and physicians' offices except for a health emergency. Such facilities and offices may also be required to focus limited resources on non-clinical trial activities, including treatment of COVID-19 patients, and may not be available, in whole or in part, for clinical trial activities related to our products under development. We have not experienced any delay in drug supply for our ongoing and planned clinical studies, including studies of Endoxifen, AT-301 and AT-H201. Additionally, while the potential economic impact brought by, and the duration of, the COVID-19 pandemic is difficult to assess or predict, the impact of the COVID-19 pandemic on the global financial markets may reduce the Company's ability to access capital, which could negatively impact the Company's short-term and long-term liquidity. The ultimate impact of the COVID-19 pandemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, financing or clinical trial activities or on healthcare systems or the global economy as a whole. However, these effects could have a material adverse impact on the Company's liquidity, capital resources, operations, financial position and business and those of the third parties on which we rely. We will continue to monitor future enrollment in studies for potential restrictions on site visits, mammograms or the impositions of new restrictions on trials as a result of the COVID-19 pandemic. The continued spread of the coronavirus globally could adversely impact our operations that are dependent on third-party service providers for a number of critical operational activities including, in particular,

- regulatory (FDA, MPA, TGA) meetings and approvals could be delayed;
- protocol review groups (IRB, HREC, IEC, etc.) meetings and approvals could be delayed;
- our drug supply chain could be interrupted and shipping may incur new surcharges;
- enrollment in our clinical studies could slow or be halted;
- operations in general could be disrupted with potential infection of employees and consultants and difficulties with a remote work force;
- quarantines of people and drugs needed for our studies could adversely affect operations;
- our stock price could be adversely impacted and access to capital could be more challenging; or
- our ability to access our facilities and timely prepare and file regulatory reports with the SEC.

The end of the COVID-19 pandemic may make our COVID-19 programs obsolete.

Although many public health authorities have said that COVID-19 will continue to be present in circulation for the foreseeable future, the end of the pandemic and the shift to an endemic phase would likely reduce the need for our COVID-19 product candidates and may make them obsolete or unnecessary. It is possible that our development timeline for these programs will exceed the duration of the pandemic such that we do not realize a positive return on these investments. To the extent that the stock market has placed value in our COVID-19 programs, positive developments relating to the end of the pandemic could have a negative impact on our stock price.

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 satisfy the continued listing standards going forward.

Although our shares of common stock are listed on The Nasdaq Capital Market, we cannot ensure that we will be able to satisfy the continued listing standards of The Nasdaq Capital Market going forward. If we cannot satisfy the continued listing standards going forward, Nasdaq may commence delisting procedures against us, which could result in our stock being removed from listing on The Nasdaq Capital Market.

If our stock price does not satisfy the $1.00 minimum bid price requirement or we otherwise fail to satisfy other continued listing requirements (and such other continued listing requirements may be enhanced during the period our stock price is below the $1.00 minimum bid requirement including a requirement that we maintain at least $5 million in stockholders' equity rather than the $2.5 million that is typically required for continued listing), we may be delisted from Nasdaq, which could adversely affect our stock price, liquidity, and our ability to raise funding. Our common stock has at times trades below the $1.00 minimum bid requirement.

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

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

Our stock price is highly volatile. During the one year prior to February 18, 2022, our stock price has ranged from $1.20 to $8.62 per share. In addition to the factors discussed in this report, the trading price of our common stock may fluctuate significantly in response to numerous factors, many of which are beyond our control, including:

- results of clinical studies;
- regulatory and FDA actions, including inspections and warning letters;
- actions of securities analysts who initiate or maintain 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 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.

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 you.

Our ownership may become concentrated among a small number of stockholders. These stockholders, acting together, will 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 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 you.

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, 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, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting, 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 is listed, the Securities and Exchange Commission, or other regulatory authorities, which could require additional financial and management resources.

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

Our Stockholder Rights Agreement that we adopted in May 2014, our amended and restated certificate of incorporation, and amended and restated bylaws contain provisions that could delay or prevent a change in control or changes in our Board of Directors that our stockholders might consider favorable. These provisions include the establishment of a staggered Board of Directors, 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, our Shareholder Rights Plan and Delaware law might discourage, delay or prevent a change in control or changes in the Board of Directors of the Company. These provisions could also discourage proxy contests and make it more difficult for an investor 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 the Board of Directors.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

As of December 31, 2021, we leased a total of approximately 202 square feet of office space in one location in Seattle, Washington, from WW 107 Spring Street LLC. We believe that our current facilities will be adequate to meet our needs for the next 12 months. This information is incorporated in this report under "PART II, ITEM 7. MANAGEMENT DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS – Commercial Lease Arrangements."

ITEM 3. LEGAL PROCEEDINGS

We are not currently a party to any material legal proceedings.

ITEM 4. MINE SAFETY DISCLOSURE

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 February 18, 2022, there were approximately 36 stockholders of record of our common stock, one of which is Cede & Co., a nominee for Depository Trust Company, or DTC and approximately 122,180 beneficial holders. 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

The Company has never declared or paid any cash dividends on our common stock. We currently intend to retain any future earnings to finance the growth and development of our business.

Issuer Purchases of Securities

We did not repurchase any of our equity securities during the fourth quarter of the year ended December 31, 2021.

Unregistered Sales of Equity Securities and Use of Proceeds

Not applicable.

ITEM 6. RESERVED

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

Overview

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

Company Overview

We are a clinical-stage biopharmaceutical company seeking to develop proprietary innovative medicines in areas of significant unmet medical need in oncology and infectious diseases, with a current focus on breast cancer, other breast conditions and COVID-19. Our drug under development for breast cancer and other breast conditions is Endoxifen which is being developed primarily in two settings: one to reduce tumor cell activity in breast cancer patients in the neoadjuvant setting, meaning prior to surgery; and another to reduce dense breast tissue in women. Our two COVID-19 drugs under development are AT-H201, an inhalation therapy to improve lung function of moderate to severely ill, hospitalized COVID-19 patients; and AT-301, a nasal spray for COVID-19 patients for at-home use. A key feature of the original SARS-CoV-2 virus that is retained in both the Delta and Omicron variants, is the furin cleavage site found on the spike protein which facilitates viral infection. Our COVID-19 programs under development are designed to interact with this cleavage site so they are expected to be effective against both current and future COVID-19 variants that continue to contain a furin cleavage site.

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

Summary of Leading Programs

Endoxifen. Endoxifen is an active metabolite of tamoxifen which is an FDA-approved drug to treat and prevent breast cancer in high-risk women. We are developing a proprietary form of Endoxifen which is administered orally for the potential treatment of breast cancer and women with breast density. We have successfully completed three Phase 1 clinical studies (including a study in men) and two Phase 2 clinical studies with our proprietary Endoxifen. We have also completed significant pre-clinical development and have developed clinical manufacturing capabilities through qualified third parties.

Endoxifen for Women with Breast Density. Mammographic breast density (MBD) is an emerging public health issue affecting over 10 million women in the U.S. Studies conducted by others have shown that MBD increases the risk of developing breast cancer and that reducing MBD can reduce the incidence of breast cancer.

In December 2021, we commenced a Phase 2 study of our proprietary oral Endoxifen. The study, known as the Karisma-Endoxifen study, is a Phase 2, randomized, double-blind, placebo-controlled, dose-response study of our proprietary oral Endoxifen in healthy premenopausal women with measurable breast density. The primary objective of the study is to determine the dose-response relationship of daily Endoxifen on breast density reduction. Secondary endpoints will assess safety and tolerability, and the trial includes an exploratory endpoint to assess durability of the breast density changes. The study is being conducted at the South General Hospital in Stockholm and will include approximately 240 participants who will receive daily doses of Endoxifen or placebo for six months. The study is being led by principal investigator Per Hall, M.D., Ph.D., Department of Medical Epidemiology and Biostatistics at Karolinska Institutet.

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

Endoxifen for Neoadjuvant Treatment of Breast Cancer. We are also developing Endoxifen to treat breast cancer in the neoadjuvant setting, which is the administration of a therapy before the surgical treatment, with a current focus on breast cancers that are classified as estrogen receptor positive (ER+). Although there are numerous neoadjuvant treatments for breast cancers that are not ER+, there are few neoadjuvant treatments for ER+ breast cancer which comprises about 78% of all breast cancers. We believe there is a compelling need for therapy with our Endoxifen in this setting.

In December 2021, we completed a PIND meeting with the FDA. The purpose of the meeting was to obtain input from the FDA on pre-clinical, clinical, manufacturing and regulatory matters in the U.S. for our proprietary Endoxifen to treat breast cancer. Based in part on the feedback from the FDA, we plan to open an IND for a multi-center Phase 2 study to further advance our Endoxifen in the neoadjuvant setting. We plan to focus our development on pre-menopausal women with ER+, human epidermal growth factor receptor 2 negative (HER2-) breast cancer for whom the current treatment options typically include drugs that suppress ovarian function and essentially force the patient into menopause.

We recently completed a Phase 2 study in Australia which enrolled 7 newly diagnosed patients with ER+ and stage 1 or 2 invasive breast cancer, requiring mastectomy or lumpectomy. In February 2021, we concluded that the study produced substantially positive results and that continuing enrollment in the study would not be necessary in advancing the program. We therefore discontinued the study based in part on results from the first six patients. In June 2021, we reported final results from the study of all 7 patients which showed that tumor cell proliferation in study participants was reduced by an average of 65%, as measured by Ki-67 expression, which is a common measure of tumor cell activity in breast cancer.

AT-301 for COVID-19. AT-301 is our proprietary drug formulation candidate intended for nasal administration in patients immediately following diagnosis of COVID-19 but who have not yet exhibited symptoms severe enough to require hospitalization. It is intended for at-home use to reduce symptoms of COVID-19 and to slow the infection rate so that a person's immune system can more effectively fight COVID-19.

AT-301 is being developed with a nasal spray delivery mechanism because many COVID-19 patients are infected via the nasal passage. Our nasal spray formulation AT-301 is being designed to contain ingredients that can potentially block SARS-CoV-2 viral entry gene proteins in nasal epithelial cells by interfering with spike protein activation by host proteases, by masking receptor binding domains via electrostatic mechanisms, and by providing a generalized mucoadhesive epithelial barrier.

In October 2020, we completed enrollment in a Phase 1 study of AT-301 which was a double-blinded, randomized, and placebo-controlled safety study of AT-301 nasal spray in 32 healthy adult subjects. An evaluation of the data indicated that there were no serious adverse events, no discontinuations, and only one of the subjects in the study experienced adverse events that were considered related to the study drug and moderate in severity. We concluded that our AT-301 nasal spray was safe and well tolerated in this study. We received input from the FDA on this program in 2021 and based in part on that input, we are now preparing to conduct additional pre-clinical studies. Following that, we expect to apply to the FDA to commence a Phase 2 study in the United States.

We may also develop our AT-301 nasal spray to potentially help prevent COVID-19 infection — particularly for people in high-risk environments, such as people living with an infected patient, people living and working in healthcare facilities, emergency responders or teachers.

AT-H201 for COVID-19. AT-H201 is a proprietary combination of two drugs previously approved by the FDA to treat other diseases. It is intended to improve compromised lung function for moderate to severely ill, hospitalized COVID-19 patients by inhalation. We also intend to study AT-H201 on long haul COVID-19 survivors. We received input from the FDA on potential pathways to develop AT-H201 and the FDA requested that we provide, among other things, additional pre-clinical results and other information on AT-H201.

In September 2021 we began enrollment in Australia in a Phase 1/2a study of AT-H201 and in February 2022, we began enrollment in the second of four parts of the study. The study plans to enroll 60 healthy participants and moderately ill hospitalized COVID-19 patients. The Australian regulatory authority will review data after each part of the study before we may proceed with subsequent parts of the study. Because the final part of the study in COVID-19 infected patients may require that we use additional study sites, approval of that part of the study, and additional sites will depend on COVID-19 infections and may therefore be delayed.

Impact of the Novel Coronavirus

The continued spread of the COVID-19 pandemic is affecting the U.S. and global economies and may affect the Company's operations and those of third parties on which the Company relies, including causing possible disruptions in the supply of the Company's Endoxifen, AT-H201, AT-301, the pace of enrollment in our clinical trials and the conduct of current and future clinical trials. In addition, the COVID-19 pandemic may affect the operations of the U.S. FDA and other health authorities including similar entities/agencies in Sweden and Australia, which could result in delays in meetings, reviews and approvals. Additionally, while the potential economic impact brought by, and the duration of, the COVID-19 pandemic is difficult to assess or predict, the impact of the COVID-19 pandemic on the global financial markets may reduce the Company's ability to access capital, which could negatively impact the Company's short-term and long-term liquidity. The ultimate impact of the COVID-19 pandemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, financing or clinical trial activities or on healthcare systems or the global economy as a whole as a result of the COVID-19 pandemic; however, we have not experienced a significant delay in the enrollment or the drug supply for our ongoing and planned clinical studies, including studies of Endoxifen, AT-301 and AT-H201. In recent weeks the number of reported cases of COVID-19 has declined in many countries. If this trend continues it may be difficult to enroll participants in our COVID-19 clinical studies.

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 Agreements

On March 1, 2021, the Company entered into an operating lease to pay $750 monthly rent for a term of 12 months with WW 107 Spring Street LLC to lease office space at 107 Spring Street, Seattle, Washington.

Critical Accounting Policies and Significant 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, or U.S. GAAP. The preparation of these 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 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.

While our significant accounting policies are more fully described in Note 3 to our consolidated financial statements included in this Form 10-k, we believe that the following accounting policies are the most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Research and Development

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

We have entered into various research and development contracts with research institutions, CRO, clinical manufacturing organizations (CMO) 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 accompanying consolidated balance sheets as prepaid expenses.

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

Stock-Based Payments

We measure all stock option awards grated to employees, non-employee directors and consultants based on the fair value on the date of grant and recognize compensation expense over the requisite estimated service period which is generally the vesting period of the respective 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 our stock options, the expected life of the options, an expectation regarding future dividends on our common stock, estimation of an appropriate risk-free interest rate and expected term. Our expected common stock price volatility assumption is based upon the historic volatility of our stock price. The expected life assumption for stock option grants is based an average of the contractual term of the options of ten 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 used for each grant was based upon prevailing short-term interest rates over the expected life of the options.

While assumptions used to calculate and account for share-based compensation awards represent management's best estimates, these estimates involve inherent uncertainties and the application of management's judgement. As a result, if revisions are made to our underlying assumptions and estimates, our share-based compensation expense could vary significantly from period to period.

Results of Operations

Comparison of Years Ended December 31, 2021 and 2020 (amounts in thousands)

Revenue and Cost of Revenue:

For the years ended December 31, 2021 and 2020, we have no source of sustainable revenue and no associated cost of revenue.

Operating Expenses: Total operating expenses were $20,521 for the year ended December 31, 2021, which is an increase of $5,914, or 40% from the year ended December 31, 2020. Operating expenses for 2021 consisted of research and development (R&D) expenses of $9,210 and general and administrative (G&A) expenses of $11,311. Operating expenses for 2020 consisted of R&D expenses of $6,608 and G&A expenses of $7,999. The basis for the increased operating expenses in 2021 is explained below.

Research and Development Expenses: R&D expenses for the year ended December 31, 2021, were $9,210, an increase of $2,602 or 39% from total R&D expenses for the year ended December 31, 2020, of $6,608. The increase in R&D expense is attributed to increased spending on clinical and non-clinical trials of $422 over 2020 due to additional pre-clinical testing and manufacturing expenses for Endoxifen. Stock-based compensation, which is a non-cash charge, increased $693 year over year. R&D compensation was also up $227 due to salary, bonus and benefit increases during 2021. 2021 R&D expenses also include a $1,000 exclusivity payment for the exclusive right to negotiate a with a leading research organization for the rights to two oncology clinical programs. Refer to Note 15 Subsequent Events, included in this Annual Report on Form 10-K. There were no similar exclusivity payments made during 2020. The remaining increase is due to increased spending on professional fees in 2021 as compared to 2020, due to the hiring of regulatory consultants and other vendors.

General and Administrative Expenses: G&A expenses were $11,311 for the year ended December 31, 2021, an increase of $3,312, or 41% from total G&A expenses for the year ended December 31, 2020, of $7,999. The increase in G&A expenses for the year ended December 31, 2021, is attributable to non-cash stock-based compensation expense of $1,555. Compensation also increased $460 due to the addition of a new employee during 2021, increased hourly employees time, and employee bonus increases over the prior year. Insurance expense has also increased $668 due to the addition of the COVID-19 program year over year. Professional fees have also increased $897 due primarily to an increase of proxy costs for investor outreach on a proposal to increase authorized shares, expense related to a special stockholder meeting and increased consulting and auditing fees. Legal fees decreased $360 year over year due to lower patent activity in 2021.

Warrant Financing Costs and Change in Fair Value of Common Stock Warrants: There were no common stock liability warrants issued during the year ended December 31, 2021. The December 11, 2020 financing including the overallotment on December 28, 2020, included the issuance of common stock liability warrants. The Company incurred financing costs associated with these common stock liability warrants of $939 upon issuance. The Company also recorded changes in the fair value of the liability warrants during the year ended December 31, 2020 of $2,333. On January 1, 2021, the Company implemented ASU No. 2020-06 and reclassified the common stock warrant liability to equity.

Income taxes: We have incurred net operating losses since inception; we did not record an income tax benefit for our incurred losses for the years ended December 31, 2021 and 2020, due to uncertainty regarding utilization of our net operating loss carryforwards and due to our history of losses.

Liquidity and Capital Resources

The Company has incurred net losses and negative operating cash flows since inception. For the year ended December 31, 2021, the Company recorded a net loss of $20,606 and used $16,472 of cash in operating activities. As of December 31, 2021, the Company had $136,377 in cash and cash equivalents and working capital of $138,114. We believe we have sufficient cash to fund our projected operating requirements for at least the next 12 months.

Cash Flows

As of December 31, 2021, we had cash, cash equivalents and restricted cash of $136,487.

Net Cash Flows from Operating Activities: Net cash used in operating activities was $16,472 for the year ended December 31, 2021, an increase of $4,902, or 42%, compared to net cash used in operating activities for the year ended December 31, 2020, of $11,570. The increase in the 2021 period as compared to 2020 resulted primarily from an increase in clinical trial activity of $422. Stock-based compensation also increased $2,248 over the same period in 2020. The decrease of $2,333 in fair value of common stock warrant liability and warrant financing expense of $939 was the result of the implementation of ASU No. 2020-06 on January 1, 2021, which resulted in the reclassification of the liability warrants to equity. An additional $1,000 of the increase year over year was attributable to a one-time fee we paid in 2021 to a leading research institution for the exclusive right to negotiate for world-wide rights to two oncology R&D programs.

Net Cash Flows from Investing Activities: Net cash used in investing activities was $9 for the year ended December 31, 2021, which was the same amount used in investing activities for the year ended December 31, 2020, of $9.

Net Cash Flows from Financing Activities: Net cash provided by financing activities was $113,304 for the year ended December 31, 2021, an increase of $74,752, or 194%, compared to net cash provided by financing activities of $38,552, for the year ended December 31, 2020. During the year ended December 31, 2021, the Company issued common stock and warrants for net proceeds of $69,668 and received proceeds from the exercise of warrants of $43,818. The 2020 financing activity of $38,552 consisted of the issuance of common stock and warrants for net proceeds of $28,954, the issuance of Series C convertible preferred stock and warrants for net proceeds of $4,947 and proceeds from issuance of common stock of $4,665.

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.

If we are unable to raise additional capital when needed, however, we could be forced to curtail or cease operations. Our future capital uses and requirements will depend on the time and expenses needed to begin and continue clinical trials for our new drug developments. As mentioned earlier, the COVID-19 outbreak could adversely impact the timing and enrollment of our clinical trials.

Additional funding may not be available to us on acceptable terms or at all. The continued spread of COVID-19 and uncertain market conditions 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, if we raise additional funds by issuing equity securities or by selling debt securities, if convertible, further dilution to our existing stockholders would result. To the extent our capital resources are insufficient to meet our future capital requirements, we will need to finance our future cash needs through public or private 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.

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.

Recent Accounting Pronouncements

Refer to Note 3 to the Consolidated Financial Statements included in this Annual Report on Form 10-K for recently issued accounting pronouncements not yet adopted.

Recently Adopted Accounting Pronouncements

Refer to Note 3 to the Consolidated Financial Statements included in this Annual Report on Form 10-K for recently adopted accounting pronouncements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements required by this item are set forth beginning on page 48 of this 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

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports that we file or submit under the Securities Exchange Act of 1934, as amended (Exchange Act), is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer (our principal executive officer) and Chief Financial Officer (our principal financial officer) as appropriate, to allow for timely decisions regarding required disclosure.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of December 31, 2021. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that as of December 31, 2021, our disclosure controls and procedures were effective.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined under the Exchange Act in Rules 13a-15(f) and 15d-15(f)). 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.

Under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting 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 the framework in Internal *Control—Integrated Framework*, our management concluded that our internal control over financial reporting was effective as of December 31, 2021. The effectiveness of the Company's internal control over financial reporting as of December 31, 2021, has been audited by BDO USA, LLP, an independent registered public accounting firm, as stated in their report, which appears herein.

Remediation of material weakness

As previously disclosed, the Company had ineffective controls over the evaluation and accounting for complex financing transactions, specifically, the Company did not have sufficient technical resources to appropriately identify errors in the accounting for warrants issued in a registered offering including whether the warrants should be classified as a liability or as equity.

The control deficiency described above created a reasonable possibility that a material misstatement to the consolidated financial statements would not be prevented or detected on a timely basis. This material weakness resulted in a material adjustment to the classification of certain warrants issued in December 2020 from equity to a liability on the consolidated balance sheet. The classification error was corrected prior to issuance of the consolidated financial statements as of and for the year ended December 31, 2020. On January 1, 2021, the Company early adopted ASU 2020-06 which resulted in the elimination of the criteria that resulted in the warrants being classified as liabilities at December 31, 2020.

The remedial actions taken included educating and re-training control owners regarding the accounting standards related to the accounting for complex financial instruments and contracting with appropriate resources to provide accounting interpretation guidance to assist us in identifying and addressing any issues that affect our consolidated financial statements. In addition, management enhanced the accounting policy, controls and review procedures related to the accounting for complex financial instruments. Management has implemented these remedial actions to ensure that the underlying causes of the material weakness are remediated such that the existing controls operate effectively.

We tested our newly established policies, procedures and control activities designed to address the above-described material weakness, and as a result, we believe that the material weakness was remediated as of December 31, 2021.

Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the year ended December 31, 2021, that has materially affected or is reasonably likely to materially affect, our disclosure controls and procedures with the exception of the material weakness remediation as described above.

Report of Independent Registered Public Accounting Firm

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

Opinion on Internal Control over Financial Reporting

We have audited Atossa Therapeutics, Inc.'s (the "Company's") internal control over financial reporting as of December 31, 2021, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (the "COSO criteria"). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2021, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the consolidated balance sheets of the Company as of December 31, 2021 and 2020, the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years then ended, and the related notes, and our report dated February 28, 2022, expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Item 9A, Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit of internal control over financial reporting in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ BDO USA, LLP

Seattle, Washington
February 28, 2022

ITEM 9B. OTHER INFORMATION

None.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS.

Not applicable

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information regarding our executive officers is set forth in Item 1 of Part I of this Report under the caption "Executive Officers."

The information required by this item is incorporated herein by reference to the sections entitled "Proposal No. 1 — Election of Directors," "Beneficial Owners and Management," "Section 16(a) Beneficial Ownership Reporting Compliance," "Director Compensation," "Corporate Governance" and "Board of Directors and Committees" in our definitive Proxy Statement for the Annual Meeting of Shareholders to be held on May 13, 2022 (the "Proxy Statement").

ITEM 11. EXECUTIVE COMPENSATION

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

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

The information required by this item is incorporated by reference to the sections entitled "Executive Compensation- Equity Compensation Plan Information" and "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 section entitled "Certain Relationships and Related Party Transactions" and "Corporate Governance" in our Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item is incorporated by reference to the sections entitled "Proposal No. 2 — Ratification of Selection of 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 10-K:

1. Financial Statements

The following financial statements are included in Part II, Item 8 of this 10-K:

2. Financial Statement Schedules

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

3. Exhibits

See the Exhibit Index set forth on page 68 of this report.

ITEM 16. FORM 10-K SUMMARY

Not applicable.

ATOSSA THERAPEUTICS, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Audited Consolidated Financial Statements:

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Atossa Therapeutics, Inc. (the "Company") as of December 31, 2021 and 2020, the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2021 and 2020, and the results of its operations and its cash flows for the years then ended**,** in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the Company's internal control over financial reporting as of December 31, 2021, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"), and our report dated February 28, 2022, expressed an unqualified opinion thereon.

Change in Accounting Principle

As discussed in Note 3 to the consolidated financial statements, the Company early adopted Accounting Standards Update No. 2020-06, *Debt – Debt with Conversion and Other Options (Topic 470) and Derivatives and Hedging – Contracts in an Entity's own Equity (Topic 815*) on a modified retrospective basis in 2021.

Basis for Opinion

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

We conducted our 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 consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our 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 consolidated 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 consolidated financial statements, and (2) involved our especially challenging, subjective, or complex judgments. The communication of a 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 separate opinions on the critical audit matter or on the accounts or disclosures to which it relates.

Accounting for Research and Development Expenses

As disclosed in Note 3 to the consolidated financial statements, the Company expenses research and development costs as incurred, which include manufacturing expense for the Company's drugs under development, expenses associated with clinical trials and associated salaries and benefits. Tracking the progress of the clinical trials, including payments made by the Company and by third-parties, allows the Company to record the appropriate expense, prepayments, and accruals under the terms of the agreements. In addition, research and development expenses include an allocation of the CEO's compensation based on an estimate of total hours expended on research and development activities, including his oversight of clinical trial activities. During the year ended December 31, 2021, the Company incurred $9,210,000 of research and development expenses. As described in Note 5 to the consolidated financial statements, the Company recorded prepaid research and development expenses of $1,853,000 as of December 31, 2021.

We identified research and development expenses as a critical audit matter. When estimating research and development expenses, the Company considers several factors including an estimation of total hours that the CEO expends on research and development activities, the delivery of drug products utilized in clinical trials, clinical trial budgets, contract amendments, the progress toward completion, and the timing of payments. Auditing these elements involved especially challenging auditor judgment due to the nature and extent of audit evidence and effort required to address these matters.

The primary procedures we performed to address this critical audit matter included:

- Testing management's estimation of research and development by (i) obtaining and inspecting significant agreements, clinical trial and drug manufacturing budgets, and contract amendments, (ii) evaluating the Company's documentation of trial progress and status, and (iii) testing a sample of transactions by comparing the costs against related invoices and agreements.

- Testing the existence, completeness and accuracy of prepaid and accrued research and development expenses by (i) evaluating publicly available information (such as press release and public databases that track clinical trials), (ii) inquiring of clinical staff outside of finance to gain an understanding of the status of significant on-going clinical trials, (iii) testing a sample of payments made by the Company during the period of audit for clinical trial expenses that relate to future periods to verify the existence of prepaid expenses, and (iv) testing payments subsequent to year end to evaluate the completeness of accrued expenses.

- Testing management's allocation of CEO compensation by (i) comparing management's accounting analysis information to source documents, (ii) agreeing compensation cost details to relevant source documents, and (iii) recalculating the percentage of compensation costs allocated to research and development.

/s/ BDO USA, LLP

We have served as the Company's auditor since 2014.
Seattle, Washington
February 28, 2022

ATOSSA THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(amounts in thousands, except for par value)

	As of December 31,	
Assets	**2021**	**2020**
Current assets		
Cash and cash equivalents	$ 136,377	$ 39,554
Restricted cash	110	110
Prepaid expenses	2,488	1,814
Research and development tax rebate receivable	1,072	635
Other current assets	1,193	657
Total current assets	141,240	42,770
Furniture and equipment, net	20	21
Intangible assets, net	-	13
Right-of-use asset	-	18
Other assets	2	17
Total Assets	$ 141,262	$ 42,839
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,717	$ 1,589
Accrued expenses	204	93
Payroll liabilities	1,184	964
Common stock warrant liability	-	13,003
Lease liability	-	18
Other current liabilities	21	4
Total current liabilities	3,126	15,671
Total Liabilities	3,126	15,671
Commitments and contingencies (Note 13)		
Stockholders' equity		
Preferred stock - $0.001 par value; 10,000 shares authorized; 1 share issued and outstanding as of December 31, 2021 and December 31, 2020, respectively	-	-
Additional paid-in capital - Series B convertible preferred stock	582	621
Common stock - $0.18 par value; 175,000 shares authorized; 126,624 and 47,550 shares issued and outstanding as of December 31, 2021 and December 31, 2020, respectively	22,792	8,559
Additional paid-in capital	243,996	129,887
Accumulated deficit	(129,234)	(111,899)
Total Stockholders' Equity	138,136	27,168
Total Liabilities and Stockholders' Equity	$ 141,262	$ 42,839

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

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

	For the Year Ended December 31,	
	2021	**2020**
Operating expenses		
Research and development	$ 9,210	$ 6,608
General and administrative	11,311	7,999
Total operating expenses	20,521	14,607
Operating loss	(20,521)	(14,607)
Change in fair value of common stock warrants	-	(2,333)
Warrant financing expense	-	(939)
Other (expense) income, net	(85)	51
Loss before income taxes	(20,606)	(17,828)
Income taxes	-	-
Net loss	$ (20,606)	$ (17,828)
Deemed dividend attributable to preferred stock	-	(4,503)
Net loss applicable to common shareholders	$ (20,606)	$ (22,331)
Loss per common share - basic and diluted	$ (0.18)	$ (1.97)
Weighted average shares outstanding - basic and diluted	116,950	11,309

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

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

	Series C Convertible Preferred Stock			Series B Convertible Preferred Stock			Common Stock				
	Shares	Amount	Additional Paid-in Capital	Shares	Amount	Additional Paid-in Capital	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2019	-	$ -	$ -	1	$ -	$ 671	9,131	$ 1,644	$ 104,912	$ (94,071)	$ 13,156
Issuance of common stock, net of issuance costs of $475	-	-	-	-	-	-	1,328	239	4,426	-	4,665
Issuance of common stock and warrants, net of issuance costs of $1,890	-	-	-	-	-	-	31,575	5,684	23,991	-	29,675
Allocation of common stock proceeds to warrant liability	-	-	-	-	-	-	-	-	(8,196)	-	(8,196)
Issuance of Series C convertible preferred stock and warrants, net of issuance costs of $260	5	-	5,165	-	-	-	-	-	-	-	5,165
Allocation of Series C convertible preferred stock to beneficial conversion feature and warrant liability	-	-	(4,243)	-	-	-	-	-	1,769	-	(2,474)
Deemed dividend on Series C convertible preferred stock	-	-	4,503	-	-	-	-	-	(4,503)	-	-
Conversion of Series B convertible preferred stock to common stock	-	-	-	-	-	(50)	15	2	48	-	-
Conversion of Series C convertible preferred stock to common stock	(5)	-	(5,425)	-	-	-	5,425	976	4,449	-	-
Common stock issued for option exercises	-	-	-	-	-	-	225	41	501	-	542
Shares withheld related to cashless exercise of options and taxes	-	-	-	-	-	-	(149)	(27)	(529)	-	(556)
Compensation cost for stock options granted	-	-		-	-				3,019	-	3,019
Net loss	-	-	-	-	-	-	-	-	-	(17,828)	(17,828)
Balance at December 31, 2020	-	-	-	1	-	621	47,550	8,559	129,887	(111,899)	27,168
Cumulative effect of adopted accounting standard	-	-	-	-	-	-	-	-	9,732	3,271	13,003
Issuance of common stock and warrants, net of issuance costs of $5,493	-	-	-	-	-	-	41,211	7,418	62,250	-	69,668
Issuance of common stock upon warrant exercise	-	-	-	-	-	-	37,451	6,741	37,077	-	43,818
Conversion of Series B convertible preferred stock to common stock	-	-	-	-	-	(39)	11	2	37	-	-
Common stock issued for option exercise	-	-	-	-	-	-	699	126	1,598	-	1,724
Shares withheld related to cashless exercise of options and taxes	-	-	-	-	-	-	(298)	(54)	(1,852)	-	(1,906)
Compensation cost for stock options granted	-	-	-	-	-	-	-	-	5,267	-	5,267
Net loss	-	-	-	-	-	-	-	-	-	(20,606)	(20,606)
Balance at December 31, 2021	-	$ -	$ -	1	$ -	$ 582	126,624	$ 22,792	$ 243,996	$ (129,234)	$ 138,136

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

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

	Year Ended December 31,	
	2021	**2020**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (20,606)	$ (17,828)
Adjustments to reconcile net loss to net cash used in operating activities		
Compensation cost for stock options granted	5,267	3,019
Disposal of assets	-	32
Depreciation and amortization	23	47
Change in fair value of common stock warrant liability	-	2,333
Warrant financing expense	-	939
Changes in operating assets and liabilities:		
Prepaid expenses	(674)	(952)
Research and development tax rebate receivable	(437)	105
Other assets	(521)	(631)
Accounts payable	128	1,295
Accrued expenses	111	15
Payroll liabilities	220	64
Other current liabilities	17	(8)
Net cash used in operating activities	(16,472)	(11,570)
CASH FLOWS FROM INVESTING ACTIVITY		
Purchase of furniture and equipment	(9)	(9)
Net cash used in investing activities	(9)	(9)
CASH FLOWS FROM FINANCING ACTIVITY		
Proceeds from issuance of common stock, net of issuance costs	-	4,665
Proceeds from issuance of common stock and warrants, net of issuance costs	69,668	28,954
Proceeds from issuance of Series C convertible preferred stock and warrants, net of issuance costs	-	4,947
Proceeds from exercise of employee stock options	391	-
Payment of taxes related to net-exercise of employee stock options	(573)	(14)
Proceeds from exercise of warrants	43,818	-
Net cash provided by financing activities	113,304	38,552
NET INCREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	96,823	26,973
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, BEGINNING BALANCE	39,664	12,691
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, ENDING BALANCE	$ 136,487	$ 39,664
SUPPLEMENTAL DISCLOSURES		
Reconciliation of cash, cash equivalents and restricted cash		
Cash and cash equivalents	$ 136,377	$ 39,554
Restricted cash	110	110
Total cash, cash equivalents and restricted cash shown in the consolidated statements of cash flows	$ 136,487	$ 39,664
NON-CASH INVESTING AND FINANCING ACTIVITIES		
Reclassification of warrant liability to equity upon adoption of accounting standard	$ 13,003	$ -
Common stock issued upon cashless exercise of stock options	$ 1,333	$ 541
Deemed dividend attributable to preferred stock	$ -	$ 4,503
Conversion of Series B convertible preferred stock to common stock	$ 39	$ 50
Conversion of Series C convertible preferred stock to common stock	$ -	$ 5,425

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

NOTE 1: NATURE OF OPERATIONS

On January 6, 2020, we changed our corporate name from Atossa Genetics Inc. to Atossa Therapeutics, Inc. Atossa Therapeutics, Inc. (the Company) was incorporated on April 30, 2009, in the State of Delaware. The Company was initially formed to develop and market medical devices, laboratory tests and therapeutics to address breast health conditions. The Company is currently focused on development of its pharmaceuticals for the treatment of the novel coronavirus (COVID-19), breast cancer and other breast conditions. The Company's fiscal year ends on December 31.

Impact of the Novel Coronavirus

The continued spread of the COVID-19 pandemic is affecting the U.S. and global economies and may affect the Company's operations and those of third parties on which the Company relies, including causing possible disruptions in the supply of the Company's Endoxifen, AT-H201, AT-301 and the pace of enrollment in our clinical trials. In addition, the COVID-19 pandemic may affect the operations of the U.S. FDA and other health authorities including similar entities/agencies in Sweden and Australia, which could result in delays in meetings, reviews and approvals. Additionally, while the potential economic impact brought by, and the duration of, the COVID-19 pandemic is difficult to assess or predict, the impact of the COVID-19 pandemic on the global financial markets may reduce the Company's ability to access capital, which could negatively impact the Company's short-term and long-term liquidity. The ultimate impact of the COVID-19 pandemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, financing or clinical trial activities or on healthcare systems or the global economy as a whole, however, we have not experienced a significant delay in the enrollment or the drug supply for our ongoing and planned clinical studies, including studies of Endoxifen, AT-301 and AT-H201. In recent weeks the number of reported cases of COVID-19 has declined in many countries. If this trend continues it may be difficult to enroll participants in our COVID-19 clinical studies.

NOTE 2: LIQUIDITY AND CAPITAL RESOURCES

The Company has incurred net losses and negative operating cash flows since inception. For the year ended December 31, 2021, the Company recorded a net loss of $20,606 and used $16,472 of cash in operating activities. As of December 31, 2021, the Company had $136,377 in cash and cash equivalents and working capital of $138,114. The Company has not yet established an ongoing source of revenue sufficient to cover its operating costs and believes it will need to continue to raise substantial additional capital to accomplish its business plan over the next several years. Management believes its currently available funding, including the funds received from warrant exercises and the issuance of common stock and warrants with net proceeds of $113,486 during 2021, will be sufficient to finance the Company's operations for at least one year from the date these consolidated financial statements are issued. The Company plans to continue to fund its losses from operations and capital funding needs through a combination of public or private equity offerings, debt financings or other sources, including potential corporate collaborations, licenses and other similar arrangements. There can be no assurance as to the availability or terms upon which such financing and capital might be available in the future. If the Company is unable to secure additional funding, it may be forced to curtail or suspend its business plans.

NOTE 3: SUMMARY OF ACCOUNTING POLICIES

Basis of Presentation:

The accompanying consolidated financial statements have been prepared pursuant to the rules of the Securities and Exchange Commission (SEC) and in accordance with accounting principles generally accepted in the United States of America (GAAP). The accompanying consolidated financial statements include the financial statements of Atossa Therapeutics, Inc. and its wholly-owned subsidiaries. All significant intercompany account balances and transactions have been eliminated in consolidation. All amounts have been presented in thousands, except for par value and per share data.

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. Actual results could differ from those estimates.

Recently Issued Accounting Pronouncements:

In November 2021, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2021-10, *Government Assistance (Topic 832) – Disclosures by Business Entities about Government Assistance*, which requires business entities to disclose information about transactions with a government that are accounted for by applying a grant or contribution model by analogy (for example, IFRS guidance in IAS 20 or guidance on contributions for not-for-profit entities in ASC 958-605). For transactions within scope, the new standard requires the disclosure of information about the nature of the transaction, including significant terms and conditions, as well as the amounts and specific financial statement line items affected by the transaction. The new guidance is effective for annual reporting periods beginning after December 15, 2021. The Company is currently evaluating the impact that the adoption of this standard will have on its consolidated financial statements.

On May 3, 2021, the FASB issued ASU No. 2021-04, *Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options* — a consensus of the FASB Emerging Issues Task Force. The ASU provides a principles-based framework to determine whether an issuer should recognize the modification or exchange as an adjustment to equity or an expense. The guidance will be effective for the Company for fiscal years beginning after December 15, 2021, and interim periods within those fiscal years. The Company is currently evaluating the impact that the adoption of this standard will have on its consolidated financial statements.

Recently Adopted Accounting Pronouncements:

On January 1, 2021, the Company early adopted ASU No. 2020-06, *Debt – Debt with Conversion and Other Options (Topic 470) and Derivative Hedging - Contracts in an Entity's Own Equity (Topic 815),* which simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts in an entity's own equity. The guidance is effective for fiscal years beginning on or after December 15, 2023, with early adoption permitted, but not earlier than fiscal years beginning after December 15, 2020. The amendments in ASU No. 2020-06 removed the requirement that an instrument or embedded feature must permit settlement in unregistered shares in order to qualify for equity classification. The removal of this criterion allowed the Company to reclassify the common stock liability to equity upon adoption. The Company implemented this ASU using the modified retrospective approach. Upon adoption, the Company recorded a cumulative adjustment to beginning Stockholders' Equity in the amount of $13,003 to reclassify the common stock warrant liability to accumulated deficit and additional paid-in capital.

The guidance removes the liability and equity separation models for convertible instruments with a cash conversion feature or beneficial conversion feature. As a result, companies will more likely account for convertible debt instruments wholly as debt, and for convertible preferred stock wholly as preferred stock (i.e. as a single unit of account). In addition, the guidance simplifies the settlement assessment that issuers perform to determine whether a contract in their own equity qualifies for equity classification. Finally, the guidance requires entities to use the if-converted method to calculate earnings per share for all convertible instruments.

The cumulative effect of initially applying the new standard was recognized as an adjustment to accumulated deficit. Upon the adoption of the new standard, the Company recognized the following adjustments:

	Ending Balance as of December 31, 2020	ASU 2020-06 Adjustments	Beginning Balance as of January 1, 2021
Warrant liability	$ 13,003	$ (13,003)	$ -
Additional paid-in capital	129,887	9,732	139,619
Accumulated deficit	(111,899)	3,271	(108,628)

The $3,271 adjustment to accumulated deficit includes warrant financing expenses of $939 and the change in fair value of common stock warrants of $2,333 subsequent to initial recognition.

On January 1, 2021, the Company adopted ASU 2019-12, *Income Taxes, (Topic 740): Simplifying the Accounting for Income Taxes*, which amends the existing guidance relating to accounting for income taxes. This ASU is intended to simplify the accounting for income taxes by removing certain exceptions to the general principles of accounting for income taxes and to improve the consistent application of U.S. GAAP for other areas of accounting for income taxes by clarifying and amending existing guidance. This ASU did not have a material effect on the consolidated financial statements.

Research and Development

Research and development (R&D) costs are generally expensed as incurred. R&D expenses include, for example, manufacturing expense for the Company's drugs under development, expenses associated with clinical trials and associated salaries and benefits. The Company has 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. The Company records accruals for estimated costs incurred for ongoing research and development activities. When evaluating the adequacy of the accrued expenses, the Company analyzes 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 the Company’s 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. The Company's CEO is involved in the development of the Company's drug candidates and oversight of the related clinical trial activity.

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 elects to accrue any interest or penalties related to income taxes as part of its income tax expense.

Cash and Cash Equivalents

Cash and cash equivalents include cash and all highly liquid instruments with original maturities of three months or less.

Furniture and Equipment

Furniture and equipment are stated at cost less accumulated depreciation. Expenditures for maintenance and repairs are charged to earnings as incurred; additions, renewals and betterments are capitalized. When furniture and equipment are retired or otherwise disposed of, the related cost and accumulated depreciation are removed from the respective accounts, and any gain or loss is included in operations.

Depreciation is computed using the straight-line method over the estimated useful lives ranging from three to five years.

Furniture and equipment amounted to $36 and $186 at December 31, 2021 and 2020, respectively. Accumulated depreciation was $16 and $165 at December 31, 2021, and 2020, respectively. Depreciation expense for the years ended December 31, 2021 and 2020, was $10 and $19, respectively.

The Company periodically evaluates the carrying value of long-lived assets to be held and used and, if necessary, records impairment losses when indicators of impairment are present and the undiscounted cash flows estimated to be generated by those assets are less than the assets' carrying amounts. In that event, a loss is recognized based on the amount by which the carrying amount exceeds the fair market value of the long-loved assets. Loss on long-lived assets to be disposed of is determined in a similar manner, except that fair market values are reduced for the cost of disposal. For the years ended December 31, 2021 and 2020, no impairment of furniture and equipment was recorded.

Fair Value Measurements

The Company records financial assets and liabilities measured on a recurring and non-recurring basis as well as all non-financial assets and liabilities subject to fair value measurement at the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. These fair value principles prioritize valuation inputs across three broad levels. Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Level 3 inputs are unobservable inputs based on the Company's assumptions used to measure assets and liabilities at fair value. An asset or liability's classification within the various levels is determined based on the lowest level input that is significant to the fair value measurement. Also refer to Note 8.

Intangible Assets

Intangible assets consist of intellectual property and software acquired. Intangibles are reviewed for impairment whenever events or changes in circumstances indicate that the carrying value of the assets might not be recoverable. Impairment losses must be recorded when indicators of impairment are present and the undiscounted cash flows estimated to be generated by those assets are less than the assets' carrying amounts. In that event, a loss is recognized based on the amount by which the carrying amount exceeds the fair market value of the assets. Estimating future cash flows related to an intangible asset involves significant estimates and assumptions. If our assumptions are not correct, there could be an impairment loss or, in the case of a change in the estimated useful life of the asset, a change in amortization expense.

No impairment charges were recorded during the years ended December 31, 2021, or December 31, 2020.

Amortization of intangible assets is computed using the straight-line method over the estimated useful lives ranging from three to ten years.

Intangible assets were fully amortized as of December 31, 2021. At December 31, 2020, intangible assets amounted to $54. Accumulated amortization was $41 at December 31, 2020. Amortization expense for the years ended December 31, 2021 and 2020, was $13 and $28, respectively.

Leases

The Company evaluates all contractual agreements at inception to determine if they contain a lease. Lease liabilities are measured at present value of lease payments not yet paid, using a discounted cash flow model that requires the use of a discount rate, or incremental borrowing rate. The Company does not record right-of-use assets or operating lease liabilities on leases with initial terms of 12 months or less. All Company leases are short term in duration; therefore no Right of Use Asset or Liability are recorded as of December 31, 2021.

Stock-based Payments

The Company measures and recognizes compensation expense for all stock-based payment awards made to employees, non-employee directors, and consultants, including employee stock options. Stock compensation expense is based on the estimated grant date fair value and is recognized as an expense over the requisite service period. The Company has made a policy election to recognize forfeitures when 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 stock options, the expected life of the options, an expectation regarding future dividends on the Company's common stock, and estimation of an appropriate risk-free interest rate. The Company's expected common stock price volatility assumption is based upon the historical volatility of our stock price. The Company has elected the simplified method for the expected life assumption for stock option grants, which averages the contractual term of the options of ten years with the vesting term, typically one to four years, as the Company does not have sufficient history of option exercise experience. The dividend yield assumption of zero is based upon the fact that the Company has never paid cash dividends and presently has no intention of paying cash dividends in the future. The risk-free interest rate used for each grant was based upon prevailing short-term interest rates over the expected life of the options.

NOTE 4: RESTRICTED CASH

The Company's restricted cash balance of $110 as of December 31, 2021 and 2020, consists entirely of cash pledged as security for the Company's issued commercial credit cards.

NOTE 5: PREPAID EXPENSES

Prepaid expenses consisted of the following:

	December 31, 2021	December 31, 2020
Prepaid research and development	$ 1,853	$ 1,216
Prepaid insurance	461	418
Professional services	124	128
Retainer and security deposits	14	14
Prepaid rent	5	5
Other	31	33
Total prepaid expenses	$ 2,488	$ 1,814

NOTE 6: RESEARCH AND DEVELOPMENT TAX REBATE RECEIVABLE

On May 23, 2017, Atossa 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 our Phase 1 and Phase 2 Endoxifen and COVID-19 clinical trials. Australia offers an R&D cash rebate of $0.435 per dollar spent on qualified R&D activities incurred in the country. During the years ended December 31, 2021 and December 31, 2020, the Company incurred qualified R&D expenses in Australia of $1,251 and $1,429, respectively. At December 31, 2021 and December 31, 2020, we had a total R&D rebate receivable of $1,072 and $635, respectively. For the years ended December 31, 2021 and 2020, the Company collected R&D cash rebates of $0 and $850, respectively.

The Company had realized (losses) and gains on foreign currency exchange during the years ended December 31, 2021 and December 31, 2020, of $72 and $42, respectively, which is included in Other (expense) income, net in the Consolidated Statements of Operations.

NOTE 7: PAYROLL LIABILITIES

Payroll liabilities consisted of the following:

	December 31, 2021	December 31, 2020
Accrued bonuses	$ 894	$ 690
Accrued vacation	183	171
Accrued payroll	107	103
Total payroll liabilities	$ 1,184	$ 964

NOTE 8: FAIR VALUE OF FINANCIAL INSTRUMENTS

Pursuant to the accounting guidance for fair value measurement and its subsequent updates, fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (i.e., the "exit price") in an orderly transaction between market participants at the measurement date. The accounting guidance establishes a hierarchy for inputs used in measuring fair value that minimizes the use of unobservable inputs by requiring the use of observable market data when available. Observable inputs are inputs that market participants would use in pricing the asset or liability based on active market data. Unobservable inputs are inputs that reflect the assumptions market participants would use in pricing the asset or liability based on the best information available in the circumstances.

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

● *Level 1* —Valuations are based on quoted prices in active markets for identical assets or liabilities and readily accessible by us at the reporting date. Examples of assets and liabilities utilizing Level 1 inputs are certain money market funds, U.S. Treasuries and trading securities with quoted prices on active markets.

● *Level 2* —Valuations based on inputs other than the quoted prices in active markets that are observable either directly or indirectly in active markets. Examples of assets and liabilities utilizing Level 2 inputs are U.S. government agency bonds, corporate bonds, commercial paper, certificates of deposit and over-the- counter derivatives.

● *Level 3* —Valuations based on unobservable inputs in which there are little or no market data, which require the Company to develop its own assumptions.

Warrants issued in the December 11, 2020 offering and December 28, 2020 overallotment closing, which are discussed further in Note 9, contained provisions that may require the Company to settle the warrants in cash in an event outside the Company's control and are therefore accounted for as liabilities, with changes in the fair values included in net loss for the respective periods. Because some of the inputs to the valuation model were either not observable or were not derived principally from or corroborated by observable market data by correlation or other means, the warrant liability was classified as Level 3 in the fair value hierarchy.

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:

December 31, 2021	Estimated Fair Value	Level 1	Level 2	Level 3
Assets:				
Money market account	$ 51,796	$ 51,796	$ -	$ -

December 31, 2020	Estimated Fair Value	Level 1	Level 2	Level 3
Assets:				
Money market account	$ 1,789	$ 1,789	$ -	$ -
Liabilities:				
Common stock warrant liability	$ 13,003	$ -	$ -	$ 13,003

The following table summarizes the changes in the Company's Level 3 warrant liability for the year ended December 31, 2021:

Warrant Liability	
Beginning balance	$ 13,003
Reclassification of equity upon adoption of accounting standard	(13,003)
Issuance of warrants	-
Change in fair value	-
Ending balance	$ -

NOTE 9: STOCKHOLDERS' EQUITY

The Company is authorized to issue a total of 185,000 shares of stock consisting of 175,000 shares of common stock, par value $0.18 per share, and 10,000 shares of preferred stock, par value $0.001 per share. The Company has designated 750 shares of Series A junior participating preferred stock, par value $0.001 per share, 4 shares of Series A convertible preferred stock, par value $0.001 per share, 25 shares of Series B convertible preferred stock, par value $0.001 and 20 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, no shares of Series A convertible preferred stock and no shares of Series C convertible preferred stock are outstanding as of December 31, 2021 and December 31, 2020.

On May 19, 2014, the Company adopted a stockholder rights agreement which provides that all stockholders of record on May 26, 2014, received a non-taxable distribution of one preferred stock purchase right for each share of the Company's common stock held by such stockholder. Each right is attached to and trades with the associated share of common stock. The rights will become exercisable only if one of the following occurs: (1) a person becomes an "Acquiring Person" by acquiring beneficial ownership of 15% or more of the Company's common stock (or, in the case of a person who beneficially owned 15% or more of the Company's common stock on the date the stockholder rights agreement was executed, by acquiring beneficial ownership of additional shares representing 2.0% of the Company's common stock then outstanding (excluding compensatory arrangements)), or (2) a person commences a tender offer that, if consummated, would result in such person becoming an Acquiring Person. If a person becomes an Acquiring Person, each right will entitle the holder, other than the Acquiring Person and certain related parties, to purchase a number of shares of the Company's common stock with a market value that equals twice the exercise price of the right. The initial exercise price of each right is $15.00, so each holder (other than the Acquiring Person and certain related parties) exercising a right would be entitled to receive $30.00 worth of the Company's common stock. If the Company is acquired in a merger or similar business combination transaction at any time after a person has become an Acquiring Person, each holder of a right (other than the Acquiring Person and certain related parties) will be entitled to purchase a similar amount of stock of the acquiring entity.

2021 Financing Transactions

On January 6, 2021, the Company entered into a securities purchase agreement with certain institutional and accredited investors relating to the offering and sale of 23,850 shares of Company common stock, par value $0.18 per share and warrants to purchase 17,888 shares of common stock. The combined purchase price for one share of common stock and a warrant to purchase 0.75 shares of common stock was $1.055. Subject to certain ownership limitations, the warrants are exercisable upon issuance. The warrants will expire on the 4.5-year anniversary of the date of issuance and have an exercise price of $1.055 per share. The common stock and warrants have been registered under the Securities Act of 1933, as amended. The Company paid the placement agent a cash fee of 7% of the aggregate gross proceeds and reimbursed the placement agent for expenses, including legal fees, up to $45. The offering closed on January 8, 2021 with net proceeds to the Company from the offering of $23,300 after deducting fees and expenses.

On March 22, 2021, the Company entered into a securities purchase agreement with certain institutional and accredited investors relating to the offering and sale of 17,361 shares of our common stock, par value $0.18 per share. Concurrently with the offering, and pursuant to the purchase agreement, the Company also commenced a private placement whereby it issued and sold warrants exercisable for an aggregate of up to 13,021 shares of common stock. The combined purchase price for one share of common stock and a purchase warrant to purchase 0.75 shares of common stock is $2.88. Subject to certain ownership limitations, the warrants are exercisable upon issuance. The warrants will expire on the 4.5-year anniversary of the date of issuance. Subsequent to the issuance of the warrants, the Company filed a registration statement on Form S-3 (File No. 333-255411) to cover the sale of an aggregate of 13,021 shares of common stock issuable upon exercise of the warrants which was declared effective by the SEC on April 29, 2021. The Company paid the placement agent a cash fee of 7% of the aggregate gross proceeds of the offering and the private placement. The Company also agreed to reimburse the placement agent for expenses, including the legal fees, up to $45. The net proceeds to the Company from the offering and the private placement are $46,400, after deducting fees and expenses.

2021 Warrants

The terms and conditions of the warrants included in the 2021 offerings are as follows:

Exercisability. Each warrant is exercisable at any time and will expire 4.5-years from the date of issuance. The warrants are exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice and payment in full for the number of shares of our common stock purchased upon such exercise, except in the case of a cashless exercise as discussed below.

The number of shares of common stock issuable upon exercise of the warrants is subject to adjustment in certain circumstances, including a stock split of, stock dividend on, or a subdivision, combination or recapitalization of the common stock. Upon the merger, consolidation, sale of substantially all of our assets, or other similar transaction, the holders of warrants shall, at the option of the Company, be required to exercise the warrants immediately prior to the closing of the transaction, or such warrants shall automatically expire. Upon such exercise, the holders of warrants shall participate on the same basis as the holders of common stock in connection with the transaction.

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

Exercise Price. Each warrant represents the right to purchase one share of common stock at an exercise price of $1.055 per share for the January 2021 financing or $2.88 per share for the March 2021 financing. In addition, the exercise price per share is subject to adjustment for stock dividends, distributions, subdivisions, combinations, or reclassifications, and for certain dilutive issuances. Subject to limited exceptions, a holder of warrants will not have the right to exercise any portion of the warrant to the extent that, after giving effect to the exercise, the holder, together with its affiliates, and any other person acting as a group together with the holder or any of its affiliates, would beneficially own in excess of 4.99% of the number of shares of our common stock outstanding immediately after giving effect to its exercise. The holder, upon notice to the Company, may increase or decrease the beneficial ownership limitation provisions of the warrant, provided that in no event shall the limitation exceed 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise of the warrant.

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

Exchange Listing. We do not intend to apply to list the warrants on any securities exchange or recognized trading system.

Rights as Stockholder. Except as set forth in the warrant, the holder of a warrant, solely in such holder's capacity as a holder of a warrant, will not be entitled to vote, to receive dividends, or to any of the other rights of our stockholders.

2020 Equity Distribution Agreements

On February 7, 2020, Atossa Therapeutics, Inc. entered into an equity distribution agreement with Oppenheimer & Co. Inc. (Oppenheimer), acting as sales agent relating to the "at-the-market" (the Oppenheimer ATM) offering and sale by Atossa of common shares, par value $0.18 per share, having an aggregate gross sales price of up to $5,000. Sales of the shares were made at Atossa's sole discretion and by means of ordinary brokers' transactions through the facilities of the Nasdaq Capital Market at market prices, in block transactions or as otherwise agreed between Atossa and Oppenheimer. The distribution agreement provided that Oppenheimer was entitled to a commission of 3.0% of the gross offering proceeds of the shares sold pursuant to the distribution agreement and reimbursement for certain specified expenses. Atossa had no obligation to offer or sell any shares under the agreement and could at any time suspend offers and sales under the agreement. Oppenheimer could also suspend or terminate the offering of shares being made through them upon proper notice to the Company. During the year ended December 31, 2020, the Company sold 1,244 shares of common stock under the Oppenheimer ATM, for net proceeds of $4,686. Total issuance costs for the year ended December 31, 2020, were $314.

On September 25, 2020, Atossa Therapeutics, Inc. entered into an equity distribution agreement with Maxim Group, LLC (Maxim), acting as sales agent relating to the "at-the-market" offering and sale by Atossa of common shares, par value $0.18 per share, having an aggregate gross sales price of up to $10,000. Sales of the shares, if any, will be made at Atossa's sole discretion and by means of ordinary brokers' transactions through the facilities of the Nasdaq Capital Market at market prices, in block transactions or as otherwise agreed between Atossa and Maxim. The distribution agreement provides that Maxim will be entitled to a commission of 3.0% of the gross offering proceeds of the shares sold pursuant to the distribution agreement and reimbursement for certain specified expenses. Atossa has no obligation to offer or sell any shares under the agreement and may at any time suspend offers and sales under the agreement. Maxim could also suspend or terminate the offering of common stock being made through them upon proper notice to the Company. Sales under the ATM with Maxim began in October. During the year ended December 31, 2020, the Company sold 84 shares of common stock under the Maxim ATM for gross proceeds to the Company of $140. Total issuance costs for the year ended December 31, 2020, were $161. On March 21, 2021, we terminated the equity distribution agreement and as a result no further sales of common stock will be made thereunder.

2020 Offering of Consisting of Common Stock, Series C Convertible Preferred Stock and Warrants

On December 8, 2020, the Company entered into an underwriting agreement with Maxim Group, LLC, pursuant to which the Company agreed to issue and sell registered units consisting of an aggregate of: (i) 14,575 shares of the Company's common stock at $1.00 per share; (ii) 5 shares of Series C convertible preferred stock, par value $0.001 per share at $1,000.00 per share and (iii) warrants convertible into up to 15,000 shares of common stock. The warrants were immediately exercisable at a price of $1.00 per share of common stock and expire four years from the date of issuance. On December 28, 2020, the Company also closed on the overallotment provision of the underwriting agreement which included the sale of an additional 3,000 shares of common stock and 2,250 warrants. Net proceeds in total were $20,976 after deducting expenses relating to the offering of $2,024, including dealer-manager fees and expenses, and excluding any proceeds received upon exercise of any warrants. Proceeds of $16,750 net of issuance costs of $825 have been included in the statement of stockholders' equity under the caption Issuance of common stock and warrants. Proceeds from the sale of common stock and warrants of $8,196 have been allocated to the common stock warrant liability. Proceeds of $5,165, net of issuance costs of $260 have been included in the statement of stockholders' equity under the caption Issuance of Series C convertible preferred stock and warrants. Proceeds from the sale of Series C convertible preferred stock and warrants of $2,474 have been allocated to the common stock warrant liability. Issuance costs of $939 that were allocated to the warrant liabilities were expensed during 2020.

Accounting Treatment

The Company allocated the proceeds from the sale of the common stock and warrant units and preferred stock and warrant units to the separate securities issued. The Company determined that, on the date of issuance, the warrants include provisions that could require net-cash settlement and therefore, the warrants should be accounted for as liabilities. At the end of December 31, 2020, the changes in fair value of the warrants during the period were recorded in non-operating expense in the consolidated statement of operations. The common stock warrant liability was reclassified to accumulated deficit and additional paid-in-capital on January 1, 2021, upon adoption of ASU No. 2020-06. See Note 3. All warrants outstanding as of December 31, 2021, are classified as equity.

The Company allocated the amount representing the fair value of the warrants at the date of issuance separately first to the warrant liability and recorded the remaining proceeds as common stock, in the case of the common stock and warrant units, or as Series C convertible preferred stock, in the case of the preferred stock and warrant units. Due to the allocation of a portion of the proceeds to the warrants, the Series C convertible preferred stock contained a beneficial conversion feature upon issuance, which was recorded in the amount of $1,769 based on the intrinsic value of the beneficial conversion feature. The discount on the Series C convertible preferred stock of $2,474 caused by allocation of the proceeds to the warrant and the issuance costs allocated to the convertible preferred stock of $260 were recorded as a deemed dividend upon issuance of the Series C convertible preferred stock. As a result, total deemed dividends of $4,503 were recorded upon issuance of the Series C convertible preferred stock, which is reflected as an addition to net loss in the consolidated statement of operations to arrive at net loss applicable to common shareholders.

Series C Convertible Preferred Stock.

The terms and provisions of our Series C convertible preferred stock are:

Conversion. Each share of Series C convertible preferred stock is convertible at our option at any time on or after the first anniversary of the closing of the rights offering or at the option of the holder at any time, into the number of shares of our common stock determined by dividing the $1,000 stated value per share of the Series C convertible preferred stock by a conversion price of $1.00 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 C convertible preferred stock will not have the right to convert any portion of the Series C convertible preferred stock to the extent that, after giving effect to the conversion, the holder, together with its affiliates, would beneficially own in excess of 9.99% of the number of shares of our common stock outstanding immediately after giving effect to its conversion.

Fundamental Transactions. In the event we effect certain mergers, consolidations, sales of substantially all of our assets, tender or exchange offers, reclassifications or share exchanges in which our common stock is effectively converted into or exchanged for other securities, cash or property, we consummate a business combination in which another person acquires 50% of the outstanding shares of our common stock, or any person or group becomes the beneficial owner of 50% of the aggregate ordinary voting power represented by our issued and outstanding common stock, then, upon any subsequent conversion of the Series C convertible preferred stock, the holders of the Series C 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 C convertible preferred stock.

Dividends. Holders of Series C 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

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

*Liquidation Preference***.** Upon our liquidation, dissolution or winding-up, whether voluntary or involuntary, holders of Series C convertible preferred stock will be entitled to receive out of our assets, whether capital or surplus, the same amount that a holder of common stock would receive if the Series C 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. We are not obligated to redeem or repurchase any shares of Series C convertible preferred stock. Shares of Series C convertible preferred stock are not otherwise entitled to any redemption rights, or mandatory sinking fund or analogous provisions.

2020 Liability Warrants

The terms and conditions of the warrants included in the December 11, 2020 offering and exercise of related overallotment option are as follows:

Exercisability. Each warrant is exercisable at any time and will expire four years from the date of issuance. The warrants are exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice and payment in full for the number of shares of our common stock purchased upon such exercise, except in the case of a cashless exercise as discussed below.

The number of shares of common stock issuable upon exercise of the warrants is subject to adjustment in certain circumstances, including a stock split or, stock dividend on, or a subdivision, combination or recapitalization of the common stock. Upon the merger, consolidation, sale of substantially all of our assets, or other similar transaction, the holders of warrants shall, at the option of the Company, be required to exercise the warrants immediately prior to the closing of the transaction, or such warrants shall automatically expire. Upon such exercise, the holders of warrants shall participate on the same basis as the holders of common stock in connection with the transaction.

Cashless Exercise. If at any time there is no effective registration statement registering, or the prospectus contained therein is not available for issuance of, the shares issuable upon exercise of the warrant, the holder may exercise the warrant on a cashless basis. When exercised on a cashless basis, a portion of the warrant is cancelled in payment of the purchase price payable in respect of the number of shares of our common stock purchasable upon such exercise. The form of the warrant does not explicitly state that the warrants will not be settled in cash.

Exercise Price. Each warrant represents the right to purchase one share of common stock at an exercise price of $1.00 per share. In addition, the exercise price per share is subject to adjustment for stock dividends, distributions, subdivisions, combinations, or reclassifications, and for certain dilutive issuances. Subject to limited exceptions, a holder of warrants will not have the right to exercise any portion of the warrant to the extent that, after giving effect to the exercise, the holder, together with its affiliates, and any other person acting as a group together with the holder or any of its affiliates, would beneficially own in excess of 4.99% of the number of shares of our common stock outstanding immediately after giving effect to its exercise. The holder, upon notice to the Company, may increase or decrease the beneficial ownership limitation provisions of the warrant, provided that in no event shall the limitation exceed 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise of the warrant.

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

Exchange Listing. We do not intend to apply to list the warrants on any securities exchange or recognized trading system.

Rights as Stockholder. Except as set forth in the warrant, the holder of a warrant, solely in such holder's capacity as a holder of a warrant, will not be entitled to vote, to receive dividends, or to any of the other rights of our stockholders.

The fair value of liability warrants issued during the year ended December 31, 2020, was calculated using the Black-Scholes option-pricing model applying the following assumptions:

Initial Valuation		
Common stock price	$	0.87-0.89
Exercise price	$	1.00
Risk-free interest rate		0.28%
Expected term		4.0 years
Dividend yield		-
Expected volatility		107%-124%
December 31, 2020 Valuation		
Common stock price	$	0.95
Exercise price	$	1.00
Risk-free interest rate		0.27%
Expected term		4.0 years
Dividend yield		-
Expected volatility		127%

2020 Offering Consisting of Common Stock and Warrants

On December 17, 2020, the Company entered into a securities purchase agreement with certain institutional and accredited investors relating to the offering and sale of 14,000 shares of Company common stock. Concurrently with the offering, the Company also commenced a private placement whereby it issued and sold warrants exercisable for an aggregate of up to 10,500 shares of common stock, which represents 75% of the shares of common stock sold in the offering. The combined purchase price for one share of common stock and a purchase warrant to purchase 0.75 shares of Common Stock was $1.00. The warrants expire 4.5 years from the anniversary of the date of issuance. The offering closed on December 21, 2020 with net proceeds of $12,925, after deducting expenses relating to the offering $1,075, including dealer-manager fees and expenses, and excluding any proceeds received upon exercise of any warrants. The net proceeds, net of issuance costs have been included in the statement of stockholders' equity under the caption Issuance of common stock and warrants.

2020 Warrants

The terms and conditions of the warrants included in the December 21, 2020, offerings are as follows:

Exercisability. Each warrant is exercisable at any time and will expire 4.5 years from the date of issuance. The warrants are exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice and payment in full for the number of shares of our common stock purchased upon such exercise, except in the case of a cashless exercise as discussed below.

The number of shares of common stock issuable upon exercise of the warrants is subject to adjustment in certain circumstances, including a stock split or, stock dividend on, or a subdivision, combination or recapitalization of the common stock. Upon the merger, consolidation, sale of substantially all of our assets, or other similar transaction, the holders of warrants shall, at the option of the Company, be required to exercise the warrants immediately prior to the closing of the transaction, or such warrants shall automatically expire. Upon such exercise, the holders of warrants shall participate on the same basis as the holders of common stock in connection with the transaction.

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

Exercise Price. Each warrant represents the right to purchase one share of common stock at an exercise price of $1.00 per share. In addition, the exercise price per share is subject to adjustment for stock dividends, distributions, subdivisions, combinations, or reclassifications, and for certain dilutive issuances. Subject to limited exceptions, a holder of warrants will not have the right to exercise any portion of the warrant to the extent that, after giving effect to the exercise, the holder, together with its affiliates, and any other person acting as a group together with the holder or any of its affiliates, would beneficially own in excess of 4.99% of the number of shares of our common stock outstanding immediately after giving effect to its exercise. The holder, upon notice to the Company, may increase or decrease the beneficial ownership limitation provisions of the warrant, provided that in no event shall the limitation exceed 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise of the warrant.

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

Exchange Listing. We do not intend to apply to list the warrants on any securities exchange or recognized trading system.

Rights as Stockholder. Except as set forth in the warrant, the holder of a warrant, solely in such holder's capacity as a holder of a warrant, will not be entitled to vote, to receive dividends, or to any of the other rights of our stockholders.

Warrants Outstanding

As of December 31, 2021, warrants to purchase 22,277 shares of common stock were outstanding including:

	Outstanding Warrants to Purchase Shares		Exercise Price	Expiration date
May 2018 warrants	762	$	4.05	May 30, 2022
December 2020 warrants	6,490	$	1.00	December 11 2024-June 21, 2025
January 2021 warrants	4,500	$	1.055	July 8, 2025
March 2021 warrants	10,525	$	2.88	September 22, 2025
	22,277			

Warrant Activity

During 2021, the Company received $43,818 from the exercises of warrants. The 2021 warrant exercises resulted in the reduction of 37,451 warrants, and the issuance of 37,451 shares of common stock. There were no warrant exercises during 2020.

Conversion of Convertible Preferred Stock

During the years ended December 31, 2021 and December 31, 2020, certain holders of the Series B convertible preferred stock exercised their conversion option and converted an aggregate of 0.039 and 0.050 shares, respectively, into 11 and 15 shares, respectively, of the Company's common stock based on the conversion ratio of 284 shares of common stock for each share of Series B convertible preferred stock.

During the year ended December 31, 2020, certain holders of the Series C convertible preferred stock exercised their conversion option and converted an aggregate of 5.425 shares, into 5,425 shares of the Company's common stock based on the conversion ratio of 1,000 shares of common stock for each share of Series C convertible preferred stock.

NOTE 10: NET LOSS PER SHARE

The Company follows the two-class method when computing net loss per share as the Company has issued warrants and preferred stock that meet the definition of participating securities. The two-class method determines net loss per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed.

Basic net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted average number of common shares outstanding. In addition, in computing the dilutive effect of convertible securities, the numerator is adjusted to add back any convertible preferred dividends. Diluted net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted average number of common shares that would have been outstanding during the period assuming the issuance of common shares for all potential dilutive common shares outstanding. Potential common shares consist of potential future exercises of outstanding stock options and common stock warrants. Because the inclusion of potential common shares would be anti-dilutive for all periods presented, they have been excluded from the calculation.

The Company's common stock warrants and preferred stock contractually entitles the holders of such securities to participate in dividends but do not contractually require the holders of such securities to participate in losses of the Company. Accordingly, in periods in which the Company reports a net loss, such losses are not allocated to such participating securities. In periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive. The Company reported a net loss attributable to common stockholders for the years ended December 31, 2021, and 2020.

The following table summarizes the Company's calculation of net loss per common share:

	Year Ended December 31,	
	2021	**2020**
Numerator		
Net loss	$ (20,606)	$ (17,828)
Deemed dividend attributable to preferred stock	-	(4,503)
Net loss attributable to common shareholders	$ (20,606)	$ (22,331)
Denominator		
Weighted average common shares outstanding used to compute net loss per share, basic and diluted	116,950	11,309
Net loss per share of common stock, basic and diluted:	$ (0.18)	$ (1.97)

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

	Year Ended December 31,	
	2021	**2020**
Options to purchase common stock	9,036	6,138
Series B convertible preferred stock	171	227
Warrants to purchase common stock	24,144	2,271
	33,351	8,636

NOTE 11: INCOME TAXES

The Company accounts for income taxes using the asset and liability method, under which deferred income tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial reporting and tax bases of assets and liabilities and are measured using enacted tax rates in effect for the year in which those temporary differences are expected to be recovered or settled. A valuation allowance is provided for the amount of deferred tax assets that, based on available evidence, are not expected to be realized.

The Company did not record an income tax benefit for its losses incurred for the years ended December 31, 2021 or 2020, due to uncertainty regarding utilization of its net operating loss carryforwards and due to its history of losses. The benefit for income taxes differs from the benefit computed by applying the federal statutory rate to loss before income taxes as follows:

	Year Ended December 31,	
	2021	2020
Expected federal income tax benefit	$ (4,327)	$ (3,744)
Stock compensation	-	26
Other permanent items	81	1,082
Other deferred items	(100)	(350)
Recognition of foreign NOLs	(557)	-
Effect of change in valuation allowance	4,903	2,986
Actual federal income tax benefit	$ -	$ -

The components of net deferred tax assets and liabilities are as follows:

	As of December 31,	
	2021	2020
Deferred tax assets		
Obsolete inventory	$ -	$ 22
Accrued vacation	38	36
Stock-based compensation	3,007	2,408
Lease obligation	-	4
Intangible assets, net	382	449
Net operating loss carryforwards	11,511	7,118
Other	-	1
Valuation allowance	(14,937)	(10,034)
Deferred tax asset	$ 1	$ 4
Deferred tax liabilities		
Fixed assets	$ (1)	$ -
Right-of-use asset	-	(4)
Net deferred tax asset	$ -	$ -

Based on an assessment of all available evidence including, but not limited to the Company's limited operating history in its core business and the Company's pre-revenue status, uncertainties of the commercial viability of its technology, the impact of government regulation and healthcare reform initiatives, and other risks normally associated with biotechnology companies, the Company has concluded that it is more likely than not that these net operating loss carryforwards and other deferred tax assets will not be realized and, as a result, a full valuation allowance has been recorded against the Company's deferred income tax assets. Utilization of the net operating loss carryforwards may be subject to a substantial annual limitation due to ownership change limitations that may have occurred or that could occur in the future, as required by the Internal Revenue Code Section 382. In general, an "ownership change," as defined by Section 382, results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percentage points of the outstanding stock of a company by certain stockholders or public groups. Any limitation may result in expiration of all or a portion of the net operating loss carryforwards before utilization. Since the Company's initial public offering, ownership changes have triggered a Section 382 limitation, which limits the ability to utilize net operating loss carryforwards.

The Company has incurred net operating losses from inception. At December 31, 2021, the Company had domestic federal net operating loss carryforwards of $94,700 and foreign net operating loss carryforwards of approximately $1,857. In 2021 and previous years, the Company completed public offerings, which triggered ownership changes under Section 382. We believe that as of December 31, 2021, the gross net operating loss carryforwards have been limited to $52,200, which are available to reduce future taxable income. Federal net operating loss carryforwards generated through December 31, 2017 expire at various dates beginning in 2029 through 2038, while federal net operating loss carryforwards generated after 2018 do not expire. Foreign net operating losses do not expire. The Company recorded a valuation allowance against all of its net deferred tax assets of $14,937 and $10,034 as of December 31, 2021, and 2020, respectively, for a net increase of $4,903 from 2020 to 2021 and a net increase of $2,986 from 2019 to 2020.

The Company files income tax returns in the U.S. The Company is subject to tax examinations for the 2015 tax year and beyond. The Company has no unrecognized tax positions 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. In the event that the Company is assessed interest or penalties at some point in the future, they will be classified in the consolidated financial statements as general and administrative expense.

NOTE 12: CONCENTRATION OF CREDIT RISK

Financial instruments that potentially subject the Company to concentration of credit risk consist principally of cash deposits. Accounts at each institution are insured by the Federal Deposit Insurance Corporation ("FDIC") up to $250. As of December 31, 2021 and December 31, 2020, the Company had $136,185 and $39,345, respectively, in excess of the FDIC insured limit, respectively.

NOTE 13: COMMITMENTS AND CONTINGENCIES

Lease Commitments

The Company evaluates all contractual agreements at inception to determine if they contain a lease. Lease liabilities are measured at present value of lease payments not yet paid, using a discounted cash flow model that requires the use of a discount rate, or incremental borrowing rate. Lease terms of 12 months or less are considering short term operating leases and no asset or liability is recognized.

The Company's operating lease assets consist of an office lease and a copier system lease. Our office lease expired February 28, 2021. On March 2021, the Company entered into a new operating lease for office space to pay monthly rent of $1 for a term of 12 months. Our copier system lease expired in October 2021 and was not renewed. None of our leases contain options to extend. As of December 31, 2021, the right of use asset and lease liability balances were $0.

In May 2020, we amended our office lease and extended the expiration from August 31, 2020, to February 28, 2021. This amendment increased our right of use asset and lease liability by $20. Total operating lease expense for the year ended December 31, 2021 and 2020, was $17 and $57, respectively, and variable lease payments of taxes and insurance were immaterial. The weighted average discount rate of our operating leases was 11.3%.

As of December 31, 2021 there are no future minimum lease payments due for 2022. Future minimum lease payments are reported in the consolidated balance sheets at December 31, 2020 net of $1 of imputed interest. The cash paid for amounts included in the measurement of operating lease liabilities for the year ended December 31, 2021 and 2020, was approximately $19 and $55, respectively.

The Company had lease expense under short term leases of $26 and $18 during the year ended December 31, 2021, and 2020, respectively.

Litigation and Contingencies

We are subject to legal proceedings and claims that arise in the normal course of business. We believe these matters are either without merit or of a kind that should not have a material effect, individually or in the aggregate, on our financial position, results of operations or cash flows.

NOTE 14: STOCK BASED COMPENSATION

Stock Option and Incentive Plan

On March 24, 2020, the Board of Directors approved the adoption of the 2020 Stock Incentive Plan (2020 Plan) to provide for the grant 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 the date that is 10 years from the date of stockholder approval. An aggregate of 3,000 shares were initially reserved for issuance in connection with awards granted under the 2020 Plan. On May 14, 2021, the stockholders approved an additional 15,000 shares available for issuance under the 2020 Plan. There are 11,936 options available for grant under the 2020 Plan as of December 31, 2021.

On September 28, 2010, the Board of Directors approved the adoption of the 2010 Stock Option and Incentive Plan (2010 Plan) to provide for the grant of equity-based awards to employees, officers, non-employee directors and other key persons providing services to the Company. Awards of incentive options could be granted under the 2010 Plan until September 2020. No other awards may be granted under the 2010 Plan after the date that is 10 years from the date of stockholder approval. Between 2016 and 2019 a total of 4,242 additional shares were shareholder approved. The automatic additions to the 2010 Plan since inception pursuant to the "evergreen" terms added an additional 740 shares. Shares may no longer be granted under the expired 2010 Stock Option Incentive Plan.

The Company granted options to purchase 3,819 and 3,140 shares of common stock to employees and directors during the years ended December 31, 2021 and December 31, 2020, respectively. The weighted average grant date fair value of options granted during 2021 and 2020 was $2.56 and $1.56, respectively. There were 699 options exercised during the year ended December 31, 2021, at an average exercise price of $2.46. The Company issued 298 new common shares upon this net option exercise. There were 225 options exercised during the year ended December 31, 2020, at an average price of $2.40. The Company issued 76 new common shares upon this net option exercise.

Included in the 2020 options granted above, the Company granted the following stock options (the "2020 Performance Options") to executives of the Company: (i) to the Chairman of the Board, President and Chief Executive Officer, an option to purchase 1,500 shares of Company common stock, 195 of which were granted under the Company's 2010 Plan and 1,305 of which were granted under the Company's 2020 Plan; and (ii) to the Chief Financial Officer, General Counsel and Secretary, an option to purchase 590 shares of Company common stock, 195 of which were granted under the 2010 Plan and 395 of which were granted under the 2020 Plan.

The 2020 Performance Options have an exercise price equal to fair market value of the Company's common stock on the date of grant which was $1.48 per share. The 2020 Performance Options vest quarterly over two years; however, vesting shall accelerate with respect to 50% of any unvested options granted under the 2020 Plan upon U.S. Federal Drug Administration (FDA) approval of certain therapies. The 2020 Performance Options are subject to the option agreements and employment agreements with the executives.

The fair value of stock options granted for the years ended December 31, 2021 and 2020, was calculated using the Black-Scholes option-pricing model applying the following assumptions:

	Year Ended December 31,	
	2021	**2020**
Risk-free interest rate	0.89% - 1.08%	0.28%-0.47%
Expected term (in years)	5.31 - 6.17	4.50-6.18
Dividend yield	-	-
Expected volatility	122% - 130%	103%-129%

Compensation costs associated with the Company's stock options are recognized, based on the grant-date fair values of these options, over the requisite service period, or vesting period. Accordingly, the Company recognized stock-based compensation expense of $5,267 and $3,019 for the years ended December 31, 2021 and 2020, respectively, which was included in the following captions in the consolidated statements of operations:

	Year Ended December 31,	
	2021	**2020**
General and administrative	$ 3,676	$ 2,121
Research and development	1,591	898
Total stock compensation expense	$ 5,267	$ 3,019

Options issued and outstanding as of December 31, 2021, and their activities during the year then ended are as follows:

	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, 2021	7,067	$ 2.74		$ -
Granted	3,819	2.98		100
Exercised	(699)	2.46		2,754
Forfeited	(160)	4.56		-
Expired	-	-		-
Outstanding as of December 31, 2021	10,027	2.82	8.27	$ 1,006
Exercisable as of December 31, 2021	6,472	$2.87	7.78	$ 938
Vested and expected to vest	10,027	$2.82	8.27	$ 1,006

At December 31, 2021, there were 3,555 unvested options outstanding and the related unrecognized total compensation cost associated with these options was $7,187. This expense is expected to be recognized over a weighted-average period of 1.38 years.

NOTE 15: SUBSEQUENT EVENTS

The Company paid a fee of $1,000 in June 2021 to a U.S. leading research institution for the exclusive right to negotiate for the period of six months for the acquisition of the world-wide rights to two oncology R&D programs. This agreement was amended on December 3, 2021, which extended the negotiation term through April 18, 2022. Those negotiations concluded in February 2022 without reaching a definitive agreement and the research institution agreed to return the $1,000 fee as they did not honor their obligation and cancelled the agreement.

On February 24, 2022, the Company granted the following stock options to executives of the Company under the Company's 2020 Stock Incentive Plan: (i) to Dr. Steven C. Quay, Chairman of the Board, President and Chief Executive Officer, an option to purchase 1,900 shares of Company Common Stock; and (ii) to Kyle Guse, Chief Financial Officer, General Counsel and Secretary, an option to purchase 747 shares of Company Common Stock. The Options vest quarterly over two years and have an exercise price equal to fair market value of the Company's Common Stock on the date of grant which was $1.25 per share.

EXHIBIT INDEX

Exhibit No.	Description	Incorporated by Reference Herein	
		Form	Date
3.1	Amended and Restated Certificate of Incorporation of Atossa Therapeutics, Inc.	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 of Atossa Therapeutics, Inc.	Current Report on Form 8-K, as Exhibit 4.1	August 26, 2016
3.3	Bylaws of Atossa Therapeutics, Inc.	Registration Statement on Form S-1, as Exhibit 3.4	June 11, 2012
3.4	Amendment to Bylaws of Atossa Therapeutics, Inc.	Current Report on Form 8-K, as Exhibit 3.1	December 20, 2012
3.5	Certificate of Designation, Preferences, and Rights of Series A Junior Participating Preferred Stock of Atossa Therapeutics, Inc.	Current Report on Form 8-K, as Exhibit 3.1	May 22, 2014
3.6	Certificate of Designation of Preference, Rights and Limitations of Series A Convertible Preferred Stock	Current Report on Form 10-Q, as Exhibit 3.1	May 11, 2017
3.7	Form of Certificate of Designation of Preference, Rights and Limitations of Series B Convertible Preferred Stock	Amendment No.1 to Registration Statement on Form S-1, as Exhibit 4.1	April 23, 2018
3.8	Amended and Restated Certificate of Incorporation of Atossa Therapeutics, Inc.	Current Report on Form 8-K, as Exhibit 3.1	January 7, 2020
3.9	Amendment to Bylaws of Atossa Therapeutics, Inc.	Current Report on Form 8-K, as Exhibit 3.2	January 7, 2020
3.10	Certificate of Amendment to Amended and Restated Certificate of Incorporation of Atossa Therapeutics, Inc.	Current Report on Form 8-K, as Exhibit 4.1	April 23, 2018
3.11	Form of 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	Registration Statement on Form S-1, as Exhibit 4.1	May 21, 2012
4.2	Form of Common Stock Purchase Warrant A	Current Report on Form 8-K, as Exhibit 4.1	December 22, 2017
4.3	Form of Common Stock Purchase Warrant B	Current Report on Form 8-K, as Exhibit 4.2	December 22, 2017
4.4	Form of Warrant Agreement	Amendment No.1 to Registration Statement on Form S-1, as Exhibit 4.2	April 23, 2018
4.5	Form of Warrant Certificate	Amendment No.1 to Registration Statement on Form S-1, as Exhibit 4.3	April 23, 2018
4.6	Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934	Current Report on Form 10K, as Exhibit 4.16	March 26, 2020
4.7	Form of Senior Indenture	Registration Statement on Form S-3, as exhibit 4.1	September 2, 2020
4.8	Form of Common Stock Purchase Warrant	Current Report on Form 8-K, as Exhibit 4.1	December 14, 2020
4.9	Form of Common Stock Purchase Warrant	Current Report on Form 8-K, as Exhibit 4.1	December 21, 2020
4.10	Form of Common Stock Purchase Warrant	Current Report on Form 8-K, as Exhibit 4.1	January 8, 2021
4.11	Form of Common Stock Purchase Warrant	Current Report on Form 8-K, as Exhibit 4.1	March 23, 2021

10.1#	Restated and Amended Employment Agreement with Steven Quay	Registration Statement on Form S-1, as Exhibit 10.3	February 14, 2012
10.2#	Form of Indemnification Agreement	Registration Statement on Form S-1, as Exhibit 10.5	May 21, 2012
10.3#	Form of 2019 Option Award Agreement	Current Report on Form 8-K, as Exhibit 4.1	January 13, 2019
10.4#	Form of Non-Qualified Stock Option Agreement for Employees	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	Registration Statement on Form S-1, as Exhibit 10.9	June 11, 2012
10.6#	Form of Restricted Stock Award Agreement	Registration Statement on Form S-1, as Exhibit 10.13	June 11, 2012
10.7#	Amended and Restated Employment Agreement between the Company and Kyle Guse dated May 18, 2016	Current Report on Form 8-K, as Exhibit 10.1	May 20, 2016
10.8#	2010 Stock Option and Incentive Plan, as amended January 13, 2019	Current Report on Form 8-K, as Exhibit 4.2	January 15, 2019
10.9	Equity Distribution Agreement, dated as of September 25, 2020, by and between Atossa Therapeutics, Inc. and Maxim Group LLC	Current Report on Form 8-K, as Exhibit 1.1	September 25, 2020
10.10#	Form of 2020 ISO Option Award Agreement	Current Report on Form 10Q, as Exhibit 4.1	May 13, 2020
10.11#	Form of 2020 Option Award Agreement	Current Report on Form 8-K, as Exhibit 4.1	April 13, 2020
10.12#	Atossa Therapeutics, Inc. 2020 Stock Incentive Plan	On Form DEF 14A, as Appendix A	April 13, 2020
22.1	List of Subsidiaries	Filed herewith	
23.1	Consent of BDO USA LLP	Filed herewith	
24.1	Powers of Attorney	Filed herewith on Powers of Attorney Page	
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act	Filed herewith	
31.2	Certification Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act	Filed herewith	
32.1	Certification of Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act	Filed herewith	
32.2	Certification of Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act	Filed herewith	
101.INS	Inline XBRL Instance Document		
101.SCH	Inline XBRL Taxonomy Extension Schema Document		
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document		
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document		
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document		
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document		
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.

SIGNATURES

Pursuant to the requirements Section 13 or 15(d) of the Securities Exchange Act of 1934, the issuer, 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 the twenty-eighth day of February 28, 2022.

Atossa Therapeutics, Inc.

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

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Steven C. Quay and Kyle Guse and each of them acting individually, as his true and lawful attorneys-in-fact and agents, each with full power of substitution, for him in any and all capacities, to sign any and all amendments to this report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, with full power of each to act alone, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully for all intents and purposes as he 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, 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, Chief Executive Officer and President (Principal Executive Officer)	February 28, 2022
/s/ Kyle Guse **Kyle Guse**	Chief Financial Officer, General Counsel and Secretary (Principal Financial and Accounting Officer)	February 28, 2022
/s/ Richard I. Steinhart **Richard I. Steinhart**	Director	February 28, 2022
/s/ Shu-Chi Chen **Shu-Chih Chen, Ph.D.**	Director	February 28, 2022
/s/ Gregory Weaver **Gregory Weaver**	Director	February 28, 2022
/s/ Stephen J. Galli **Stephen J. Galli, M.D.**	Director	February 28, 2022
/s/ H. Lawrence Remmel **H. Lawrence Remmel**	Director	February 28, 2022

Exhibit 22.1

LIST OF SUBSIDIARIES

Atossa Genetics UK Ltd.
Atossa Genetics AUS Pty Ltd.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Atossa Therapeutics, Inc.
Seattle, Washington

We hereby consent to the incorporation by reference in the Registration Statements on Form S-1 (No. 333-250820 and 333-223949), Form S-3 (No. 333-255411, 333-254548, 333-252335, 333-248555, 333-192390 and 333-220572), and Form S-8 (No. 333-254905, 333-185625 and 333-193952) of Atossa Therapeutics, Inc. of our reports dated February 28, 2022, relating to the consolidated financial statements and the effectiveness of Atossa Therapeutics, Inc.'s internal control over financial reporting, which appear in this Form 10-K.

/s/ BDO USA, LLP

Seattle, Washington
February 28, 2022

Exhibit 31.1

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

I, Steven C. Quay, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: February 28, 2022

/s/Steven C. Quay
Steven C. Quay
Chief Executive Officer and President
(Principal executive officer)

Exhibit 31.2

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

I, Kyle Guse, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: February 28, 2022

/s/Kyle Guse
Kyle Guse
Chief Financial Officer, General Counsel and Secretary
(Principal financial and accounting officer)

Exhibit 32.1

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

In connection with the Annual Report of Atossa Therapeutics, Inc. (the "Company") on Form 10-K for the period ended December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Steven C. Quay, Chief Executive Officer and President of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: February 28, 2022

/s/ Steven C. Quay
Steven C. Quay
Chief Executive Officer and President
(Principal executive officer)

Exhibit 32.2

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

In connection with the Annual Report of Atossa Therapeutics, Inc. (the "Company") on Form 10-K for the period ended December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Kyle Guse, Chief Financial Officer, General Counsel and Secretary of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: February 28, 2022

/s/ Kyle Guse
Kyle Guse
Chief Financial Officer, General Counsel and Secretary
(Principal financial and accounting officer)