

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

FORM S-3
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

ATOSSA THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other Jurisdiction of
incorporation or organization)

26-4753208
(I.R.S. Employer Identification No.)

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Seattle, Washington 98104
Telephone: (866) 893-4927
(Address, including zip code, and telephone number, including
area code, of Registrant's principal executive offices)

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Approximate Date of Commencement of Proposed Sale to the Public: From time to time after this Registration Statement becomes effective, as determined by the registrant.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box.

If this Form is used to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act Registration Statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act Registration Statement number of the earlier effective registration statement for the same offering.

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box.

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box.

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

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 7(a)(2)(B) of the Securities Act.

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount to be registered(1)	Proposed maximum offering price per unit(2)	Proposed maximum aggregate offering price	Amount of registration fee
Common stock, par value \$0.18	10,500,000	\$1.00	\$10,500,000	\$1,145.55

- (1) This Registration Statement registers 10,500,000 shares of common stock of the Registrant issuable upon the exercise of warrants (the “warrants”) acquired by the selling stockholders in a December 17, 2020 private placement transaction (the “private placement”). Pursuant to Rule 416 of the Securities Act of 1933, as amended (the “Securities Act”), this Registration Statement also covers such additional securities as may become issuable to prevent dilution resulting from stock splits, stock dividends and similar events.
- (2) Estimated solely for the purpose of calculating the registration fee in accordance with Rule 457(g) under the Securities Act. The proposed maximum offering price for shares of common stock underlying the warrants is based on their exercise price of \$1.00 per share.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to Completion, dated January 22, 2021

PROSPECTUS



ATOSSA THERAPEUTICS, INC.

10,500,000 Shares
Common Stock

This prospectus covers the sale of an aggregate of 10,500,000 shares (the “shares”) of our common stock, \$0.18 par value per share (the “common stock”), by the selling stockholders identified in this prospectus (collectively with any of the holder’s transferees, pledgees, donees or successors, the “selling stockholders”). The shares are issuable upon the exercise of warrants (the “warrants”) purchased by the selling stockholders in a private placement transaction exempt from registration under Section 4(a)(2) of the Securities Act of 1933, as amended (the “Securities Act”), pursuant to a Securities Purchase Agreement dated December 17, 2020 (the “Purchase Agreement”). We are registering the resale of the shares of common stock covered by this prospectus as required by the Purchase Agreement.

The Company will not receive any proceeds from the sale by the selling stockholders of the shares, however, we will receive proceeds from the exercise of the warrants if the warrants are exercised for cash. We intend to use those proceeds, if any, for general corporate purposes. We are paying the cost of registering the shares covered by this prospectus as well as various related expenses. The selling stockholders are responsible for all selling commissions, transfer taxes and other costs related to the offer and sale of the shares.

Sales of the shares by the selling stockholders may occur at fixed prices, at market prices prevailing at the time of sale, at prices related to prevailing market prices, or at negotiated prices. The selling stockholders may sell shares to or through underwriters, broker-dealers or agents, who may receive compensation in the form of discounts, concessions or commissions from the Selling Stockholder, the purchasers of the shares, or both. If required, the number of shares to be sold, the public offering price of those shares, the names of any underwriters, broker-dealers or agents and any applicable commission or discount will be included in a supplement to this prospectus, called a prospectus supplement. Because all of the shares offered under this prospectus are being offered by the selling stockholders, we cannot currently determine the price or prices at which the shares may be sold under this prospectus.

Our common stock is currently quoted on the NASDAQ Capital Market under the symbol “ATOS”. On January 21, 2021 the last reported sale price per share of our common stock on the NASDAQ Capital Market was \$1.67. You are urged to obtain current market quotations for our common stock.

Our principal executive offices are located at 107 Spring Street, Seattle, Washington 98104.

Investing in our securities involves risks. You should carefully consider the Risk Factors beginning on page 8 of this prospectus before you make an investment in our securities.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is _____, 2021

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, or SEC, utilizing a shelf registration process. Under the shelf registration process, the selling stockholders may, from time to time, offer and sell the shares described in this prospectus in one or more offerings. Information about the selling stockholders may change over time.

This prospectus provides you with a general description of the shares the selling stockholders may offer. Each time the selling stockholders sell our shares using this prospectus, to the extent necessary and required by law, we will provide a prospectus supplement that will contain specific information about the terms of that offering, including the number of shares being offered, the manner of distribution, the identity of any underwriters or other counterparties and other specific terms related to the offering. The prospectus supplement may also add, update or change information contained in this prospectus. To the extent that any statement made in a prospectus supplement is inconsistent with statements made in this prospectus, the statements made in this prospectus will be deemed modified or superseded by those made in the prospectus supplement. You should read this prospectus, any applicable prospectus supplement and the information incorporated by reference in this prospectus before making an investment in shares of our common stock. See “Where You Can Find Additional Information” for more information.

Neither we nor the selling stockholders have authorized anyone to provide any information other than that contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we may have referred you. Neither we nor the selling stockholders take any responsibility for, nor can provide assurance as to the reliability of, any other information that others may give you. Neither we nor the selling stockholders have authorized any other person to provide you with different or additional information, and neither of us are making an offer to sell the shares in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus is accurate only as of the date on the front cover of this prospectus, regardless of the time of delivery of the prospectus or any sale of the ordinary shares. Our business, financial condition, results of operations and prospects may have changed since the date on the front cover of this prospectus.

For investors outside of the United States, neither we nor the selling stockholders have done anything that would permit the offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to the offering and the distribution of this prospectus outside of the United States.

THE OFFERING

We are registering for resale by the selling stockholders named herein the 10,500,000 shares as described below:

Securities Offered	10,500,000 shares of our common stock issuable upon exercise of warrants acquired by the selling stockholders in a private placement transaction on December 17, 2020.
Use of Proceeds	We will not receive any of the proceeds from the sale or other disposition of shares of our common stock by the selling stockholders. However, we will receive proceeds from the exercise of the warrants if the warrants are exercised for cash.
Risk Factors	Investing in our securities involves a high degree of risk. See the information contained in or incorporated by reference under the heading “ <i>Risk Factors</i> ” in this prospectus and in the documents incorporated by reference into this prospectus and any free writing prospectus that we authorize for use.
Market symbol and trading:	Our common stock is listed on the Nasdaq Capital Market under the symbol “ATOS.”

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains, in addition to historical information, certain information, assumptions and discussions that may constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities 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 prospectus, we cannot assure you that the forward-looking statements set out in this prospectus 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 prospectus include, but are not limited to, statements about:

- the impact of the ongoing coronavirus 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 successfully initiate and complete clinical trials of our pharmaceutical candidates under development, including our oral and topical Endoxifen (an active metabolite of Tamoxifen);
- the success, cost and timing of our product and drug development activities and clinical trials, including whether our study using our oral Endoxifen will enroll a sufficient number of subjects or be completed in a timely fashion or at all;
- whether we will successfully initiate and complete our clinical trial of oral Endoxifen to reduce mammographic breast density and whether the study will meet its objective;
- 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;
- 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 the 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.

These and other forward-looking statements made herein are presented as of the date of this prospectus. We have included important factors in the cautionary statements included in this prospectus, particularly in the section titled "*Risk Factors*" that we believe could cause actual results or events to differ materially from the anticipated results as set forth in 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 prospectus. 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 or circumstances or otherwise.

ABOUT THE COMPANY

We are a clinical-stage biopharmaceutical company seeking to discover and develop innovative medicines in areas of significant unmet medical need with a focus on coronavirus (“COVID-19”), breast cancer and other breast conditions. Our two COVID-19 drugs under development are AT-H201, to improve lung function of moderate to severely ill, hospitalized COVID-19 patients by inhalation, and AT-301, a nasal spray for COVID-19 patients for at-home use. 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 “window of opportunity” between diagnosis of breast cancer and surgery; and another for women with dense breast tissue to reduce the density and/or to act as an adjunct to mammography.

Summary of Leading Programs

A summary of our four leading programs is as follows:

AT-301. 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 proactively reduce symptoms of COVID-19 and to slow the infection rate so that a person’s immune system can more effectively fight COVID-19. We also intend to conduct testing to determine whether AT-301 can be used as a prophylaxis to prevent or mitigate SARS-CoV-2, with the goal that it could complement any traditional vaccine that may be developed in that a traditional vaccine may not be effective in all people and may not be taken by all people.

AT-301 is being developed with a nasal spray delivery mechanism because many COVID-19 patients are infected via the nasal passage. Collectively, the components of AT-301 are believed to help maintain a protective mucosal like layer within the nasal cavity with both anti-viral properties and a protective mucosal like barrier that may lead to lower infectivity and reduced symptoms in COVID-19 patients due to their interference with the spike protein of the virus in the nasal cavity and upper respiratory tract. 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 (“RBD”) 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.

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 divided into two study groups. Part A consisted of two single-dose cohorts receiving either active therapy, AT-301B, or the placebo comparator AT-301A at two doses. Part B was a multiple dose arm with cohorts receiving either AT-301A or AT-301B for 14 days at two doses. The primary objective of the study is to evaluate the safety and tolerability of single and multiple doses of AT-301 administered via nasal instillation to healthy volunteers. Secondary objectives are to assess the incidence and severity of local irritation and bronchospasm following administration of AT-301 via nasal instillation. A preliminary evaluation of the blinded 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 moderate in severity; all other adverse events were considered mild. Our preliminary assessment is that our AT-301 nasal spray was safe and well tolerated in this study. We expect to report final data in the first quarter 2021. These preliminary results support advancing this program into a Phase 2 study. In December 2020, we submitted a pre-IND meeting request with the U.S. FDA, and in January 2021 we received useful guidance from the FDA indicating additional data that we must produce prior to commencing a Phase 2 study of AT-301 in the U.S.

AT-H201. 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. There are five known key steps the coronavirus must take to signal the cell to open up and let the virus in. AT-H201 is being designed to function like a “chemical vaccine” by blocking all five of those steps, similar to what antibodies would be expected to do when a vaccine is administered. In May 2020, we completed in vitro testing of AT-H201 which 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. Developing new drugs that combine drugs previously approved by the FDA typically requires pre-clinical and clinical studies of the individual components of the new drug as well as the combination of the components in the new drug. In the second quarter 2020, we requested a pre-IND meeting with the FDA to discuss the AT-201 program, including a proposed study at NYC Health + Hospitals/Metropolitan in New York City. The FDA requested that we provide, among other things, additional pre-clinical and other information on AT-H201. We also requested a pre-IND meeting with the FDA to discuss one of the components of AT-H201, to which the FDA provided guidance. We are evaluating conducting the study outside the United States. We are working with contract research organizations and medical investigators and plan to commence the initial clinical study of AT-H201 following agreement on the clinical study design.

We have filed provisional patent applications on AT-H201 to treat COVID-19 patients and on AT-301 to treat patients diagnosed with, or to prevent, COVID-19 via nasal spray.

Endoxifen for MBD. 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 2019, we contracted with Stockholm South General Hospital to conduct a randomized, double-blinded, placebo-controlled study of our oral Endoxifen in pre-menopausal women with MBD who will be dosed over six months. This study will evaluate safety, tolerability and efficacy. The primary endpoint is the change of MBD after six months of daily Endoxifen treatment. The study is subject to approval by the European Medical Product Authority and ethics board. We expect to open this study in Stockholm soon after receiving all necessary regulatory approvals, provided COVID-19 restrictions, which are in place now and may be reimposed in the future even if lifted, permit patient recruitment. See "Impact of Novel Coronavirus" below.

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 20mg daily dose level. MBD was reduced by an average of 14.3% in the group applying 20mg daily topical Endoxifen, which was statistically significant ($p=0.02$). In the lower dose group (10mg), MBD was reduced by an average of 9.0%, but was not statistically significant. Approximately 70% of participants receiving 20mg topical Endoxifen experienced a reduction in MBD, and of those, the mean reduction in MBD was 27%. Many participants in this study, however, experienced adverse skin reactions and dropped out of the study. We plan to reevaluate our development strategy for the topical form of Endoxifen once we complete the Phase 2 study of oral Endoxifen to reduce MBD.

Endoxifen for Window of Opportunity. We are currently conducting a Phase 2 study in Australia in the window of time between diagnosis of breast cancer and surgical treatment. The study will enroll up to 25 newly-diagnosed patients with ER+ and human epidermal growth factor receptor 2 negative ("HER2-") stage 1 or 2 invasive breast cancer, requiring mastectomy or lumpectomy. Patients will receive Atossa's proprietary oral Endoxifen for at least 14 days from the time of diagnosis up to the day of surgery. The primary endpoint is to determine if the administration of oral Endoxifen reduces the tumor activity as measured by Ki-67. The secondary endpoints are safety and tolerability and assessment of the study drug on expression levels of both estrogen and progesterone receptors. The impact on additional markers of cellular activity will also be explored.

In May 2020, we reported interim results from our window of opportunity study. A statistically significant ($p=0.031$) reduction of about 74% in tumor cell proliferation, as measured by Ki-67, over the 22 days of dosing was achieved in the initial patients. Ki-67 is a recognized standard measurement of breast cancer cell proliferation. The purpose of this study is to determine if Atossa's oral Endoxifen reduces breast cancer tumor cell proliferation as measured by several biomarkers, including Ki-67. Six out of six (100%) patients experienced a significant reduction in Ki-67. A summary of these results includes:

- Ki-67 was reduced by more than 50% in every patient in the window of opportunity between initial biopsy and surgery, with an overall relative reduction of 74%.
- All six patients had a Ki-67 below 25% after treatment. In a paper entitled, "Prognostic value of different cut-off levels of Ki-67 in breast cancer: a systematic review and meta-analysis of 64,196 patients," Ki-67 was an independent prognostic value for predicting overall survival in ER+ breast cancer patients. Ki-67 levels below 25% were associated with the lowest risk of death in this systematic review and meta-analysis.
- Treatment ranged from 16-40 days with an average of 22 days.
- There were no safety or tolerability issues, including vasomotor symptoms such as hot flashes and night sweats, which are often a tolerability challenge for patients on tamoxifen.
- A seventh patient has recently completed the study and will be included in the final data set.

Based on the positive results of the study to date and our assessment that additional data from the study will not be useful in advancing the program, we plan to discontinue the study and seek regulatory approval to conduct a clinical study in the U.S. or other major country.

About Endoxifen

Endoxifen is an active metabolite of tamoxifen which is an FDA-approved drug to treat and prevent breast cancer in high risk women. Endoxifen has been studied in 70 participants in Atossa-conducted Phase 1 clinical studies. No serious adverse events were reported in any of the studies.

Expanded Access (Compassionate Use) of Endoxifen as Adjuvant Treatment for ER+ Breast Cancer

In December 2018, we began providing our oral Endoxifen to a pre-menopausal, estrogen-receptor positive ("ER+"), lacking CYP2D6 function, breast cancer patient under an FDA-approved expanded access, single patient, or "compassionate use" program. The purpose of this therapeutic approach was to reduce activity of the cancer cells prior to surgery. The patient received daily doses of our oral Endoxifen for approximately three weeks prior to surgery. There were no safety or tolerability issues and her surgery was successfully completed. The cancer cell biological activity was reduced, based on the estrogen receptor activity of the tumor cells and a 50% reduction in Ki-67. The FDA has also permitted use of our Endoxifen for this patient following her surgery, under the compassionate use program, as part of her long-term breast cancer treatment regimen. The use of our proprietary oral Endoxifen is restricted solely to this patient. In July 2020, we reported an update on this patient, who has now received Endoxifen for over 18 months post-surgery. We indicated that the patient has not had a recurrence of breast cancer, has not had treatment-related changes in periodic laboratory blood tests and the treatment has been well tolerated, including an absence of typically seen vasomotor symptoms (night sweats and hot flashes).

Impact of the Novel Coronavirus

The continued spread of the COVID-19 pandemic is affecting the United States 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 conduct of current and future clinical trials. In addition, the COVID-19 pandemic may affect the operations of the U.S. Food and Drug Administration 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 the Company's 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 the Company's products under development. 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. The Company does not yet know the full extent of potential delays or impacts on its 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. The Company has not experienced any delay in drug supply for its ongoing and planned clinical studies, including studies of Endoxifen, AT-301 and AT-H201. The Company anticipates commencing the MBD Endoxifen trial soon after receiving all necessary regulatory approvals; subject to COVID-19 related restrictions that are in place in Stockholm being lifted which could take several months or longer. The Company opened enrollment in the AT-301 trial during the third quarter of 2020 and completed enrollment in the fourth quarter 2020. The Company 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.

RISK FACTORS

Investors should carefully consider the risks and uncertainties and all other information contained or incorporated by reference in this prospectus, including the risks and uncertainties discussed under “Risk Factors” in our most recent Annual Report on Form 10-K, as may be amended from time to time, and in subsequent filings, including our most recent Quarterly Report on Form 10-Q, that are incorporated herein by reference. All of these “Risk Factors” are incorporated by reference herein in their entirety. These risks and uncertainties are not the only ones facing us. Our business, financial condition or results of operations could be materially adversely affected by any of these risks. The trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment. This prospectus and the incorporated documents also contain forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including the risks mentioned in this prospectus.

USE OF PROCEEDS

We are registering these shares for resale by the selling stockholders. We will not receive any proceeds from the sale of the shares offered by this prospectus. However, we will receive proceeds from the exercise of the warrants if the warrants are exercised for cash. We intend to use those proceeds, if any, for general corporate purposes.

PLAN OF DISTRIBUTION

The selling stockholders and any of their pledgees, donees, transferees, assignees or other successors-in-interest may, from time to time, sell, transfer or otherwise dispose of any or all of their shares of common stock or interests in shares of common stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These dispositions may be at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market price, at varying prices determined at the time of sale, or at negotiated prices. These sales may be affected in transactions, which may involve crosses or block transactions. The selling stockholders may use one or more of the following methods when disposing of the shares or interests therein:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- through brokers, dealers or underwriters that may act solely as agents;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- through the writing or settlement of options or other hedging transactions entered into after the effective date of the registration statement of which this prospectus is a part, whether through an options exchange or otherwise;
- settlement of short sales entered into after the effective date of the registration statement of which this prospectus is a part;
- broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of disposition; and
- any other method permitted pursuant to applicable law.

The selling stockholders may also sell shares under Rule 144 under the Securities Act, if available, or Section 4(a)(1) under the Securities Act, rather than under this prospectus, provided that they meet the criteria and conform to the requirements of those provisions.

If the selling stockholders effect such transactions by selling shares of common stock to or through underwriters, broker-dealers or agents, such underwriters, broker-dealers or agents engaged by the selling stockholders may arrange for other broker-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated. The selling stockholders do not expect these commissions and discounts to exceed what is customary in the types of transactions involved.

The selling stockholders may, from time to time, pledge or grant a security interest in some or all of the shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock from time to time under this prospectus, or under a supplement or amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act amending, if necessary, the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus.

Each Selling Stockholder has informed the Company that it is not a registered broker-dealer and does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the common stock. If the Company is notified in writing by a Selling Stockholder that any material arrangement has been entered into with a broker-dealer for the sale of common stock through a block trade, special offering, exchange distribution or secondary distribution or a purchase by a broker or dealer, we will file a supplement to this prospectus, if required, pursuant to Rule 424(b) under the Securities Act, disclosing (i) the name of each such Selling Stockholder and of the participating broker-dealer(s), (ii) the number of shares involved, (iii) the price at which such shares of common stock were sold, (iv) the commissions paid or discounts or concessions allowed to such broker-dealer(s), where applicable, (v) that such broker-dealer(s) did not conduct any investigation to verify the information set out or incorporated by reference in this prospectus, and (vi) other facts material to the transaction. In addition, upon being notified in writing by a Selling Stockholder that a donee or pledge intends to sell more than 500 shares of common stock, the Company will file a supplement to this prospectus if then required in accordance with applicable securities law.

The selling stockholders also may transfer the shares of common stock in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

In connection with the sale of the shares of common stock or interests in shares of common stock, the selling stockholders may enter into hedging transactions after the effective date of the registration statement of which this prospectus is a part with broker-dealers or other financial institutions, which may in turn engage in short sales of the common stock in the course of hedging the positions they assume. The selling stockholders may also sell shares of common stock short after the effective date of the registration statement of which this prospectus is a part and deliver these securities to close out their short positions, or loan or pledge the common stock to broker-dealers that in turn may sell these securities. The selling stockholders may also enter into option or other transactions after the effective date of the registration statement of which this prospectus is a part with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The selling stockholders and any broker-dealers or agents that are involved in selling the shares may be deemed to be “underwriters” within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. The maximum commission or discount to be received by any member of the Financial Industry Regulatory Authority (“FINRA”) or independent broker-dealer will not be greater than eight percent of the initial gross proceeds from the sale of any security being sold.

The Company has advised the selling stockholders that they are required to comply with Regulation M promulgated under the Securities Exchange Act of 1934, as amended, during such time as they may be engaged in a distribution of the shares. The foregoing may affect the marketability of the common stock.

The aggregate proceeds to the selling stockholders from the sale of the common stock offered by them will be the purchase price of the common stock less discounts or commissions, if any. Each of the selling stockholders reserves the right to accept and, together with their agents from time to time, to reject, in whole or in part, any proposed purchase of common stock to be made directly or through agents. The Company will not receive any of the proceeds from this offering.

The Company is required to pay all fees and expenses incident to the registration of the shares. The Company has agreed to indemnify the selling stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act or otherwise.

The Company has agreed with the selling stockholders to keep the registration statement of which this prospectus constitutes a part effective until the earlier of (a) such time as all of the shares covered by this prospectus have been disposed of pursuant to and in accordance with the registration statement, or (b) the date on which the shares of common stock covered by this prospectus may be sold or transferred by non-affiliates without any volume limitations or pursuant to Rule 144 of the Securities Act.

SELLING STOCKHOLDERS

We have prepared this prospectus to allow the selling stockholders to offer for resale, from time to time, up to 10,500,000 shares of our common stock issuable to the selling stockholders upon exercise of certain warrants currently held by the respective selling stockholders.

On December 17, 2020, the Company entered into a securities purchase agreement with certain institutional and accredited investors (the “Purchase Agreement”) whereby, among other things, it issued and sold warrants (the “warrants”) exercisable for an aggregate of up to 10,500,000 shares of common stock (the “shares”) and an exercise price of \$1.00 per share. The warrants will expire on the 4.5 year anniversary of the date of issuance.

The warrants and the shares of common stock issuable thereunder were sold and issued without registration under the Securities Act of 1933, in reliance on the exemptions provided by Section 4(a)(2) of the Securities Act as transactions not involving a public offering and Rule 506 promulgated under the Securities Act as sales to accredited investors.

The selling stockholders listed in the table below may from time to time offer and sell any or all shares of our common stock set forth below pursuant to this prospectus. When we refer to “selling stockholders” in this prospectus, we mean the persons listed in the table below, and the pledgees, donees, permitted transferees, assignees, successors and others who later come to hold any of the selling stockholders’ interests in shares of our common stock other than through a public sale.

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The following table sets forth, as of the date of this prospectus, the name of the selling stockholders for whom we are registering shares for resale to the public, and the number of such shares that each such selling stockholder may offer pursuant to this prospectus. Applicable percentages are based on 71,574,280 shares of common stock outstanding on January 21, 2021.

We cannot advise as to whether the selling stockholders will in fact sell any or all of such shares. In addition, the selling stockholders may have sold, transferred or otherwise disposed of, or may sell, transfer or otherwise dispose of, at any time and from time to time, the shares in transactions exempt from the registration requirements of the Securities Act after the date on which they provided the information set forth on the table below.

Selling Stockholders(1)	Number of Shares beneficially owned through January 21, 2021	Number of Shares that may be sold in this Offering	Shares beneficially owned after this Offering(2)	
			Number of Shares	Percentage of total outstanding common stock
Armistice Capital Master Fund Ltd. (3)	3,475,000	1,312,500	2,162,500	3.0%
Anson Investments Master Fund LP(4)	5,878,125	1,603,125	4,275,000	5.9%
Anson East Master Fund LP(4)	1,246,875	534,375	712,500	*%
CVI Investments, Inc.	6,450,000	1,500,000	4,950,000	6.9%
Empery Asset Master, Ltd(5)	2,595,948	751,262	1,844,686	2.5%
Empery Tax Efficient, LP(6)	448,239	196,752	251,487	*%
Empery Tax Efficient III, LP(7)	1,718,313	364,486	1,353,827	1.9%
Hudson Bay Master Fund Ltd.(8)	4,762,500	1,312,500	3,450,000	4.8%
Intracoastal Capital, LLC(9)	4,050,000	1,312,500	2,737,500	3.8%
Sabby Volatility Warrant Master Fund, Ltd.(10)	6,862,500	1,612,500	5,250,000	7.3%

*Denotes less than 1%.

- If required, information about other selling stockholders, except for any future transferees, pledgees, donees or successors of the Selling Stockholder named in the table above, will be set forth in a prospectus supplement or amendment to the registration statement of which this prospectus is a part. Additionally, post-effective amendments to the registration statement will be filed to disclose any material changes to the plan of distribution from the description contained in the final prospectus.
- Assumes all shares offered by the selling stockholders hereby are sold and that the selling stockholders buys or sells no additional shares of common stock prior to the completion of this offering.
- The shares are directly held by Armistice Capital Master Fund Ltd., a Cayman Islands exempted company (the "Master Fund"), and may be deemed to be indirectly beneficially owned by: (i) Armistice Capital, LLC ("Armistice Capital"), as the investment manager of the Master Fund; and (ii) Steven Boyd, as the Managing Member of Armistice Capital. The number of shares includes 3,375,000 shares of common stock issuable upon exercise of the Warrants, which are subject to certain beneficial ownership limitations. Armistice Capital and Steven Boyd disclaim beneficial ownership of the securities except to the extent of their respective pecuniary interests therein.
- Anson Advisors Inc and Anson Funds Management LP, the Co-Investment Advisers of Anson Investments Master Fund LP ("Anson Investments") and Anson East Master Fund LP ("Anson East", and collectively with Anson Investments, "Anson"), hold voting and dispositive power over the Common Shares held by Anson. Bruce Winson is the managing member of Anson Management GP LLC, which is the general partner of Anson Funds Management LP. Moez Kassam and Amin Nathoo are directors of Anson Advisors Inc. Mr. Winson, Mr. Kassam and Mr. Nathoo each disclaim beneficial ownership of these Common Shares except to the extent of their pecuniary interest therein. The principal business address of Anson is Walkers Corporate Limited, Cayman Corporate Centre, 27 Hospital Road, George Town, Grand Cayman KY1-9008, Cayman Islands.
- Empery Asset Management LP, the authorized agent of Empery Asset Master Ltd ("EAM"), has discretionary authority to vote and dispose of the shares held by EAM and may be deemed to be the beneficial owner of these shares. Martin Hoe and Ryan Lane, in their capacity as investment managers of Empery Asset Management LP, may also be deemed to have investment discretion and voting power over the shares held by EAM. EAM, Mr. Hoe and Mr. Lane each disclaim any beneficial ownership of these shares.
- Empery Asset Management LP, the authorized agent of Empery Tax Efficient, LP ("ETE"), has discretionary authority to vote and dispose of the shares held by ETE and may be deemed to be the beneficial owner of these shares. Martin Hoe and Ryan Lane, in their capacity as investment managers of Empery Asset Management LP, may also be deemed to have investment discretion and voting power over the shares held by ETE. ETE, Mr. Hoe and Mr. Lane each disclaim any beneficial ownership of these shares.
- Empery Asset Management LP, the authorized agent of Empery Tax Efficient III, LP ("ETE III"), has discretionary authority to vote and dispose of the shares held by ETE III and may be deemed to be the beneficial owner of these shares. Martin Hoe and Ryan Lane, in their capacity as investment managers of Empery Asset Management LP, may also be deemed to have investment discretion and voting power over the shares held by ETE III. ETE III, Mr. Hoe and Mr. Lane each disclaim any beneficial ownership of these shares.
- Hudson Bay Capital Management LP, the investment manager of Hudson Bay Master Fund Ltd., has voting and investment power over these securities, which are issuable upon exercise of warrants, and are subject to certain beneficial ownership limitations. Sander Gerber is the managing member of Hudson Bay Capital GP LLC, which is the general partner of Hudson Bay Capital Management LP. Each of Hudson Bay Master Fund Ltd. and Sander Gerber disclaims beneficial ownership over these securities.
- Mitchell P. Kopin ("Mr. Kopin") and Daniel B. Asher ("Mr. Asher"), each of whom are managers of Intracoastal Capital LLC ("Intracoastal"), have shared voting control and investment discretion over the securities reported herein that are held by Intracoastal. As a result, each of Mr. Kopin and Mr. Asher may be deemed to have beneficial ownership (as determined under Section 13(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act")) of the securities reported herein that are held by Intracoastal.
- Sabby Management, LLC, the investment manager of Sabby Volatility Warrant Master Fund, Ltd., and Hal Mintz, manager of Sabby Management, LLC, may be deemed to share voting and dispositive power with respect to these securities. Each of Sabby Management, LLC and Hal Mintz disclaims beneficial ownership over the securities listed except to the extent of their pecuniary interest therein. The principal business address of Sabby Volatility Warrant Master Fund, Ltd. is c/o Ogier Fiduciary Services (Cayman) Limited, 89 Nexus Way, Camana Bay, Grand Cayman KY1-9007, Cayman Islands. The principal business address of Sabby Management, LLC and Hal Mintz is 10 Mountainview Road, Suite 205, Upper Saddle River, New Jersey 07458.

DESCRIPTION OF COMMON STOCK

The following description of our common stock is a summary and does not purport to be complete. It is subject to and qualified in its entirety by reference to our Certificate of Incorporation, as amended (the “certificate of incorporation”) and our Amended and Restated Bylaws (the “bylaws”), each of which are incorporated by reference as an exhibit to the Annual Report on Form 10-K of which this exhibit is a part. We encourage you to read our certificate of incorporation, our bylaws and the applicable provisions of the Delaware General Corporation Law (the “DGCL”) for additional information.

Authorized Shares. We are authorized to issue up to 175,000,000 shares of common stock.

Voting Rights. The holders of our common stock are entitled to one vote per share on all matters to be voted upon by the stockholders. When a quorum is present at any meeting of our stockholders, the affirmative vote of a majority of the votes properly cast on the matter (excluding any abstentions or broker non-votes) will be the act of the stockholders with respect to all matters other than the contested election of directors (which will be elected by a plurality of all votes properly cast), or as otherwise provided in the bylaws, the certificate of incorporation or a preferred stock designation, or as otherwise required by law.

Dividends. Subject to preferences that may be applicable to any outstanding preferred stock, the holders of our common stock are entitled to receive ratably all dividends, if any, as may be declared from time to time by our Board of Directors out of the funds legally available.

Other Rights. In the event of the liquidation, dissolution or winding up of the Company, the holders of our common stock are entitled to share ratably in all assets remaining after payment of liabilities, subject to prior distribution rights of preferred stock, if any, then outstanding. The common stock has no preemptive or conversion rights. There are no redemption or sinking fund provisions applicable to the common stock. All outstanding shares of common stock are fully paid and non-assessable.

Transfer Agent. The transfer agent and registrar for our common stock is VStock Transfer, LLC, 18 Lafayette Place, Woodmere, New York 11598 (Telephone: (212) 828-8436; Facsimile (646) 536-3179).

Listing. Our common stock is currently listed on The Nasdaq Capital Market under the symbol “ATOS”.

Certain Provisions Affecting Control of the Company

Certificate of Incorporation and Bylaw Provisions. Some provisions of the DGCL and our certificate of incorporation and bylaws contain provisions that could make the following transactions more difficult:

- acquisition of us by means of a tender offer;
- acquisition of us by means of a proxy contest or otherwise; or
- removal of our incumbent officers and directors.

These provisions, summarized below, are intended to discourage coercive takeover practices and inadequate takeover bids and to promote stability in our management. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our Board of Directors.

Undesignated Preferred Stock. The ability to authorize undesignated preferred stock makes it possible for our Board of Directors to issue one or more series of preferred stock with voting or other rights or preferences that could impede the success of any attempt to change control of us. These and other provisions may have the effect of deferring hostile takeovers or delaying changes in control or management of our company.

Advance Notice Procedures. The advance notice procedures in our bylaws with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of our stockholders provide that notice of stockholder proposals must be timely given in writing to our corporate secretary prior to the meeting at which the action is to be taken. Generally, to be timely, notice must be received at our principal executive offices not less than 90 days nor more than 120 days prior to the first anniversary date of the annual meeting for the preceding year. Our bylaws specify the requirements as to form and content of all such stockholder notices. These requirements may have the effect of precluding stockholders from bringing proposals relating to the nomination of candidates for election as directors or new business before the stockholders at an annual or special meeting.

Delaware Anti-Takeover Statute. We are subject to Section 203 of the DGCL. This law prohibits a publicly held Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the date that the stockholder became an interested stockholder unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding those shares owned by persons who are directors and also officers and by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or subsequent to the date of the transaction, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 of the DGCL defines “business combination” to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the corporation’s assets involving the interested stockholder;
- in general, any transaction that results in the issuance or transfer by the corporation of any of its stock to the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 of the DGCL defines an “interested stockholder” as an entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

EXPERTS

The consolidated financial statements as of December 31, 2019 and 2018 and for each of the two years in the period ended December 31, 2019 incorporated by reference in this Prospectus have been so incorporated in reliance on the report of BDO USA, LLP, an independent registered public accounting firm, incorporated herein by reference, given on the authority of said firm as experts in auditing and accounting. The report on the consolidated financial statements contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

LEGAL MATTERS

Certain legal matters relating to the validity of the securities offered by this prospectus will be passed upon for us by Gibson, Dunn & Crutcher LLP, San Francisco, California.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

The Company files annual, quarterly and special reports, proxy statements and other information with the SEC. The SEC maintains an Internet site that contains all reports and other information that we file electronically with the SEC. The address of that website is www.sec.gov.

This prospectus is part of a registration statement we filed with the SEC. This prospectus does not contain all of the information set forth in the registration statement and the exhibits to the registration statement. Statements contained in this prospectus as to the contents of any contract or other document are not necessarily complete, and in each instance we refer you to the copy of the contract or document filed as an exhibit to the registration statement, each such statement being qualified in all respects by such reference.

For further information with respect to us and the securities we are offering under this prospectus, we refer you to the registration statement and the exhibits and schedules filed as a part of the registration statement (or incorporated by reference). Neither we nor any agent, underwriter or dealer has authorized any person to provide you with information that is different from that contained in this prospectus or in any free writing prospectus we may authorize to be delivered or made available to you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We are not making an offer of these securities in any state where the offer is not permitted. You should not assume that the information in this prospectus is accurate as of any date other than the date on the front page of this prospectus, regardless of the time of delivery of this prospectus or any sale of the securities offered by this prospectus.

We maintain a website at www.atossatherapeutics.com. Information contained in or accessible through our website does not constitute a part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

INFORMATION INCORPORATED BY REFERENCE

The SEC allows us to “incorporate by reference” information into this prospectus. This means that we can disclose important information about us and our financial condition to you by referring you to another document filed separately with the SEC. The information incorporated by reference is considered to be a part of this prospectus, except any information that is superseded by information that is included in a document subsequently filed with the SEC.

This prospectus incorporates by reference the documents listed below that we have previously filed with the SEC and any future filings we make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), from the date of this prospectus until the termination of an offering of securities, except that we are not incorporating by reference any information furnished (and not filed) with the SEC, including any information furnished pursuant to Items 2.02 or 7.01 of Form 8-K or related exhibits furnished pursuant to Item 9.01 of Form 8-K:

- The Company’s Annual Report on Form 10-K for the fiscal year ended [December 31, 2019](#), filed with the SEC on March 26, 2020 (including the portions of our Proxy Statement for our 2020 Annual General Meeting of Shareholders incorporated by reference therein);
- The Company’s Quarterly Reports on Forms 10-Q for the quarters ended [March 31, 2020](#), [June 30, 2020](#) and [September 30, 2020](#) filed with the SEC respectively on May 19, 2020, August 13, 2020 and November 13, 2020;
- The Company’s Definitive Proxy Statement on Schedule 14A, filed with the SEC on [April 13, 2020](#);
- The Company’s Current Reports on Forms 8-K filed with the SEC on [January 8, 2021](#), and in 2020 on the following dates: [January 7](#), [February 10](#), [April 13](#), [May 19](#), [September 25](#), [November 30](#), [December 8](#), [December 14](#) and [December 21](#) (in each case, except for information furnished rather than filed);
- The description of the Company’s common stock contained in the registration statement on Form 8-A filed with the Commission on [July 24, 2012](#) pursuant to Section 12 of the Exchange Act of 1934, as amended (the “Exchange Act”), including any amendment or report filed for the purpose of updating that description; and
- All documents filed by the Company pursuant to Sections 13(a), 13(c), 14 and 15(d) of the Exchange Act, after the date of the original Registration Statement and prior to effectiveness of the registration statement of which this prospectus is a part, provided that all documents “furnished” by the Company to the SEC and not “filed” are not deemed incorporated by reference herein.

Any statement contained in a document, all or a portion of which is incorporated or deemed to be incorporated by reference herein, will be deemed to be modified or superseded to the extent that a statement contained herein or in any other subsequently filed document which also is or is deemed to be incorporated by reference herein modifies or supersedes such statement. Any statement so modified will not be deemed to constitute a part hereof, except as so modified, and any statement so superseded will not be deemed to constitute a part hereof. Under no circumstances will any information filed under items 2.02 or 7.01 of Form 8-K be deemed to be incorporated by reference unless such Form 8-K expressly provides to the contrary.

A copy of any document incorporated by reference in this prospectus may be obtained at no cost by writing or telephoning us at the following address and telephone number:

Atossa Therapeutics, Inc.
107 Spring Street,
Seattle, Washington, 98104
(866) 893-4927

We maintain a website at www.atossatherapeutics.com. Information about us, including our reports filed with the SEC, is available through that site. Such reports are accessible at no charge through our website and are made available as soon as reasonably practicable after such material is filed with or furnished to the SEC. Our website and the information contained on that website, or connected to that website, are not incorporated by reference in this prospectus.

You may read and copy any materials we file with the SEC at the SEC’s website mentioned under the heading “Where You Can Find Additional Information.” The information on the SEC’s website is not incorporated by reference in this prospectus.

PART II
INFORMATION NOT REQUIRED IN PROSPECTUS

ITEM 13. Other Expenses of Issuance and Distribution

The following are the estimated expenses of the distribution of the shares registered hereunder on Form S-3. None of the expenses listed below are to be borne by any of the Selling Stockholder named in the prospectus that forms a part of this registration statement. The amounts set forth above are estimate, except the SEC Registration Fee:

Registration Fee—Securities and Exchange Commission	\$ 1,145.55
Accountants Fees and Expenses	\$ 10,000.00
Legal Fees and Expenses	\$ 20,000.00
Miscellaneous	\$ 5,310.00
Total	\$ 36,455.55

The amounts set forth above, except for the SEC Registration Fee, are estimated.

ITEM 14. Indemnification of Directors and Officers.

Section 145 of the Delaware General Corporation Law, or the DGCL, authorizes a corporation to indemnify its directors and officers against liabilities arising out of actions, suits and proceedings to which they are made or threatened to be made a party by reason of the fact that they have served or are currently serving as a director or officer to a corporation. The indemnity may cover expenses (including attorneys' fees) judgments, fines and amounts paid in settlement actually and reasonably incurred by the director or officer in connection with any such action, suit or proceeding. Section 145 permits corporations to pay expenses (including attorneys' fees) incurred by directors and officers in advance of the final disposition of such action, suit or proceeding. In addition, Section 145 provides that a corporation has the power to purchase and maintain insurance on behalf of its directors and officers against any liability asserted against them and incurred by them in their capacity as a director or officer, or arising out of their status as such, whether or not the corporation would have the power to indemnify the director or officer against such liability under Section 145.

We have adopted provisions in our certificate of incorporation and bylaws that limit or eliminate the personal liability of our directors to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended. Consequently, a director will not be personally liable to us or our stockholders for monetary damages or breach of fiduciary duty as a director, except for liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- any unlawful payments related to dividends or unlawful stock purchases, redemptions or other distributions; or
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not alter director liability under the federal securities laws and do not affect the availability of equitable remedies such as an injunction or rescission.

In addition, our bylaws provide that:

- we will indemnify our directors, officers and, in the discretion of our Board of Directors, certain employees to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended; and
- we will advance reasonable expenses, including attorneys' fees, to our directors and, in the discretion of our Board of Directors, to our officers and certain employees, in connection with legal proceedings relating to their service for or on behalf of us, subject to limited exceptions.

We have entered into indemnification agreements with each of our directors and certain of our executive officers. These agreements provide that we will indemnify each of these directors and executive officers to the fullest extent permitted by Delaware law. We will advance expenses, including attorneys' fees, judgments, fines and settlement amounts, to each indemnified director, executive officer or affiliate in connection with any proceeding in which indemnification is available and we will indemnify our directors and officers for any action or proceeding arising out of that person's services as an officer or director brought on behalf of the Company or in furtherance of our rights.

We maintain general liability insurance that covers certain liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers, including liabilities under the Securities Act.

ITEM 16. Exhibit Index.

<u>Exhibit No.</u>	<u>Description</u>	<u>Form</u>	<u>Date</u>
1.1	Securities Purchase Agreement dated December 17, 2020	Current Report on Form 8-K, as Exhibit 1.1	December 21, 2020
1.2	Placement Agency Agreement between Atossa Therapeutics, Inc. and Maxim Group LLC, dated December 17, 2020	Current Report on Form 8-K, as Exhibit 1.2	December 21, 2020
3.1	Amended and Restate 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	Amended and Restated Certificate of Incorporation of Atossa Therapeutics, Inc.	Current Report on Form 8-K, as Exhibit 3.1	January 7, 2020
3.6	Amendment to Bylaws of Atossa Therapeutics, Inc.	Current Report on Form 8-K, as Exhibit 3.2	January 7, 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 Private Placement Warrant	Current Report on Form 8-K, as Exhibit 4.1	December 21, 2020
4.3	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
5.1	Opinion of Gibson, Dunn & Crutcher LLP	Filed herewith	January 22, 2021
23.1	Consent of BDO USA LLP	Filed herewith	January 22, 2021
23.2	Consent of Gibson, Dunn & Crutcher LLP	Filed as part of Exhibit 5.1 to this Registration Statement on Form S-3	January 22, 2021
24.1	Powers of Attorney	Included on the signature page in Part II of this Registration Statement on Form S-3	January 22, 2021

ITEM 17. Undertakings.

The undersigned registrant hereby undertakes:

- (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
 - (i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;
 - (ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement.
 - (iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;
- provided, however, that paragraphs (a)(1)(i), (a)(1)(ii) and (a)(1)(iii) of this section do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.*
- (2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
 - (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.
 - (4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:
 - (A) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in this Registration Statement; and
 - (B) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of this Registration Statement or made in any such document immediately prior to such effective date.
 - (5) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities: The undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:
 - (i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;
 - (ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;
 - (iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and
 - (iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the registrant's annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered herein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

Insofar as indemnification for liabilities arising under the Securities Act, as amended, may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of

any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the Company certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in Seattle, Washington, on January 22, 2021.

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 individual whose signature appears below constitutes and appoints Steven C. Quay and Kyle Guse as their true and lawful attorney-in-fact and agent, with full power of substitution, for them and in their name, place and stead, in any and all capacities, to sign this registration statement and any and all amendments thereto, including post-effective amendments, and to file the same, with all exhibits thereto, any related registration filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all the said attorney-in-fact and agent or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement on Form S-3 has been signed by the following persons in the capacities and on the dates indicated.

Signature	Office(s)	Date
<u>/s/ Steven C. Quay</u> Steven C. Quay, M.D., Ph.D.	Chairman, Chief Executive Officer and President (Principal Executive Officer)	January 22, 2021
<u>/s/ Kyle Guse</u> Kyle Guse	Chief Financial Officer, General Counsel and Secretary (Principal Financial and Accounting Officer)	January 22, 2021
<u>/s/ Shu-Chih Chen</u> Shu-Chih Chen, Ph.D.	Director	January 22, 2021
<u>/s/ Richard Steinhart</u> Richard Steinhart	Director	January 22, 2021
<u>/s/ Stephen J. Galli</u> Stephen J. Galli, M.D.	Director	January 22, 2021
<u>/s/ H. Lawrence Rimmel</u> H. Lawrence Rimmel	Director	January 22, 2021
<u>/s/ Gregory L. Weaver</u> Gregory L. Weaver	Director	January 22, 2021

GIBSON DUNN

Gibson, Dunn & Crutcher LLP
555 Mission Street
San Francisco, CA 94105-0921
Tel 415.393.8200
www.gibsondunn.com

January 22, 2021

Atossa Therapeutics, Inc.
107 Spring Street
Seattle, Washington 98104

Re: *Atossa Therapeutics, Inc.*
Registration Statement on Form S-3

Ladies and Gentlemen:

We have examined the Registration Statement on Form S-3 (the "Registration Statement"), of Atossa Therapeutics, Inc., a Delaware corporation (the "Company"), filed with the Securities and Exchange Commission (the "Commission") pursuant to the Securities Act of 1933, as amended (the "Securities Act"), in connection with the offering by the Selling Stockholders identified in the Registration Statement (the "Selling Stockholders") of up to 10,500,000 shares (the "Shares") of the Company's common stock, par value \$0.18 per share (the "Common Stock"), issuable upon the exercise of warrants (the "Warrants") acquired by the Selling Stockholders in a December 17, 2020 private placement.

In arriving at the opinion expressed below, we have examined originals, or copies certified or otherwise identified to our satisfaction as being true and complete copies of the originals, of the Warrants and such other documents, corporate records, certificates of officers of the Company and of public officials and other instruments as we have deemed necessary or advisable to enable us to render the opinions set forth below. In our examination, we have assumed without independent investigation the genuineness of all signatures, the legal capacity and competency of all natural persons, the authenticity of all documents submitted to us as originals and the conformity to original documents of all documents submitted to us as copies.

Based upon the foregoing, and subject to the assumptions, exceptions, qualifications and limitations set forth herein, we are of the opinion that the Shares, when issued in accordance with the terms of the Warrants, will be validly issued, fully paid and non-assessable.

We consent to the filing of this opinion as an exhibit to the Registration Statement, and we further consent to the use of our name under the caption "Legal Matters" in the Registration Statement and the prospectus that forms a part thereof. In giving these consents, we do not thereby admit that we are within the category of persons whose consent is required under Section 7 of the Securities Act or the Rules and Regulations of the Commission.

Very truly yours,

/s/ Gibson, Dunn & Crutcher LLP

Consent of Independent Registered Public Accounting Firm

Atossa Therapeutics, Inc.
Seattle, Washington

We hereby consent to the incorporation by reference in the Prospectus constituting a part of this Registration Statement on Form S-3 of our report dated March 26, 2020, relating to the consolidated financial statements of Atossa Therapeutics, Inc. (the “Company”), appearing in the Company’s Annual Report on Form 10-K for the year ended December 31, 2019. Our report contains an explanatory paragraph regarding the Company’s ability to continue as a going concern.

We also consent to the reference to us under the caption “Experts” in the Prospectus.

/s/ BDO USA, LLP
Seattle, Washington

January 22, 2021