

PROSPECTUS SUPPLEMENT
(To Prospectus dated September 10, 2020)



ATOSSA THERAPEUTICS, INC.
Up to \$10,000,000
Common Stock

We have entered into an Equity Distribution Agreement, dated September 25, 2020, or the Distribution Agreement, with Maxim Group LLC, or Maxim, relating to shares of our common stock, par value \$0.18 per share, offered by this prospectus supplement and the accompanying prospectus. In accordance with the terms of the Distribution Agreement, we may offer and sell our common stock having an aggregate offering price of up to \$10,000,000 from time to time through Maxim acting as our sales agent, at our discretion.

Our common stock is listed on the Nasdaq Capital Market under the symbol "ATOS." On September 24, 2020, the last reported sale price of our common stock as reported on the Nasdaq Capital Market was \$2.31 per share.

Sales of our common stock, if any, under this prospectus supplement may be made in sales deemed to be an "at the market offering" as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, or the Securities Act, or in privately negotiated transactions. Subject to terms of the Distribution Agreement, Maxim is not required to sell any specific number or dollar amount of securities but will act as our sales agent using commercially reasonable efforts consistent with its normal trading and sales practices, on mutually agreed terms between Maxim and us. There is no arrangement for funds to be received in any escrow, trust or similar arrangement.

Maxim will be entitled to a commission of 3.0% of the gross sales price per share sold under the Distribution Agreement. See "Plan of Distribution" in this prospectus supplement for additional information regarding Maxim's compensation. In connection with the sale of our common stock on our behalf, Maxim will be deemed to be an "underwriter" within the meaning of the Securities Act and the compensation of Maxim will be deemed to be underwriting commissions or discounts. We have also agreed to provide indemnification and contributions to Maxim against certain civil liabilities, including liabilities under the Securities Act.

The aggregate market value of our outstanding shares of common stock held by non-affiliates was \$45,096,172, based on 10,395,001 shares of common stock outstanding as of August 13, 2020, of which 10,366,936 shares were held by non-affiliates, and a per share price of \$4.35 based on the closing sale price of our common stock on July 29, 2020, as reported by Nasdaq. During the prior 12 calendar month period that ends on, and includes, the date of this prospectus supplement, we have offered and sold securities with an aggregate market value of \$5 million pursuant to General Instruction I.B.6 of Form S-3. Pursuant to General Instruction I.B.6 of Form S-3, in no event will we sell securities registered on this registration statement in a public primary offering with a value exceeding more than one-third of our public float in any 12-month period so long as our public float remains below \$75.0 million.

INVESTING IN OUR COMMON STOCK INVOLVES A HIGH DEGREE OF RISK. YOU SHOULD REVIEW CAREFULLY THE RISKS AND UNCERTAINTIES DESCRIBED UNDER THE HEADING "RISK FACTORS" IN THIS PROSPECTUS SUPPLEMENT, AND UNDER SIMILAR HEADINGS IN THE DOCUMENTS THAT ARE INCORPORATED BY REFERENCE INTO THIS PROSPECTUS SUPPLEMENT AND THE ACCOMPANYING PROSPECTUS.

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

Maxim Group LLC

The date of this prospectus supplement is September 25, 2020

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ABOUT THIS PROSPECTUS SUPPLEMENT

This prospectus supplement and the accompanying prospectus relate to an offering of shares of our common stock. Before buying any of the common stock that we are offering, we urge you to carefully read this prospectus supplement and the accompanying prospectus, together with the information incorporated by reference as described under the headings “Where You Can Find More Information” and “Incorporation of Certain Information by Reference” in this prospectus supplement. These documents contain important information that you should consider when making your investment decision.

This document is in two parts. The first part is this prospectus supplement, which describes the terms of this offering of common stock and also adds to, updates and changes information contained in the accompanying prospectus and the documents incorporated by reference. The second part is the accompanying prospectus, which gives more general information. Generally, when we refer to this prospectus, we are referring to both parts of this document combined. To the extent the information contained in this prospectus supplement differs from or conflicts with the information contained in the accompanying prospectus or any document incorporated by reference, the information in this prospectus supplement will control. If any statement in one of these documents is inconsistent with a statement in another document having a later date—for example, a document incorporated by reference into this prospectus supplement and the accompanying prospectus—the statement in the document having the later date modifies or supersedes the earlier statement.

We have not, and the sales agent has not, authorized anyone to provide you with information different from that which is contained in or incorporated by reference in this prospectus supplement, the accompanying prospectus and in any free writing prospectus that we may authorize for use in connection with this offering. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give to you. No one is making offers to sell or seeking offers to buy these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information contained in this prospectus supplement is accurate as of the date on the front cover of this prospectus supplement only and that any information we have incorporated by reference or included in the accompanying prospectus is accurate only as of the date given in the document incorporated by reference or as of the date of the prospectus, as applicable, regardless of the time of delivery of this prospectus supplement, the accompanying prospectus, any related free writing prospectus, or any sale of our common stock. Our business, financial condition, results of operations and prospects may have changed since those dates.

We further note that the representations, warranties and covenants made by us in any agreement that is filed as an exhibit to any document that is incorporated by reference into this prospectus supplement or the accompanying prospectus were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreements, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

Unless the context otherwise requires, references in this prospectus supplement to “Atossa,” “we,” “us,” “our” and “ours” refer to Atossa Therapeutics, Inc., and include its consolidated subsidiaries where the context so requires. Furthermore, on January 6, 2020 we changed the name of our company from Atossa Genetic Inc. to Atossa Therapeutics, Inc. Accordingly, any reference to Atossa Genetics Inc. in the accompanying prospectus means Atossa Therapeutics, Inc.

This prospectus supplement, the accompanying prospectus and the information incorporated herein and therein by reference include trademarks, servicemarks and tradenames owned by us or other companies. All trademarks, servicemarks and tradenames included or incorporated by reference in this prospectus supplement or the accompanying prospectus are the property of their respective owners.

PROSPECTUS SUPPLEMENT SUMMARY

This summary highlights certain information about us and this offering and selected information contained elsewhere in or incorporated by reference into this prospectus supplement and the accompanying prospectus. This summary is not complete and does not contain all of the information that you should consider before deciding whether to invest in our common stock. For a more complete understanding of our company and this offering, we encourage you to read and consider carefully the more detailed information in this prospectus supplement and the accompanying prospectus, including the information incorporated by reference into this prospectus supplement and the accompanying prospectus, and the information included in any free writing prospectus that we authorize for use in connection with this offering, including the information contained in and incorporated by reference under the heading "Risk Factors" in this prospectus supplement, and under similar headings in the other documents that are filed after the date hereof and incorporated by reference into this prospectus supplement and the accompanying prospectus.

We are a clinical-stage biopharmaceutical seeking to discover and develop innovative medicines in areas of significant unmet medical need with a focus on coronavirus ("COVID-19") and breast cancer. 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 who are not sufficiently ill to require hospitalization. Our breast cancer drug under development 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 high mammographic breast density ("MBD") 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-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 and well as the combination of the components in the new drug.

We recently applied to the FDA to commence a clinical trial of AT-H201 which we contracted for with the NYC Health + Hospitals/Metropolitan in New York City. The FDA has requested, among other things, that we submit additional pre-clinical and other information on AT-H201 before approving the study. We are in the process of providing the necessary information to the FDA and are evaluating conducting the study outside the United States. We anticipate receiving regulatory approval to commence the initial clinical study of one of the components of AT-H201 in the fourth quarter of 2020.

AT-301. AT-301 is our proprietary drug 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 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.

We have contracted with Avance Clinical, a CRO in Australia, to conduct a Phase 1 study of AT-301 which is designed as 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 consists of two single-dose cohorts receiving either active therapy, AT-301B, or the placebo comparator AT-301A at two doses. Part B is 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. As of the date of this prospectus supplement we have received positive safety assessments for the first two cohorts and have enrolled and dosed the first three cohorts.

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. 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 double-blinded, placebo-controlled Phase 2 study of our oral Endoxifen in pre-menopausal women with MBD who will be dosed over six months. We anticipate launching this study in Stockholm in the fourth quarter of 2020. The upcoming study in Stockholm is subject to approval by the European Medical Product Authority ("MPA") and the re-opening of mammography clinics in Stockholm following the COVID-19 closures.

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 and surgery. 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 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. The Phase 2 study is being conducted on behalf of Atossa by Avance Clinical, which successfully completed four Phase 1 studies of Atossa's Endoxifen.

In May 2020, we reported interim results from our Phase 2 study of oral Endoxifen in the window of opportunity. 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. The open-label study was designed to permit an interim analysis of the Ki-67 change. The requirement was to achieve a meaningful Ki-67 change in at least two of eight patients. 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.

This study continues to be open for enrollment.

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. In 2017, we successfully completed our initial Phase 1 placebo-controlled clinical trial of our proprietary oral and topical formulations of Endoxifen in 48 healthy women, supporting the continued development of this drug. There were no clinically significant safety signals and no clinically significant adverse events, and both the oral and topical Endoxifen were well tolerated. In the topical arm of the study, low but measurable Endoxifen levels were detected in the blood in a dose-dependent fashion. In the oral arm of the study, participants exhibited dose-dependent Endoxifen levels that met or exceeded the published therapeutic level. The median time for patients in the study who took daily doses of oral Endoxifen to reach steady-state serum levels of Endoxifen was approximately seven days. Published literature indicates that it can take approximately 50 to 200 days for patients to reach steady-state Endoxifen levels from daily doses of oral tamoxifen.

In May 2020, we reported a regulatory update that the FDA recently provided written input on our clinical path for oral Endoxifen to reduce MBD. The input was provided pursuant to a pre-IND meeting request which was scheduled for April 30, 2020. The input received from the FDA was very useful and will inform our clinical trial strategy and study design both in the U.S. and in Stockholm, Sweden where we are planning a Phase 2 study to reduce MBD.

Compassionate Use of Endoxifen

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 received Endoxifen for 18 months post-surgery. To date, 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).

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.

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. Currently, enrollment is open in Australia for the Endoxifen window of opportunity study for which enrollment continues to be slow due in part to disruption caused by COVID-19. The Company anticipates launching the Endoxifen MBD trial in the fourth quarter of 2020 and will continue to monitor the future enrollment for potential restrictions of site visits, mammograms or the impositions of new restrictions on trials as a result of the COVID-19 pandemic.

In response to the Coronavirus pandemic, the Coronavirus Aid, Relief and Economic Security Act ("CARES Act") was signed into law on March 27, 2020. The CARES Act, among other things, includes provisions related to refundable payroll tax credits, deferment of employer side social security payments, net operating loss utilization and carryback periods, modifications to the net interest deduction limitations, increased limitations on qualified charitable contributions, and technical corrections to tax depreciation methods for qualified improvement property. The CARES Act had no material impact on the Company's income tax provision for the three and six months ended June 30, 2020. The Company continues to examine the elements of the CARES Act and the impact it may have on its financial position, results of operations and cash flows.

Corporate Information

We were incorporated in the state of Delaware in 2009. On January 6, 2020, we changed our corporate name from Atossa Genetics Inc. to Atossa Therapeutics, Inc. Our corporate headquarters are located at 107 Spring Street, Seattle, Washington 98104. Our telephone number is (206) 588-0256 and our Internet website address is www.atossatherapeutics.com. We do not incorporate the information on our website into this prospectus supplement, and you should not consider it part of this prospectus supplement.

THE OFFERING

Common stock offered by us	Shares of our common stock having an aggregate offering price of up to \$10.0 million.
Common stock to be outstanding after the offering	Up to 14,724,005 shares of our common stock, assuming sales of 4,329,004 shares of our common stock in this offering at an assumed offering price of \$2.31 per share, which was the last reported sale price of our common stock on the Nasdaq Capital Market on September 24, 2020. The actual number of shares issued will vary depending on the sales prices at which our common stock is sold under this offering.
Plan of Distribution	“At the market offering” that may be made from time to time through our sales agent, Maxim. See “Plan of Distribution” in this prospectus supplement.
Use of Proceeds	We intend to use the net proceeds from this offering for general corporate purposes. See “Use of Proceeds” in this prospectus supplement.
Risk Factors	Investing in our common stock involves a high degree of risk. See the information contained in or incorporated by reference under the heading “Risk Factors” in this prospectus supplement, in the accompanying prospectus and in the documents incorporated by reference into this prospectus supplement and any free writing prospectus that we authorize for use in connection with this offering.
Nasdaq Capital Market symbol	“ATOS”

The number of shares of our common stock to be outstanding after this offering is based on 10,395,001 shares of our common stock outstanding as of September 24, 2020 and excludes:

- 1,070,028 shares of common stock issuable upon the exercise of outstanding warrants as of June 30, 2020, at an exercise price of \$4.05 per share;
- 7,223,383 shares of common stock issuable upon the exercise of options issued under the Company’s 2010 Stock Option and Incentive Plan (the “2010 Plan”) at a weighted average exercise price of \$2.72 per share as of June 30, 2020;
- 177,831 shares of common stock issuable upon the conversion of outstanding Series B Convertible preferred stock as of June 30, 2020; and
- 1,031,669 shares of common stock reserved for issuance pursuant to future equity awards under our 2020 Plan and 2010 Plan as of June 30, 2020, as well as any future increases in the number of shares of our common stock reserved for future issuance under the 2020 plan.

RISK FACTORS

Investing in our securities involves risks. Before making an investment decision, you should carefully consider the risks and other information we include or incorporate by reference in this prospectus supplement and the accompanying prospectus, and in any free writing prospectus that we have authorized for use in connection with this offering. In particular, you should consider the risk factors described under the heading "Risk Factors" in our most recent Annual Report on Form 10-K, as may be revised or supplemented by our subsequent Quarterly Reports on Form 10-Q or Current Reports of Form 8-K, each of which are on file with the SEC and are incorporated herein by reference, and which may be amended, supplemented or superseded from time to time by other reports we file with the SEC in the future. In addition to those risk factors, there may be additional risks and uncertainties of which are not currently known to us or that we currently deem immaterial. Our business, financial condition or results of operations could be materially adversely affected by any of these risks. The occurrence of any of these risks might cause you to lose all or part of your investment in the offered securities.

Risks Related to This Offering

You may experience future dilution as a result of future equity offerings.

In order to raise additional capital, we may at any time, including during the pendency of this offering, offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that may not be the same as the price per share in this offering. We may sell shares or other securities in any other offering at a price per share that is less than the price per share paid by investors in this offering, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders. The price per share at which we sell additional shares of our common stock, or securities convertible or exchangeable into common stock, in future transactions may be higher or lower than the price per share paid by investors in this offering

We have broad discretion in the use of our cash and cash equivalents, including the net proceeds we receive in this offering, and may not use them effectively.

Our management has broad discretion to use our cash and cash equivalents, including the net proceeds we receive in this offering, to fund our operations and could spend these funds in ways that do not improve our results of operations or enhance the value of our common stock, and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending their use to fund our operations, we may invest our cash and cash equivalents, including the net proceeds from this offering, in a manner that does not produce income or that loses value.

Sales of our common stock in this offering, or the perception that such sales may occur, could cause the market price of our common stock to fall.

We may issue and sell shares of our common stock for aggregate gross proceeds of up to \$10.0 million from time to time in connection with this offering. The actual number of shares of common stock that may be issued and sold in this offering, as well as the timing of any such sales, will depend on a number of factors, including, among others, the prices at which any shares are actually sold this offering (which may be influenced by market conditions, the trading price of our common stock and other factors) and our determinations as to the appropriate timing, sources and amounts of funding we need. The issuance and sale from time to time of these new shares of common stock, or the mere fact that we are able to issue and sell these shares in this offering, could cause the market price of our common stock to decline.

Because we do not intend to declare cash dividends on our shares of common stock in the foreseeable future, stockholders must rely on appreciation of the value of our common stock for any return on their investment.

We have never declared or paid cash dividends on our common stock. We currently anticipate that we will retain future earnings, if any, for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends in the foreseeable future. In addition, the terms of any existing or future debt agreements may preclude us from paying dividends. As a result, we expect that only appreciation of the price of our common stock, if any, will provide a return to investors in this offering for the foreseeable future.

It is not possible to predict the actual number of shares of common stock we will sell under the Distribution Agreement, or the gross proceeds resulting from those sales.

Subject to certain limitations in the Distribution Agreement and compliance with applicable law, we have the discretion to deliver a placement notice to Maxim at any time throughout the term of the Distribution Agreement. The number of shares that are sold through Maxim after delivering a placement notice will fluctuate based on a number of factors, including the market price of our shares during the sales period, the limits we set with Maxim in any applicable placement notice, and the demand for our shares during the sales period. Because the price per share of each share sold will fluctuate during this offering, it is not currently possible to predict the number of shares that will be sold or the gross proceeds to be raised in connection with those sales.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains 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 and Section 21E of the Securities Exchange Act of 1934, as amended. 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 herein 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 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, or FDA, or foreign regulatory health bodies, to commence our clinical studies 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 the ongoing clinical study using our oral Endoxifen will enroll a sufficient number of subjects or be completed in a timely fashion or at all;
- 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 within the current 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 and technologies;
- 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 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;
- our ability to raise capital; and
- other risks more fully discussed in the “Risk Factors” section in this prospectus supplement, the accompanying prospectus and the risk factors and cautionary statements described in other documents that we file from time to time with the SEC, specifically under “Risk Factors” and elsewhere in our most recent Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q.

Other factors not currently anticipated may also materially and adversely affect our results of operations, cash flows and financial position. We do not undertake any obligation to update or alter any statements whether as a result of new information, future events or otherwise, except as required by law.

USE OF PROCEEDS

We may issue and sell up to \$10.0 million of our common stock from time to time. Because there is no minimum offering amount required as a condition to close this offering, the actual total public offering amount, commissions and proceeds to us, if any, are not determinable at this time. There can be no assurance that we will sell any shares under or fully utilize the Distribution Agreement with Maxim as a source of financing.

We intend to use the net proceeds from this offering for general corporate purposes.

As of the date of this prospectus supplement, we cannot specify with certainty all of the particular uses of the proceeds, if any, from this offering. Accordingly, we will retain broad discretion over the use of any such proceeds. Pending the use of the net proceeds, from this offering as described above, we intend to invest the net proceeds in investment-grade, interest-bearing instruments.

PLAN OF DISTRIBUTION

We have entered into an Equity Distribution Agreement, dated September 25, 2020, or the Distribution Agreement, with Maxim Group LLC., or Maxim, relating to shares of our common stock, par value \$0.18 per share, offered by this prospectus supplement. In accordance with the terms of the Distribution Agreement, we may offer and sell our common stock having an aggregate offering price of up to \$10,000,000 from time to time through Maxim acting as our sales agent. The Distribution Agreement has been filed as an exhibit to a Current Report on Form 8-K and incorporated by reference into this prospectus supplement and the accompanying prospectus.

Upon delivery of a placement notice and subject to the terms and conditions of the Distribution Agreement, Maxim may offer and sell shares of our common stock by any method permitted by law deemed to be an “at the market offering” as defined in Rule 415(a)(4) promulgated under the Securities Act, or in privately negotiated transactions. We may instruct Maxim not to sell common stock if the sales cannot be effected at or above the price designated by us from time to time. We or Maxim may suspend the offering of common stock upon notice and subject to other conditions.

We will pay Maxim commissions, in cash, for its services in acting as agent in the sale of our common stock. Maxim is entitled to compensation at a commission rate of 3.0% of the gross sales price per share sold under the Distribution Agreement. Because there is no minimum offering amount required as a condition to close this offering, the actual total public offering amount, commissions and proceeds to us, if any, are not determinable at this time. We have also agreed to reimburse Maxim for certain specified expenses, including the reasonable and documented fees and disbursements of its legal counsel in an amount not to exceed (a) \$40,000 in connection with the establishment of this at-the-market offering, and (b) thereafter, \$2,500 on a quarterly basis (such approval not to be unreasonably withheld, conditioned or delayed). We estimate that the total expenses for the offering under this prospectus supplement, excluding compensation and reimbursements payable to Maxim under the terms of the Distribution Agreement, will be approximately \$123,500.

Settlement for sales of shares of common stock will occur on the second business day following the date on which any sales are made, or on some other date that is agreed upon by us and Maxim in connection with a particular transaction, in return for payment of the net proceeds to us. Sales of our common stock as contemplated in this prospectus supplement will be settled through the facilities of The Depository Trust Company or by such other means as we and Maxim may agree upon. There is no arrangement for funds to be received in an escrow, trust or similar arrangement.

Maxim will use its commercially reasonable efforts, consistent with its sales and trading practices, to solicit offers to purchase the shares of common stock under the terms and subject to the conditions set forth in the Distribution Agreement. In connection with the sale of the shares of common stock on our behalf, Maxim will be deemed to be an “underwriter” within the meaning of the Securities Act and the compensation of Maxim will be deemed to be underwriting commissions or discounts. We have agreed to provide indemnification and contribution to Maxim (and its partners, members, directors, officers, employees and agents) against certain civil liabilities, including liabilities under the Securities Act.

We will report, consistent with our obligations under the Securities Act and the Exchange Act, the number of shares of common stock sold under the Distribution Agreement, the net proceeds to us and the compensation paid by us to Maxim in connection with the sales of our shares of common stock.

The offering of shares of our common stock pursuant to the Distribution Agreement will terminate upon the termination of the Distribution Agreement as permitted therein. We and Maxim may each terminate the Distribution Agreement at any time upon ten days' prior notice.

Maxim and its affiliates may in the future provide various investment banking, commercial banking and other financial services for us, our subsidiaries and our affiliates, for which services they may in the future receive customary fees. To the extent required by Regulation M, Maxim will not engage in any market making activities involving our common stock while the offering is ongoing under this prospectus supplement.

This prospectus supplement and the accompanying prospectus in electronic format may be made available on a website maintained by Maxim and Maxim may distribute this prospectus supplement and the accompanying prospectus electronically.

LEGAL MATTERS

The validity of the shares of common stock offered hereby will be passed upon for us by Gibson, Dunn & Crutcher, LLP. Certain legal matters relating to this offering will be passed upon for Maxim by Ellenoff Grossman & Schole LLP, New York, New York.

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 supplement have been so incorporated in reliance on the report of BDO USA, LLP, an independent registered public accounting firm (the report on the consolidated financial statements contains an explanatory paragraph regarding the Company's ability to continue as a going concern), incorporated herein by reference, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and current reports, proxy statements and other information with the SEC. We also filed a registration statement on Form S-3, including exhibits, under the Securities Act with respect to the securities offered by this prospectus supplement and the accompanying prospectus. This prospectus supplement and the accompanying prospectus are a part of that registration statement, but do not contain all of the information included in the registration statement or the exhibits. You can find our public filings with the SEC on the internet at a web site maintained by the SEC located at www.sec.gov.

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows the Company to “incorporate by reference” the information that is filed by the Company with the SEC, which means that the Company can disclose important information to you by referring you to those documents. The documents incorporated by reference are:

1. The Company’s [Annual Report on Form 10-K for the fiscal year ended December 31, 2019](#);
2. The Company’s Quarterly Reports on Form [10-Q for the quarters ended March 31, 2020, June 30, 2020](#);
3. The Company’s [Definitive Proxy Statement on Schedule 14A, filed with the SEC on April 13, 2020](#);
4. The Company’s Current Reports on [Form 8-K, filed with the SEC in 2020 on the following dates: January 7, February 10, March 26, April 13, May 13, May 19, August 13](#);
5. 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](#), including any amendment or report filed for the purpose of updating that description; and
6. 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 incorporated or deemed to be incorporated by reference herein shall be deemed to be modified or superseded for purposes of this registration statement 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 such statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this registration statement. 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.

The Company will provide, without charge, to each person, including any beneficial owner, to whom a copy of this prospectus is delivered, upon such person’s written or oral request, a copy of any and all of the information incorporated by reference in this prospectus, other than exhibits to such documents, unless such exhibits are specifically incorporated by reference into the information that this prospectus incorporates. Requests should be directed to the Secretary at Atossa Therapeutics, Inc., 107 Spring Street, Seattle, Washington, 98104, phone (866) 893-4927. You may also find these documents in the “Investor Relations” section of our website, www.atossatherapeutics.com. The information on our website is not incorporated into this prospectus.

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 September 2, 2020

PRELIMINARY PROSPECTUS



ATOSSA THERAPEUTICS, INC.

\$100,000,000

Common Stock
Preferred Stock
Debt Securities
Warrants

We may offer and sell an indeterminate number of shares of our common stock, preferred stock, debt securities and warrants from time to time under this prospectus. We may offer these securities separately or together in combination with other securities registered by this prospectus. We will describe in a prospectus supplement the securities we are offering and selling, as well as the specific terms of the securities.

We may offer these securities in amounts, at prices and on terms determined at the time of offering. We may sell the securities directly to you, through agents we select, or through underwriters and dealers we select. If we use agents, underwriters or dealers to sell the securities, we will name them and describe their compensation in a prospectus supplement or sales agreement prospectus.

Our Common Stock is currently quoted on the NASDAQ Capital Market under the symbol "ATOS". On August 28, 2020 the last reported sale price per share of our Common Stock on the NASDAQ Capital Market was \$2.63. 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 5 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 _____, 2020

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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, we may offer shares of our common stock and preferred stock, various series of debt securities and warrants to purchase any of such securities with a total value of up to \$100,000,000 from time to time under this prospectus at prices and on terms to be determined by market conditions at the time of offering. This prospectus provides you with a general description of the securities we may offer. Each time we offer a type or series of securities, we will provide a prospectus supplement (which term includes, as applicable, the sales agreement prospectus filed with the registration statement of which this prospectus forms a part) that will describe the specific amounts, prices and other important terms of the securities.

We may also authorize one or more free writing prospectuses to be provided to you that may contain material information relating to these offerings. A prospectus supplement or free writing prospectus may include a discussion of risks or other special considerations applicable to us or the offered securities. A prospectus supplement or free writing prospectus may also add, update or change information in this prospectus. If there is any inconsistency between the information in this prospectus and the applicable prospectus supplement, you must rely on the information in the prospectus supplement. Please carefully read both this prospectus and the applicable prospectus supplement in their entirety together with additional information described under the heading “Where You Can Find More Information” in this prospectus. This prospectus may not be used to offer or sell any securities unless accompanied by a prospectus supplement.

We have not authorized any broker-dealer, salesperson or other person to give any information or to make any representation other than those contained or incorporated by reference in this prospectus and any accompanying supplement to this prospectus. You must not rely upon any information or representation not contained or incorporated by reference in this prospectus or any accompanying prospectus supplement. This prospectus and any accompanying supplement to this prospectus do not constitute an offer to sell or the solicitation of an offer to buy securities, nor do this prospectus and any accompanying supplement to this prospectus constitute an offer to sell or the solicitation of an offer to buy securities in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation. The information contained in this prospectus and any accompanying prospectus supplement speaks only as of the date set forth on the cover page and you should assume that such information may not reflect subsequent changes in our business, financial condition, results of operations and prospects even though this prospectus and any accompanying prospectus supplement is delivered, or securities are sold, on a later date.

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference into it contain, 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") 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 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 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.

This prospectus also contains estimates and other statistical data provided by independent parties and by us relating to market size and growth and other industry data. These and other forward-looking statements made in this prospectus are presented as of the date on which the statements are made. We have included important factors in the cautionary statements included in this prospectus, particularly in the section entitled "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 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 seeking to discover and develop innovative medicines in areas of significant unmet medical need with a focus on coronavirus ("COVID-19") and breast cancer. 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 who are not sufficiently ill to require hospitalization. Our breast cancer drug under development 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 high mammographic breast density ("MBD") 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-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 and well as the combination of the components in the new drug.

We recently applied to the FDA to commence a clinical trial of AT-H201. The FDA has requested, among other things, that we submit additional pre-clinical and other information on AT-H201 before approving the study. We are in the process of providing the necessary information to the FDA and anticipate receiving approval from the FDA to commence the initial clinical study of one of the components of AT-H201 in the second half of 2020.

AT-301. AT-301 is our proprietary drug 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 become a "bridge to the vaccine" and be useful in the next phase of the coronavirus pandemic.

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 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.

We have contracted with Avance Clinical, a CRO in Australia, to conduct a Phase 1 study of AT-301 which is designed as 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 consists of two single-dose cohorts receiving either active therapy, AT-301B, or the placebo comparator AT-301A at two doses. Part B is 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. This study commenced in August 2020.

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. 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 double-blinded, placebo-controlled Phase 2 study of our oral Endoxifen in pre-menopausal women with MBD who will be dosed over six months. We anticipate receiving regulatory approval and opening this study in Stockholm in the second half of 2020. The upcoming study in Stockholm is subject to approval by the European Medical Product Authority ("MPA") and the opening of mammography clinics in Stockholm following the COVID-19 closures.

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 and surgery. 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 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. The Phase 2 study is being conducted on behalf of Atossa by Avance Clinical, which successfully completed four Phase 1 studies of Atossa's Endoxifen.

In May 2020, we reported interim results from our Phase 2 study of oral Endoxifen in the window of opportunity. 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. The open-label study was designed to permit an interim analysis of the Ki-67 change. The requirement was to achieve a meaningful Ki-67 change in at least two of eight patients. 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.

This study continues to be open for enrollment.

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. In 2017, we successfully completed our initial Phase 1 placebo-controlled clinical trial of our proprietary oral and topical formulations of Endoxifen in 48 healthy women, supporting the continued development of this drug. There were no clinically significant safety signals and no clinically significant adverse events, and both the oral and topical Endoxifen were well tolerated. In the topical arm of the study, low but measurable Endoxifen levels were detected in the blood in a dose-dependent fashion. In the oral arm of the study, participants exhibited dose-dependent Endoxifen levels that met or exceeded the published therapeutic level. The median time for patients in the study who took daily doses of oral Endoxifen to reach steady-state serum levels of Endoxifen was approximately seven days. Published literature indicates that it can take approximately 50 to 200 days for patients to reach steady-state Endoxifen levels from daily doses of oral tamoxifen.

In May 2020, we reported a regulatory update that the FDA recently provided written input on our clinical path for oral Endoxifen to reduce MBD. The input was provided pursuant to a pre-IND meeting request which was scheduled for April 30, 2020. The input received from the FDA was very useful and will inform our clinical trial strategy and study design both in the U.S. and in Stockholm, Sweden where we are planning a Phase 2 study on the use of oral Endoxifen to reduce MBD.

Compassionate Use of Endoxifen

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 received Endoxifen for 18 months post-surgery. To date, 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).

Other Programs

We are evaluating Endoxifen to prevent and/or reduce gynecomastia, which is male breast enlargement and pain. We completed a successful Phase 1 study using Endoxifen in male patients in Australia. Endoxifen is also being evaluated to treat breast cancer patients after surgery to prevent a recurrence. We have not commenced clinical studies for this potential indication.

We are also developing our proprietary intraductal delivery technology to potentially target the delivery of therapies, including fulvestrant, immunotherapies and Chimeric Antigen Receptor T-cell therapies (CAR-T therapies), close to the site of breast cancer in the breast ducts. In 2019 we contracted with Johns Hopkins University to conduct a Phase 2 study using our intraductal technology to deliver fulvestrant.

After reviewing our recent clinical progress with Endoxifen and the potential opportunities with our COVID-19 programs, we have concluded that allocating additional resources to our Endoxifen and COVID-19 programs has a greater potential return for our stockholders than our ongoing study utilizing our intraductal microcatheter technology to treat early stage breast cancer with fulvestrant. We are therefore discontinuing the fulvestrant study using our intraductal delivery technology so that we can focus resources on our Endoxifen studies and our COVID-19 programs.

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 will retain broad discretion over the use of the net proceeds from the sale of our securities offered hereby. Except as described in any prospectus supplement, we currently anticipate using the net proceeds from the sale of our securities offered hereby primarily for general corporate purposes, which include, but are not limited to, funding our ongoing and future development of our drugs and devices under development, and for general and administrative expenses. We may also use a portion of the net proceeds to pay off outstanding indebtedness, if any, and/or acquire or invest in complementary businesses, products and technologies. Further, from time to time we may evaluate acquisition opportunities and engage in related discussions with other companies. Pending the use of the net proceeds, we intend to invest the net proceeds in short-term, interest-bearing, investment-grade securities.

PLAN OF DISTRIBUTION

We may sell the securities covered by this prospectus from time to time in one or more offerings. Registration of the securities covered by this prospectus does not mean, however, that those securities will necessarily be offered or sold.

We may sell the securities separately or together:

- through one or more underwriters or dealers in a public offering and sale by them;
- directly to investors; or
- through agents.

We may sell the securities from time to time:

- in one or more transactions at a fixed price or prices, which may be changed from time to time;
- at market prices prevailing at the times of sale;
- at prices related to such prevailing market prices; or
- at negotiated prices.

We will describe the method of distribution of the securities and the terms of the offering in the prospectus supplement. Any discounts or concessions allowed or re-allowed or paid to dealers may be changed from time to time.

If underwriters are used in the sale of any securities, the securities will be acquired by the underwriters for their own account and may be resold from time to time in one or more transactions described above. The securities may be either offered to the public through underwriting syndicates represented by managing underwriters, or directly by underwriters. Generally, the underwriters' obligations to purchase the securities will be subject to conditions precedent and the underwriters will be obligated to purchase all of the securities if they purchase any of the securities. We may use underwriters with whom we have a material relationship. We will describe in the prospectus supplement, naming the underwriter, the nature of any such relationship.

We may authorize underwriters, dealers or agents to solicit offers by certain purchasers to purchase the securities from us at the public offering price set forth in the prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on a specified date in the future. The contracts will be subject only to those conditions set forth in the prospectus supplement, and the prospectus supplement will set forth any commissions we pay for solicitation of these contracts.

We may enter into derivative transactions with third parties, or sell securities not covered by this prospectus to third parties in privately negotiated transactions. If the applicable prospectus supplement indicates, in connection with those derivatives, the third parties may sell securities covered by this prospectus and the applicable prospectus supplement, including in short sale transactions. If so, the third party may use securities pledged by us or borrowed from us or others to settle those sales or to close out any related open borrowings of stock, and may use securities received from us in settlement of those derivatives to close out any related open borrowings of stock. The third party in such sale transactions will be an underwriter and will be identified in the applicable prospectus supplement or in a post-effective amendment.

Underwriters, dealers and agents may be entitled to indemnification by us against certain civil liabilities, including liabilities under the Securities Act, or to contribution with respect to payments made by the underwriters, dealers or agents, under agreements between us and the underwriters, dealers and agents.

We may grant underwriters who participate in the distribution of securities an option to purchase additional securities to cover over-allotments, if any, in connection with the distribution.

Underwriters, dealers or agents may receive compensation in the form of discounts, concessions or commissions from us or our purchasers, as their agents in connection with the sale of securities. These underwriters, dealers or agents may be considered to be underwriters under the Securities Act. As a result, discounts, commissions or profits on resale received by the underwriters, dealers or agents may be treated as underwriting discounts and commissions. The prospectus supplement will identify any such underwriter, dealer or agent and describe any compensation received by them from us. Any initial public offering price and any discounts or concessions allowed or re-allowed or paid to dealers may be changed from time to time.

Unless otherwise specified in the related prospectus supplement, all securities we offer, other than common stock, will be new issues of securities with no established trading market. Any underwriters may make a market in these securities, but will not be obligated to do so and may discontinue any market making at any time without notice. Any common stock sold pursuant to a prospectus supplement will be listed for trading on the NASDAQ Capital Market or other principal market for our common stock. We may apply to list any series of debt securities, preferred stock or warrants on an exchange, but we are not obligated to do so. Therefore, there may not be liquidity or a trading market for any series of securities.

Any underwriter may engage in over-allotment transactions, stabilizing transactions, short-covering transactions and penalty bids in accordance with Regulation M under the Exchange Act. Over-allotment involves sales in excess of the offering size, which create a short position. Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum. Short covering transactions involve purchases of the securities in the open market after the distribution is completed to cover short positions. Penalty bids permit the underwriters to reclaim a selling concession from a dealer when the securities originally sold by the dealer are purchased in a covering transaction to cover short positions. Those activities may cause the price of the securities to be higher than it would otherwise be. If commenced, the underwriters may discontinue any of the activities at any time. We make no representation or prediction as to the direction or magnitude of any effect that such transactions may have on the price of the securities. For a description of these activities, see the information under the heading "Underwriting" or "Plan of Distribution" in the applicable prospectus supplement.

Underwriters, broker-dealers or agents who may become involved in the sale of the common stock may engage in transactions with and perform other services for us in the ordinary course of their business for which they receive compensation.

DESCRIPTION OF CAPITAL STOCK

We may offer shares of our common stock, preferred stock, various series of debt securities and warrants to purchase any such securities with a total value of up to \$100,000,000 from time to time under this prospectus at prices and on terms to be determined by market conditions at the time of offering. Each time we offer a type or series of securities, we will provide a prospectus supplement that will describe the specific amounts, prices and other important terms of the securities.

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.

Preferred Stock

We may issue shares of our preferred stock from time to time, in one or more series. Under our certificate of incorporation, our board of directors has the authority, without further action by stockholders, to designate up to 10,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges, qualifications and restrictions granted to or imposed upon the preferred stock, including dividend rights, conversion rights, voting rights, rights and terms of redemption, liquidation preference and sinking fund terms, any or all of which may be greater than the rights of the common stock.

If we issue preferred stock, we will fix the rights, preferences, privileges, qualifications and restrictions of the preferred stock of each series that we sell under this prospectus and applicable prospectus supplements in the certificate of designations relating to that series. If we issue preferred stock, we will incorporate by reference into the registration statement of which this prospectus is a part the form of any certificate of designations that describes the terms of the series of preferred stock we are offering before the issuance of the related series of preferred stock. We urge you to read the prospectus supplement related to any series of preferred stock we may offer, as well as the complete certificate of designations that contains the terms of the applicable series of preferred stock.

Series A Junior Participating Preferred Stock. In connection with our May 19, 2014 Shareholder Rights Plan, discussed below, the Company has designated 750,000 shares of Series-A Junior Participating Preferred Stock, par value \$0.001 per share through the filing of a certificate of designation with the Delaware Secretary of State. The shareholder rights agreement 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 our 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 our Common Stock (or, in the case of a person who beneficially owned 15% or more of our Common Stock on the date the stockholder rights agreement was executed, by acquiring beneficial ownership of additional shares representing 2.0% of our 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 our 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 our 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.

Series A Convertible Preferred Stock. In connection with our April 2017 financing, we designated 4,000 shares of the 10,000,000 authorized shares of preferred stock as Series A Convertible Preferred. As of the date of this prospectus, no shares of Series A Convertible Preferred are outstanding.

Series B Convertible Preferred Stock. In connection with our May 2018 rights offering, we designated 20,000 shares of the 10,000,000 authorized shares of preferred stock as Series B Convertible Preferred. As of the date of this prospectus, 626 shares of Series B Convertible Preferred Stock are outstanding.

DESCRIPTION OF DEBT SECURITIES

We may issue debt securities from time to time, in one or more series, as either senior or subordinated debt or as senior or subordinated convertible debt. While the terms we have summarized below will apply generally to any debt securities that we may offer under this prospectus, we will describe the particular terms of any debt securities that we may offer in more detail in the applicable prospectus supplement. The terms of any debt securities offered under a prospectus supplement may differ from the terms described below. Unless the context requires otherwise, whenever we refer to the indenture, we also are referring to any supplemental indentures that specify the terms of a particular series of debt securities.

We will issue the debt securities under an indenture to be entered into between us and a trustee to be named in a prospectus supplement. The indenture will be qualified under the Trust Indenture Act of 1939, as amended (the “Trust Indenture Act”). We have filed the form of indenture as an exhibit to the registration statement of which this prospectus is a part, and supplemental indentures and forms of debt securities containing the terms of the debt securities being offered will be filed as exhibits to the registration statement of which this prospectus is a part or will be incorporated by reference from reports that we file with the SEC.

The following summary of material provisions of the debt securities and the indentures is subject to, and qualified in its entirety by reference to, all of the provisions of the indenture applicable to a particular series of debt securities. We urge you to read the applicable prospectus supplements and any related free writing prospectuses related to the debt securities that we may offer under this prospectus, as well as the complete indenture that contains the terms of the debt securities.

General

The indenture does not limit the amount of debt securities that we may issue. It provides that we may issue debt securities up to the principal amount that we may authorize and may be in any currency or currency unit that we may designate. Except for the limitations on consolidation, merger and sale of all or substantially all of our assets contained in the indenture, the terms of the indenture do not contain any covenants or other provisions designed to give holders of any debt securities protection against changes in our operations, financial condition or transactions involving us.

We may issue the debt securities issued under the indenture as “discount securities,” which means they may be sold at a discount below their stated principal amount. These debt securities, as well as other debt securities that are not issued at a discount, may be issued with “original issue discount,” or OID, for U.S. federal income tax purposes because of interest payment and other characteristics or terms of the debt securities. Material U.S. federal income tax considerations applicable to debt securities issued with OID will be described in more detail in any applicable prospectus supplement.

We will describe in the applicable prospectus supplement the terms of the series of debt securities being offered, including:

- the title of the series of debt securities;
- any limit upon the aggregate principal amount that may be issued;
- the maturity date or dates;
- the form of the debt securities of the series;
- the applicability of any guarantees;
- whether or not the debt securities will be secured or unsecured, and the terms of any secured debt;
- whether the debt securities rank as senior debt, senior subordinated debt, subordinated debt or any combination thereof, and the terms of any subordination;
- if the price (expressed as a percentage of the aggregate principal amount thereof) at which such debt securities will be issued is a price other than the principal amount thereof, the portion of the principal amount thereof payable upon declaration of acceleration of the maturity thereof, or if applicable, the portion of the principal amount of such debt securities that is convertible into another security or the method by which any such portion shall be determined;
- the interest rate or rates, which may be fixed or variable, or the method for determining the rate and the date interest will begin to accrue, the dates interest will be payable and the regular record dates for interest payment dates or the method for determining such dates;
- our right, if any, to defer payment of interest and the maximum length of any such deferral period;
- if applicable, the date or dates after which, or the period or periods during which, and the price or prices at which, we may, at our option, redeem the series of debt securities pursuant to any optional or provisional redemption provisions and the terms of those redemption provisions;
- the date or dates, if any, on which, and the price or prices at which we are obligated, pursuant to any mandatory sinking fund or analogous fund provisions or otherwise, to redeem, or at the holder’s option to purchase, the series of debt securities and the currency or currency unit in which the debt securities are payable;
- the denominations in which we will issue the series of debt securities, if other than denominations of \$1,000 and any integral multiple thereof;
- any and all terms, if applicable, relating to any auction or remarketing of the debt securities of that series and any security for our obligations with respect to such debt securities and any other terms which may be advisable in connection with the marketing of debt securities of that series;
- whether the debt securities of the series shall be issued in whole or in part in the form of a global security or securities; the terms and conditions, if any, upon which such global security or securities may be exchanged in whole or in part for other individual securities; and the depository for such global security or securities;
- if applicable, the provisions relating to conversion or exchange of any debt securities of the series and the terms and conditions upon which such debt securities will be so convertible or exchangeable, including the conversion or exchange price, as applicable, or how it will be calculated and may be adjusted, any mandatory or optional (at our option or the holders’ option) conversion or exchange features, the applicable conversion or exchange period and the manner of settlement for any conversion or exchange;
- if other than the full principal amount thereof, the portion of the principal amount of debt securities of the series which shall be payable upon declaration of acceleration of the maturity thereof;
- additions to or changes in the covenants applicable to the particular debt securities being issued, including, among others, the consolidation, merger or sale covenant;

- additions to or changes in the events of default with respect to the securities and any change in the right of the trustee or the holders to declare the principal, premium, if any, and interest, if any, with respect to such securities to be due and payable;
- additions to or changes in or deletions of the provisions relating to covenant defeasance and legal defeasance;
- additions to or changes in the provisions relating to satisfaction and discharge of the indenture;
- additions to or changes in the provisions relating to the modification of the indenture both with and without the consent of holders of debt securities issued under the indenture;
- the currency of payment of debt securities if other than U.S. dollars and the manner of determining the equivalent amount in U.S. dollars;
- whether interest will be payable in cash or additional debt securities at our or the holders' option and the terms and conditions upon which the election may be made;
- the terms and conditions, if any, upon which we will pay amounts in addition to the stated interest, premium, if any and principal amounts of the debt securities of the series to any holder that is not a "United States person" for federal tax purposes;
- any restrictions on transfer, sale or assignment of the debt securities of the series; and
- any other specific terms, preferences, rights or limitations of, or restrictions on, the debt securities, any other additions or changes in the provisions of the indenture, and any terms that may be required by us or advisable under applicable laws or regulations.

Events of Default and Remedies

Unless otherwise described in the applicable prospectus supplement, an event of default with respect to any series of debt securities will be defined in the indenture or applicable supplemental indenture or authorizing resolution as being:

- our failure to pay interest on any debt security of such series when the same becomes due and payable and the continuance of any such failure for a period of 30 days;
- our failure to pay the principal or premium of any debt security of such series when the same becomes due and payable at maturity, upon acceleration, redemption or otherwise;
- our failure or the failure of any restricted subsidiary to comply with any of its agreements or covenants in, or provisions of, the debt securities of such series or the indenture (as they relate thereto) and such failure continues for a period of 60 days after our receipt of notice of the default from the trustee or from the holders of at least 25% in aggregate principal amount of the then outstanding debt securities of that series (except in the case of a default with respect to the provisions of the indenture regarding the consolidation, merger, sale, lease, conveyance or other disposition of all or substantially all of the assets of us (or any other provision specified in the applicable supplemental indenture or authorizing resolution), which will constitute an event of default with notice but without passage of time);
- default under any mortgage, indenture or instrument under which there may be issued or by which there may be secured or evidenced any indebtedness (other than non-recourse indebtedness, as defined in the indenture) for money borrowed by us or any of our restricted subsidiaries (or the payment of which is guaranteed by us or any of our restricted subsidiaries), whether such indebtedness or guarantee now exists or is created after the date we issue debt securities, if that default: (a) is caused by a failure to pay at final stated maturity the principal amount of such indebtedness prior to the expiration of the grace period provided in such indebtedness on the date of such default (a "Payment Default"); or (b) results in the acceleration of such indebtedness prior to its express maturity without such indebtedness having been discharged or such acceleration having been cured, waived, rescinded or annulled for the period and after the notice had been provided, and, in each case, the principal amount of any such indebtedness, together with the principal amount of any other such indebtedness under which there has been a Payment Default or the maturity of which has been so accelerated, aggregates \$50 million or more; or
- certain events of bankruptcy, insolvency or reorganization occur with respect to us or any restricted subsidiary that is a significant subsidiary (as defined in the indenture).

The indenture will provide that the trustee may withhold notice to the holders of any series of debt securities of any default, except a default in payment of principal or interest, if any, with respect to such series of debt securities, if the trustee considers it in the interest of the holders of such series of debt securities to do so.

The indenture will provide that if any event of default has occurred and is continuing with respect to any series of debt securities, the trustee or the holders of not less than 25% in principal amount of such series of debt securities then outstanding may declare the principal of all the debt securities of such series to be due and payable immediately. However, the holders of a majority in principal amount of the debt securities of such series then outstanding by notice to the trustee may waive any existing default and its consequences with respect to such series of debt securities, other than any event of default in payment of principal or interest. Holders of a majority in principal amount of the then outstanding debt securities of any series may rescind an acceleration with respect to such series and its consequences, except an acceleration due to nonpayment of principal or interest on such series, if the rescission would not conflict with any judgment or decree and if all existing events of default with respect to such series have been cured or waived.

The holders of a majority of the outstanding principal amount of the debt securities of any series will have the right to direct the time, method and place of conducting any proceedings for any remedy available to the trustee with respect to such series, subject to limitations specified in the indenture.

Defeasance

The indenture will permit us to terminate all our respective obligations under the indenture as they relate to any particular series of debt securities, other than the obligation to pay interest, if any, on and the principal of the debt securities of such series and certain other obligations, at any time by:

- depositing in trust with the trustee, under an irrevocable trust agreement, money or government obligations in an amount sufficient to pay principal of and interest, if any, on the debt securities of such series to their maturity or redemption; and
- complying with other conditions, including delivery to the trustee of an opinion of counsel to the effect that holders will not recognize income, gain or loss for federal income tax purposes as a result of our exercise of such right and will be subject to federal income tax on the same amount and in the same manner and at the same times as would have been the case otherwise.

The indenture will also permit us to terminate all of our respective obligations under the indenture as they relate to any particular series of debt securities, including the obligations to pay interest, if any, on and the principal of the debt securities of such series and certain other obligations, at any time by:

- depositing in trust with the trustee, under an irrevocable trust agreement, money or government obligations in an amount sufficient to pay principal and interest, if any, on the debt securities of such series to their maturity or redemption; and
- complying with other conditions, including delivery to the trustee of an opinion of counsel to the effect that (A) we have received from, or there has been published by, the Internal Revenue Service a ruling, or (B) since the date such series of debt securities were originally issued, there has been a change in the applicable federal income tax law, in either case to the effect that, and based thereon such opinion of counsel shall state that, holders will not recognize income, gain or loss for federal income tax purposes as a result of our exercise of such right and will be subject to federal income tax on the same amount and in the same manner and at the same times as would have been the case otherwise.

In addition, the indenture will permit us to terminate substantially all our respective obligations under the indenture as they relate to a particular series of debt securities by depositing with the trustee money or government obligations sufficient to pay all principal and interest on such series at its maturity or redemption date if the debt securities of such series will become due and payable at maturity within one year or are to be called for redemption within one year of the deposit.

Transfer and Exchange Rights

A holder will be able to transfer or exchange debt securities only in accordance with the indenture. The registrar may require a holder, among other things, to furnish appropriate endorsements and transfer documents, and to pay any taxes and fees required by law or permitted by the indenture.

Consolidation, Merger or Sale

Unless we provide otherwise in the prospectus supplement applicable to a particular series of debt securities, the indenture will not contain any covenant that restricts our ability to merge or consolidate, or sell, convey, transfer or otherwise dispose of our assets as an entirety or substantially as an entirety. However, any successor to or acquirer of such assets (other than a subsidiary of ours) must assume all of our obligations under the indenture or the debt securities, as appropriate.

Amendment, Supplement and Waiver

Without notice to or the consent of any holder, we and the trustee may amend or supplement the indenture or the debt securities of a series to:

- cure any ambiguity, omission, defect or inconsistency;
- comply with the provisions of the indenture regarding the consolidation, merger, sale, lease, conveyance or other disposition of all or substantially all of our assets;
- provide that specific provisions of the indenture shall not apply to a series of debt securities not previously issued or to make a change to specific provisions of the indenture that only applies to any series of debt securities not previously issued or to additional debt securities of a series not previously issued;
- create a series and establish its terms;
- provide for uncertificated debt securities in addition to or in place of certificated debt securities;
- add a guarantor subsidiary in respect of any series of debt securities;
- secure any series of debt securities;
- comply with requirements of the SEC in order to effect or maintain the qualification of the indenture under the Trust Indenture Act;
- make any change that does not adversely affect the rights of any holder; or
- conform the provisions of the indenture to the final offering document in respect of any series of debt securities.

With the exceptions discussed below, we and the trustee may amend or supplement the indenture or the debt securities of a particular series with the written consent of the holders of at least a majority in principal amount of the debt securities of such series then outstanding. In addition, the holders of a majority in principal amount of the debt securities of such series then outstanding may waive any existing default under, or compliance with, any provision of the debt securities of a particular series or of the indenture relating to a particular series of debt securities, other than any event of default in payment of interest or principal. These consents and waivers may be obtained in connection with a purchase of, or tender offer or exchange offer for, debt securities.

Without the consent of each holder affected, we and the trustee may not:

- reduce the amount of debt securities of such series whose holders must consent to an amendment, supplement or waiver;
- reduce the rate of or extend the time for payment of interest, including defaulted interest;
- reduce the principal of or extend the fixed maturity of any debt security or alter the provisions with respect to redemptions or mandatory offers to repurchase debt securities;
- make any change that adversely affects any right of a holder to convert or exchange any debt security into or for shares of our common shares or other securities, cash or other property in accordance with the terms of such security;
- modify the ranking or priority of the debt securities;
- make any change to any provision of the indenture relating to the waiver of existing defaults, the rights of holders to receive payment of principal and interest on the debt securities, or to the provisions regarding amending or supplementing the indenture or the debt securities of a particular series with the written consent of the holders of such series;
- waive a continuing default or event of default in the payment of principal of or interest on the debt securities; or
- make any debt security payable at a place or in money other than that stated in the debt security, or impair the right of any holder of a debt security to bring suit as permitted by the indenture.

The right of any holder to participate in any consent required or sought pursuant to any provision of the indenture, and our obligation to obtain any such consent otherwise required from such holder, may be subject to the requirement that such holder shall have been the holder of record of debt securities with respect to which such consent is required or sought as of a record date fixed by us in accordance with the indenture.

Governing Law

The laws of the State of New York will govern the indenture and the debt securities.

DESCRIPTION OF WARRANTS

The following description, together with the additional information we may include in any applicable prospectus supplements and free writing prospectuses, summarizes the material terms and provisions of the warrants that we may issue under this prospectus, which may consist of warrants to purchase common shares, preference shares or debt securities and may be issued in one or more series. Warrants may be issued independently or together with common shares, preference shares or debt securities offered by any prospectus supplement, and may be attached to or separate from those securities. While the terms we have summarized below will apply generally to any warrants that we may offer under this prospectus, we will describe the particular terms of any series of warrants that we may offer in more detail in the applicable prospectus supplement and any applicable free writing prospectus. The terms of any warrants offered under a prospectus supplement may differ from the terms described below. However, no prospectus supplement will fundamentally change the terms that are set forth in this prospectus or offer a security that is not registered and described in this prospectus at the time of its effectiveness.

We will file as exhibits to the registration statement of which this prospectus is a part, or will incorporate by reference from reports that we file with the SEC, the form of warrant agreement, if any, including a form of warrant certificate, that describes the terms of the particular series of warrants we are offering before the issuance of the related series of warrants. The following summaries of material provisions of the warrants and the warrant agreements are subject to, and qualified in their entirety by reference to, all the provisions of the warrant agreement and warrant certificate applicable to the particular series of warrants that we may offer under this prospectus. We urge you to read the applicable prospectus supplements related to the particular series of warrants that we may offer under this prospectus, as well as any related free writing prospectuses, and the complete warrant agreements and warrant certificates that contain the terms of the warrants.

General

We will describe in the applicable prospectus supplement the terms relating to a series of warrants being offered, including:

- the offering price and aggregate number of warrants offered;
- the currency for which the warrants may be purchased;
- if applicable, the designation and terms of the securities with which the warrants are issued and the number of warrants issued with each such security or each principal amount of such security;
- if applicable, the date on and after which the warrants and the related securities will be separately transferable;
- in the case of warrants to purchase debt securities, the principal amount of debt securities purchasable upon exercise of one warrant and the price at which, and currency in which, this principal amount of debt securities may be purchased upon such exercise;
- in the case of warrants to purchase common shares or preference shares, the number of common shares or preference shares, as the case may be, purchasable upon the exercise of one warrant and the price at which, and the currency in which, these shares may be purchased upon such exercise;
- the effect of any merger, consolidation, sale or other disposition of our business on the warrant agreements and the warrants;
- the terms of any rights to redeem or call the warrants;
- the terms of any rights to force the exercise of the warrants;
- any provisions for changes to or adjustments in the exercise price or number of securities issuable upon exercise of the warrants;
- the dates on which the right to exercise the warrants will commence and expire;
- the manner in which the warrant agreements and warrants may be modified;
- a discussion of any material or special United States federal income tax consequences of holding or exercising the warrants;
- the terms of the securities issuable upon exercise of the warrants; and
- any other specific terms, preferences, rights or limitations of or restrictions on the warrants.

Before exercising their warrants, holders of warrants will not have any of the rights of holders of the securities purchasable upon such exercise, including:

- in the case of warrants to purchase debt securities, the right to receive payments of principal of, or premium, if any, or interest on, the debt securities purchasable upon exercise or to enforce covenants in the applicable indenture; or
- in the case of warrants to purchase common shares or preference shares, the right to receive dividends, if any, or, payments upon our liquidation, dissolution or winding up or to exercise voting rights, if any.

Exercise of Warrants

Each warrant will entitle the holder to purchase the securities that we specify in the applicable prospectus supplement at the exercise price that we describe in the applicable prospectus supplement. Unless we otherwise specify in the applicable prospectus supplement, holders of the warrants may exercise the warrants at any time up to the specified time on the expiration date that we set forth in the applicable prospectus supplement. After the close of business on the expiration date, unexercised warrants will become void.

Unless we otherwise specify in the applicable prospectus supplement, holders of the warrants may exercise the warrants by delivering the warrant certificate representing the warrants to be exercised together with specified information, and paying the required amount to the warrant agent in immediately available funds, as provided in the applicable prospectus supplement. We will set forth on the reverse side of the warrant certificate and in the applicable prospectus supplement the information that the holder of the warrant will be required to deliver to the warrant agent in connection with the exercise of the warrant.

Upon receipt of the required payment and the warrant certificate properly completed and duly executed at the corporate trust office of the warrant agent or any other office indicated in the applicable prospectus supplement, we will issue and deliver the securities purchasable upon such exercise. If fewer than all of the warrants represented by the warrant certificate are exercised, then we will issue a new warrant certificate for the remaining amount of warrants. If we so indicate in the applicable prospectus supplement, holders of the warrants may surrender securities as all or part of the exercise price for warrants.

Upon any purchase of common shares pursuant to the exercise of a warrant, the holder of such common shares will be subject to the provisions of our amended and restated bye-laws which provide that any U.S. person, other than any excluded person, whose controlled shares would constitute 9.5% or more of the total voting power of our issued share capital, will have their aggregate votes reduced by our board of directors to the extent necessary such that the controlled shares of such U.S. person will constitute less than 9.5% of the voting power of all issued and outstanding shares, all as further described above under "Description of Share Capital—Common Shares."

Governing Law

Unless we provide otherwise in the applicable prospectus supplement, the warrants and warrant agreements will be governed by and construed in accordance with the laws of the State of New York.

DESCRIPTION OF UNITS

We may issue units consisting of any combination of common stock, preferred stock, debt securities or warrants to purchase shares of our common stock, shares of our preferred stock or debt securities offered under this prospectus in one or more series. We may elect to evidence each series of units by unit certificates that we will issue under a separate unit agreement. We may enter into unit agreements with a unit agent. Each unit agent will be a bank or trust company that we select. We will indicate the name and address of the unit agent in the applicable prospectus supplement relating to a particular series of units.

The following description, together with the additional information included in any applicable prospectus supplement, summarizes the general features of the units that we may offer under this prospectus. You should read any prospectus supplement related to the series of units being offered, as well as the complete unit agreements that contain the terms of the units. Specific unit agreements will contain additional important terms, and we will file as an exhibit to the registration statement of which this prospectus is a part, or will incorporate by reference from another report that we file with the SEC, the form of each unit agreement relating to units offered under this prospectus.

If we offer any units, certain terms of that series of units will be described in the applicable prospectus supplement, including, without limitation, the following, as applicable:

- the title of the series of units;
- identification and description of the separate constituent securities comprising the units;
- the price or prices at which the units will be issued;
- the date, if any, on and after which the constituent securities comprising the units will be separately transferable;
- a discussion of certain U.S. federal income tax considerations applicable to the units; and
- any other material terms of the units and their constituent securities.

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 (the report on the consolidated financial statements contains an explanatory paragraph regarding the Company's ability to continue as a going concern), incorporated herein by reference, given on the authority of said firm as experts in auditing and accounting.

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](#) and [June 30, 2020](#) filed with the SEC respectively on [May 13, 2020](#) and [August 13, 2020](#);
- The Company’s Current Reports on Forms 8-K filed with the SEC on [January 7, 2020](#), [February 10, 2020](#), [April 13, 2020](#), and [May 19, 2020](#) (in each case, except for information contained therein which is 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.

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 More Information.” The information on the SEC’s website is not incorporated by reference in this prospectus.