

ATOSSA GENETICS INC
Form DEFA14A
April 16, 2018

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

SCHEDULE 14A

PROXY STATEMENT PURSUANT TO SECTION 14(a) OF THE
SECURITIES EXCHANGE ACT OF 1934

Filed by the Registrant

Filed by a Party other than the Registrant

Check the appropriate box:

Preliminary Proxy Statement
Definitive Proxy Statement
Confidential, for Use of the Commission Only (as permitted by Rule 14a-6(e)(2))
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Soliciting Material Pursuant to sec. 240.14a-11(c) or sec. 240.14a-12

ATOSSA GENETICS INC.
(Name of Registrant as Specified In Its Charter)

N/A
(Name of Person(s) Filing Proxy Statement, if other than the Registrant)

Payment of Filing Fee (Check the appropriate box):

Fee not required.

Fee computed on table below per Exchange Act Rules 14a-6(i)(1) and 0-11.

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(4) Proposed maximum aggregate value of transaction.

(5) Total fee paid.

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Atossa Genetics Requests Shareholders to Vote

SEATTLE (Globe Newswire) – April 16, 2018 -- Atossa Genetics Inc. (NASDAQ: ATOS), a clinical-stage pharmaceutical company developing novel therapeutics and delivery methods for breast cancer and other breast conditions, urges shareholders to vote on two of our most recent proposals that still remain open from our April 12, 2018 annual stockholder meeting. They are:

Proposal No. 4 — Approval of an amendment to Atossa's certificate of incorporation to effect a reverse stock split within a range of 1:3 to 1:15.

Proposal No. 5 — Approval of an amendment to Atossa's certificate of incorporation to increase the number of authorized shares of common stock by 100,000,000 shares.

Each of these proposals must be approved by the affirmative vote of the holders of a majority of the shares of common stock outstanding and entitled to vote on the Record Date which was March 12, 2018.

These proposals were presented at the annual shareholder meeting on April 12, 2018 and, because these proposals have not yet garnered sufficient votes, the polls have remained open to allow additional time for shareholders to exercise their right to vote. Shareholders will reconvene at a meeting now scheduled for April 19, 2018 at 107 Spring Street, Seattle, Washington at 1:00 PM Pacific time.

Note that votes must be cast by that time. Shareholders who have not voted or wish to change their vote are encouraged to vote by internet or telephone by following the proxy voting instructions received by mail.

Shareholders as of the record date may also vote by phone by calling (877) 777-8133. Please join our shareholders by exercising your right to vote!

About Breast Cancer

The American Cancer Society (ACS) estimates that approximately 266,000 women will be diagnosed with breast cancer in the United States this year and that approximately 41,000 will die from the disease. It is the second leading cause of cancer death in American women. Although about 100 times less common than women, breast cancer also affects men. The ACS estimates that the lifetime risk of men getting breast cancer is about 1 in 1,000; 2,550 new cases of invasive breast cancer will be diagnosed; and 480 men will die from breast cancer in 2018.

Similar to women, the treatment for male breast cancer is typically surgery (with or without radiation) and chemotherapy. Breast cancer in men is deadlier than breast cancer in women: men with early-stage breast cancer have a lower five-year survival rate than women and breast cancer in men tends to be detected at a later stage of development than women (Jon M. Greif, DO, FACS, et al., May 2012, *American Society of Breast Surgeons*). Although tamoxifen is the standard of care for women to prevent new and recurrent breast cancer, there is no FDA-approved treatment for male breast cancer.

About Endoxifen

Oral tamoxifen has been widely used for over 40 years to both treat and prevent breast cancer. Tamoxifen, however, has significant drawbacks: First, it can cause side effects including headaches, nausea and early menopausal symptoms as well as rare but serious side effects such as cataracts, strokes and cancer of the uterus. Second, tamoxifen is a “pro-drug,” meaning that it must be processed by the liver in order to produce therapeutic (“active”) metabolites. The metabolite in tamoxifen that accounts for most of its therapeutic activity is called Endoxifen. Unfortunately, up to 50% of breast cancer survivors who are taking tamoxifen do not produce therapeutic levels of Endoxifen (meaning they are “refractory”) for a number of reasons, including that they, due to their genotype, do not have the requisite liver enzymes. Additionally, it can take from 50-200 days for tamoxifen to reach “steady-state” meaning that the drug may be providing little or no benefit for up to several months after starting treatment.

Atossa is developing topical Endoxifen for women with mammographic breast density, or MBD, and for men with gynecomastia or breast cancer. There is no FDA-approved therapeutic for gynecomastia and male breast cancer. We estimate that approximately ten million women in the United States have MBD, for which there is no FDA-approved treatment. Although oral tamoxifen is approved to prevent breast cancer in “high-risk” women, it is used by less than 5% of women with an increased risk of developing breast cancer because of the actual or perceived side effects and risks of tamoxifen. We believe our topical Endoxifen may provide an effective treatment for MBD because, unlike an oral medication, it is applied directly to the breast and penetrates the skin; it does not require metabolism by the liver; and it may produce fewer side effects than tamoxifen. Moreover, our topical Endoxifen may improve mammography accuracy and patient care by unmasking cancerous tumors that are otherwise hidden by breast density, and reduce the risks of over diagnosing potential tumors when more highly sensitive imaging methods are used.

Second, we are developing oral Endoxifen for breast cancer patients who are refractory to tamoxifen. Approximately one million breast cancer patients take tamoxifen to prevent recurrent and new breast cancer; however, up to 50% of those patients are refractory to tamoxifen. We believe our oral Endoxifen may provide an effective treatment supplement or option for these refractory patients because Endoxifen, unlike tamoxifen, does not require liver metabolism.

We recently completed a comprehensive Phase 1 study in 48 healthy women in Australia using both the topical and oral forms of our proprietary Endoxifen. We concluded that all objectives were successfully met in both arms of the study: 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, there were low but measurable Endoxifen levels detected in the blood in a dose-dependent fashion and in the oral arm of the study participants exhibited dose-dependent Endoxifen levels in published reports of the therapeutic range. The median time for patients in the study to reach the steady-state serum levels of Endoxifen while taking daily doses of oral Endoxifen was 7 days. Published literature indicates that it takes approximately 50-200 days for patients to reach steady-state Endoxifen levels when taking daily doses of oral tamoxifen. Finally, the median time for patients in the study to reach the maximum serum level of Endoxifen after taking Atossa's oral Endoxifen ranged from 4 to 8 hours (depending on dose). The 4 mg dose of Endoxifen produced a maximum serum level of Endoxifen in 4 to 8 hours at levels above the generally accepted threshold for a therapeutic effect on estrogen-dependent breast cancer.

In September 2017, we contracted Stockholm South General Hospital in Sweden to conduct a Phase 2 study of our topical Endoxifen. The primary endpoint is MBD reduction, as well as safety and tolerability. We also plan to commence a Phase 2 clinical study using our oral Endoxifen for patients who are refractory to tamoxifen. Our Phase 1 study of topical Endoxifen in men is now underway and we have enrolled the first of three cohorts in that study.

About Atossa Genetics

Atossa Genetics Inc., is a clinical-stage pharmaceutical company developing novel therapeutics and delivery methods to treat breast cancer and other breast conditions. For more information, please visit www.atossagenetics.com.

Forward-Looking Statements

Forward-looking statements in this press release, which Atossa undertakes no obligation to update, are subject to risks and uncertainties that may cause actual results to differ materially from the anticipated or estimated future results, including the risks and uncertainties associated with any variation between preliminary and final clinical results, actions and inactions by the FDA, the outcome or timing of regulatory approvals needed by Atossa, lower than anticipated rate of patient enrollment, preliminary and final results of clinical studies, the safety and efficacy of Atossa's products and services, performance of clinical research organizations and investigators, obstacles resulting from proprietary rights held by others with respect to fulvestrant, such as patent rights, and other risks detailed from time to time in Atossa's filings with the Securities and Exchange Commission, including without limitation its periodic reports on Form 10-K and 10-Q, each as amended and supplemented from time to time.

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