ATOSSA GENETICS INC
Form FWP
May 16, 2018
Filed Pursuant to Rule 433

Issuer Free Writing Prospectus dated May 16, 2018

Relating to Prospectus dated May 10, 2018

Registration Statement No. 333-223949

1 NASDAQ: ATOS WWW . ATOSSAGENETICS . COM ©2018 A TOSSA G ENETICS , I NC . A LL R IGHTS R ESERVED . C ORPORATE P RESENTATION M AY 16, 2018 Filed Pursuant to Rule 433 Issuer Free Writing Prospectus dated May 16, 2018 Relating to Prospectus dated May 10, 2018 Registration Statement No. 333 - 223949

2 Some of the information presented herein may contain projections or other forward - looking statements regarding future events or the future financial performance of the Company which the Company undertakes no obligation to update. These statements are based on management’s current expectations and 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 preliminar y s tudy results varying from final results, estimates of potential markets for drugs under development, clinical trials, actions by t he FDA and other governmental agencies including failure to approve commencement of studies, regulatory clearances, responses to regulatory matters, the market demand for and acceptance of Atossa's products and services, performance of clinical research organizations and other risks detailed from time to time in Atossa's filings with the Securities and Exchange Commission (the “SEC”), including without limitation its most recent annual report on form 10 - K, subsequent quarterly reports on Forms 10 - Q and Forms 8 - K, each as amended and supplemented from time to time . This presentation does not constitute an offer to sell securities including but not limited to within any jurisdiction in which th e s ale of such securities would be unlawful. This presentation does not constitute a solicitation or offer to sell securities. Such o ffer and the information set forth herein have not been reviewed, approved or disapproved, nor has the accuracy or adequacy of the information set forth herein been passed upon, by the SEC or any state securities administrator. Any representation to the co ntr ary is a criminal offense. An investment in the securities offered by the company is speculative and involves a high degree of ri sk. Investment in the securities offered hereby is suitable only for persons of substantial financial means who can afford a tota l l oss of their investment . The Company has filed a Registration Statement and a prospectus with the SEC for the offering for which this presentation rel ate s. Before you invest, you should read the Company’s Registration Statement and the prospectus, and any amendments or supplements thereto and other documents the Company has filed with the SEC for more complete information about the Company and this offering. The Registration Statement and the prospectus, as may be amended or supplemented from time to time, may be accessed through the SEC’s website at www.sec.gov. Alternatively, the Company, any underwriter or any dealer participating in the off eri ng will arrange to send you the prospectus and any amendments or supplements thereto if you request it through Maxim Group LLC, 405 Lexington Ave, New York, NY 10174, Attn: Prospectus Department or by Tel :(800) 724 - 0761. This presentation contains statistics and other data that has been obtained from or compiled from information made available by third parties service providers. The Company has not independently verified such statistics or data. The information presented in this presentatio n i s as of May 16, 2018, unless indicated otherwise. Forward - Looking Statements

Corporate Summary Issuer: Atossa Genetics Inc. (NASDAQ: ATOS) Our Mission: Develop novel pharmaceuticals and delivery systems to treat breast cancer and other breast conditions Debt Mar. 31, 2018: None Cash Mar. 31, 2018: $4.8 million Capital Structure Mar. 31, 2018: 2.65M common shares; no preferred stock 883K warrants exercisable at $3.78 31k warrants exercisable at >$225.00 Corporate Headquarters: Seattle, Washington 5

Steven Quay, MD, PhD Chairman, CEO and President Kyle Guse, CPA, ESQ, MBA CFO and General Counsel Janet R. Rea, MSPH, RAC SVP Regulatory, Quality and Clinical Affairs Seasoned Management 4

Corporate Summary Issuer: Atossa Genetics Inc. (NASDAQ: ATOS) Our Mission: Develop novel pharmaceuticals and delivery systems to treat breast cancer and other breast conditions Debt Mar. 31, 2018: None Cash Mar. 31, 2018: $4.8 million Capital Structure Mar. 31, 2018: 2.65M common shares; no preferred stock 883K warrants exercisable at $3.72 33k warrants exercisable at >$60.00 Corporate Headquarters: Seattle, Washington 5

Drug Programs Using our Proprietary Endoxifen : • Topical Endoxifen Mammographic breast density (MBD) reduction Gynecomastia (male) • Oral Endoxifen - Adjuvant therapy in breast cancer patients Drug Programs 6

Programs Using Proprietary Microcatheter Technology: • Microcatheters for Transpapillary CAR - T Delivery (TRAP CAR - T) - R&D program • Intraductal Microcatheters for Drug Delivery - Phase 2 study underway Drug Delivery Programs 7

Suspicious Lump Biopsy Surgery and Radiation/ Chemotherapy Diagnosis Tamoxifen (5 - 10 years) Intraductal : - Fulvestrant - TRAP CAR - T Oral Endoxifen Neoadjuvant Phase Adjuvant Phase Prevention Window Topical Endoxifen Mammographic Breast Density Breast Cancer Timeline 8

Pivotal Preclinical Phase 1 NDA* Market Drug/Device Program * Estimated FDA or Ex - US submission Phase 2 Phase 3 TRAP CAR - T Microcatheters Ph. 2 Underway Fulvestrant - DCIS and BC R&D 2020 2021 Ph. 2 start in 1H ‘18 MBD Refractory t o Tamoxifen Ph. 2 start in 1H ‘18 Topical Endoxifen Oral Endoxifen 2020 2021 Gynecomastia Ph. 1 Underway Program Pipeline 9

(1) Nat’l Cancer Inst.: Prevalence of Mammographically Dense Breasts in the United States (Retrieved from https ://www.ncbi.nlm.nih.gov/pmc/articles/PMC4200066/) (2) Mayo Clinic (retrieved from: https:// www.mayoclinic.org /diseases - conditions/ gynecomastia /symptoms - causes/syc - 20351793) (3) American Cancer Society, Inc : https://www.cancer.org/content/dam/cancer - org/research/cancer - facts - and - statistics/annual - cancer - facts - and - figures/2018/estimated - number - of - new - cancer - cases - and - deaths - by - sex - us - 2018. pdf . See also Nat’l Cancer Inst.: https:// www.cancer.gov /types/breast/breast - hormone - therapy - fact - sheet (4) Data from Defined Health: SERM Report January 2017 (5) Data from Breastcancer.org (Retrieved from: http:// www.breastcancer.org / diagnosis/tripneg/behavior) Large Market Opportunities 10 Program Opportunity Topical Endoxifen 10M High MBD (BI - RAD C/D) (1) 10M Gynecomastia (25% of all 50 - 69 yrs) (2) Oral Endoxifen 1M ER + Survivors/5 Yrs (3) Intraductal Fulvestrant $800M U.S. sales for pre - surgery and surgery replacement therapy (4) TRAP - CAR - T 35K Triple Negative Breast Cancer/Yr. (5)

Intraductal Microcatheters • Provides alternative to systemic delivery, which can have: - Systemic adverse effects - Limited tumor drug level • ATOS microcatheter technology may: - Increase drug to tumor ratio - Improve efficacy - Reduce toxicity - CAR - T cells may follow lymphatic migration of cancer Topical Endoxifen for MBD • No approved treatment Oral Endoxifen for Refractory • Up to 500k tamoxifen patients have low Endoxifen (1, 2) • Tamoxifen delay (50 - 200 days) (3) Gynecomastia • No approved treatment (1) Patient reluctance toward tamoxifen for breast cancer primary prevention, Ann. Surg Oncol , 2001 Aug 8(7):580 - 5 (2) Breast Care (Basel): Clinical Relevance of CYP2D6 Genetics for Tamoxifen Response in Breast Cancer (Retrieved from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2931018 /) (3) Source: Nat'l Cancer Inst.; retrieved from : https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3357105/ The Unmet Need 11

• Most active metabolite of tamoxifen • Tamoxifen has been widely studied • Tamoxifen is a pro - drug • Up to 50% of patients can’t make enough E ndoxifen (1) Tamoxifen Endoxifen (1) Breast Care (Basel): Clinical Relevance of CYP2D6 Genetics for Tamoxifen Response in Breast Cancer (Retrieved from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2931018 /) Endoxifen - Overview 12

Source: http ://woodtv.com/2015/05/11/are - you - dense - know - your - numbers / MBD Can Mask Tumors 13

Source: http ://slideplayer.com/slide/1557508 / MBD Correlates with Cancer Incidence 14

• Female Phase 1: Completed Q3 2017 • Pharmacokinetics; safety and tolerability • Placebo controlled, double - blinded • 49 female volunteers • Oral (single and repeat dose) and topical (28 - day repeat dose) arms at varying dose levels
Endoxifen – Phase 1 Clinical Trial 15

• Safety : no clinically significant safety signals and no clinically significant adverse events. • Tolerability: tolerated at each dose level through out the study. • Pharmacokinetics : • Topical - crossed the skin barrier when applied daily to the breast, as demonstrated by low but measurable Endoxifen blood levels detected in a dose - dependent fashion. • Oral - demonstrated blood levels that have been associated with a therapeutic effect in the adjuvant setting in women with breast cancer. Endoxifen – Phase 1 Results 16

• Underserved markets in Gynecomastia • Gynecomastia (breast enlargement and pain): – Affects 25% of men ages 50 - 69 (1), approx. 10m men – Causes: androgen deprivation therapy to treat prostate enlargement and prostate cancer; anti - anxiety medications; cancer treatments (chemotherapy), and some heart medications – Treatments: breast bud i rradiation, compression garments and plastic surgery – No FDA - approved therapeutic (1) Mayo Clinic (retrieved from: https:// www.mayoclinic.org /diseases - conditions/ gynecomastia /symptoms - causes/syc - 20351793) Topical Endoxifen for Men 17

Topical Endoxifen Phase 1 Study - Male Cohort Dose Level Number of Participants (mg/breast) (Total mg) (Z) - Endoxifen Placebo 1 1 2 6 2 2 3 6 6 2 3 5 10 6 2 18

Atossa Oral Endoxifen May Solve the “Tamoxifen Delay ” Endoxifen Source Time to Steady State Oral Tamoxifen (daily) Approx. 50 to 200 days (1) Atossa Oral Endoxifen (daily) 7 days (1) https ://www.ncbi.nlm.nih.gov/pmc/articles/PMC3357105/ Oral Endoxifen – Potentially Faster Therapy 19

Single Dose Pharmacokinetics Time, hours Potential Therapeutic Level Time to maximum Endoxifen level is less than 8 hours Pharmacokinetics Summary – Oral Study 20

Oral Tamoxifen Yields Much Slower Blood Levels of Endoxifen 50 to >200 days to reach endoxifen steady - state levels Reference: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3357105/ The difference is metabolizer status Oral Tamoxifen Pharmacokinetics 21

29 Days +29 Days This is 25 th percentile on breast cancer growth rate in women 50 - 59, as measured by mammography (1) (1) https://breast - cancer - research.biomedcentral.com/articles/10.1186/bcr2092 Oral Endoxifen Oral Tamoxifen Endoxifen / Tamoxifen – Treatment Timeline 22

Entry Criteria: ER + breast cancer patients on tamoxifen Measure Endoxifen Levels >35 nM Endoxifen Continue on tamoxifen ≤35 nM Endoxifen Add Oral Endoxifen (4 mg/day) Oral Endoxifen – Refractory Clinical Trial 23

Program could qualify for designation under the 505(b)(2) status. Advantages: • A single clinical study of safety and efficacy • Limited additional clinical or pre - clinical studies • Multi - year market exclusivity possible Endoxifen Regulatory Pathway 24

• Potential advantages - higher local drug/CAR - T exposure; lower systemic concentrations (lower toxicity) vs systemically delivered agents; potential for lymphatic migration of T - cells • Recent Activity - Kite Pharma acquisition by Gilead; Juno acquired by Celgene ; FDA approved Novartis's Kymriah ™ for B - cell Acute Lymphoblastic Leukemia • Phase 2 study - fulvestrant for DCIS or breast cancer (Montefiore) • Fulvestrant - FDA approved (AstraZeneca); opportunities with other drugs and immunotherapies Intraductal Microcatheters 25

Thirty women with ER + DCIS or Invasive Breast Cancer 6 24 Drug Administered 30 - 45 days B efore S urgery Assessments Efficacy Safety Pharmacokinetic Pathological Response: Bio - Marker Expression FACT - ES: Side Effects Tissue and Blood Levels of Fulvestrant Intramuscular Administration Intraductal Administration Microcatheter Fulvestrant - Clinical Trial Study 26

Local Delivery of CAR - T for Breast Cancer • Safety : Reduced risk of systemic complications • Efficacy : Delivery of CAR - T cells to the site of the cancer cells. Greater CAR - T to cancer cell ratio. • Dose : Fewer cells would be required • Reduced cost • Increased access (due to production, cost) • Indication : Disease localized to the breast 27

Source: NIH Step 1 : Remove blood and genetically modify T - cells to kill cancer Step 2 : Atossa’s Transpapillary (TRAP) microcatheters deliver CAR modified T - cells to breast ducts containing cancer cells Microcatheters – TRAP CAR - T 28

TRAP CAR - T - Seeking partners Topical Endoxifen : (1) 2Q 2018 – Open Phase 2 study for MBD (Sweden) (2) 2Q 2018 – Complete enrollment in Phase 1 study in men Oral Endoxifen : 2Q 2018 – Open Phase 2 study in patients refractory to Tamoxifen Upcoming Milestones 29

30 NASDAQ: ATOS WWW . ATOSSAGENETICS . COM ©2018, A TOSSA G ENETICS I NC . A LL R IGHTS R ESERVED . F OR M ORE I NFORMATION : K YLE G USE , CFO AND G ENERAL C OUNSEL KYLE . GUSE @ ATOSSAGENETICS . COM