

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

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): February 21, 2018

Atossa Genetics Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation)

001-35610

(Commission File Number)

26-4753208

(I.R.S. Employer
Identification No.)

107 Spring Street
Seattle, Washington

(Address of principal executive offices)

98104

(Zip Code)

Registrant's telephone number, including area code: (206) 325-6086

Not Applicable

Former name or former address, if changed since last report

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 7.01. Regulation FD Disclosure

On February 21, 2018, Atossa Genetics Inc. (the “Company”) updated its corporate slide presentation, a copy of which is attached as Exhibits 99.1 to this current report on Form 8-K, and which is incorporated herein by reference.

* * *

The Company is furnishing the information in this Current Report on Form 8-K to comply with Regulation FD. Such information shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference into any of the Company’s filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof and regardless of any general incorporation language in such filings, except to the extent expressly set forth by specific reference in such a filing.

“Safe harbor” statement under the Private Securities Litigation Reform Act of 1995: 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 preliminary study results varying from final results, estimates of potential markets for drugs under development, clinical trials, actions by the FDA and other governmental agencies, regulatory clearances, responses to regulatory matters, the market demand for and acceptance of the Company’s products and services, performance of clinical research organizations and other risks detailed from time to time in the Company’s filings with the Securities and Exchange Commission, 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.

Item 8.01 Other Events.

See item 7.01 above which is incorporated into this Item 8.01 by this reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Corporate Slide Presentation, dated February 21, 2018

* * *

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: February 21, 2018

Atossa Genetics Inc.

By: /s/ Kyle Guse

Kyle Guse

Chief Financial Officer, General Counsel and
Secretary

Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
<u>99.1</u>	<u>Corporate Slide Presentation, dated February 21, 2018</u>



FEBRUARY 21, 2018

NASDAQ: ATOS

WWW.ATOSSAGENETICS.COM



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 preliminary study results varying from final results, estimates of potential markets for drugs under development, clinical trials, actions by the FDA and other governmental agencies, 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.



- Clinical-stage company
- Novel pharmaceuticals
- Novel drug delivery methods
- Breast cancer & other breast conditions





Drug Programs Using our Proprietary Endoxifen:

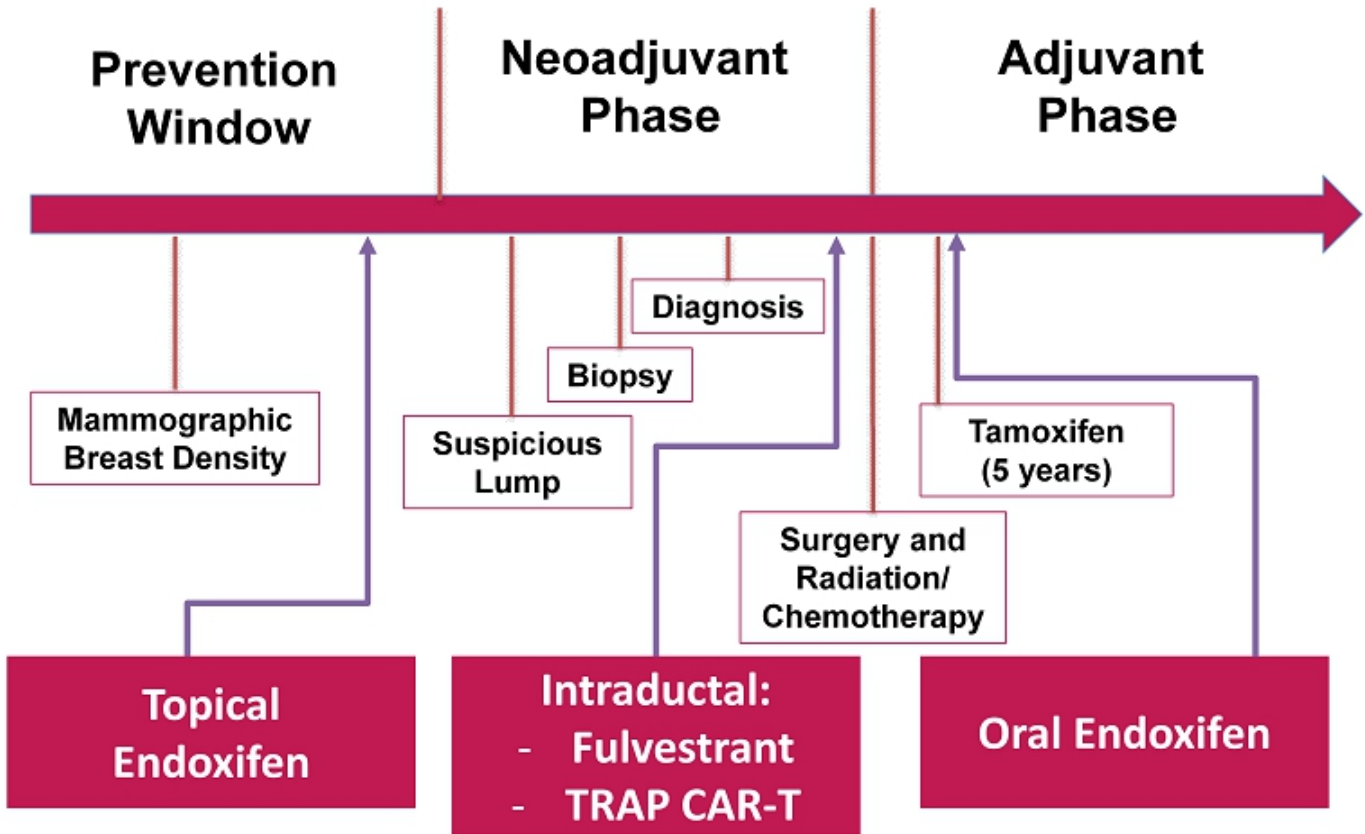
- **Topical Endoxifen**
 - ✧ For mammographic breast density (MBD) reduction
 - ✧ **All** Phase 1 objectives met
 - ✧ 1H 2018: Phase 2 study for MBD in Sweden
- **Oral Endoxifen**
 - ✧ For “tamoxifen-refractory” patients
 - ✧ **All** Phase 1 objectives met
 - ✧ 1H 2018: Phase 2 for tamoxifen-refractory patients



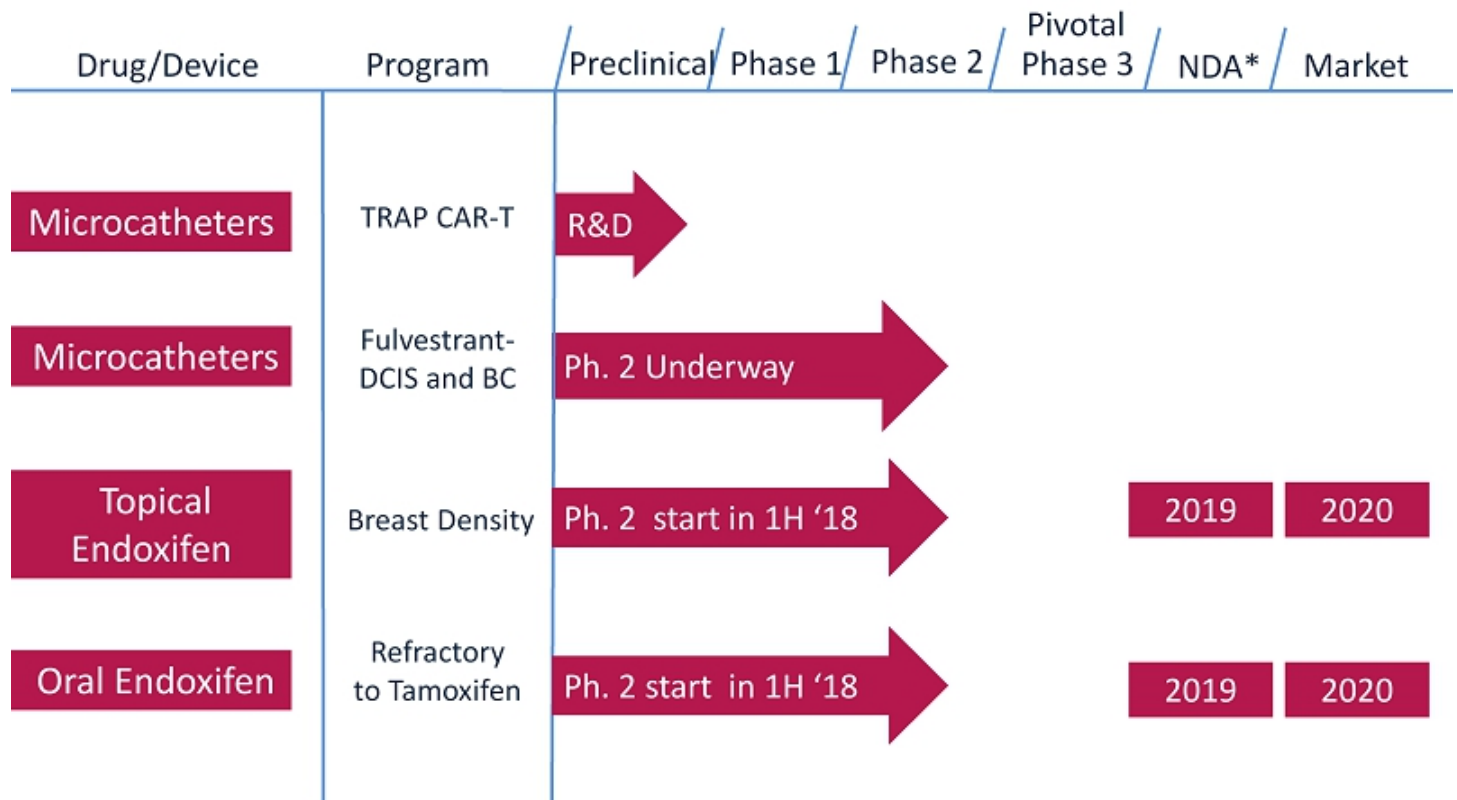
Two Programs Using Proprietary Microcatheter Technology:

- **Microcatheters for Transpapillary CAR-T Delivery (TRAP CAR-T)** – In R&D phase with goals of reducing toxicity, improving efficacy and the potential of T-cells migrating along the lymphatic pathway
- **Intraductal Microcatheters for Drug Delivery**
Enrollment underway in Phase 2 study for delivery of fulvestrant for treatment of ductal carcinoma in-situ (DCIS) and breast cancer

Breast Cancer Timeline



Program Pipeline



* Estimated FDA or Ex-US submission



The Need: Breast Cancer Statistics

- 250,000 cancers and 60,000 DCIS in U.S. in 2017^(1, 2)
- 40,000 deaths in U.S. in 2017⁽¹⁾
- 15% of BC are triple negative; 3x deadlier in 5 years⁽³⁾

Endoxifen: \$1B U.S. market

For treatment and chemoprevention of breast cancer⁽⁴⁾

Intraductal Fulvestrant: \$800M U.S. market

in DCIS pre-surgery and replacement to surgery⁽⁴⁾

TRAP CAR-T: TBD U.S. Market

Triple neg. – 37k patients/yr.; can't use hormone therapy⁽³⁾

- (1) American Cancer Society, Inc: Data reported by North American Association of Central Cancer Registries (NAACCR)
(2) Data from Breastcancer.org (Retrieved from: <http://www.breastcancer.org/symptoms/types/dcis>)
(3) Data from Breastcancer.org (Retrieved from: <http://www.breastcancer.org/diagnosis/tripneg/behavior>)
(4) Data from Defined Health: SERM Report January 2017



Topical Endoxifen for Density

- No FDA approved treatment
- 10 million women⁽¹⁾
- Tamoxifen use minimal

Oral Endoxifen for Refractory

- Up to 500,000 tamoxifen patients under-treated (too-little Endoxifen)^(2, 3)
- Raising Endoxifen levels may reduce risk of recurrent or new lesions

Intraductal Microcatheters

- Provides alternative to Systemic delivery, which has:
 - 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

(1) National Cancer Inst.: Prevalence of Mammographically Dense Breasts in the United States (Retrieved from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC420066/>)

(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) Cancer.net: Hormonal Therapy for Early-Stage Hormone Receptor-Positive Breast Cancer (Retrieved from: <https://www.cancer.net/research-and-advocacy/asco-care-and-treatment-recommendations-patients/hormonal-therapy-early-stage-hormone-receptor-positive-breast-cancer>)

Endoxifen – Rationale for Development



- Develop TWO formulations for two large unmet medical needs:
 - Topical to reduce density: less than 5% of patients at increased risk of breast cancer will take oral tamoxifen because of actual or perceived side effects⁽¹⁾
 - Oral: up to 50% of patients taking tamoxifen are refractory⁽²⁾
 - Tamoxifen Treatment Delay: it takes 50-200 days for tamoxifen to have treatment effect



- Extensive existing data on Tamoxifen

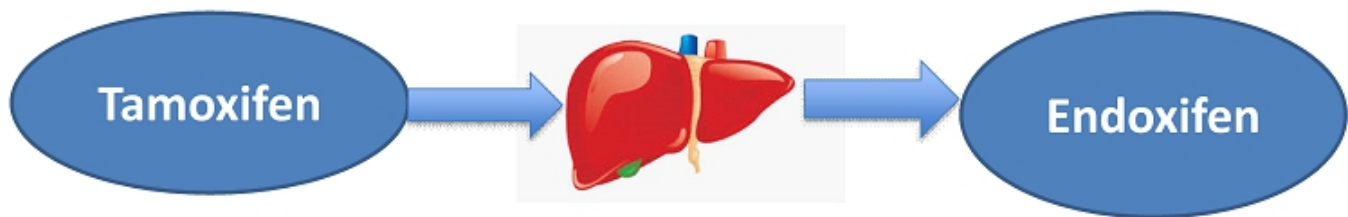
(1) Patient reluctance toward tamoxifen for breast cancer primary prevention, *Ann. Surg. Oncol.*, 2001 Aug 8(7):580-5
(2) Data from Defined Health: SERM Report January 2017



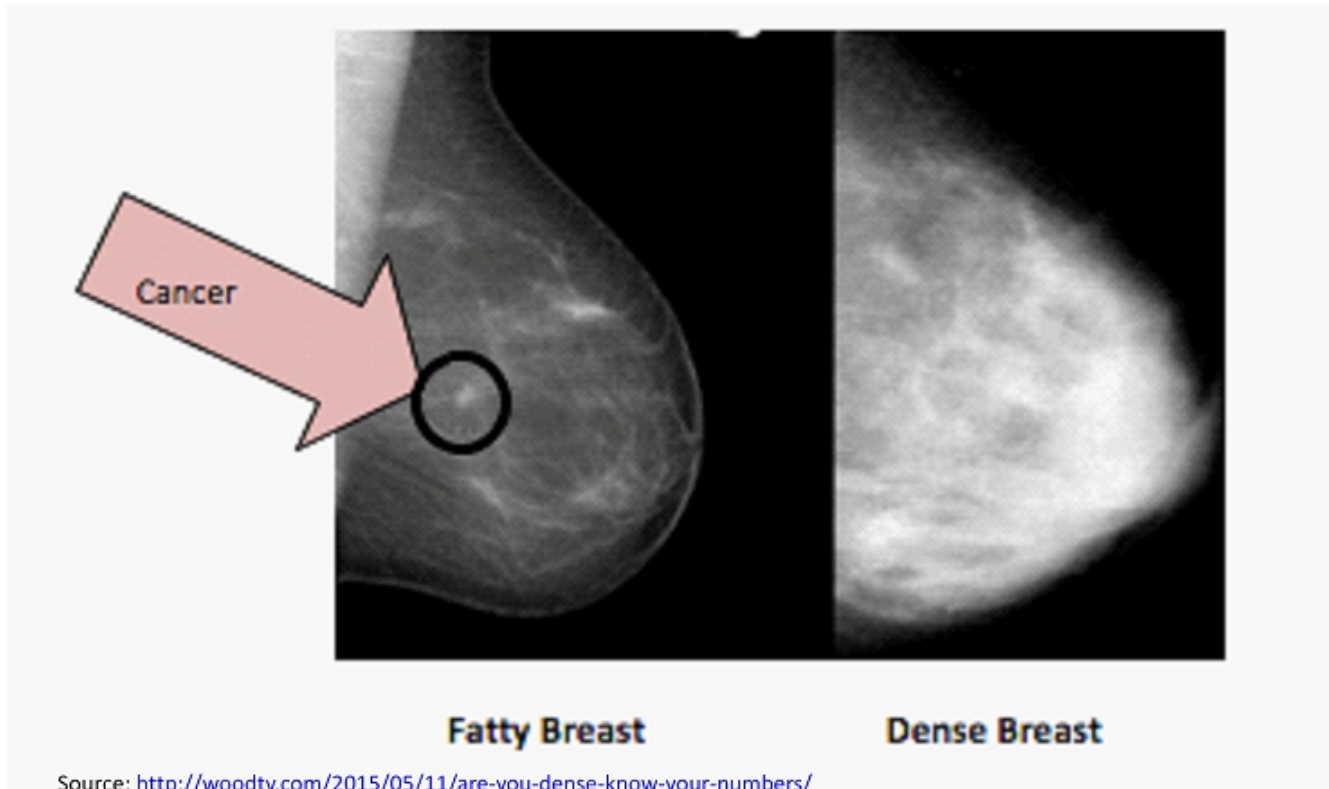
- Low levels of circulating Endoxifen during tamoxifen adjuvant therapy correlate to an increased risk of recurrent or new breast cancers
- Identified as an independent risk factor
- Known and unknown causes for low endoxifen levels during tamoxifen therapy
- Most active tamoxifen metabolite
- It may save more lives



- Most active metabolite of tamoxifen
- Tamoxifen has been widely studied
- Tamoxifen is a pro-drug
- Up to 50% of patients can't make enough Endoxifen⁽¹⁾

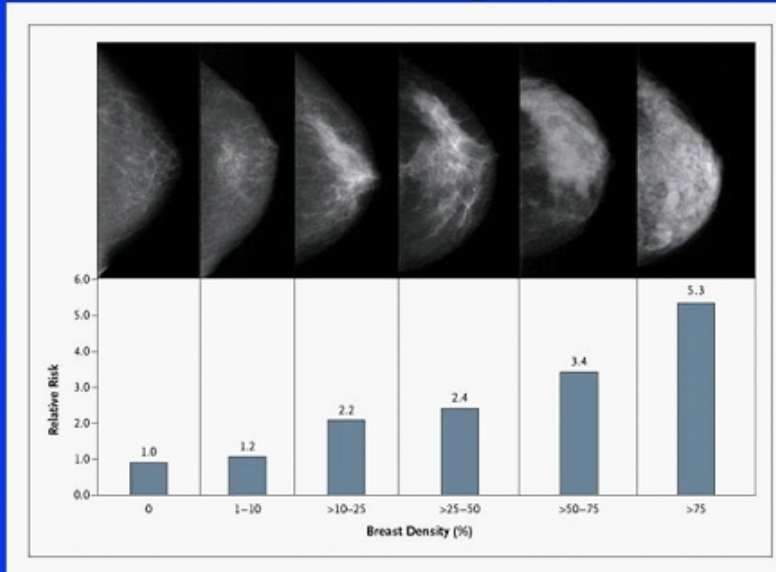


(1) Breast Care (Basel): Clinical Relevance of CYP2D6 Genetics for Tamoxifen Response in Breast Cancer (Retrieved from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2931018/>)





A Newly Recognized Breast Cancer Risk Factor: Mammographic Density



Several states have now mandated reporting of high breast density as seen on mammograms to both patient and primary care provider



- Study started in Q2 2017 in Australia; completed Q3 2017
- Pharmacokinetics; safety and tolerability
- Placebo controlled, double-blinded
- 48 female volunteers
- Oral and topical arms at varying dose levels
- Single, 28 day repeat dose





All objectives in both topical and oral arms successfully met:

- **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.

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/>



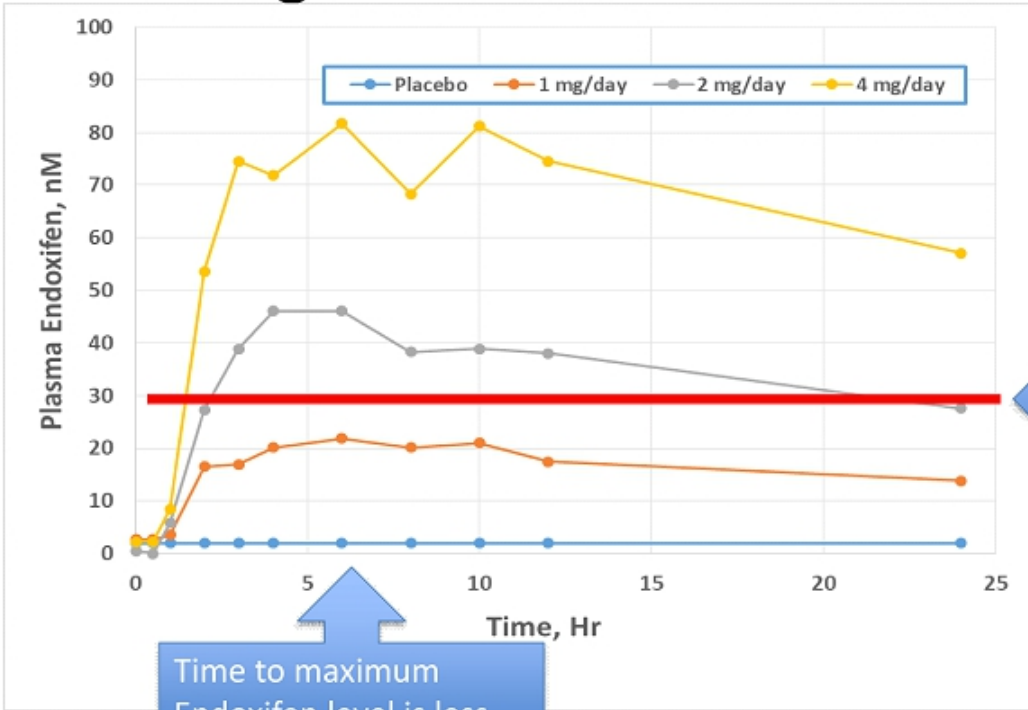
Oral Endoxifen may solve the “Tamoxifen Delay”

- Low Endoxifen levels in breast cancer patients who take oral tamoxifen correlate with an increased risk of developing new tumors or recurrence
- Steady-state of Endoxifen in the serum as a metabolite from daily oral tamoxifen occurs approx. 50 to 200 days from the initiation of dosing (depending on the metabolism capabilities of the patient’s liver)
- Steady-state of Endoxifen in the serum derived from Atossa’s oral Endoxifen occurs in seven days

Atossa Oral Endoxifen may provide Endoxifen levels weeks or months earlier than Tamoxifen



Single Dose Pharmacokinetics

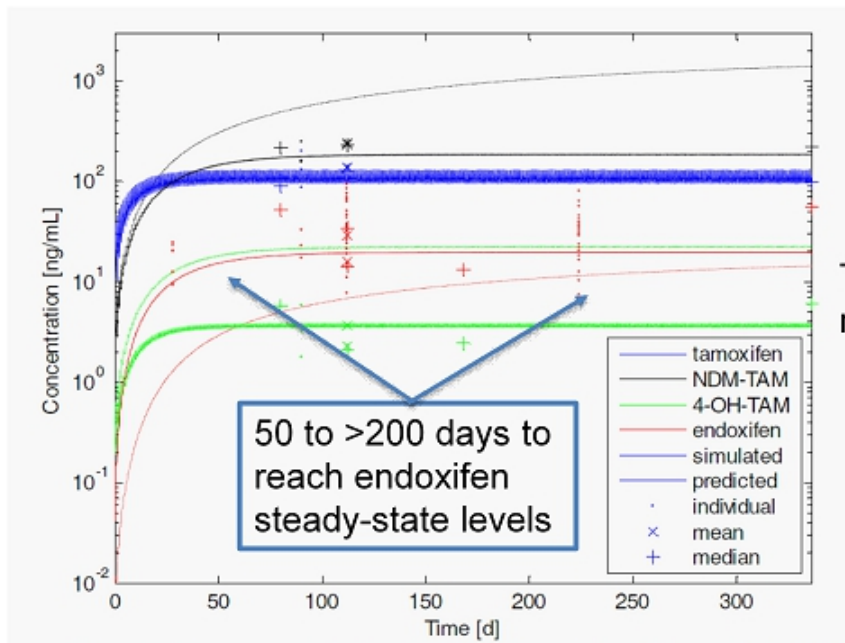


Time to maximum Endoxifen level is less than 8 hours

Potential Therapeutic Level



Oral Tamoxifen Yields Much Slower Blood Levels of Endoxifen



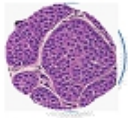
The difference is metabolizer status

Reference: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3357105/>

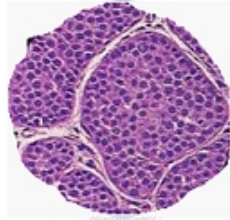
Endoxifen/Tamoxifen – Treatment Timeline



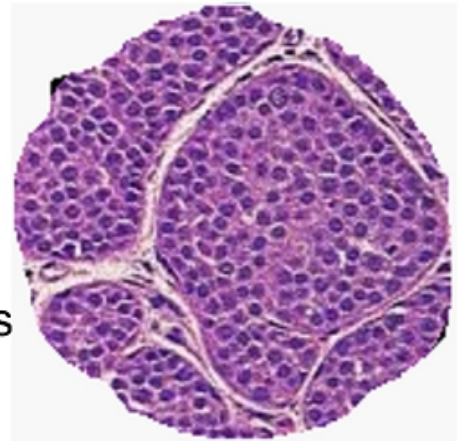
This is 25th percentile on breast cancer growth rate in women 50-59, as measured by mammography⁽¹⁾



29 Days



+29 Days



Oral Endoxifen

Oral Tamoxifen



(1) <https://breast-cancer-research.biomedcentral.com/articles/10.1186/bcr2092>

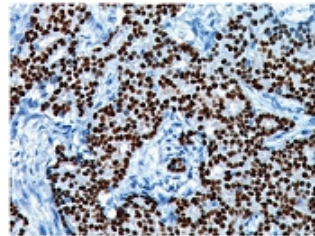
Oral Endoxifen – Refractory Clinical Trial



Entry Criteria:
Pre-menopausal ER⁺
breast cancer
patients on
tamoxifen



**Measure
Endoxifen Levels**



**>TBD nM
Endoxifen
Continue on
tamoxifen
(20 mg/day)**

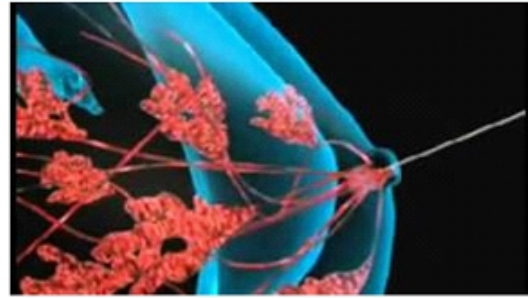
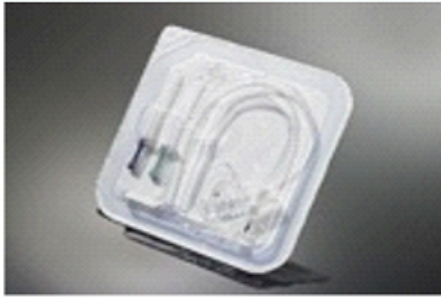


**≤TBD nM
Endoxifen
Add Oral Endoxifen
(2 or 4 mg/day)**

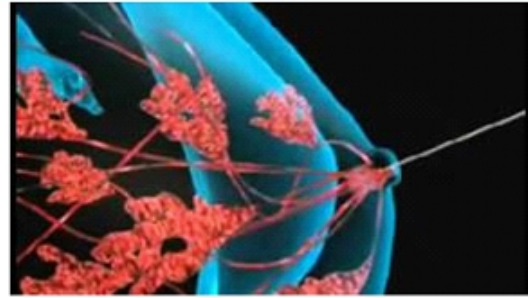
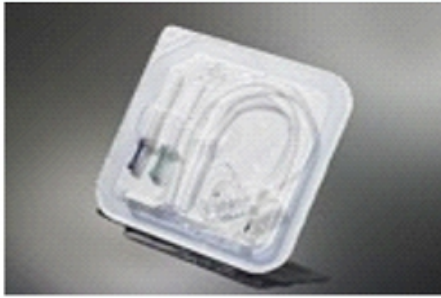


Program could qualify for designation under the 505(b)(2) status. Advantages:

- A single clinical study of safety and efficacy
- Limited additional clinical or pre-clinical studies
- Multi-year market exclusivity possible



- Potential advantages: higher local drug/CAR-T exposure; lower systemic concentrations (lower toxicity) vs systemically delivered agents; potential for lymphatic migration of T-cells
- 1 issued and 3 pending patent app's (US and PCT) for intraductal delivery of drugs and CAR-T
- Kite Pharma acquisition by Gilead; Juno acquired by Celgene; FDA approved Novartis's Kymriah™ for B-cell Acute Lymphoblastic Leukemia



- Phase 2 study for delivery of fulvestrant in patients with DCIS or breast cancer (initiated at Columbia; transferred to Montefiore)
- Advantages: potentially higher local drug exposure and lower systemic concentrations vs systemically delivered agents
- Fulvestrant is FDA approved for intramuscular administration (AstraZeneca); opportunities with other drugs and biotherapeutics

Microcatheter Fulvestrant - Clinical Trial Study



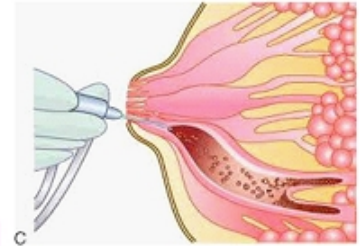
Thirty women with ER⁺ DCIS
or Invasive Breast Cancer



Intramuscular
Administration

6

24



Intraductal
Administration

Drug Administered
30-45 days Before Surgery

Assessments

Efficacy

Safety

Pharmacokinetic

Pathological
Response: Bio-
Marker Expression

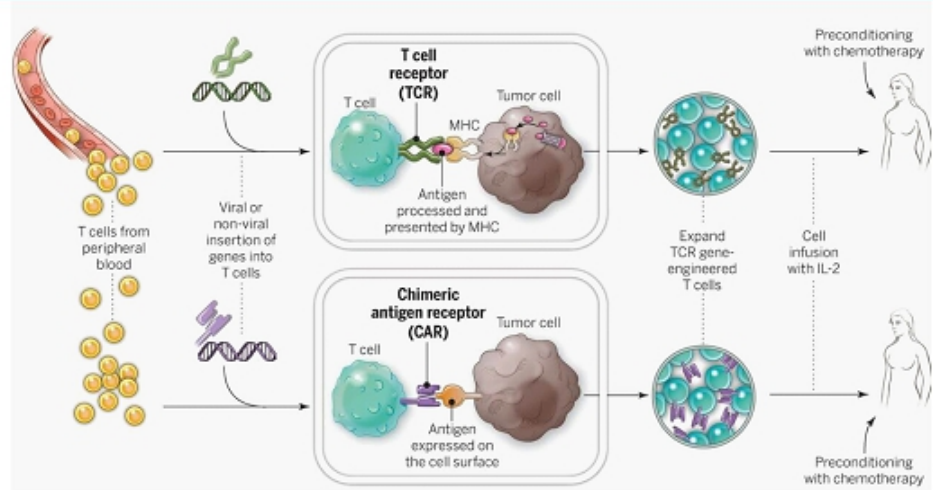
FACT-ES:
Side Effects

Tissue and Blood
Levels of
Fulvestrant

Microcatheters – TRAP CAR-T

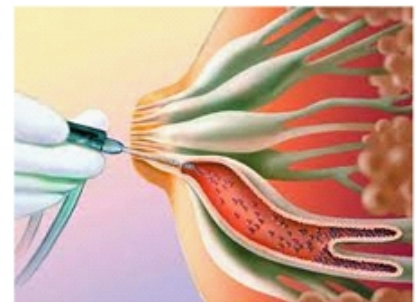


Step 1: Remove blood and genetically modify T-cells to kill cancer



Source: NIH

Step 2: Atossa's Transpapillary (TRAP) microcatheters deliver CAR modified T-cells to breast ducts containing cancer cells



Upcoming Milestones



Oral Endoxifen: 1H 2018 - Phase 2 study in patients refractory to Tamoxifen (AUS)



Topical Endoxifen: 1H 2018 - Phase 2 study for MBD with Karolinska Institute Investigator (Sweden)



TRAP CAR-T - Seeking partners



Seasoned Management



Steven Quay, MD, PhD
*Chairman, CEO and
President*



Kyle Guse, CPA, ESQ, MBA
CFO and General Counsel



Janet R. Rea, MSPH, RAC
*Sr. VP Regulatory,
Quality and Clinical Affairs*



Atossa Genetics Inc.	NASDAQ: ATOS
Our Mission	Develop novel pharmaceuticals and delivery systems to treat breast cancer and other breast conditions
Long-Term Debt ⁽¹⁾ (Sept. 30, 2017)	None
Cash (pro forma Sept. 30, 2017 incl. Oct. offering)	\$7.8m
Capital Structure (Dec. 20, 2017)	26.5M common shares; no preferred stock 10.6M warrants exercisable at \$.31 400k warrants exercisable at >\$5
Corporate Headquarters	Seattle, Washington



Atossa
G E N E T I C S

FOR MORE INFORMATION:

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NASDAQ: ATOS

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