

U.S. 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): July 27, 2016

Atossa Genetics Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or jurisdiction of incorporation or organization)

001-35610

(Commission File Number)

26-4753208

(I.R.S. Employer Identification Number)

2300 Eastlake Ave. East, Suite 200, Seattle, WA 98102

(Address of principal executive offices (Zip Code))

Registrant's telephone number: (206) 325-6086

N/A

(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 (see General Instruction A.2. below):

- 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 (17CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17CFR 240.13e-4(c))
-

Item 8.01 Other Events.

A copy of the corporate presentation of Atossa Genetics Inc. provided to investors on July 27, 2016 is attached to this Current Report on Form 8-K as Exhibit 99.1 and incorporated into this Item 8.01 by this reference. The corporate presentation was previously posted to the Company's web site in compliance with Regulation FD.

This Current Report on Form 8-K contains "forward-looking" statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, including statements related to the potential future sale of shares of the Company's common stock and price for such sales under the Purchase Agreement. The words "may," "will," "could," "would," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue," "ongoing" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. While the Company believes its plans, intentions and expectations reflected in those forward-looking statements are reasonable, these plans, intentions or expectations may not be achieved. The Company's actual results, performance or achievements could differ materially from those contemplated, expressed or implied by the forward-looking statements. For information about the factors that could cause such differences, please refer to the Company's Annual Report on Form 10-K for the year ended December 31, 2015, including the information discussed under the captions "Item 1 Business," "Item 1A. Risk Factors" and "Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations," as well as the Company's various other filings with the SEC including reports on Forms 10-Q and 8-K. Given these uncertainties, you should not place undue reliance on these forward-looking statements. The Company assumes no obligation to update any forward-looking statement.



Atossa
G E N E T I C S

CORPORATE PRESENTATION

JULY 27, 2016

NASDAQ: ATOS

WWW.ATOSSAGENETICS.COM

Forward-Looking Statements



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 clinical trials, actions by the FDA, 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, 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.



Atossa Genetics is a healthcare company focused on developing novel pharmaceuticals and delivery methods to treat breast conditions including breast cancer.

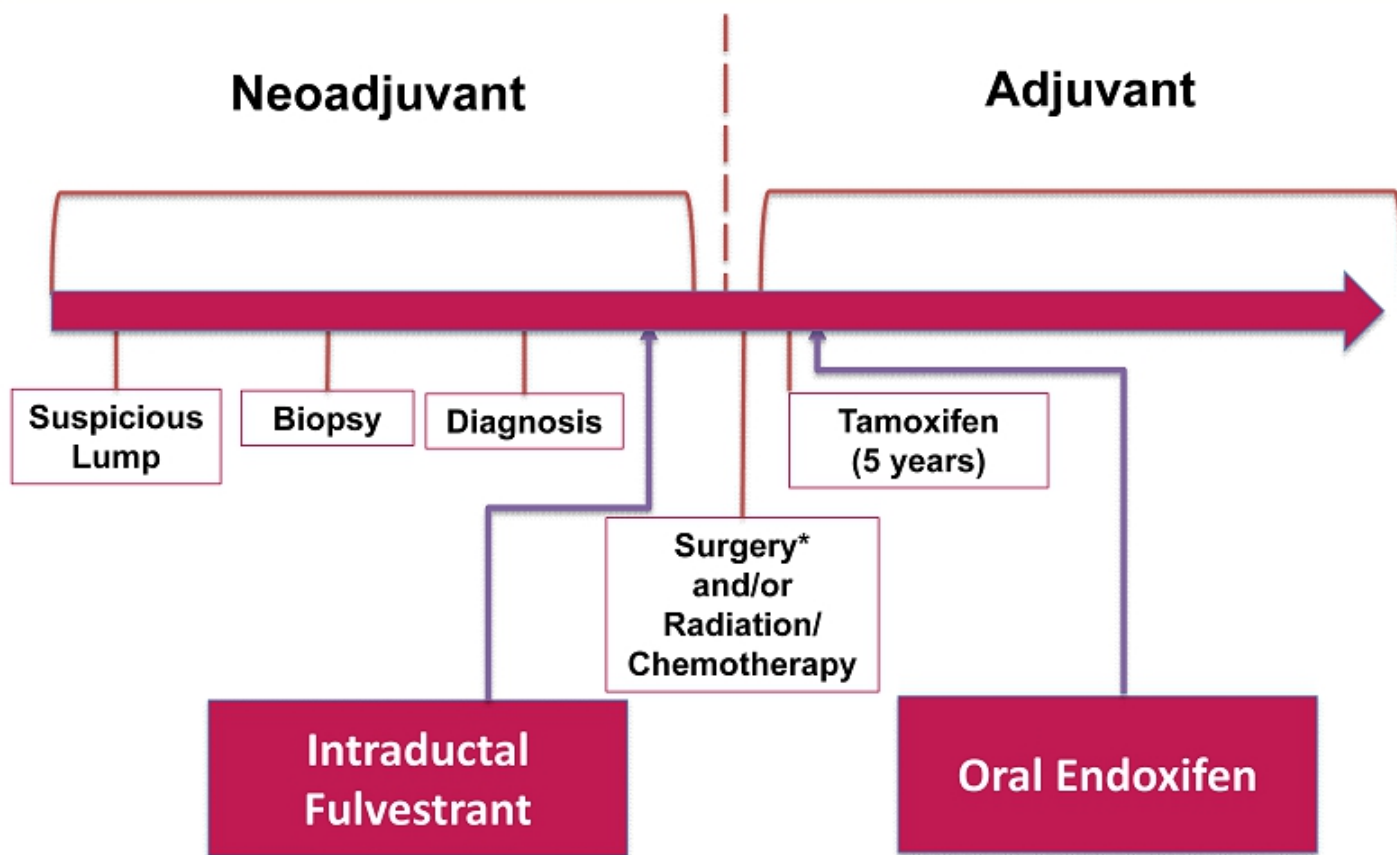




Drug Development and Delivery Programs

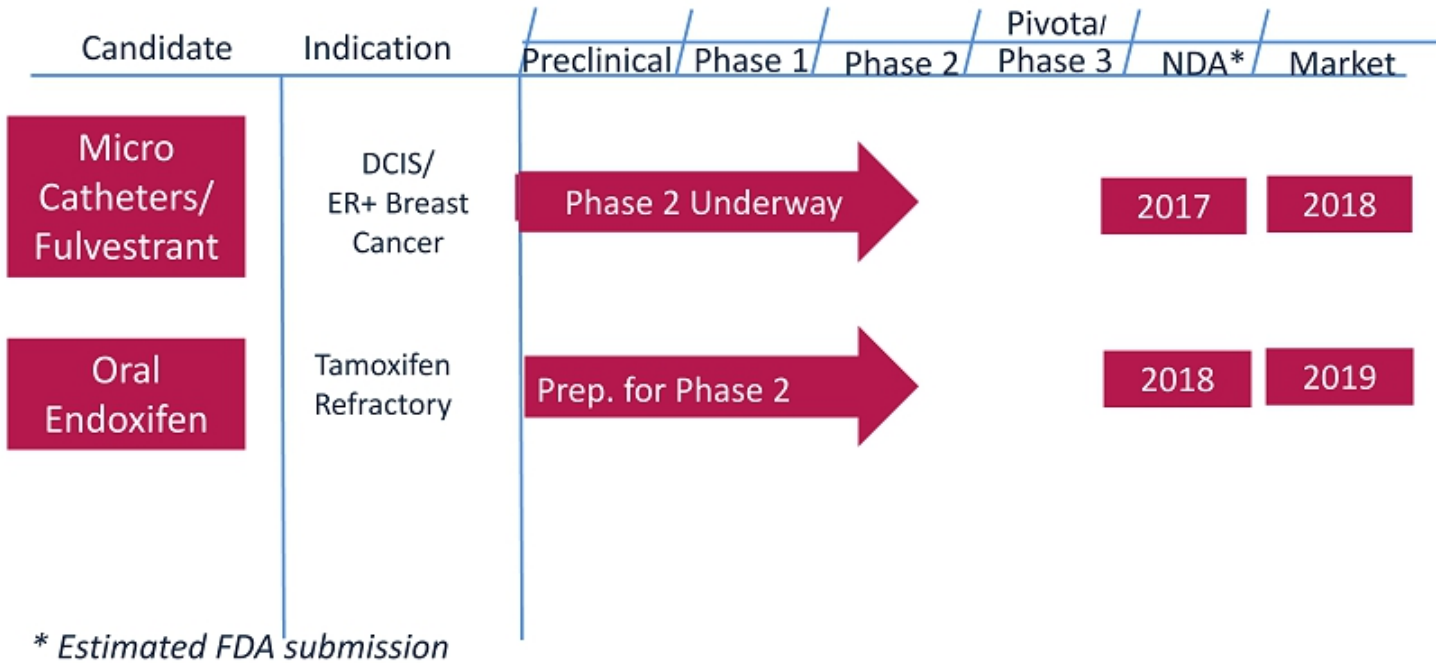
- ✧ **Intraductal Microcatheters** – Ongoing Phase 2 study at Columbia University to deliver fulvestrant for neoadjuvant treatment of ductal carcinoma in-situ (DCIS) and estrogen receptor positive (ER+) breast cancer
- ✧ **Oral Endoxifen** – Preparing for Phase 2 – adjuvant therapy for breast cancer patients who are refractory to tamoxifen

Breast Cancer Timeline



*Mastectomy or lumpectomy

Program Pipeline





Neoadjuvant Intruductal Fulvestrant

Current therapies: use systemic delivery, which can have adverse effects and potentially limited tumor tissue concentration

U.S. annual incidence: 235,000 breast cancers and 60,000 DCIS

Potential market: intramuscular Fulvestrant is \$14,000 per dose; \$700M expanding market

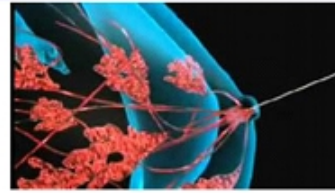
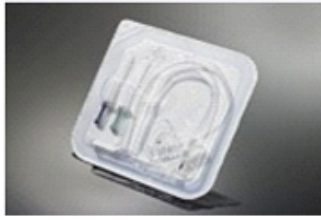
Adjuvant Oral Endoxifen

1 million women take tamoxifen in the U.S. annually

50% of patients taking tamoxifen may be refractory – meaning they make inadequate Endoxifen and have an increased rate of recurrence

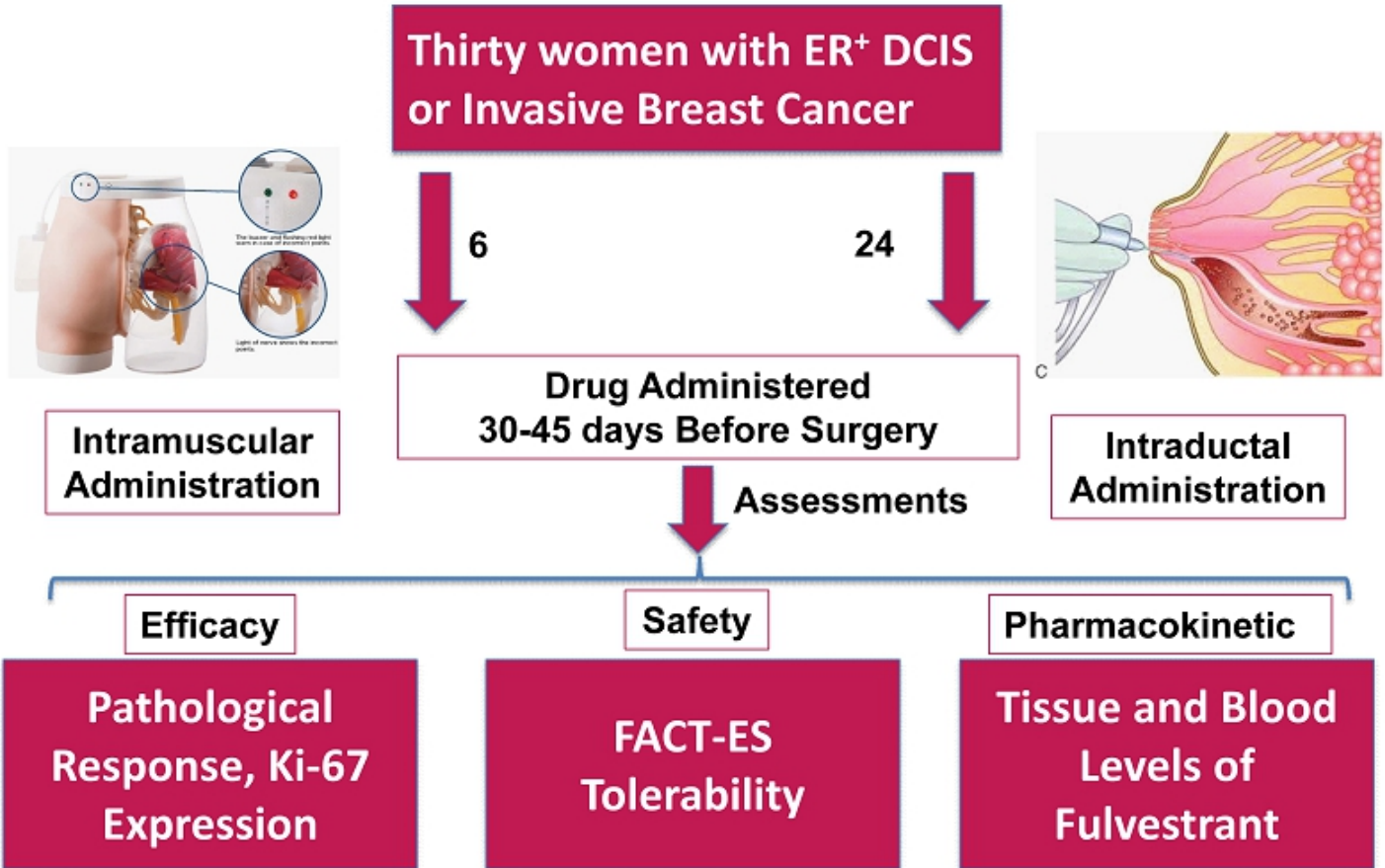
Potential market: >\$2.0 billion

Neoadjuvant: Intraductal Microcatheters



- Being developed for transpapillary, local delivery of therapeutics
- Ongoing Phase 2 study at Columbia University for delivery of fulvestrant in patients with DCIS or ER+ breast cancer
- Advantages: paradigm shift towards local treatment with potentially higher local drug exposure and lower systemic concentrations vs systemically delivered agents
- 1 issued and 3 pending patent app's (US and PCT) for intraductal drug delivery
- Fulvestrant is FDA approved for intramuscular admin (AstraZeneca)

Intraductal Fulvestrant - Clinical Trial Study Design





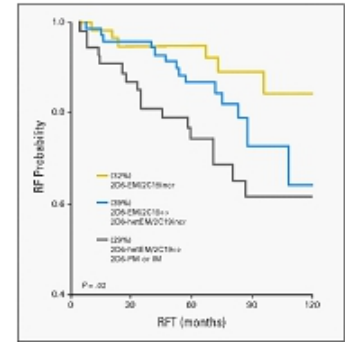
The FDA issued a “Safe to Proceed” letter in Q4 2015

A combination drug/device could qualify for designation under the 505(b)(2) status. Advantages:

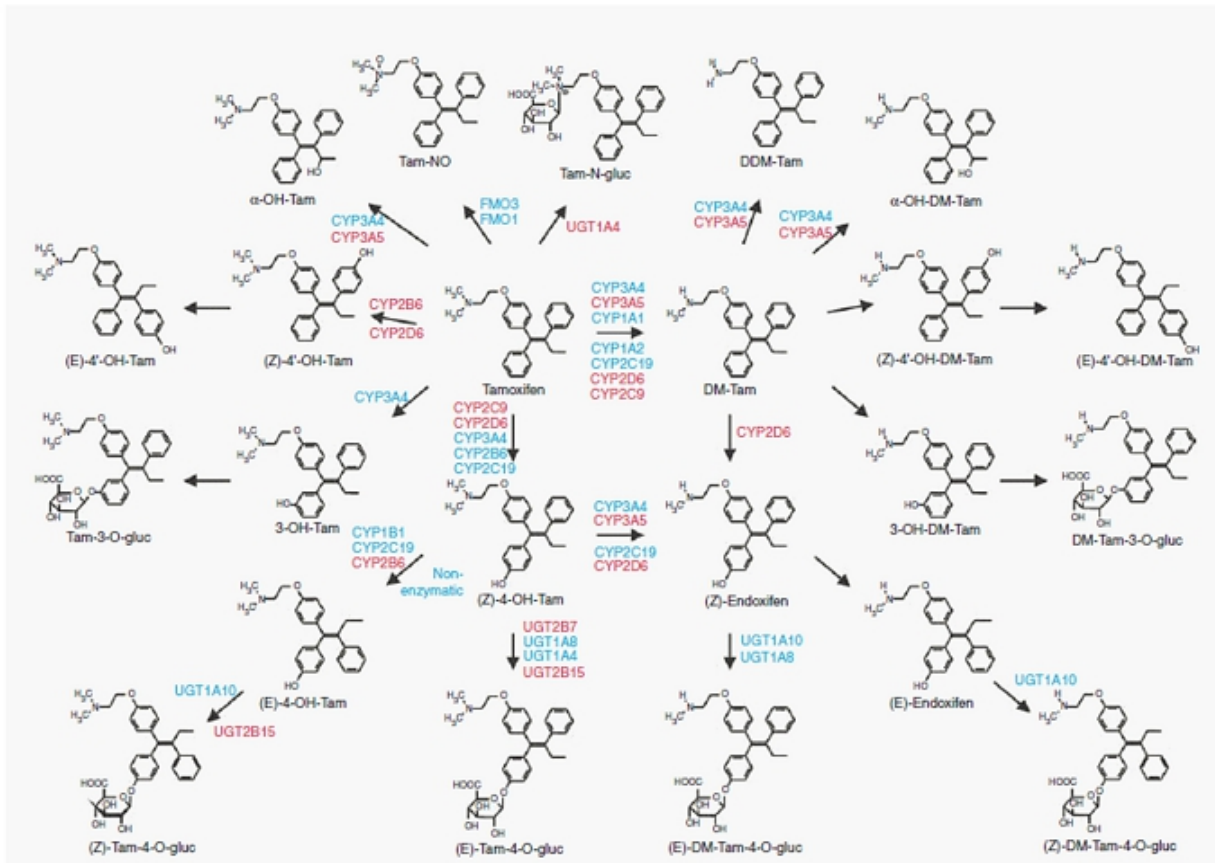
- ✧ A single clinical study of safety and efficacy
- ✧ Limited additional clinical or pre-clinical studies
- ✧ Market exclusivity possible

Adjuvant Solution: Oral Endoxifen

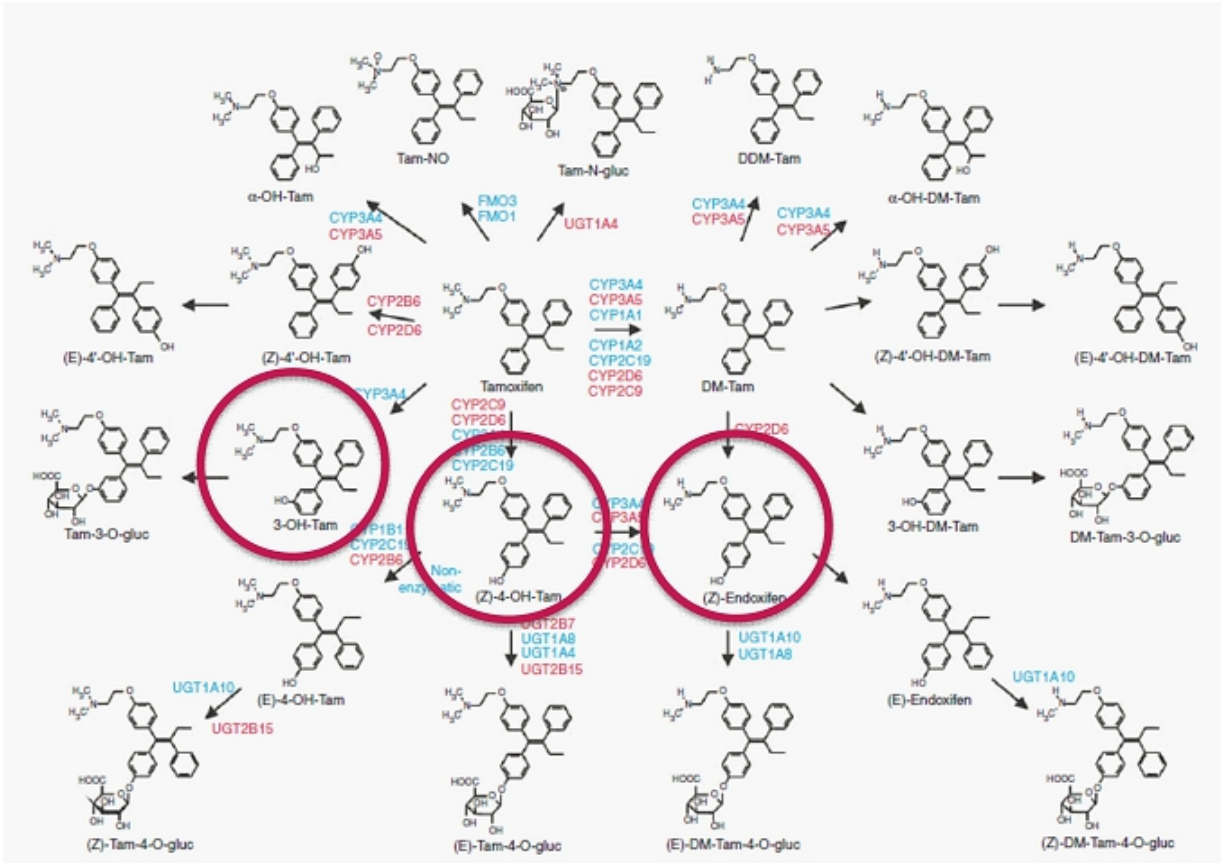
- Significance of unmet need: >500,000 are tamoxifen refractory and have increased risk of recurrence (see chart at right; Journal of Clinical Oncology Vol. 25, No. 33, Schroth et al.)
- IP: Composition of Matter and Methods of Treatment applications have been filed
- Existing data: Abundant pre-clinical and clinical data support approach
- Speed to market: Potential for rapid approval
- Potential competition: No known current commercial clinical development underway
- Regulatory pathway: 505(b)(2) pathway potential



Tamoxifen is a Pro-Drug with Many Metabolites



Only Three Have Cancer Inhibition Activity...

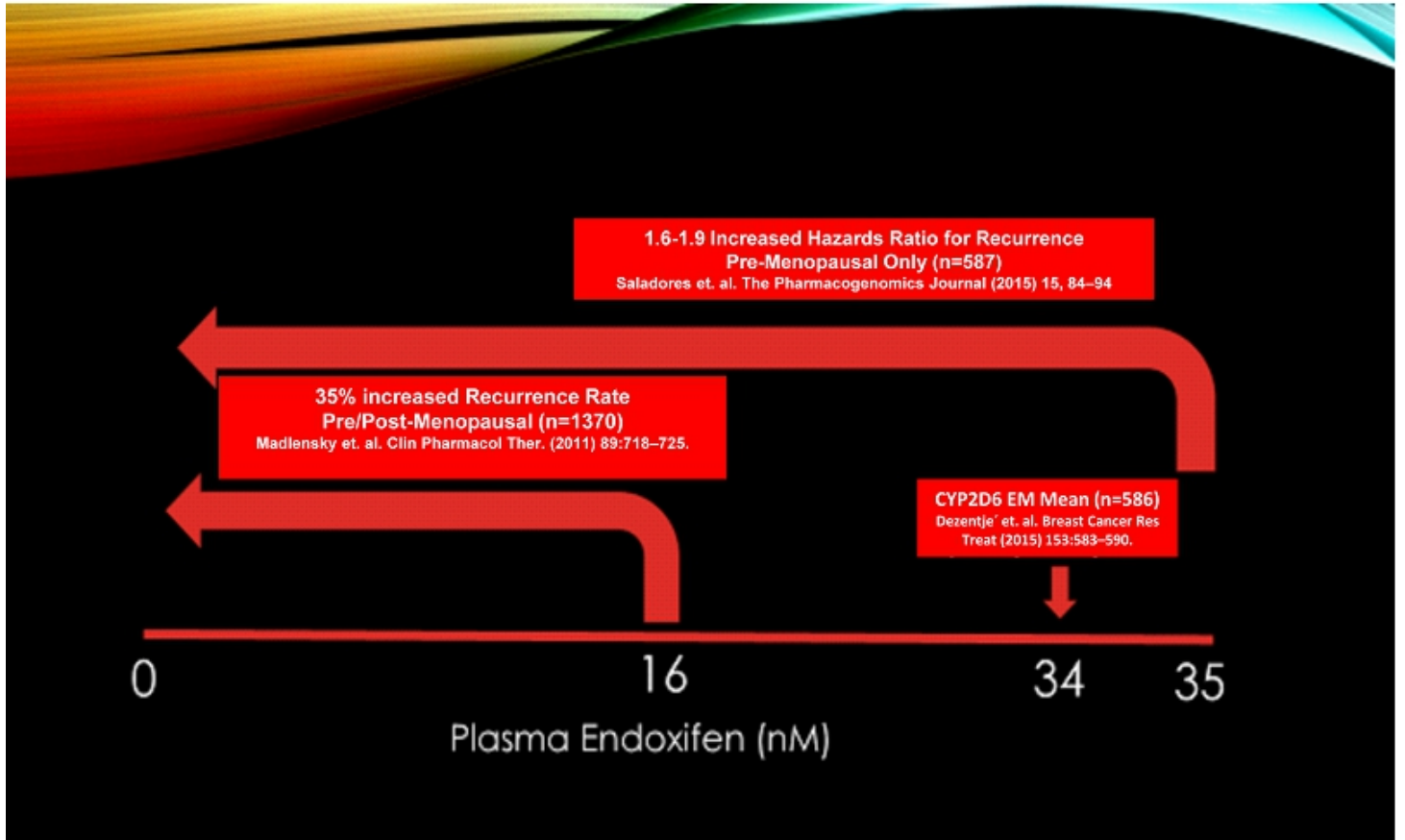


Major Tamoxifen Metabolites



Compound	Plasma Level (nM)	IC ₅₀ Estrogen Receptor Effect (nM)	PL/IC ₅₀
Endoxifen	29.1	3	9.7
4-OH-Tamoxifen	5.8	7	0.8 (8%)
3-OH-Tamoxifen	0.7	94	<0.01 (0.1%)

Low Plasma Endoxifen Predicts Recurrence

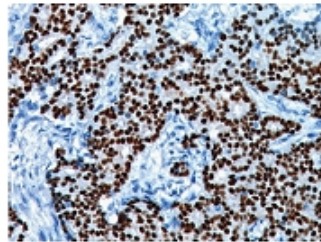


Endoxifen - Clinical Trial Design



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

**Perform Test to
Measure Endoxifen**



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



**≤TBD nM
Endoxifen
Add Oral Endoxifen
(1-2 mg/day)**

2016 Value Creation Points



Ongoing Microcatheter/Fulvestrant
Phase 2 Trial



Secured Financing Facility with Aspire
Capital – Up to \$10M over 30 Months



Oral Endoxifen Progress Provides
Significant Near Term Opportunity



Investment/Financial Highlights



- ✓ Drug Development Programs: intraductal fulvestrant in Phase 2 and a Phase 2 planned for oral endoxifen
- ✓ Favorable clinical and regulatory pathways
- ✓ Multi-billion dollar markets
- ✓ No debt, no preferred stock
- ✓ Up to \$10M financing facility with Aspire Capital
- ✓ Patent applications filed covering composition and methods
- ✓ Experienced management team



Seasoned Management



Steven Quay,
MD, PhD
Chairman
and CEO



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



Janet Rose Rea,
MSPH
VP Regulatory,
Quality and
Clinical Affairs

Corporate Summary



Atossa Genetics Inc. (IPO November 8, 2012)	NASDAQ: ATOS
Our Mission	Develop novel pharmaceuticals and delivery systems to treat breast conditions including breast cancer
Debt (March 31, 2016)	NONE
Cash (March 31, 2016)	\$3.2M
Shares Outstanding (May 31, 2016)	39M
Corporate Headquarters	Seattle, Washington



Atossa
G E N E T I C S

FOR MORE INFORMATION:

KYLE GUSE, CFO AND GENERAL COUNSEL

KYLE.GUSE@ATOSSAGENETICS.COM

NASDAQ: ATOS

WWW.ATOSSAGENETICS.COM