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): September 14, 2017

Atossa Genetics Inc.

(Exact name of registrant as specified in its charter)

Delaware	001-35610	26-4753208
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

107 Spring Street Seattle, Washington	98104
(Address of principal executive offices)	(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))

Item 7.01. Regulation FD Disclosure

On September 14, 2017, Atossa Genetics Inc. (the "Company") issued a press release announcing preliminary results from its Phase 1 study of topical Endoxifen. Also on September 14, 2017, the Company plans to hold a conference call and present information about the preliminary results from the Phase 1 study of topical Endoxifen. A copy of the press release and slides for the conference call are attached as Exhibit 99.1 and 99.2, respectively, to this current report and are 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

Exhibit No.	Description
99.1	Press Release, dated September 14, 2017
99.2	Topical Endoxifen Slide Presentation, dated September 14, 2017

* * *

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: September 14, 2017

Atossa Genetics Inc.

By: /s/ Kyle Guse
Kyle Guse
Chief Financial Officer, General Counsel and Secretary

Exhibit Index

Exhibit No.	Description
99.1	Press Release, dated September 14, 2017
99.2	Topical Endoxifen Slide Presentation, dated September 14, 2017

Exhibit 99.1

Atossa Genetics Announces

Preliminary Results from Phase 1 Study of Topical Endoxifen

*****All Objectives Successfully Met*****

Conference Call To Be Held Today at 2pm Eastern Time

SEATTLE, September 14, 2017 -- Atossa Genetics Inc. (NASDAQ: ATOS), a clinical-stage pharmaceutical company developing novel therapeutics and delivery methods for breast cancer and other breast conditions, reported preliminary results from its Phase 1 dose escalation study of its proprietary topical Endoxifen. All objectives were successfully met:

- **Safety:** There were no clinically significant safety signals and no clinically significant adverse events in participants receiving topical Endoxifen.
- **Tolerability:** Topical Endoxifen was well tolerated at each dose level and for the dosing duration utilized in the study.
- **Pharmacokinetics:** Topical Endoxifen 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.

These data demonstrate the suitability of topical endoxifen for further clinical development.

Atossa expects to announce results from the oral arm of the Phase 1 study in the next 30-60 days.

The Phase 1 Study

The Phase 1 study was a double-blind, placebo-controlled, repeat dose study of 48 healthy female subjects. Atossa assessed safety, tolerability and the pharmacokinetics of proprietary formulations of both topical and oral Endoxifen dosage forms in varying dose levels over 28 days. The study was conducted in two parts based on route of administration. Results from the oral arm of the study are expected in the next 30 to 60 days.

Atossa's Proprietary Endoxifen

Endoxifen is an active metabolite of tamoxifen. Tamoxifen is an FDA-approved drug to prevent new breast cancer as well as recurrent breast cancer in breast cancer patients. Tamoxifen itself must be broken down by the liver into active compounds (metabolites), of which Endoxifen is the most active.

Topical Endoxifen. A condition called breast density (or, MBD), typically diagnosed by a mammogram, has been shown to be an independent breast cancer risk factor. To date, 30 states require that findings of MBD be directly communicated to the patient. We believe a topical form of Endoxifen could potentially reduce MBD. Although oral tamoxifen has been shown to reduce MBD, the benefit-cost ratio is not acceptable to most physicians and their patients. For example, it is estimated that only ~ 2% of women at high-risk of developing breast cancer including those with MBD take oral tamoxifen to prevent breast cancer because of the risk of, or actual side-effects of, oral tamoxifen. Therefore we expect our next study to focus on the potential for Atossa's topical Endoxifen to reduce MBD.

Oral Endoxifen. Although approximately one million breast cancer survivors take tamoxifen annually, up to half of them do not benefit from tamoxifen, meaning they are "refractory," for a number of reasons including that they do not properly metabolize tamoxifen. Low endoxifen levels in breast cancer patients taking oral tamoxifen are associated with an increased risk of recurrence or the development of new breast tumors. Thus providing oral Endoxifen directly to the patient without having to be metabolized may help to address this problem.

Based on the number of women at high-risk of developing breast cancer and the number of patients who have survived breast cancer but are not benefiting from tamoxifen, Atossa estimates that the potential markets for its proprietary oral and topical formulations of Endoxifen could each potentially exceed $1 billion in annual sales.

Next Steps

"Based on these positive preliminary results, we are advancing our topical Endoxifen into Phase 2 studies" commented Dr. Steven C. Quay, CEO and President. "We look forward to announcing the results from the oral arm of our Phase 1 study in the coming 30 to 60 days," continued Dr. Quay.

Breast Cancer Statistics

The American Cancer Society (ACS) estimates that approximately 250,000 women will be diagnosed with breast cancer in the United States this year and that approximately 40,000 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; 2,470 new cases of invasive breast cancer will be diagnosed; and 460 men will die from breast cancer in 2017.

Conference Call

Atossa Genetics will host a conference call to discuss preliminary results today at 2pm eastern time.

To listen to the call by phone, interested parties within the U.S. should call 1-844-824-3830 and International callers should call 1-412-317-5140. All callers should ask for the Atossa Genetics conference call. The conference call will also be available through a live webcast at www.atossagenetics.com. Details for the webcast may be found on the Company's IR events page at http://ir.atossagenetics.com/ir-calendar.

A replay of the call will be available approximately one hour after the end of the call through October 14, 2017. The replay can be accessed via Atossa's website or by dialing 877-344-7529 (domestic) or 412-317-0088 (international) or Canada Toll Free at 855-669-9658. The replay conference ID number is 10112105.

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, estimated market size of drugs under development, 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, potential market sizes for Atossa's drugs under development 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.

Atossa Genetics Company Contact:

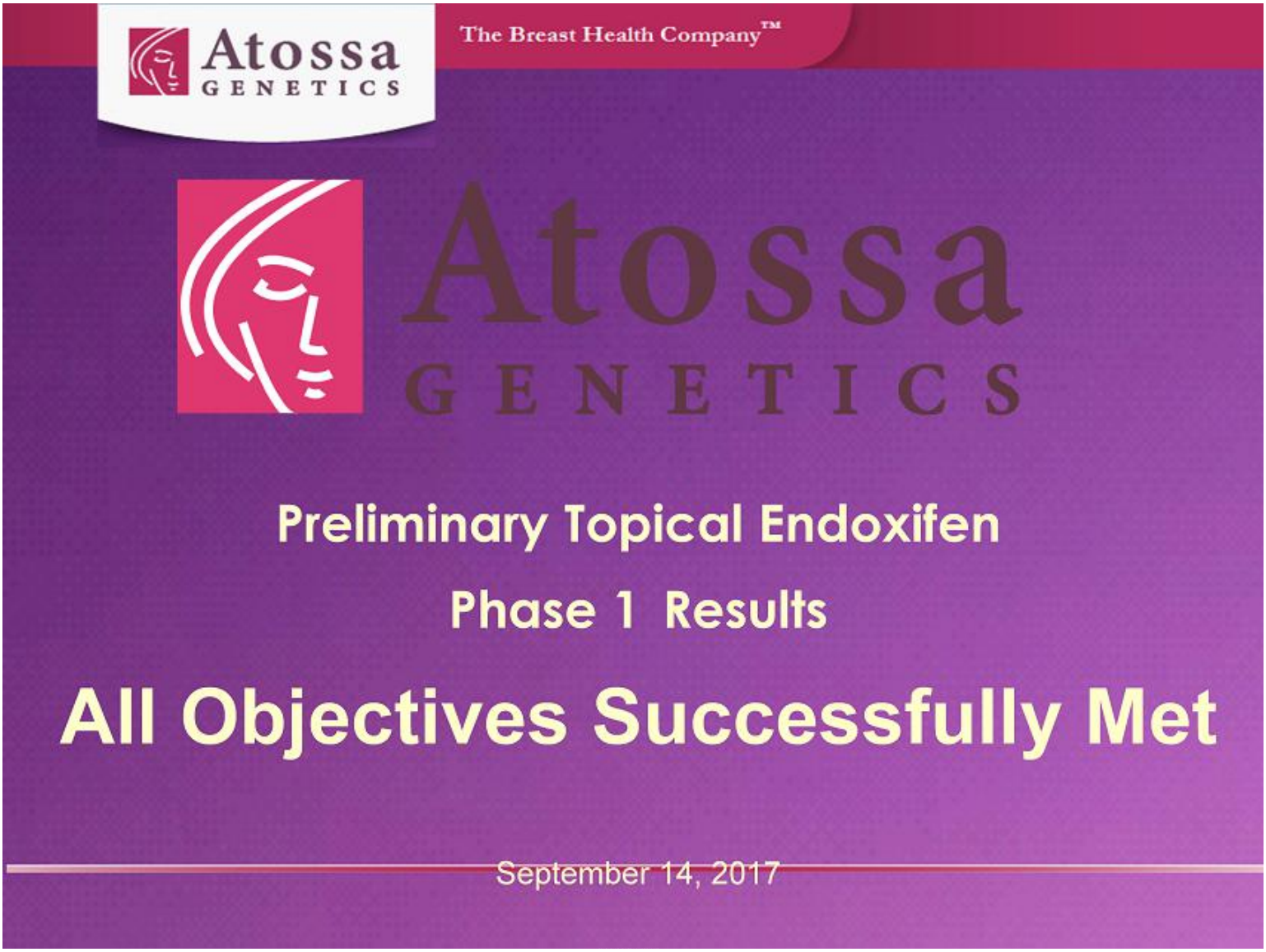
Atossa Genetics Inc.
Kyle Guse
CFO and General Counsel
(O) 866 893-4927
kyle.guse@atossagenetics.com

Investor Relations Contact:

Scott Gordon
CoreIR
377 Oak Street
Concourse 2
Garden City, NY 11530
Office: 516 222-2560
scottg@CoreIR.com

Source: Atossa Genetics Inc.

Exhibit 99.2


Atossa GENETICS
The Breast Health Company™
Atossa GENETICS
Preliminary Topical Endoxifen
Phase 1 Results
All Objectives Successfully Met
September 14, 2017

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 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, 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.

DISCUSSION TOPICS

- Atossa Genetics Overview
- Endoxifen
- Phase 1 Study
- Safety Summary
- Tolerability Summary
- Pharmacokinetic Summary
- Upcoming Milestones

Atossa GENETICS

The Breast Health Company™

Atossa Genetics Overview

Atossa Genetics:

- Clinical-stage
- Novel drugs & delivery methods
- Breast Cancer & other breast conditions
- Headquartered in Seattle, WA

Endoxifen

Endoxifen

- Most active metabolite of tamoxifen
- Tamoxifen has been widely studied
- Tamoxifen was first approved in 1977

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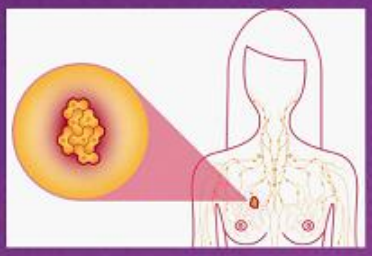
Current Paradigm for Tamoxifen Use in US

10 million patients with a high risk of breast cancer are indicated for chemoprevention with oral tamoxifen

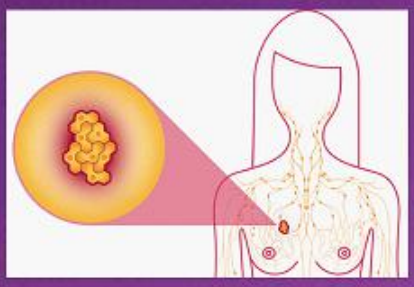


1 million breast cancer patients take oral tamoxifen for at least five years

Source: Freedman AN, Graubard BI, Rao SR, McCaskill-Stevens W, Ballard-Barbash R, Gail MH. Estimates of the number of US women who could benefit from tamoxifen for breast cancer chemoprevention. J Natl Cancer Inst. 2003;95:526–32

Unmet Medical Needs Are >$1B Markets

9.9 million high risk patients won't take oral tamoxifen because of actual or the risk of systemic side effects



500,000 breast cancer patients don't benefit from tamoxifen because of metabolism problems

Source: Freedman AN, Graubard BI, Rao SR, McCaskill-Stevens W, Ballard-Barbash R, Gail MH. Estimates of the number of US women who could benefit from tamoxifen for breast cancer chemoprevention. J Natl Cancer Inst. 2003;95:526–32

Emerging Unmet Medical Need

- Breast Density
  - Independent risk for breast cancer
  - Patients required to be notified in 30 states
  - No approved treatment
    - Tamoxifen reduces breast density

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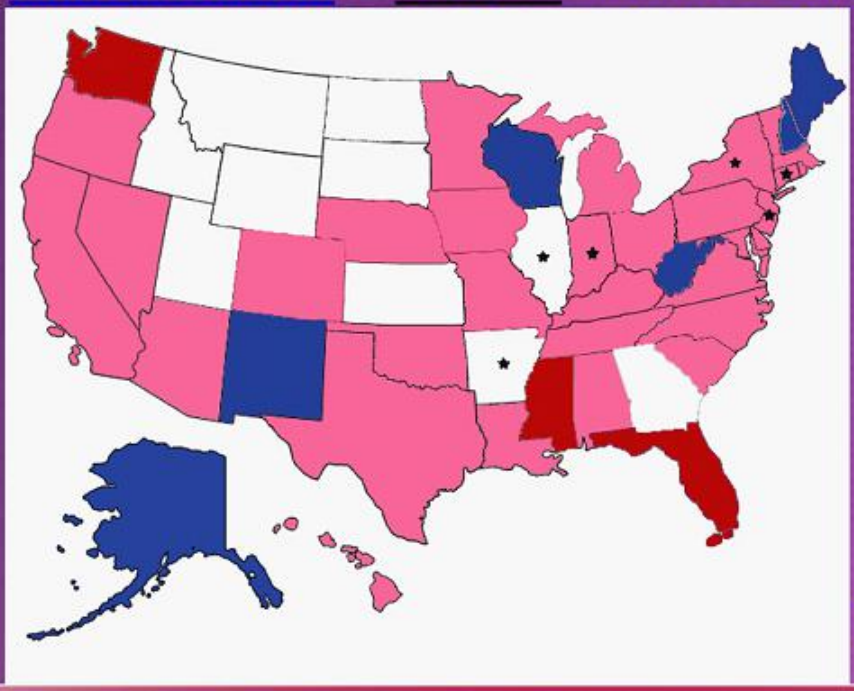
Mandatory Patient Notification of BD

PINK: Enacted Law — **RED:** Introduced Bill — **BLUE:** Working on Bill — **WHITE: No Action** — **BLACK**: Insurance Coverage Law



From: AreYouDense.org

Why Endoxifen?

- Address unmet medical needs for:
  - Providing a topical alternative to oral tamoxifen for reducing breast density
  - Enhancing the chemoprevention properties of tamoxifen in those patients who are refractory
- Extensive characterization of tamoxifen, the parent drug

Phase 1 Study

Preliminary Phase 1 Topical Results

- Study objectives achieved
- Demonstrated:
  - Safety
  - Tolerability
  - Verification of transdermal delivery

Supports continued development

Q2 2106	• Contracted to develop endoxifen API
Q3 2016	• First batch of API for clinical use
Q4 2016	• Topical formulation development in US • Retained CRO in Australia
Q1 2017	• Retained CMO in Australia (for topical and oral presentations)
Q2 2017	• Approval to start study • First cohort enrolled • Shipped drug product to CRO
Q3 2017	• Last cohort completed

Preliminary Study Conclusions

- **All study objectives successfully achieved**
  - **Safety:** There were no clinically significant safety signals and no clinically significant adverse events in participants receiving topical Endoxifen.
  - **Tolerability:** Topical Endoxifen was well tolerated at each dose level and for the dosing duration utilized in the study.
  - **Pharmacokinetics:** Topical Endoxifen 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.

Phase 1 Study Design

PART A (Topical). Cohorts, dose levels and number of participants.

Cohort	Dose Level		Number of Participants	
	(mg per breast)	(Total mg)	(Z)-Endoxifen	Placebo
1	1	2	6	2
2	3	6	6	2
3	5	10	6	2

PART B (Oral). Cohorts, dose levels and number of participants.

	Dose Level (mg/day)	(Z)-Endoxifen	Placebo
4	1	6	2
5	2	6	2
6	4	6	2

Study Design Summary

- Two-part double-blinded, placebo controlled, dose escalation trial investigating the safety and pharmacokinetics of (Z)-Endoxifen in healthy female volunteers
  - Part A: Topical – liquid applied to the breasts
  - Part B: Capsule – taken orally
- Single dose "sachet" (one per breast/day)

Topical Design Summary

Cohort	Dose		Number of Participants	
	mg per Breast	Total mg	(Z)-Endoxifen	Placebo
1	1	2	6	2
2	3	6	6	2
3	5	10	6	2

- ✓ Healthy females, 18 to 65 years of age
- ✓ Body Mass Index of 18 to 30
- ✓ No chronic or acute disease
- ✓ Daily administration diaries

Safety Summary

Safety Summary

- No safety signals observed in weekly assessments of/in:
  - Blood chemistry
  - Coagulation parameters
  - Hematology parameters
  - Urinalysis
  - Vital Signs
  - Heart
  - Physical Examinations

Adverse Events

- There were no Serious Adverse Events
- Two subjects (one placebo and one active) experienced a Treatment Emergent Adverse Event of moderate severity and possibly drug-related
  - Headache
  - Nausea

Tolerability Summary

Tolerability Data – by Participant

Parameter	Participant Identification			
	Dose Group			
Itching	Low	Intermediate	High	Placebo
Mild	#11	#27	#37	#29
Moderate				
Pain			#33, #31	
Mild	#14		#37	#28
Moderate	#11		#36	
Redness				
Mild		#27		#32
Moderate				
Burning				
Mild			#33, #37	
Moderate				
Irritation				
Mild			#33	
Moderate			#37	

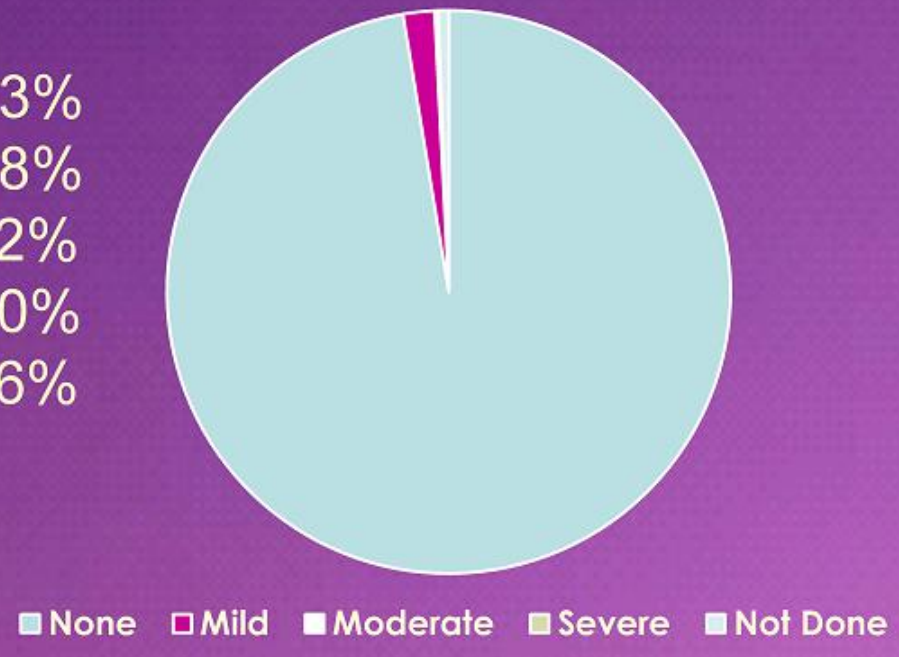
10 participants experienced one or more instances.

Local Tolerability By Instances

- A daily self-assessment of local tolerance was performed
  - 24 subjects for 28 days for a total of 672 daily assessments
- Redness, Burning, Pain, Itching and Irritation were assessed each day
- Scoring was None, Mild, Moderate or Severe for all five parameters

Overall Tolerability Scoring Based on Instance

None	97.3%
Mild	1.8%
Moderate	0.2%
Severe	0.0%
Not Done	0.6%



Parameter Summary by Instance

Parameter	None
Redness	99%
Burning	99%
Pain	98%
Itching	97%
Irritation	97%

- One subject had mild irritation 17/28 days and moderate irritation on the End of Study assessment

In-person Interview

- Each participant was interviewed every seven days for side-effect information

	Result					
Cohort	Not at All	A little Bit	Some-what	Quite a Bit	Very Much	Not Done
Low	6/6					
Intermediate	6/6					
High	3/6	2/6	1/6			
Placebo	6/6	1/6				

- The participant at the highest dose who was bothered by side-effects was the same who reported topical irritation

Pharmacokinetic Summary

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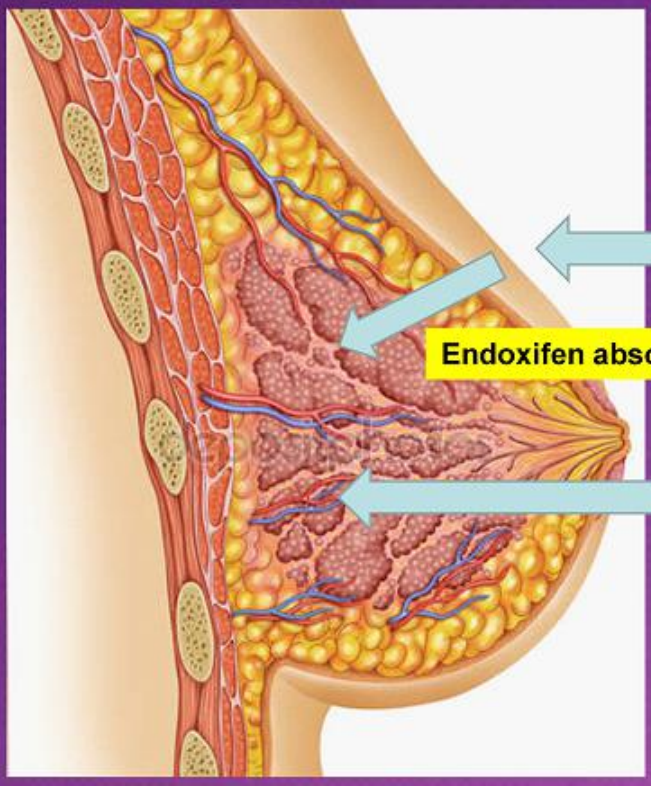
Pharmacokinetic Objective



Goal was to prove absorption with measurable blood levels that are low enough to limit systemic exposure

Formulation placed on skin surface

Endoxifen absorbed into breast tissue to bind to ER and retard growth

Breast blood vessels connect to systemic circulation taking "excess" endoxifen into systemic circulation

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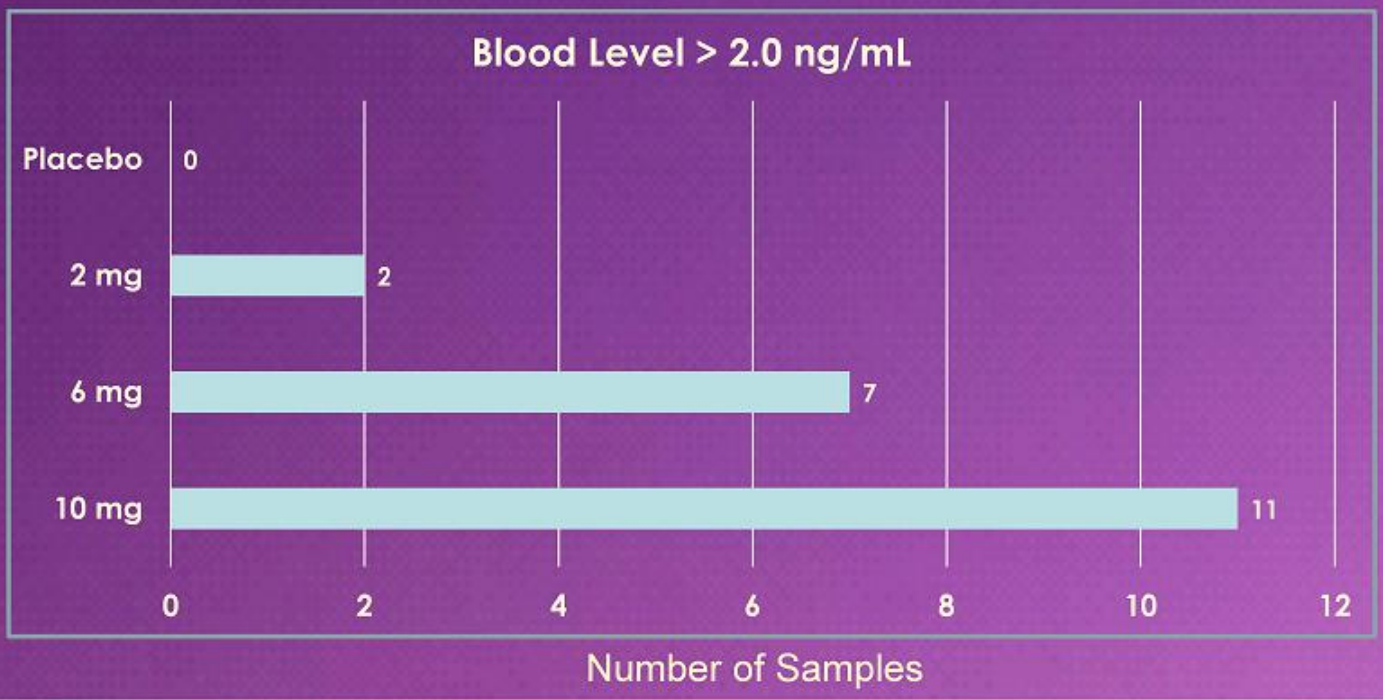
Endoxifen was detected in blood



107 Spring St.
Seattle WA 98104

Preliminary Study Conclusions

- **All primary and secondary endpoints successfully met**
  - **Safety:** There were no clinically significant safety signals and no clinically significant adverse events in participants receiving topical Endoxifen.
  - **Tolerability:** Topical Endoxifen was well tolerated at each dose level and for the dosing duration utilized in the study.
  - **Pharmacokinetics:** Topical Endoxifen 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.
- **Therefore, the topical Endoxifen is suitable for continued development**

Up Coming Milestones

- 2017
  - Complete analysis of oral endoxifen Phase 1 data
  - Finalize Phase 2 Study design for topical endoxifen
  - Finalize Phase 2 Study design for oral endoxifen
  - Final report of combined topical and oral Phase 1 by CRO
  - IRB and government submission for Phase 2
  - Advance both oral and topical formulations

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NASDAQ: ATOS