



**Atossa**  
**G E N E T I C S**

**Preliminary Topical Endoxifen**

**Male Phase 1 Results**

**All Objectives Successfully Met**

September 13, 2018

# 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
- Preliminary Safety Summary
- Preliminary Tolerability Summary
- Preliminary Pharmacokinetic Summary
- Next Steps

# **Atossa Genetics Overview**

# Atossa Genetics:

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

# Senior Management



**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*

# Corporate Summary

<b>Company:</b>	Atossa Genetics Inc. (NASDAQ: ATOS)
<b>Our Mission:</b>	Develop novel pharmaceuticals and delivery systems to treat breast cancer and other breast conditions
<b>Debt June 30, 2018:</b>	None
<b>Cash June 30, 2018:</b>	\$15.2M
<b>Capital Structure Sept. 5, 2018:</b>	5.5M shares common stock 1.0M shares preferred stock, as converted basis 3.9M warrants exercisable at \$4.05/share 442K warrants exercisable at \$3.78/share
<b>Corporate Headquarters:</b>	Seattle, Washington

# Clinical Program Summary

- Phase 2 study to determine if oral Endoxifen reduces tumor activity in early stage breast cancer patients in the “window of opportunity” between diagnosis of breast cancer and surgery (now enrolling in Australia)
- Phase 2 study to determine if topical Endoxifen reduces mammographic breast density (now enrolling in Sweden)
- Phase 1 study of topical Endoxifen in men (study complete with preliminary results announced today)
- Phase 2 study of topical Endoxifen to treat gynecomastia in men starting prostate cancer therapy (retaining CRO in Q4 2018)
- Phase 2 study of oral Endoxifen for patients who are “refractory” to Tamoxifen (retaining CRO in Q4 2018)
- Phase 2 study of Atossa’s proprietary intra ductal microcatheter technology to administer Fulvestrant in breast cancer patients prior to surgery (enrolling in the U.S. at Montefiore Medical Center, NY)



# Near-Term Milestones

- Q4 2018: Complete enrollment in Phase 2 study to reduce MBD
- Q4 2018: Retain CRO for Phase 2 study of topical Endoxifen to treat gynecomastia in prostate cancer patients
- Q4 2018: Retain CRO for Phase 2 study of oral Endoxifen for patients who are “refractory” to Tamoxifen
- Q4 2018: Release final data from Phase 1 study of topical Endoxifen to treat gynecomastia
- Q4 2018: Develop pre-clinical model using our proprietary microcatheter technology for immuno-oncology
- 2019: Progress clinical programs

# Endoxifen

# Phase 1 Study - Men

# Preliminary Phase 1 Topical Results

- Study objectives achieved
- Demonstrated:
  - No Safety Issues
  - No Tolerability Issues
  - Topical Endoxifen not detected in the blood stream

***Supports continued development***

# 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 was not detected in the blood at any dosing level.

# Topical Design Summary

Double-blinded, placebo controlled, dose escalation trial investigating the safety, tolerability and pharmacokinetics of topical (Z)-Endoxifen in healthy male volunteers

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 males, 18 to 65 years of age
- ✓ Body Mass Index of 18 to 32
- ✓ 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
- No significant treatment-emergent Adverse Events related to study drug

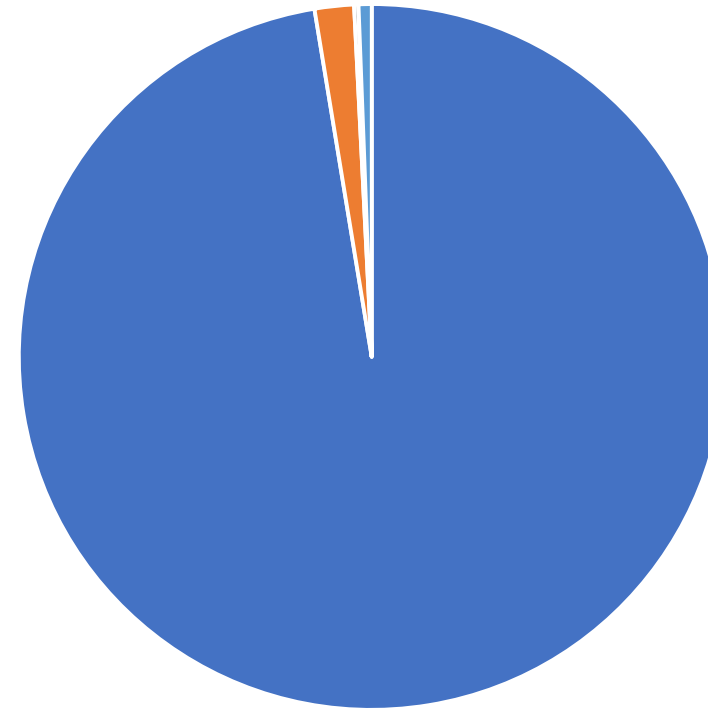
# Tolerability Summary

# 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

<b>None</b>	<b>97.2%</b>
Mild	2.5%
Moderate	0.3%
Severe	0.0%



■ None ■ Mild ■ Moderate ■ Severe ■ Not Done

# Parameter by Instance

Parameter	Percent Reporting None
Redness	96%
Burning	98%
Pain	99%
Itching	95%
Irritation	97%

One subject reported itching, irritation, redness and burning, and accounted for over 50% of the reports skin reactions

# In-person Interview Results for Side-effects

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

Cohort	Responses per Participant*					
	Not at All	A little Bit	Some-what	Quite a Bit	Very Much	Not Done
Low	6/6					
Intermediate	6/6					
High	6/6					
Placebo	5/6	1/6				

There were sporadic reports of weight change (gain or loss), breast tenderness and headache

A participant who received placebo reported the highest frequency of side-effects and itching, irritation, redness and burning

# Pharmacokinetic Summary

Endoxifen blood levels below detection  
limit of assay

# Next Steps in Gynecomastia

- Q4 2018: Report final data
- Q4 2018: Retain CRO for male Phase 2 study of topical Endoxifen to reduce/prevent gynecomastia and maintain and/or improve quality of life





**Atossa**  
**GENETICS**

**NASDAQ: ATOS**