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 Therapeutics Overview
• Endoxifen
• Phase 1 Study
• Preliminary Safety Summary
• Preliminary Tolerability Summary
• Preliminary Pharmacokinetic Summary
• Next Steps
Atossa Therapeutics
Overview
Atossa Therapeutics:

• 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

<table>
<thead>
<tr>
<th>Company:</th>
<th>Atossa Therapeutics Inc. (NASDAQ: ATOS)</th>
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</thead>
<tbody>
<tr>
<td><strong>Our Mission:</strong></td>
<td>Develop novel pharmaceuticals and delivery systems to treat breast cancer and other breast conditions</td>
</tr>
<tr>
<td><strong>Debt June 30, 2018:</strong></td>
<td>None</td>
</tr>
<tr>
<td><strong>Cash June 30, 2018:</strong></td>
<td>$15.2M</td>
</tr>
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</table>
| **Capital Structure Sept. 5, 2018:** | 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 |
| **Corporate Headquarters:**   | 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

<table>
<thead>
<tr>
<th>Cohort</th>
<th>Dose</th>
<th>Number of Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>mg per Breast</td>
<td>Total mg</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>2</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>3</td>
<td>5</td>
<td>10</td>
</tr>
</tbody>
</table>

✓ 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

None: 97.2%
Mild: 2.5%
Moderate: 0.3%
Severe: 0.0%
### Parameter by Instance

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Percent Reporting None</th>
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<tbody>
<tr>
<td>Redness</td>
<td>96%</td>
</tr>
<tr>
<td>Burning</td>
<td>98%</td>
</tr>
<tr>
<td>Pain</td>
<td>99%</td>
</tr>
<tr>
<td>Itching</td>
<td>95%</td>
</tr>
<tr>
<td>Irritation</td>
<td>97%</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Cohort</th>
<th>Responses per Participant*</th>
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<tbody>
<tr>
<td></td>
<td>Not at All</td>
</tr>
<tr>
<td>Low</td>
<td>6/6</td>
</tr>
<tr>
<td>Intermediate</td>
<td>6/6</td>
</tr>
<tr>
<td>High</td>
<td>6/6</td>
</tr>
<tr>
<td>Placebo</td>
<td>5/6</td>
</tr>
</tbody>
</table>

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