



Atoossa
THERAPEUTICS

March 23, 2023

www.atossatherapeutics.com

Investor Presentation

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, 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 achieving development plans, any variation between interim and final clinical results, whether in vitro test results will also be achieved in clinical studies, actions and inactions by the FDA and other regulators, the outcome or timing of regulatory approvals needed by Atossa including those needed to commence studies of (Z)-endoxifen, lower than anticipated rate of patient enrollment, estimated market size of drugs under development, the safety and efficacy of Atossa's products, performance of clinical research organizations and investigators, obstacles resulting from proprietary rights held by others such as patent rights, whether reduction in Ki-67 and reduction in mammographic breast density are approvable endpoints, impact of the COVID-19 pandemic 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.

Corporate Summary

Company

Atossa Therapeutics, Inc. (NASDAQ: ATOS)

Our Mission

To develop innovative proprietary medicines to address significant unmet needs in cancer

Debt

None (December 31, 2022)

Cash

\$111M (December 31, 2022)

Capital (Dec. 31, 2022)

- 126.62M shares common stock
- 165k shares preferred stock, as converted basis
- 11.0M warrants exercisable at \$1.00 or \$1.05/share
- 10.5M warrants exercisable at \$2.88/share
- 10.3M options exercisable at ave. \$2.59/share

Corporate HQ

Seattle, Washington, USA



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

Steven Quay, MD, PhD, Chairman, CEO and President - Dr. Quay is a physician-scientist and inventor of seven FDA-approved pharmaceutical products. He holds 88 U.S. patents and is a named inventor on 678 published international patent applications. Dr. Steven Quay has 390+ published contributions to medicine and has been cited over 11,000 times, placing him in the top 1% of scientists worldwide. He received his M.D. and Ph.D. from The University of Michigan, was a postdoctoral fellow in the Chemistry Department at MIT with Nobel Laureate H. Gobind Khorana, a resident at the Harvard-MGH Hospital, and spent almost a decade on the faculty of Stanford University School of Medicine.



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

Kyle Guse, CPA, ESQ, MBA, CFO and General Counsel, has served as Chief Financial Officer, General Counsel and Secretary since January 2013. His experience includes 30 years of counselling life sciences and other rapid growth companies through all aspects of finance, corporate governance, securities laws and commercialization. Mr. Guse has practiced law at several of the largest international law firms, including from January 2012 through January 2013 as a partner at Baker Botts LLP and, prior to that, from October 2007 to January 2012, as a partner at McDermott Will & Emery LLP. Before working at McDermott Will & Emery, Mr. Guse previously served as a partner at Heller Ehrman LLP. Mr. Guse began his career as an accountant at Deloitte & Touche and he is a licensed Certified Public Accountant in the state of California. Mr. Guse earned a B.S. in Business Administration and an M.B.A. from California State University, Sacramento, and a J.D. from Santa Clara University School of Law.



B. Heather Fraser, PhD - *VP Clinical, Regulatory and CMC*

Heather Fraser, PhD, VP Clinical, Regulatory and CMC, brings over 20 years of extensive industry experience in the biotech industry to the Company, recently serving in a leadership role as VP Clinical Operations & Program Management at Cerecor, Inc. She held positions with increasing levels of responsibility at Anthera Pharmaceuticals and CV Therapeutics (acquired by Gilead Sciences) where the roles included preclinical and clinical sciences and regulatory affairs. Dr. Fraser has experience in drug development across diverse therapeutic areas including psychiatry, central nervous system disorders, cardiovascular disorders, and rare diseases; and she has been involved in all stages of drug development from pre-clinical through Phase 4. Dr. Fraser received her BS in Zoology from the University of British Columbia, her MS in Pharmaceutical Sciences from the University of Montana and her PhD in Pharmacology from the University of Alberta. She also completed a post-doctoral fellowship at Johns Hopkins University School of Medicine.

Experienced Leadership continued



Delly Behen, PHR, SHRM-CP - *VP, Administration and Human Resources*

Delly Behen, PHR, SHRM-CP has served as Atossa's VP, Administration & Human Resources since July 2014. Delly brings over 20 years of human resources, administrative, and operational experience to the company. Her experience includes leading people, culture and administration at various biotech companies throughout the Puget Sound. Most recently, she served as Impel NeuroPharma's HR Consultant, where she helped grow the company and implement HR policies and procedures. She also held positions with increasing responsibilities at CTI Biopharma. Delly received her B.A. degree from the University of Washington and her HR certification from Seattle Pacific University.



Heather Rees - *VP, Finance and Accounting*

Heather Rees, VP, Finance and Accounting, brings more than 25 years of experience in finance and accounting leadership roles within publicly traded, IPO startups and global organizations. Prior to her current role, Ms. Rees served as Atossa's Controller from 2017 through early 2021. She previously spent ten years working as an independent financial consultant serving public and private companies including, Avalara, Getty Images, Fisher Communications, and Flow International. Heather began her career with Deloitte & Touche and worked nine years in the audit practice. Ms. Rees earned a Bachelor of Business Administration in accounting from Gonzaga University. She is a CPA in the state of Washington (inactive).



Eric Van Zanten - *VP, Investor and Public Relations*

Eric Van Zanten, VP, Investor and Public Relations, brings over 25 years of corporate communications experience working within the biopharmaceutical, finance and healthcare industries. He oversees corporate, executive and digital communications, investor relations, thought leadership, and branding for the Company. Prior to joining Atossa, Mr. Van Zanten led corporate affairs at Faron Pharmaceuticals, a clinical stage biopharmaceutical company focused on tackling difficult-to-treat cancers via precision macrophage immunotherapy and Urogen Pharma, a commercial stage biotech delivering innovative solutions that treat specialty cancers. He was also formerly Head of Commercial and Medical Communications and Director of Oncology Communications at Bristol-Myers Squibb. Earlier in his career he held communications leadership roles at Deloitte, Booz Allen & Hamilton, Children's Hospital of Philadelphia and Unisys Corporation. Mr. Van Zanten is a graduate of Franklin and Marshall College, where he received his BA in Political Science and Government.

Board of Directors

Shu-Chih Chen, Ph.D.



Dr. Chen has served as founder and director since April 2009. She is an inventor on 39 US patents and applications and has authored numerous scientific papers.

H. Lawrence Remmel, Esq. PRYOR CASHMAN

Mr. Remmel is currently a partner of the law firm Pryor Cashman LLP, located in New York City, where he chairs the Banking and Finance practice group.

Stephen J. Galli, M.D.



Before joining Stanford, Mr. Galli was on the faculty of Harvard Medical School. He holds 14 U.S. patents and has over 400 publications.

Richard I. Steinhart

Mr. Steinhart is currently the Vice President and Chief Financial Officer of BioXcel Therapeutics, Inc.

Steven C. Quay, M.D., Ph.D.



Dr. Quay is a founder of Atossa Therapeutics and has served as Chief Executive Officer, President and Board Chairman since April 2009.

Gregory L. Weaver



Mr. Weaver is currently the Chief Financial Officer of BioIntelliSense, Inc.

Clinical Development Pipeline

Breast Cancer Program – (Z)-endoxifen

EVANGELINE

Neoadjuvant ER+ / HER2- Breast Cancer

- Window of Opportunity – successful Phase 2 completed in AUS
- First patient dosed in Phase 2 U.S. study in February 2023
- Participants receive treatment for up to six months, followed by surgery

I-SPY 2

Neoadjuvant ER+ Breast Cancer

- Collaborative effort among major cancer research centers, the FDA, Quantum Leap Healthcare Collaborative and the FNHI Cancer Biomarkers Consortium
- Initiated March 2023
- New study arm in the Endocrine Optimization Pilot Protocol

Karisma- Endoxifen

Mammographic Breast Density (MBD)

- Ongoing Phase 2 started December 2021
- Participants receive daily treatment for six months
- Mammograms are conducted to measure reduction in MBD

Preclinical

Phase 1

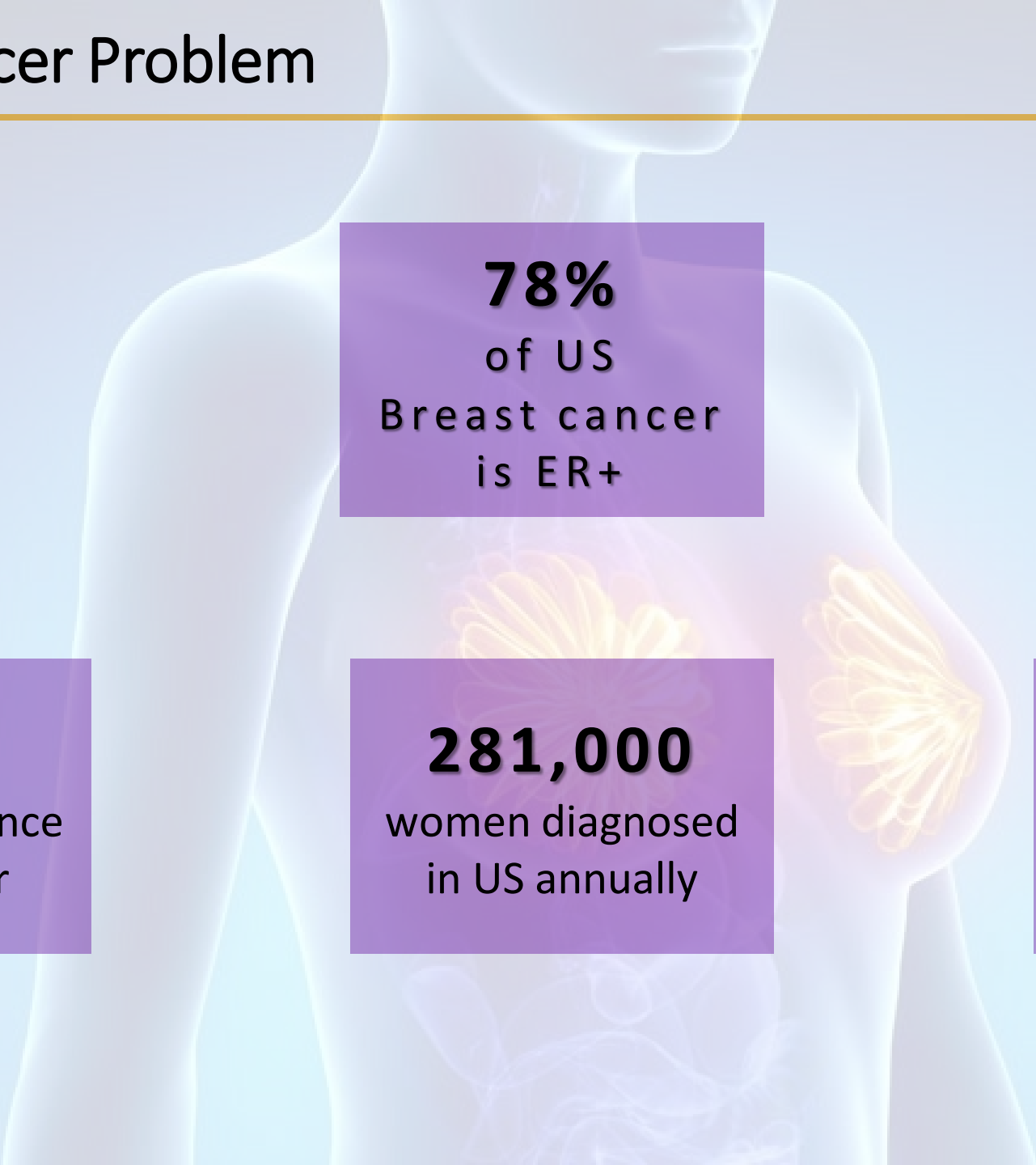
Phase 2

Phase 3

NDA/MAA

Commercial

The Breast Cancer Problem



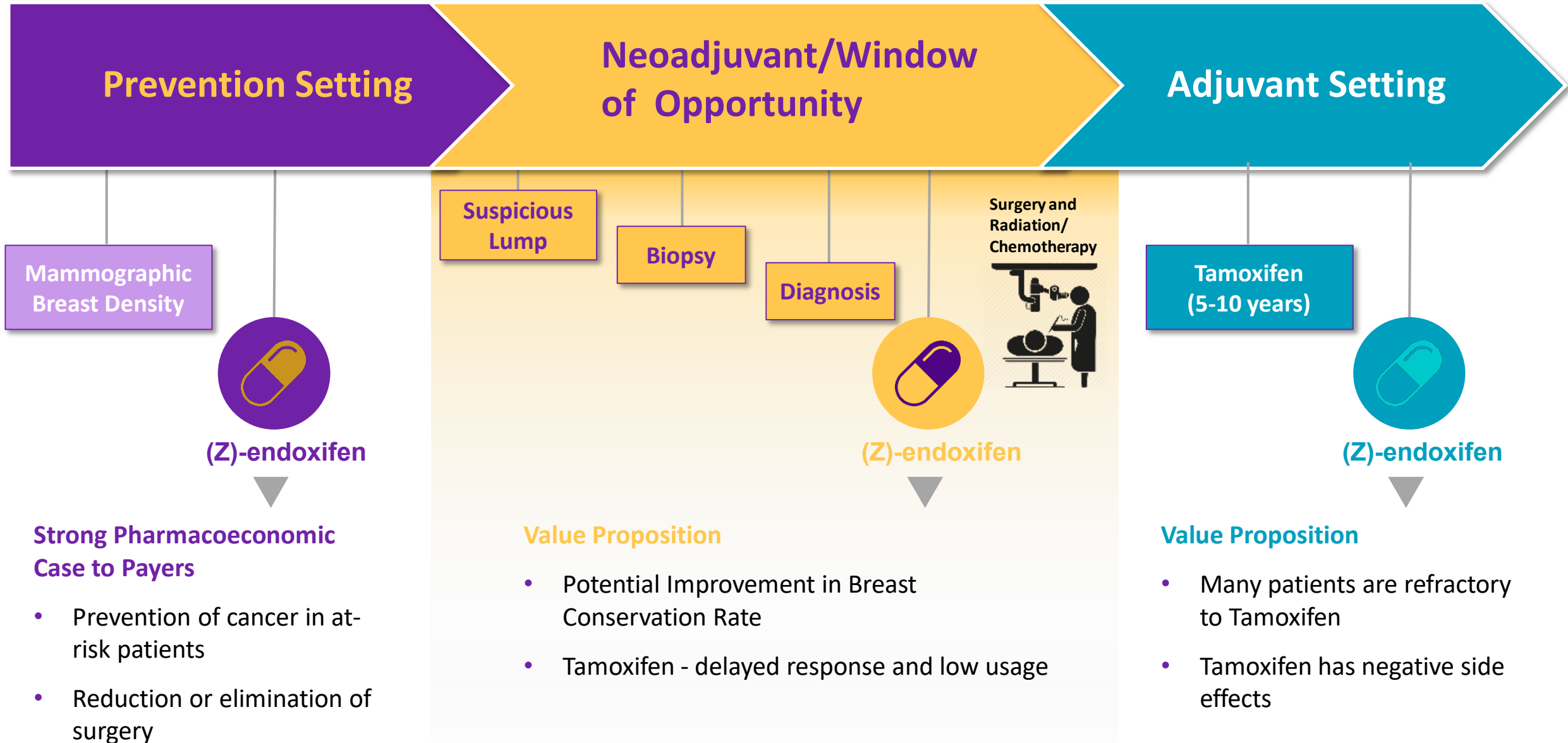
78%
of US
Breast cancer
is ER+

1 in 8
women experience
breast cancer

281,000
women diagnosed
in US annually

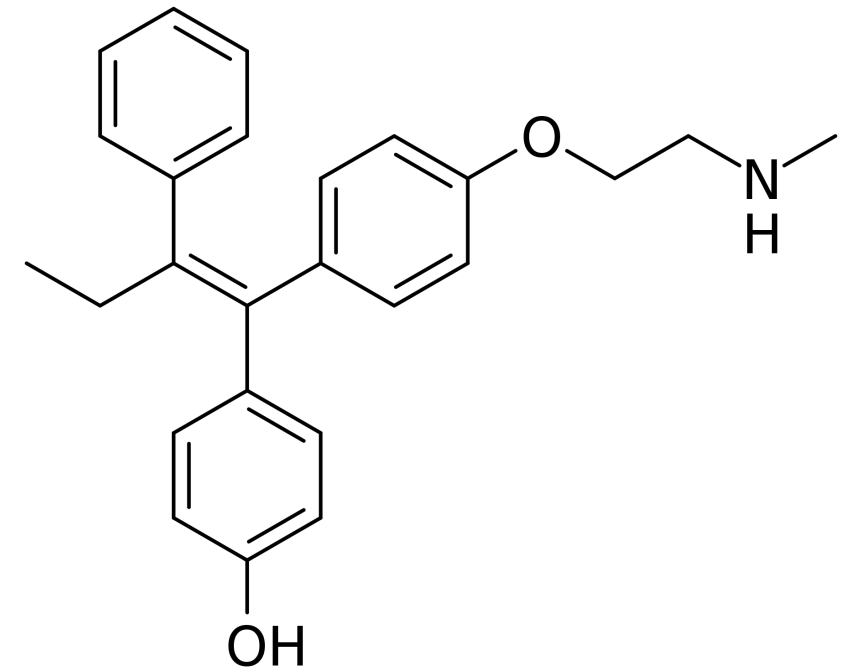
2nd
leading cause of
cancer death in
American women

Clinical Positioning In Breast Cancer



(Z)-endoxifen – New, Proprietary SERM

- According to published studies, (Z)-endoxifen is a competitive inhibitor of ER α and represses ER α transcriptional activity
 - (Z)-endoxifen is 100-fold more potent in anti-estrogen activity compared to other SERMs⁽¹⁾
 - (Z)-endoxifen binds to and disrupts protein kinase C beta one function (PKC β 1, a known oncogenic protein)
- The National Cancer Institute (NCI) and others have studied (Z)-endoxifen and have demonstrated promising results in the treatment of breast cancer as well as for the treatment of other solid tumors
- Treatment with (Z)-endoxifen may avoid off target effects of tamoxifen and remaining metabolites potentially increasing adherence by improving safety profile



(1) Source: National Center for Biotechnology Information – “Endoxifen and fulvestrant regulate estrogen-receptor α and related DEADbox proteins”
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7774761/>

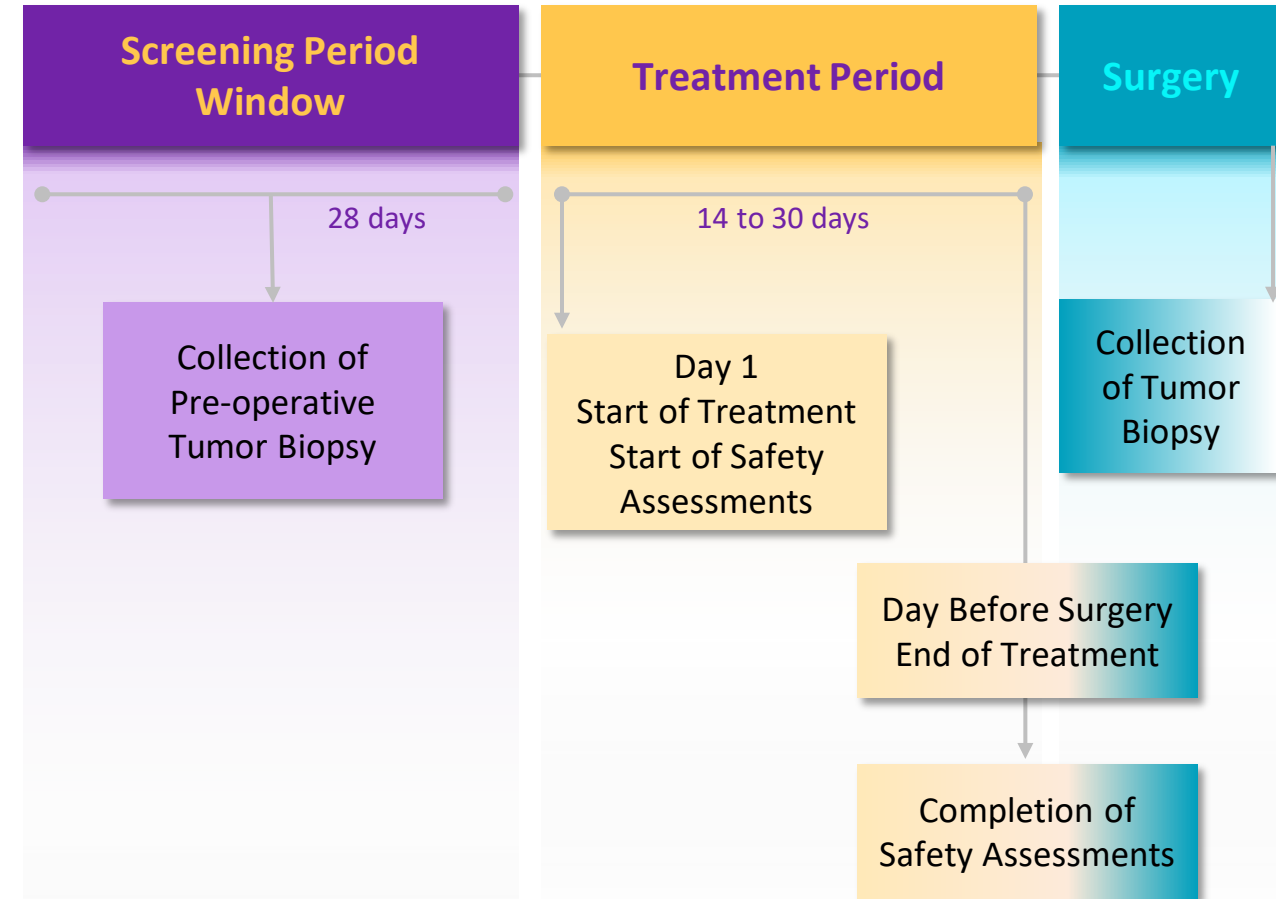
- Atossa has a patented (Z)-endoxifen chemical process and composition of matter
 - Enhanced stability of (Z)-endoxifen on the shelf
- Atossa also has a patented oral enteric capsule formulation of (Z)-endoxifen
 - Enhanced stability following oral administration
 - Capsules of 10 mg and 40 mg are being evaluated in neoadjuvant setting
- Atossa's (Z)-endoxifen has been studied in numerous non-clinical studies and in four completed Phase 1 or 2 studies at doses of 1 mg/day to 4 mg/day with an acceptable safety profile



(Z)-endoxifen – Successful Phase 2 Study in AUS

Phase 2 Open Label Study Of (Z)-endoxifen In Patients With Invasive Breast Cancer (WoO Study)

- Population: ER+, HER2- invasive breast cancer requiring lumpectomy or mastectomy
- Daily oral dosing – time period between diagnosis and surgery
 - 6/7 pts had 65% reduction in Ki-67 and 7/7 <25% Ki-67 at surgery
- No adverse safety signals or laboratory findings
- Favorable results allowed early termination in Feb. 2021



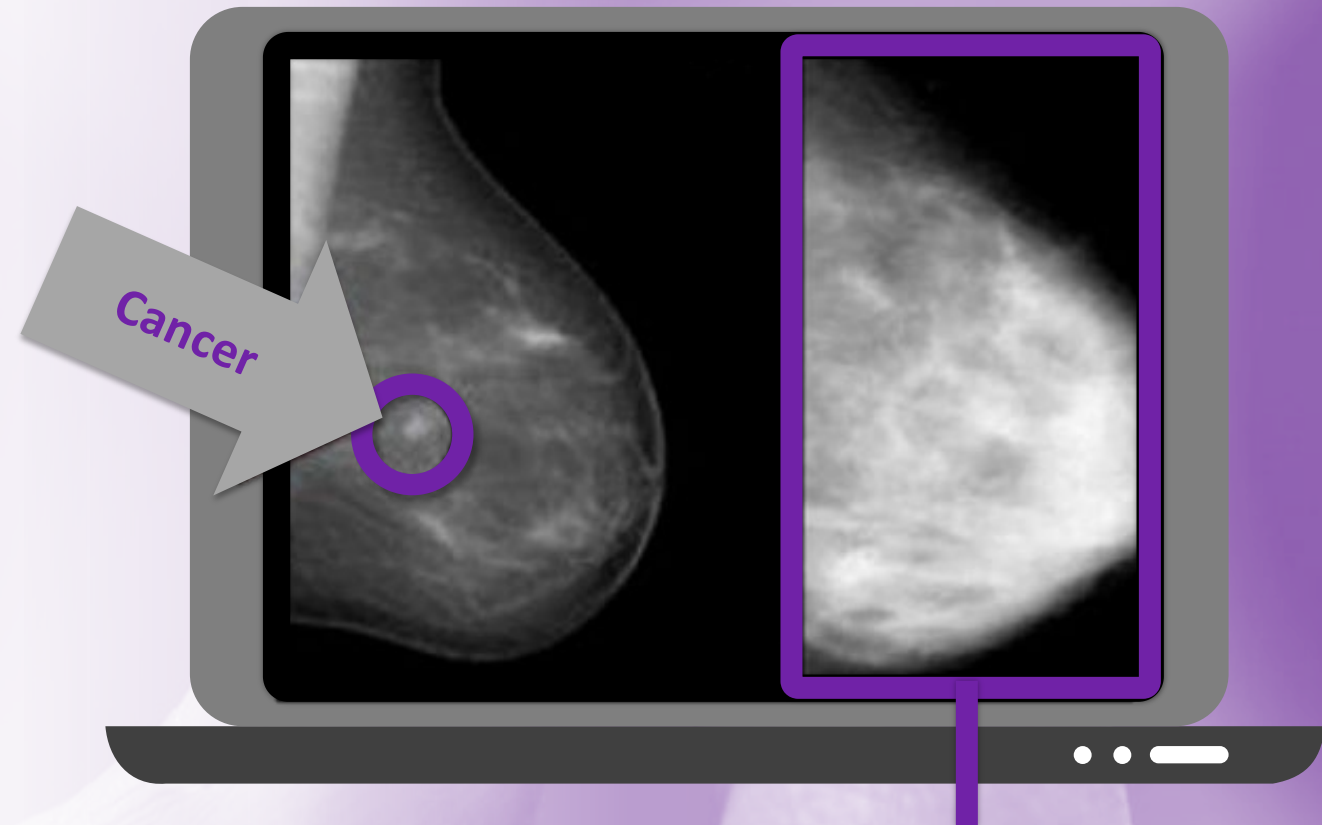
- Open-label, randomized, Phase 2 study in premenopausal women with Grade 1 or 2 ER+/HER2- breast cancer – first patient was enrolled in February 2023
- Subjects are enrolled with the intent of surgical treatment in the involved breast(s) after completing neoadjuvant study treatment
- Expected to enroll approximately 175 patients at up to 25 sites across the United States
- Primary objective is to evaluate the endocrine sensitive disease rate, measured by Ki-67 compared to treatment with current standard of care
- Current SOC includes medication given to block the ovaries from making estrogen, which in premenopausal women is associated with significant morbidity and inadequate compliance, which compromises efficacy and increases the risk of mortality

- Ground-breaking platform trial for neoadjuvant treatment of locally advanced breast cancer
- (Z)-endoxifen is being evaluated in the Endocrine Optimization Pilot Protocol targeting patients with newly diagnosed ER+ invasive breast cancer for whom chemotherapy is expected to provide little or no benefit
- These patients have substantial risk for recurrence
- Approximately 20 patients will be treated with (Z)-endoxifen for up to 24 weeks prior to surgery
- Enrolling patients at all 41 I-Spy sites across the United States

(Z)-endoxifen Phase 2 Study in Stockholm

- Being conducted in Stockholm by So. Gen. Hospital – Per Hall, M.D., Ph.D., Head of the Department of Medical Epidemiology and Biostatistics at Karolinska Institute
- Primary objective – PD study to determine the dose-response relationship of daily endoxifen on MBD reduction
- Randomized, double-blinded and placebo-controlled
- 240 pre-menopausal women with measurable MBD dosed for six months
- Full enrollment expected by the end of 2023

Mammograms need help!



MBD Can Mask Tumors

BREAST CANCER PATIENT:

- 51 y/o premenopausal woman
- ER+, PR+, Her-2-
- CYP2D6*4/*4, a non-functioning variant
- >36 months of treatment pre- and post-surgery
- Cancer-free by clinical assessment

PROGRAM

OPPORTUNITY

Neoadjuvant / Window of Opportunity

200k
ER+ Breast Cancers/Yr. in U.S.⁽¹⁾

Mammographic Breast Density

39M/yr.
Mammograms/10M High MBD in U.S.
(BI-RAD C/D)⁽²⁾

(1) American Cancer Society; WebMD: Types of Cancer

(2) Nat'l Cancer Inst.: Prevalence of Mammographically Dense Breasts in the United States; NYU Langone: Combination of Artificial Intelligence & Radiologists More Accurately Identified Breast Cancer; Nat'l Cancer Inst.

CORPORATE / INVESTORS:

Kyle Guse, CFO and General Counsel

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NASDAQ: ATOS

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