

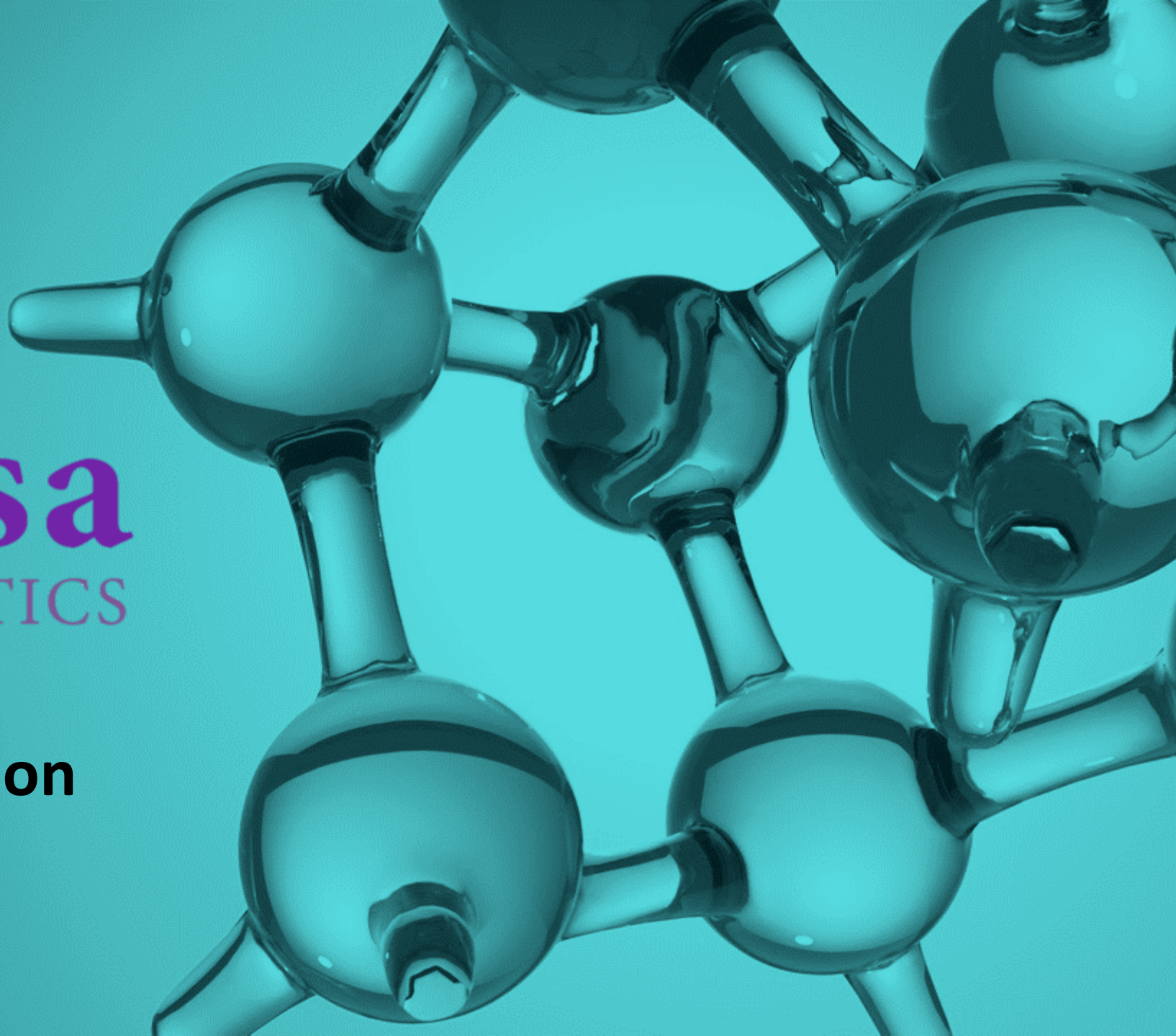


**Atossa**  
THERAPEUTICS

**Investor Presentation**  
**September 2023**

**NASDAQ: ATOS**

[www.atossatherapeutics.com](http://www.atossatherapeutics.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. These statements, which Atossa undertakes no obligation to update, are subject to risks and uncertainties that may cause actual results, outcomes, or the timing of actual results or outcomes, to differ materially from those projected or anticipated, including risks and uncertainties associated with: macroeconomic conditions and increasing geopolitical instability; the expected timing of releasing data; any variation between interim and final clinical results; actions and inactions by the FDA and foreign regulatory bodies; the outcome or timing of regulatory approvals needed by Atossa, including those needed to continue our planned (Z)-endoxifen trials; our ability to satisfy regulatory requirements; our ability to successfully develop and commercialize new therapeutics; the success, costs and timing of our development activities, including our ability to successfully initiate or complete our clinical trials, including our (Z)-endoxifen trials; our anticipated rate of patient enrollment; our ability to contract with third-parties and their ability to perform adequately; our estimates on the size and characteristics of our potential markets; our ability to successfully defend litigation and other similar complaints and to establish and maintain intellectual property rights covering our products; whether we can successfully complete our clinical trial of oral (Z)-endoxifen in women with mammographic breast density and our trials of (Z)-endoxifen in women with breast cancer, and whether the studies will meet their objectives; our expectations as to future financial performance, expense levels and capital sources, including our ability to raise capital; our ability to attract and retain key personnel; our anticipated working capital needs and expectations around the sufficiency of our cash reserves; and other risks and uncertainties detailed from time to time in Atossa's filings with the Securities and Exchange Commission, including without limitation its Annual Reports on Form 10-K and Quarterly Reports on 10-Q. Forward-looking statements are presented as of the date of this presentation. Except as required by law, we do not intend to update any forward-looking statements, whether as a result of new information, future events or circumstances or otherwise.

# LEADERSHIP



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



**Greg Weaver**  
*Chief Financial Officer*



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



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



**Heather Rees, CPA**  
*VP, Finance and Accounting*



**Delly Behen, PHR, SHRM-CP**  
*VP, Admin and HR*





- Lead compound, (Z)-endoxifen being investigated in multiple ongoing and completed Phase 2 trials for breast cancer / breast conditions
- Deep intellectual property portfolio
- Large, unaddressed / underserved market opportunities in prevention and treatment settings
- \$99M cash at 6/30/23, three-year operating runway
- Experienced management team with extensive life sciences background
- World class R&D collaborators

# THE BREAST CANCER PROBLEM

---

**40% - 50%**

of women have dense  
breasts<sup>1</sup>

**1 in 8**

women experience  
breast cancer<sup>2</sup>

**298,000**

women diagnosed in  
US annually<sup>2</sup>

**78%**

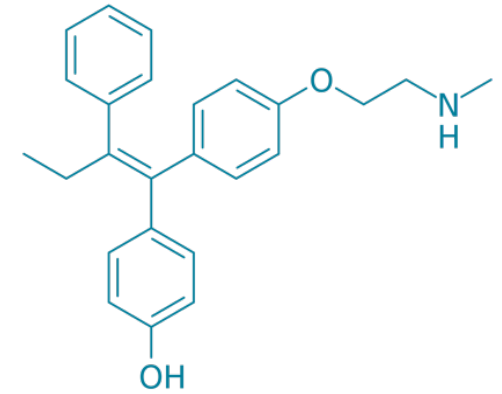
of US Breast cancer  
is ER+<sup>2</sup>

(1) Sprague BL, Gangnon RE, Burt V, et al. Prevalence of mammographically dense breasts in the United States. J Natl Cancer Inst. 106(10), 2014.

(2) American Cancer Society, Inc.

# NOVEL SERM, DE-RISKED, STRONG IP

- **(Z)-endoxifen:**
  - Competitive inhibitor of ER $\alpha$  and represses ER $\alpha$  transcriptional activity
  - 100-fold more potent in anti-estrogen activity compared to other SERMs(1)
  - Binds to and disrupts protein kinase C beta one function (PKC $\beta$ 1, a known oncogenic protein)
- **De-risked**
  - The National Cancer Institute (NCI) and others have demonstrated promising results in the treatment of breast cancer and other solid tumors
  - Studied in numerous non-clinical studies and in four completed Ph1 or 2 studies at various doses with an acceptable safety profile
- **May have improved safety profile**
  - Opportunity to avoid ovarian function suppression and off target effects associated with tamoxifen and remaining metabolites, may potentially increasing adherence
- **Strong IP**
  - Patented (Z)-endoxifen chemical process and composition of matter → enhanced stability of (Z)-endoxifen on the shelf
  - Patented oral enteric capsule formulation of (Z)-endoxifen → enhanced stability following oral administration
  - Patented suspension formulation of (Z)-endoxifen → enhanced ease of delivery, increased bioavailability of drug dosage



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

# FUNDED R&D COLLABORATORS



**Per Hall, M.D., PhD**  
Karisma Principal Investigator



**Laura Esserman, M.D., MBA**  
I-Spy Principal Investigator



**Matthew Goetz, M.D.**  
*EVANGELINE* Principal Investigator



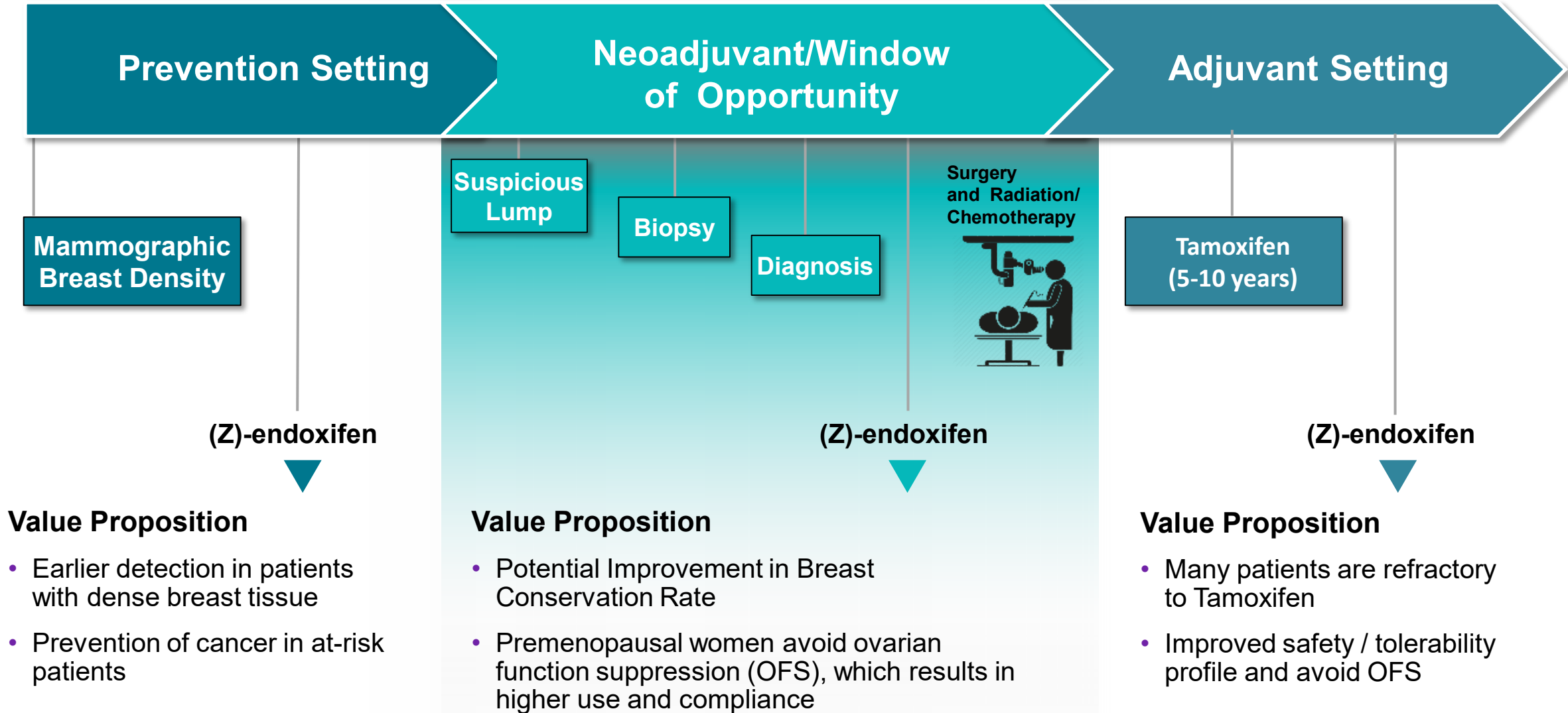
**David Lyden, M.D., PhD**  
*TNBC Research Lead*



**Kaitlyn Andreano, PhD**  
*Consultant*

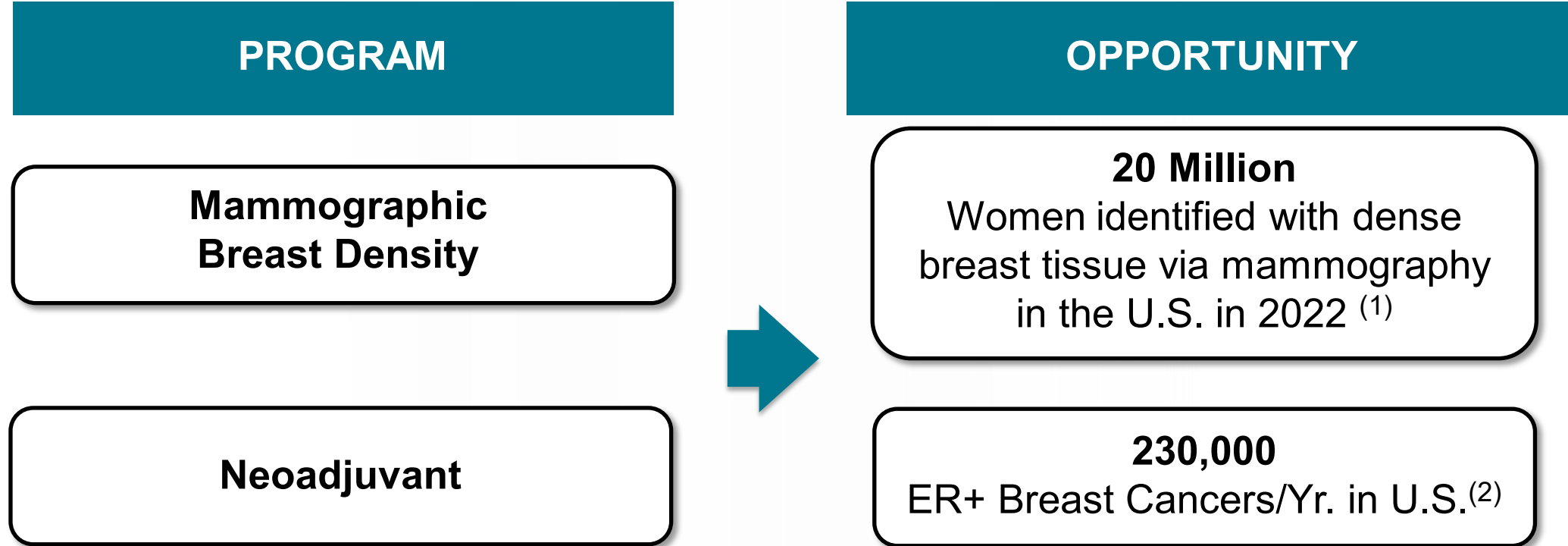


# CLINICAL POSITIONING IN BREAST CANCER





# LARGE MARKET OPPORTUNITIES

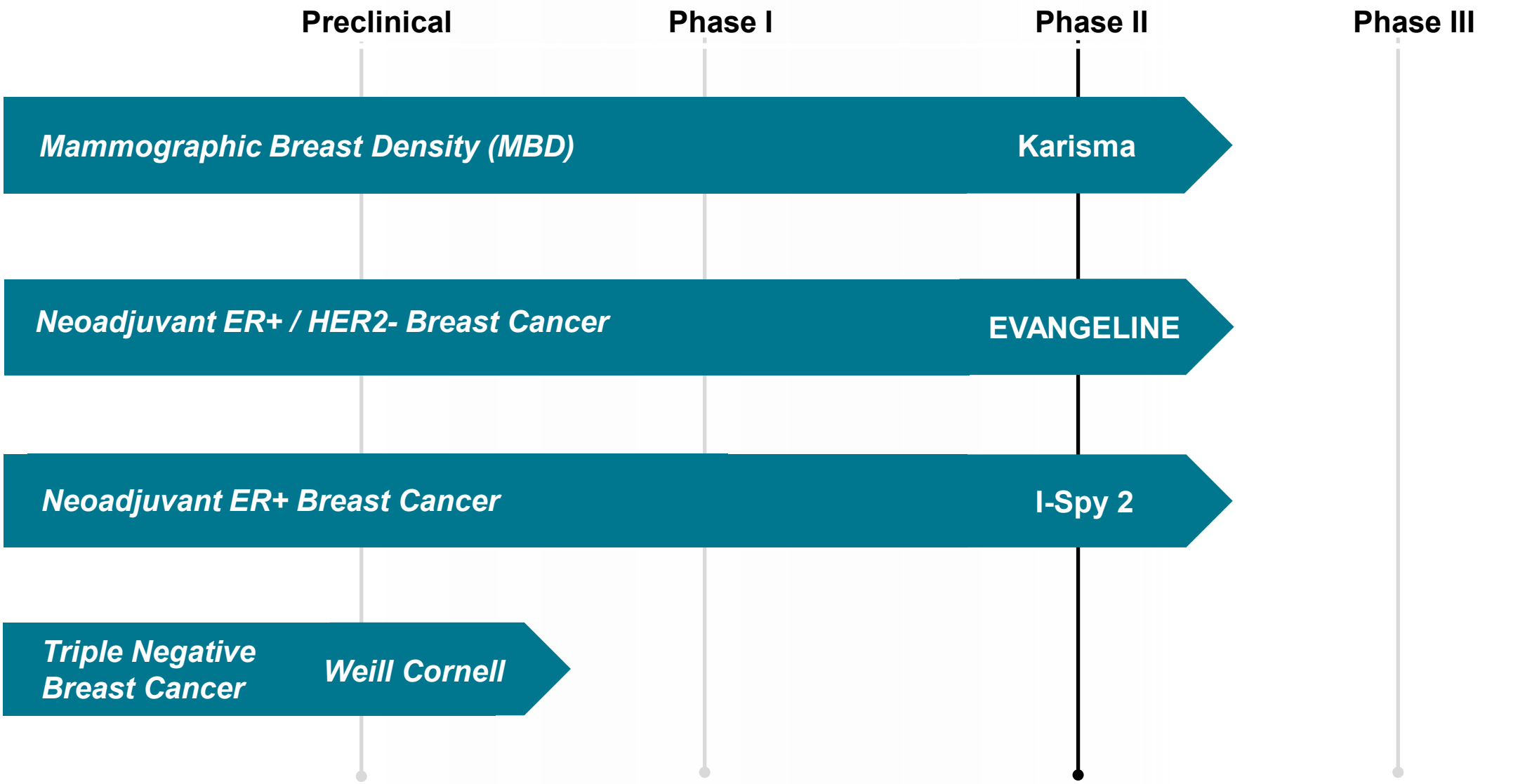


(1) National Cancer Institute: Dense Breasts: Answers to Commonly Asked Questions and Centers for Disease Control and Prevention: National Center for Disease Statistics

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

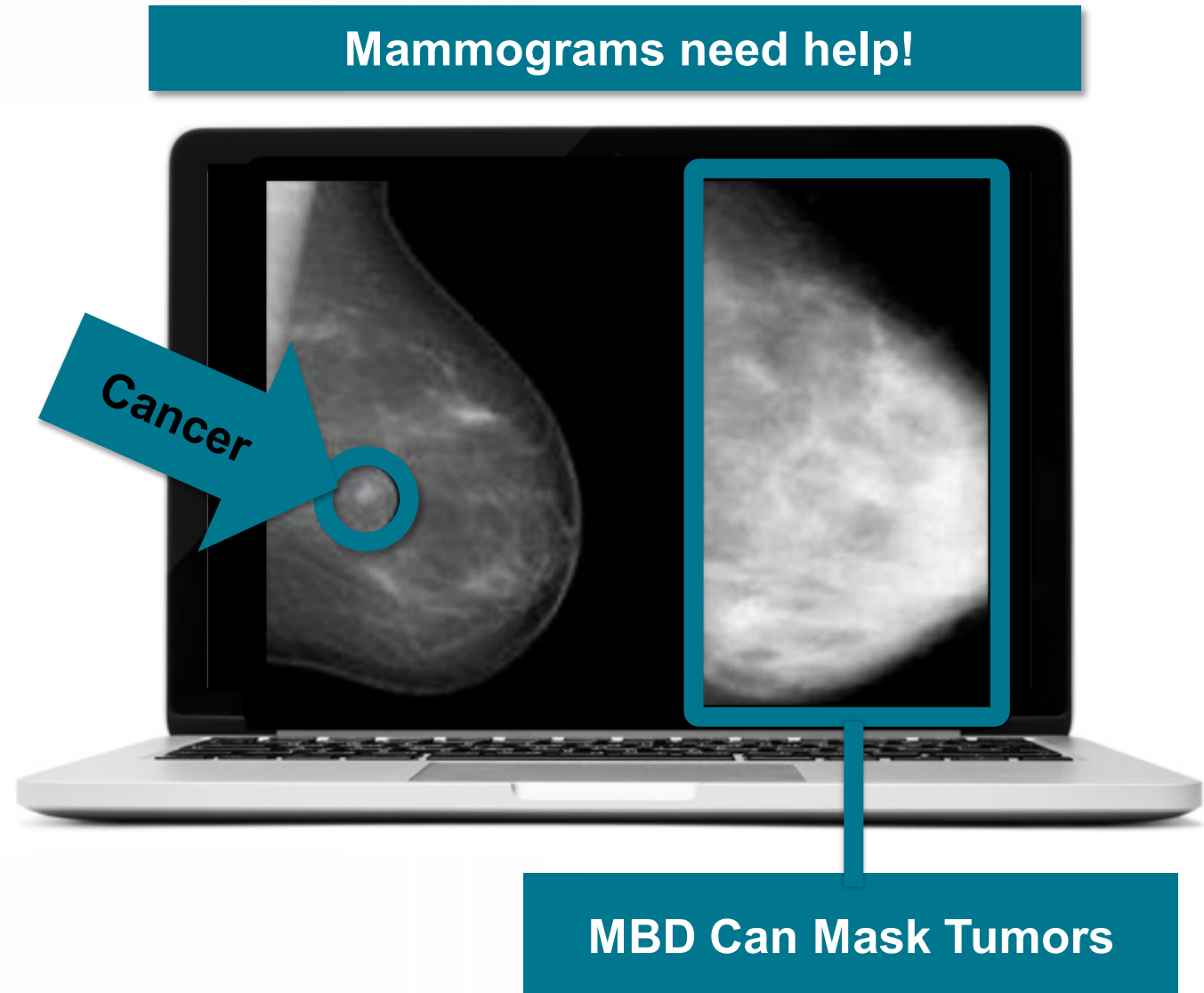
# CLINICAL DEVELOPMENT PIPELINE

## Breast Cancer Program – (Z)-endoxifen



# KARISMA-ENDOXIFEN PHASE 2 MBD STUDY

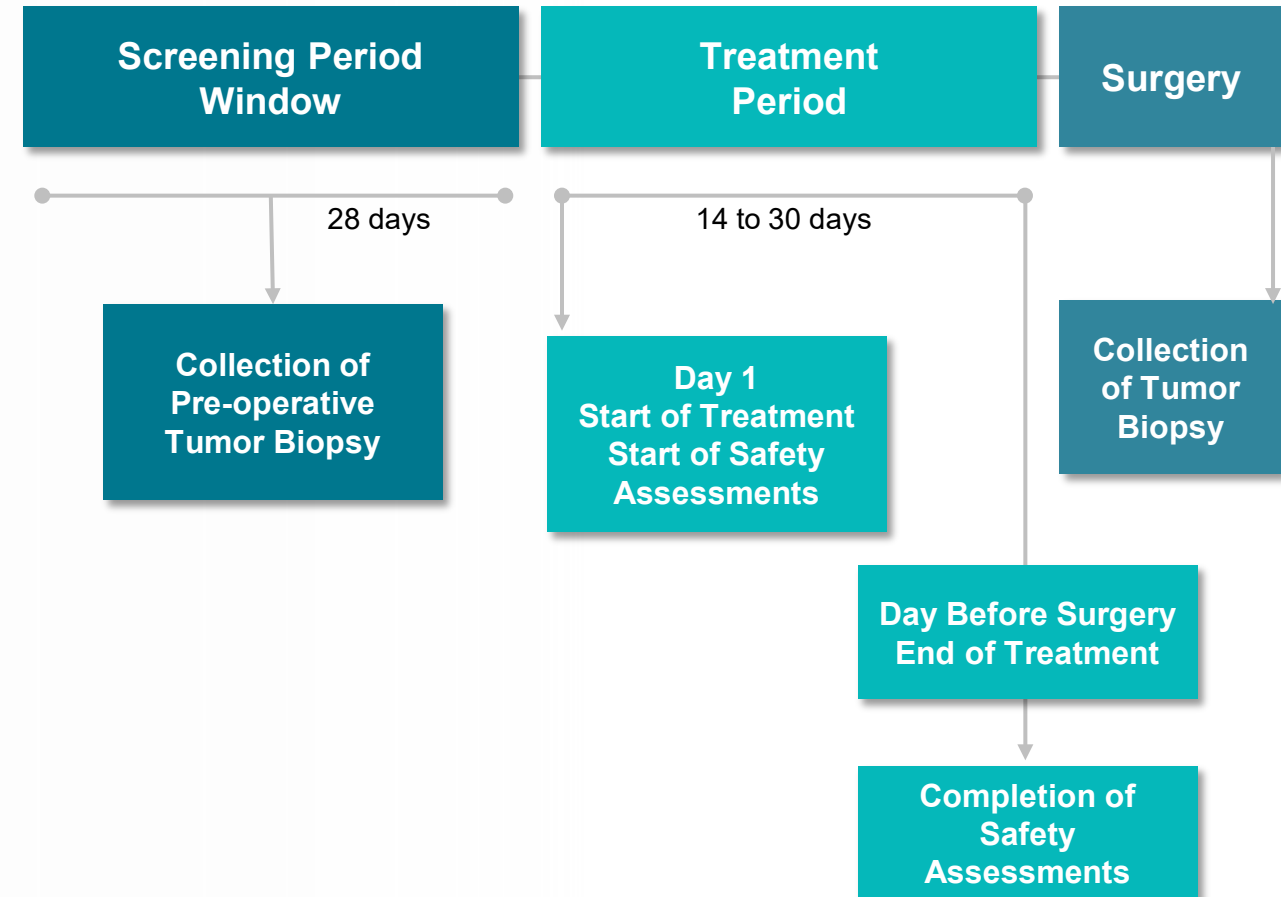
- Ongoing study in Stockholm by So. Gen. Hospital – Per Hall, M.D., Ph.D., Head of the Department of Medical Epidemiology and Biostatistics at Karolinska Institute
- Primary objective – determine the dose-response relationship of (Z)-endoxifen on MBD reduction
- Randomized, double-blinded and placebo-controlled
- 240 pre-menopausal women with measurable MBD dosed for six months
- Six-month efficacy data expected Q3 2024
- Patients followed for 24 months to assess durability of density reduction



# (Z)-ENDOXIFEN – SUCCESSFUL PHASE 2 STUDY

## Phase 2 Open Label Study Of (Z)-endoxifen in Australia

- Population: ER+, HER2- invasive breast cancer requiring lumpectomy or mastectomy
- Daily oral dosing in 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
- Early termination in February 2021 based on substantially positive results



***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***

- Ongoing study led by Matthew Goetz, M.D., Principal Investigator, Mayo Clinic Breast Cancer Specialized Program of Research Excellence
- Expected to enroll approximately 175 patients at up to 25 sites across the United States and Canada
- Primary objective is to evaluate the endocrine sensitive disease rate, measured by Ki-67 compared to treatment with current standard of care
- Current standard of care includes aromatase inhibitor plus medication given to block the ovaries from making estrogen, which in some premenopausal women is associated with significant morbidity and inadequate compliance
- Multiple secondary efficacy endpoints including biomarkers and MRI to measure tumor shrinkage



## ***Ground-breaking platform trial for neoadjuvant treatment of locally advanced breast cancer***

- Ongoing study led by Laura Esserman, M.D., MBA, Director of the Carol Franc Buck Breast Care Center at the University of California, San Francisco School of Medicine.
- (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
- 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
- Full enrollment expected in Q1 2024 with data in Q3 2024

## ***Studying the potential of inducing estrogen receptor (ER) expression in triple-negative breast cancer (TNBC) – kicked off in July 2023***

- Led by David Lyden, M.D., Ph.D., the Stavros S. Niarchos Professor in Pediatric Cardiology and Director of the Department of Pediatrics' Physician Scientist Training Program at Weill Cornell Medicine
- TNBC tends to grow and spread faster, has fewer treatment options, has a higher risk of recurrence, and tends to have a worse prognosis compared to other types of breast cancer
- Goal of research is to determine if treating TNBC with extracellular vesicles carrying the ER will convert the tumor to ER+ and render it sensitive to treatment with (Z)-endoxifen
- Converting the cancer phenotype to ER+ would fundamentally transform the treatment approach and outlook for these patients

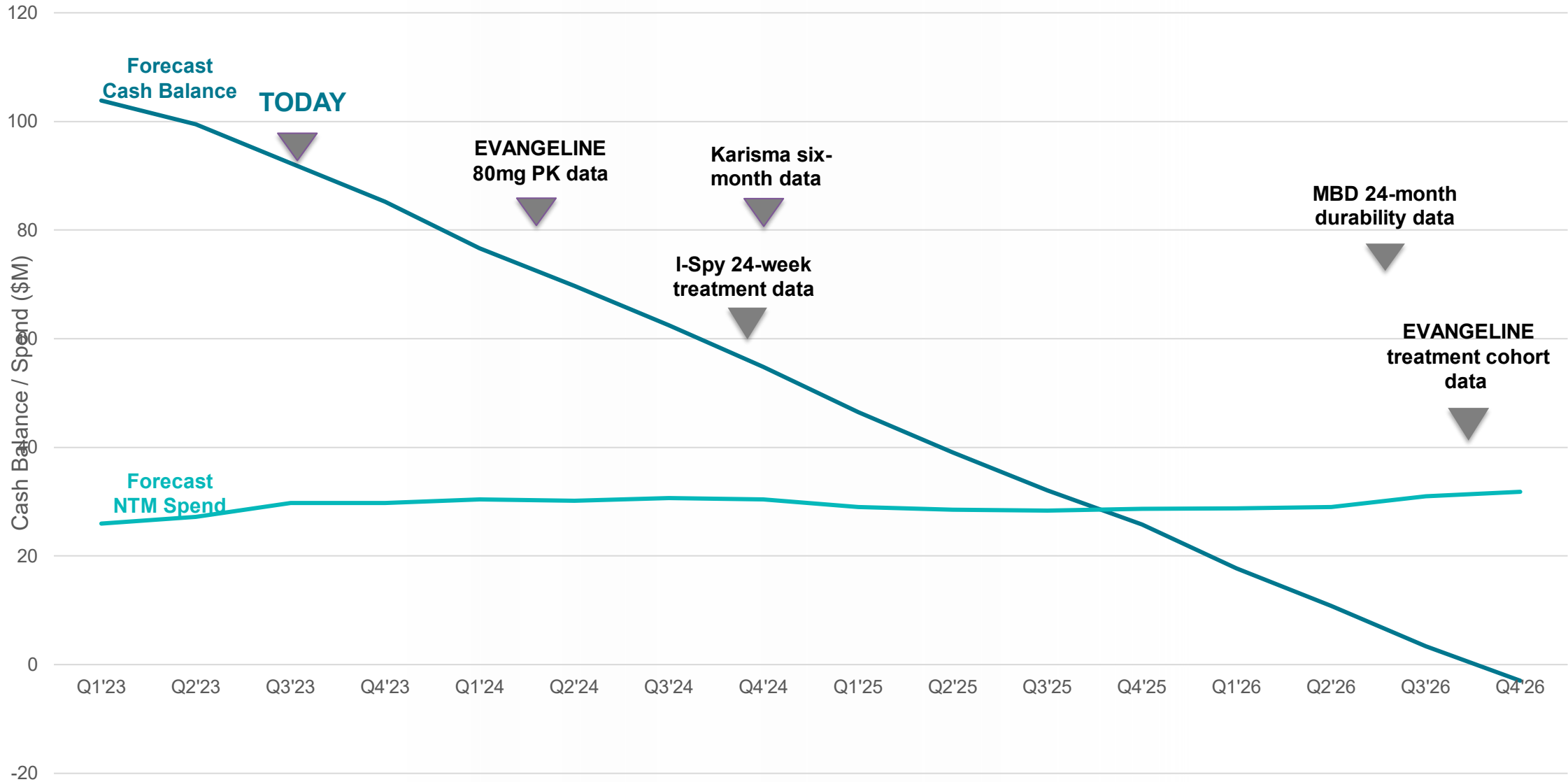
## 2023 YTD

- Mammographic Breast Density study 70% enrolled
- I-Spy study 30% enrolled
- Completed EVANGELINE 40mg PK run-in cohort
- Secured enteric capsule and suspension formulation patents
- Established research program with Weill Cornell Medicine

## Near Term Catalysts

- Mammographic Breast Density
  - Complete enrollment Q4 '23
  - Six-month data available 2H '24
- I-Spy
  - Complete enrollment Q1 '24
  - Data available Q3 '24
- EVANGELINE
  - Initiate 80mg PK run-in Q3 '23
  - Complete 80 mg PK run-in Q1 '24
  - Initiate treatment arm – Q2 '24

# MILESTONES and CASH RUNWAY





# Atossa

THERAPEUTICS

**CONTACT:**

Eric Van Zanten, VP, Investor and Public Relations

[eric.vanzanten@atossainc.com](mailto:eric.vanzanten@atossainc.com)

**NASDAQ: ATOS**

[www.atossatherapeutics.com](http://www.atossatherapeutics.com)

