



# CORPORATE PRESENTATION

FEBRUARY 26, 2019

NASDAQ: ATOS

[WWW.ATOSSAGENETICS.COM](http://WWW.ATOSSAGENETICS.COM)

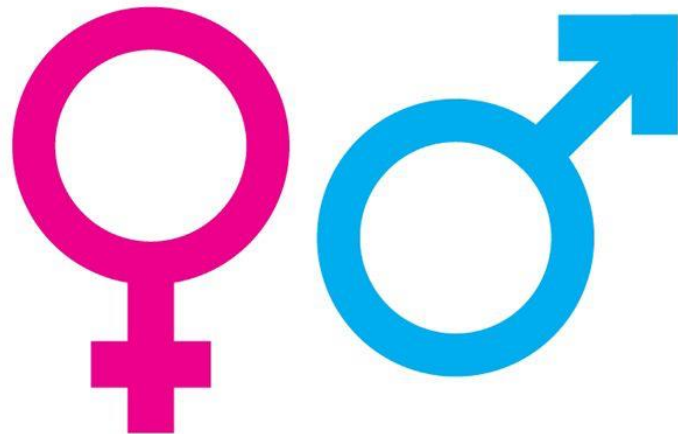
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Some of the information presented herein may contain projections or other forward-looking statements regarding future events or the future financial performance of the Company which the Company undertakes no obligation to update. These statements are 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 including failure to approve commencement of studies, 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 (the "SEC"), 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.

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## Atossa Genetics (NASDAQ: ATOS)

- Clinical-stage company
- Novel pharmaceuticals
- Novel drug delivery methods
- Breast cancer, gynecomastia & other breast conditions



## Seasoned 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*

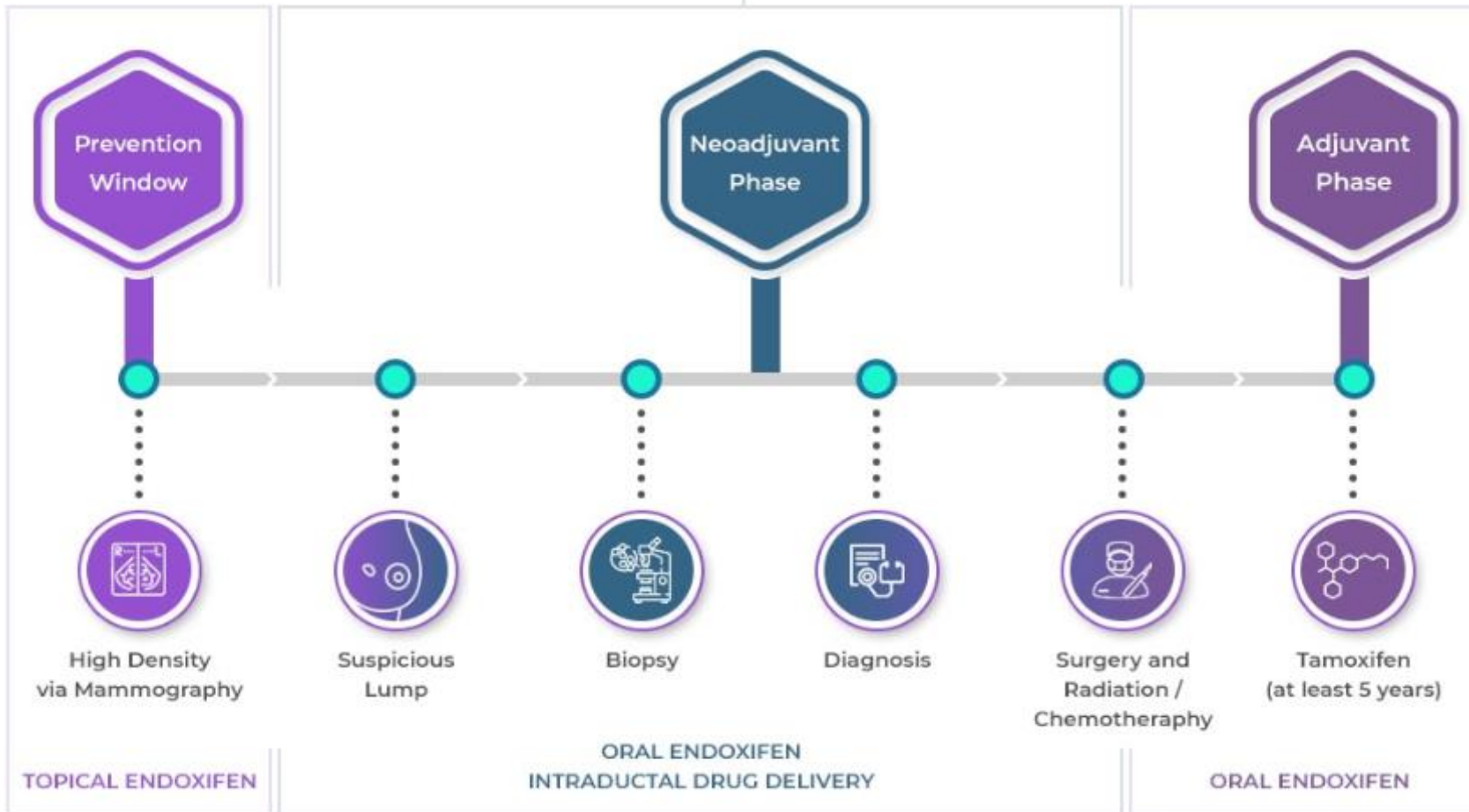
# Corporate Summary

|   |   |
|---|---|
| Issuer:                                 | Atossa Genetics Inc. (NASDAQ: ATOS)   |
| Our Mission:                            | Develop novel pharmaceuticals and delivery systems to treat breast cancer and other breast conditions   |
| Debt Sept. 30, 2018:                    | None  |
| Cash Sept. 30, 2018:                    | \$13M   |
| Capital Structure<br>February 26, 2019: | 6.2M shares common stock<br>350k shares preferred stock, as converted basis<br>3.9M warrants exercisable at \$4.05/share<br>784k options exercisable at \$12.70/share<br>3.1M conditional options exercisable at \$1.36 |
| Corporate HQ:                           | Seattle, Washington   |

## Development Summary

- Three Phase 2 studies underway (one fully enrolled)
- Two Phase 1 studies completed with all objectives met
- Up to two additional Phase 2 studies planned
- R&D program in immuno-oncology (CAR-T)

**BREAST CANCER TIMELINE**



| Program                        | Product     | Preclinical                           | Phase 1       | Phase 2                                      | Phase 3 | NDA/MAA (Target) | Commercial |
|--------------------------------|-------------|---------------------------------------|---------------|--|---------|------------------|------------|
| Intraductal/<br>Microcatheters | Fulvestrant |                                       |               | Fulvestrant Study (I.S) - DCIS/Breast Cancer |         |                  |            |
|                                | CAR-T       | Model development/<br>study execution |               |  |         |                  |            |
| Endoxifen                      | Topical     |                                       | Females (AUS) | Mammographic Breast Density (Sweden)         |         |                  |            |
|                                |             |                                       | Males (AUS)   | Gynecomastia (TBD)                           |         |                  |            |
|                                | Oral        |                                       | Females (AUS) | Window of Opportunity (Pre-surgery) (AUS)    |         |                  |            |
|                                |             |                                       |               | Refractory-Endoxifen supplementation (TBD)   |         |                  |            |

|  |                |
|--|----------------|
|  | N/A            |
|  | In-progress    |
|  | Completed      |
|  | Planning Stage |



# Large Market Opportunities

| Program                               | Opportunity  |
|---------------------------------------|--|
| Topical Endoxifen                     | 10M High MBD (BI-RAD C/D) <sup>(1)</sup><br>10M Gynecomastia (25% of all 50-69 yrs) <sup>(2)</sup> |
| Oral Endoxifen                        | 1M ER <sup>+</sup> Survivors/5 Yrs <sup>(3)</sup><br>200k ER <sup>+</sup> Breast Cancers/Yr. U.S.  |
| Intraductal - Fulvestrant             | \$800M U.S. sales for pre-surgery and surgery replacement therapy <sup>(4)</sup>                   |
| Intraductal - Immuno-oncology (CAR-T) | 35K Triple Negative Breast Cancers/Yr. <sup>(5)</sup>  |

- (1) Nat'l Cancer Inst.: Prevalence of Mammographically Dense Breasts in the United States (Retrieved from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC420066/>)
- (2) Mayo Clinic (retrieved from: <https://www.mayoclinic.org/diseases-conditions/gynecomastia/symptoms-causes/syc-20351793>)
- (3) American Cancer Society, Inc: <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2018/estimated-number-of-new-cancer-cases-and-deaths-by-sex-us-2018.pdf>. See also Nat'l Cancer Inst.: <https://www.cancer.gov/types/breast/breast-hormone-therapy-fact-sheet>
- (4) Data from Defined Health: SERM Report January 2017
- (5) Data from Breastcancer.org (Retrieved from: <http://www.breastcancer.org/diagnosis/tripneg/behavior>)

# The Unmet Need

Topical Endoxifen for MBD - No FDA-approved treatment

Oral Endoxifen for Refractory

- Up to 500k tamoxifen patients have low Endoxifen<sup>(1, 2)</sup>
- Tamoxifen delay (50-200 days)<sup>(3)</sup>

Oral Endoxifen for Window of Opp'y

200K ER<sup>+</sup> BC/yr in U.S.

Gynecomastia - No FDA-approved treatment

Intraductal Microcatheters

- Provides alternative to systemic delivery, which can have:
  - Systemic adverse effects
  - Limited tumor drug level
- ATOS intraductal microcatheter technology may:
  - Increase drug to tumor ratio
  - Improve efficacy
  - Reduce toxicity
  - CAR-T cells may follow lymphatic migration of cancer

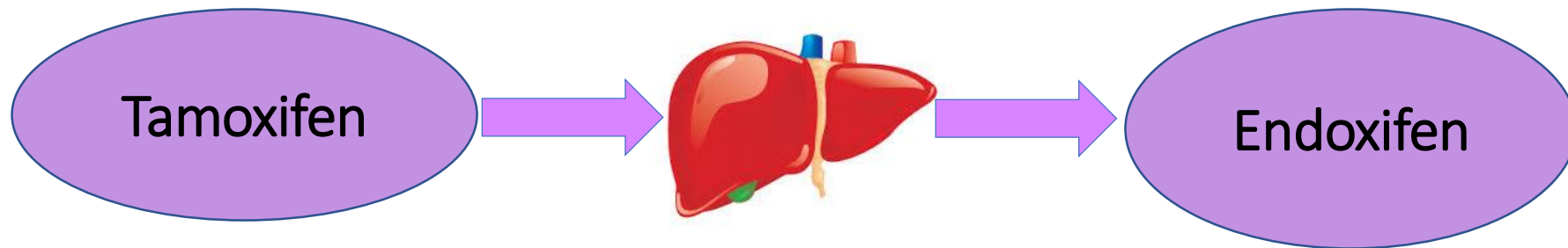
(1) Patient reluctance toward tamoxifen for breast cancer primary prevention, *Ann. Surg Oncol*, 2001 Aug 8(7):580-5

(2) Breast Care (Basel): Clinical Relevance of CYP2D6 Genetics for Tamoxifen Response in Breast Cancer (Retrieved from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2931018/>)

(3) Source: Nat'l Cancer Inst.; retrieved from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3357105/>

# Endoxifen - Overview

- Most active metabolite of tamoxifen
- Tamoxifen has been widely studied
- Tamoxifen is a pro-drug
- Up to 50% of patients can't make enough Endoxifen<sup>(1)</sup>



(1) Breast Care (Basel): Clinical Relevance of CYP2D6 Genetics for Tamoxifen Response in Breast Cancer (Retrieved from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2931018/>)

# Endoxifen – Phase 1 Completed

Two comprehensive placebo-controlled, double-blind Phase 1 studies completed: oral and topical in women (49) and topical in men (24).

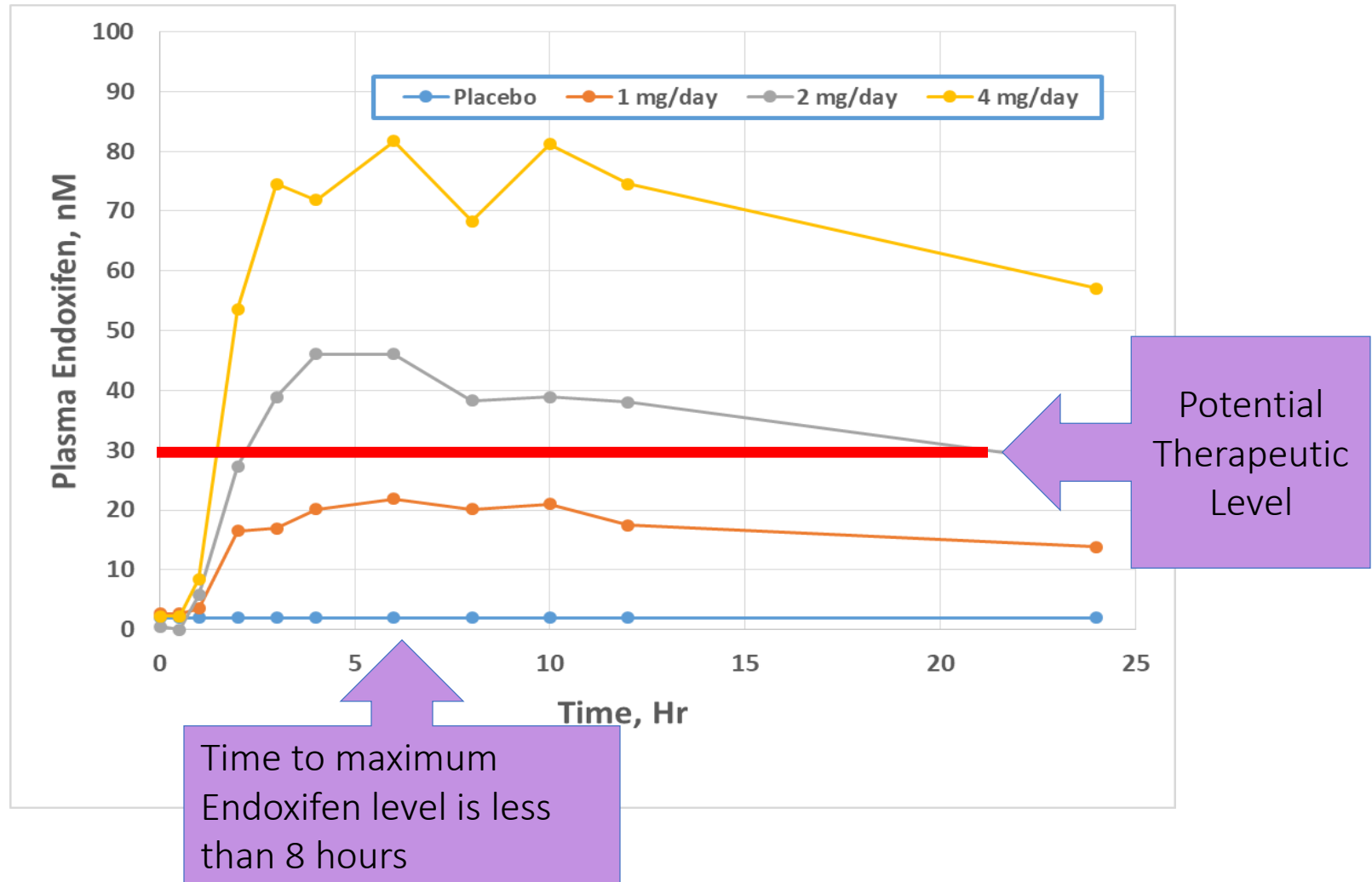
- **Safety/tolerability:** no clinically significant safety signals or adverse events. Tolerated at each dose level.
- **Pharmacokinetics:**
  - Topical – Female: crossed the skin barrier as demonstrated by low but measurable dose-dependent Endoxifen blood levels. Male: blood levels below detection limit of assay
  - Oral - blood levels at or above the therapeutic effect in the adjuvant setting.
- **Solution to Tamoxifen Delay?** Atossa oral Endoxifen reaches steady state in 7 days vs. 50-200<sup>(1)</sup> for Tamoxifen. BC tumors can double in size in 29 days.<sup>(2)</sup>

(1) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3357105/>

(2) <https://breast-cancer-research.biomedcentral.com/articles/10.1186/bcr2092>

# Endoxifen Phase 1, cont.

## Single Dose Oral Pharmacokinetics



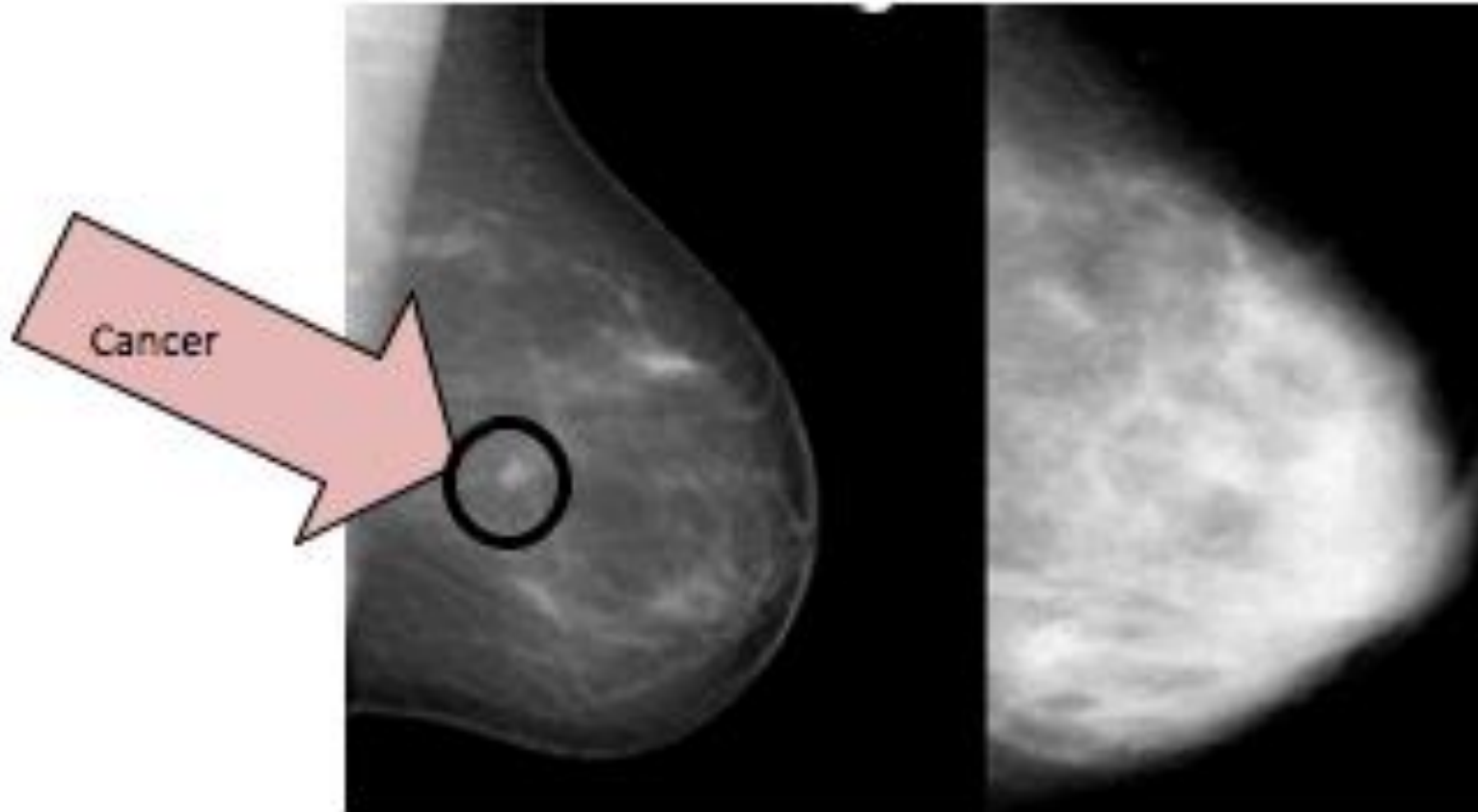
## Topical Endoxifen – Phase 2 for MBD

- Phase 2 study to reduce MBD now fully enrolled in Stockholm, Sweden
- 90 subjects post-menopausal, placebo controlled, double blind
- Some discontinuing study based on skin reactions
- 6 months of daily topical dosing
- Mammograms at -0, 3 and 6 months
- Objectives: measure change in MBD to determine sample size for subsequent Phase 3 study



## Topical Endoxifen – Phase 2 for MBD

MBD can mask tumors



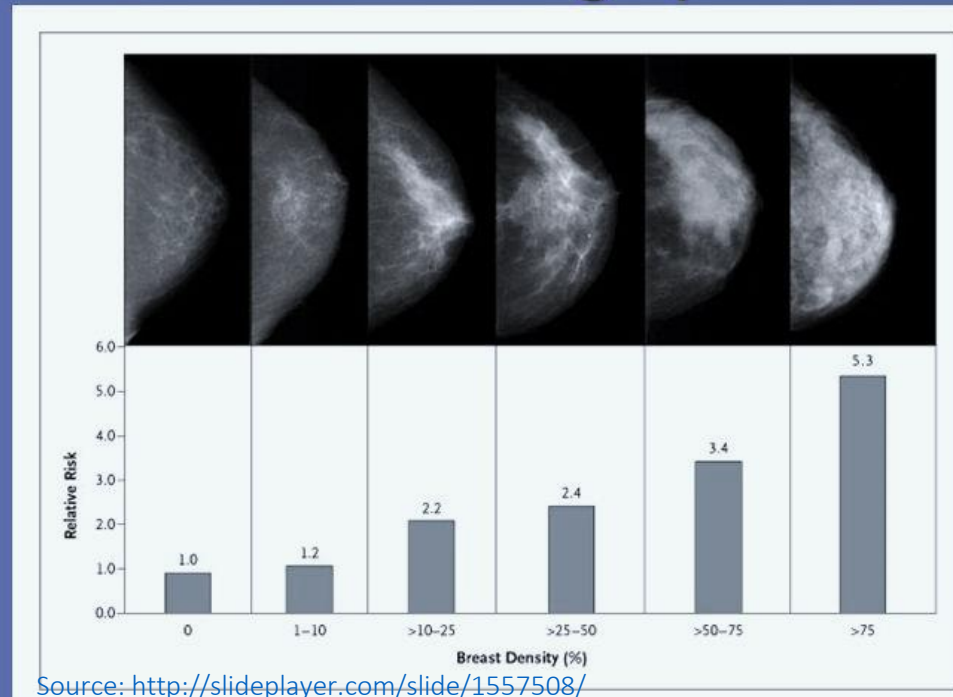
**Fatty Breast**

**Dense Breast**

Source: <http://woodtv.com/2015/05/11/are-you-dense-know-your-numbers/>

# Topical Endoxifen - Phase 2 for MBD

## A Newly Recognized Breast Cancer Risk Factor: Mammographic Density



Source: <http://slideplayer.com/slide/1557508/>

New Federal law requires that the FDA develop requirements that women be informed of their density



# Topical Endoxifen for Men

- Underserved markets in Gynecomastia
- Gynecomastia (breast enlargement and pain):
  - Affects 25% of men ages 50-69<sup>(1)</sup>, approx. 10m men
  - Causes: androgen deprivation therapy to treat prostate enlargement and prostate cancer; anti-anxiety medications; cancer treatments (chemotherapy), and some heart medications
  - Treatments: breast bud irradiation, compression garments and plastic surgery
  - Quality of life issues
  - No FDA-approved therapeutic
- Planning Phase 2 study

(1) Mayo Clinic (retrieved from: <https://www.mayoclinic.org/diseases-conditions/gynecomastia/symptoms-causes/syc-20351793>)

## Oral Endoxifen – Phase 2 “WOO” Study

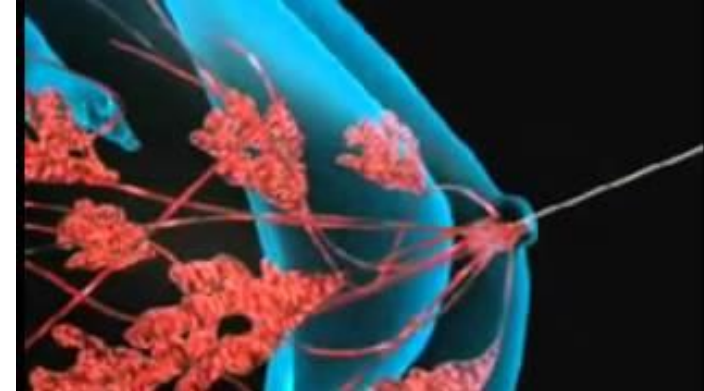
- Window of Opportunity (WOO) – time period between diagnosis and surgery.
- Being performed in Australia by CPR Pharma.
- Pilot Phase: Daily oral Endoxifen for 21 days in up to 8 ER<sup>+</sup> stage 1 or 2 patients scheduled for lumpectomy or mastectomy.
- Expansion Phase: 17 additional patients.
- Primary Endpoint: reduced tumor activity measured by Ki67.  
Secondary Endpoints: safety, tolerability and assessment of Endoxifen on expression levels of both estrogen and progesterone receptors.

## Endoxifen Regulatory Pathway

Program could qualify for designation under the 505(b)(2) status. Advantages:

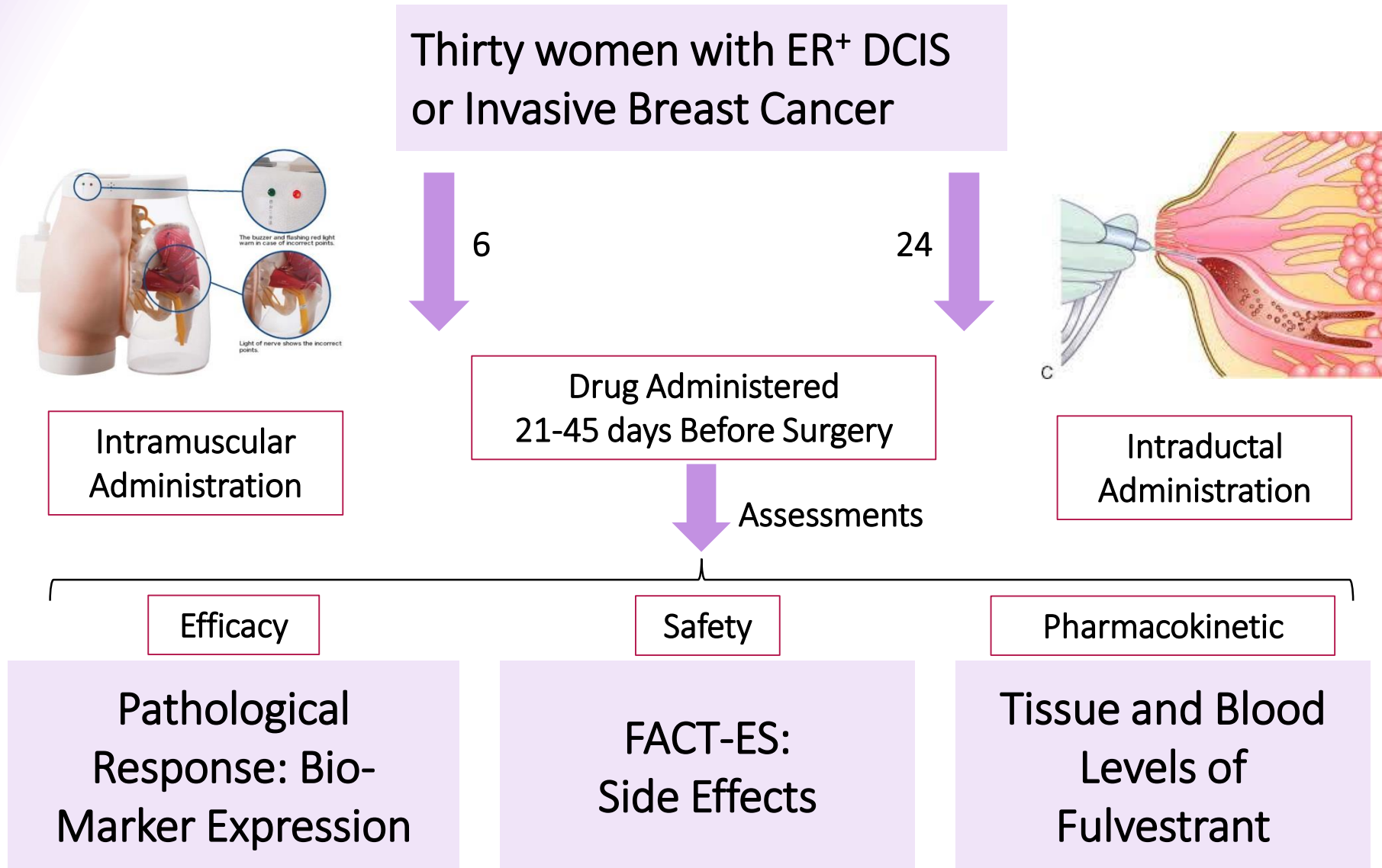
- A single clinical study of safety and efficacy
- Limited additional clinical or pre-clinical studies
- Multi-year market exclusivity possible

# Intraductal Microcatheters



- Potential advantages - higher local drug/immuno-therapy exposure; lower systemic concentrations (lower toxicity) vs systemically delivered agents; potential for lymphatic migration of T-cells
- Recent Activity - Kite Pharma acquisition by Gilead; Juno acquired by Celgene; FDA approved Novartis's Kymriah™ for B-cell Acute Lymphoblastic Leukemia
- Phase 2 study - fulvestrant for DCIS or breast cancer (Montefiore)
- Fulvestrant - FDA approved (AstraZeneca); opportunities with other drugs and immunotherapies

# Microcatheter Fulvestrant – Phase 2 Study



## Local Delivery of CAR-T/Immunotherapy for Breast Cancer

- Safety: Reduced risk of systemic complications
- Efficacy: Delivery of CAR-T cells to the site of the cancer cells. Greater CAR-T to cancer cell ratio.
- Dose: Fewer cells would be required
  - Reduced cost
  - Increased access (due to production, cost)
- Indication: Disease localized to the breast

## Upcoming Milestones

Oral Endoxifen: Planning MBD study to start Q2 '19

Topical Endoxifen:

- (1) Apr. '19: complete dosing in Phase 2 MBD study
- (2) Q2 '19: announce preliminary results from Phase 2 MBD study

TRAP CAR-T – Complete pre-clinical studies in 2019





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