



CORPORATE PRESENTATION

NOVEMBER 13, 2018

NASDAQ: ATOS

WWW.ATOSSAGENETICS.COM

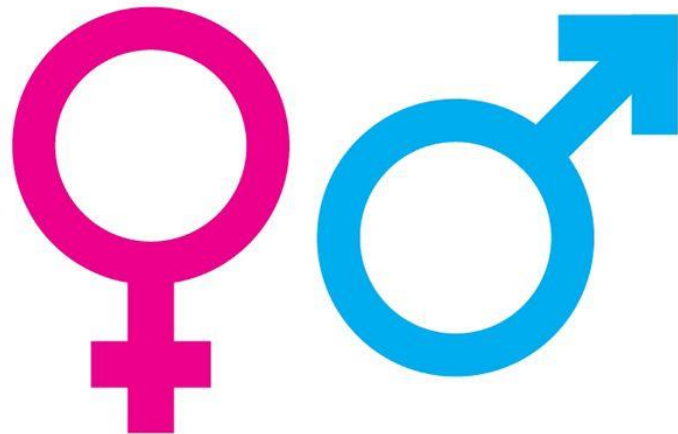
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Atossa Genetics (NASDAQ: ATOS)

- 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



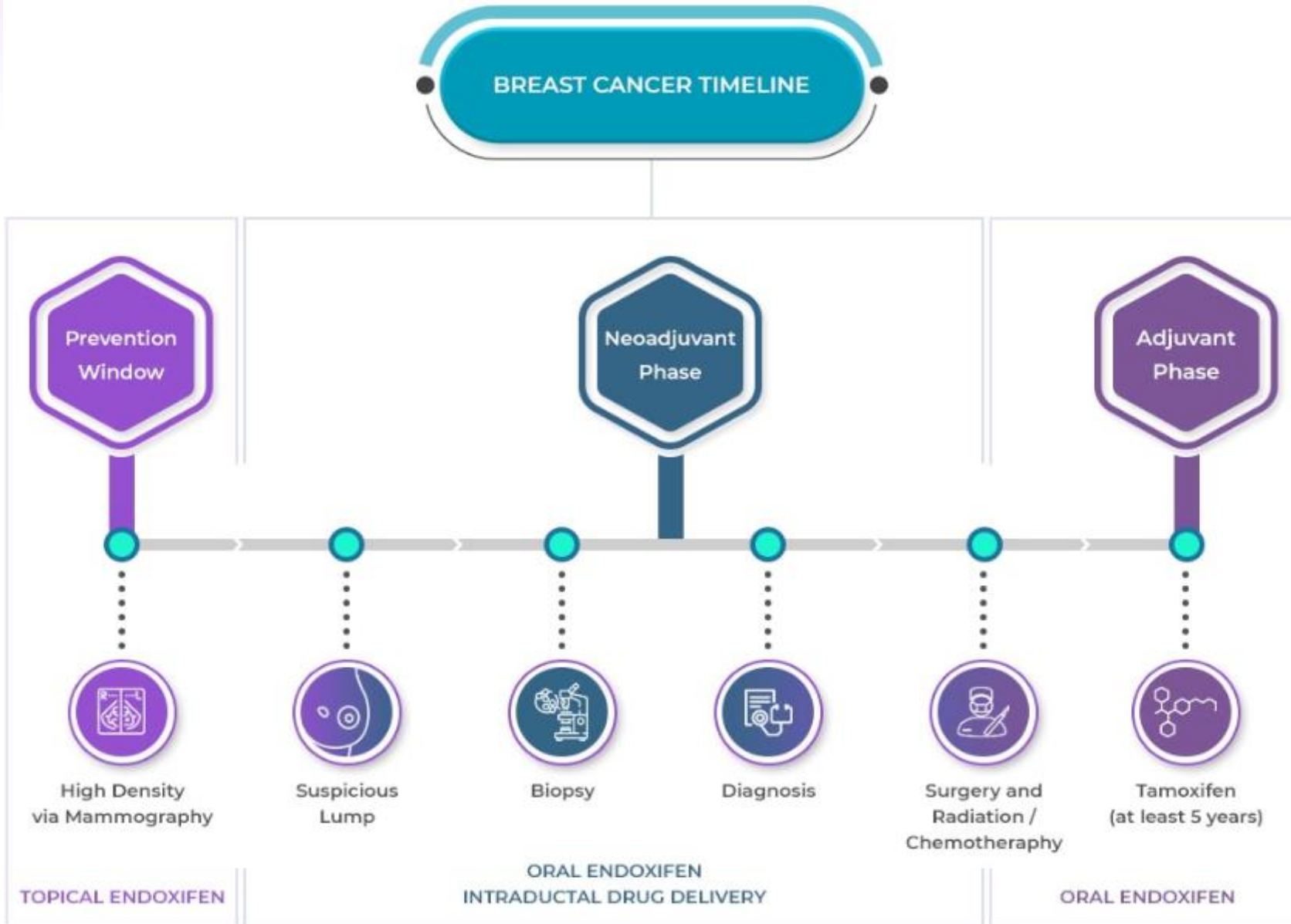
Janet R. Rea, MSPH, RAC
*SVP Regulatory,
Quality and Clinical Affairs*

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 Nov. 9, 2018:	<p>5.6M shares common stock</p> <p>896k shares preferred stock, as converted basis</p> <p>3.9M warrants exercisable at \$4.05/share</p> <p>442K warrants exercisable at \$3.78/share</p> <p>784k options exercisable at \$12.70/share</p> <p>3M options exercisable at \$2.38/share</p>
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)



Program	Product	Preclinical	Phase 1	Phase 2	Phase 3	NDA/MAA (Target)	Commercial
Intraductal/ Microcatheters	Fulvestrant			Fulvestrant Study (I.S) - DCIS/Breast Cancer			
	CAR-T	Model development/ 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) ⁽¹⁾ 10M Gynecomastia (25% of all 50-69 yrs) ⁽²⁾
Oral Endoxifen	1M ER ⁺ Survivors/5 Yrs ⁽³⁾ 200k ER ⁺ Breast Cancers/Yr. U.S.
Intraductal - Fulvestrant	\$800M U.S. sales for pre-surgery and surgery replacement therapy ⁽⁴⁾
Intraductal - Immuno-oncology (CAR-T)	35K Triple Negative Breast Cancers/Yr. ⁽⁵⁾

- (1) Nat'l Cancer Inst.: Prevalence of Mammographically Dense Breasts in the United States (Retrieved from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4200066/>)
- (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^(1, 2)
- Tamoxifen delay (50-200 days)⁽³⁾

Oral Endoxifen for Window of Opp'y

200K ER⁺ 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

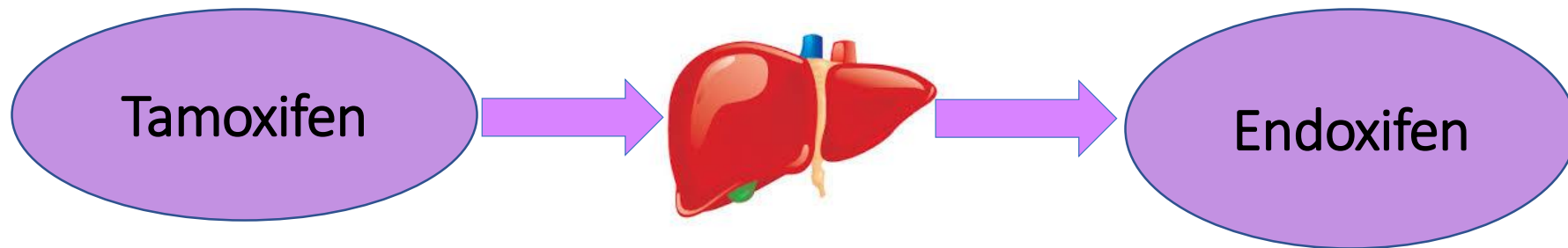
(1) Patient reluctance toward tamoxifen for breast cancer primary prevention, *Ann. Surg Oncol*, 2001 Aug 8(7):580-5

(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⁽¹⁾



(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).

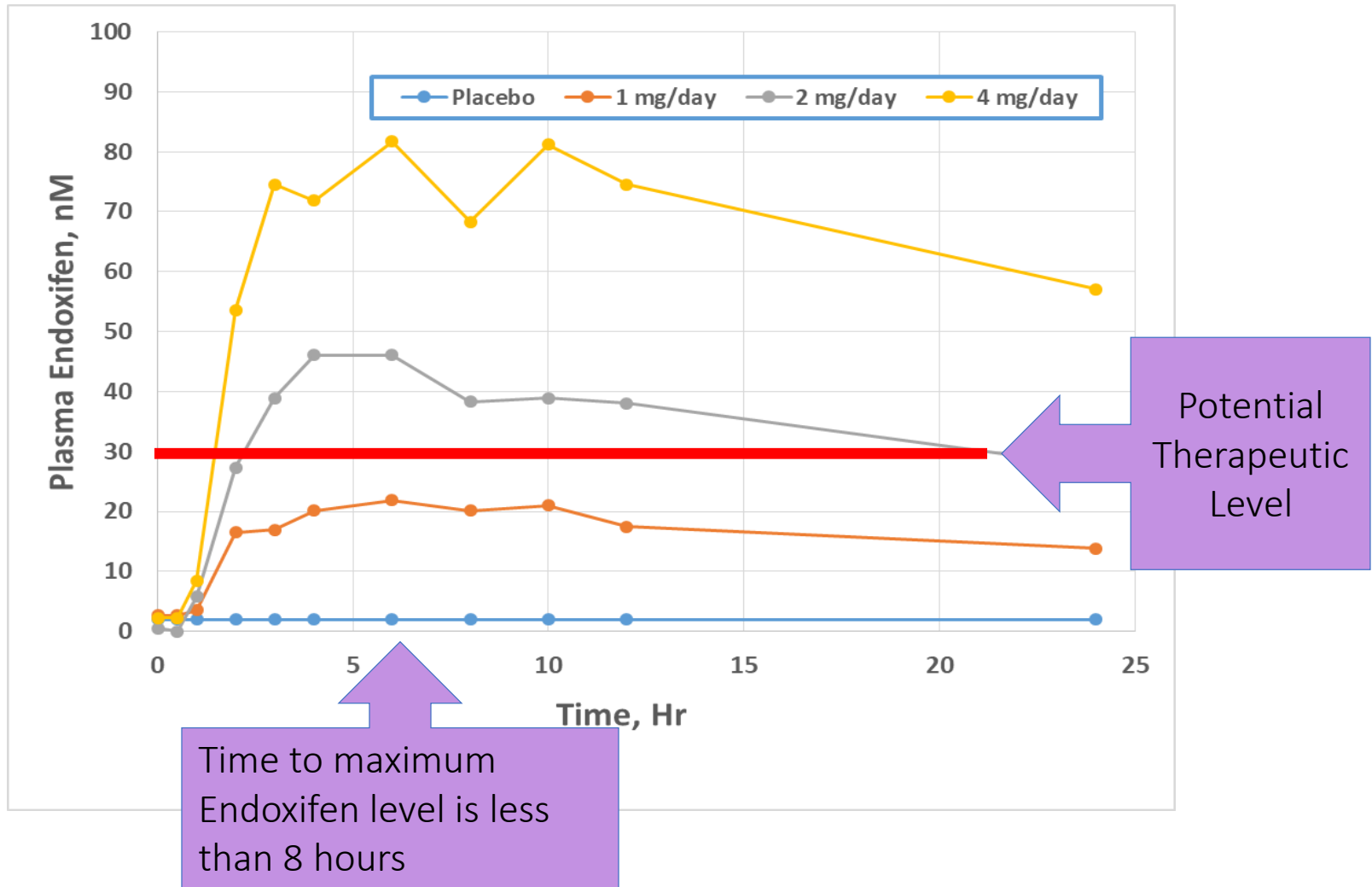
- **Safety/tolerability:** no clinically significant safety signals or adverse events. Tolerated at each dose level.
- **Pharmacokinetics:**
 - Topical – Female: crossed the skin barrier as demonstrated by low but measurable dose-dependent Endoxifen blood levels. Male: blood levels below detection limit 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⁽¹⁾ for Tamoxifen. BC tumors can double in size in 29 days.⁽²⁾

(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



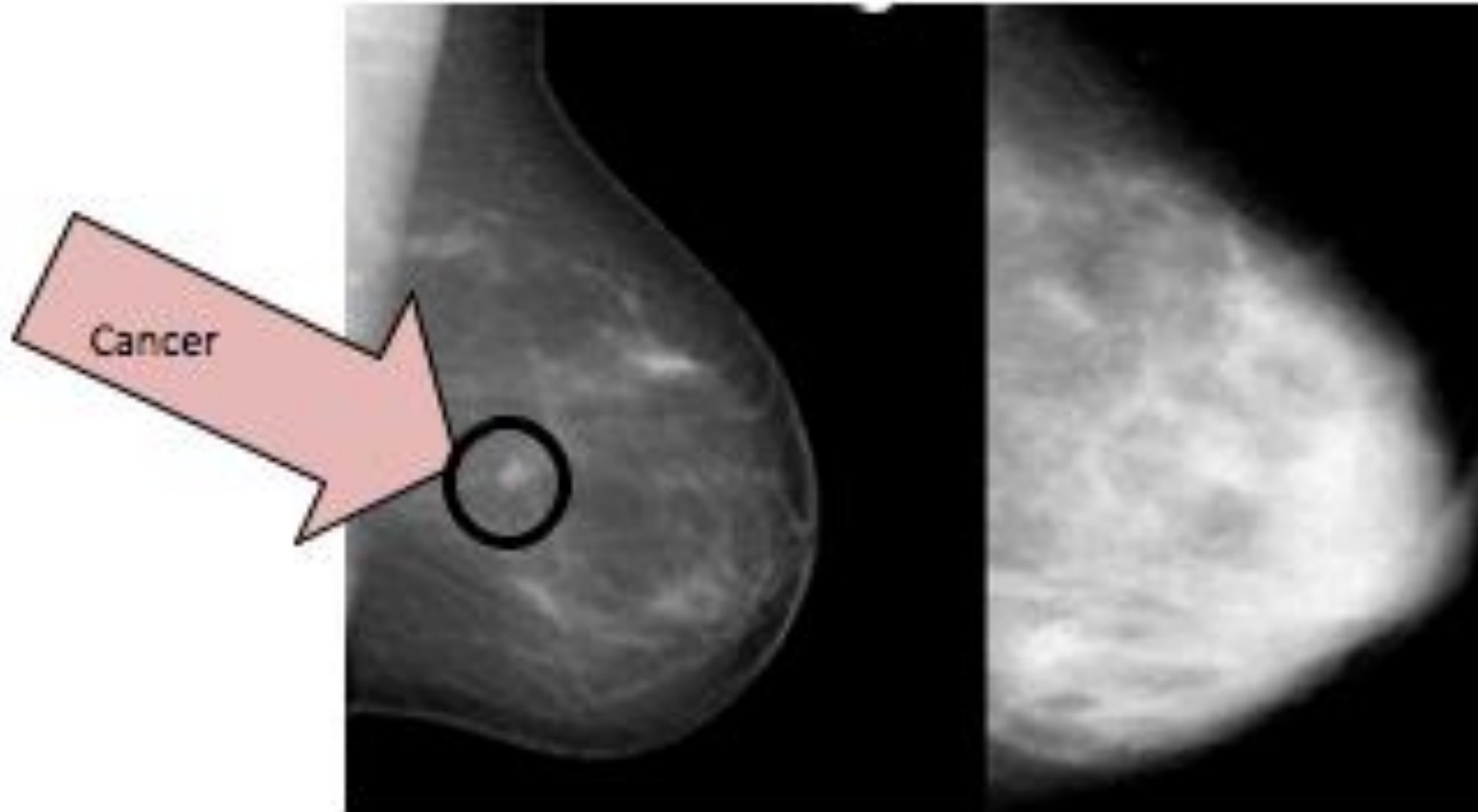
Topical Endoxifen – Phase 2 for MBD

- 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 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



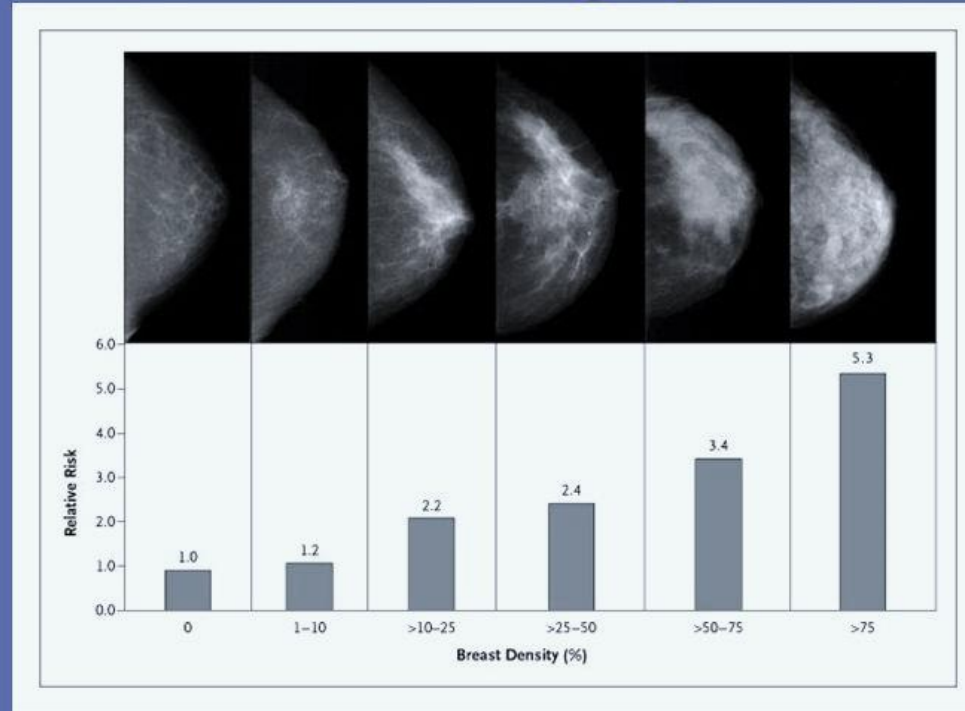
Fatty Breast

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



Several states have now mandated reporting of high breast density as seen on mammograms to both patient and primary care provider

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

Topical Endoxifen for Men

- Underserved markets in Gynecomastia
- Gynecomastia (breast enlargement and pain):
 - Affects 25% of men ages 50-69⁽¹⁾, 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

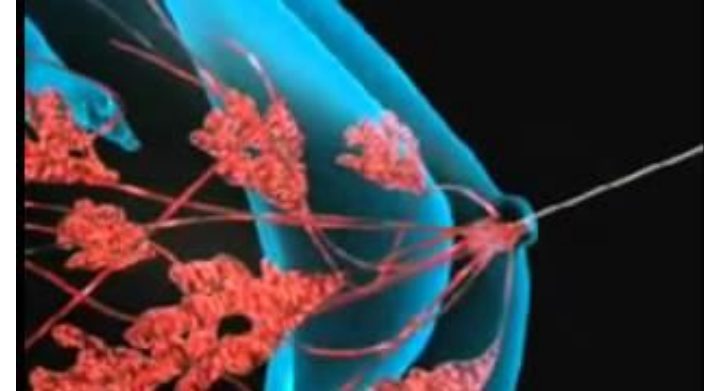
- Window of Opportunity (WOO) – time period between diagnosis and surgery.
- Being performed in Australia by CPR Pharma.
- Pilot Phase: Daily oral Endoxifen for 21 days in up to 8 ER⁺ stage 1 or 2 patients scheduled for lumpectomy or mastectomy.
- Expansion Phase: 17 additional patients.
- Primary Endpoint: 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:

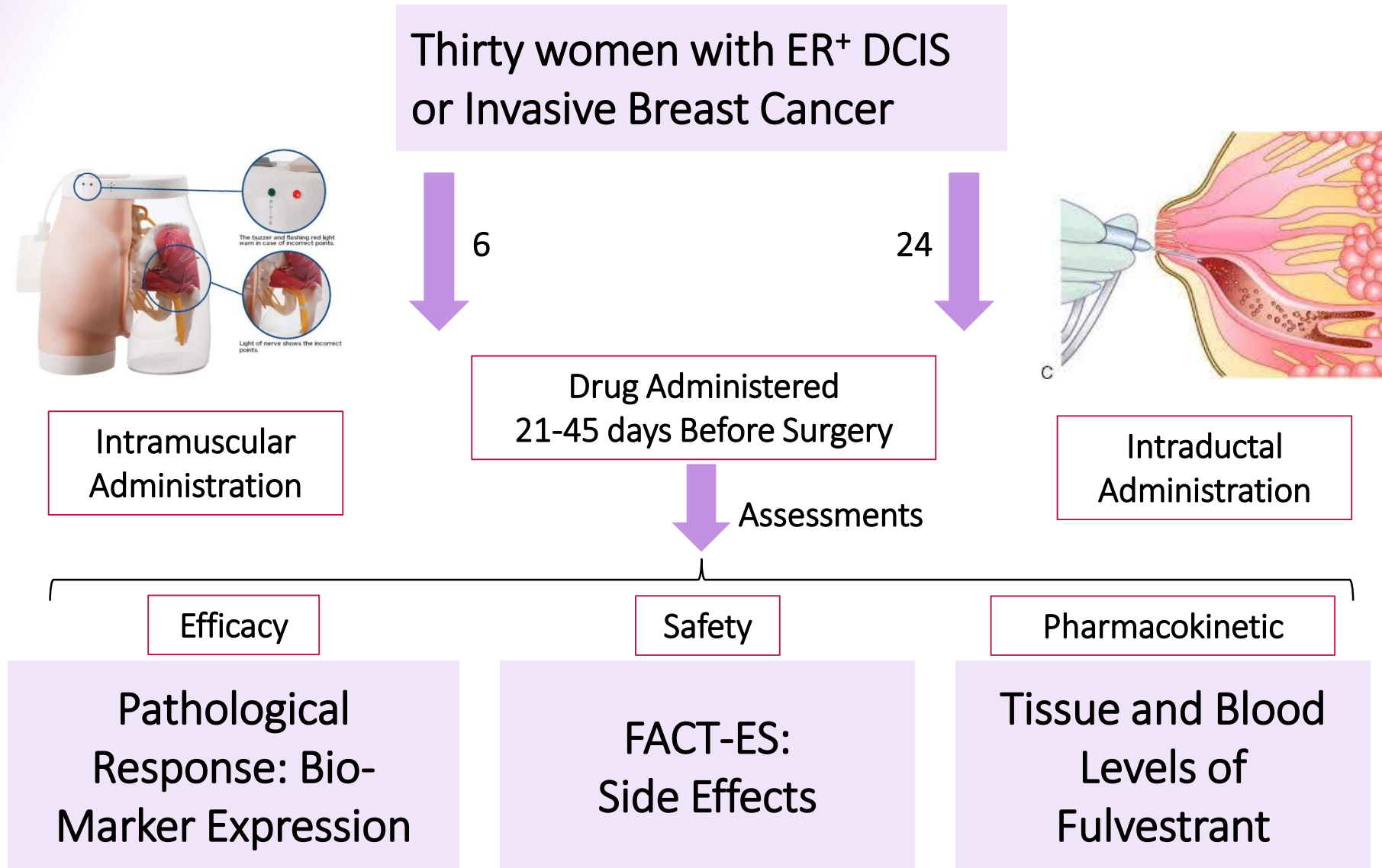
- A single clinical study of safety and efficacy
- Limited additional clinical or pre-clinical studies
- Multi-year market exclusivity possible

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 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: Retain CRO for refractory
Phase 2 study

Topical Endoxifen:

- (1) Q4 '18 – Retain CRO for Gynecomastia
Phase 2 study
- (2) Q1 '19: complete first 3 months dosing in
Phase 2 study MBD
- (3) Q2 '19: complete Phase 2 MBD study

TRAP CAR-T - Seeking research partners





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