# Seven-Gene Signature Test for Prediction of Breast Cancer Recurrence

*This technology is a seven gene signature for the prediction of breast cancer recurrence.  Currently the gold-standard test for predicting breast cancer recurrence, Oncotype Dx (Genomic Health), is used to help physicians and patients quantify risks and make better treatment decisions.  Oncotype Dx relies on expression analysis of 21 genes and is only approved for a specific subset of the breast cancer patients. Our gene signature can be used to predict breast cancer recurrence using only seven genes and has been validated retrospectively using breast cancer samples from broader patient populations that currently have no approved test.*

## COMMERCIAL OPPORTUNITY

- Treatment decisions for breast cancer patients are currently based on a complicated algorithm combining information on tumor morphology, presence of metastasis, hormone receptor expression, and physician judgment on likelihood of recurrence.

- Both ASCO and NCCN have recently recommended use of a 21-gene signature test (Oncotype Dx) that quantifies likelihood of recurrence to assist physicians in their recommendations to patients for various treatment combinations.

- A high Oncotype Dx score predicts an increased risk of cancer recurrence that is associated with greater benefit from adjuvant chemotherapy in lymph node (-) patients.  A high score from our test shows a statistically significant correlation with increased recurrence risk in lymph node (-) and (+) patient samples.

- If prospectively validated in lymph node (-)/(+) patients, the market for our gene signature should exceed that of Oncotype Dx, which had annualized 2013 revenue of $248M.

- Also, our test uses expression data from only seven gene targets to predict recurrence as opposed to 21 genes in the Oncotype Dx test, thereby reducing reagent costs.

## TECHNOLOGY

This test consists of  analyzing expression levels of our seven gene set and converting those levels to a malignancy risk (MR) score.  The gene signature was developed by examining expression levels of certain genes in normal breast tissue sampled from areas next to patient tumors.  Patient samples that produce a higher MR score are statistically significantly associated with increased risk of breast cancer recurrence in various patient populations. To validate this, gene expression profiles were analyzed retrospectively from three independent breast cancer patient sample sets.  Studying 263 samples from early stage breast cancer patients with both (-) and (+) lymph nodes revealed an almost 3-fold increase in rate of recurrence in high MR score versus low MR score patients ($p < 0.0001$).  In 155 tamoxifen-treated patients, a high MR score was associated with a >2-fold increase in recurrence rate versus a low MR score ($p = 0.0002$). High versus low MR score correlated with a 2-fold increased rate of recurrence in 286 estrogen-receptor (+)/lymph node (-) patient samples ($p = 0.0001$).

## PUBLICATION/PATENT

- US Nationalized patent application filed 1/12/2009 for Drs. Chen and Yeatman
- Chen DT, et al. (2010) *Breast Cancer Res. Treat.* 120(1):25-34

## CONTACT

Haskell Adler PhD MBA
Senior Licensing Manager
Haskell.Adler@Moffitt.org
(813) 745-6596

## LICENSING OPPORTUNITY

**MOFFITT**
CANCER CENTER

08A016.2013.07