

Executive summary

VALUE PROPOSITION	PET/X provides a method to quickly and reliably predict the efficacy of therapies for each breast-cancer patient. Selection of breast-cancer therapy relies on matching disease phenotype obtained from biopsy samples with targeted therapies. Often this first-line therapy is ineffective, requiring second- or third-line therapies. Current practice for assessing efficacy is to look for changes in tumor size or recurrence during the course of therapy, which takes many months. In contrast, a PET/X scanner verifies patient compatibility within a week or two by measuring metabolic response at a molecular level.
MARKET NEED / CHALLENGE ADDRESSED	World wide there are more than 1.5 million new breast cancer patients each year seeking effective treatment. Over 230,000 of these are in the US alone. The average direct cost of breast-cancer healthcare exceeds \$80,000 per patient per recurrence. Newly developed and targeted breast cancer therapies (e.g. endocrine therapies) are effective in only a subset of patients expressing the target (60-90% depending on disease type). Costs, side effects, and delays associated with administering ultimately ineffective therapies are a great burden to patients and the health care system. Additionally, the process of developing new therapies lacks effective early screening methods for testing efficacy in human subjects.
ADDRESSABLE MARKET	Primary purchasers of PET/X are registered hospitals and mammography clinics. These centers total nearly 10,000 in the US market and about double that for the worldwide market. An analysis of customer return on investment indicates an early market penetration of 10%. As the market matures and the PET/X scanner proves its value in healthcare and cost savings, the serviceable-market will grow to 20% or greater.
KEY VALUE / BENEFITS	PET/X can determine which targeted breast-cancer therapies will be effective for individual patients, thus ensuring optimal treatment and avoiding the delays, side-effects, and costs of ineffective treatment. PET/X is also valuable for testing efficacy of new treatments. PET/X aims to <i>improve efficacy and reduce cost of treating breast cancer</i> .
TECHNOLOGY DESCRIPTION	PET/X integrates positron emission tomography and mammography to provide radiographic-pathology, i.e. biomarker data from a hybrid PET/mammogram image. During a window of opportunity between diagnosis and surgery, a baseline (pre-treatment) PET image is taken of the tumor in situ. Then, after a short regimen of therapy, a second PET scan reveals tumor responses to treatment, which guides selection of post-surgery adjuvant therapy. For this treatment paradigm to be broadly accepted and widely used, the scanner needs to be higher resolution, more compact, and less expensive than standard whole-body PET scanners. In addition a high level of quantitative accuracy is needed. To reduce cost, while still meeting quantitative imaging performance goals, the PET/X scanner uses innovative detector design, optimized signal multiplexing technology, and statistical-based positioning and image-reconstruction methods.
INTELLECTUAL PROPERTY STRATEGY	The UW filed the preliminary patent for the PET/X system in Oct. 2011 and has patents on several of the sub-systems of a PET/X scanner. PET/X LLC is negotiating with UW for licenses of these patents.
COMPETITIVE LANDSCAPE	Inadequate options exist. Whole-body PET cannot resolve early-stage breast cancer (< 2 cm). Dedicated breast PET and other modalities are used for detection, but do not provide quantitative biomarker data. Genetic tests (e.g. MammaPrint, OncotypeDx) are limited to results of sub-sampled <i>in vitro</i> tissue assays. PET/X is a high-resolution, quantitative tool that provides non-invasive, <i>in situ, in vivo</i> assay of the disease.
LEADERSHIP	William Hunter, Chief Science & Executive Officer Paul Kinahan, Co-founder, UW Professor of Radiology, Physics, Electrical and Bio Engineering, IEEE Fellow Larry MacDonald, Co-founder, UW Assistant Professor of Radiology