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Cellanyx is developing a first-in-class live tumor cell, phenotypic platform for precision risk stratification in cancer to help clinical treatment decision making. The company's lead test is for prostate cancer.

### **Opportunity and Cellanyx's Novel Approach**

The paucity of reliable risk stratification tests is a major barrier to precision cancer care. PSA (prostate specific antigen testing) leads to over-diagnosis and over-treatment of low to intermediate risk prostate cancers, for example. Genomic tests that make predictions based on selected genes and cellular pathways have proved insufficient and/or incomplete, as alterations in discrete genes alone do not provide a comprehensive picture of a cancer's dynamic complexity.

Cellanyx's platform directly assesses the dynamic behavior of thousands of live tumor cells and their phenotypic biomarkers and quantifies the hallmarks of cancer and cancer aggressiveness such as cell movement and protein dynamics. Big data and machine vision learning techniques are utilized to select biomarkers that predict adverse pathology at the time of surgery. Cellanyx's technology is based on the ability to culture primary cancer cells from tissue biopsies as recently reported in [Urology](#). The platform also uses high content imaging, machine vision and machine learning algorithms to prioritize relevant biomarkers and quantify disease risk. The potential of live cell phenotypic biomarkers' potential was recently highlighted in a recent [Nature Precision Oncology](#) publication.

### **Lead Prostate Cancer Test**

Prostate cancer is the most common cancer in men, but very heterogeneous – few patients die from prostate cancer presenting a major challenge in discriminating indolent from aggressive prostate cancer. The immediate potential market is 1.3 million prostate biopsies per year in the U.S. The Gleason scoring histopathologic grading system, using formalin-fixed tissue, is currently the main prostate cancer risk stratification tool but has led to significant over-diagnosis and over-treatment of low and intermediate risk prostate cancer.

Cellanyx's proof-of-concept study in over 300 men with prostate cancer undergoing radical prostatectomy demonstrated very significant correlation with prediction of adverse pathology. Cellanyx's data has been presented at major urology scientific congresses, including the American Urological Association's 2016 annual meeting, where the company's poster was recognized as the best prostate cancer biomarker poster.

Cellanyx's prostate test is being developed as a Laboratory Developed Test (LDT) for use with traditional microscopic pathology tests. Cellanyx's test integrates seamlessly into the biopsy diagnostic testing workflow in the clinic.

### **Breast Cancer Test and Pipeline**

There is strong interest in improved risk stratification in breast cancer. For example, 60,000 women annually in the US are diagnosed with a non-aggressive form of breast cancer, termed Ductal or Lobular Carcinoma *In Situ* (DCIS or LCIS). Using its first-in-class platform, Cellanyx is developing a test that is designed to help risk stratify DCIS and LCIS patients who may need aggressive treatment and identify those patients that can be spared unnecessary surgery such as double mastectomies. Currently, there are no adequate tools to discriminate among these patients. The company has completed analytical validation of its phenotypic test in 60 breast cancer samples obtained following mastectomy or lumpectomy.

The company has also generated initial proof-of-principle for its phenotypic technology in other tumors, such as kidney, lung and bladder.

### **Patents**

Cellanyx has broad intellectual property protection covering its tests and key components (such as protein formulation, biomarkers, microfluidic device, and computational analytical suite). To date, two key international patents have been issued.

### **Financing**

Cellanyx was founded in 2013 with technology spun out of Columbia University and MIT. The team includes an active, experienced scientific and business advisory group, which has allowed it to be capital efficient. To date, the company has raised \$1.3 M from TIE Boston Angels (MA) TreeHouse Health (MN) and other private investors. Cellanyx is raising a new round of financing to support the clinical development of lab developed tests for prostate and breast cancer.

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