

## Executive Summary – Cellanyx Diagnostics

Anurag Mathur

Department of Bioengineering and California Institute for Quantitative Biosciences (QB3), UC Berkeley, Berkeley, CA, United States

**Overview:** Current prostate cancer diagnostics lack the ability to predict tumor aggressiveness and up to 80% of patients with low to moderate risk tumors still receive aggressive treatment, including surgery or radiation which is associated with severe long-term side effects.

Cellanyx's *in vitro* diagnostic service will address this unmet need by providing urologists and patients with a predictive and quantitative measure of a tumor's aggressiveness and metastatic potential in addition to aiding the decision to perform or avoid surgery. Cellanyx's diagnostic platform has the ability to eliminate unnecessary treatment for 140,000 men, potentially saving payers \$4.9 billion per year. Harnessing the predictive power of novel biomarkers enabled by live-cell analysis and microfluidic technology, Cellanyx will offer a diagnostic CLIA, lab-developed diagnostic test service for prostate cancer.

**Technology:** Cellanyx's proprietary technology consists of 3 components:

- Suite of biomarkers, a set of > 12 phenotypic, molecular, and biophysical biomarkers
- Diagnostic chip, designed to culture cells in a specific manner to measure biomarkers
- Software algorithm, processes biomarkers to generate prognostic results

Cellanyx will provide a central lab service to physicians and hospitals. When urologists take a prostate biopsy, they will send a small sample of the tissue to Cellanyx's central laboratory. Cellanyx then processes the biopsy using its proprietary technology and provides the urologist with two prognostic values:

- (1) Oncogenic potential – a quantitative prediction of the tumor's growth potential
- (2) Metastatic potential – a quantitative prediction of whether the tumor will invade other tissues

**Market and Competitive Advantage:** Value-based and comparable pricing suggests a \$4,000 price point for Cellanyx's diagnostic. Conservatively, 25% of the 1 million prostate biopsies performed annually in the US are diagnosed as positive for cancer, resulting in an immediate U.S. market opportunity of over \$1 billion per annum. The majority of companies developing technologies for this potential market are based on genetic signatures. Cellanyx's competitive advantage is its use of phenotypic, molecular and biophysical biomarkers to predict tumor behavior. Cellanyx's biomarkers, as compared to genetic biomarkers, are relevant to a wider patient base, have high signal - low noise, account for tumor heterogeneity, and are more consistent in predicting outcomes and assessing risk – minimizing false negatives and false positives. Leveraging machine vision, this new class of biomarkers brings objective and quantitative assessment of tumor behavior to a wider patient base than previously possible. It is Cellanyx's ability to culture

biopsy cells *in vitro* and its patent pending device that enable this previously inaccessible class of biomarkers to be utilized. Cellanyx's diagnostic will provide value both when determining therapy and during active surveillance. Importantly, Cellanyx's technology fits seamlessly into the current treatment paradigm and does not displace existing methodology; rather, Cellanyx's test has the potential to create additional long-term revenue for both general urologists and pathologists. Therefore, Cellanyx's 'biopsy-on-a-chip' test is both technically differentiated as well as more versatile and robust compared to its competition. Interestingly, Cellanyx's major competitors (Genomic Health, Myriad Genetics, GenomeDx Biosciences, Bostwick Laboratories, and Metamark Genetics) are also natural strategic acquirers as a means to differentiate their own technology from other genomic technologies.

**Commercialization Strategy.** Cellanyx is developing a lab-developed test or LDT. Cellanyx's clinical trial strategy will drive its commercialization. Cellanyx has designed its trials to prove diagnostic accuracy and clinical utility, secure regulatory approval, and encourage adoption by patients, physicians, and payers. This strategy consists of initial studies (60 samples over 5 months) using fresh-frozen human tissue to demonstrate the capability to differentiate between cancer and normal biopsies. Cellanyx will continue with a larger study (300 samples over 8 months) providing the statistical power to differentiate between low-risk and high-risk cancer. During the course of the 60- and 300-sample studies, Cellanyx will begin to generate revenue via licensing deals and strategic partnerships toward potential acquisition. After a 2000 sample study to control for population variability, Cellanyx can bring its diagnostic test service to market via the CAP / CLIA route. Cellanyx has begun early discussions with contract research organizations and College of American Pathologists towards securing CAP / CLIA certification. To build advocacy for broad clinical adoption, Cellanyx will publish the results of its large retrospective trial in major journals. Cellanyx will gain the support of key opinion leaders (KOLs) in prostate cancer, including urologists at major cancer centers. With high-quality published evidence and support from respected KOLs, Cellanyx will promote its inclusion in treatment guidelines published by the American Urological Association (AUA) and National Cancer Institute. In order to prove reimbursement value, Cellanyx will start discussions with payers (i.e. Medicare, Aetna, BlueCross/BlueShield) to demonstrate the cost effectiveness of utilizing its diagnostic. Cost-effectiveness analyses will accompany each of Cellanyx's studies to support value-based reimbursement by private payers and approval under the existing 84999 code or emerging MAAA code under CMS guidelines.