# ProCare Diagnostics

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## Technology description

PAGE SUMMARY

ProCare Diagnostics is focused on the development, manufacturing and commercialization of a novel prostate diagnostic test, to be used in the screening, prognosis, therapy selection, and monitoring of Prostate Cancer. The company was founded in 2015, and the licensing agreement secured from Drexel University in 2015.

Unmet Need

Prostate Cancer remains a significant health care issue. In 2014, 233 thousand new cases were identified, and 29 thousand men died. Currently there are 2 million men that are diagnosed with prostate cancer that are living in the U.S. 1 in 6 men will be diagnosed with prostate cancer in their lifetime.The standard of care for diagnosing Prostate Cancer is PSA, with about 45 million tests worldwide, and 19 million in the U.S. Unfortunately, specificity of the test is poor, so many men have to undergo biopsies, which can lead to infection, and at times can cause urinary incontinence and sexual dysfunction.There are about 1.3 million biopsies performed each year, and about 700 thousand are negative, with 25% false negative, contributing to about $808 million to the healthcare system.Given the need for better diagnostic testing, a number of products were launched around 2012, that were either PSA based (free PSA, pro-PSA), or new markers or genetics test. They represent an improvement over PSA, but are only about 80% of the time accurate. Molecular diagnostic tests were also launched to monitor the patient following Prostatectomy.Urologists, general physicians, and payers are still looking for better tests to detect prostate cancer, particularly the aggressive strands, and save healthcare costs.

The Solution

A novel, highly specific marker known as Prostate Cancer Associated Diagnostic Marker (PCADM-1). Antibodies designed to target PCADM-1 can be used to detect prostate cancer from a urine sample. The levels of the marker appear to be well correlated to the stages of prostate cancer. Importantly, unlike PSA, the marker is independent of adrenoreceptors, so it can detect some strains of metastatic cancer that PSA is unable to, enabling patients to get better personalized therapies, improving prognosis.

Research was conducted at Drexel University, and the findings published in a peer reviewed journal. Performance of the marker is at 83% specificity, far above the performance of PSA.

Developmental Plan

In Q2 2017, we have successfully produced recombinant PCADM-1 protein and monoclonal antibodies required for the development of our assay, and completing the process for large scale production of antibodies for the ELISA test. Our plan is to initially develop a laboratory developed test (CLIA)-Q3, 2019), and make it available in a CLIA lab to generate initial sales. Following the LDT we will launch an ELISA kit which will offer access to larger number of clients (PMA FDA submission and approval by Q4, 2021). A lateral flow device (POC) will be launched in Q1, 2023. The development program for ELISA 2016-2021 will cost about $8 million and that of POC will be approximately $4 million.

Commercialization Opportunities

Target audience are urologists, GP’ s, Payers, and Patients. We will position the product as an ideal test to aid in the diagnosis of prostate cancer in men over the age of 50, getting the right patients into care, and selecting the right therapeutic management, improving prognosis and reducing healthcare costs. We will initially focus in the U.S., Europe, and India, and then further globalize. We will seek out appropriate partners to maximize impact, and likely will build modest infrastructure as well, to include a specialized field force. The WW addressable market is about $3.2 billion, and we believe our plans can ultimately generate a +$180 million in revenue.

## Institution

Drexel University

# 联系我们


叶先生

电 话：021-65679356

手 机：13414935137

邮 箱：yeyingsheng@zf-ym.com