

MedHeximLLC

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Background: Prostate cancer (PCa) is a leading cause of cancer deaths in men in developed countries. 230,000 men were diagnosed and 30,000 died in 2014 in US. The main challenge facing PCa is the lack of a definitive test that provides accurate information for early diagnosis, prognosis and management. The absence of specific test(s) for PCa significantly affects management of the disease as reflected by the incorporation of unnecessary procedures, patient quality of life, and overtreatment cost estimated at \$3 billion each year in the United States¹

Market Opportunity: Diagnostic and Treatment of PCa Prostate cancer (PCa) is the second most frequently diagnosed cancer of men. The market for PCa diagnosis and screening is estimated to grow to over \$17 billion by 2017². MedHeximLLC's non-invasive test is intended to provide an accurate and specific detection of aggressive prostate cancer. Monitoring men with MedHexim's biomarker (Hexim1Dx) will help in appropriate management of the disease, enabling physicians to distinguish between indolent or aggressive PCa. Our company has also developed novel therapeutics designed to target Hexim1 to accentuate its tumor suppressor role during castrate-resistant prostate cancer (CRPC). The prostate cancer drug market forecast is estimated at \$ 8 billion for 2019.³

Company History: MedHeximLLC was founded to bring diagnostics and therapeutics for disease management. Its key product is the identification of novel cancer specific modifications of Hexim1 protein, which will enable physicians in better patient diagnosis, disease prognosis and management. MedHeximLLC is also developing therapeutic products for the treatment of CRPC.

Product Development:

1. Diagnostics of aggressive prostate cancer (Gleason Score > 7) Binary Biopsy Screen
2. Noninvasive Biofluid based Diagnosis of aggressive prostate cancer immunoassay.
3. Preclinical studies of lead compounds targeting CRPC.

Commercial Milestones:

¹ Prostate Cancer Foundation, 2013. *Moving beyond the PSA debate*. [online]

² BCC Research, 2013. *Prevention and Treatment of Prostate Cancer: Technologies and Global Markets*

³ Companies and Markets, "Prostate Cancer Therapeutics Market

From 2015 to 2016, we aim to develop a prototype for Human biofluid assay for Hexim1Dx, and to establish a high throughput system to acquire quantitative measurement of modified Hexim1 signal in biopsy samples. During the same period, we are developing a network with physician to use the Hexim1Dx tests. From 2015 to 2017 we will be validating the lead compounds in preclinical studies using inhibition of cell invasion in prostate cancer cell lines, and *in vivo*.

Intellectual Property:

MedHexim's founders have developed the intellectual property⁴ while working at SUNY and currently are in the process of obtaining the exclusive licenses. SUNY Downstate Medical School and SUNY College at Old Westbury have filed US Patent Application (Diagnostic and treatment of prostate cancer), and another Provisional US Patent filing (Method for diagnosis of Prostate Cancer).

Competition:

1. **Biopsy based PCa diagnostic.** Hexim1Dx biomarker detects advance stage of prostate cancer in biopsies with a gleason score equal or greater than 7 in over 80% of the samples tested.
 - 1.1 Metamark (ProMark, PCA3)
 - 1.2 ConfirmDX (DNA based epigenetic)
 - 1.3 Prolaris (Myriad)
 - 1.4 Oncotype Dx
2. **Biofluid Based Diagnostics.** MedHexim1Dx can be a standalone biomarker test due to its specificity and accuracy. It can also be used to supplement the current screening test.
 - 2.1 Prostate Health Index (PHI) total PSA, free PSA, proPSA.
 - 2.2 4Kscore incorporates total PSA, free PSA, intact PSA, human kallikrein2.

Please indicate primary purpose of Presentation:

Seeking \$2,000,000 for developing the ELISA prototype, the biopsy detection system and preclinical studies. Additional \$3,000,000 will be needed to perform clinical evaluations.

Scientific Advisory Board

- Mark L. Heaney, M.D.-Ph.D. Division of Hematology/Oncology at Columbia University
- J. Raina Ph.D. President ImmunoDx
- John Haley, Ph.D. Director, Developmental Therapeutics Cancer Center at Stony Brook University

⁴ US Patent Appln No. 62/032,883

Diagnostic and treatment of prostate cancer

Patent:US PCT/US2012/030105

Method for diagnosis of Prostate Cancer

2014

2012