



# OPKO Health Acquires Next Generation Prostate Cancer Tests

## New Biomarkers Significantly Reduce Need for Biopsy

MIAMI--(BUSINESS WIRE)-- OPKO Health, Inc. (NYSE:[OPK](#)) today announced the acquisition of an exclusive license from Arctic Partners Ab Oy (Turku, Finland) for two biomarkers in the kallikrein family which, used together with prostate specific antigen (PSA), can reduce the need for prostate biopsies by over 50%. These novel biomarkers were developed by investigators at the University of Malmo, Sweden, University of Turku, Finland, and Memorial Sloan Kettering Cancer Center, New York. The research results indicate that these markers can predict initial biopsy results in men suspected of having prostate cancer; they have been tested in over 8,000 men and were independently validated in the European Randomized Study of Prostate Cancer Screening (Rotterdam).

The value of PSA testing in men who would otherwise not be screened was assessed in the European Randomized Study of Prostate Cancer. Approximately 182,000 men in seven European countries were randomized for PSA screening or to serve as controls. At a median follow-up of approximately 9 years, PSA screening was associated with a 20% reduction in deaths from prostate cancer. Despite this finding, it is noted that 48 men would need to be treated to prevent one death from prostate cancer.<sup>1</sup> While quite specific to the prostate gland, PSA is not specific for prostate cancer. As a result, in the U.S., an estimated 750,000 men receive unnecessary prostate biopsies annually.<sup>2</sup> The OPKO test panel will combine PSA and two novel kallikrein markers to provide significantly greater accuracy.

"These two new biomarkers provide us with a unique opportunity to greatly improve the value of prostate cancer screening. The higher specificity of our new panel of markers will provide better and more efficient outcomes, while lowering overall costs," said Phillip Frost, M.D., Chairman and CEO of OPKO Health.

"As a physician who sees many men with elevated PSA levels, I believe this novel panel of kallikrein biomarkers will help us to greatly reduce the number of unnecessary prostate biopsies performed with their attendant side effects and added costs. The research supporting the value of this panel is sound, and has been validated in thousands of patients in different clinical settings, including initial PSA screening, repeated screenings, and in men with a previous negative biopsy. I believe this panel of tests will eventually replace PSA measures alone for the early detection of prostate cancer that needs to be treated, helping us to avoid dealing with small, indolent cancers that should be left alone," said Peter Scardino, M.D. (Chief of Surgery, Memorial Sloan Kettering Cancer Center, New York).

<sup>1</sup>Schroder, FH, Hugosson J, Roobol MJ, Tammela TL, Ciatto S, Nelen V, Kwiatkowski M, Lujan M, Lilja H, Zappa M, et al: **Screening and prostate cancer mortality in a randomized European study**. *N Engl J Med* 2009, 360(13): 1320-1328.

<sup>2</sup>Vickers AJ, Cronin AM, Aus G, Pihl CG, Becker C, Petersson K, Scardino PT, Hugosson J, Lilja H: **A panel of kallikrein markers can reduce unnecessary biopsy for prostate cancer: data from the European Randomized Study of Prostate Cancer Screening in Goteborg, Sweden.** *BMC Med* 2008, 6:19.

### **About OPKO Health, Inc.**

OPKO is a multi-national biopharmaceutical and diagnostics company that seeks to establish industry-leading positions in large and rapidly growing medical markets by leveraging its discovery, development and commercialization expertise and novel and proprietary technologies.

*This press release contains "forward-looking statements," as that term is defined under the Private Securities Litigation Reform Act of 1995 (PSLRA), which statements may be identified by words such as "expects," "plans," "projects," "will," "may," "anticipates," "believes," "should," "intends," "estimates," and other words of similar meaning, including statements regarding the potential benefits of the new biomarkers, the ability of the new biomarkers to predict or reduce the need for biopsies, whether OPKO will be able to commercialize a diagnostic product utilizing the new biomarkers, whether the new biomarkers will offer higher specificity or greater accuracy than current diagnostics or provide better or lower healthcare costs as well as other non-historical statements about our expectations, beliefs or intentions regarding our business, technologies and products, financial condition, strategies or prospects. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements. These factors include those described in our filings with the Securities and Exchange Commission, and risks inherent in funding, developing and obtaining regulatory approvals of new, commercially-viable and competitive products and treatments. In addition, forward-looking statements may also be adversely affected by general market factors, competitive product development, product availability, federal and state regulations and legislation, the regulatory process for new products and indications, manufacturing issues that may arise, patent positions and litigation, among other factors. The forward-looking statements contained in this press release speak only as of the date the statements were made, and we do not undertake any obligation to update forward-looking statements. We intend that all forward-looking statements be subject to the safe-harbor provisions of the PSLRA.*

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