Aspira Women’s Health Signs an Exclusive Licensing Agreement with Dana Farber Cancer Institute for the Development of microRNA-based Ovarian Cancer Test

Description

New blood-based test could use microRNA alone or in combination with other biomarkers for earlier diagnosis of ovarian cancer

May 11, 2023 08:00 ET

AUSTIN, Texas, May 11, 2023 (GLOBE NEWSWIRE) — Aspira Women’s Health Inc. (Nasdaq: AWH), a bio-analytical based women’s health company focused on gynecologic disease, today announced it has signed an exclusive licensing agreement with the Dana-Farber Cancer Institute (“DFCI”) for the design and development of a new noninvasive miRNA-based ovarian cancer diagnostic tool. The new test will utilize circulating microRNAs, either alone or in conjunction with proteins or other factors, to identify ovarian cancer in women with adnexal masses. It will be offered to healthcare providers as an expansion of the Company’s OvaSuite porfolio.

Dipanjan Chowdhury, co-developer and Chief of the Division of Radiation and Genome Stability at DFCI added, “This technique may help address a significant unmet diagnostic need in ovarian cancer with a non-invasive, easy, fast, and affordable diagnostic.”

The new test will utilize a proprietary DFCI microRNA ovarian cancer signature in conjunction with Aspira’s proprietary AI/machine learning algorithms to assess ovarian cancer risk. Micro-RNAs, a type of RNA that originates in the cell nucleus with a small amount leaking into the bloodstream, are easily isolated from the blood and can be amplified for detection with PCR-based or next generation sequencing technologies.

“Diagnosing ovarian cancer at its earliest stages is crucial to improving survival outcomes,” said Dr. Ryan Phan, Aspira’s Chief Scientific and Operating Officer. “MicroRNA offers tremendous opportunity to make this a reality as it appears earlier compared with other testing targets, like circulating tumor cells or proteins. Use of microRNA may help address a significant unmet diagnostic need in ovarian cancer.”

Nicole Sandford, President and Chief Executive Officer of Aspira Women’s Health stated, “We are thrilled to be on the cutting edge of development with this prestigious partner as we develop and expand upon our OvaSuite of products. Adding this new non-invasive, molecular based risk assessment tool to our porfolio will be another significant step forward in arming physicians with information to determine an appropriate treatment pathway.”

The agreement is in addition to the current sponsored research agreement between Aspira and a consortium of institutions led by DCFI for the development of a noninvasive test to aid in the detection of endometriosis using circulating microRNAs and proteins.

About Aspira Women's Health Inc.
Aspira Women's Health Inc. is transforming women's gynecological health with the discovery, development, and commercialization of innovative testing options for women of all races and ethnicities, starting with ovarian cancer.

Our ovarian cancer risk assessment portfolio is marketed to healthcare providers as OvaSuite℠. OvaWatch℠ is a non-invasive, blood-based test intended for use in the initial clinical assessment of ovarian cancer risk in women with benign or indeterminate adnexal masses for which surgical intervention may be either premature or unnecessary. With a negative predictive value (NPV) of 99%, OvaWatch allows physicians to confidently rule out ovarian cancer malignancy and choose the appropriate clinical management for the right patient at the right time. Ova1Plus® combines our FDA-cleared products, Ova1® and Overa®, to detect risk of ovarian malignancy in women with adnexal masses planned for surgery.

EndoCheck™, Aspira's first-of-its-kind non-invasive diagnostic test for endometriosis, is currently in development. Visit our website for more information at www.aspirawh.com.

Forward-Looking Statements
This press release contains forward-looking statements, as defined in the Private Securities Litigation Reform Act of 1995, including statements regarding the potential effects of widespread use of OvaWatch and the availability of OvaWatch in New York. Forward-looking statements involve a number of risks and uncertainties. Words such as "may," "expects," "intends," "anticipates," "believes," "estimates," "plans," "seeks," "could," "should," "continue," "will," "potential," "projects" and similar expressions are intended to identify forward-looking statements. These forward-looking statements speak only as of the date of this press release and are subject to a number of risks, uncertainties and assumptions, including those described in the section entitled "Risk Factors" in Aspira's Annual Report on Form 10-K for the year ended December 31, 2022. These risks include, but are not limited to: our ability to continue as a going concern; our ability to comply with Nasdaq's continued listing requirements; impacts resulting from potential changes to coverage of Ova1 through our Medicare Administrative Carrier for Ova1; impacts resulting from or relating to the COVID-19 pandemic and actions taken to contain it; anticipated use of capital and its effects; our ability to increase the volume of our product sales; failures by third-party payers to reimburse for our products and services or changes to reimbursement rates; our ability to continue developing existing technologies and to develop, protect and promote our proprietary technologies; plans to develop and perform laboratory developed tests; our ability to comply with Food and Drug Administration ("FDA") regulations that relate to our products and to obtain any FDA clearance or approval required to develop and commercialize medical devices; our ability to develop and commercialize additional diagnostic products and achieve market acceptance with respect to these products; our ability to compete successfully; our ability to obtain any regulatory approval required for our future diagnostic products; or our suppliers' ability to comply with FDA requirements for production, marketing and post-market monitoring of our products; our ability to maintain sufficient or acceptable supplies of immunoassay kits from our suppliers; in the event that we succeed in commercializing our products outside the United States, the political, economic and other conditions affecting other countries; changes in healthcare policy; our ability to comply with the additional laws and regulations that apply to us in connection with the operation of ASPiRA LABS; our ability to use our net operating loss carryforwards; our ability to use intellectual

property; our ability to successfully defend our proprietary technology against third parties; our ability to obtain licenses in the event a third party successfully asserts proprietary rights; the liquidity and trading volume of our common stock; the concentration of ownership of our common stock; our ability to retain key employees; our ability to secure additional capital on acceptable terms to execute our business plan; business interruptions; the effectiveness and availability of our information systems; our ability to integrate and achieve anticipated results from any acquisitions or strategic alliances; future litigation against us, including infringement of intellectual property and product liability exposure; and additional costs that may be required to make further improvements to our laboratory operations. The events and circumstances reflected in Aspira's forward-looking statements may not be achieved or occur, and actual results could differ materially from those projected in the forward-looking statements. Aspira expressly disclaims any obligation to update, amend or clarify any forward-looking statements whether as a result of new information, future events or otherwise, except as required by law.

Investor Relations Contact:

Monique Kosse
Managing Director
LifeSci Advisors, LLC
Tel: 212-915-3820