

Aspira Women's Health Signs Exclusive Sample Procurement Agreement with The University of Oxford

Description

August 31, 2023 08:00 ET

Samples to be used in validating the Company's EndoCheckSM test in development for the diagnosis of endometriosis

AUSTIN, Texas, Aug. 31, 2023 (GLOBE NEWSWIRE) — Aspira Women's Health Inc. ("Aspira" or "the Company") (Nasdaq: AWH), a bio-analytical based diagnostic company focused on gynecologic health, today announced a material transfer agreement with The University of Oxford for the procurement of serum samples to be used to verify and validate the Company's endometriosis blood test algorithms. Aspira expects to use the samples to support the launch of EndoCheckSM, its first-generation blood test to aid in the diagnosis of endometriosis, by the end of 2023.

"We are excited to enter into this agreement with The University of Oxford. With their samples, we will be able to drive our EndoCheck validation process forward and bring this much needed test to market," said Nicole Sandford, Chief Executive Officer of Aspira. "There are currently more than six million women suffering from endometriosis in the U.S., with many facing years of pain before getting a diagnosis. We intend to provide clinicians with a highly effective tool to assess the likelihood that a patient's chronic pain is caused by endometriosis without an invasive procedure. I believe the availability of a simple blood test will support the development and adoption of new therapeutic solutions for this devastating disease, and help patients access treatments sooner than is possible today."

Professor Christian Becker, from the Nuffield Department of Women's and Reproductive Health, University of Oxford and Co-Director of the Oxford Endometriosis Care (EndoCaRe) Centre said, "An important step towards improving outcomes for women with endometriosis is faster, more reliable diagnosis. We are excited to support Aspira Women's Health in developing a much-needed test for the identification of this debilitating disease."

About EndoCheckSM

EndoCheck is a non-invasive blood test in development to be used in conjunction with other non-surgical modalities to aid in the diagnosis of endometriosis and guide in the clinical care for patients with suspected endometriosis earlier in their prognosis journey. Current detection methods for endometriosis require surgery and a surgical biopsy diagnosis and/or visualization diagnosis. EndoCheck is intended to address this large patient population by using a non-invasive solution with comparable sensitivity and specificity when compared to invasive methods such as surgical biopsy and/or visualization.

About Aspira Women's Health Inc.

Aspira Women's Health Inc. is transforming 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 OvaSuiteSM, which includes OvaWatchSM, 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.

EndoCheckSM, 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, and as supplemented in Aspira’s 10-Q filings for the quarters ended March 31, 2023 and June 30, 2023. 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

monique@lifesciadvisors.com