Aspira Women's Health Provides a Development Update on its Portfolio of Noninvasive Tests for Endometriosis

Description

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Data supports EndoCheck™ to be the first blood test for the identification of localized endometriosis, including endometrioma

Platform migration to begin on the Company's EndoMDx™ test for broader endometriosis indications

AUSTIN, Texas, Dec. 06, 2023 (GLOBE NEWSWIRE) — Aspira Women's Health Inc. ("Aspira" or "the Company") (Nasdaq: AWH), a bio-analytical based women's health company focused on the development of gynecologic disease diagnostic tools, today announced that it has completed the design of EndoCheck based on the analysis of samples received from The University of Oxford in October. Data show EndoCheck to be a high-performing blood test for localized endometriosis, including ovarian endometriosis masses known as endometrioma. The Company is collaborating with The University of Oxford on an abstract for presentation and a manuscript for publication to support a commercial launch in 2024. Independent verification of the EndoCheck test for endometriomas, the next step in its development, will begin shortly with data to be provided by The Dana Farber Cancer Institute.

Endometrioma is a localized form of endometriosis that has formed an ovarian mass. It is one of the most common types of endometriosis. All endometriosis, including endometriomas, are currently diagnosed through invasive laparoscopic surgery. Performance of the EndoCheck test is expected to be sufficient to offer a non-invasive clinical alternative to laparoscopic surgery for endometriomas.

Up to 44%[1] of patients with endometriosis of all stages are found to have an endometrioma. With over 6 million women in the U.S. estimated to be suffering from endometriosis, the addressable market for the non-invasive test for identifying endometrioma is estimated by the Company to be up to 2.5 million. The Company plans to expand the intended use of the test in other forms of endometriosis through additional research to further increase EndoCheck's addressable market.

"EndoCheck builds upon our unique know-how with AI machine learning and knowledge of gynecologic disease, which are the hallmark of our tests," said Nicole Sandford, President, and CEO of Aspira. "This is an incredibly complex disease, and the development of the test has taken longer than expected. Nonetheless, we are excited to have a test with such a clear signal – a truly first-of-its kind accomplishment. Our next priority is to ensure a successful commercial launch through a thoughtful introduction of EndoCheck into the payor and provider markets in 2024. We are working with our Clinical Advisory Board and our network of academic and clinical collaborators to do just that."

EndoCheck was developed on an FDA-cleared platform in the Company's CLIA laboratory, which will

support a rapid launch as a Lab Developed Test upon completion of the remaining validation steps, assessment of the commercial application, and publication of a peer reviewed manuscript.

In addition to EndoCheck, the Company has continued its progress with the development of EndoMDx which incorporates miRNA, proteins, and clinical characteristics to identify all types and locations of endometriosis. Aspira is developing EndoMDx through a sponsored research agreement with a consortium of world-class academic and research institutions led by The Dana Farber Cancer Institute. Platform migration and test validation of a proprietary EndoMDx signature, delivered earlier this year, is underway. Aspira believes samples from The Dana Farber Cancer Institute, its existing endometriosis biobank, and the ongoing EndoCheck Clinical Study will be sufficient to complete design and development of EndoMDx in 2024.

Dr. Jody Berry, Chief Scientific Officer of Aspira, noted, “Our knowledge and understanding of endometriosis grows every day. With its complex spectrum of phenotypes, the successful development of noninvasive methods to identify all presentations of endometriosis will require a portfolio approach. We are excited that data show our EndoCheck test to be highly effective in identifying localized ovarian endometriosis and expect development for a broader indication to accelerate now that the design of a potentially high performing EndoMDx signature is complete.”

Ms. Sandford concluded, “Our progress has generated renewed interest in our approach and scientific achievements. We are accelerating our conversations with potential partners in the industry that can further our strategic options and drive long-term shareholder value. I am proud of the advancements we have made and look forward to sharing more details with investors at an Analyst Day event in January 2024.”

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℠, which includes OvaWatch℠, 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. Forward-looking statements generally are accompanied by words such as “will,” “plan,” “intend,” “potential,” “expect,” “could,” or the negative of these words and similar expressions that predict or indicate future events or trends or that are not statements of historical matters. These forward-

looking statements include, but are not limited to, statements regarding the development of diagnostic tools, ability to offer patients and physicians a range of cost effective, non-invasive alternatives for diagnosing endometriosis, the verification of tests in other forms of endometriosis, validation and timing of the launch of EndoCheck, the impact on EndoCheck's addressable market, and ability to drive long-term shareholder value . These statements are based on various assumptions, whether or not identified in this press release, and on the current expectations of the management of Aspira and are not predictions of actual performance. These forward-looking statements are provided for illustrative purposes only and are not intended to serve as, and must not be relied on as a guarantee, an assurance, a prediction, or a definitive statement of fact or probability. Actual events and circumstances are difficult or impossible to predict and will differ from assumptions. Many actual events and circumstances are beyond the control of Aspira. These forward-looking statements are subject to a number of risks and uncertainties, including but 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; 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; the impact of additional costs that may be required to make further improvements to our laboratory operations; and all other factors discussed in Aspira's Annual Report on Form 10-K for the year ended December 31, 2022 and Aspira's Quarterly Report on Form 10-Q for the quarter ended September 30, 2023 under the heading "Risk Factors," and other documents Aspira has filed, or will file, with the Securities and Exchange Commission. If any of these risks materialize or our assumptions prove incorrect, actual results could differ materially from the results implied by these forward-looking statements. There may be additional risks that Aspira presently does not know, or that Aspira currently believes are immaterial, that could also cause actual results to differ from those contained in the forward-looking statements. In addition, forward-looking statements reflect Aspira's expectations, plans, or forecasts of future events and views as of the date of

this press release. Aspira anticipates that subsequent events and developments will cause its assessments to change. However, while Aspira may elect to update these forward-looking statements at some point in the future, Aspira specifically disclaims any obligation to do so, except as required by law. These forward-looking statements should not be relied upon as representing Aspira's assessments of any date after the date of this press release. Accordingly, undue reliance should not be placed upon the forward-looking statements.

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[1] Engin Oral, Berfu Demir, and Umit Inceboz**;** "Endometriosis and Ovarian Reserve"; *Sage Journals Women's Health Special Report*; Volume 11, Issue 5; September 2015.