Aspira Women's Health Supports Centers for Medicare & Medicaid Services (CMS) Proposed Rule to Crosswalk Medicare Reimbursement Rate for OvaWatch

Description

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The proposed rule would allow for OvaWatch℠ to be reimbursed at the same rate as Ova1® at $897 per test and will become final following a brief public comment period

AUSTIN, Texas, Nov. 09, 2023 (GLOBE NEWSWIRE) — Aspira Women's Health Inc. ("Aspira" or "the Company") (Nasdaq: AWH), a bio-analytical company focused on the development and commercialization of women's health diagnostic tools for gynecologic diseases, today announced that during the 2024 Clinical Laboratory Fee Schedule (CLFS) rate setting process, the Centers for Medicare & Medicaid Services (CMS) has proposed to crosswalk the fee paid to the company for OvaWatch to the fee paid historically for Ova1. If finalized later this month (as was preliminarily approved in September), Aspira would be reimbursed at a rate of $897 for all OvaWatch and Ova1 tests processed for Medicare patients meeting applicable coverage requirements beginning in January 2024. The public comment period ended on October 27.

"Crosswalking" refers to a process for setting the Medicare reimbursement rate for a new laboratory test by assigning the new code the same rate as a comparable existing test. Aspira supports the proposal to crosswalk OvaWatch to Ova1 and believes it is appropriate given the similarity of pre-analytical, analytical, and post-analytical characteristics of the two assays.

"CMS's proposal to crosswalk the OvaWatch reimbursement rate is a notable step in our journey as we continue our mission of gaining broad reimbursement coverage for our OvaSuite℠ tests, the only non-invasive tests that aid in the identification of ovarian cancer in women with pelvic masses," said Nicole Sandford, President and Chief Executive Officer of Aspira. "We are one step closer to achieving our mission of ensuring this ground-breaking technology is available to all women when they are facing an ovarian cancer diagnosis."

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, 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 quarter ended March 31, 2023, June 30, 2023, and September 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.

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