Aspira Women's Health Receives Final Crosswalk Pricing Determination from the Centers for Medicare & Medicaid Services (CMS)

Description

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CMS approves OvaWatch℠ 2024 price at $897 per test

AUSTIN, Texas, Nov. 27, 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 approved the crosswalk of the fee to be paid to the company for OvaWatch to the fee paid historically for Ova1. Aspira will be reimbursed at a rate of $897 for all OvaWatch and Ova1 tests processed for Medicare patients meeting applicable coverage requirements beginning on January 1, 2024.

"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.

"Nothing is more important than reliable clinical data when a patient is facing a possible ovarian cancer diagnosis. With CMS's approval of OvaWatch's price on the 2024 laboratory fee schedule, we are closer than ever to ensuring that our ground-breaking technology is available to all women with an adnexal mass," said Nicole Sandford, President and Chief Executive Officer of Aspira.

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, as amended by Form 10-K/A filed on October 26, 2023, 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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