Aspira Women's Health Announces Fourth Quarter Operational Metrics and Provides Updates on Its OvaWatch and EndoCheck Programs

Description

Fourth quarter OVA1 volume grew 23.4% to 4,750 units

Plans underway for staged launches of EndoCheck and OvaWatch

AUSTIN, Texas —Jan 5, 2022 — Aspira Women's Health Inc. (Nasdaq: AWH), a bioanalytical-based women's health company, today announced preliminary fourth quarter operational results and provided a corporate update.

Operational Metrics Update

- OVA1® volume in the fourth quarter of 2021 grew approximately 23.4% year over year to 4,750 units compared to 3,849 units in the fourth quarter of 2020. The number of tests for the fourth quarter represented a quarterly record and a 11% increase sequentially compared to the third quarter test volume of 4,281.

- The number of ordering physicians increased to approximately 3,211 for the fourth quarter of 2021, representing a year over year increase of 22.8% and a sequential increase of 10.2% for the quarter. The number of new physician additions increased 31% from third quarter of 2021 vs fourth quarter of 2021. The increase was largely driven by the improved productivity of sales representatives gaining tenure and the conversion of physicians who are engaging through the use of the Synergy platform, which was just launched in October 2021.

Pipeline Update

- **OvaWatch:** We plan to launch our laboratory developed test (LDT) OvaWatch in two stages – single use and serial monitoring. For the single use test, we submitted the analytical validation manuscript in late November and will be submitting the clinical validation manuscript to a peer reviewed publication. We plan to launch the single use test following acceptance of both manuscripts.
    - Launch of the serial monitoring test is currently planned for the end of 2022/early 2023 though the timing will ultimately depend upon the outcome of our publication of data from the ongoing prospective serial monitoring clinical study.
    - Ultimately launch under the LDT pathway will be driven by our ongoing test validation activities and by our continuing evaluation of the regulatory landscape with respect to LDTs.

- **EndoCheck:** We are developing an LDT with the specimens provided by our collaborators, ObsEva S.A. and AbbVie Inc., while simultaneously seeking FDA Breakthrough Designation for EndoCheck with the first FDA "Principles for Good Machine Learning Practices."

- This dual track approach pursues the commercialization of an EndoCheck LDT, whereby real-world clinical utility data will be developed that also should support the data needed for an FDA marketing authorization, subsequent to any Breakthrough Designation decision by the FDA.
    - Estimates for the number of LDTs in the U.S. range from 60,000 to 100,000+, with 15,000 to 20,000 of these LDTs falling under moderate or high risk per FDA classification. There are much fewer FDA cleared moderate to high-risk tests on the market.
    - The LDT validation process allows us to improve our machine-learning algorithms in a dynamic fashion as we continue to expand our diverse biobank of valuable clinical specimens and collaborate with industry leading specialists.
- We plan to hold a key opinion leader (KOL) event in the first quarter of 2022 with top thought leaders in the field to discuss the disease, the clinical gaps, the regulatory opportunity with LDT's, and our science.

"Early results indicate a solid performance in our test volumes this quarter. We are focused on continuing to execute and are pleased by the progress in the development of our OvaWatch and EndoCheck programs," said Valerie Palmieri, Chief Executive Officer of Aspira. "We look forward to 2022 and to providing financial results on our fourth quarter and full year 2021 earnings call in March."

About Aspira Women's Health Inc.
Aspira Women's Health Inc. is transforming women's health with the discovery, development, and commercialization of innovative testing options and bio-analytical solutions that help physicians assess risk, optimize patient management, and improve gynecologic health outcomes for women. Aspira Women's Health is particularly focused on closing the ethnic disparity gap in ovarian cancer risk assessment and developing solutions for pelvic diseases such as pelvic mass risk assessment and endometriosis. OVA1plusTM combines our FDA-cleared products, OVA1® and OVERA®, to detect risk of ovarian malignancy in women with adnexal masses. Aspira GenetiXTM testing offers both targeted and comprehensive genetic testing options with a gynecologic focus. With over 10 years of expertise in ovarian cancer risk assessment, Aspira Women's Health is working to deliver a portfolio of pelvic mass products over a patient's lifetime with our cutting-edge research. The next generation of products in development include OVAWatchTM and EndoCheckTM. To improve patient accessibility, Aspira Women's Health has recently launched our Aspira Synergy technology transfer platform to empower health systems, academics, regional labs, and physician group labs to conduct genetic and specialty tests in-house. Visit our website for more information at www.aspirawh.com.

[1],[2] https://www.cdc.gov/cliac/docs/april-2021/12_Aisner_Moving-Mountains-REvolution-of-LDT-Regulation.pdf#:~:text=Estimates%20for%20the%20number%20of%20LDTs%20in%20the,is%20like%20an%20