



Aspira Women's Health Reports Third Quarter 2021 Financial Results

Total Revenue Increased 34% to \$1.67 million; OVA1 Volume Grew 19% to 4,281 Units

Successful completion of Proof of Concept with Harvard Dana Farber Cancer Institute Collaboration

Achieved Over 194 Million Covered Lives for Ova1

Conference Call and Webcast Today at 8:30 a.m. ET

AUSTIN, Texas — November 10, 2021 — Aspira Women's Health Inc. ("Aspira") (Nasdaq: AWH), a bio-analytical based women's health company focused on gynecologic disease, today reported its financial results for the third quarter ended September 30, 2021.

"We are very pleased with the growth in positive medical policy coverage with the addition of AIM Guidelines Medicaid coverage and credentialing for OVA1. In addition, in spite of renewed COVID-19 restrictions we were able to grow in specific markets" indicated Valerie Palmieri, Aspira's Chief Executive Officer. "We are also making positive progress on our product collaboration with the Dana Farber Cancer Institute with the successful completion of the Phase 1 of our proof of concept study relating to our OvaInherit trial. We had continued positive dialogue with the Food and Drug Administration regarding our planned EndoCheck product and expect resolution on our optimal regulatory path forward for Endocheck by the end of the year."

Recent Corporate Highlights

- **Coverage for OVA1® increased to over 194 Million Covered Lives**

We increased covered lives during the third quarter to a total of 194 million. This is an 8% increase from our prior base of approximately 179 million covered lives. The Company's OVA1 test, a pelvic mass risk assessment for ovarian cancer, has been determined to be medically necessary according to AIM Specialty Health's Clinical Appropriateness Guidelines in addition to the eviCore Guidelines. Our market access strategy made significant progress with reaching 194 million covered lives and we believe inclusion in the AIM and eviCore guidelines provides us with further validation and credibility in our discussions with **ALL** health plans.

- **Medicaid Coverage**

We are now credentialed in the top 5 states by Medicaid population for OVA! Including California, New York, Texas, Florida, and Pennsylvania, bringing the total credentialed national Medicaid population to nearly 61 million Medicaid lives, which represents approximately 77% of the U.S. Medicaid population.

- **Collaboration with Harvard Dana Farber Cancer Institute miRNA Technology Passes Phase 1 Proof of Concept**

We have completed with the teams at Dana Farber Cancer Institute, Brigham and Women's and University of Lutz the Phase 1 of the Proof of Concept evaluation. The evaluation surpassed all required metrics and based on the outcome of the evaluation, the Aspira Innovation team along with the collaborators from the institutions

have begun implementing Phase 2. With the first critical stage gate passed, we are proceeding to evaluate the combined potential impact of our protein biomarker algorithms and the miRNA technology in the development of a combined technology and platform which we believe will set the foundation for a high risk ovarian cancer screening application, which is branded as our Ovainherit trial.

- **Publication in Third Quarter Demonstrates OVA1 Superiority versus CA125, the most common Ovarian Cancer Risk Assessment Used Today**

In a special ovarian cancer edition of *Diagnostics*, we published a paper entitled “*Salvaging detection of early-stage ovarian malignancies when CA125 is not informative.*” In a retrospective study of 2,305 patients, OVA1 detected over 50% of ovarian malignancies in premenopausal women of all cancer stages, that CA125 would have missed. OVA1 also correctly identified 63% of early-stage cancers missed by CA125. This paper further validates and supports the superior early-stage risk detection of ovarian cancer of OVA1 versus CA125 in a large population.

- **OvaSight Development Progress**

We have determined that we will be branding the OvaSight test as OvaWatch which we believe is more descriptive of the utility of the test. The test was developed through a rigorous scientific and clinical-based process based on data from our NYS LDT and from our FDA regulatory process in 3000 patients. We will be performing additional scientific and market review with the intent to refine the intended use for OvaWatch.

Financial Highlights

- **Quarter over Quarter Results – Third Quarter of 2021 versus Third Quarter of 2020:**
 - Total product and genetics revenue increased 34% to \$1,663,000 up from \$1,239,000
 - Total product and genetics volumes increased 20% to 4,386 units up from 3,660 units
- **Quarter over Quarter Results – Third Quarter 2021 versus Second Quarter 2021:**
 - Total product and genetics revenue decreased 7% to \$1,663,000 down from \$1,797,000 in the second quarter of this year.
 - Total product and genetics volumes decreased 7% to 4,386 units down from 4,708 units in the second quarter of this year.

Highlights of Third Quarter 2021 vs. Third Quarter 2020:

- Product revenue was \$1,614,000 for the three months ended September 30, 2021, compared to \$1,217,000 for the same period in 2020, an increase of 33%.
- The number of OVA1plus tests performed increased 19% to 4,281 OVA1plus tests during the three months ended September 30, 2021, compared to 3,596 OVA1plus tests for the same period in 2020.
- The revenue per OVA1plus test performed increased to approximately \$377 compared to \$338 for the same period in 2020, an increase of 11%. This increase was primarily driven by an increase in payments by contracted payers and improved collections.
- Gross profit margin for OVA1plus was 57% in the third quarter compared to 45% in the third quarter of 2020. The year on year increase was driven by volume improvement.
- Research and development expenses for the three months ended September 30, 2021 increased by \$923,000, or 155%, compared to the same period in 2020. This increase was primarily due to clinical utility and product



development costs related to OVASight as well as investments in bioinformatics, investments in Aspira Synergy and consulting expenses associated with EndoCheck regulatory clearance.

- Sales and marketing expenses for the three months ended September 30, 2021 increased by \$2,931,000, or 136%, compared to the same period in 2020. This increase was primarily due to increased personnel, consulting and recruiting costs.
- General and administrative expenses for the three months ended September 30, 2021 increased by \$1,873,000 or 95%, compared to the same period in 2020. This increase was primarily due to an increase in stock compensation expenses, headcount, and personnel expenses.
- We ended the third quarter with approximately \$44.9 million in unrestricted cash. Cash used in operations in the third quarter of 2021 was \$7.9 million compared to \$3.1 million in the third quarter of 2020. This increase was across all elements of operating expenses but primarily employment costs and travel and entertainment as commercial travel in the prior year was depressed due to COVID-19 pandemic related travel restriction.

Highlights of Third Quarter 2021 vs. Second Quarter 2021:

- Product revenue was \$1,614,000 for the three months ended September 30, 2021, compared to \$1,718,000 for the second quarter of 2021, a decrease of 6%.
- The number of OVA1plus tests performed decreased 6% to 4,281 OVA1plus tests during the three months ended September 30, 2021, compared to 4,553 OVA1plus tests for the second quarter of 2021.
- The revenue per OVA1plus test performed remained flat at approximately \$377 compared to the second quarter of 2021.
- Gross profit margin for OVA1plus was 57% in the third quarter compared to 52% in the second quarter of 2021.
- Research and development expenses for the three months ended September 30, 2021 increased by \$47,000, or 3%, compared to the second quarter of 2021.
- Sales and marketing expenses for the three months ended September 30, 2021 increased by \$1,065,000, or 27%, compared to the second quarter of 2021. The increase was primarily driven by increases in personnel costs and investments in marketing.
- General and administrative expenses for the three months ended September 30, 2021 increased by \$560,000, or 17%, compared to the second quarter of 2021.
- We ended the third quarter with approximately \$44.9 million in unrestricted cash. Cash used in operations in the third quarter of 2021 was \$7.9 million compared to \$6.5 million in the second quarter of 2021. The increase was primarily driven by new hires, consultants, marketing and promotional activities as well as research and development spending focused on EndoCheck.

Conference Call and Webcast

Aspira will host a call today at 8:30 a.m. Eastern Time to discuss results followed by a question-and-answer period.

Domestic: 877-407-4018
International: 201-689-8471
Conference ID: 13724440
Webcast: <https://78449.themediaframe.com/dataconf/productusers/vvdb/mediarame/47156/index1.html>



About Aspira Women’s Health Inc.

Aspira Women’s Health Inc. (formerly known as Vermillion, Inc., Nasdaq: VRML) 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. OVA1plus™ combines our FDA-cleared products, OVA1® and OVERA®, to detect risk of ovarian malignancy in women with adnexal masses. Aspira GenetiX™ testing offers both targeted and more 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 are OVASight™, which we are rebranding as OvaWatch, and EndoCheck™. 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 expectations with respect to studies relating to OvaInherit and plans with respect to OvaSight/OvaWatch, including its rebranding, scientific and market review and launch dates. 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, 2020, as supplemented by the section entitled “Risk Factors” in Aspira’s Quarterly Report on Form 10-Q for the quarter ended June 30, 2021. 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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