

## Aspira Women's Health Reports Third Quarter 2021 Financial Results

### Description

*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*

For a link to a pdf of this press release please [click here](#)

**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 Ovalnherit 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 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/mediaframe/47156/indexl.htm>