

Aspira Women's Health Reports Second Quarter 2021 Financial Results

Description

For a PDF of this press release, including balance sheets [click here](#).

Total Revenue Increased 141% to \$1.8 million; OVA1 Volume Grew 85% to 4,553 Accessions

New Publication Demonstrates OVA1 Superiority to Standard of Care

Expanded Access of OVA1 Through AIM Specialty Health

Conference call scheduled for today, August 12 at 4:30 p.m. ET

AUSTIN, Texas — August 12, 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 second quarter ended, June 30, 2021.

"We are pleased with the volume growth in our products as the economy has somewhat emerged from COVID-19 restriction as well as with the advancement of our preparations for our fourth quarter 2021 launch of OVASight" indicated Valerie Palmieri, Chief Executive Officer. "We are making positive progress on our product collaboration with the Dana Farber Cancer Institute as we disclosed in the first quarter of 2021. We have also continued to have a positive dialogue with the FDA regarding our planned EndoCheck product."

Recent Corporate Highlights

Coverage for OVA1® in the AIM Specialty Health Laboratory Medicine Clinical Guidelines

The Company's OVA1 test, a pelvic mass risk assessment for ovarian cancer, is now considered medically necessary according to AIM Specialty Health's Clinical Appropriateness Guidelines. AIM is a member of the Anthem Blue Cross Blue Shield family of companies and promotes optimal care through the use of evidence-based clinical guidelines and real-time decision support for both providers and their patients. AIM is a wholly owned subsidiary of Anthem, Inc., serving more than 50 million members across 50 states, D.C., and US territories.

Publication demonstrates OVA1 superiority versus Standard of Care

A paper has been published in a special ovarian cancer edition of Diagnostics 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 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 detection of ovarian cancer versus the current standard of care in a large population.

Released Analytical and Initial Clinical Validation Performance for OVASight at ASCO 2021

OVASight (MIA3G) is the Company's third-generation OVA technology and is a laboratory-developed, blood-based pelvic mass risk assessment test for ovarian cancer in a low prevalence population. It was developed to increase specificity, maintain high sensitivity with early-stage disease, and allow for conservative management of suspected benign masses in women. A total of 596 samples collected from real-world patients were used to validate the OVASight diagnostic algorithm. Validation data demonstrated 89% specificity, 91% sensitivity and

a negative predictive value of 99.6% in a low prevalence population (3.8%). In addition, overall sensitivity as well as sensitivity in early-stage disease were significantly better than assessing risk with CA-125 alone.

Expansion of Leadership Team

In May 2021, Laura McPadden joined the Company as Head of People and Culture. Laura joined us with over 25 years of experience leading human resources and talent engines and providing strategic guidance for employee relations, performance management, talent acquisition and organizational design.

Capital Resources

- Effective May 27, 2021, the United States Small Business Administration confirmed the waiver of Aspira's repayment of the \$1,005,767 Payroll Protection Plan loan issued to the Company on May 1, 2020. The Company recognized a gain on forgiveness of debt of \$1,005,767 and reduced long- and short-term indebtedness by the same amount.

Financial Highlights

- **Quarter over Quarter Results – Second Quarter of 2021 versus Second Quarter of 2020:**
 - Total product and genetics revenue increased 142% to \$1,797,000 up from \$743,000
 - Total product and genetics volumes increased 88% to 4,708 units up from 2,506 units
- **Quarter over Quarter Results – Second Quarter 2021 versus First Quarter 2021:**
 - Total product and genetics revenue increased 20% to \$1,797,000 up from \$1,496,000 in the first quarter of this year
 - Total product and genetics volumes increased 19% to 4,708 units up from 3,950 units in the first quarter of this year.

Highlights Second Quarter 2021 vs. Second Quarter 2020:

- Product revenue was \$1,718,000 for the three months ended June 30, 2021, compared to \$726,000 for the same period in 2020, an increase of 137%.
- The revenue per OVA1plus test performed increased to approximately \$377 compared to \$295 for the same period in 2020, an increase of 28%. This increase was primarily driven by an increase in payments by contracted payers and improved collections
- Gross profit margin for OVA1plus was 52% in the second quarter compared to 37% in the second

quarter of 2020.

- Research and development expenses for the three months ended June 30, 2021, increased by \$1,091,000, or 287%, compared to the same period in 2020. This increase was primarily due to clinical utility and product development costs related to OVASight, our third-generation product, as well as investments in bioinformatics, Aspira Synergy and consulting expenses associated with EndoCheck regulatory clearance.
- Sales and marketing expenses for the three months ended June 30, 2021, increased by \$2,285,000, or 132%, compared to the same period in 2020. This increase was primarily due to increased personnel and consulting costs.
- General and administrative expenses for the three months ended June 30, 2021, increased by \$1,413,000, or 76%, 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 second quarter with approximately \$53.0 million in cash. Cash used in operations in the second quarter of 2021 was \$6.5 million compared to \$3.4 million in the second 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 Second Quarter 2021 vs. First Quarter 2021:

- Product revenue was \$1,718,000 for the three months ended June 30, 2021, compared to \$1,416,000 for the first quarter of 2021, an increase of 21%.
- The number of OVA1plus tests performed increased 21% to 4,553 OVA1plus tests during the three months ended June 30, 2021, compared to 3,775 OVA1plus tests for the first quarter of 2021.
- The revenue per OVA1plus test performed increased to approximately \$377 compared to \$375 for the first quarter of 2021, an increase of 1%. This increase was primarily driven by an increase in payments by contracted payers.
- Gross profit margin for OVA1plus was 52% in the second quarter compared to 54% in the first quarter of 2021. The decrease was driven primarily by non-recurring costs associated with a switch in our kit assembly vendor.
- Research and development expenses for the three months ended June 30, 2021, increased by \$599,000, or 69%, compared to the first quarter of 2021. This increase was primarily due to clinical utility and product development costs related to OVASight, as well as investments in bioinformatics, Aspira Synergy and consulting expenses associated with EndoCheck regulatory clearance.
- Sales and marketing expenses for the three months ended June 30, 2021, increased by \$910,000, or 29%, compared to the first quarter in 2021. This increase was primarily due to increased personnel and consulting costs.
- General and administrative expenses for the three months ended June 30, 2021, increased by \$770,000, or 31%, compared to the first quarter 2021. This increase was primarily due to an increase in headcount and personnel expenses, as well as stock compensation expenses.
- We ended the second quarter with approximately \$53.0 million in cash. Cash used in operations in the second quarter of 2021 was \$6.5 million compared to the first quarter of 2021 of \$5.2 million. The increase was primarily driven by new hires and 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 4:30 p.m. Eastern Time to discuss results followed by a question and answer period.

Domestic: 877-407-4018

International: 201-689-8471

Conference ID: 1372054

Webcast: <http://public.viavid.com/index.php?id=145272>