

Aspira Women's Health Reports Fourth Quarter and Full Year 2023 Financial Results

Description

March 28, 2024 07:30 ET

2023 OvaSuite revenue of \$9.2 million, an increase of 15% year-over-year

2023 OvaSuite volume of 23,990 units, an increase of 12% year-over-year

Cash utilization declined in both the fourth quarter and full-year 2023 to \$3.5 million and \$15.9 million, respectively

Conference Call and Webcast scheduled for today at 8:30 am ET

AUSTIN, Texas, March 28, 2024 (GLOBE NEWSWIRE) — Aspira Women's Health Inc. ("Aspira" or the "Company") (Nasdaq: AWH), a bio-analytical based women's health company focused on the development of gynecologic disease diagnostic tools, today reported its financial results for the fourth quarter and year ended December 31, 2023.

"We made a great deal of progress in 2023. Not only were we able to cut our cash used in operations in half by aligning spending to business needs, but we simultaneously increased revenues and test volume, implemented enhancements to our commercial organization and achieved important market access milestones," said Nicole Sandford, Chief Executive Officer of Aspira. "Progress in our innovation program continued to accelerate with the announcement in December of the first ever proteomic blood test to identify endometriomas and the achievement of major milestones in the development of our promising AI-enabled protein and miRNA diagnostic tests for ovarian cancer and endometriosis."

Sandford continues, "Now, we turn towards 2024 with a strong, talented team and unprecedented momentum for women's health progress at both the Federal and state levels. The hard work of the past two years has positioned us to rise to these opportunities and reach our full potential."

Fourth Quarter 2023 and Recent Corporate Highlights

- Raised \$5.5 million in gross proceeds through a registered direct offering with a single healthcare focused institutional investor alongside participation from Nicole Sandford, CEO of Aspira, as well as certain existing shareholders.

- Received final crosswalk pricing determination from the Centers for Medicare & Medicaid Services (CMS) and approval of 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.
- Announced an exclusive 5-year distribution agreement with Hi-Precision Laboratories, one of the largest medical laboratories in the Philippines.
- Presented a poster, entitled: *“Improving the diagnostic accuracy of an ovarian cancer triage test using a joint miRNA-protein model,”* at the AACR Special Conference in Cancer Research. The poster highlighted data showing miRNA’s potential to improve the diagnostic accuracy of non-invasive diagnostic tests suggesting that using combined approaches could improve the triaging of patients with suspected ovarian cancers.
- Presented a late-breaking poster entitled *“A Protein Biomarker Test and Artificial Intelligence-Based Algorithm for Ovarian Endometriosis,”* at the 71st Annual Scientific Meeting for the Society for Reproductive Investigation. The poster highlighted data from the first non-invasive test for ovarian endometriosis.
- Secured reimbursement for Ova1Plus from the California Department of Health Care Services. Aspira will be reimbursed at a rate of \$897 for all Ova1Plus tests processed for Medi-Cal patients meeting applicable coverage requirements.
- Established a Clinical Advisory Board as an element of the company’s overall mission to develop and distribute high-impact diagnostic tools for gynecologic disease. Each member of the Board is a recognized thought-leader with deep clinical expertise in gynecologic health.
- Named Dr. Sandra Milligan as President with direct responsibilities for Research and Development, Operations, Information Technology, and Human Resources.

Fourth Quarter 2023 Financial Highlights

- Product revenue was \$2.1 million for the three months ended December 31, 2023, compared to \$2.1 million for the same period in 2022. The number of OvaSuite tests performed was approximately 5,659 during the three months ended December 31, 2023, flat when compared to the approximately 5,642 OvaSuite tests for the same period in 2022. The average unit price (AUP) increased to \$376 for the three months ended December 31, 2023, compared to \$369 for the same period in 2022.
- Gross profit margin was 57.2% for the three months ended December 31, 2023, compared to 57.6% for the same period in 2022.
- Research and development expenses for the three months ended December 31, 2023, increased by \$0.1 million, or 7%, compared to the same period in 2022.

- Sales and marketing expenses for the three months ended December 31, 2023, decreased by \$1.1 million, or 40%, compared to the same period in 2022. This decrease was primarily due to decreased employment-related expenses and travel costs.
- General and administrative expenses for the three months ended December 31, 2023, increased by \$0.1 million, or 4%, compared to the same period in 2022.

Full Year 2023 Highlights

- Product revenue was \$9.2 million for the year ended December 31, 2023, compared to \$8.0 million for the same period in 2022. The 15% product revenue increase was due to the addition of the Company's OvaWatch product, and an increase in the average unit price (AUP) per test to \$382 for the year ended December 31, 2023, compared to \$372 for the same period in 2022.
- The number of OvaSuite tests performed increased 12% to approximately 23,990 tests during the year ended December 31, 2023, compared to approximately 21,423 tests for the same period in 2022.
- Gross profit margin was 57.5% for the year ended December 31, 2023, compared to 52.8% for the year ended December 31, 2022. The change in gross margin was primarily due to a decrease in variable lab supply and shipping costs compared to the prior year.
- Research and development expenses for the year ended December 31, 2023, decreased by \$1.9 million, or 32%, compared to the same period in 2022. The decrease was primarily due to a decrease in costs related to the Company's sponsored research collaboration agreements, a decrease in consulting expenses and a decrease in costs due to the closure of a research and development lab in 2023.
- Sales and marketing expenses for the year ended December 31, 2023, decreased by \$7.1 million, or 48%, compared to the same period in 2022. This decrease was primarily due to decreased employment-related expenses and travel costs.
- General and administrative expenses for the year ended December 31, 2023, decreased by \$2.4 million, or 16%, compared to the same period in 2022. This decrease was primarily due to a decrease in employment-related expenses and a decrease in outside legal costs, offset by increased accounting costs.

Balance Sheet Highlights

As of December 31, 2023, Aspira had \$2.9 million in cash, including restricted cash. Subsequent to the end of the quarter, Aspira raised \$5.5 million in gross proceeds in a registered direct offering and concurrent private placement. Cash used in operating activities was \$3.5 million for the three months ended December 31, 2023, compared to \$7.1 million in the same period in 2022. Cash used in operating activities for the year ended December 31, 2023, was \$15.9 million, a 49% decrease compared to \$31.1 million in the same period in 2022.

Conference Call and Webcast Details

Aspira will host a conference call beginning at 8:30 am ET today, March 28, 2024. Conference call and webcast details are as follows:

Time: 8:30 am ET
Toll Free: 877-407-4018
International: 201-689-8471
Webcast: [Click HERE](#)

The webcast will also be available on the Events & Presentations page of the Aspira Women's Health Investor Relations website. An archive of the webcast replay will be available on the Company's website for up to 90 days.

About Aspira Women's Health Inc.

Aspira Women's Health Inc. is dedicated to the discovery, development, and commercialization of noninvasive, AI-powered tests to aid in the diagnosis of gynecologic diseases.

OvaWatch® and Ova1Plus® are offered to clinicians as OvaSuiteSM. Together, they provide the only comprehensive portfolio of blood tests to aid in the detection of ovarian cancer for the 1.2+ million American women diagnosed with an adnexal mass each year. OvaWatch provides a negative predictive value of 99% and is used to assess ovarian cancer risk for women where initial clinical assessment indicates the mass is indeterminate or benign, and thus surgery may be premature or unnecessary. Ova1Plus is a reflex process of two FDA-cleared tests, Ova1® and Overa®, to assess the risk of ovarian malignancy in women planned for surgery.

Our in-development test pipeline is designed to expand our ovarian cancer portfolio and addresses the tremendous need for noninvasive diagnostics for endometriosis, a debilitating disease that impacts millions of women worldwide. In ovarian cancer, our OvaMDxSM risk assessment is designed to combine microRNA and protein biomarkers with patient data to further enhance the sensitivity and specificity of our current tests. In endometriosis, EndoCheckSM is the first-ever noninvasive test designed to identify endometriomas, one of the most commonly occurring forms of endometriosis. The EndoMDxSM test is designed to combine microRNA and protein biomarkers with patient data to identify all endometriosis.

Forward-Looking Statements

This press release contains forward-looking statements, as defined in the Private Securities Litigation Reform Act of 1995. Forward-looking statements involve a number of risks and uncertainties. Such forward-looking statements include statements regarding, among other things, the timing and completion of any products in the pipeline development and other statements that are predictive in nature. Actual results could differ materially from those discussed due to known and unknown risks, uncertainties, and other factors. These forward-looking statements generally can be identified by the use of words such as “designed to,” “expect,” “plan,” “anticipate,” “could,” “may,” “intend,” “will,” “continue,” “future,” other words of similar meaning and the use of future dates. Forward-looking statements in this press release and other factors that may cause such differences include the satisfaction of customary closing conditions related to the offering and the expected timing of the closing of the offering. These and additional risks and uncertainties are described more fully in the company’s filings with the SEC, including those factors identified as “Risk Factors” in our most recent Annual Report on Form 10-K, for the fiscal year ended December 31, 2023, and subsequent Quarterly Reports on Form 10-Q. If any of these risks materialize or our assumptions prove incorrect, actual results could differ materially from the results implied by these forward-looking statements. There may be additional risks that Aspira presently does not know, or that Aspira currently believes are immaterial, that could also cause actual results to differ from those contained in the forward-looking statements. In addition, forward-looking statements reflect Aspira’s expectations, plans, or forecasts of future events and views as of the date of this press release. Subsequent events and developments may cause the Company’s assessments to change. However, while Aspira may elect to update these forward-looking statements at some point in the future, Aspira expressly disclaims any obligation to do so, except as required by law. These forward-looking statements should not be relied upon as representing Aspira’s assessments of any date after the date of this press release. Accordingly, undue reliance should not be placed upon the forward-looking statements.

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Aspira Women’s Health Inc.
Condensed Consolidated Balance Sheets

(Amounts in Thousands, Except Share and Par Value Amounts)
 (Unaudited)

	December 31, 2023	December 31, 2022
Assets	<u>(Unaudited)</u>	
Current assets:		

Cash and cash equivalents	\$	2,597	\$	13,306
Accounts receivable, net of reserves of \$15 and \$9, at September 30, 2023 and December 31, 2022, respectively		1,459		1,245
Prepaid expenses and other current assets		997		1,442
Inventories		227		316
Total current assets		5,280		16,309
Property and equipment, net		165		368
Right-of-use assets		528		282
Restricted cash		258		251
Other assets		31		163
Total assets	\$	6,262	\$	17,373
Liabilities and Stockholders' (Deficit) Equity				
Current liabilities:				
Accounts payable	\$	1,261	\$	881
Accrued liabilities		2,863		3,402
Current portion of long-term debt		166		403
Short-term debt		670		764
Lease liability		159		77
Total current liabilities		5,119		5,527
Non-current liabilities:				
Long-term debt		1,430		2,315
Lease liability		427		272
Warrant liabilities		1,651		2,280
Total liabilities		8,627		10,394
Commitments and contingencies				
Stockholders' (deficit) equity:				
Common stock, par value \$0.001 per share, 200,000,000 and 150,000,000 shares authorized at December 31, 2023 and December 31, 2022, respectively; 10,645,049 and 8,306,326 shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively		11		8
Additional paid-in capital		515,927		508,584
Accumulated deficit		(518,303)		(501,613)
Total stockholders' (deficit) equity		(2,365)		6,979
Total liabilities and stockholders' (deficit) equity	\$	6,262	\$	17,373

Aspira Women's Health Inc.
Condensed Consolidated Statements of Operations
(Amounts in Thousands, Except Share and Per Share Amounts)

(Unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Revenue:				
Product	\$ 2,130	\$ 2,080	\$ 9,153	\$ 8,812
Genetics	–	73	1	–
Total revenue	2,130	2,153	9,154	8,812
Cost of revenue:				
Product	911	926	3,892	3,892
Genetics	–	(13)	–	–
Total cost of revenue	911	913	3,892	3,892
Gross profit	1,219	1,240	5,262	4,920
Operating expenses:				
Research and development	1,077	1,002	4,035	3,812
Sales and marketing	1,743	2,888	7,812	7,812
General and administrative	2,534	2,441	12,267	11,812
Total operating expenses	5,354	6,331	24,114	23,436
Loss from operations	(4,135)	(5,091)	(18,852)	(18,516)
Other income (expense), net:				
Change in fair value of warrant liabilities	862	468	629	–
Interest income, net	2	27	48	–
Forgiveness of DECD loan	–	–	1,000	–
Other income (expense), net	182	5	485	–
Total other income (expense), net	1,046	500	2,162	–
Net loss	\$ (3,089)	\$ (4,591)	\$ (16,690)	\$ (18,516)
Net loss per share – basic and diluted	\$ (0.30)	\$ (0.55)	\$ (1.81)	\$ (1.81)
Weighted average common shares used to compute basic and diluted net loss per common share	10,408,132	8,299,729	9,233,306	7,760,000