

Aspira Women's Health Reports First Quarter 2024 Financial Results

Description

May 15, 2024 07:30 ET

Q1 2024 OvaSuiteSM revenue of \$2.2 million and volume of 5,829 units

Q1 2024 cash utilization of \$4.4 million, a decrease of 22% compared to Q1 2023

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

AUSTIN, Texas, May 15, 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 first quarter ended March 31, 2024.

"Our continued focus on growth, innovation and operational excellence has positioned us for an exciting year," said Nicole Sandford, Chief Executive Officer of Aspira. "We saw OvaWatch® volume grow 114% this quarter when compared to the first quarter of last year, and we continued our two-year trend of cost reductions across the company. Moreover, the price volatility we anticipated following the introduction of OvaWatch in 2022 never materialized, and our gross margin remains strong."

"OvaWatch offers an incredible opportunity for our growth, especially now that its features have been expanded to allow for repeat testing at provider-prescribed intervals. Moreover, clinical evidence to support the use of OvaWatch is stronger than ever. Recent publications showed that clinicians may have been able to avoid surgery for a majority of women with low- or indeterminate ovarian cancer risk if OvaWatch had been used as part of clinical decision-making. This one-of-a-kind tool offers clear benefits to patients, providers and payers alike, and is poised to improve outcomes for patients that choose to delay or avoid surgery in favor of a watchful waiting approach."

"Our team is more prepared than ever to take advantage of the expanded commercially available OvaSuite test portfolio. We saw very strong signs of a return to growth now that our commercial strategy has reached the execution phase. March was the strongest month of the first quarter and that momentum carried into April, the second largest volume month in company history."

Recent Corporate Highlights

- Published a study that demonstrated OvaWatch significantly improves patient selection for surgery in ovarian cancer management. The study entitled: "*Ovarian Cancer Surgical Consideration is Markedly Improved by the Neural Network Powered-MIA3G Multivariate Index Assay*," evaluated 785 surgical results in women with an adnexal mass. Results demonstrated that the use of OvaWatch would have

reduced the number of surgeries by 62% overall, and by 77% in pre-menopausal women. Had physicians utilized OvaWatch scores for surgery selection, results demonstrated a 431% improvement in the ability to predict malignancy.

- Published a study of 500 women validating the use of OvaWatch as a tool to monitor adnexal masses over time. The study, entitled “*Neural Network-derived Multivariate Index Assay Demonstrates Effective Clinical Performance in Longitudinal Monitoring of Ovarian Cancer Risk*,” found serial testing with OvaWatch to be a useful clinical tool in monitoring cancer risk of an adnexal mass.
- Enhanced the Company’s commercial offering with the formal launch of the longitudinal monitoring feature of OvaWatch. The new feature offers physicians a tool for assessing malignancy risk over time and determining the appropriate personalized treatment path. OvaWatch utilizes an AI-powered algorithm to assess malignancy risk of adnexal masses when initial clinical assessment indicates the mass is indeterminate or low-risk.
- Announced a new agreement with Anthem Blue Cross in California for reimbursement coverage of the Company’s OvaSuite portfolio of risk assessment tests effective June 1, 2024. Anthem Blue Cross will provide coverage for its commercial and government lines of business, including Medicare Advantage and Medicaid, which represents a total of approximately six million covered lives in California. The Company was credentialed by Anthem during the first quarter of 2024, allowing for its affiliates to partner with Aspira, and more contracts are expected to follow.

First Quarter 2024 Financial Highlights

- Product revenue was \$2.2 million for the three months ended March 31, 2024, compared to \$2.3 million for the same period in 2023. The number of OvaSuite tests performed was approximately 5,829 during the three months ended March 31, 2024, a 7% decrease compared to the approximately 6,259 OvaSuite tests for the same period in 2023. The average unit price (AUP) for the Company’s OvaSuite tests was \$369 for the three months ended March 31, 2024, compared to \$370 for the same period in 2023. Sales efficiency, as measured by volume per full-time sales representative, increased 22% in the first quarter compared to the same period in 2023.
- Gross profit margin was 56% for the three months ended March 31, 2024, compared to 51% for the same period in 2023.
- Research and development expenses for the three months ended March 31, 2024, were \$0.9 million, a decrease of 28% compared to \$1.3 million for the same period in 2023. This decrease was primarily due to decreases in personnel costs.
- Sales and marketing expenses for the three months ended March 31, 2024, were \$1.9 million, a decrease of 27%, compared to \$2.6 million for the same period in 2023. This decrease was primarily due to decreased consulting, personnel, and travel costs.
- General and administrative expenses for the three months ended March 31, 2024, were \$3.1 million, a decrease of 13%, compared to \$3.6 million for the same period in 2023. This decrease was primarily due to a decrease in personnel costs, as well as outside accounting and consulting costs.

Balance Sheet Highlights

As of March 31, 2024, Aspira had \$3.7 million in cash, including restricted cash, up from \$2.9 million in cash, including restricted cash as of December 31, 2023. Aspira raised \$5.6 million in gross proceeds in a registered direct offering during the first quarter 2024. Cash used in operating activities was \$4.4 million for

the three months ended March 31, 2024, compared to \$5.7 million in the same period in 2023, a 22% decrease. The Company's operating cash utilization target for 2024 remains between \$15 million and \$18 million.

Conference Call and Webcast Details

Aspira's management team will host a conference call beginning at 8:30 am ET today, May 15, 2024. Investors and other interested parties may participate in the conference call by dialing 1-877-407-4018. The call will be available via webcast by [clicking HERE](#) or on the events page of the Company's website after the conclusion of the call.

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 comprised 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 may contain forward-looking statements that are made pursuant to the safe harbor provisions of the federal securities laws, including those relating to the timing and completion of any products in the pipeline development and other statement 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 and subsequent Quarterly Reports on Form 10-Q. We are providing this information as of the date of this press release and do not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future

events or otherwise, except as required by law.

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Condensed Consolidated Balance Sheets (unaudited)
 (Amounts in Thousands, Except Share and Par Value Amounts)

	March 31, 2024	December 31, 2023
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 3,413	\$ 2,597
Accounts receivable, net of reserves of \$2 and \$15, as of March 31, 2024 and December 31, 2023, respectively	1,531	1,459
Prepaid expenses and other current assets	942	997
Inventories	236	227
Total current assets	<u>6,122</u>	<u>5,280</u>
Property and equipment, net	131	165
Right-of-use assets	620	528
Restricted cash	260	258
Other assets	31	31
Total assets	<u><u>\$ 7,164</u></u>	<u><u>\$ 6,262</u></u>
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	\$ 1,643	\$ 1,261
Accrued liabilities	2,797	2,863
Current portion of long-term debt	249	166
Short-term debt	416	670
Current maturities of lease liabilities	188	159
Total current liabilities	<u>5,293</u>	<u>5,119</u>
Non-current liabilities:		
Long-term debt	1,347	1,430
Non-current maturities of lease liabilities	487	427
Warrant liabilities	1,400	1,651
Total liabilities	<u><u>8,527</u></u>	<u><u>8,627</u></u>

Commitments and contingencies

Stockholders' deficit:

Common stock, par value \$0.001 per share, 200,000,000 and 150,000,000 shares authorized at March 31, 2024 and December 31, 2023, respectively; 12,344,104 and 10,645,049 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively

	12	11
Additional paid-in capital	521,557	515,927
Accumulated deficit	(522,932)	(518,303)
Total stockholders' deficit	(1,363)	(2,365)
Total liabilities and stockholders' deficit	<u>\$ 7,164</u>	<u>\$ 6,262</u>

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

	Three Months Ended	
	March 31,	
	2024	2023
Revenue:		
Product	\$ 2,153	\$ 2,315
Genetics	-	1
Total revenue	<u>2,153</u>	<u>2,316</u>
Cost of revenue:		
Product	939	1,130
Total cost of revenue	<u>939</u>	<u>1,130</u>
Gross profit	1,214	1,186
Operating expenses:		
Research and development	906	1,267
Sales and marketing	1,889	2,595
General and administrative	3,129	3,604
Total operating expenses	<u>5,924</u>	<u>7,466</u>
Loss from operations	(4,710)	(6,280)
Other income (expense), net:		
Change in fair value of warrant liabilities	251	(24)
Interest (expense) income, net	(5)	26
Other expense, net	(165)	(300)
Total other income (expense), net	<u>81</u>	<u>(298)</u>
Net loss	<u>\$ (4,629)</u>	<u>\$ (6,578)</u>
Net loss per share – basic and diluted	<u>\$ (0.39)</u>	<u>\$ (0.79)</u>

Weighted average common shares used to compute basic and diluted net loss per common share	<u>11,846,075</u>	<u>8,313,091</u>
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