

Aspira Women's Health Reports Second Quarter 2024 Financial Results

Description

August 12, 2024 16:05 ET

Q2 2024 OvaSuiteSM revenue of \$2.4 million and volume of 6,471 units

Q2 2024 cash utilization decreased by 16% compared to Q1 2024

Full year 2024 cash guidance decreased to \$13-\$14.5 million

Conference Call and Webcast scheduled for today at 4:30 pm ET

AUSTIN, Texas, Aug. 12, 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 second quarter ended June 30, 2024.

"OvaWatch product volume grew an impressive 48% in the second quarter when compared to last year, which we believe is the most important indicator of future growth," said Nicole Sandford, Chief Executive Officer of Aspira. "We expanded the addressable market of our commercial portfolio to between 2 and 4 million tests per year when we launched the longitudinal mass monitoring application of the OvaWatch test based on powerful new data published in May. This is ten times the addressable market of the Ova1Plus test, which currently enjoys a 5-10% market share. With the hard work of rebuilding the commercial team and tools from the ground up, I believe we are uniquely positioned to take full advantage of the opportunity in front of us. We are now fully focused on making our OvaSuite test portfolio the universal standard of care for every woman diagnosed with an adnexal mass."

Ms. Sandford added, "We continue to aggressively pursue nondilutive sources of cash. However, our recent financing brought in the cash we needed to stay focused on our goals based on our lower cash projections for the year. Each person in the company sees it as their personal responsibility to continue forward progress while minimizing costs."

Dr. Sandy Milligan, President of Aspira said, "Our in-development molecular tests for ovarian cancer and endometriosis have the potential to be truly ground-breaking for women's health. Our focus on prudent, properly paced R&D spending has not materially impacted our progress towards our near-term milestones. I am excited to continue leading the design and development of cutting-edge diagnostic tools for gynecologic diseases that have plagued women for far too long."

Recent Corporate Highlights

- Announced its poster entitled: “Association of the Endometriosis Health Profile-5 (EHP-5) with Non-invasive Biomarkers in Patients with Suspected Endometriosis,” will be presented on September 26 and 27th at the 27th Annual National Association of Nurse Practitioners in Women’s Health (NPWH) Women’s Healthcare Conference being held in Chicago, IL.
- Announced its poster entitled “Application of Deep Neural Network-Based Algorithm to Provide Additional Information in the Assessment of Adnexal Masses Classified as Indeterminate by Imaging” will be presented on September 12, 2024, at The Menopause Society’s 2024 Annual Meeting being held in Chicago, IL.
- Appointed Mr. John Ragard to its Board of Directors. Mr. Ragard is an accomplished executive with extensive experience successfully managing several billion-dollar portfolios over his career.
- Closed private placement for the issuance and sale of shares of the Company’s common stock and accompanying warrants to purchase an equal number of shares for gross proceeds of \$1.9 million in July 2024.
- Completed a warrant exercise transaction with gross proceeds of \$2.1 million in July 2024.
- Announced the appointment of John Kallassy as interim chief financial officer, effective August 15, 2024.

Second Quarter 2024 Financial Highlights

- Product revenue for the three months ended June 30, 2024, was \$2.4 million compared to \$2.5 million for the same period in 2023. The number of OvaSuite tests performed was approximately 6,471 during the three months ended June 30, 2024, a 3% increase compared to the approximately 6,289 OvaSuite tests for the same period in 2023. The average unit price (AUP) for the Company’s OvaSuite tests was \$374 for the three months ended June 30, 2024, compared to \$396 for the same period in 2023 (\$381 when adjusted for a change in estimate). Sales efficiency, as measured by volume per average full-time sales representative, increased 29% for the first six months of the year when compared to the same period of 2023.

Field Sales
Rep
Ending
Quantity

2024 Q2	17
2024 Q1	13
2023 Q4	15
2023 Q3	16
2023 Q2	18
2023 Q1	18

2022 Q4	24
2022 Q3	32
2022 Q2	27
2022 Q1	26

- Gross profit margin for the three months ended June 30, 2024, was 59% compared to 62% for the same period in 2023. Gross profit was impacted by an increase in shipping costs this quarter.
- Research and development expenses for the three months ended June 30, 2024, were \$1.0 million, an increase of 37%, compared to \$0.7 million for the same period in 2023. This increase was primarily due to an increase in collaboration costs for the Company’s molecular test product development program offset by a decrease in personnel costs.
- Sales and marketing expenses for the three months ended June 30, 2024, were \$2.1 million, an increase of 21%, compared to \$1.8 million for the same period in 2023. The increase was primarily due to an increase in personnel costs for strategic account leaders, marketing, and inside sales.
- General and administrative expenses for the three months ended June 30, 2024, were \$2.7 million, a decrease of 20%, compared to \$3.4 million for the same period in 2023. This decrease was primarily due to a decrease in personnel and consulting costs.

Balance Sheet Highlights

As of June 30, 2024, Aspira had \$1.0 million in cash, compared to \$2.9 million in cash as of December 31, 2023. Subsequent to the end of the quarter, Aspira raised \$1.9 million in gross proceeds in a registered direct offering and \$2.1 million in a warrant inducement offering. Adjusting for this, the cash balance as of June 30, 2024, would have been \$5.0 million. Additionally, the Company entered into a \$4.5 million at-the-market facility with H.C. Wainwright.

Cash used in operating activities was \$3.7 million for the three months ended June 30, 2024. The Company is updating its expected operating cash utilization target for the balance of 2024 to be between \$4.8 million and \$6.3 million, or \$13 million and \$14.5 million for the full year 2024, down from its original 2024 target of between \$15 million and \$18 million.

Conference Call and Webcast Details

Aspira’s management team will host a conference call beginning at 4:30 pm ET today, August 12, 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.

Investor Relations Contact:

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Aspira Women’s Health Inc.
Condensed Consolidated Balance Sheets (unaudited)
(Amounts in Thousands, Except Share and Par Value Amounts)

	June 30, 2024	December 31, 2023
Assets	(Unaudited)	
Current assets:		
Cash and cash equivalents	\$ 962	\$ 2,597
Accounts receivable, net of reserves of \$0 and \$15, as of June 30, 2024 and December 31, 2023, respectively	1,445	1,459
Prepaid expenses and other current assets	618	997
Inventories	226	227
Total current assets	<u>3,251</u>	<u>5,280</u>
Property and equipment, net	120	165
Right-of-use assets	559	528
Restricted cash	–	258
Other assets	31	31
Total assets	<u>\$ 3,961</u>	<u>\$ 6,262</u>
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	\$ 1,943	\$ 1,261
Accrued liabilities	2,856	2,863
Current portion of long-term debt	316	166
Short-term debt	166	670
Current maturities of lease liabilities	177	159
Total current liabilities	<u>5,458</u>	<u>5,119</u>
Non-current liabilities:		
Long-term debt	1,264	1,430
Non-current maturities of lease liabilities	437	427
Warrant liabilities	511	1,651
Total liabilities	<u>7,670</u>	<u>8,627</u>
Commitments and contingencies		
Stockholders' deficit:		
Common stock, par value \$0.001 per share, 200,000,000 and 150,000,000 shares authorized at June 30, 2024 and December 31, 2023, respectively; 12,825,090 and 10,645,049 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively	13	11
Additional paid-in capital	522,740	515,927
Accumulated deficit	<u>(526,462)</u>	<u>(518,303)</u>
Total stockholders' deficit	<u>(3,709)</u>	<u>(2,365)</u>

Total liabilities and stockholders' deficit \$ 3,961 \$ 6,262

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenue:				
Product	\$ 2,423	\$ 2,491	\$ 4,576	\$ 4,806
Genetics	—	—	—	1
Total revenue	<u>2,423</u>	<u>2,491</u>	<u>4,576</u>	<u>4,807</u>
Cost of revenue:				
Product	1,002	941	1,941	2,071
Total cost of revenue	<u>1,002</u>	<u>941</u>	<u>1,941</u>	<u>2,071</u>
Gross profit	1,421	1,550	2,635	2,736
Operating expenses:				
Research and development	952	693	1,858	1,960
Sales and marketing	2,137	1,772	4,026	4,367
General and administrative	2,725	3,406	5,854	7,010
Total operating expenses	<u>5,814</u>	<u>5,871</u>	<u>11,738</u>	<u>13,337</u>
Loss from operations	(4,393)	(4,321)	(9,103)	(10,601)
Other income (expense), net:				
Change in fair value of warrant liabilities	889	992	1,140	968
Interest (expense) income, net	(10)	8	(15)	34
Forgiveness of DECD loan	—	1,000	—	1,000
Other expense, net	(16)	4	(181)	(296)
Total other income (expense), net	<u>863</u>	<u>2,004</u>	<u>944</u>	<u>1,706</u>
Net loss	<u>\$ (3,530)</u>	<u>\$ (2,317)</u>	<u>\$ (8,159)</u>	<u>\$ (8,895)</u>
Net loss per share – basic and diluted	<u>\$ (0.28)</u>	<u>\$ (0.28)</u>	<u>\$ (0.67)</u>	<u>\$ (1.06)</u>
Weighted average common shares used to compute basic and diluted net loss per common share	<u>12,518,725</u>	<u>8,400,157</u>	<u>12,181,481</u>	<u>8,357,013</u>

