Aspira Women's Health® Reports Second Quarter 2023 Financial Results

Description

August 14, 2023 16:01 ET

Continued growth trend with second quarter revenue of $2.5 million, an increase of 23% over the second quarter of 2022.

OvaSuite℠ volume of 6,289 units, an increase of 16% year-over-year

Achieved cash used in operations of $3.4 million, a decrease of 46% compared to the second quarter of 2022

Conference Call and Webcast scheduled for today 4:30 pm Eastern Time

AUSTIN, Texas, Aug. 14, 2023 (GLOBE NEWSWIRE) — Aspira Women's Health Inc. ("Aspira") (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, 2023.

"Our optimism continues to grow as we achieved sustained improvement across the company this quarter. OvaWatch℠ test volume grew 80% in its second full quarter, contributing 14% of the total 6,289 OvaSuite tests performed. Test volume per field representative continues to improve, growing more than 69% to 598 for the six months ended June 30, 2023, as a result of the ongoing strategic refresh of our commercial programs," said Nicole Sandford, Aspira's President and Chief Executive Officer. "As we look to the second half of the year, our focus is on the successful expansion of OvaWatch as a longitudinal monitoring test, and the launch of our EndoCheck blood test. Both efforts are progressing as planned."

Sandford continued, "Cash used in operations was $3.4 million, a decrease of nearly 46% compared to the second quarter of last year. Fiscal discipline, combined with the forgiveness of $1 million of debt, and an equity raise in July that brought in net proceeds of $4.3 million, has strengthened our balance sheet and sets us up for a successful second half."

The company lowered its operating cash utilization guidance for the second half of the year to between $6 and $8 million.

Upcoming Milestones

- 4Q 2023: Anticipated completion of clinical study to support adoption of OvaWatch for use as a longitudinal monitoring test.
- 4Q 2023: Launch a first generation EndoCheck diagnostic blood test.

Second Quarter and Recent Corporate Highlights

- Received a $1 million loan forgiveness from the Connecticut Department of Economic and Community Development (DECD). Following the loan forgiveness, the Company's total outstanding debt obligations are approximately $1.6 million. Additionally, the DECD agreed to defer all principal and interest payments due under all outstanding loan agreements until December 1, 2023.
- Announced online publication of three abstracts supporting the clinical utility of OvaWatch at the 2023 American Society of Clinical Oncology (ASCO) Meeting. The abstracts, co-authored by the Aspira Women's Health innovation team and Dr. Gerard Reilly, Director of Clinical Research and Innovation, at Axia Women's Health, support the clinical efficacy of OvaWatch and its potential to safely reduce surgical management of adnexal masses.
- Announced the hiring of Dr. Torsten Hombeck to our senior leadership team as Chief Financial Officer. Dr. Hombeck brings over two decades of biotech experience, having served in several senior positions at life science companies.
- Appointed Dr. Winfred Parnell as a new independent director on the Aspira Board of Directors. Dr. Parnell is a board-certified physician in obstetrics and gynecologic care.
- Announced the departure of Dr. Ryan Phan as Chief Scientific Officer/Chief Operating Officer, effective September 15, 2023.
- Reduced cash used in operations to $3.4 million in the second quarter of 2023, compared to $6.3 million in the second quarter of 2022, a reduction of 46% year-over-year.
- Raised $4.7 million in gross proceeds, before deducting underwriting discounts, commissions, and other estimated offering expenses, in a July 2023 registered direct offering of 1,694,820 shares of its common stock. Net proceeds from the offering were approximately $4.3 million. Cash and cash equivalents and restricted cash as of June 30, 2023, were $4.5 million.

Second Quarter 2023 Financial Highlights

- Total product revenue for the three months ended June 30, 2023, was $2.5 million, an increase of 23%, compared to $2.0 million for the same period in 2022. The increase in revenue was primarily driven by an increase in OvaSuite^{SM} tests performed during the quarter, which increased 16% to 6,289 compared to 5,411 for the same period in 2022.
- Revenue per OvaSuite test performed for the three months ended June 30, 2023, increased 6% to $396 compared to $373 for the same period in 2022, reflecting better-than-anticipated collections for OvaWatch in its second quarter of adoption.
- Gross profit margin was 62% for the three months ended June 30, 2023, compared to 47% for the same period in 2022.
- Research and development expenses for the three months ended June 30, 2023, were $0.7 million, a decrease of 51% compared to $1.4 million for the same period in 2022. The decrease was primarily due to decreases in consulting, clinical trials, and supply costs.
- Sales and marketing expenses for the three months ended June 30, 2023, were $1.8 million, a decrease of 51% compared to $3.6 million for the same period in 2022. The decrease was primarily

due to decreased personnel costs and improved sales force and commercial partnership efficiencies.
- General and administrative expenses for the three months ended June 30, 2023, were $3.4 million, a decrease of 19% compared to $4.2 million for the same period in 2022. This decrease was primarily due to a decrease in personnel expenses and outside legal costs.
- Total cash, cash equivalents and restricted cash as of June 30, 2023, was approximately $4.5 million. Cash used in operations for the three months ended June 30, 2023, was $3.4 million compared to $6.3 million for the same period in 2022. This is primarily due to cost cutting and personnel realignment activities taken in 2022.

First Half 2023 Financial Highlights

- Total product revenue for the six months ended June 30, 2023, was $4.8 million, an increase of 25%, compared to $3.9 million for the same period in 2022. The increase in revenue was primarily driven by an increase in OvaSuite℠ tests performed during the quarter, which increased 22% to 12,548 compared to 10,257 for the same period in 2022.
- Revenue per OvaSuite test performed for the six months ended June 30, 2023, increased 2% to $383 compared to $376 for the same period in 2022.
- Gross profit margin was 57% for the six months ended June 30, 2023, compared to 49% for the same period in 2022.
- Research and development expenses for the six months ended June 30, 2023, were $1.9 million, a decrease of 30% compared to $2.8 million for the same period in 2022. The decrease was primarily due to decreases in consulting costs, clinical trials, and supply costs.
- Sales and marketing expenses for the six months ended June 30, 2023, were $4.3 million, a decrease of 46% compared to $8.1 million for the same period in 2022. The decrease was primarily due to decreased personnel costs.
- General and administrative expenses for the six months ended June 30, 2023, were $6.6 million, a decrease of 23% compared to $8.6 million for the same period in 2022. This decrease was primarily due to a decrease in personnel expenses and outside legal costs.

Conference Call and Webcast Details

Aspira will host a conference call today beginning at 4:30 p.m. Eastern Time. Conference call and webcast details are as follows:

Time:	4:30 pm Eastern Time
Toll Free:	(877) 407-4018
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 transforming women's gynecological health with the discovery, development, and commercialization of innovative testing options for women of all races and ethnicities, starting with ovarian cancer.

Our ovarian cancer risk assessment portfolio is marketed to healthcare providers as OvaSuite℠. OvaWatch℠ is a non-invasive, blood-based test intended for use in the initial clinical assessment of ovarian cancer risk in women with benign or indeterminate adnexal masses for which surgical intervention may be either premature or unnecessary. With a negative predictive value (NPV) of 99%, OvaWatch allows physicians to confidently rule out ovarian cancer malignancy and choose the appropriate clinical management for the right patient at the right time. Ova1Plus® combines our FDA-cleared products, Ova1® and Overa®, to detect risk of ovarian malignancy in women with adnexal masses planned for surgery.

EndoCheck™, the first-of-its-kind non-invasive diagnostic test for endometriosis, is currently in development. Visit our website for more information at www.aspirawh.com.

Forward-Looking Statements

This press release contains forward-looking statements, as defined in the Private Securities Litigation Reform Act of 1995, including statements regarding the potential effects of widespread use of OvaWatch and the availability of OvaWatch in New York. Forward-looking statements involve a number of risks and uncertainties. Words such as "may," "expects," "intends," "anticipates," "believes," "estimates," "plans," "seeks," "could," "should," "continue," "will," "potential," "projects" and similar expressions are intended to identify forward-looking statements. These forward-looking statements speak only as of the date of this press release and are subject to a number of risks, uncertainties, and assumptions, including those described in the section entitled "Risk Factors" in Aspira's Annual Report on Form 10-K for the year ended December 31, 2022, and as supplemented in Aspira's 10-Q filing for the quarter ended March 31, 2023. These risks include, but are not limited to: our ability to continue as a going concern; our ability to comply with Nasdaq's continued listing requirements; impacts resulting from potential changes to coverage of Ova1 through our Medicare Administrative Carrier for Ova1; impacts resulting from or relating to the COVID-19 pandemic and actions taken to contain it; anticipated use of capital and its effects; our ability to increase the volume of our product sales; failures by third-party payers to reimburse for our products and services or changes to reimbursement rates, including our ability to continue secure reimbursement for our products; our ability to continue developing existing technologies and to develop, protect and promote our proprietary technologies; plans to develop and perform laboratory developed tests; our ability to comply with Food and Drug Administration ("FDA") regulations that relate to our products and to obtain any FDA clearance or approval required to develop and commercialize medical devices; our ability to develop and commercialize additional diagnostic products and achieve market acceptance with respect to these products; our ability to compete successfully; our ability to obtain any regulatory approval required for our future diagnostic products; or our suppliers' ability to comply with FDA requirements for production, marketing and post-market monitoring of our products; our ability to maintain sufficient or acceptable supplies of immunoassay kits from our suppliers; in the event that we succeed in commercializing our products outside the United States, the political, economic and other conditions affecting other countries; changes in healthcare policy; our ability to comply with the additional laws and regulations that apply to us in connection with the operation of Aspira Labs; our ability to use our net operating loss carryforwards; our ability to use intellectual property; our ability to successfully defend our proprietary technology against third

parties; our ability to obtain licenses in the event a third party successfully asserts proprietary rights; the liquidity and trading volume of our common stock; the concentration of ownership of our common stock; our ability to retain key employees; our ability to secure additional capital on acceptable terms to execute our business plan; business interruptions; the effectiveness and availability of our information systems; our ability to integrate and achieve anticipated results from any acquisitions or strategic alliances; future litigation against us, including infringement of intellectual property and product liability exposure; and additional costs that may be required to make further improvements to our laboratory operations. The events and circumstances reflected in Aspira's forward-looking statements may not be achieved or occur, and actual results could differ materially from those projected in the forward-looking statements. Aspira expressly disclaims any obligation to update, amend or clarify any forward-looking statements whether as a result of new information, future events or otherwise, except as required by law.

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

	June 30, 2023	December 31, 2022
Assets	(Unaudited)	
Current assets:		
Cash and cash equivalents	$ 4,246	$ 13,306
Accounts receivable, net of reserves of $57 and $9, at June 30, 2023 and December 31, 2022, respectively	1,638	1,245
Prepaid expenses and other current assets	706	1,442
Inventories	272	316
Total current assets	6,862	16,309
Property and equipment, net	261	368

Right-of-use assets	342	282
Restricted cash	255	251
Other assets	–	163
Total assets	$ 7,720	$ 17,373
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 1,072	$ 881
Accrued liabilities	3,549	3,650
Current portion of long-term debt	259	403
Short-term debt	306	764
Lease liability	188	77
Total current liabilities	5,374	5,775
Non-current liabilities:		
Long-term debt	1,334	2,315
Lease liability	228	272
Warrant liabilities	1,312	2,280
Total liabilities	8,248	10,642
Commitments and contingencies		
Stockholders' equity (deficit):		
Common stock, par value $0.001 per share, 200,000,000 and 150,000,000 shares authorized at June 30, 2023 and December 31, 2022, respectively; 8,473,363 and 8,306,326 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	9	8
Additional paid-in capital	506,745	505,621
Accumulated deficit	(507,282)	(498,898)
Total stockholders' equity (deficit)	(528)	6,731
Total liabilities and stockholders' equity (deficit)	$ 7,720	$ 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 June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**

Revenue:				
Product	$ 2,491	$ 2,018	$ 4,806	$ 3,853
Genetics	–	48	1	106
Total revenue	2,491	2,066	4,807	3,959
Cost of revenue[1]:				
Product	941	1,036	2,066	1,893
Genetics	–	64	–	139
Total cost of revenue	941	1,100	2,066	2,032
Gross profit	1,550	966	2,741	1,927
Operating expenses:				
Research and development[2]	693	1,410	1,924	2,758
Sales and marketing[3]	1,772	3,580	4,334	8,077
General and administrative[4]	3,406	4,196	6,573	8,559
Total operating expenses	5,871	9,186	12,831	19,394
Loss from operations	(4,321)	(8,220)	(10,090)	(17,467)
Change in fair value of warrant liabilities	992	–	968	–
Interest income (expense), net	8	(10)	34	(28)
Other income (expense), net	1,004	(13)	704	(16)
Net loss	$ (2,317)	$ (8,243)	$ (8,384)	$ (17,511)
Net loss per share – basic and diluted	$ (0.28)	$ (1.10)	$ (1.00)	$ (2.34)
Weighted average common shares used to compute basic and diluted net loss per common share	8,400,157	7,482,860	8,357,013	7,479,435
Non-cash stock-based compensation expense included in cost of revenue and operating expenses:				
[1] Cost of revenue	$ 2	$ 35	$ 15	$ 87
[2] Research and development	56	53	133	49
[3] Sales and marketing	139	58	122	205
[4] General and administrative	291	464	351	1,107