Aspira Women's Health Reports Second Quarter 2022 Financial Results

Description

August 10, 2022 07:30 ET

Increased product revenue by 17% to $2.0 million; Grew OVA1plus volume by 19% to 5,411 units

Entered into a research agreement with Harvard's Dana Farber Cancer Institute, Brigham & Women's Hospital, and Medical University of Lodz for development of a diagnostic test for endometriosis

Reduced cash utilization by $3.9 Million in the Second Quarter 2022

Conference Call and Webcast scheduled for today, August 10th at 8:30 a.m. ET

AUSTIN, Texas, Aug. 10, 2022 (GLOBE NEWSWIRE) — 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, 2022.

"We are pleased by our continued progress and execution during the second quarter, particularly on our three key strategic initiatives: Growth, Innovation, and Operational Excellence. Our commercial team achieved strong sequential and year-over-year growth that will be further fueled in the second half by our recently announced OVA1plus co-marketing agreement with BioReference," said Nicole Sandford, President and Chief Executive Office of Aspira.

Ms. Sandford continued, "On the innovation side, we reiterate our intention to launch OvaWatch – our next generation ovarian cancer laboratory developed test – by the end of the year. Today, we also announce an exciting expansion to our relationship with a consortium of world-class academic institutions that we believe will accelerate our endometriosis product development. Operationally, we reduced our cash utilization by $3.9 million compared to the first quarter of 2022 without sacrificing progress on our most strategic priorities. I am encouraged by our progress on all strategic fronts and look forward to continuing to deliver on our Growth, Innovation, and Operational Excellence initiatives."

Recent Corporate Highlights

- **Entered into an exclusive sponsored research agreement** with Harvard's Dana-Farber Cancer Institute, Brigham & Women's Hospital, and Medical University of Lodz for the generation of a multi-omic, non-invasive diagnostic aid to identify endometriosis based on circulating microRNAs and proteins. The results of this collaboration will be advanced, co-developed technology to guide medical and clinical management of women presenting with symptoms of endometriosis. This collaboration is expected to accelerate the development and commercialization of future endometriosis products.

- **Established a national partnership to co-market and distribute OVA1plus with BioReference Laboratories, Inc.**, the largest full-service specialty laboratory in the United States with a leading position in women's health, oncology, and urology, and 40 years of expertise in clinical diagnostics. Aspira and BioReference are working closely together on launch plans, which is targeted in the second half 2022. The relationship is expected to drive incremental volume in 2023 and beyond. Both Aspira and BioReference are deeply committed to enhancing health outcomes for women. Separately, Aspira Women's Health has established a standalone agreement with Scarlet Health, an innovative mobile phlebotomy solution providing collections for Aspira's patients from the comfort of their home.

- **Announced publication of the peer reviewed paper** entitled: *Analytical Validation of a Deep Neural Network Algorithm for the Detection of Ovarian Cancer* in the JCO Clinical Cancer Informatics. The paper demonstrated the accuracy of OvaWatch in assessing the risk of ovarian malignancy in patients with pelvic masses. With its superior negative predictive value, OvaWatch is a non-invasive test that provides additional data points for a clinician's initial assessment of women with adnexal masses. This lab developed test will support physicians in making informed clinical decisions in the management of care for women with adnexal masses.
- **Reduced Cash Utilization** by $3.9 million. In the second quarter, the company utilized $6.4 million in cash compared to $10.3 million in the first quarter of 2022.

Highlights of Second Quarter 2022 vs. Second Quarter 2021

- Product revenue for the three months ended June 30, 2022 was $2.0 million compared to $1.7 million for the same period in 2021, an increase of 17%. The increase in revenue was driven by an increase in the number of OVA1plus tests performed during the quarter, partially offset by a 1% decrease in the revenue per test performed.
- The number of OVA1plus tests performed during the quarter increased 19% to 5,411 compared to 4,553 for the same period in 2021.
- The revenue per OVA1plus test performed decreased 1% to $373 for the three months ended June 30, 2022 compared to $378 for the same period in 2021.
- Gross profit margin for OVA1plus was 49% for the three months ended June 30, 2022, compared to 52% for the same period in 2021.
- Research and development expenses for the three months ended June 30, 2022, decreased by $61,000, or 4%, compared to the same period in 2021.
- Sales and marketing expenses for the three months ended June 30, 2022 decreased by $438,000, or 11%, compared to the same period in 2021. This decrease was primarily due to lower personnel, recruiting and consulting expenses.

- General and administrative expenses for the three months ended June 30, 2022 increased by $917,000, or 28%, compared to the same period in 2021 due primarily to increased personnel expenses and legal fees.

Highlights of Second Quarter 2022 vs. First Quarter 2022:

- Product revenue was $2.0 million for the three months ended June 30, 2022, compared to $1.8 million for the three months ended March 31, 2022, an increase of 10%.
- The number of OVA1plus tests performed increased 12% to 5,411 OVA1plus tests during the three months ended June 30, 2022, compared to 4,846 OVA1plus tests for the three months ended March 31, 2022**.**
- The revenue per OVA1plus test performed for the three months ended June 30, 2022 decreased to approximately $373 compared to $379 for the three months ended March 31, 2022, a decrease of 2%.
- Gross profit margin for OVA1plus was 49% for the three months ended June 30, 2022 compared to 53% for the three months ended March 31, 2022. The sequential decrease was primarily driven by software license fees.
- Research and development expenses for the three months ended June 30, 2022 increased by $62,000, or 5%, compared to the three months ended March 31, 2022. This increase was primarily due to increased consulting costs.
- Sales and marketing expenses for the three months ended June 30, 2022 decreased by $917,000, or 20%, compared to the three months ended March 31, 2022. This decrease was primarily due to compensation expenses and costs associated with our first quarter commercial reorganization.
- General and administrative expenses for the three months ended June 30, 2022 decreased by $167,000 or 4%, compared to the three months ended March 31, 2022. This decrease was primarily due to lower consulting and other professional services costs.

Balance Sheet Highlights

- As of June 30, 2022, Aspira had $20.7 million in cash and short-term investments. Aspira utilized $6.4 million in the second quarter of 2022, compared to $10.3 million in the first quarter of 2022 and $6.4 million for the second quarter of 2021.

Conference Call and Webcast Details

Aspira will host a conference call with investors today at 8:30am Eastern Time to discuss financial results and provide a corporate update followed by a question-and-answer period.

Toll Free:	1-877-407-4018
International:	1-201-689-8471
Conference ID:	13730747
Webcast:	https://viavid.webcasts.com/starthere.jsp?ei=1556156&tp_key=c5bafc5645

About Aspira Women’s Health Inc.
Aspira Women’s Health Inc. is transforming women’s health with the discovery, development, and commercialization of innovative testing options and bio-analytical solutions that help physicians assess risk, optimize patient management, and improve gynecologic health outcomes for women. Aspira Women’s Health is particularly focused on closing the ethnic disparity gap in ovarian cancer risk assessment and developing solutions for pelvic diseases such as pelvic mass risk assessment and endometriosis.

OVA1plus™ combines our FDA-cleared products, OVA1® and OVERA®, to detect risk of ovarian malignancy in women with adnexal masses. Aspira GenetiX™ testing offers both targeted and comprehensive genetic testing options with a gynecologic focus. The next generation of products in development include OvaWatch™ and EndoCheck™. 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 expected launch timing for OvaWatch; theexpected results of the collaboration with Dana-Farber Cancer Institute, Brigham and Women's Hospital,and Medical University of Lodz; the expected launch timing and sales and margin impacts of Aspira'sagreement with BRL; and the Company's cash management for the remainder of 2022. Forward-lookingstatements 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'sAnnual Report on Form 10-K for the year ended December 31, 2021. These risks include, but are notlimited to: our ability to continue as a going concern; our ability to comply with Nasdaq's continued listingrequirements; 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 bythird-party payers to reimburse for our products and services or changes to reimbursement rates; ourability to continue developing existing technologies and to develop, protect and promote our proprietarytechnologies; plans to develop and perform LDTs; 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 todevelop and commercialize medical devices; our ability to develop and commercialize additional diagnosticproducts and achieve market acceptance with respect to these products; our ability to competesuccessfully; our ability to obtain any regulatory approval required for our future diagnostic products; or oursuppliers' ability to comply with FDA requirements for production, marketing and post-market monitoring ofour products; our ability to maintain sufficient or acceptable supplies of immunoassay kits from oursuppliers; in the event that we succeed in commercializing our products outside the United States, thepolitical, economic and other conditions affecting other countries; changes in healthcare policy; our abilityto comply with environmental laws; our ability to comply with the additional laws and regulations that applyto us in connection with the operation of ASPiRA LABS; our ability to use our net operating losscarryforwards; our ability to use intellectual property; our ability to successfully defend our proprietarytechnology against third parties; our ability to obtain licenses in the event a third party successfully assertsproprietary rights; the liquidity and trading volume of our common stock; the concentration of ownership ofour common stock; our ability to retain key employees; our ability to secure additional capital on acceptableterms to execute our business plan; business interruptions; the effectiveness and availability of ourinformation systems; our ability to integrate and achieve anticipated results from any acquisitions orstrategic alliances; future litigation against us, including infringement of intellectual property and productliability exposure; and additional costs that may be required to make further improvements to our laboratoryoperations.

Investor Relations Contact:
Ashley R. Robinson
LifeSci Advisors, LLC
Tel: 617-430-7577
Arr@lifesciadvisors.com

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

	June 30, 2022 (Unaudited)	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$20,480	$37,180
Accounts receivable	1,112	1,027
Prepaid expenses and other current assets	1,173	1,624
Inventories	191	174
Total current assets	22,956	40,005
Property and equipment, net	438	464
Right-of-use assets	315	346
Restricted cash	250	250
Other assets	57	14
Total assets	$24,016	$41,079
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$1,374	$1,501
Accrued liabilities	5,059	5,299
Current portion of long-term debt	283	201
Short-term debt	260	779
Lease liability	68	60
Total current liabilities	7,044	7,840
Non-current liabilities:		
Long-term debt	2,536	2,718
Lease liability	314	349

Total liabilities	9,894	10,907
Commitments and contingencies		
Stockholders' equity:		
Common stock, par value $0.001 per share, 150,000,000 shares authorized at June 30, 2022 and December 31, 2021; 112,296,388 and 112,138,741 shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively	112	112
Additional paid-in capital	503,249	501,788
Accumulated deficit	(489,239)	(471,728)
Total stockholders' equity	14,122	30,172
Total liabilities and stockholders' equity	$24,016	$41,079

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,	
	2022	**2021**	**2022**	**2021**
Revenue:				
Product	$2,018	$1,720	$3,853	$3,136
Genetics	48	79	106	159
Total revenue	2,066	1,799	3,959	3,295
Cost of revenue[(1)]:				
Product	1,036	839	1,893	1,494
Genetics	64	264	139	502
Total cost of revenue	1,100	1,103	2,032	1,996
Gross profit	966	696	1,927	1,299
Operating expenses:				
Research and development[(2)]	1,410	1471	2,758	2,343
Sales and marketing[(3)]	3,580	4,018	8,077	7,126
General and administrative[(4)]	4,196	3,279	8,559	5,788
Total operating expenses	9,186	8,768	19,394	15,257
Loss from operations	(8,220)	(8,072)	(17,467)	(13,958
Interest income (expense), net	(10)	3	(28)	(21
Other income (expense), net	(13)	995	(16)	985
Net loss	$(8,243)	$(7,074)	$(17,511)	$(12,994

Net loss per share – basic and diluted	$(0.07)	$(0.06)	$(0.16)	$(0.12
Weighted average common shares used to compute basic and diluted net loss per common share	112,242,893	111,958,928	112,191,520	110,311,666
Non-cash stock-based compensation expense included in cost of revenue and operating expenses:				
(1) Cost of revenue	$35	$54	$87	$88
(2) Research and development	53	95	49	121
(3) Sales and marketing	58	336	205	475
(4) General and administrative	464	797	1,107	1,087