

Aspira Women's Health Reports First Quarter 2022 Financial Results

Description

May 11, 2022 07:30 ET

Product Revenue Increased 30% to \$1.8 million; OVA1plus Volume Grew 28% to 4,819 Units

New Ordering Physicians in the First Quarter Grew 47% to 603 Year Over Year

Board and Leadership appointments announced

Conference Call and Webcast scheduled for today, May 11th at 8:30 a.m. ET

AUSTIN, Texas, May 11, 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 first quarter ended March 31, 2022.

"We are pleased to announce our first quarter 2022 results. Strong commercial performance – especially the trend in new ordering physicians – should set the stage for commercial success for the rest of the year," said Nicole Sandford, Aspira's President and Chief Executive Officer. "We are also pleased to announce the acceptance of our OVAWatch manuscript, an important milestone on the path to the expansion of our ovarian cancer product portfolio. We believe these developments – along with the addition of an outstanding Executive to our leadership team and the nomination of two highly qualified Board Members – are strong indicators of things to come."

Recent Corporate Highlights

- **Key Scientific and Operational Leadership Appointment.** Ryan Phan, Ph.D., will join Aspira as Chief Operating and Scientific Officer. Dr. Phan joins Aspira from CareDx where he served as Senior Vice President of Lab Services and Medical Director. At CareDx, Dr. Phan led the clinical testing service operations, clinical development pipelines, manufacturing, supply chain, regulatory affairs and compliance, and automation and engineering divisions. He also served as the Chief Medical Director of the company's CLIA and CAP accredited laboratories and played a key role in the expansion of the company's product portfolio. Prior to joining CareDx, Dr. Phan was Managing Director and Head of Regional Molecular Genetic Pathology and Cytogenetics at Kaiser Permanente in Northern California, where he led a series of programs related to strategic clinical development, laboratory expansion, and clinical testing. Before that, Dr. Phan was a faculty member of the University of California at Los Angeles and the Los Angeles VA Medical Center. Dr. Phan received his bachelor's degree from the University of California at Berkeley and his Ph.D from Columbia University. He completed his post-doctoral training in Cancer Genetics and Immunology at Harvard Medical School

where he was a Cancer Research Institute Fellow and American Society of Hematology Scholar.

- **Strong Commercial Performance.** Product revenue in the first quarter of 2022 increased 30% over the first quarter in 2021 despite strong COVID-related headwinds in January of 2022. The number of base ordering physicians increased to approximately 3,275 for the first quarter of 2022, representing a year-over-year increase of 26% and a sequential increase of 2% for the quarter. The total number of new ordering physicians in the first quarter of 2022 was approximately 600, a record high, an increase of 47% over the same period in the prior year, and an increase of 3% sequentially versus the fourth quarter of 2021.
- **OVAWatch Publication.** The OVAWatch manuscript, “Analytical Validation of a Deep Neural Network Algorithm for the Detection of Ovarian Cancer,” was accepted for peer reviewed publication in JCO Clinical Cancer Informatics on March 22, 2022. OVAWatch has been developed and is validated for use in Aspira’s CLIA-certified high complexity lab as a non-invasive risk assessment test for use in conjunction with clinical assessment and imaging to determine ovarian cancer risk for patients with an adnexal mass. We plan to launch the OVAWatch test as an LDT in two stages. Phase I will be a single use point in time test, and Phase II will allow for serial monitoring. We will focus on advancing to the commercial phase of the OVAWatch launch plan, including driving provider adoption and reimbursement, during the second half of 2022. The launch of the serial monitoring test remains targeted for 2023 contingent upon publication of data from the ongoing prospective serial monitoring clinical study.
- **Expansion of the Board of Directors.** Aspira’s board of directors has nominated two new candidates for election at Aspira’s 2022 annual meeting of stockholders. Dr. Bob Auerbach is the retired President of CooperSurgical Inc., a medical device and fertility company and wholly owned subsidiary of The Cooper Companies, Inc. (NYSE: COO). Dr. Auerbach previously held Executive Vice President positions including Chief Medical Officer and Chief Strategy Officer at CooperSurgical, Inc. He continues to serve as an adjunct faculty member and as an Executive Board Member of the Center for Biomedical Innovation and Technology at Yale University and has also been a member of the Yale School of Medicine clinical faculty. He currently serves on the board of directors of OCON Healthcare, Escala Medical and Empress Medical and as an advisor to CooperSurgical and GestVision. Aspira’s board of directors believes that our board will benefit greatly from Dr. Auerbach’s extensive experience in the medical industry and corporate board and executive experience.

Ruby Sharma joined strategic advisory firm RNB Strategic Advisors after she retired from Ernst & Young LLP in 2017. Ms. Sharma serves as a member of the board of directors of ShotSpotter, Inc. (Nasdaq: SSTI) and is an advisory council member for HIRE. She previously served as the Chair of the Audit Committee at Penn Medicine Princeton Health, as a member of the Board of Trustees for the National Ascend Organization and as a member of the Asia Society Business Council. Aspira’s board of directors believes that Ms. Sharma will bring a wealth of financial, strategic and leadership skills and experience to the board.

Highlights of First Quarter 2022 vs. First Quarter 2021:

- Product revenue was \$1,835,000 for the three months ended March 31, 2022, compared to \$1,416,000 for the same period in 2021, an increase of 30%.
- The number of OVA1plus tests performed increased 28% to 4,819 OVA1plus tests during the three months ended March 31, 2022, compared to 3,775 OVA1plus tests for the same period in 2021.
- The revenue per OVA1plus test performed increased to \$380 compared to \$375 for the same period in 2021, an increase of 1%.
- Gross profit margin for OVA1plus was 53% for the three months ended March 31, 2022, compared to 54% for the same period in 2021.
- Research and development expenses for the three months ended March 31, 2022 increased by \$476,000, or 55%, compared to the same period in 2021.
- Sales and marketing expenses for the three months ended March 31, 2022 increased by \$1,389,000, or 45%, compared to the same period in 2021. The increase was primarily driven by increases in personnel costs.
- General and administrative expenses for the three months ended March 31, 2022 increased by \$1,854,000, or 74%, compared to the same period in 2021.
- We ended March 31, 2022 with approximately \$27.1 million in total cash. Cash used in operations for the three months ended March 31, 2022 was \$10.2 million compared to \$5.3 million for the same period in 2021. The increase was primarily driven by investment in new hires, as well as payments associated with our recent commercial reorganization.

Highlights of First Quarter 2022 vs. Fourth Quarter 2021:

- Product revenue was \$1,835,000 for the three months ended March 31, 2022, compared to \$1,815,000 for the three months ended December 31, 2021, an increase of 1%.
- The number of OVA1plus tests performed increased 1% to 4,819 OVA1plus tests during the three months ended March 31, 2022, compared to 4,750 OVA1plus tests for the three months ended December 31, 2021.
- The revenue per OVA1plus test performed for the three months ended March 31, 2022 decreased to approximately \$380 compared to \$382 for the three months ended December 31, 2021, a decrease of 1%. This decrease was primarily driven by the mix of low average unit price payer groups such as Medicaid and patient payers.
- Gross profit margin for OVA1plus was 53% for the three months ended March 31, 2022 compared to 56% for the three months ended December 31, 2021. The sequential decrease was primarily driven by additional staffing added in anticipation of commercial growth.
- Research and development expenses for the three months ended March 31, 2022 decreased by \$105,000, or 7%, compared to the three months ended December 31, 2021. This decrease was primarily due to reduced consulting costs.
- Sales and marketing expenses for the three months ended March 31, 2022 decreased by \$380,000, or 8%, compared to the three months ended December 31, 2021. This decrease was primarily due to variable compensation expenses.
- General and administrative expenses for the three months ended March 31, 2022 increased by

\$733,000 or 20%, compared to the three months ended December 31, 2021. This increase was primarily due to increased personnel expenses.

- We ended March 31, 2022 with approximately \$27.1 million in total cash. Cash used in operations in the first quarter of 2022 was \$10.2 million compared to \$7.6 million in the fourth quarter of 2021. This increase was primarily driven by research and development investment, Operational investment, payments relating to the annual performance plan and legal expenses and separation payments in connection with our recent reorganization.

Conference Call and Webcast Details

Aspira will host a call today at 8:30 a.m. Eastern Time to discuss results followed by a question-and-answer period.

Toll Free: 1-844-826-3033

International: 1-412-317-5185

Conference ID: 10166732

Webcast: https://viavid.webcasts.com/starthere.jsp?ei=1546648&tp_key=889c6ae07f

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. With over 10 years of expertise in ovarian cancer risk assessment, Aspira Women's Health is working to deliver a portfolio of pelvic mass products over a patient's lifetime with our cutting-edge research. The next generation of products in development include OVAWatch™ and EndoCheck™. To improve patient accessibility, Aspira Women's Health has recently launched our Aspira Synergy™ technology transfer platform to empower health systems, academics, regional labs, and physician group labs to conduct genetic and specialty tests in-house. 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 future effects of our commercial performance and the pending publication of our OVAWatch manuscript and our plans to launch OVAWatch. 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, 2021.

These risks include, but are not limited to: 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; 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 environmental laws; our ability to comply with the additional laws and regulations that apply to us in connection with the operation of ASPIRA LABS, Inc.; 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)

March 31, December 31,

	2022	2021
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$26,855	\$37,180
Accounts receivable	1,136	1,027
Prepaid expenses and other current assets	1,620	1,624
Inventories	189	174
Total current assets	29,800	40,005
Property and equipment, net	480	464
Right-of-use assets	331	346
Restricted cash	250	250
Other assets	–	14
Total assets	\$30,861	\$41,079
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$1,298	\$1,501
Accrued liabilities	4,035	5,299
Current portion of long-term debt	223	201
Short-term debt	519	779
Lease liability	64	60
Total current liabilities	6,139	7,840
Non-current liabilities:		
Long-term debt	2,646	2,718
Lease liability	332	349
Total liabilities	9,117	10,907
Commitments and contingencies		
Stockholders' equity:		
Common stock, par value \$0.001 per share, 150,000,000 shares authorized at March 31, 2022 and December 31, 2021; 112,141,741 and 112,138,741 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively	112	112
Additional paid-in capital	502,628	501,788
Accumulated deficit	(480,996) (471,728
Total stockholders' equity	21,744	30,172
Total liabilities and stockholders' equity	\$30,861	\$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	
	March 31,	
	2022	2021
Revenue:		
Product	\$ 1,835	\$ 1,416
Genetics	58	80
Total revenue	1,893	1,496
Cost of revenue ⁽¹⁾ :		
Product	857	655
Genetics	75	238
Total cost of revenue	932	893
Gross profit	961	603
Operating expenses:		
Research and development ⁽²⁾	1,348	872
Sales and marketing ⁽³⁾	4,497	3,108
General and administrative ⁽⁴⁾	4,363	2,509
Total operating expenses	10,208	6,489
Loss from operations	(9,247) (5,886
Interest income (expense), net	(18) (24
Other income (expense), net	(3) (10
Net loss	\$(9,268) \$(5,920
Net loss per share – basic and diluted	\$(0.08) \$(0.05
Weighted average common shares used to compute basic and diluted net loss per common share	112,139,038	108,661,712
Non-cash stock-based compensation expense included in cost of revenue and operating expenses:		
(1) Cost of revenue	\$52	\$34
(2) Research and development	(4) 26
(3) Sales and marketing	147	139
(4) General and administrative	643	290

