Aspira Womenâ??s Health Reports Third Quarter 2022 Financial Results

Description

November 10, 2022 07:00 ET

Increased year-over-year product revenue by 26% to $2.0 million and year-over-year product volume by 29% to 5,524 units

Reconfirmed fourth quarter launch of OvaWatch ovarian cancer risk assessment and announced rebranding of the ovarian cancer product portfolio as OvaSuite

Executed and fully funded a sponsored research agreement with Harvardâ??s Dana Farber Cancer Institute, Brigham & Womenâ??s Hospital, and Medical University of Lodz for development of our endometriosis diagnostic testing portfolio

Launched co-marketing and distribution arrangement with BioReference in the fourth quarter

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

AUSTIN, Texas, Nov. 10, 2022 (GLOBE NEWSWIRE) — Aspira Womenâ??s Health Inc. (â??Aspiraâ?•) (Nasdaq: AWH), a bio-analytical based womenâ??s health company focused on gynecologic disease, today reported its financial results for the third quarter ended September 30, 2022.

â??This quarter was about sustained execution across our strategic priorities for growth, innovation, and operational excellence,â?• said Nicole Sandford, President and Chief Executive Office of Aspira. â??Following the successful reorganization of our sales and marketing organization in the first quarter, we continued to see year-over-year growth in Ova1Plus volume. We increased volume this quarter despite a $1 million reduction in sales and marketing expenses compared to the same period of 2021, demonstrating significant gains in sales efficiency.â?•

Ms. Sandford continued, â??On the innovation side, we reiterate our intention to launch OvaWatchâ?¢ in the fourth quarter of 2022. This will be a significant expansion of our ovarian cancer portfolio that is now branded as OvaSuite. With a negative predictive value of 99%, this lab developed test will offer healthcare providers a powerful tool in the initial clinical assessment of all women with adnexal masses. This launch, combined with the acceleration of our research and development related to a non-invasive test for endometriosis, demonstrates our leadership in the innovation of diagnostic technologies for gynecological diseases.â?•

Recent Corporate Highlights

- **Raised cash through a public offering** in the amount of $9 million in gross proceeds before

deducting underwriting discounts and expenses. Aspira intends to use the net proceeds of $7.7 million from the offering for working capital and other general corporate purposes, including product portfolio expansion and commercialization.

- **Entered into an exclusive sponsored research agreement** with Harvardâ??s Dana Farber Cancer Institute, Brigham & Womenâ??s Hospital, and Medical University of Lodz (the â??Sponsored Research Agreementâ?•) for the generation of a multi-omic, non-invasive diagnostic aid to identify endometriosis based on circulating microRNAs and proteins. We expect the results of this collaboration to 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 our endometriosis diagnostic portfolio.

- **Announced the formal launch of a co-marketing and distribution agreement with BioReference.** A national full-service specialty laboratory, with a focus on womenâ??s health, oncology and urology. Both Aspira and BioReference are deeply committed to enhancing health outcomes for women.

Aspira also announced the departure of long-time CFO, Robert Beechey, who will leave the company for another employment opportunity effective December 1. He has agreed to serve as a consultant during the selection and transition of a successor. Ms. Sandford commented, â??The Board and I are grateful to Bob for his contribution to Aspiraâ??s progress since joining the company in 2017. He leaves behind a strong team of finance professionals who will serve us well during the transition. We wish Bob all the best in his future endeavors.â?•

Highlights of Third Quarter 2022 vs. Third Quarter 2021

- Product revenue for the three months ended September 30, 2022 was $2,037,000 compared to $1,617,000 for the same period in 2021, an increase of 26%. The number of Ova1Plus tests performed during the quarter increased 29% to 5,524 compared to 4,281 for the same period in 2021. The revenue per test performed decreased 2% to $369 for the three months ended September 30, 2022 compared to $378 for the same period in 2021.

- Gross profit margin for Ova1Plus remained relatively flat at 57% for the three months ended September 30, 2022, compared to 56% for the same period in 2021.

- Research and development expenses for the three months ended September 30, 2022, increased by $639,000, or 42%, compared to the same period in 2021 due primarily to the cost of the Sponsored Research Agreement.

- Sales and marketing expenses for the three months ended September 30, 2022 decreased by $1,133,000, or 22%, compared to the same period in 2021. This decrease was primarily due to lower personnel, recruiting and promotional support expenses.

- General and administrative expenses for the three months ended September 30, 2022 increased by $907,000, or 24%, compared to the same period in 2021 due primarily to the non-cash change in the

fair market value of warrant liabilities.

Highlights of Third Quarter 2022 vs. Second Quarter 2022

- Product revenue was $2,037,000 for the three months ended September 30, 2022, compared to $2,018,000 for the three months ended June 30, 2022, an increase of 1%. The number of Ova1Plus tests performed increased 2% to 5,524 during the three months ended September 30, 2022, compared to 5,411 for the three months ended June 30, 2022**.** The revenue per test performed for the three months ended September 30, 2022 decreased to approximately $369 compared to $373 for the three months ended June 30, 2022, a decrease of 1%.

- Gross profit margin for Ova1Plus was 57% for the three months ended September 30, 2022 compared to 49% for the three months ended June 30, 2022. The sequential increase was primarily driven by lower employment costs and software license fees.

- Research and development expenses for the three months ended September 30, 2022 increased by $747,000, or 53%, compared to the three months ended June 30, 2022. This increase was primarily due to the cost of the Sponsored Research Agreement.

- Sales and marketing expenses for the three months ended September 30, 2022 increased by $370,000, or 10%, compared to the three months ended June 30, 2022. This increase was primarily due to compensation-related expenses.

- General and administrative expenses for the three months ended September 30, 2022 increased by $550,000, or 13%, compared to the three months ended June 30, 2022. This increase was primarily due to the non-cash change in the fair market value of warrant liabilities.

Balance Sheet Highlights

- As of September 30, 2022, Aspira had $20.8 million in cash and short-term investments. Aspira raised $9 million gross proceeds in a public offering during the third quarter of 2022. Aspira utilized $8.1 million in operating activities during the third quarter of 2022, compared to $6.4 million in the second quarter of 2022 and $8.0 million for the third quarter of 2021.The third quarter cash utilization includes one-time payments for the Sponsored Research Agreement and other EndoCheck development activities and nonrecurring severance payments.

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:	13730748

Webcast: https://viavid.webcasts.com/starthere.jsp?ei=1556165&tp_key=17a5d8269d

About Aspira Womenâ??s Health Inc.

Aspira Womenâ??s Health Inc. is transforming womenâ??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 Womenâ??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. Ova1plusâ?¢ combines our FDA-cleared products, Ova1Â® and OVERAÂ®, to detect risk of ovarian malignancy in women with adnexal masses. Aspira GenetiXâ?¢ testing offers both targeted and comprehensive genetic testing options with a gynecologic focus. The next generation of products in development include OvaWatchâ?¢ and EndoCheckâ?¢. 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 and expected performance of OvaWatch; the expected results of the collaboration with Dana-Farber Cancer Institute, Brigham and Womenâ??s Hospital, and Medical University of Lodz; and the expected launch timing and product volume impacts of Aspiraâ??s agreement with BRL. Forward-looking statements involve a number of risks and uncertainties. Words such as â??may,â?• â??expects,â?• â??intends,â?• â??anticipates,â?• â??believes,â?• â??estimates,â?• â??plans,â?• â??seeks,â?• â??could,â?• â??should,â?• â??continue,â?• â??will,â?• â??potential,â?• â??projectsâ?• 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 â??Risk Factorsâ?• in Aspiraâ??s Annual Report on Form 10-K for the year ended December 31, 2021, as supplemented by the section entitled â??Risk Factorsâ?• in Aspiraâ??s Quarterly Report on Form 10-Q for the quarter ended June 30, 2022. These risks include, but are not limited to: our ability to continue as a going concern; our ability to comply with Nasdaqâ??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; our ability to continue developing existing technologies and to develop, protect and promote our proprietary technologies; plans to develop and perform LDTs; our ability to comply with Food and Drug Administration (â??FDAâ?•) 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 suppliersâ?? 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; 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.

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

	September 30, 2022	December 31, 2021
Assets	(Unaudited)	
Current assets:		
Cash and cash equivalents	$ 20,551	$ 37,180
Accounts receivable, net of allowance of $6 and $23, respectively	1,201	1,027
Prepaid expenses and other current assets	944	1,624
Inventories	280	174
Total current assets	22,976	40,005
Property and equipment, net	417	464
Right-of-use assets	299	346
Restricted cash	250	250
Other assets	–	14
Total assets	$ 23,942	$ 41,079
Liabilities and Stockholdersâ?? Equity		
Current liabilities:		

Accounts payable	$ 1,893	$ 1,501
Accrued liabilities	4,988	5,299
Current portion of long-term debt	343	201
Short-term debt	–	779
Lease liability	73	60
Total current liabilities	7,297	7,840
Non-current liabilities:		
Long-term debt	2,426	2,718
Lease liability	293	349
Warrant liabilities	2,748	–
Total liabilities	12,764	10,907
Commitments and contingencies		
Stockholdersâ?? equity:		
Common stock, par value $0.001 per share, 150,000,000 shares authorized at September 30, 2022 and December 31, 2021; 124,445,639 and 112,138,741 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	124	112
Additional paid-in capital	504,851	501,788
Accumulated deficit	(493,797)	(471,728)
Total stockholdersâ?? equity	11,178	30,172
Total liabilities and stockholdersâ?? equity	$ 23,942	$ 41,079

Aspira Womenâ??s Health Inc.
Condensed Consolidated Statements of Operations
(Amounts in Thousands, Except Share and Per Share Amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Revenue:				
Product	$ 2,037	$ 1,617	$ 5,890	$ 4,753
Genetics	35	49	141	208
Total revenue	2,072	1,666	6,031	4,961
Cost of revenue[(1)]:				
Product	875	715	2,768	2,209
Genetics	41	202	180	704
Total cost of revenue	916	917	2,948	2,913

Gross profit	1,156	749	3,083	2,048
Operating expenses:				
Research and development[2]	2,157	1,518	4,915	3,861
Sales and marketing[3]	3,950	5,083	12,027	12,209
General and administrative[4]	4,746	3,839	13,305	9,627
Total operating expenses	10,853	10,440	30,247	25,697
Loss from operations	(9,697)	(9,691)	(27,164)	(23,649)
Change in fair value of warrant liabilities	5,004	–	5,004	–
Interest income (expense), net	18	(14)	(10)	(35)
Other income (expense), net	117	(2)	101	983
Net loss	$ (4,558)	$ (9,707)	$ (22,069)	$ (22,701)
Net loss per share – basic and diluted	$ (0.04)	$ (0.09)	$ (0.19)	$ (0.20)
Weighted average common shares used to compute basic and diluted net loss per common share	117,118,136	112,077,133	113,863,079	110,904,824
Non-cash stock-based compensation expense included in cost of revenue and operating expenses:				
(1) Cost of revenue	$ (23)	$ 49	$ 64	$ 137
(2) Research and development	65	115	114	236
(3) Sales and marketing	76	368	281	543
(4) General and administrative	428	646	1,535	1,733