Aspira Women's Health Reports Third Quarter 2023 Financial Results

Description

November 13, 2023 16:05 ET

Product revenue increased 9% to $2.2 million for the quarter, and 19% to $7.0 million year to date

OvaSuite sales volume increased 5% to 5,783 units for the quarter, and 16% to 18,331 units year to date

Third quarter cash utilization of $3.3 million, a decrease of 56% compared to third quarter last year

Conference call and webcast scheduled for today 4:30 pm Eastern Time

AUSTIN, Texas, Nov. 13, 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 three- and nine-month period ended September 30, 2023.

"We are pleased to report another quarter of year-over-year growth, with revenues this quarter of $2.2 million. We saw OvaWatch continue to become an important part of clinician's assessment of ovarian cancer risk for women with adnexal masses, and it is now approaching nearly 20% of our overall volume; notably, the 1,015 OvaWatch tests performed this quarter represented nearly half of the total number of tests performed since its launch late last year," said Nicole Sandford, Aspira's President and Chief Executive Officer. "While we experienced some moderate seasonal impacts in the third quarter, we grew both volume and revenue with a leaner and more efficient sales team. During the first nine months of this year, we performed 18,331 OvaSuite tests representing an increase of 16% versus the same period of 2022."

Ms. Sandford continued, "Our focus on the future is clear. The submission of the OvaWatch longitudinal monitoring paper is a significant achievement which we believe will expand the addressable market for our OvaSuite test portfolio. Exciting progress was made in the development of our other near-term products including OvaMDx, EndoCheck and EndoMDx. In addition, we remained committed to our operational excellence goals and are spending less to achieve more as a result. We are excited to move into 2024 from a position of strength."

Third Quarter and Recent Corporate Highlights

- A poster entitled "*Improving the diagnostic accuracy of an ovarian cancer triage test using a joint miRNA-protein model*," related to an in-development miRNA-based ovarian cancer test was presented by Dr. Kevin Elias, director of the gynecologic oncology laboratory at Brigham & Women's Hospital and Assistant Professor of Obstetrics, Gynecology and Reproductive Biology at Harvard

Medical School, at the American Association of Cancer Research (AACR) Special Conference for Ovarian Cancer. Dr. Elias highlighted data showing miRNA's potential to improve the diagnostic accuracy of non-invasive blood tests for women with adnexal masses based on his extensive ovarian cancer research. The study combined serum protein and patient clinical information from Aspira's ovarian cancer clinical studies with miRNA identified by the Elias Laboratory in collaboration with a consortium of world-renowned academic researchers. Among other findings, the presentation concluded that the combination of miRNAs, proteins, and metadata identified 90% of early-stage and 100% of late-stage ovarian cancers in the studied populations. This important research forms the basis of OvaMDx, which is expected to become part of the Company's OvaSuite portfolio under a previously announced licensing agreement.

- Established a new Clinical Advisory Board (CAB) to provide clinical input and guidance throughout the development of the Company's portfolio of products. The CAB will be chaired by Dr. Leo Twiggs, Director of Medical Affairs; initial members will include Dr. Levi Downs, Medical Director for Gynecologic Oncology, Park Nicollet Health System, Methodist Hospital; Dr. Nisha Garg, Gynecologic Surgeon, Arizona Gynecology Consultants; and Dr. Tamika Sea, Founder and Owner, Advanced Women's Care Center.
- Signed Material Transfer Agreement with The University of Oxford for the procurement of serum samples to be used to verify and validate the Company's endometriosis blood test algorithms.
- Named Dr. Jody Berry as the Company's new Chief Scientific Officer, and Michelle Snider as Senior Vice President, Commercial Strategy and Operations. Dr. Berry brings a proven track record of innovation and scientific achievement in his two decades of commercial, government, and academic experience. Ms. Snider, a seasoned sales and marketing veteran, rejoins Aspira after successful roles leading sales at Sema4Genomics and Sonic Reference Laboratory, Inc.

Third Quarter 2023 Financial Highlights

Product revenue for the three months ended September 30, 2023, was $2,217,000, an increase of 9%, compared to $2,037,000 for the same period in 2022. The increase in revenue was primarily due to an increase in OvaSuite test volume compared to the prior year, and the addition of the Company's OvaWatch product, as well as an increase in the Average Unit Price (AUP) of OvaSuite to $383 per test compared to $369 for the same period in 2022. Revenue per test is expected to be volatile during 2023 as the Company seeks broad payer adoption of the OvaWatch test launched in the fourth quarter of 2022.

Total OvaSuite test volume for the three months ended September 30, 2023, increased 5% to 5,783 compared to 5,524 for the same period in 2022. This increase is a result of 1,015 OvaWatch tests performed in the third quarter of 2023, increased access to provider offices following COVID-19 restrictions in place in 2022, and the Company's focus on improving field sales efficiencies.

Gross profit margin for the three months ended September 30, 2023 was 59.0%, compared to 55.8% for the same period in 2022.

Research and development expenses for the three months ended September 30, 2023, decreased by $1,159,000, or 54%, compared to the same period in 2022. The decrease was primarily due to decreases in costs related to the Company's collaboration with the Dana Farber Cancer Institute, Brigham Women's Hospital, and Medical University of Lodz. The Company expects research and development expenses to

increase over the fourth quarter of 2023, as a result of the addition of sites in its EndoCheck clinical study and anticipated milestones in its research collaboration agreements.

Sales and marketing expenses for the three months ended September 30, 2023, decreased by $2,248,000, or 57%, compared to the same period in 2022. The decrease was primarily due to decreased personnel costs of $1,634,000, travel costs of $336,000 and other marketing costs of $170,000. The Company expects sales and marketing expenses to increase modestly in the fourth quarter of 2023 as the Company focuses on the commercialization of OvaWatch.

General and administrative expenses for the three months ended September 30, 2023, decreased by $906,000, or 25%, compared to the same period in 2022. This decrease was primarily due to a decrease in personnel expenses of $841,000, and outside legal costs of $129,000. The Company expects general and administrative expenses to remain flat for the fourth quarter of 2023.

Nine-Months 2023 Financial Highlights

Product revenue for the nine months ended September 30, 2023, was $7,023,000, an increase of 19%, compared to $5,890,000 for the same period in 2022. The increase in revenue was primarily due to an increase in OvaSuite test volume compared to the prior year, and the addition of the Company's OvaWatch product, as well as an increase in the Average Unit Price (AUP) of OvaSuite to $383 per test compared to $373 for the same period in 2022. Revenue per test is expected to be volatile during 2023 as the Company seeks broad payer adoption of the OvaWatch test launched in the fourth quarter of 2022.

Total OvaSuite test volume for the nine months ended September 30, 2023, increased 16% to 18,331 compared to 15,781 for the same period in 2022. This increase is a result of 2,390 OvaWatch tests performed in 2023, increased access to provider offices following COVID-19 restrictions in place in 2022, and the Company's focus on improving field sales efficiencies.

Gross profit margin for the nine months ended September 30, 2023 was 57.6%, compared to 51.1% for the same period in 2022.

Research and development expenses for the nine months ended September 30, 2023, decreased by $1,957,000, or 40%, compared to the same period in 2022. The decrease was primarily due to decreases in costs related to the Company's collaboration with the Dana Farber Cancer Institute, Brigham Women's Hospital, and Medical University of Lodz.

Sales and marketing expenses for the nine months ended September 30, 2023, decreased by $5,958,000, or 50%, compared to the same period in 2022. The decrease was primarily due to decreased personnel costs of $5,238,000, including severance and other costs related to the sales force reorganization in 2022, and other travel costs of $487,000.

General and administrative expenses for the nine months ended September 30, 2023, decreased by $2,455,000, or 20%, compared to the same period in 2022. This decrease was primarily due to a decrease in personnel expenses of $2,544,000, and outside legal costs of $397,000, partially offset by increased consulting fees of $349,000 and audit fees of $202,000.

Balance Sheet Highlights

Total cash, cash equivalents and restricted cash as of September 30, 2023, was approximately $5.4 million. Cash used in operations for the three months ended September 30, 2023, was $3.3 million compared to $7.5 million for the same period in 2022. Our cash balance this quarter benefited from the registered direct offering where we raised $4.7 million in gross proceeds. The Company reiterates its operating cash utilization target for the second half of 2023 to between $6.0 million and $8.0 million.

Conference Call and Webcast Details

Aspira will host a conference call today beginning at 4:30 p.m. Eastern Time today, November 13, 2024. Conference call and webcast details are as follows:

Time:	4:30 pm Eastern Time
Toll Free:	1-877-407-4018
International:	1-201-689-8471
Conference ID:	13738303
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℠, which includes OvaWatch℠, 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℠, Aspira's 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. Forward-looking statements involve a number of risks and uncertainties. Such forward-

looking statements include statements regarding, among other things, financial guidance, our plans and strategies, ability to expand the addressable market for our products, potential to improve the diagnostic accuracy of non-invasive blood tests, potential milestones and publications. 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, as amended by Form 10-K/A filed on October 26, 2023, and as supplemented in Aspira’s Quarterly Report on Form 10-Q for the quarter ended September 30, 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; 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 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. If any of these risks materialize or our assumptions prove incorrect, actual results could differ materially from the results implied by these forward-looking statements. There may be additional risks that Aspira presently does not know, or that Aspira currently believes are immaterial, that could also cause actual results to differ from those contained in the forward-looking statements. In addition, forward-looking statements reflect Aspira’s expectations, plans, or forecasts of future events and views as of the date of this press release. Subsequent events and developments may cause the Company’s assessments to change. However, while Aspira may elect to update these forward-looking statements at some point in the future, Aspira expressly disclaims any obligation to do so, except as required by law. These forward-looking statements should not be relied upon as representing Aspira’s assessments of any date after the date of this press release.

Accordingly, undue reliance should not be placed upon the forward-looking statements.

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

	September 30, 2023	December 31, 2022
Assets	(Unaudited)	
Current assets:		
Cash and cash equivalents	$ 5,100	$ 13,306
Accounts receivable, net of reserves of $35 and $9, at September 30, 2023 and December 31, 2022, respectively	1,590	1,245
Prepaid expenses and other current assets	581	1,442
Inventories	301	316
Total current assets	7,572	16,309
Property and equipment, net	221	368
Right-of-use assets	600	282
Restricted cash	256	251
Other assets	13	163
Total assets	$ 8,662	$ 17,373
Liabilities and Stockholders' (Deficit) Equity		
Current liabilities:		
Accounts payable	$ 1,382	$ 881
Accrued liabilities	3,089	3,402
Current portion of long-term debt	378	403
Short-term debt	77	764
Lease liability	236	77
Total current liabilities	5,162	5,527

Non-current liabilities:		
Long-term debt	1,217	2,315
Lease liability	429	272
Warrant liabilities	2,513	2,280
Total liabilities	9,321	10,394
Commitments and contingencies		
Stockholders' (deficit) equity:		
Common stock, par value $0.001 per share, 200,000,000 and 150,000,000 shares authorized at September 30, 2023 and December 31, 2022, respectively; 10,287,182 and 8,306,326 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	11	8
Additional paid-in capital	514,544	508,584
Accumulated deficit	(515,214)	(501,613)
Total stockholders' (deficit) equity	(659)	6,979
Total liabilities and stockholders' (deficit) equity	$ 8,662	$ 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 September 30,		Nine Months Ended September 30,	
	2023	2022 (as restated)	2023	2022 (as restated)
Revenue:				
Product	$ 2,217	$ 2,037	$ 7,023	$ 5,890
Genetics	–	35	1	141
Total revenue	2,217	2,072	7,024	6,031
Cost of revenue[1]:				
Product	910	875	2,981	2,768
Genetics	–	41	–	180
Total cost of revenue	910	916	2,981	2,948
Gross profit	1,307	1,156	4,043	3,083
Operating expenses:				
Research and development[2]	998	2,157	2,958	4,915
Sales and marketing[3]	1,702	3,950	6,069	12,027

General and administrative[4]	2,723	3,629	9,733	12,188
Total operating expenses	5,423	9,736	18,760	29,130
Loss from operations	(4,116)	(8,580)	(14,717)	(26,047)
Change in fair value of warrant liabilities	(1,201)	1,236	(233)	1,236
Interest income (expense), net	12	18	46	(10)
Other income (expense), net	599	(457)	1,303	(473)
Net loss	$ (4,706)	$ (7,783)	$ (13,601)	$ (25,294)
Net loss per share – basic and diluted	$ (0.48)	$ (1.00)	$ (1.54)	$ (3.33)
Weighted average common shares used to compute basic and diluted net loss per common share	9,776,436	7,807,876	8,838,342	7,590,872
Non-cash stock-based compensation expense included in cost of revenue and operating expenses:				
(1) Cost of revenue	$ 7	$ (23)	$ 26	$ 64
(2) Research and development	65	65	224	114
(3) Sales and marketing	(105)	76	19	281
(4) General and administrative	451	428	1,033	1,535