

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

Description

May 11, 2023 16:01 ET

First Quarter total product revenue of \$2.3 million, an increase of 26% year-over-year

First Quarter OvaSuite volume of 6,259 units, an increase of 29% year-over-year

First Quarter cash used in operations of \$5.7 million, a decrease of 44% year-over-year

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

AUSTIN, Texas, May 11, 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 first quarter ended March 31, 2023.

"We saw record growth in both revenues and volume in the first quarter of 2023. Clearly, our recently implemented sales and marketing strategies have gained traction, driving a record increase in new ordering physicians and broad improvement in commercial effectiveness," said Nicole Sandford, Aspira's President and Chief Executive Officer. "Volume per sales rep nearly doubled in this quarter versus the same period last year, a reflection of both field sales efficiency and growth of volume from commercial partners. OvaWatch™ has been well received by patients, payors, and providers since its launch in December 2022, and contributed 491 of the total tests performed in the first full quarter of its launch. We are confident in the OvaSuiteSM franchise, with Ova1Plus® continuing to grow, OvaWatch showing strength in the market and the launch of the serial monitoring test planned for the second half of this year. We remain optimistic of our plan to launch an EndoCheck™ diagnostic blood test by the end of the year."

"Our OvaSuite franchise and pipeline opportunities are also helping to attract top talent to our company. We announced the appointment of three new Board members, Stefanie Cavanaugh, Jannie Herchuk, and Lynn O'Connor Vos," added Ms. Sandford. "Each of them joins because of the compelling growth prospects and strong management leadership at Aspira coupled with a driving passion to help change the standard of care in women's health care."

Ms. Sanford continued, “Our disciplined focus on cost containment and the prudent use of our resources since I joined the company have led to a significant decrease in cash utilization this quarter when compared to the first quarter of 2022. Cash used in operations was down more than 44% to \$5.7 million, a reflection of our fiscal discipline and commitment to meeting our cash utilization goals for 2023. With momentum building in our sales, a strong management team and board supporting our strategies, and the expansion of our capital raising capabilities through new facilities executed in the first quarter, we are more prepared than ever to face the path ahead.”

Upcoming Milestones

- 2H 2023: Anticipated completion of clinical study to support expansion of OvaWatch for use as a serial monitoring test
- 2H 2023: Launch a first generation EndoCheck diagnostic blood test

First Quarter and Recent Corporate Highlights

- Created funding alternatives for up to \$22.5 million of capital infusion by executing an at-the-market stock sales facility with Cantor Fitzgerald and a committed stock purchase agreement with Lincoln Park Financial.
- Announced an exclusive licensing agreement with Dana-Farber Cancer Institute for a microRNA-based ovarian cancer risk assessment product. The new non-invasive molecular-based test could use microRNA alone or in combination with other biomarkers to provide critical medical management tools for ovarian cancer for women with adnexal masses.
- Announced in March 2023, coverage for OvaWatch by one of the nation’s top national health insurance companies.
- Reduced cash used in operations to \$5.7 million in the first quarter of 2023, compared to \$10.2 million in the first quarter of 2022.
- Welcomed three new Board members: Stefanie Cavanaugh, Jannie Herchuk, and Lynn O’Connor Vos.

First Quarter 2023 Financial Highlights

- Total product revenue for the three months ended March 31, 2023, was \$2.3 million, an increase of 26%, compared to \$1.8 million for the same period in 2022. The increase in revenue was primarily driven by an increase in OvaSuiteSM tests performed during the quarter, which increased 29% to 6,259 compared to 4,846 for the same period in 2022.
- Revenue per OvaSuite test performed for the three months ended March 31, 2023, decreased 2% to \$370 compared to \$379 for the same period in 2022 due to the mix of products and payers. We expect revenue per test to be volatile during 2023 as we seek broad payer adoption of the OvaWatch test launched in the fourth quarter of 2022.
- Gross profit margin was 51.4% for the three months ended March 31, 2023, compared to 50.8% for the same period in 2022.
- Research and development expenses for the three months ended March 31, 2023, were \$1.2 million, a decrease of 9% compared to \$1.3 million for the same period in 2022. The decrease was primarily due to decreases in clinical trials and supply costs and consulting costs.
- Sales and marketing expenses for the three months ended March 31, 2023, were \$2.6 million, a decrease of 43% compared to \$4.5 million for the same period in 2022. The decrease was primarily due to a decrease in personnel costs including severance related to the company's sales force reorganization in the first quarter of 2023, offset by higher consulting costs.
- General and administrative expenses for the three months ended March 31, 2023, were \$3.2 million, a decrease of 27% compared to \$4.4 million for the same period in 2022. This decrease was primarily due to a decrease in personnel expenses, consulting costs, and outside legal costs.
- Total cash as of March 31, 2023, was approximately \$7.5 million. Cash used in operations for the three months ended March 31, 2023, was \$5.7 million compared to \$10.2 million for the same period in 2022. This is primarily as a result of cost cutting and personnel realignment activities taken in 2022. The company reiterates its operating cash utilization target for the remainder of 2023 to between \$10.3 million and \$13.3 million.

At the Company's Annual Stockholders Meeting held on May 9, 2023, the Company's stockholders approved a proposal to its Amended and Restated Certificate of Incorporation to effect a reverse stock split of its outstanding shares of common stock, par value \$0.001 per share, by a ratio of any whole number between 1-for-10 to 1-for-20, the implementation and timing of which was subject to the discretion of the Company's Board of Directors. On May 9, 2023, the Board of Directors approved a 1-for-15 reverse split, and on May 11, 2023, the Company filed a Certificate of Amendment to its Amended and Restated Certificate of Incorporation to effect the reverse stock split. Unless otherwise noted, all financial information presented in this press release reflects the impact of the reverse stock split.

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: 1-800-945-9434
International: 1-212-231-2937
Conference ID: 22026795
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. OvaWatchSM 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[™], 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, including statements regarding the planned launches of our serial monitoring test and our EndoCheck diagnostic blood test by the end of 2023. 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. 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; 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; 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; material weaknesses in our internal control over financial reporting; 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, 2023	December 31, 2022
Assets	(Unaudited)	
Current assets:		
Cash and cash equivalents	\$ 7,535	\$ 13,306

Accounts receivable, net of allowance of \$10 and \$9, respectively	1,554	1,245
Prepaid expenses and other current assets	1,137	1,442
Inventories	302	316
Total current assets	<u>10,528</u>	<u>16,309</u>
Property and equipment, net	305	368
Right-of-use assets	265	282
Restricted cash	253	251
Other assets	145	163
Total assets	<u><u>\$ 11,496</u></u>	<u><u>\$ 17,373</u></u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 867	\$ 881
Accrued liabilities	3,984	3,650
Current portion of long-term debt	442	403
Short-term debt	535	764
Lease liability	83	77
Total current liabilities	<u>5,911</u>	<u>5,775</u>
Non-current liabilities:		
Long-term debt	2,204	2,315
Lease liability	250	272
Warrant liabilities	2,304	2,280
Total liabilities	<u>10,669</u>	<u>10,642</u>
Commitments and contingencies		
Stockholders' equity:		
Common stock, par value \$0.001 per share, 13,333,333 and 10,000,000 shares authorized at March 31, 2023 and December 31, 2022, respectively; 8,329,543 and 8,306,326 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	8	8
Additional paid-in capital	505,784	505,621
Accumulated deficit	(504,965)	(498,898)
Total stockholders' equity	<u>827</u>	<u>6,731</u>
Total liabilities and stockholders' equity	<u><u>\$ 11,496</u></u>	<u><u>\$ 17,373</u></u>

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,	
	2023	2022
Revenue:		
Product	\$ 2,315	\$ 1,835
Genetics	1	58
Total revenue	<u>2,316</u>	<u>1,893</u>
Cost of revenue ⁽¹⁾ :		
Product	1,125	857
Genetics	–	75
Total cost of revenue	<u>1,125</u>	<u>932</u>
Gross profit	1,191	961
Operating expenses:		
Research and development ⁽²⁾	1,231	1,348
Sales and marketing ⁽³⁾	2,562	4,497
General and administrative ⁽⁴⁾	3,167	4,363
Total operating expenses	<u>6,960</u>	<u>10,208</u>
Loss from operations	(5,769)	(9,247)
Change in fair value of warrant liabilities	(24)	–
Interest income (expense), net	26	(18)
Other income (expense), net	(300)	(3)
Net loss	<u>\$ (6,067)</u>	<u>\$ (9,268)</u>
Net loss per share – basic and diluted	<u>\$ (0.73)</u>	<u>\$ (1.24)</u>
Weighted average common shares used to compute basic and diluted net loss per common share	<u>8,313,091</u>	<u>7,475,936</u>
Non-cash stock-based compensation expense included in cost of revenue and operating expenses:		
(1) Cost of revenue	\$ 13	\$ 52
(2) Research and development	77	(4)
(3) Sales and marketing	(17)	147
(4) General and administrative	60	643

