Aspira Women’s Health Reports Fourth Quarter and Full Year 2022 Financial Results

Description

March 22, 2023 16:05 ET

2022 total revenue of $8.2 million, an increase of 20% year-over-year

2022 total OvaSuite℠ volume of 21,423 units, an increase 23% year-over-year

Fourth quarter 2022 cash utilization of $7.1 million

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

AUSTIN, Texas, March 22, 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 fourth quarter and year ended December 31, 2022.

“2022 was a year of tremendous transformation as we focused on our three strategic initiatives: growth, innovation, and operational excellence. While we exited the year a much leaner company in terms of headcount, we achieved many of our most important goals, including the launch of OvaWatch℠ late last year,” said Nicole Sandford, President and Chief Executive Office of Aspira. “Our optimism for OvaWatch and its market potential has only grown, especially in light of the recent national coverage by a leading payer mere months after its commercial launch. We now turn our attention to the second phase of the OvaWatch launch as a serial use ovarian cancer risk assessment that will significantly enhance health providers’ adnexal mass monitoring capabilities.”

Ms. Sandford added, “Our development of EndoCheck™ continues, as we target the launch of a first-generation endometriosis blood test this year. We remain optimistic about our competitive positioning and the importance of a test like EndoCheck for clinicians in identifying the millions of women suffering from endometriosis.”

Ms. Sandford continued, “On the growth front, the Company achieved full year-over-year revenue of $8.2 million, representing a 20% increase, while simultaneously increasing gross margin by 8 percentage points and reducing sales and marketing expenses by 13% on a full-year basis. Our momentum continued in the first quarter of 2023 with dramatic daily volume growth in January and February.”

Ms. Sandford concluded, “Our hard work this past year has positioned us well for the challenges ahead. Our purpose-driven focus on execution and prudent use of resources will be the key to positioning Aspira as a leader in women’s gynecologic health diagnostics. We look forward to sharing an update to our pipeline strategy at a product-focused investor R&D presentation on May 23, 2023.”

2022 and Recent Corporate Highlights

- Announced, in March 2023, coverage by one of the nation’s top national health insurance companies, continuing the progress made since the launch for reimbursement coverage for OvaWatch as momentum builds for reimbursement across the portfolio: a new PLA code for OvaWatch granted by the American Medical Association; the expansion of Medicaid coverage of Ova1Plus® into an additional 5 states; and the potential for national Medicare coverage for multi-marker ovarian cancer testing – which would include Ova1Plus and OvaWatch – through the 2023 Omnibus Spending Bill.
- Continued focus on disciplined spending, reducing cash utilization to $7.1 million in the fourth quarter of 2022, compared to $10.2 million in the first quarter of 2022.
- Launched OvaWatch, Aspira’s new non-invasive blood-based test for the assessment of ovarian cancer risk in the more than one million women a year that are diagnosed with adnexal masses that are likely benign or indeterminate and for which surgical intervention may be either premature or unnecessary. OvaWatch is the only test of its kind and is part of the Company’s OvaSuite portfolio of commercialized ovarian cancer risk assessment tests, including FDA-cleared assays, Ova1® and Ova1Plus®.
- Announced the publication of the paper entitled “*Validation of Deep Neural Network-based Algorithm Supporting Clinical Management of Adnexal Mass*,” in the peer reviewed journal Frontiers in Medicine. The paper presented findings from a multi-site clinical study of OvaWatch that confirmed the negative predictive value of 99%, validating its usefulness as a personalized risk assessment for women presenting with adnexal masses where surgery is not planned.

Fourth Quarter 2022 Financial Highlights

- Total revenue for the three months ended December 31, 2022 was $2.2 million, an increase of 16% compared to $1.9 million for the same period in 2021. The increase in revenue was primarily driven by an increase in the number of OvaSuite℠ tests performed during the quarter, which increased 18% to 5,642 compared to 4,768 for the same period in 2021.
- Revenue per OvaSuite test performed for the three months ended December 31, 2022 decreased 3% to $369 compared to $381 for the same period in 2021. The decrease in revenue per test was primarily due to a shift in payer mix towards Medicaid.
- Gross profit margin was 57% for the three months ended December 31, 2022, compared to 55% for the same period in 2021, primarily attributable to targeted cost control measures in laboratory and information technology spending.
- Research and development expenses for the three months ended December 31, 2022 were $1.0 million, a decrease of $0.4 million, or 29%, compared to the same period in 2021. The decrease was primarily due to the elimination of consulting expense.
- Sales and marketing expenses for the three months ended December 31, 2022 were $2.9 million, a

decrease of $2.0 million, or 40%, compared to the same period in 2021. This decrease was primarily due to a decrease in personnel and marketing costs offset by an increase in travel expenses.
- General and administrative expenses for the three months ended December 31, 2022 were $2.9 million, a decrease of $0.8 million, or 21%, compared to the same period in 2021. This decrease was primarily due to a decrease in outside legal costs.

Full Year 2022 Highlights

- Total revenue was $8.2 million for the year ended December 31, 2022, an increase of 20% compared to $6.8 million for the same period in 2021. The increase in revenue was primarily due to an increase in OvaSuite test volume compared to the prior year, which increased 23% to 21,423 tests for the year ended December 31, 2022 compared to 17,377 tests for the same period in 2021.
- Revenue per OvaSuite test performed for the year ended December 31, 2022 decreased to approximately $372 compared to $378 for the year ended December 31, 2021. The decrease in revenue per test was primarily due to a shift in payer mix towards Medicaid.
- Gross profit margin was 53% for the year ended December 31, 2022 compared to 45% for the year ended December 31, 2021, primarily attributable to targeted cost control measures in laboratory and information technology spending.
- Research and development expenses for the year ended December 31, 2022 were $6.0 million, an increase of $0.6 million, or 12%, compared to the year ended December 31, 2021. This increase was primarily due to costs related to our sponsored research collaboration agreements, and increases in employment-related expenses, partially offset by a decrease in costs attributed to clinical trials.
- Sales and marketing expenses for the year ended December 31, 2022 were $14.9 million, a decrease of $2.1 million or 13%, compared to the year ended December 31, 2021. This decrease was primarily due to a decrease in employment related expenses, consulting expenses, and other marketing expenses, offset by an increase in travel costs.
- General and administrative expenses for the year ended December 31, 2022 were $16.2 million, an increase of $2.9 million, or 22%, compared to the year ended December 31, 2021. The increase was primarily due to legal costs, severance and role eliminations, incremental cost of the Executive Chair position, and costs related to our capital raise.

Balance Sheet Highlights

As of December 31, 2022, Aspira had $13.6 million in cash and short-term investments. Cash used in operations for the year was $32.2 million compared to $27.4 million in 2021. Aspira utilized $7.1 million in the fourth quarter of 2022 compared to $7.6 million in the fourth quarter of 2021. Cash utilization for operations in 2023 is anticipated to be between $16 million and $19 million.

Conference Call and Webcast Details

Aspira will host a conference call with investors today, March 22, 2023 at 4:30 pm Eastern Time to discuss financial results and provide a corporate update. Investors and interested parties may participate in the call using the dial-in information below:

Toll Free:	1-877-407-4018

International:	1-201-689-8471
Conference ID:	13736207
Webcast:	Click HERE

A replay of the call will be available on the Events section of the Company's website.

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. 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 right treatment 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 potential effects of widespread use of OvaWatch and the availability of OvaWatch in New York. 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, as supplemented by the section entitled "Risk Factors" in Aspira's Quarterly Report on Form 10-Q for the quarter ended September 30, 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 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. 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)

	December 31, 2022	December 31, 2021
Assets	(Unaudited)	
Current assets:		
Cash and cash equivalents	$ 13,306	$ 37,180
Accounts receivable, net of allowance of $9 and $23, respectively	1,245	1,027
Prepaid expenses and other current assets	1,442	1,624
Inventories	316	174
Total current assets	16,309	40,005
Property and equipment, net	368	464

Right-of-use assets	282	346
Restricted cash	251	250
Other assets	163	14
Total assets	$ 17,373	$ 41,079
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 881	$ 1,501
Accrued liabilities	3,650	5,299
Current portion of long-term debt	403	201
Short-term debt	764	779
Lease liability	77	60
Total current liabilities	5,775	7,840
Non-current liabilities:		
Long-term debt	2,315	2,718
Lease liability	272	349
Warrant liabilities	2,280	–
Total liabilities	10,642	10,907
Commitments and contingencies		
Stockholders' equity:		
Common stock, par value $0.001 per share, 150,000,000 shares authorized at December 31, 2022 and December 31, 2021; 124,594,888 and 112,138,741 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively	125	112
Additional paid-in capital	505,504	501,788
Accumulated deficit	(498,898)	(471,728)
Total stockholders' equity	6,731	30,172
Total liabilities and stockholders' equity	$ 17,373	$ 41,079

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

	Three Months Ended December 31,		Year Ended December 31,	
	2022	**2021**	**2022**	**2021**
Revenue:				
Product	$ 2,080	$ 1,815	$ 7,970	$ 6,568

Genetics	73	36	214	244
Total revenue	2,153	1,851	8,184	6,812
Cost of revenue[1]:				
Product	930	807	3,698	3,016
Genetics	(13)	30	167	734
Total cost of revenue	917	837	3,865	3,750
Gross profit	1,236	1,014	4,319	3,062
Operating expenses:				
Research and development[2]	1,038	1,453	5,953	5,314
Sales and marketing[3]	2,921	4,877	14,948	17,086
General and administrative[4]	2,878	3,630	16,183	13,257
Total operating expenses	6,837	9,960	37,084	35,657
Loss from operations	(5,601)	(8,946)	(32,765)	(32,595
Change in fair value of warrant liabilities	468	–	5,472	–
Interest income (expense), net	27	(13)	17	(48
Other income (expense), net	5	(2)	106	981
Net loss	$ (5,101)	$ (8,961)	$ (27,170)	$ (31,662
Net loss per share – basic and diluted	$ (0.04)	$ (0.08)	$ (0.23)	$ (0.28
Weighted average common shares used to compute basic and diluted net loss per common share	124,495,936	112,123,006	116,536,631	111,210,614
Non-cash stock-based compensation expense included in cost of revenue and operating expenses:				
(1) Cost of revenue	$ 16	$ 24	$ 80	$ 161
(2) Research and development	89	74	203	310
(3) Sales and marketing	75	289	356	1,132
(4) General and administrative	502	203	2,037	1,936