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Aspira Women's Health charts a new path for ovarian cancer with its OvaSuite risk assessments

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> Nicole Sandford

CEOCFO: ***Ms. Sandford, what is the vision behind Aspira Women's Health?***
Ms. Sandford: Aspira is one of the only public companies that is exclusively focused on the innovation of diagnostic tools related to gynecological diseases. This is an area of medicine that traditionally has been under-funded and overlooked but has received greater interest in recent years.

We offer a portfolio of clinically-available ovarian cancer risk assessment blood tests that healthcare providers can use to better understand malignancy risk for women with a pelvic mass. This includes Ova1Plus®, a combination of our FDA-cleared ovarian cancer risk assessments for women with pelvic masses who are planned for surgery, and our recently launched OvaWatch℠ test, which is the first ever ovarian cancer risk assessment tool for pelvic masses that are benign or indeterminate.

Our pipeline of future products includes the first ever blood test to aid in the detection of endometriosis, a devastating disease that affects the health, quality of life, and fertility of millions of women.

CEOCFO: ***What do the tests find?***
Ms. Sandford: The tests rely on information about biomarkers in the blood. Those biomarkers behave a certain way when ovarian cancer is

present in the body. Our proprietary algorithm has been trained to identify the signals - based on the relationships of those various biomarkers and other information like age and menopause status - and will indicate to a physician the likelihood that there is ovarian cancer present.

CEOCFO: ***Is the medical community onboard? Do they recognize, in general, that these biomarkers together do make a difference?***
Ms. Sandford: Yes. Our Ova1Plus test is in included in professional guidelines and has seen steady growth in adoption rates over time. There has been a great deal of research performed regarding our test, including two papers that were published just this year. The first was an analytical validation for OvaWatch based on a study of data from over 3,000 patients. The second was based on a study in the Philippines where ovarian cancer risk is very high. Both papers supported the superior performance of our multivariate assays and are available on our website.

More broadly, it has taken some time for the medical community to understand the power of nontraditional diagnostic tools rooted in data science and bioinformatics. Importantly, risk assessment tests like Aspira's do not replace a healthcare provider's clinical judgment and experience, or the information provided by diagnostic imaging. Our tests offer valuable insights leading to a higher degree of confidence in treatment decisions for each patient whether they decide to proceed to surgery, refer the patient to a gynecological oncologist, or take a watchful waiting approach. As more of these types of tests have been introduced, healthcare providers have grown to appreciate their value.

CEOCFO: ***How standard is assessing ovarian cancer risk in distinguishing between a woman that may have a problem and one that is likely okay? Is that becoming more commonplace?***
Ms. Sandford: Ovarian cancer presents unique challenges in terms of diagnosis. It is a tumor, which does not lend itself to a biopsy due to the risk of rupturing the tumor and spreading the cancer. It is very difficult to definitively identify ovarian cancer solely based on diagnostic imaging, such as an ultrasound, because benign and malignant masses are often very similar in appearance. Because the cancer is contained, you do not see a lot of ovarian cancer cells being released into the blood stream so you generally won't find traces of it – especially in the earlier stages - in a standard blood sample. It is a contained tumor, until it is not. By the time you could find ovarian cancer in the blood or definitively identify it on an ultrasound, it is likely to be quite advanced.

In the past, physicians have relied on a biomarker called CA-125 which has only been recommended for as a tool for ovarian cancer recurrence monitoring. Despite this, and as a result of viable alternatives, doctors have been willing to use it off-label. CA-125 on its own is not particularly effective, especially in identifying early-stage cancers. Studies have also shown that CA-125's predictive value is even lower in women of color.

Many doctors and patients have defaulted to the removal of the ovaries as the only "safe" path because there has not been an effective way to

rule out ovarian cancer in a suspicious mass. We're looking to change that with the introduction of OvaWatch.

In addition to providing doctors with the CA-125 result, which is familiar and comfortable to many providers, our test provides the added insight of an additional four to six biomarkers depending on whether the test is being used for surgical triage, or as part of an initial clinical assessment.

CEOCFO: ***How does the medical community, how do women, make that leap, from removing ovaries "just in case" to trusting a new technology?***
Ms. Sandford: Before the launch of OvaWatch, physicians did not have a tool that could reliably determine that a mass was benign without surgical removal and biopsy. And frankly, that is what is the most exciting about this product. We are talking about a true paradigm shift. For the first time ever, a physician can say to a woman with a mass, "This simple blood test has a 99% negative predictive value. If this test tells us that you do not have ovarian cancer, with 99% certainty, you do not have ovarian cancer. You can keep your ovaries."

That has never been available to women and as a result many of them have let fear of the unknown drive their decision making.

Aiding in the earlier detection ovarian cancer will always be the most important goal of our risk assessment tests. However, with OvaWatch, it is also going to be about giving women agency over the decision about when - and if - to have our ovaries removed. This enables women to avoid the numerous negative health effects of unnecessary surgical removal of the ovaries. OvaWatch is truly historic in that we can finally allow women to make that life-changing decision based on science instead of fear.

CEO/CFO: ***Are your various tests covered by insurance? Are they easy for a doctor to order and to understand the results?***
Ms. Sandford: Let us start with ordering. Our test is quite easy to order. It is a standard blood draw that can be done using one of our kits or through a phlebotomy partner. Ova1Plus is covered by Medicare and many Medicare Advantage, national commercial and regional insurance plans. As a company, we believe it is both a moral and business imperative to make our tests available to all women regardless of socioeconomic circumstances and have made it a priority to secure Medicaid. More than 60% of women covered by Medicaid are able to obtain the Ova1Plus test.

We are in the process of securing similar coverage for OvaWatch. In the meantime, it is available on a "patient pay" basis for a modest out-of-pocket cost. We offer financial assistance for those who are eligible and payment plans for everyone to ensure that our test is accessible to every woman that needs it.

CEOCFO: ***You took on the role of President CEO at Aspira Women's Health this past March. What led you to do that?***
Ms. Sandford: I had a wonderful, 30 years with Deloitte where I was given the blessing of many interesting roles. Over time, I became

someone the firm looked to for start-ups and business transformations. I loved that work, so when I retired a few years ago, I decided to join boards and continue consulting on my own.

I first heard about Aspira was when I participated in a panel with the former CEO, Valerie Palmieri, who is now our executive chair. We were on a panel discussion together where she told the story of the company. It piqued my interest so I started doing my own research. I saw that the performance of the technology was like nothing that I had ever seen before with respect to a cancer that kills so many women.

I think almost all of us have been touched by this terrible disease. My grandmother passed away from ovarian cancer in the 1960s and I watched a friend pass away from the disease when she was only in her 30s. I am a cancer survivor myself and I know that novel technology like ours is the key to changing outcomes for women in the future.

I started buying the stock and following the company. Later, I joined the board as the Audit Committee Chair and was given the opportunity to become the CEO when Valerie decided that she was interested shifting her priorities and I haven't looked back!

I am so passionate about what this company is doing. I believe in the technology. I believe in the team. I believe that doctors and insurance companies will adopt this life changing technology when they understand its power and its promise. I just felt a calling to jump in and bring everything I had learned over my career to the table here at Aspira.

CEOCFO: ***How easy, or how difficult is it to read the results? What is the mechanism of deciding or of knowing what the test result means?***
Ms. Sandford: The report itself will depend on the test performed. In general, however, our test results are quite easy to read. A personalize risk assessment score is provided along with benchmarks and individual results for some biomarkers like CA-125. We provide a great deal of contextual information regarding the results. We also employ physicians who are familiar with the technology and have treated patients with ovarian cancer to provide consultations to any physician who wants one.

CEOCFO: ***How does the medical community, how do women, make that leap from removing overaries "just in case" to trusting that this test really is meaningful? How do you go from one paradigm to the other?***
Ms. Sandford: Before the launch of OvaWatch, physicians did not have a tool that could reliably determine that a mass was benign without surgical removal and biopsy. And frankly, that is what is the most exciting about this product. We are talking about a true paradigm shift. For the first time ever, a physician can say to a woman with a mass, "This simple blood test has a 99% negative predictive value. If this test tells us that you do not have ovarian cancer, with 99% certainty, you do not have ovarian cancer. You can keep your ovaries."

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CEOCFO: *Is the investment community paying attention?*
Ms. Sandford: It is probably not a huge shock to anyone that a women's heath company does not get a ton of attention from the investment community. Having said that, Aspira has some amazing long-term investors who have stood by the company, believe in the technology and are passionate for the mission. I feel incredibly lucky to have these investors by our side. Having said that, I am disappointed that I do not have more women investors. I would love to see more women putting money behind companies like Aspira. If we do not care enough to put our money at work advancing this kind of technology, why should we expect men to do it for us?

The whole industry, the whole sector around diagnostics, is very confused right now. Investors are having a hard time sorting between the companies that are not going to make it because they do not have a commercial product or the resources to launch it with the capital markets being what they are, and companies like ours. We have commercially viable technologies and an experienced sales team to drive it into the care pathway. While we are in a very different place, the market is treating us all the same right now, and that is unfortunate. Part of my job is to make sure that we just stay focused on execution. The market will have to catch up to us.

CEOCFO: *Why pay attention to Aspira Women's Health?*
Ms. Sandford: We are a company that is innovating in an area of women's health that has tremendous opportunities for improvement. No one else is focused exclusively on improving and saving the lives of women who are impacted by gynecological disease.

These risk assessment technologies work very, very well. It is just a matter of time until adoption catches up. We believe that payers and providers will want to adopt a test that works as well in women of color as it does in white women. Therefore, I think there is just a tremendous amount of opportunity for the company, and it is a great time to buy in.

What we believe is exciting about OvaWatch is that OvaWatch gives the clinician and the patient a means of assessing the risk of whether the adnexal mass is cancer or not. The test has a high negative predictive value -meaning that if the test is negative the chance of there being ovarian cancer at the moment is extremely unlikely. Such an assessment should give the clinician and patient more comfort in their decision making. Possibly utilizing the OvaWAtch test could lead to the ability to reduce unnecessary surgical removal of a woman's ovaries, which is very, very exciting. The implications of premenopausal women of having their ovaries removed are significant.