

Non-Invasive Tests for the Identification of Gynecologic Disease

Corporate Presentation
May 2024



### Safe Harbor

This presentation contains forward-looking statements, as defined in the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, included in this presentation are forward-looking statements. These forward-looking statements include, among others, statements about the strategies and objectives of Aspira Women's Health Inc. (the "Company"), including product and financial goals, potential addressable market and revenue opportunity, potential product expansion, anticipated timing of product launches and expected development of commercial relationships. The Company's actual results may differ materially from the views expressed in these forward-looking statements. Words such as "may," "expects," "intends," "anticipates," "believes," "estimates," "plans," "seeks," "could," "should," "continue," "will," "potential," "projects" and similar expressions are intended to identify such forward-looking statements.

The events and circumstances reflected in the Company's forward-looking statements may not be achieved or occur, and actual results could differ materially from those projected in the forward-looking statements. Readers are cautioned that these forwardlooking statements speak only as of the date of this presentation, and the Company does not assume any obligation to update, amend or clarify them to reflect events, new information or circumstances after such date except as required by law. Company estimates set forth in this presentation are based on various sources of information and various assumptions and judgments made by the Company, which Company management believes are reasonable. However, the Company cannot assure you that Company estimates are correct, and actual data may materially differ from Company estimates.

The forward-looking statements are subject to certain risks, uncertainties and assumptions, including the risks and uncertainties inherent in the Company's business and including those described in the section entitled "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 2023, and in the Company's Quarterly Reports on Form 10-Q for the quarter ended March 31, 2024.



# Aspira Women's Health Investment Highlights



Revenue Generating Company

Revenue generating commercial diagnostics company focused on products to aid in the detection of gynecologic disease



Steady Growth Metrics

Steady year-over-year revenue and volume growth since 2020



Innovative Products

OvaSuite<sup>sм</sup> proprietary, Al-powered blood tests to aid in the diagnosis of ovarian cancer ordered by physicians **>200,000 times** 



Near-Term Pipeline

\$1B pipeline opportunity for blood tests in ovarian cancer and endometriosis



Market Access & Reimbursement

Medicare reimbursement of OvaWatch® and Ova1Plus® established at \$897 per test Reimbursement by several national/regional commercial and state Medicaid plans



Experienced Management

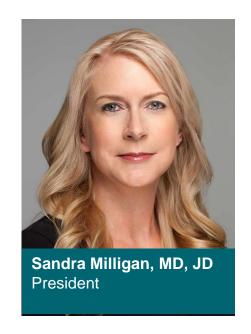
Mission-driven executives with relevant experience and proven success in small and mid-cap companies, including in women's health and diagnostics



# An Experienced Executive Team



**Deloitte.** 







**Genentech**A Member of the Roche Group





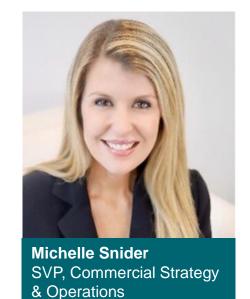












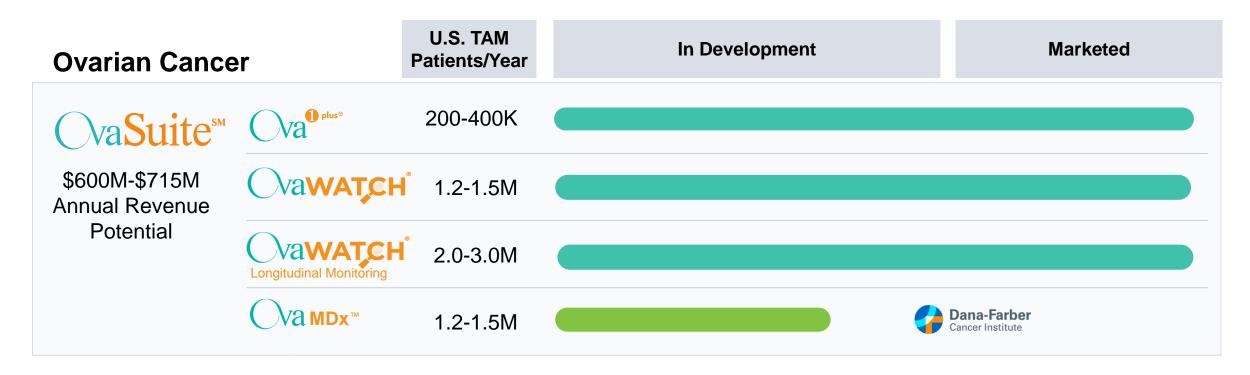




Myriad genetics



# Commercial Products with Rich Pipeline: \$1B U.S. Revenue Potential



#### **Endometriosis**

\$1B+ Annual
Revenue
Potential

Potential

2.5M

Cancer Institute
Brigham and Women's Hospital
Founding Member, Mass General Brigham

6.5M

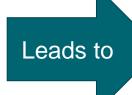


# Adnexal Masses: A Diagnostic Dilemma

Each year, 1.2M+ women will present with an adnexal mass – a lump of tissue near the uterus, usually in/on the ovary or fallopian tube. **Most relate to benign conditions, but about 20,000 are ovarian cancer.**Historical diagnostic methods used to understand the nature of the mass have often led to poor outcomes.

# Traditional methods of diagnosis are ineffective

- Non-surgical tissue sample may result in dissemination of cancer cells
- Ultrasounds are rarely definitive
- Off-label use of CA-125 is not sensitive or specific for diagnosis



# Late-stage cancer detection and unnecessary surgery

- 65% of ovarian cancers are found at Stages III and IV when 5-year survival rate is less than 30%
- 80%+ of women that undergo surgery to remove their ovaries do NOT have cancer



# A Non-Invasive Solution: Right Patient, Right Treatment, Right Time

### Physicians have ordered >200,000 OvaSuite tests





#### **Non-Surgical Management**

For the initial and periodic assessment of risk when an adnexal mass is likely benign or indeterminate in nature

Negative Predictive Value (NPV) = 99.4%



#### **Planned for Surgery**

A reflex process for women with an adnexal mass that are planned for surgical intervention

Ova1<sup>®</sup> has a sensitivity of 96% with clinical assessment. Adding Overa<sup>®</sup> to the reflex process improves specificity to 72%.





# Initial and Periodic Ovarian Cancer Risk Assessment Test

### Supported by multiple peer-reviewed publications

- Neural network-derived multivariate index assay demonstrates effective clinical performance in longitudinal monitoring of ovarian cancer risk (Gynecologic Oncology, 2024)
- Ovarian Cancer surgical consideration is markedly improved by the neural network powered-MIA3G multivariate index assay (Frontiers in Medicine, 2024)
- Validation of a deep neural network-based algorithm supporting clinical management of adnexal mass (Frontiers in Medicine, 2023)
- Analytical Validation of a Deep Neural Network Algorithm for the Detection of Ovarian Cancer (American Journal of Clinical Oncology, 2023)



#### PATIENT INFORMATION

Last Name: OVAWATCHREPORT

First Name: NEW MRN: DOB:01/01/1992

Age: 31 Ethnicity: CAUCASIAN Clinical Info: Premenopausal

#### PROVIDER INFORMATION

Ordering Provider: TEST PHYSICIAN Practice Name: TEST CLIENT Street Address: TEST ADDRESS

City, State, Zip: TEST ADDRESS

Tol: TEST PHONE Fax:

Copy-to-Physician:

Fax:

#### LAB INFORMATION

Accession No: AZ002686

Client No: TEST

Collection Date: 08/08/2023 Received Date: 08/08/2023 Report Date: 08/08/2023

Comments:

Results:	Score	Status	Reference Range	NPV*	PPV**
○vawat,ch°	2.5		Low probability of malignancy <5.0 Indeterminate ≥5.0	99%	N/A

#### OvaWatch® Scores

Report date: 17 August 2022



#### LOW PROBABILITY **OF MALIGNANCY**

OvaWatch result indicates a low probability of malignancy for this adnexal mass. Consultation with gynecology and monitoring is recommended. If indicated, follow up imaging and clinical studies.

Collection Date:	30-Jul-22	8-Nov-22	8-Aug-23
OvaWatch Score:	2.6	2.4	2.1

The scores shown were determined at the time points indicated. No conclusion can be drawn from the score changes from point to point.

NR: No Result; TNP: Test Not Performed



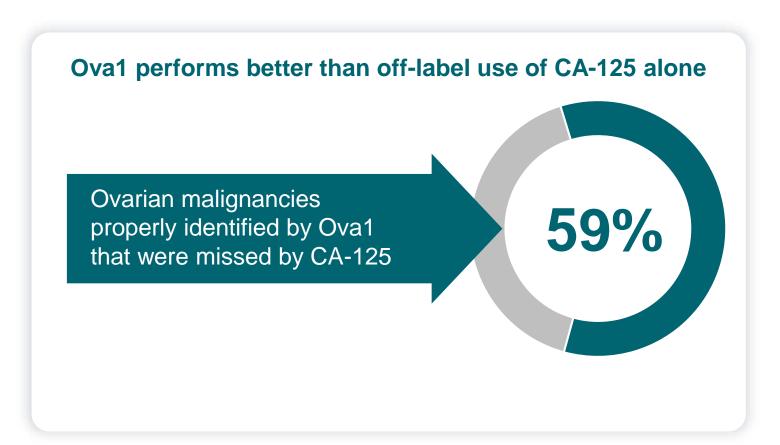


# For Women with Adnexal Masses Planned for Surgery

### Ova1Plus is a proprietary reflex process

Included in Guidelines for Adnexal Mass Management









### Market Access and Reimbursement

### We aim to make our OvaSuite of products available to all women



2024 Laboratory Test Fee Schedule for OvaWatch and Ova1Plus \$897



California, Illinois, Nevada, Georgia, New York, New Mexico, South Carolina, North Dakota

























- Anthem Blue Cross is contracted for OvaSuite in California. Other states to follow.
- State of California Medicaid Program (Medi-Cal) added Ova1Plus to fee schedule at \$897/test.
- 18 States have passed biomarker testing coverage laws. 10 additional states have bills in process.





# **Enhanced Assay for Improved Performance**

### **Aspira's Advantages**



Existing protein-based FDA approved test



Exclusive rights to miRNA identified by Dana Farber



Experience in AI developed tests and proprietary algorithms



Brand recognition with healthcare providers



Access to large biobank for verification and validation

### **OvaMDx Assay Features**

A promising new Al-powered blood test to aid in the identification of ovarian cancer in women diagnosed with an adnexal mass.

- Non-invasive, blood-based assay utilizing multiple, differentiating biomarkers
- Combines Aspira's protein biomarkers with miRNAs licensed from Dana Farber and clinical data in a proprietary algorithm for:
  - Improved specificity for all stage cancers vs. proteins alone
  - Improved sensitivity for early-stage cancers vs. proteins alone
- Platform migration in process with CRO partner





# **Development Pathway**

OvaMDx is an Al-powered multivariate blood test for the identification of ovarian cancer in women diagnosed with an adnexal mass. AWH has an exclusive license for the Dana Farber miRNA technology.

#### **Discovery: Complete**

miRNA signature published using NGS and qPCR

Establish miRNA detection feasibility on BioRad ddPCR

Establish performance of initial combined protein/miRNA signature

#### **Design: In Process**

Establish miRNA analytical properties on ddPCR

Down-select miRNAs

Complete miRNA/protein algorithm revision

Complete assay design inputs

Software design inputs

#### Verification & Validation

Complete Algorithm and software design outputs

Algorithm/ Assay Design freeze

Initial Reagent Lot Manufacture

Analytical and Clinical **Validations** 

#### Regulatory & Launch

Regulatory strategy for efficient registration/ clearance pathway

Commercialization and launch activities



# Endometriosis: A Diagnostic Dilemma

Endometriosis is a debilitating condition in which tissue similar to the lining of the uterus grows outside the uterus. It effects an estimated 6.5 million women in the US alone.

Only 50% of women who undergo a laparoscopic procedure are diagnosed with endometriosis.

### Lack of effective tools for diagnosis

- Symptoms overlap with other conditions
- Currently requires an invasive procedure, typically laparoscopy with or without histologic verification



Leads to:

### Potentially long times to diagnosis

- 4-11 years from first symptom onset to surgical diagnosis
- Symptoms may be ignored by patient or dismissed by physician





# First-ever Protein-based Assay for Diagnosis of Endometriomas

### **Aspira's Advantages**



A-approved platform



Validating in CLIA/CAP/ NY/CA/MD/PA/RI stateapproved laboratory



Experienced in Al developed tests utilizing protein biomarkers and proprietary algorithms

### **EndoCheck Assay Features**

Designed to aid in the diagnosis endometriomas, which are present in approximately 40%+ of women with endometriosis.

- Non-invasive, blood-based assay utilizing multiple, differentiating biomarkers
- Proprietary algorithm leverages core Aspira technologies and experience
- Developed with histology confirmed endometriosis and appropriate control cohorts

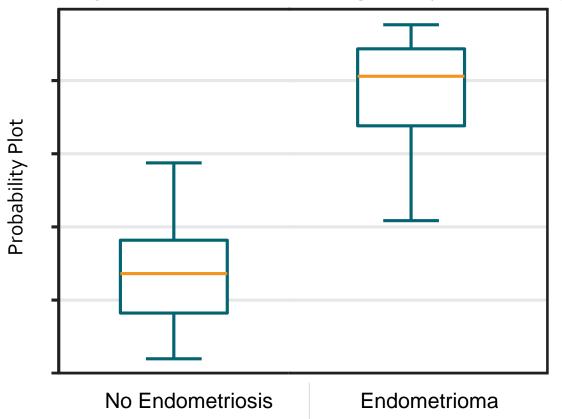
Currently running clinical validation with additional patient samples in **CLIA-certified laboratory environment** 





### Identification of Endometriomas with an AI-powered Protein Algorithm

Prediction Values for subsets of Oxford Dataset presented at Society of Reproductive Investigation (March 2024)



Clear grouping of the endometrioma populations from non-endometriomas.

First-of-its-kind blood test with preliminary accuracy of 85% for the identification of endometriomas and preliminary specificity of 90-93%

Performance of the EndoCheck algorithm was verified using statistically significant set of histologically confirmed samples obtained from the University of Oxford.

"If a physician can rule out ovarian cancer with OvaWatch and rule in or out endometrioma using EndoCheck, it allows for more confidence in understanding the diagnosis prior to initiating a treatment plan." -Kevin Elias M.D.





# **Development Pathway**

EndoCheck is an Al-powered multivariate blood test to aid in the diagnosis of endometrioma, an endometriosis mass located on the ovary

#### **Discovery: Complete**

Protein signature pattern discovered at Aspira has been verified for endometrioma with samples from Oxford University

#### **Design: Complete**

Down-select protein biomarkers and refined algorithm for endometrioma

#### **Verification & Validation**

Verified in three separate cohorts (Oxford, DFCI and AWH)

Ongoing validation with prospective clinical study samples

### Regulatory & Launch

Regulatory strategy for efficient registration/ clearance pathway

Commercialization and launch strategy TBD





# Protein + miRNAs-based Assay for Diagnosis of All Types of Endometriosis

### **Aspira's Advantages**



Leverages OvaMDx platform development



Ongoing clinical study providing samples to complete development



### **EndoMDx Assay Features**

**EndoMDx** is being designed to aid in the diagnosis of all endometriosis.

- Expands patient population beyond endometrioma
- Non-invasive, blood-based assay utilizing proteins, clinical factors, and miRNAs
- Proprietary IP for miRNAs identified by DFCI under terms of our Sponsored Research Agreement
- Platform migration underway for simple ddPCR test for OvaMDx; EndoMDx will follow on same BioRad platform





# **Development Pathway**

### EndoMDx is an Al-powered multivariate blood test to aid in the diagnosis of all endometriosis

#### **Discovery: In Process**

miRNA and protein candidate features for endometriosis discovered at DFCI under sponsored RD agreement

Establish miRNA detection feasibility on BioRad ddPCR

Establish protein detection feasibility on commercial clinic platform



Establish miRNA analytical properties on ddPCR

Down-select miRNAs

Down-select proteins

Complete miRNA/protein algorithm revision

Complete assay design

Software design inputs



Complete Algorithm and software design outputs

Algorithm/Assay Design freeze

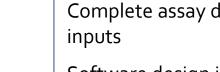
Initial Reagent Lot Manufacture

**Analytical and Clinical Validations** 

#### Regulatory & Launch

Regulatory strategy for efficient registration/ clearance pathway

Commercialization and launch activities





# Financial Performance Snapshot

### **Q1 2024 YoY Comparison**







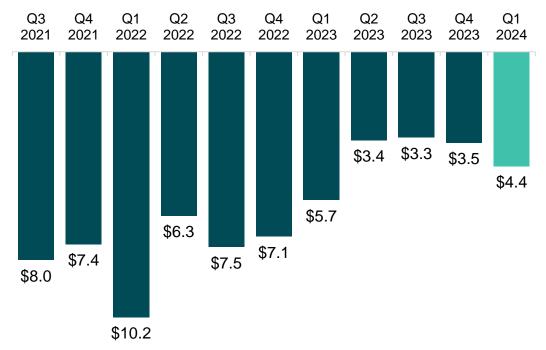


#### **Balance Sheet**

#### **Cash Position**

Cash as of March 31, 2024: \$3.4M\* \$15 to \$18M 2024 Operating cash utilization target:

#### **Cash Used in Operations (in Millions)**



<sup>\*</sup> Includes cash, cash equivalents and restricted cash



# Sales Force Productivity: Doing More with Less

Shift to targeted marketing, turn-over of underperforming reps, commercial partnerships and inside sales led to consistent improvement in the number of tests sold by each full-time sales representative.



Current team of 16 field sales reps today:

- Average tenure of 2 years at Aspira
- Top two salespeople have been with Aspira for 5 and 11 years, respectively.
- 203 years of combined sales experience
- 87 years of combined women's health sales experience

\*Calculated by dividing total volume per quarter by the average of the number of reps on the first and last days of the quarter.



# 2024 Product Development Milestones





# 2024 Key Growth Drivers

### OvaSuite Adoption and Growth



Complete commercial refresh to capture the large patient population of women with adnexal masses

### Accelerate Innovation and R&D



Planned expansion of product portfolio

### Market Access and Reimbursement



Expand OvaSuite payer adoption and improve average unit price

### **Collaboration Opportunities**



Secure additional development and commercial partnerships







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