ASPIRA
WOMEN'S HEALTH®

# Using Risk Assessment Tests to Transform Gynecological Health Starting with Ovarian Cancer

Corporate Overview
September 2023

# 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 forward-looking 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, 2022, as supplemented by the section entitled "Risk Factors" in the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2023.

# Investment Highlights

| | |
|---|---|
| Revenue Generating Company | Commercial diagnostics company with revenue producing blood tests processed in our own CLIA-certified laboratory |
| Strong Growth Metrics | Consistent revenue and volume growth since Q2 2020 |
| Innovative Products | OvaSuite℠: A group of unique ovarian cancer risk assessment assays |
| Near-Term Pipeline | 2H 2023: Expansion of OvaWatch℠ for longitudinal monitoring<br>4Q 2023: Commercial launch of EndoCheck℠ for endometriosis |
| Market Access & Reimbursement | Nationwide Medicare reimbursement rate of $897 for Ova1Plus®<br>OvaWatch℠ crosswalk in process<br>Unique PLA code for OvaWatch℠ effective as of April 1, 2023 |
| Experienced Management | Leadership team of mission-driven executives with significant, relevant experience in small and mid-cap diagnostic companies |

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# A New Executive Team and a Fresh Perspective

**Nicole Sandford**
CEO, President & Director

Deloitte.

**Torsten Hombeck, PhD**
SVP, Chief Financial Officer

AKARI THERAPEUTICS

PROMETHERA BIOSCIENCES

cytonet

**Minh Merchant**
SVP, General Counsel, & Compliance Officer

Myriad genetics

genome MEDICAL

McKESSON

**Michelle Snider**
SVP, Commercial Strategy & Operations

sema4

SONIC REFERENCE LABORATORY

Myriad genetics

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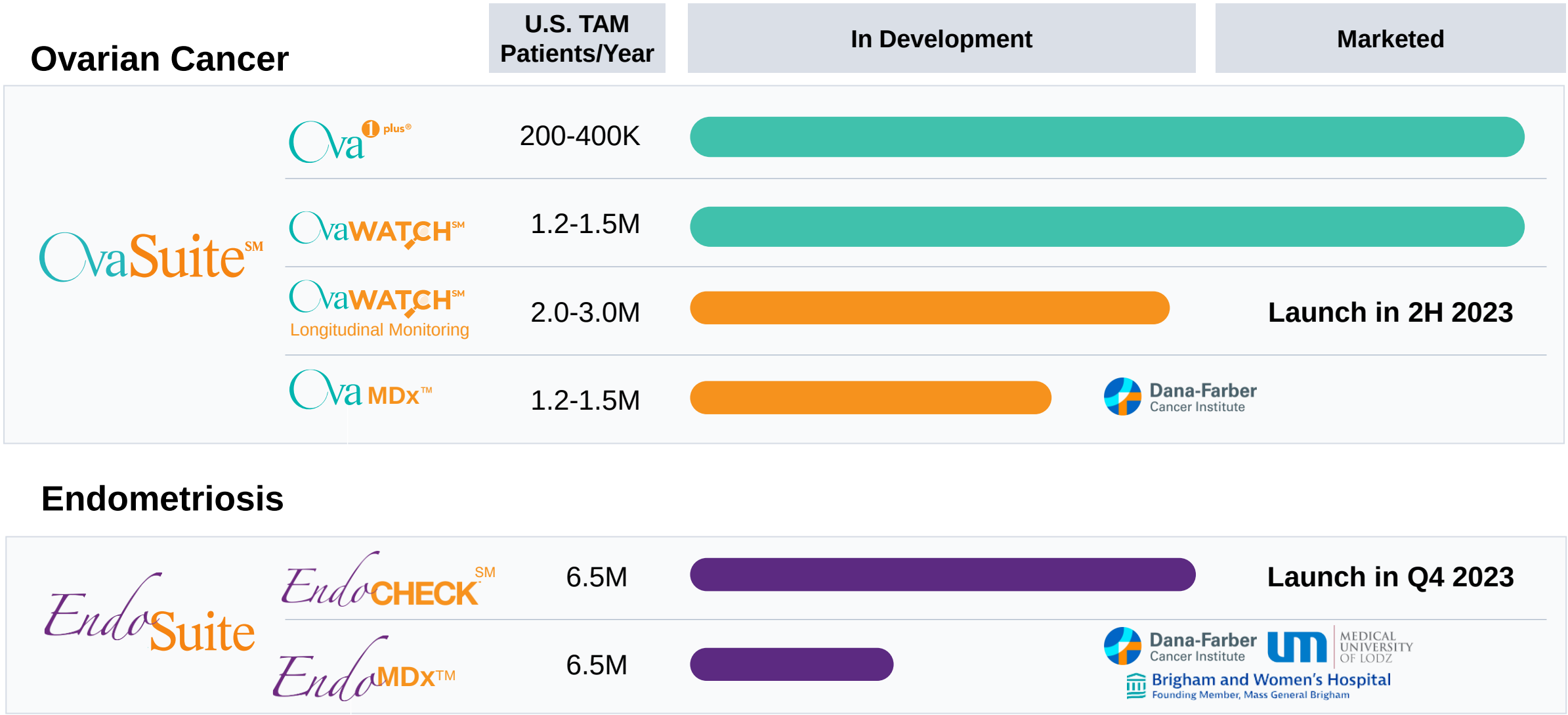
# Commercial Products with Rich Pipeline of Near-Term Assets

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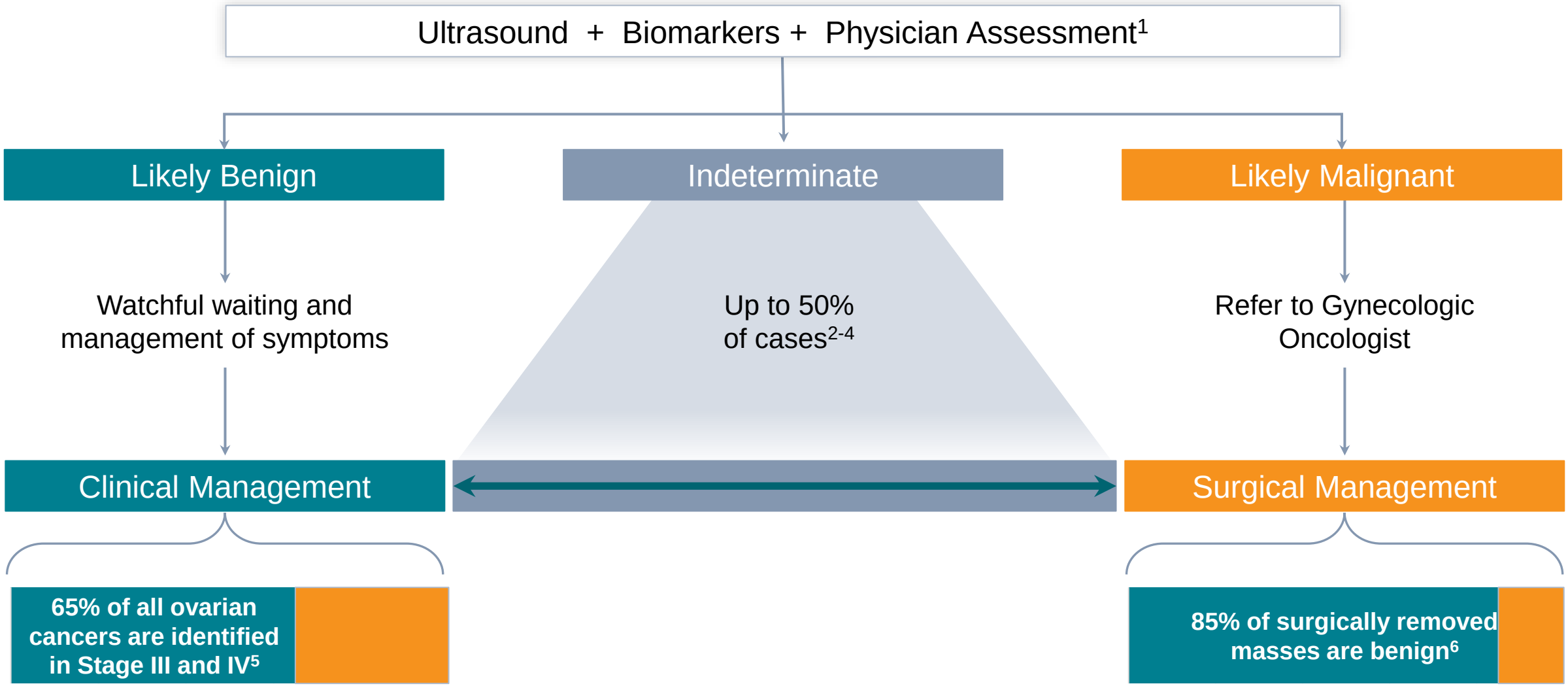
Total Addressable Market (TAM)

# Ovarian Cancer Presents A Diagnostic Dilemma




1. American College of Obstetricians and Gynecologists' Committee on Practice Bulletins—Gynecology. Practice Bulletin No. 174: Evaluation and Management of Adnexal Masses. Obstet Gynecol. 2016;128(5):e210-e226. doi:10.1097/AOG.0000000000001768; 2. Meys EMJ, Kaijser J, Kruitwagen RFPM, et al. Subjective assessment versus ultrasound models to diagnose ovarian cancer: a systematic review and meta-analysis. Eur J Cancer. 2016;58:17-29. doi:10.1016/j.ejca.2016.01.007; 3. Froyman W, Landolfo C, De Cock B, et al. Risk of complications in patients with conservatively managed ovarian tumours (IOTA5): a 2-year interim analysis of a multicentre, prospective, cohort study. Lancet Oncol. 2019;20(3):448-458. doi:10.1016/S1470- 2045(18)30837-4; 4. https://seer.cancer.gov/statfacts/html/ovary.html; 5. Stampler K, DeFilippis DJ, Holtz DO, Twiggs LB, & Dunton CJ. (2023, March 25–28). Pelvic ultrasound findings: Prevalence of adnexal masses with indeterminate features in community settings. Society of Gynecologic Oncology National Meeting on Women's Cancer, Tampa, FL, United States.; 6. Alcázar JL, Pascual MA, Graupera B, et al. External validation of IOTA simple descriptors and simple rules for classifying adnexal masses. Ultrasound Obstet Gynecol. 2016;48(3):397-402. doi:10.1002/uog.15854

# A Comprehensive Suite of Ovarian Cancer Risk Assessment Tests

OvaSuite℠

## OvaWATCH℠

**Initial Clinical Assessment**

For adnexal masses evaluated by initial clinical assessment as indeterminate or benign.

## Ova1 plus®

**Planned for Surgery**

For women with pelvic masses that are planned for surgical management.

**In combination with ultrasound and physical examination, OvaSuite ℠ products provide physicians with data to develop appropriate treatment plans for all women with pelvic masses.**

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# Ova1Plus® for Women with Pelvic Masses Planned for Surgery

Combines two FDA-cleared tests (Ova1® and Overa®)

**With 4 additional biomarkers and a proprietary algorithm, Ova1® has dramatically improved performance compared to CA-125 alone.**


**Ova1 has increased sensitivity compared to CA-125 alone to capture early-stage cancers (stage I and II)[2]**

1 .Dunton, C. J., Hutchcraft, M. L., Bullock, R. G., Northrop, L. E., & Ueland, F. R. (2021). Salvaging detection of early-stage ovarian malignancies when ca125 is not informative. *Diagnostics*, *11*(8), 1440. 2. Bristow, R. E., Smith, A., Zhang, Z., Chan, D. W., Crutcher, G., Fung, E. T., & Munroe, D. G. (2013). Ovarian malignancy risk stratification of the adnexal mass using a multivariate index assay. Gynecologic oncology, 128(2), 252-259.

# OvaWatch℠ for Initial Clinical Assessment of Adnexal Masses

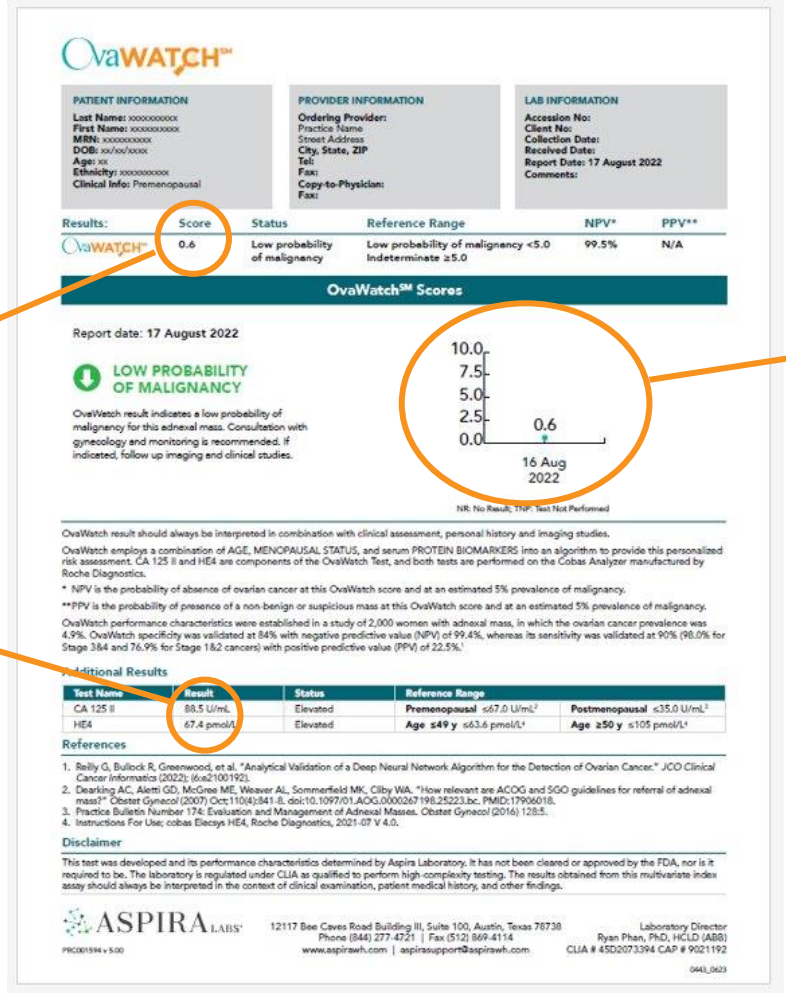
OvaWatch℠ is intended for use as a non-invasive test to assess the risk of ovarian cancer for women with adnexal masses, evaluated by initial clinical assessment as indeterminate or benign.

***The OvaWatch℠ report includes:***

OvaWatch℠ risk score

CA-125 and HE4 results

Ovarian cancer risk assessment chart



OvaWATCH℠

PATIENT INFORMATION
Last Name: xxxxxxxxxx
First Name: xxxxxxxxxx
MRN: xxxxxxxxxx
DOB: xx/xx/xxxx
Age: xx
Ethnicity: xxxxxxxxxx
Clinical Info: Premenopausal

PROVIDER INFORMATION
Ordering Provider:
Practice Name
Street Address
City, State, ZIP
Tel:
Fax:
Copy-to-Physician:
Fax:

LAB INFORMATION
Accession No:
Client No:
Collection Date:
Received Date:
Report Date: 17 August 2022
Comments:

| Results: | Score | Status | Reference Range | NPV* | PPV** |
|---|---|---|---|---|---|
| OvaWATCH℠ | 0.6 | Low probability of malignancy | Low probability of malignancy <5.0<br>Indeterminate ≥5.0 | 99.5% | 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.

10.0
7.5
5.0
2.5
0.0
0.6
16 Aug 2022

NR: No Result, TNP: Test Not Performed

OvaWatch result should always be interpreted in combination with clinical assessment, personal history and imaging studies.

OvaWatch employs a combination of AGE, MENOPAUSAL STATUS, and serum PROTEIN BIOMARKERS into an algorithm to provide this personalized risk assessment. CA 125 II and HE4 are components of the OvaWatch Test, and both tests are performed on the Cobas Analyzer manufactured by Roche Diagnostics.

* NPV is the probability of absence of ovarian cancer at this OvaWatch score and at an estimated 5% prevalence of malignancy.

**PPV is the probability of presence of a non-benign or suspicious mass at this OvaWatch score and at an estimated 5% prevalence of malignancy.

OvaWatch performance characteristics were established in a study of 2,000 women with adnexal mass, in which the ovarian cancer prevalence was 4.9%. OvaWatch specificity was validated at 84% with negative predictive value (NPV) of 99.4%, whereas its sensitivity was validated at 90% (98.0% for Stage 3&4 and 76.9% for Stage 1&2 cancers) with positive predictive value (PPV) of 22.5%.[1]

Additional Results

| Test Name | Result | Status | Reference Range | |
|---|---|---|---|---|
| CA 125 II | 88.5 U/mL | Elevated | Premenopausal ≤67.0 U/mL[2] | Postmenopausal ≤35.0 U/mL[2] |
| HE4 | 67.4 pmol/L | Elevated | Age ≤49 y ≤63.6 pmol/L[4] | Age ≥50 y ≤105 pmol/L[4] |

References

1. Reilly G, Bullock R, Greenwood, et al. "Analytical Validation of a Deep Neural Network Algorithm for the Detection of Ovarian Cancer." *JCO Clinical Cancer Informatics* (2022): (6:e2100192).
2. Dearking AC, Aletti GD, McGree ME, Weaver AL, Sommerfield MK, Cliby WA. "How relevant are ACOG and SGO guidelines for referral of adnexal mass?" *Obstet Gynecol* (2007) Oct;110(4):841-8. doi:10.1097/01.AOG.0000267198.25223.bc. PMID:17906018.
3. Practice Bulletin Number 174: Evaluation and Management of Adnexal Masses. *Obstet Gynecol* (2016) 128:5.
4. Instructions For Use; cobas Elecsys HE4, Roche Diagnostics, 2021-07 V 4.0.

Disclaimer

This test was developed and its performance characteristics determined by Aspira Laboratory. It has not been cleared or approved by the FDA, nor is it required to be. The laboratory is regulated under CLIA as qualified to perform high complexity testing. The results obtained from this multivariate index assay should always be interpreted in the context of clinical examination, patient medical history, and other findings.

ASPIRA LABS

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Laboratory Director
Ryan Phan, PhD, HCLD (ABB)
CLIA # 45D2073394 CAP # 9021192

PRC001594 v 5.00

0443_0623

**Provides a single risk assessment score delivering a Negative Predictive Value of over 99%[1]**

Analytical Validation of a Deep Neural Network Algorithm for the Detection of Ovarian Cancer. Reilly G, Bullock R, Greenwood J, Ure DR, Stewart E, Davidoff P, DeGrazia J, Fritsche H, Dunton CJ, Bhardwaj N, and Northrop LE. *JCO Clinical Cancer Informatics* 6:e2100192 2022

# OvaWatch℠ Meets a Critical Unmet Need for Initial and Longitudinal Assessment

## OvaWatch℠ benefits

With **Sensitivity* (81.8%) and Specificity* (87.4%),** OvaWatch℠ may provide healthcare professionals with many benefits including:

- Enhanced provider confidence in the chosen medical management plan
- Efficient triaging of specialist referrals for only higher risk patients
- Avoidance of potentially unnecessary or premature surgeries

**December 2022**

Initial launch of single use test

**April 2023**

Unique PLA Code for ordering and billing

**May 2023**

Three Abstracts accepted by ASCO

**2H 2023**

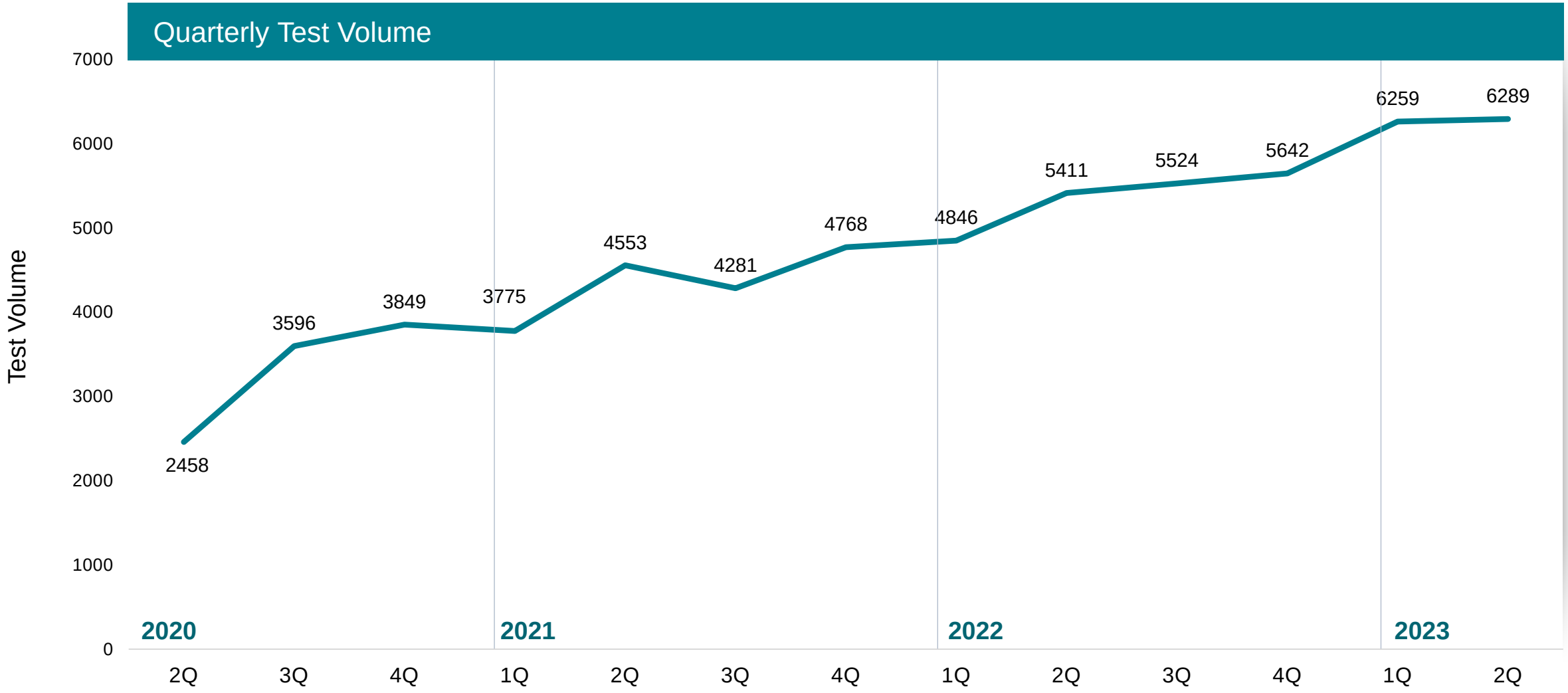
Clinical Data for Longitudinal Monitoring

*Validation of a deep neural network-based algorithm supporting clinical management of adnexal mass. Frontiers in Medicine, 10. Reilly, et al. (2023).

# OvaSuite℠ Test Volumes Have Grown Consistently

23% Annual CAGR over the past 3 years

**>170,000 tests since launch**

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# Market Access and Coverage

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

## Coverage

HCSC Health Care Service Corporation

Cigna®

TRICARE®

HIGHMARK.

WellCare Health Plans

Medicare

Medicare Contracted Ova1Plus® Price $897

Medicaid

Medicaid Contracted (Average) Ova1Plus® Price $541

## Critical Factors for Success in Expanding Coverage

- Clinical Utility Study for Ova1® published in 2023
- Crosswalk request for OvaWatch℠ based on Ova1Plus® CMS pricing pending for 2024
- Leverage high-volume users in key states to drive Medicaid contracting
- Federal and State legislative efforts to put pressure on both government and commercial payers

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EndoCHECK℠

# A Non-invasive Assay for the Diagnosis of Endometriosis



 

# Endometriosis: Large Market with Clear Need for Better Diagnostic

EndoSuite

*Endometriosis* is a debilitating condition in which tissue similar to the lining of the uterus grows outside the uterus.

## 6.5 million women impacted in the U.S.[1]

Untreated endometriosis leads to pain, excessive menstrual bleeding, digestive distress, and infertility

Endometriosis can only be definitively diagnosed through laparoscopy which provides sensitivity = 90% and specificity = 40%[2]

Clinicians and patients are seeking a noninvasive alternative with similar performance

## New Treatment Options Require Dx

**There is no available clinical assay supporting identification of patients for coverage of commercial stage therapeutic medications.**

AbbVie ORILISSA® (GnRH antagonist)

Myovant MYFEMBREE® (GnRH antagonist + Estradiol +NETA)

**Current diagnostic methods are inadequate**

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1. Esther Eisenberg, M.D., M.P.H., Medical Officer, Project Scientist, Reproductive Medicine Network, Fertility and Infertility Branch, National Institute of Child Health and Human Development 2. Gratton, S. M., Choudhry, A. J., Vilos, G. A., Vilos, A., Baier, K., Holubeshen, S., ... & Chen, I. (2022). Diagnosis of endometriosis at laparoscopy: a validation study comparing surgeon visualization with histologic findings. *Journal of Obstetrics and Gynaecology Canada*, *44*(2), 135-141.

# First-of-its-Kind Noninvasive Assay for the Diagnosis of Endometriosis

EndoCHECK℠

## EndoCheck℠ Assay Features

- Noninvasive, blood-based assay utilizing multiple, differentiating biomarkers
- Proprietary algorithm leverages core Aspira technologies and experience
- Developed with histology confirmed endometriosis and appropriate control cohorts
- Validated in CLIA-certified laboratory environment

## Aspira's Advantages

- CLIA-certified platform
- Validating in CLIA/CAP/NY/CA state-approved laboratory
- Experience with both FDA-cleared and Lab Developed Tests utilizing protein biomarkers and proprietary algorithms

**EndoCheck℠ is a simple, non-invasive blood test:**

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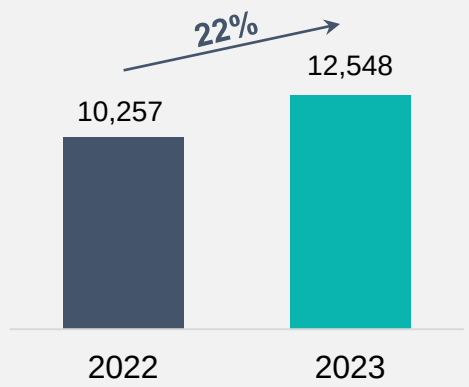
# EndoCheck℠ Commercial Launch Timeline

- EndoCheck℠ to be launched by the end of 2023
- Currently being validated in the same CLIA lab environment where it will be processed commercially
- Validation is in process with manuscript submission planned
- Multi-site clinical study launched in 2022 will provide additional clinical data supporting launch of additional endometriosis products, including the in-development EndoMDx™ led by a consortium of leading research partners including Harvard's Dana Farber Cancer Institute
- Launch activities related to reimbursement, pricing, marketing, and partnerships to prepare for successful commercial launch are ongoing

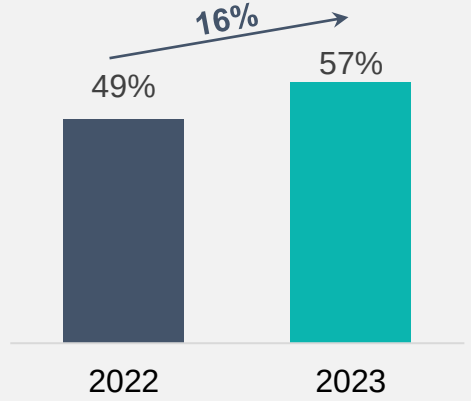
# Financial Performance Snapshot

## YTD Year over Year Comparison

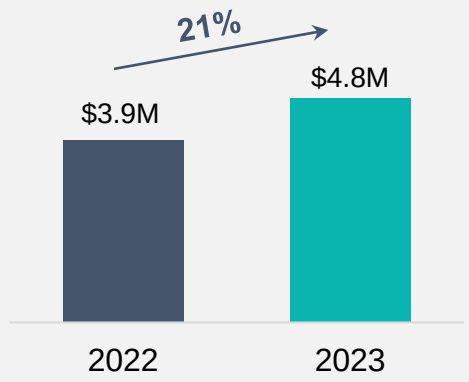
### Product Volume



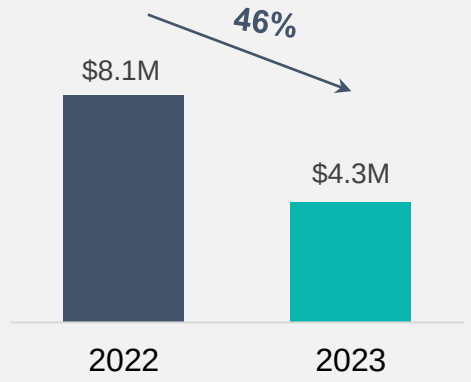

### Gross Margin




### Revenue




### Sales & Marketing Expense

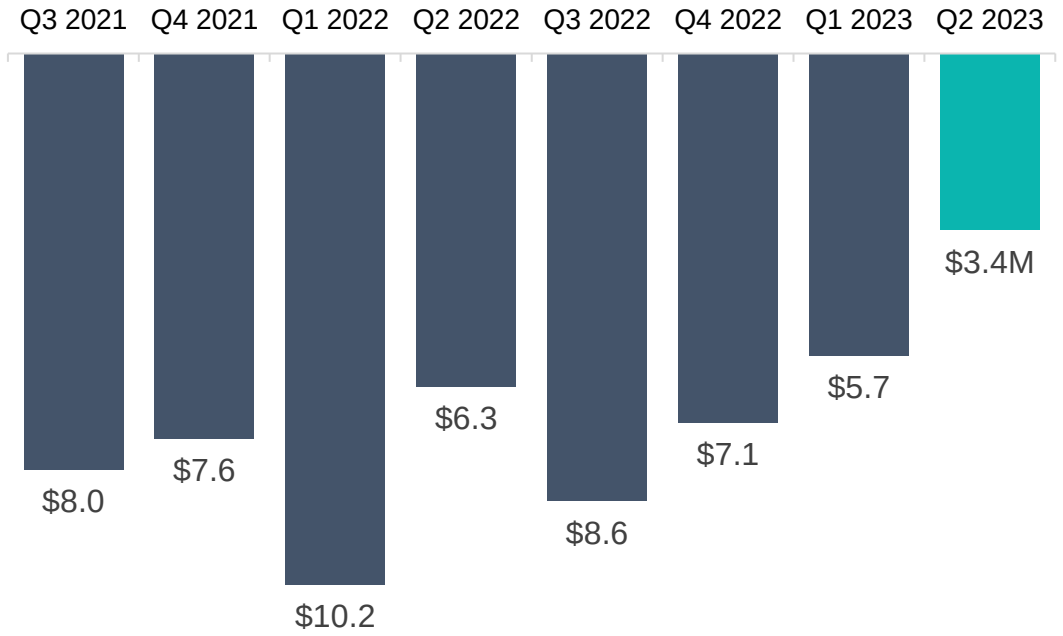



## Balance Sheet

### Cash Position

| | |
|---|---|
| Cash* as of June 30, 2023: | $4.5M |
| *Proforma cash† as of June 30, 2023* | $8.8M |
| 2H23 Operating cash utilization target: | $6 to 8M |

### Cash Used in Operations (in Millions)




* Includes cash, cash equivalents and restricted cash
† Includes $4.3M net proceeds from registered direct offering in July 2023

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# 2023 Key Growth Drivers

## OvaSuite Adoption and Growth

Capture the large patient population of women with adnexal masses

## Reimbursement Coverage

Expand OvaSuite payer adoption and improve average unit price

## Continued Innovation/R&D

EndoCheck development proceeding with anticipated launch in 2H2023

## Collaboration Opportunities

Accelerate the MDx collaborations and expand commercial partnerships

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