



Diagnostic Bioinformatic Solutions to Change Gynecologic Outcomes

NASDAQ: VRML
AUGUST 2016

The logo for Aspira Labs, featuring a stylized 'A' composed of two curved lines, one white and one teal, followed by the text 'ASPIRA LABS' in a white, sans-serif font with a registered trademark symbol, and the tagline 'YOUR HEALTH. OUR PASSION.' in a smaller white font below it.

ASPIRA LABS®
YOUR HEALTH. OUR PASSION.

The logo for Aspira IVD, featuring a stylized 'A' composed of two curved lines, one white and one teal, followed by the text 'ASPIRA IVD' in a teal, sans-serif font with a registered trademark symbol.

ASPIRA IVD®

FORWARD-LOOKING STATEMENTS

This presentation contains forward-looking statements, as defined in the Private Securities Litigation Reform Act of 1995. 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.

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The forward-looking statements reflect the views of the Company as of the date of this presentation and are subject to certain risks, uncertainties and assumptions, 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, 2015 and quarterly report on Form 10-Q for the quarter ended March 31, 2016.

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Company Overview

- **Ticker Symbol: VRML** (NASDAQ CM)
- **Market Cap (8-3-2016): \$67.9M**
 - Shares Outstanding (7-31-2016): 52.2M
- **Cash and Cash Equivalents (6-30-2016): \$11.1M**
- **Enterprise Value: \$58.8M**

Vermillion's Focus is Gynecologic Health

Our Vision

To be the global diagnostic leader in advancing women's health with information and technologies to improve outcomes!

Our Mission

To allow women with pelvic pain and masses to have painless and disease free lives!

Collaborations

With leading scientific and clinical institutions such as **Johns Hopkins, UCI, MD Anderson, Moffitt, Kaiser, DOD and Quest Diagnostics**

Flagship Product/Platform

OVA1[®], the first FDA-cleared, multi-biomarker **liquid biopsy** for pre-surgical triage of ovarian cancer, >80,000 performed to date



Commercial Partner



Collaborators



Investment Highlights

- Target market expanding to > \$1 billion with the OVA family of products*
- Key investor support from Jack W. Schuler and Oracle Investment Management

2015:

- **April:** Strategic partnership with Kaiser Permanente (So. CA) announced
- **August:** All OVA1[®] testing migrated from Quest Diagnostics to ASPiRA Labs
- **October:** Overa[™], the next generation OVA1 test, CE marked in the EU
- **December:** Published OVA1 cost effectiveness data

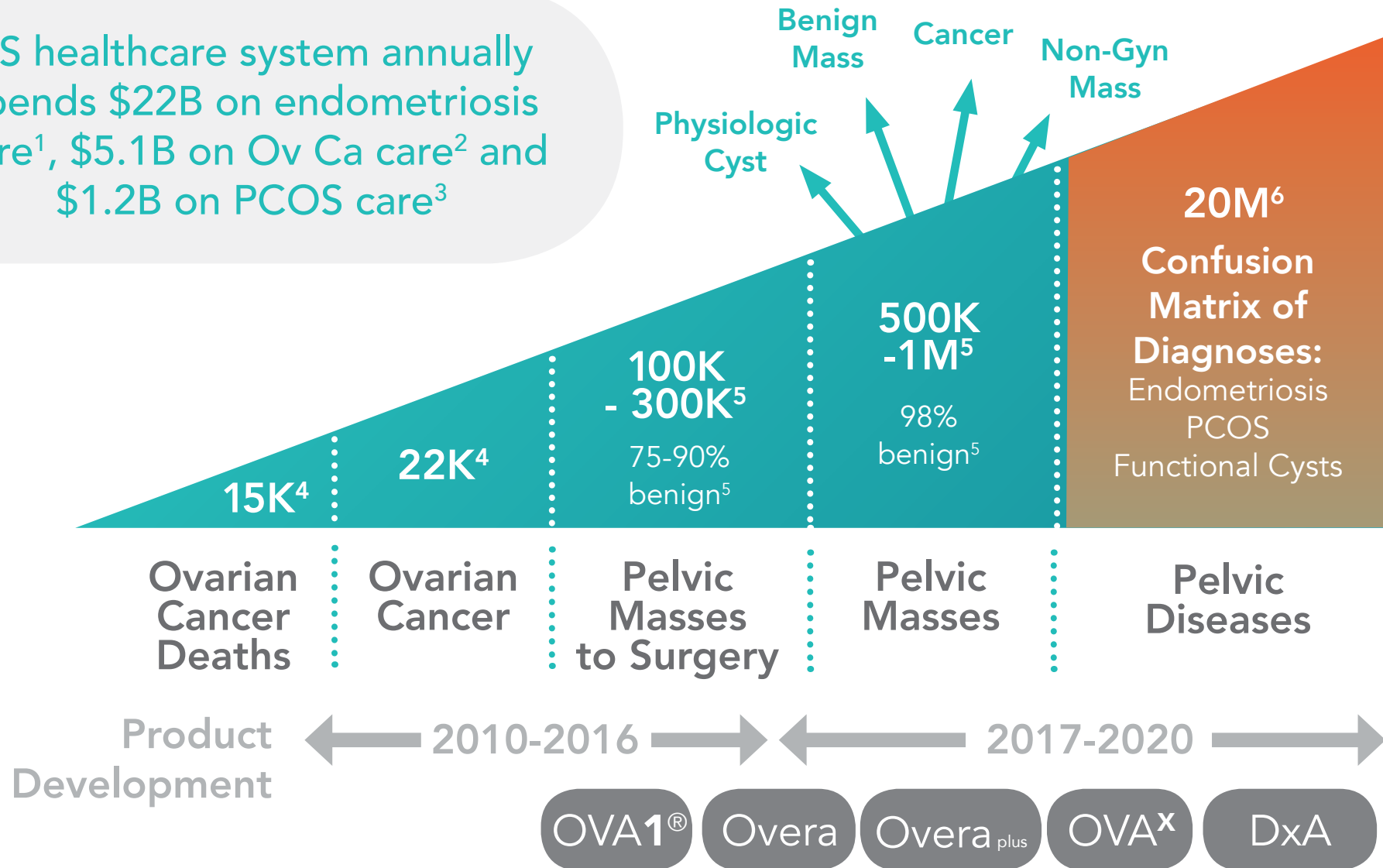
2016:

- **March:** Direct to Women Campaign launched-Ovarian cancer survivors partners; Shannon Miller and NASCAR driver Martin Truex, Jr/Sherry Pollex, plus www.KnowPelvicMass.com
- **March:** 510(k) marketing clearance from the US Food and Drug Administration (FDA) for Overa
- **April:** Published significant clinical utility data for OVA1
- **May:** Presented Overa vs. ROMA initial top-line results at ACOG
- **May:** First international distribution agreement signed Biomedical Solutions of South Korea
- **June:** Recorded initial revenue from ASPiRA IVD operations
- **July:** Signed payer contracts with Priority Health Managed Benefits, Independent Medical Systems and Sutter Valley Medical Foundation (d/b/a Gould Medical Foundation)

*According to Company estimates

Vermillion Has a Large Market Opportunity

US healthcare system annually spends \$22B on endometriosis care¹, \$5.1B on Ov Ca care² and \$1.2B on PCOS care³



Ovarian Cancer - The Size of the Problem

Ovarian cancer stage at presentation and survival

Stage	Description	Incidence	5-Year Survival
Stage I	Confined to the ovary	23%	90%
Stage II	Extends to true pelvis	13%	80%
Stage III	Extends beyond the true pelvis	47%	15-20%
Stage IV	Distant disease	16%	<5%

>60% of ovarian cancers are diagnosed at late stages

Cancer Site	Ovary	Breast
5-Year Survival	45.6%	89.7%

SEER data
Adapted from Barakat RR, et al. Principles and Practice of
Gynecologic Oncology, 5th ed. Baltimore, MD: Lippincott Williams
& Wilkins, 2012

Despite This Unmet Clinical Need...

...no solution exists.

Current standard of care is inadequate to manage patients and results in **poor outcomes** and **increased costs**



1. Current clinical assessment is inadequate

- Physical exam is specialist-dependent
- Imaging is subjective

2. CA-125 is used off-label¹ /Alternative Technology-ROMA

- Both have High rate of false negatives^{2,3}
- CA-125 is non-specific-elevated in endometriosis, liver, GI, breast, etc.⁴

3. Preoperative biopsy is medically inappropriate

1. Moss ET, et al., Clin Pathol 2005;58:308-312

2. Bristow RE, et al., Gynecol Oncol. 2013;128:252-259

3. Lennox G, et. al., Int'l J Gynecol Cancer. 2015; 809-14, Vol 25

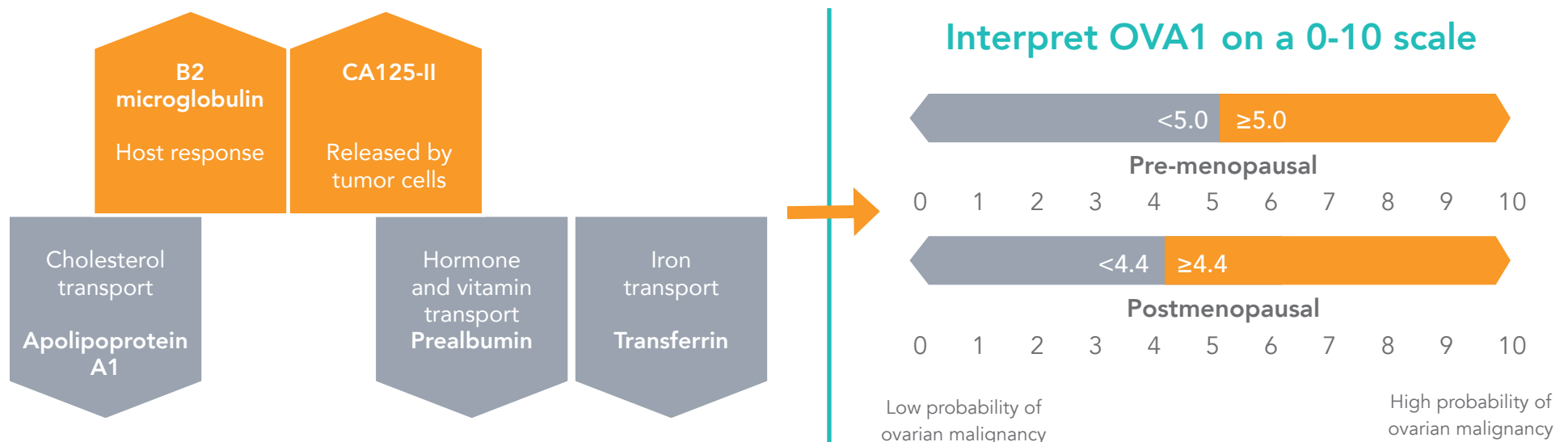
4. Fristche HA, and Bast RC, Clin Chem. 1998 Jul;44(7):1379-80

Vermillion's Solution - 1st Generation



FDA-cleared liquid biopsy test, which pre-operatively assesses risk of ovarian cancer and helps triage high risk patients

The OvaCalc[®] algorithm combines five biomarker results into a single numerical "test value" related to the probability of malignancy



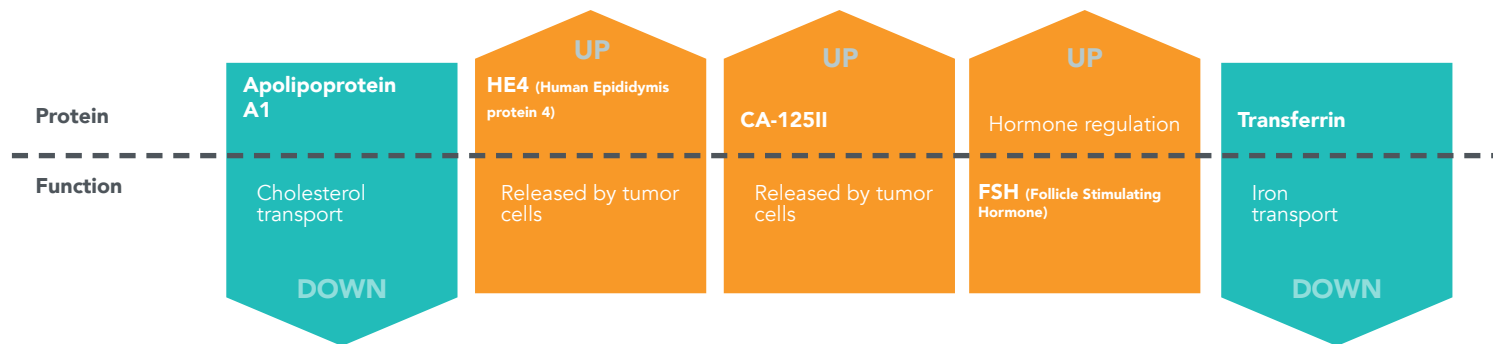
Vermillion's Solution - 2nd Generation



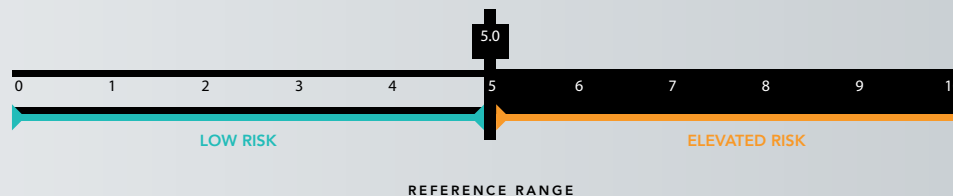
**FDA Cleared
March 2016
Target Launch
August 2016**

FDA-cleared liquid biopsy test, which pre-operatively assesses risk of ovarian cancer and helps triage high risk patients

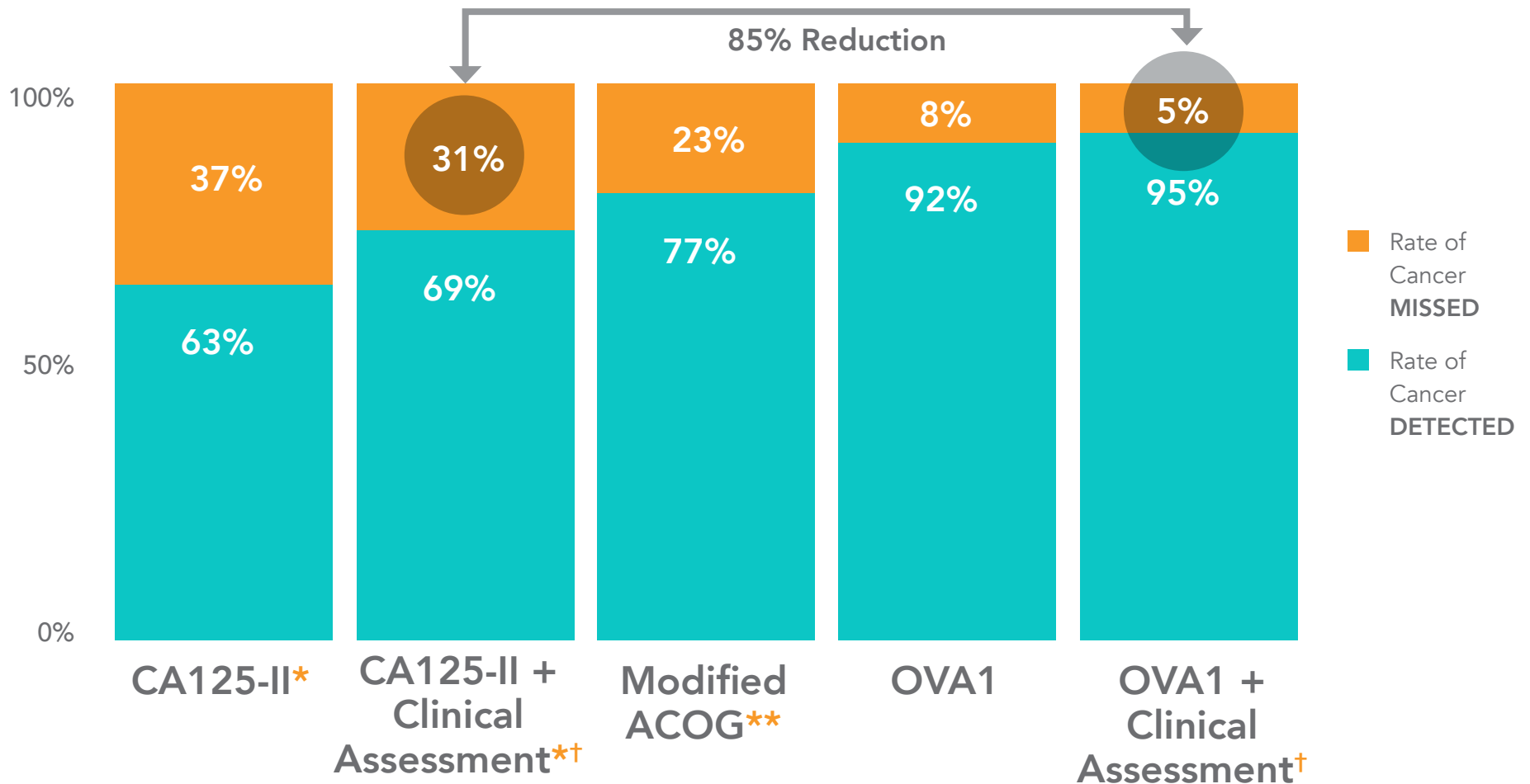
The OvaCalc[®] algorithm combines five biomarker results into a single numerical "test value" related to the probability of malignancy



- Overa test result:
One Cutoff for all Women.



OVA1[®] vs Standard of Care¹ – Stage I and II



(n= 1016 surgeries, with 86 early stage cases, 61 Stage I, 25 Stage II)






† Clinical Impression included physician physical examination and imaging, per the study inclusion criteria, and CA 125, if used

* Significant difference in sensitivity as compared to OVA1 + Clinical Assessment (from McNemar's test p<0.05)

** High risk pre-menopausal: CA 125 (>67 U/mL), ascites, or evidence of abdominal/distant metastasis. Postmenopausal women: CA 125 (>35 U/mL), nodular or fixed pelvic mass, ascites, or evidence of abdominal/distant metastasis.

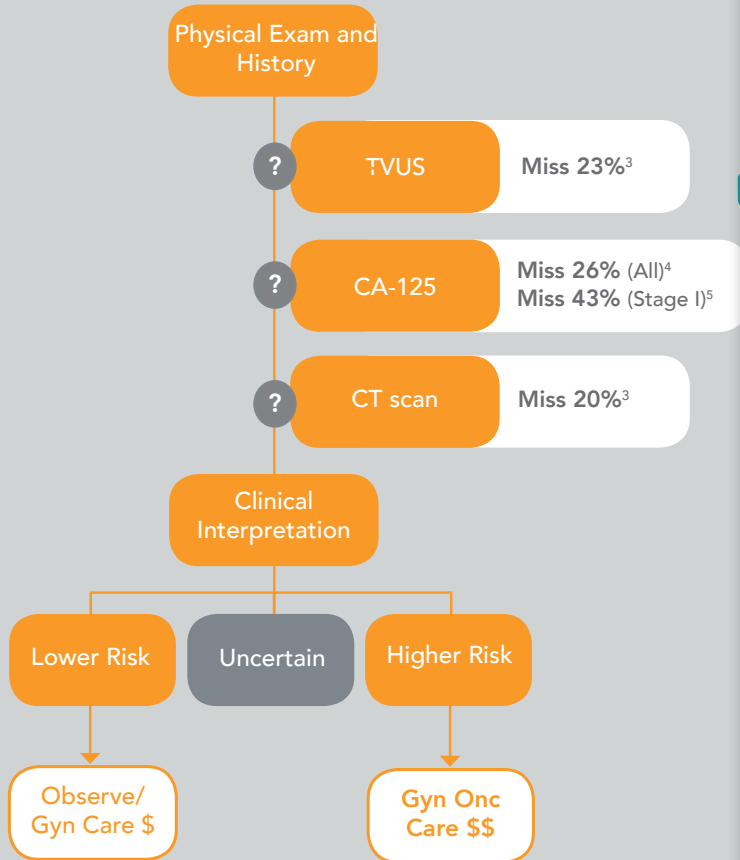
1. Longoria TC, et al. 2014. Clinical performance of a multivariate index assay for detecting early-stage ovarian cancer. Am J Obstet Gynecol doi: 10.1016/j.ajog.2013.09.017.

Key Publications

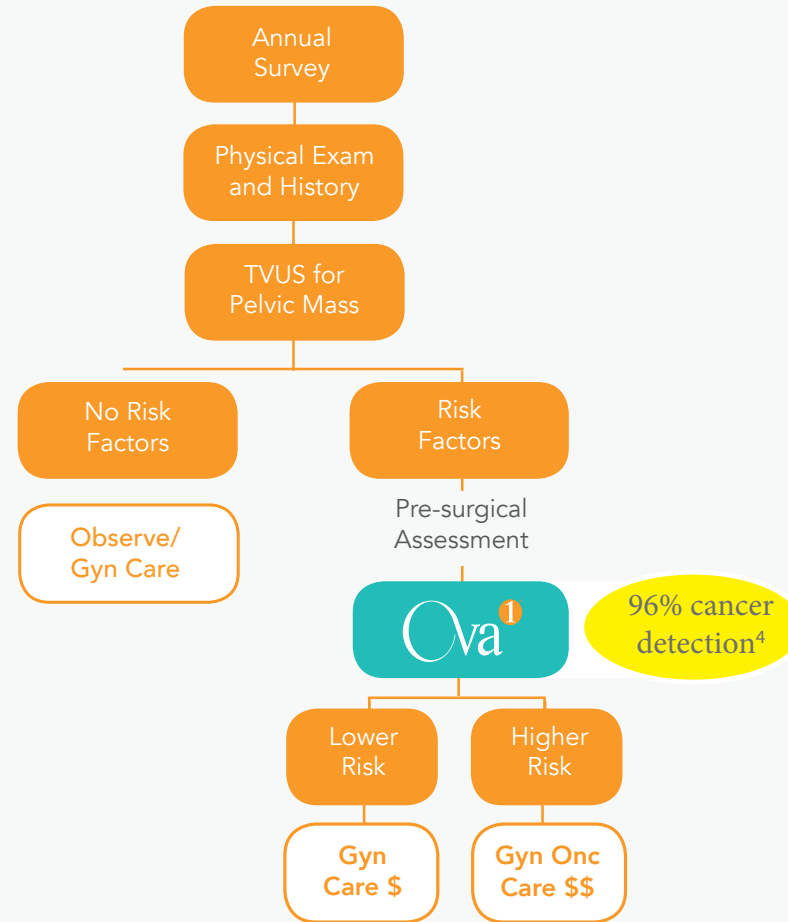
Title	Author, Institution	N	Conclusions
 <p>Effectiveness of a multivariate index assay in the preoperative assessment of ovarian</p>	<p>Ueland, et al. University of Kentucky</p>	<p>590 patients</p>	<ul style="list-style-type: none"> • First pivotal trial of OVA1®, n = 590 • <u>OVA1 detected 76% of malignancies missed by CA-125</u> • The performance of OVA1 was consistent in early- and late-stage cancers
 <p>Ovarian malignancy risk stratification of the adnexal mass using a multivariate index assay</p>	<p>Bristow, et al. UC Irvine</p>	<p>494 patients</p>	<ul style="list-style-type: none"> • Second pivotal trial of OVA1 with 494 surgeries • <u>OVA1 added to clinical impression (CI) reduced cancers missed from 26% to 4%</u> • NPV was 98%, PPV was 31%
 <p>Clinical performance of a multivariate index assay for detecting early-stage ovarian cancer</p>	<p>Longoria, et al., UC Irvine</p>	<p>1016 patients</p>	<ul style="list-style-type: none"> • Compared CA125, CI or mod-ACOG standard of care to OVA1 in early-stage OvCa • OVA1 showed superior sensitivity for risk stratification vs CA125, CI and mod-ACOG • <u>OVA1 with CI reduced early-stage cancers missed from 31% to just 5%</u>
 <p>The effect of ovarian imaging on the clinical interpretation of a multivariate index assay</p>	<p>Goodrich, et al. University of Kentucky</p>	<p>1024 patients</p>	<ul style="list-style-type: none"> • Compared OVA1 head-to-head or in combination with ultrasound or CT scan • <u>US missed 23% of OvCa, CT missed 20%</u> • <u>Using OVA1 with US reduced OvCa missed to just 2%</u> • Study suggested that OvCa risk can be personalized by a multi-modality algorithm
 <p>Validation of a second-generation multivariate index assay for malignancy risk of adnexal masses</p>	<p>Coleman, et al.</p>	<p>493 patients</p>	<ul style="list-style-type: none"> • Overa's sensitivity & NPV higher than CA-125 or mod-ACOG industry benchmarks • Higher sensitivity for early-stage and each primary ovarian cancer subtype • <u>Specificity (69%) and PPV (40%) improved over OVA1 (54% & 31%, respectively)</u> • <u>Same high-risk cutoff for all women, unlike CA-125, mod-ACOG, ROMA or OVA1</u>

Vermillion's Solution: How It is Used in Practice

Before:



After:



- It may take 7-9 months from initial symptoms to ovarian cancer diagnosis¹
- 2/3 ovarian cancer patients today are not optimally managed by a specialist²

1. Lloyd H. et al., Cancer. 2005 Oct 1;104(7):1398-407.
 2. Earle CC, et al., J Natl Cancer Inst. 2006 Feb 1;98(3):172-80
 3. Goodrich ST, et al., Am J Obstet Gynecol. 2014 Jul;211(1):65.e1-65.e11.

4. Bristow RE, et al., Gynecol Oncol. 2013;128:252-259
 5. Longoria TC, et al. 2014. Am J Obstet Gynecol doi: 10.1016/j.ajog.2013.09.017.

Overa™ vs Standard of Care

	CA-125 [†]	CA-125/TVUS/ Clinical assessment	Ova ¹	Overa <small>Resolute. Clearly. Confidently.</small>
Sensitivity Across Stages*				
Stage I	✗	✗	✓	✓
Stage II	✗	✗	✓	✓
Stage III	✓	✓	✓	✓
Stage IV	✓	✓	✓	✓
Sensitivity Across Menopausal Status*				
Pre-menopausal	✗	✗	✓	✓
Post-menopausal	✓	✓	✓	✓
Sensitivity Across Histological Subtypes*				
Epithelial ovarian cancer	✓	✓	✓	✓
Non-epithelial cancer	✗	✗	✓	✓
Low malignant potential	✗	✗	✓	✓
Metastatic	✓	✓	✓	✓
Non-ovarian cancer	✗	✗	✓	✓

*Bristow RE, et al., Gynecol Oncol. 2013;128:252-259
80% sensitivity to cancer

[†] Cut-off: pre-menopausal subjects CA125>200U/mL; postmenopausal subjects CA125>35U/mL
TVUS: Trans-vaginal Ultrasound

Publications Drive Standard of Care/Reimbursement

Published Evidence

Guidelines

Positive
Medical Policy

Ueland, et al.

Obstetrics and Gynecology, 2011

Bristow, et al.

Gynecologic Oncology, 2013
Am J Gynecol, 2013

Longoria, et al.

Am J Obstet Gynecol, 2013

Goodrich, et al.

Am J Obstet Gynecol, 2015

Forde, et al.

Curr Med Res Opin. 2015

Coleman, et al.

Am J Obstet Gynecol, 2016

Eskander, et.al.

Am J Obstet Gynecol, 2016



**Society of Gynecologic
Oncology**

**Position Statements
Issued 2011, Updated 2013**

Tests measuring blood levels of five proteins may be useful in identifying women with an ovarian mass who should be referred to a gynecologic oncologist.



The American College of Obstetricians and Gynecologists
Women's Health Care Physicians

COMMITTEE OPINION



**BlueCross
BlueShield**

Strong IP Protection

Granted			Pending			Family
USA	Ex US	Total	USA	Ex US	Total	
19	58	77	14	40	54	25

- Issued patents covering various ovarian cancer biomarkers
- Pending patent applications covering OVA1[®] and Overa[™] products
- Algorithm - kept as trade secret

Overa™ - Breakthrough in Ovarian Cancer Management

Standalone Risk Stratification

	Sensitivity	Specificity	PPV	NPV
OVA1¹ (95%CI)	92% (85.1–96.3)	54% (48.6–58.3)	31% (26.0–37.0)	97% (93.6–98.5)
Veracyte² Afirma GEC	92%	52%	32-47%	93-96%
Overa (95%CI)	92%	69%	40%	97%

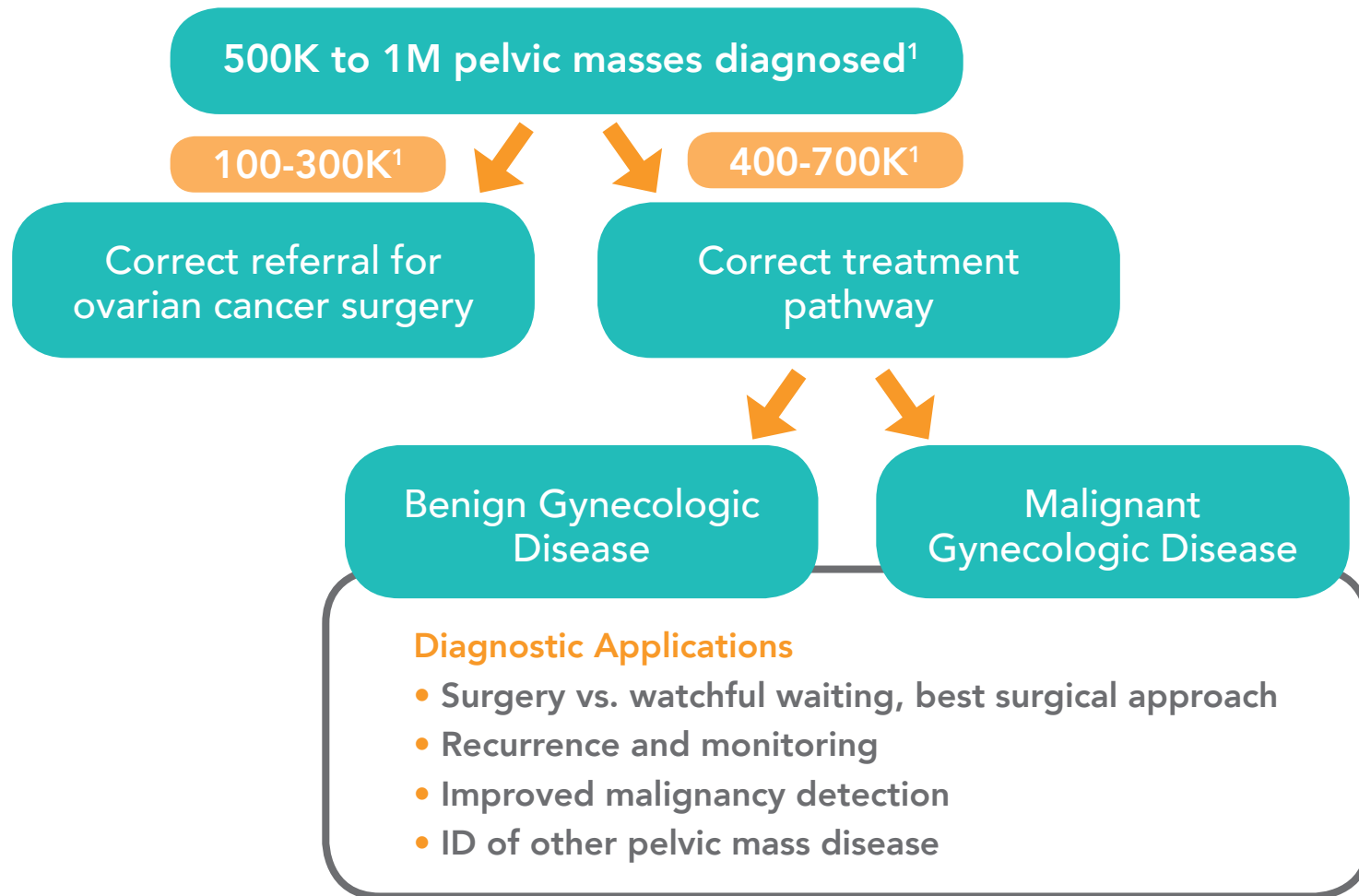
1. Bristow RE, et al., Gynecol Oncol. 2013;128:252-259

2. Alexander EK, et al., N Engl J Med. 2012 Aug 23;367(8):705-15
2015 ASCO poster on OVA2 validation available upon request as PDF or hard copy

- Overa performance exceeds OVA1 performance statistically
- Overa performance meets or exceeds OVA1
- Overa performance lower than OVA1, but not statistically different

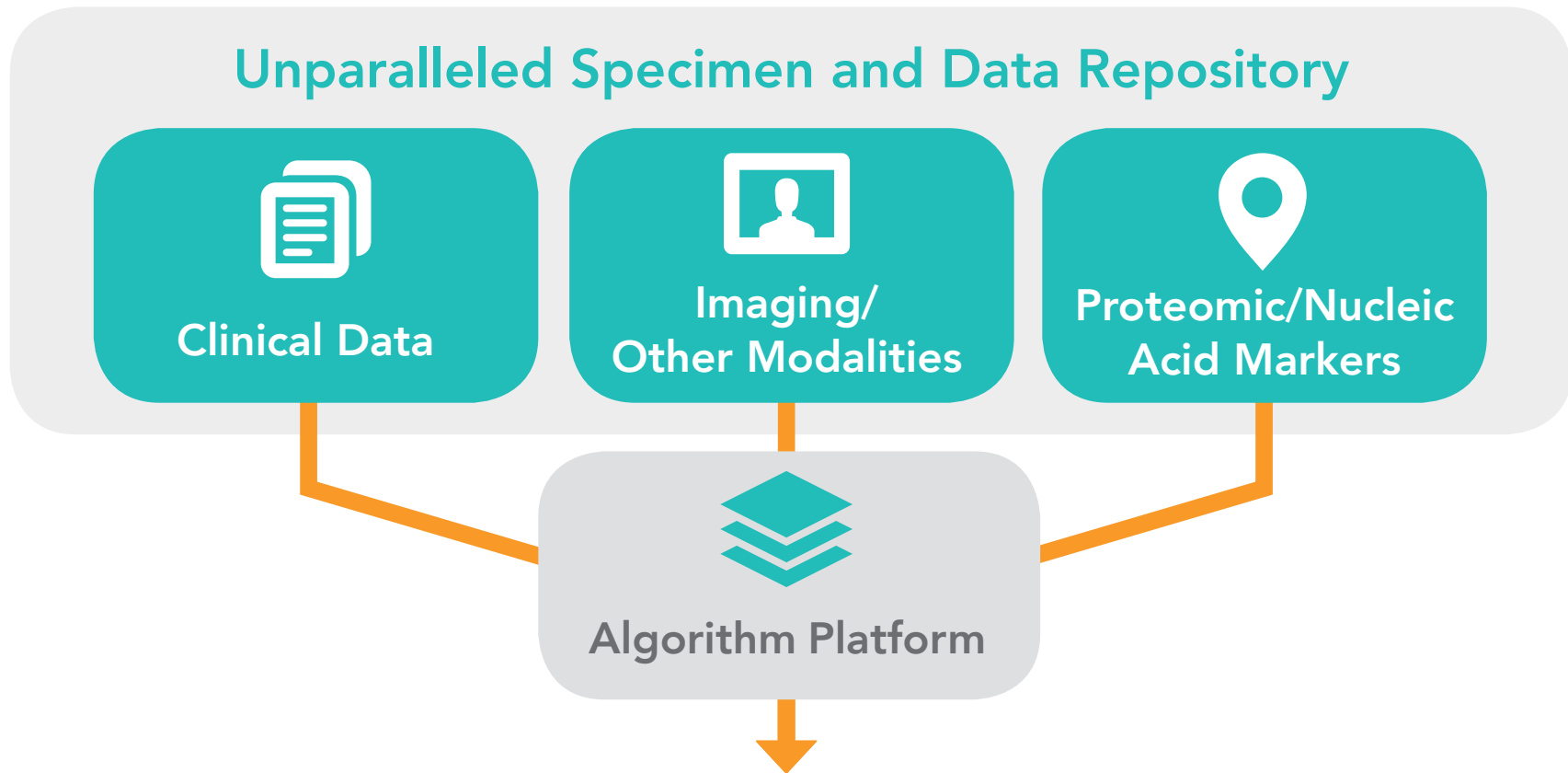
We Save More Lives and Reduce More Cost By Evolving Our Strategy with Overa™

To radically improve patient care, we have expanded our scope by classifying **all** pelvic mass patients to determine the best disease management care path



Building on Our Big Data Foundation

To impact this expanded scope, biomarkers alone are limited in terms of needed algorithm development and accuracy



Impact more than 1M patients¹
A platform that can be commercially replicated

Building on Our Foundation - Our Expertise

OVA SERIES



IMAGING

- ✓ FDA/LDT expertise
 - ✓ Biomarkers
 - ✓ Algorithm development
 - ✓ Multi-center studies
 - ✓ IP
- ✓ Proof of concept studies

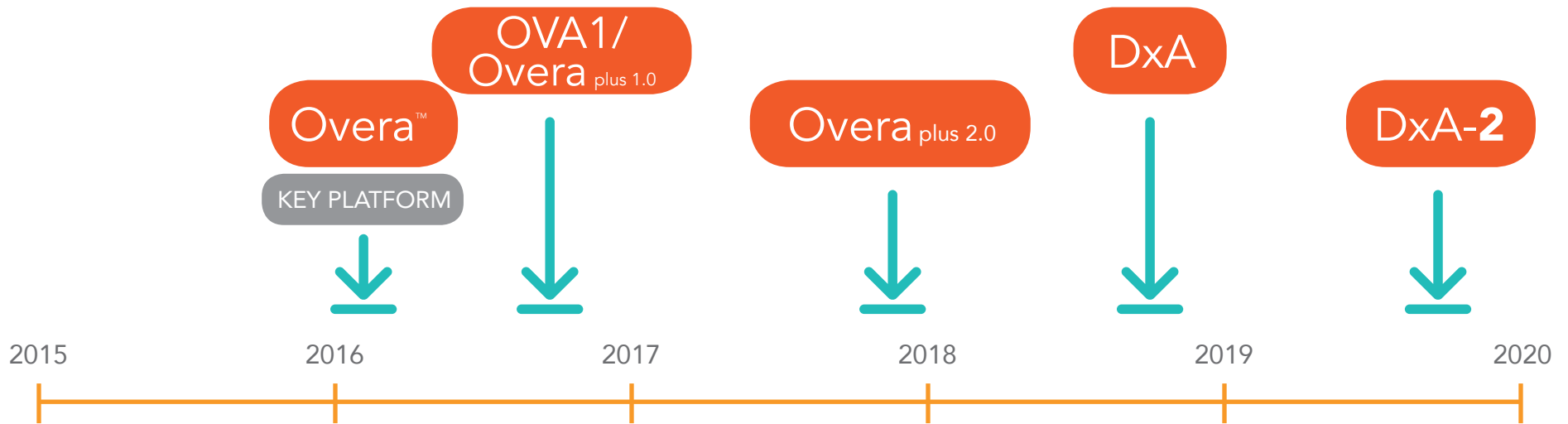


**PROVEN
COMPETENCIES**



**OVA^x,
future
products**

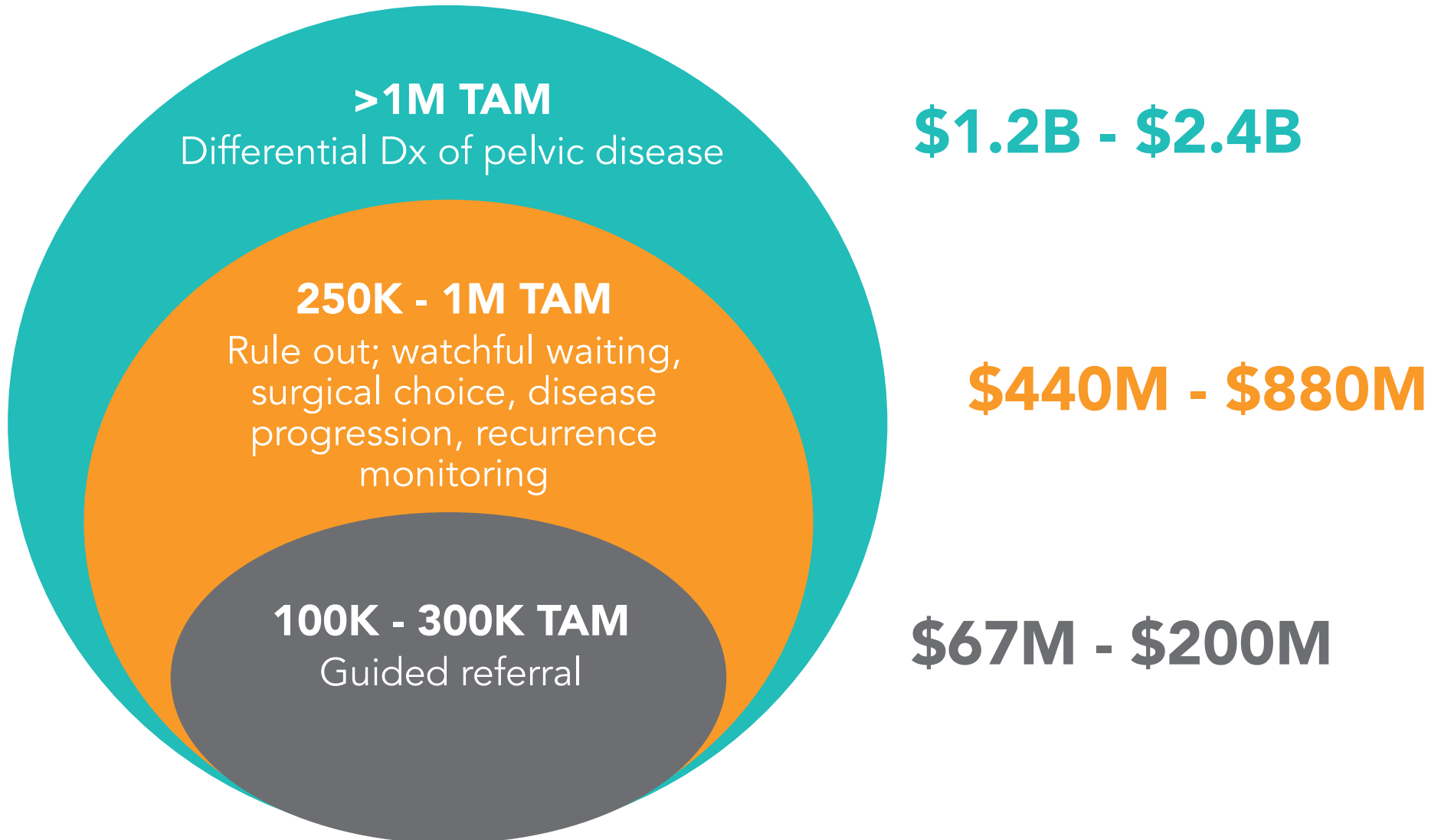
Product Pipeline of ASPiRA Labs



Product	OVA1®	Overa™	Overa plus 1.0	Overa plus 2.0	DxA	DxA-2
Proposition	Correct specialist referral	Correct specialist referral	Rule-out, surgical pathway choice, progression	Rule-out, surgical pathway choice, progression	Previous, plus differential Dx of endometriosis	Previous, plus differential Dx of PCOS
Market size ¹	100-300K	100-300K	250K-1M	250K-1M	>1M	>1M
Supporting studies	Ueland, et al. Bristow, et al.	Clinical and analytic validation studies	Goodrich, et al.	Symptom index studies	TBD	TBD

← Data Registry →

Expanded Opportunity Size (U.S.)



\$1.2B - \$2.4B

\$440M - \$880M

\$67M - \$200M

All TAM and revenue numbers according to Company estimates

The Value of Vermillion's Solution for all Customers

To Patients



- Improve time to Tx
- **Low risk:** peace of mind
- **High risk:** get to the right specialist

To Providers



- Improved differential Dx
- **Low risk:** keep patient
- **High risk:** refer to Gyn Onc
- Increased control of quality outcomes in ACA climate

To Payers

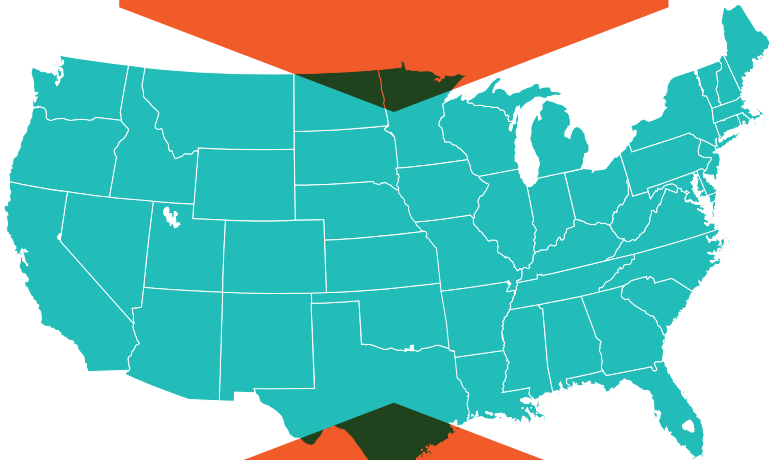


- Reduction in unnecessary procedures
- Improved health economics demonstrates significant QALY
- Right Tx / right patient / right cost

Our Roll-Out Plans Include US and International Opportunities

U.S.

Top down, high-touch approach to IDNs, systems, ACOs



Bottom up low-touch approach to patients, providers

INTERNATIONAL

2015: CE marked and ISO certified
2016: Phased geographic roll-out with selected partners*



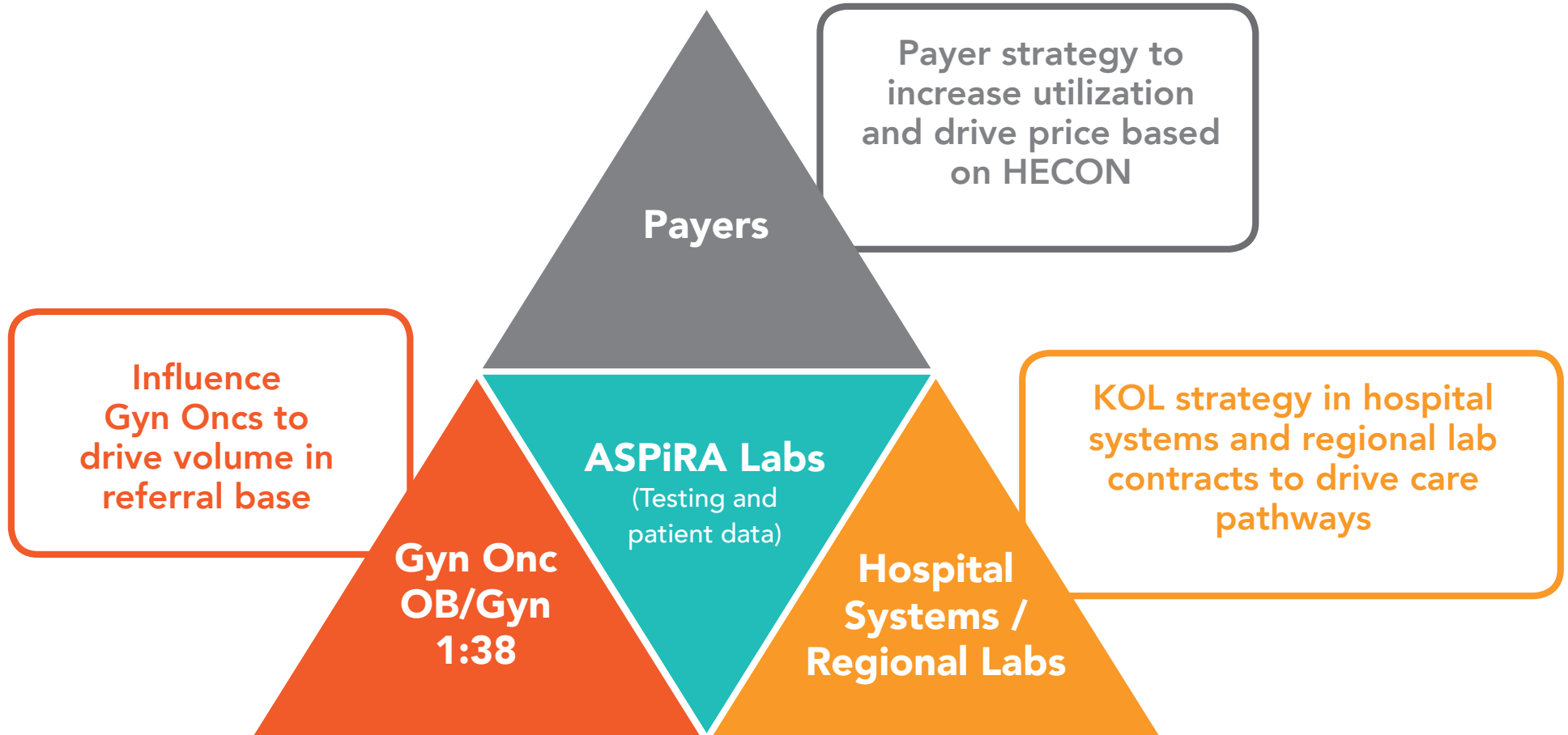
IVD or service offering

- 90% of Ov Ca occurs ex-U.S.
- Overa CE mark an expanded label vs. OVA1 in U.S. ("considered" for surgery)*
- Expanded label combined w/world-wide Ov Ca incidence point to much more Overa opportunity ex-U.S. vs. U.S. OVA1
- Launch 2H 2016

← IVD/Service Offering →

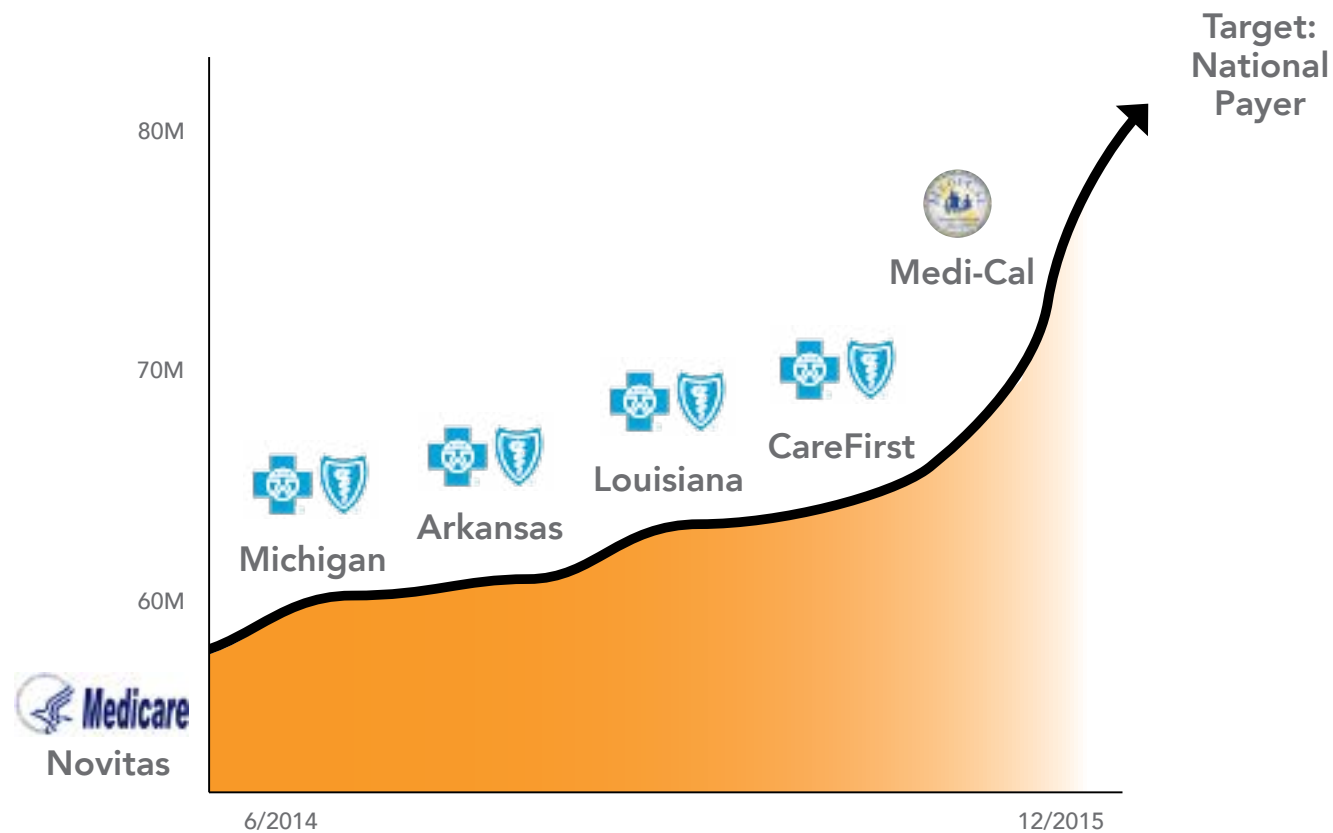
*Overa™ platform: Roche Cobas 6000 (10,000 installed worldwide) according to <http://www.cobas.com/home/product/clinical-and-immunochemistry-testing/cobas-6000-analyzer-series.html>

Commercialization Strategy



OVA1[®] Coverage YTD - Patient Lives in Millions

Goal: Targeted Growth with Positive Medical Policy Decisions



Clinical Utility Publication*

- **Purpose:** To assess Ova1's ability to drive referral of ovarian cancer patients to GYN ONC prior to their first surgical intervention
- **Method:** Retrospective standardized survey of OVA1 prescriber's to report on ovarian cancer cases where OVA1 was prescribed

- 22 physicians with \geq OVA1 results
- 136 OVA1-positive cases scored
- **122 Surgeries resulted from these**
 - 42 benign tumors
 - 3 non-ovarian malignancies
 - 65 primary ovarian cancers**
 - 10 of these LMP
 - 31 of these early-stage (48%)**

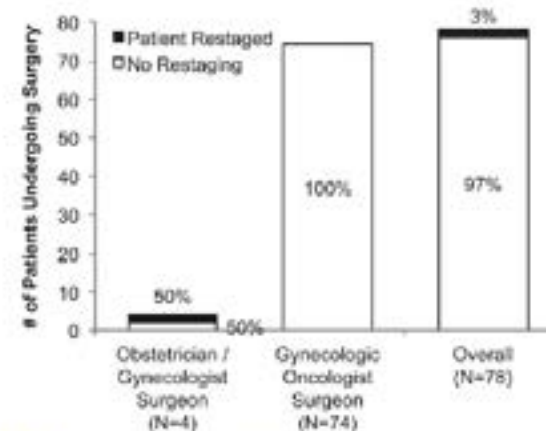
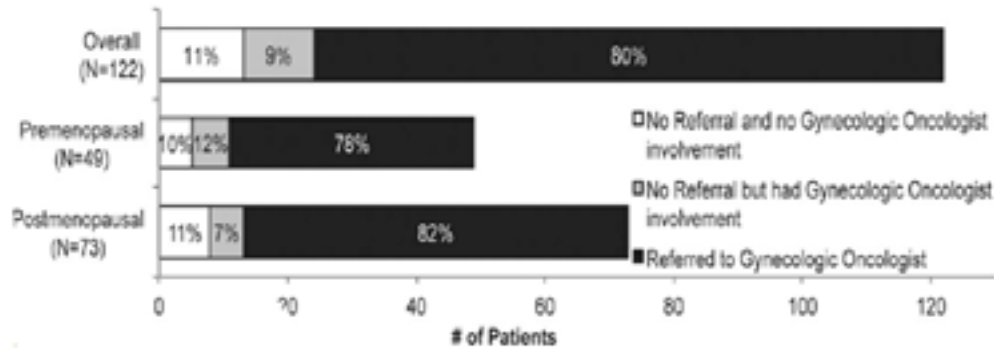


Figure 3. Frequency of restaging surgeries in primary ovarian cancer patients by specialty of surgeon on initial surgery. An obstetrician/gynecologist indicated that two patients underwent lymph node dissection with a gynecologic oncologist following initial surgery. None of the patients who had an initial surgery with a gynecologic oncologist required restaging.

Conclusion: High-risk OVA1 was associated with 94% Gyn Onc surgery and 100% consultation if primary OvCa, **demonstrating clinical utility of the test**

*Current Medical Research and Opinion, 2016, Vol. 32, No. 6, 1161-1165 <http://dx.doi.org/10.1080/03007995.2016.1176014>, Article FT-0129.R1-0000.XO/1176014
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Cost Effectiveness Model Analysis

Assay	Lab	List Price	ICER
OVA1*	ASPiRA	~\$1,495	\$12,189/QALY ¹
OVA1**	ASPiRA	~\$1,495	\$35,094/QALY ¹
BRCA1/2	Myriad Genetics	~\$4,040	\$36,845/QALY ²
Oncotype DX	Genomic Health	~\$4,175	\$15,578/QALY ³
Considered cost effective when under threshold			\$50,000/QALY

- Use of OVA1 resulted in fewer projected re-operations and pre-treatment CT scans versus CA 125-II (69% fewer) or mACOG (51% fewer)
- OVA1 increased the quality adjusted life years (QALY) of the patient cohort
- OVA1 was shown to be cost effective versus mACOG (\$35,094/QALY) or CA-125 (\$12,189/ QALY) as both were below the \$50,000/QALY ICER threshold

Incremental cost-effectiveness ratio (ICER): Average incremental cost associated with one additional unit of the measure of effect (i.e., QALY) between two possible interventions

Quality-adjusted life-year (QALY): A measure of quality of life that takes into account both the quantity and the quality of life generated by interventions

*Compared to CA-125II **Compared to modified ACOG guidelines

1. Forde GK, et al., Curr Med Res Opin. 2015 Dec 7:1-9.

2. Li Q, et al., San Antonio Breast Cancer Symposium 2011, San Antonio, TX

3. Vanderlaan BF, et al., 2011. Am J Manage Care. 2011;17(7):455-464

Experienced Management Team in Place

	Title	Experience
Valerie Palmieri	President and CEO	  
Fred Ferrara	Chief Information Officer	  
Eric Schoen	SVP, Finance & Chief Accounting Officer	  
Patrick Carpenter	GM of ASPiRA Labs	  
Robert Schroder	VP, Global Business Development	  

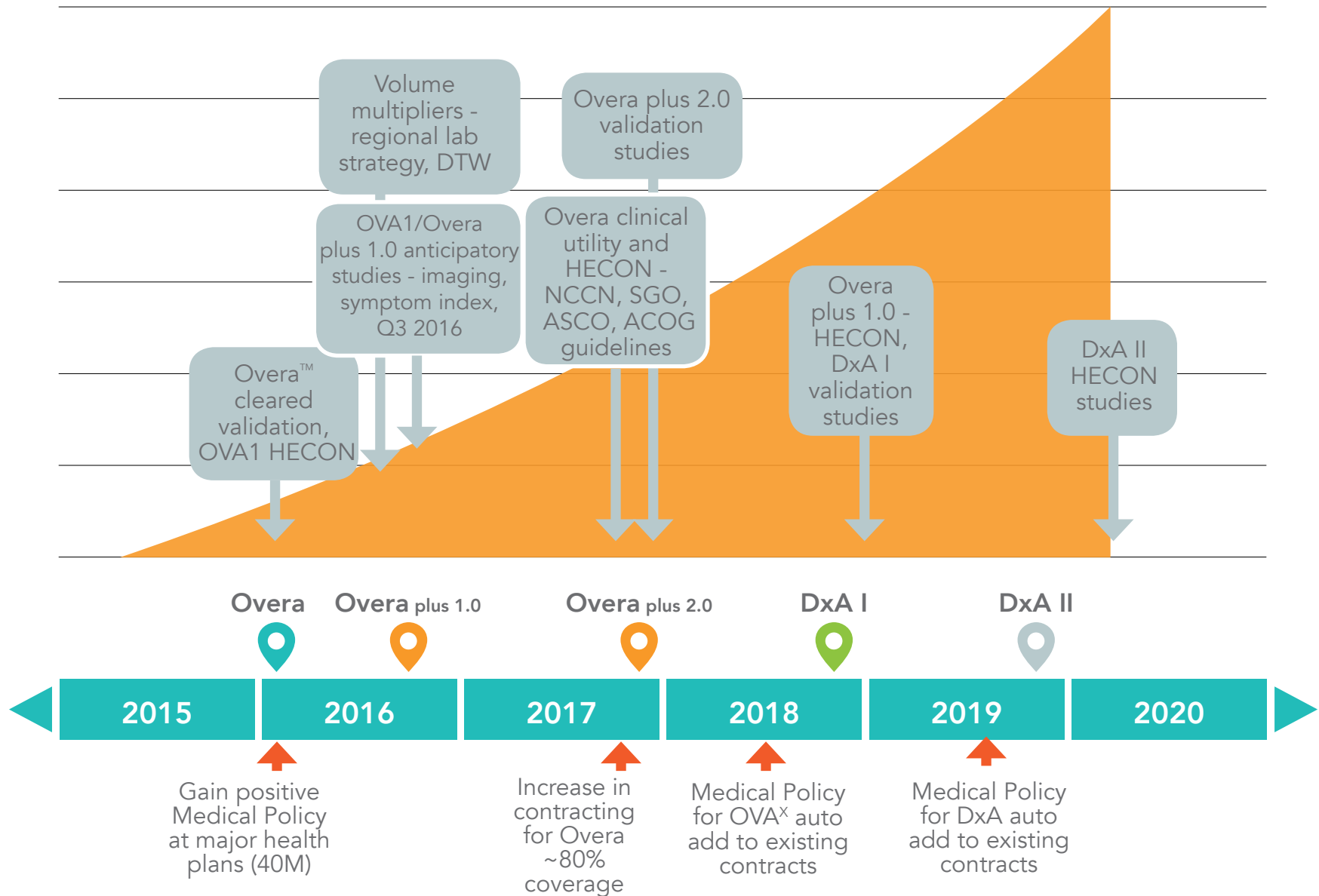
2015 Achievements / 2016 Anticipated Milestones

- ✓ Strategic partnership and quality benchmarking study with Kaiser Permanente (So. CA) announced - April 14, 2015
- ✓ Disclose Overa data (ASCO) - May 29, 2015
- ✓ Conversion of OVA1 volume from Quest Diagnostics to ASPiRA Labs-August 2015
- ✓ Overa CE mark registration - October 12, 2015
- ✓ NCCN Guideline submission - October 14, 2015
 - Engage with SGO on new position statement for Overa
- ✓ Publish OVA1 cost effectiveness data - December 4, 2015
- ✓ Overa FDA Clearance
- ✓ Announce international distribution partnerships - 2016
- ✓ Clinical Validation published - March 2016
- ✓ Analytical Validation of Overa with JHU - H2 2016
- ✓ Contracting payer coverage -H1 2016
 - Full contract coverage Sutter Valley Medical Foundation (d/b/a Gould Medical Foundation) -CA
 - Full contract coverage Independent Medical Systems, TX
 - Full contract coverage Priority Health - MI
- Goal national payer contract by end of 2016
- OVA1 Plus product launch - Q3/Q4 2016
- Unparalleled pelvic mass specimen and data repository expected to be initiated

Current Financial Priorities

- Price (maintain / build value)
- Sales ramp / penetration (build on existing market share / call point)
- Margins (>80% over 2016 - 2019)
- Reimbursement - revenue cycle management

Vermillion Expects to Be a Market Leader by 2020 - Anticipated Milestones



Sustainable Advantages, Tailwinds and Headwinds

Sustainable Advantages

- Biomarker IP
- Trade secret algorithm
- ASPIRA Labs data structure and source

Tailwinds

- FDA and LDT process experience
- Robust clinical / health economics publication pipeline
- World-class clinical partners

Headwinds

- Payer contracting – driving rigorous plan forward
- Test adoption / habit
- Cumbersome guideline process

Vermillion's Strategy: Built for the Future

Strategic Strengths and Capabilities	Myriad	Gx Health	Exact Sci	VRML/ ASPiRA
FDA-cleared product	✗*	✗	✓	✓
Unique Category 1 CPT code (AMA)	✓	✓	✓	✓
Medicare Coverage/Gap Fill Pricing	✓	✓	✓	✓
IVD kit	✗	✗	✗	✓
CLIA lab for LDTs	✓	✓	✓	✓
Multi-modal predictive analytics	✗	✗	✗	✓
Proprietary disease registry/samples	✓	✓	✓	✓
Leading peer-reviewed publications	✓	✓	✓	✓
Strong outreach: KOLs/advocacy	✓	✓	✓	✓

Creating Value by Embracing the Challenging Future of Healthcare

Conclusions

- First of its kind, FDA-cleared multi-variate global technology platform
- FDA cleared Overa™ improved specificity while maintaining high sensitivity
- In two pivotal trials, OVA1® detected >80% cancers missed by clinical assessment^{1,2}
- Market leader expertise: biomarkers, algorithm development and clinical/data partnering to develop solutions
- Risks mitigated -Strong barriers to entry
 - Trade secret algorithm
 - Pending patent applications OVA1 and Overa
 - Other patents covering various ovarian cancer biomarkers



www.vermillion.com

Corporate Headquarters

12117 Bee Caves Rd.
Building III, Suite 100
Austin, TX 78738

Tel: 512.519.0400
Fax: 512.439.6980

ASPiRA IVD

35 Nutmeg
Suite 260
Trumbull, CT 06611

Tel: 203.993.8294
Fax: 203.502.8689

Investor Relations

Michael Wood
LifeSci Advisors LLC

Tel: 646.597.6983
mwood@lifesciadvisors.com