

## ASPiRA Labs Announces Release of Final CMS Reimbursement Rate for OVA1

### Description

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AUSTIN, Texas, November 20, 2017 – ASPiRA Labs, a Vermillion company (NASDAQ: VRML) and the exclusive distributor of OVA1 (Multivariate Index Assay) (MIA), and Overa (MIA2G), today announced that the Center for Medicare Services (CMS) has released the Final 2018 Clinical Lab Fee Schedule, effective January 1, 2018.

Under the new fee schedule, the price for OVA1(MIA) (code 81503) is \$897. This is a four-fold increase over the current CMS rate, and this new rate is based on the median of private payer payments submitted to CMS by companies, including ASPiRA Labs, as part of the market-based payment reform mandated through Protecting Access to Medicare Act of 2014 (PAMA). *The rate is scheduled to be in effect for a three-year term from January 2018 thru December 2020.*

“We are very excited that CMS has finally priced OVA1 based on market pricing which is directly related to improved patient outcomes and health economic impact. Historically, pricing has not reflected OVA1’s benefit to improved patient outcomes, as well as the cost reductions to the healthcare system,” stated Valerie Palmieri, President and Chief Executive Officer of Vermillion, Inc. “Our health economics study published last week is another confirmation of the value of our technology. In addition to being appropriately priced, OVA1 is now included on the Clinical Lab Fee Schedule (CLFS) for the very first time. We expect that leveraging guidelines, payer coverage and price will be key catalysts for growth in 2018.”

“The inclusion of OVA1 on the CLFS should accelerate our contracting efforts throughout 2018,” stated Fred Ferrara, Chief Operating Officer of ASPiRA Labs. “Several large plans use the CLFS to determine price. We view the added CLFS visibility for our testing that was calculated using the PAMA rates as a very positive event. We plan to expand the ASPiRA Labs sales team in strategic markets to deliver OVA1 to more women going forward, particularly given the substantial increase in covered lives expected to take effect from October 2017 through February 2018.”

The lifetime risk for all U.S. women to develop a pelvic mass is 20%. There is a 5-10% lifetime risk of requiring surgery for a suspected ovarian neoplasm. Due to the majority of the masses are benign, triaging the low and high risk masses is vital to improved patient outcomes. Today, more than 60% of U.S. ovarian

cancer patients do not receive National Comprehensive

Cancer Network (NCCN) guideline treatment, which includes surgical treatment by a gynecologic oncologist, and, as a result, the survival rate is reduced by 30-40%. OVA1 helps ensure that rare ovarian cancer is triaged appropriately to the gynecological oncologist and benign cysts are managed by the general practitioner, *in a very cost-effective and efficient way*. Vermillion's goal is to have the *right* patient managed by the *right* specialist, with the *right* treatment the *first* time.

OVA1 is now considered a Level B Recommendation by The American College of Obstetricians and Gynecologists (ACOG). Given the November 2016 ACOG bulletin, the 2017 NCCN update and the 2013 Society of Gynecologic Oncology positive position statement, OVA1 can be the physician's first choice in biomarker panels to best triage patients' pelvic masses to the most appropriate care pathway. There is no other comparable technology on the market today.

CMS also published a final price for Overa of \$752, which was benchmarked to the only proteomic test currently on the CLFS that uses biomarkers and an algorithm to produce a prognostic score. The price for Overa will be re-reviewed now that OVA1 is on the CLFS.

Links to multiple clinical studies showing OVA1's strong performance compared to existing technologies, such as CA125 and ROMA, can be found on our website:

<https://aspiralsc.wpengine.com/providers/ova-1/clinical-validation-studies/>.

## **About Vermillion**

Vermillion, Inc. is dedicated to the discovery, development and commercialization of novel high-value diagnostic and bio-analytical solutions that help physicians diagnose, treat and improve gynecologic health outcomes for women. Vermillion, along with its prestigious scientific collaborators, discovers, develops, and delivers innovative diagnostic and technology tools that help women with serious diseases. The company's initial in vitro diagnostic test, OVA1® (MIA), was the first FDA-cleared, protein-based In Vitro Diagnostic Multivariate Index Assay, and represented a new class of software-based liquid biopsy in vitro diagnostics. In March 2016, Vermillion received FDA clearance for Overa™, a Multivariate Index Assay 2<sup>nd</sup> Generation (MIA2G) test with significantly improved specificity and ease of use. For additional information, including published clinical trials, visit [www.aspirawh.com](http://www.aspirawh.com).

## Forward-Looking Statements

This press release contains forward-looking statements, as that term is defined in the Private Securities Litigation Reform Act of 1995, that involve significant risks and uncertainties, including statements regarding the expected catalysts for Vermillion's growth, the anticipated impact of the inclusion of OVA1 on the CLFS on Vermillion's contracting efforts, plans to expand the ASPIRA Labs sales team and expected increases in the number of covered lives. 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. The forward-looking statements contained in this press release are based on Vermillion's expectations as of the date of this press release. A variety of factors could cause actual results and experience to differ materially from the anticipated results or other expectations expressed in such forward-looking statements, including changes to interpretations of existing laws and regulations and other factors that are described in Vermillion's Form 10-K for the year ended December 31, 2016 and Form 10-Q for the quarter ended March 31, 2017 as filed with the Securities and Exchange Commission. Vermillion expressly disclaims any obligation to update, amend or clarify any forward-looking statements to reflect events, new information or circumstances occurring after the date of this press release, except as required by law.

## Investor Relations Contact:

Michael Wood  
LifeSci Advisors LLC  
Tel 1-646-597-6983  
[mwood@lifesciadvisors.com](mailto:mwood@lifesciadvisors.com)