Vermillion Reports Fourth Quarter and Full Year 2016 Results

Description

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Conference Call at 4:30 p.m. ET Today
AUSTIN, Texas — March 29, 2017 — Vermillion, Inc. (NASDAQ: VRML), a bio-analytical solutions company focused on gynecologic disease, reported on its results for the fourth quarter and full year ended December 31, 2016.
“2016 marked a pivotal year for us with our first clinical utility publication, ACOG guideline inclusion, international distribution agreements, major reimbursement progress with Medicare, positive medical policy coverage and in network payer agreements. In addition we cleared our 2nd generation product Overa (MIA2G) and launched ASPiRA IVD. We believe the stage is well set for continued progress in 2017,” stated Valerie Palmieri, President and CEO of Vermillion, Inc.
Key Q4 2016 and Q1 2017 Developments:

- December – Received an FDA Clarification Letter regarding OVA1 – Multivariate Index Assay (MIA) and Overa (MIA2G). This letter was in reference to the September 7, 2016 FDA Safety Communication advising women and their physicians against the use of ovarian cancer screening tests for asymptomatic women. The Clarification Letter, dated December 21, 2016, from Jeffrey Shuren, M.D, J.D., Director: Center for Devices and Radiological Health at the FDA, agreed that the Safety Communication did not apply to Vermillion’s FDA-cleared tests and further stated, “FDA cleared OVA1 (MIA) and Overa (MIA2G) as aids to further assess the likelihood that malignancy is present when the physician’s independent clinical and radiological evaluation does not indicate malignancy. The intended uses of the two assays are the same-to help physicians more reliably identify which patients would benefit from consultation with or referral to a gynecologic oncologist. OVA1 (MIA) and Overa (MIA2G) are indicated for women who present with an adnexal mass.”
- December – Received a Proprietary Laboratory Analyses code (#0003U) for Overa, Vermillion’s second-generation FDA cleared Multivariate Index Assay test for determining the risk of ovarian cancer in a woman with a diagnosed pelvic mass, from the American Medical Association’s CPT® Editorial Panel.
- January 9 – Announced that OVA1, Vermillion’s first-generation Multivariate Index Assay, was included on the list of clinical diagnostic laboratory test procedure codes as one for which the Centers for Medicare & Medicaid Services would require reporting of private payer rates as part of the implementation of Protecting Access to Medicare Act of 2014 (PAMA). Future Medicare pricing of OVA1 is expected to be based *on the weighted median of final private payer rates from January through June* 2016. New rates are scheduled to take effect on January 1, 2018. Currently, ASPiRA Labs reimbursement has been established by the local Medicare Administrative Contractor for OVA1.
- February 17 – Completed a private placement of common stock and warrants with initial gross proceeds to the Company totaling $5.6 million.
- March – Announced a contract for coverage of OVA1 with BlueCross BlueShield of Michigan, which

serves over six million beneficiaries throughout Michigan and surrounding states, and receipt of out-of-state provider status with Medi-Cal, California's Medicaid program.**Q4 2016 Results**OVA1 tests performed during the fourth quarter of 2016 decreased 11% to 2,258 compared to 2,529 OVA1 tests performed in the prior year quarter. Test volume has been stable in 2016 after an initial volume loss associated with the transition of OVA1 testing from Quest Diagnostics to ASPiRA LABS in August 2015. Revenue on a per test performed basis, however, increased to $301 in the fourth quarter of 2016 compared to $143 in the fourth quarter of 2015. This number compared to $257 in the third quarter of 2016 and has increased five quarters sequentially, although approximately $45,000 or $20 per test of the 2016 fourth quarter increase was attributed to the resolution of billing issues with Novitas (Medicare contractor).Total operating expenses in the fourth quarter of 2016 decreased to $2.9 million from $4.9 million in the fourth quarter of 2015. The 41% decrease was primarily due to planned lower commercialization costs and consulting expenses. In addition, research and development costs were lower as a result of the completion of our collaboration agreement with The Johns Hopkins University School of Medicine and clearance of Overa. **Full Year 2016 Financial Results** Total revenue for the full year 2016 was $2.6 million compared to $2.2 million in the prior year. Total revenue in 2016 was comprised of $2.3 million in product revenue from OVA1 and $322,000 in service revenue from ASPiRA IVD. Total revenue in 2015 was comprised of $1.9 million in product revenue including a one-time recognition of $163,000 in deferred revenue upon the signing of our logistics agreement with Quest Diagnostics in March 2015 as well as $316,000 in license revenue. Service revenue was $322,000 for the year ended December 31, 2016. There was no service revenue in 2015 as ASPiRA IVD began operations in 2016. Cost of service revenue was $724,000 for the full year 2016. There was no cost of service revenue in 2015 as ASPiRA IVD did not commence operations until June 2016.For the full year of 2016, net loss was $15.0 million or $(0.29) per share as compared to a net loss of $19.1 million or $(0.41) per share in 2015.

Conference Call and Webcast

- As of December 31, 2016, cash and equivalents totaled $5.2 million. In February 2017, we received $5.6 million in gross proceeds from our private placement of common stock and warrants. The company utilized $2.8 million in cash in the fourth quarter of 2016. We expect cash utilization to decrease further to approximately $2.6 million in the first quarter of 2017, net of offering proceeds and expenses. We plan for cash utilization to continue to decrease in the second quarter of 2017 with a goal of reducing our cash utilization to under $2.0 million per quarter over the balance of 2017.
- Total operating expenses in 2016 were $14.9 million as compared to $19.1 million in 2015. The 22% decrease in expense was due primarily to planned lower commercialization and consulting expenses following our February 2016 restructuring. In addition, research and development costs decreased after the completion of our collaboration with The Johns Hopkins University School of Medicine and also due to lower personnel costs following the clearance of Overa. The decreases were partially offset by start-up costs to launch ASPiRA IVD.
- Cost of product revenue for the full year 2016 decreased $335,000 or 15% compared to 2015. Cost of product revenue for 2015 included significant one-time costs associated with the cutover of volume from Quest Diagnostics to ASPiRA LABS in August 2015. Thus, cost of product revenue in 2016 decreased compared to 2015 even though ASPiRA LABS processed significantly more OVA1 tests in 2016 compared to 2015.

- Our total OVA1 and Overa volume was 9,125 for 2016. All of the OVA1 and Overa tests were performed by ASPiRA LABS. Total OVA1 volume was 13,598 for 2015. This was comprised of 8,937 tests performed by Quest Diagnostics and 4,661 OVA1 tests performed by ASPiRA LABS. The 33% decrease in volume from 2015 to 2016 was due primarily to the transition of OVA1 testing from Quest Diagnostics to ASPiRA LABS. Product revenue, however, increased 25% in 2016 compared to 2015 despite the decrease in volume due to gains in average unit price in 2016 and as compared to the fixed fee per test from Quest Diagnostics in 2015.
- Net loss for the fourth quarter of 2016 was $2.8 million or $(0.05) per share, as compared to a net loss of $5.0 million or $(0.10) per share in the prior year quarter.
- Cost of product revenue for the fourth quarter of 2016 totaled $458,000 and was consistent with the comparable prior year quarter. In the fourth quarter of 2016, cost of service revenue totaled $308,000 for ASPiRA IVD services.
- Total revenue in the fourth quarter of 2016 was $805,000 compared to $361,000 in the same year-ago quarter. The fourth quarter 2016 revenue included $680,000 from product sales of OVA1 by ASPiRA LABS and $125,000 of service revenue from ASPiRA IVD. All prior year revenue was from product sales of OVA1 as ASPiRA IVD began operations in June 2016, and thus there was no comparable service revenue in the prior year. Product revenue increased 88% in the fourth quarter of 2016 compared to the prior year quarter.
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Vermillion's President and CEO Valerie Palmieri will host a call today to discuss results followed by a question and answer period.

Wednesday, March 29th @ 4:30pm Eastern Time.
Domestic: 888-256-1035
International: 913-312-0947
Conference ID: 2832934
Webcast: http://public.viavid.com/index.php?id=123159
Replay dial-in numbers, available through April 12th, 2017:
Domestic: 844-512-2921
International: 412-317-6671
Replay PIN: 2832934

Please call the conference telephone number five minutes prior to the start time. An operator will register your name and organization. If you have any difficulty connecting with the conference call, please contact Vermillion at (512) 519-0400.

About Vermillion

Vermillion, Inc. (NASDAQ: VRML) 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 second generation OVA1 (MIA2G) test with significantly improved specificity and ease of use. For additional information, including published clinical trials, visit www.aspirawh.com.

About Overa® and Overa™ (MIA2G)

- OVA1 (MIA) is a proprietary FDA-cleared blood test designed to help physicians assess the risk of ovarian cancer prior to surgery, facilitating more effective referral of high risk patients to a specialist (gynecologic oncologist) for surgical treatment.
- OVA1 (MIA) now has an ACOG Level B recommendation for the Evaluation and Management of Adnexal Masses (ACOG Practice Bulletin #174, November 2016).

The OvaCalc® proprietary algorithm combines five biomarker results into a single numerical “risk score” that stratifies patients into “higher risk” and “lower risk” when combined with clinical assessment.

- In two pivotal clinical trials, OVA1 (MIA) plus clinical assessment (ca) detected 94% of all malignancies vs. only 77% for CA125 plus ca, and OVA1 (MIA) plus ca detected 95.3% of all malignancies vs. only 80% for CA125 plus ca.
- In a study focused on early-stage ovarian cancer detection, 31% of cases were missed by clinical impression alone. This was reduced to 5% when OVA1 (MIA) was added to clinical impression, a reduction of 85%.
- Overa (MIA2G) measures the levels of five proteins found in the blood and then uses a second-generation OvaCalc® algorithm to stratify risk. A woman’s risk of cancer is measured by using a 0-10 scale with a single cut-off point of 5 eliminating the ambiguity in determining menopausal status. A high Overa score is not a diagnosis of cancer, rather it indicates an increased risk of malignancy when used as intended.
- OVA1 (MIA) has shown clinical utility in increasing the rate of referrals of malignant adnexal masses to gynecologic oncologists. The increased involvement of specialists may lead to increased adherence to National Comprehensive Cancer Network guidelines which includes surgical treatment by a gynecologic oncologist, which is associated with improved cancer outcomes, including overall survival. In a study focused on specialist involvement in ovarian cancer treatment, 94% of patients with an elevated-risk OVA1 (MIA) result who had primary ovarian malignancies were appropriately referred to a gynecologic oncologist.
- PRECAUTION: OVA1® and Overa tests should not be used without an independent clinical/radiological evaluation and are **not** intended to be a screening test or to determine whether a patient should proceed to surgery. Incorrect use of OVA1® or Overa carries the risk of unnecessary testing, surgery and/or delayed diagnosis.

Forward-Looking Statements

This press release contains forward-looking statements, as that term is defined in the Private Litigation Reform Act of 1995, that involve significant risks and uncertainties, including business plans, anticipated Medicare pricing and expected cash utilization in future periods. 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. Factors that could cause actual results to materially differ from those projected in such forward-looking statements include but are not limited to: (1) Vermillion's ability to increase the volume of OVA1 or Overa sales; (2) Vermillion's ability to market its test through sales channels other than ASPiRA LABS; (3) failures by third-party payers to reimburse OVA1 or Overa or changes or variances in reimbursement rates; (4) Vermillion's ability to secure additional capital on acceptable terms to execute its business plan; (5) Vermillion's ability to commercialize Overa both within and outside the United States; (6) in the event that Vermillion succeeds in commercializing Overa outside the United States, the political, economic and other conditions affecting other countries (including foreign exchange rates); (7) Vermillion's ability to develop and commercialize additional diagnostic products and achieve market acceptance with respect to these products; (8) Vermillion's ability to compete successfully; (9) Vermillion's ability to obtain any regulatory approval required for Vermillion's future diagnostic products; (10) Vermillion's or its suppliers' ability to comply with FDA requirements for production, marketing and post market monitoring of its products; (11) additional costs that may be required to make further improvements to Vermillion's manufacturing operations; (12) Vermillion's ability to maintain sufficient or acceptable supplies of immunoassay kits from its suppliers; (13) Vermillion's ability to continue to develop, protect and promote its proprietary technologies; (14) future litigation against Vermillion, including infringement of intellectual property and product liability exposure; (15) Vermillion's ability to retain key employees; (16) business interruptions; (17) legislative actions resulting in higher compliance costs; (18) changes in healthcare policy; (19) Vermillion's ability to comply with environmental laws; (20) Vermillion's ability to generate sufficient demand for ASPiRA LABS' services to cover its operating costs; (21) Vermillion's ability to comply with the additional laws and regulations that apply to it in connection with the operation of ASPiRA LABS; (22) Vermillion's ability to comply with FDA regulations that relate to its products and to obtain any FDA clearance or approval required to develop and perform laboratory developed tests; (23) ASPiRA IVD's lack of operating history; (24) ASPiRA IVD's ability to generate and maintain business; (25) fluctuations over time with respect to ASPiRA IVD's operating results; (26) ASPiRA IVD's ability to enter into profitable contracts; (27) ASPiRA IVD's ability to maintain effective information systems without significant interruption; (28) ASPiRA IVD's ability to perform its services in compliance with contractual requirements, regulatory standards and ethical considerations; and (29) other factors that are described in Vermillion's Form 10-K for the year ended December 31, 2015 and Form 10-Q for the quarter ended March 31, 2016 as filed with the Securities and Exchange Commission (the "SEC"). 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.

This release should be read in conjunction with the consolidated financial statements and notes thereto included in Vermillion's most recent reports on Form 10-K and Form 10-Q. Copies are available through the SEC's Electronic Data Gathering Analysis and Retrieval system (EDGAR) at www.sec.gov.

Investor Relations Contact:
Michael Wood
LifeSci Advisors LLC
Tel 1-646-597-6983
mwood@lifesciadvisors.com

PDF document below includes Consolidated Balance Sheets and Consolidated Statements of

Operations
PDF Document – VRML_03 29 17 Earnings Release