Vermillion Reports Third Quarter 2016 Results

Description

AUSTIN, Texas — Vermillion, Inc. (NASDAQ: VRML), a bio-analytical solutions company focused on gynecologic disease, reported its financial results for the third quarter ended September 30, 2016.
Valerie Palmieri, President and CEO of Vermillion, Inc., stated, “We continued to execute on our short-term and long-term goals, including reimbursement, publications, and awareness, as well as our ASPiRA pelvic mass specimen and data repository. We believe this foundation will allow us to provide solutions for women affected by a pelvic mass. Pelvic mass conditions impact 20 million women in the US and are a significant burden to the healthcare system and the patient lives they impact.”
Recent Corporate Developments:

- **September 2016 – FDA Safety Communication Released on Ovarian Cancer Screening.** We believe this may be an historic opportunity to move physicians from managing pelvic masses using what we believe to be inferior technology, such as CA125, to our FDA cleared technology (OVA1/Overa).
- **September 2016 – Major Managed Care Contract Closed.** Announced an agreement for coverage of OVA1 with CareFirst BlueCross BlueShield. CareFirst serves over three million patients throughout Maryland, Washington, D.C., and Virginia.
- **September 2016** – **Launched “Everyone Knows Someone” campaign.** For ovarian cancer awareness month, September, we launched a campaign that profiled people who have been impacted by ovarian cancer. The campaign was led by New York Yankees Manager, Joe Girardi.
- **October 2016 – Launched Pelvic Mass Specimen and Data Repository.** ASPiRA Labs started collection of Institutional Review Board patient consents for collection and cataloging of serum samples for future research purposes.
- **October 2016 – Overa Launched in the US via Targeted Launch Program**. Initial two key accounts converted from OVA1 to Overa.

Q3 2016 Financial Results
Total revenue in the third quarter of 2016 was $623,000 compared to $330,000 in the same year-ago quarter. The third quarter 2016 revenue included $581,000 from product sales of OVA1 by ASPiRA LABS and $42,000 of service revenue from ASPiRA IVD. Third quarter revenue in 2015 was comprised of $190,000 in OVA1 product revenue from Quest Diagnostics sales and $140,000 in OVA1 product revenue from ASPiRA LABS. ASPiRA IVD began operations in the second quarter of 2016, and thus there was no comparable service revenue in the prior year.
Product revenue in the third quarter of 2016 was derived from 2,257 OVA1 tests performed by ASPiRA LABS. ASPiRA LABS performed a total of 1,665 tests in the third quarter of the prior year in addition to the 1,518 OVA1 tests performed at Quest Diagnostics. Revenue on a per test performed basis increased to $257 in the third quarter of 2016 compared to $104 in the third quarter of 2015.

Cost of product revenue for the third quarter of 2016 totaled $461,000 compared to $757,000 in the comparable prior year quarter. The decrease was attributed primarily to one-time items in 2015 associated with the transition of OVA1 testing from Quest Diagnostics to ASPiRA LABS in August 2015 not being repeated in 2016. In the third quarter of 2016, cost of service revenue totaled $356,000 for ASPiRA IVD services.

Total operating expenses in the third quarter of 2016 decreased to $3.3 million compared to $4.7 million in the same year-ago quarter. The decrease was due primarily to lower sales personnel and personnel-related expenses following our February 2016 restructuring as well as lower research and development collaboration costs, partially offset by costs related to establishing the laboratory for ASPiRA IVD.

Net loss for the third quarter of 2016 was $3.5 million or $(0.07) per share, as compared to a net loss of $5.1 million or $(0.10) per share in the same year-ago quarter.

As of September 30, 2016, cash and equivalents totaled $8.1 million. We utilized $3.0 million in cash in the third quarter of 2016 and expect net cash utilization to be less than $3.0 million in the fourth quarter of 2016.

Conference Call and Webcast

Replay dial-in numbers (available through): November 24, 2016

Domestic: 1-844-512-2921

International: 1-412-317-6671

Replay PIN: 6709878

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. To view the consolidated balance sheets and consolidated statements of operations, click here.

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 debilitating diseases. The company's initial in vitro diagnostic test, OVA1®, 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 test with significantly improved specificity and ease of use and which uses widely distributed platforms. For additional information, including published clinical trials, visit www.aspirawh.com.

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 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 sales; (2) Vermillion’s ability to market its test through sales channels other than Quest Diagnostics, including ASPiRA LABS; (3) failures by third-party payers to reimburse OVA1 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 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; ASPiRA IVD’s ability to perform its services in compliance with contractual requirements, regulatory standards and ethical considerations; and (24) 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.

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