Vermillion Reports Third Quarter 2017 Results

Description

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Conference Call at 4:30 p.m. ET Today
AUSTIN, Texas — November 8, 2017 — Vermillion, Inc. (NASDAQ: VRML), a bio-analytical solutions company focused on gynecologic disease, reported on its financial results for the third quarter ended September 30, 2017.

Valerie Palmieri, President and CEO, stated, “Third quarter inflection points and recent releases mark milestones that have been years in the making. We believe that obtaining positive medical policy for 26 million lives including plans that comprise a national payer, Health Care Service Corporation (HCSC), coupled with the Center for Medicare and Medicaid Service’s (CMS) preliminary issuance of PAMA pricing, and the expected addition of OVA1 and Overa to the Clinical Lab Fee Schedule (CLFS) at ‘first time’ fair market value rates, set the stage for meaningful growth in 2018.”
Recent Corporate Developments

- CMS published a preliminary Protecting Access to Medicare Act of 2014 (PAMA) price for OVA1 (MIA) at a four-fold increase over the current CMS price and that Overa (MIA2G) will not be gap-filled but rather crosswalked to a current CLFS technology. The preliminary OVA1 rate is based on the median of private payer payments submitted by Vermillion as part of the market-based payment reforms mandated through PAMA.The Overa price was benchmarked to the only proteomic test currently on the CLFS that uses biomarkers and an algorithm to produce a prognostic score. The new rates, once finalized, are scheduled to become effective on January 1, 2018.

- Substantially expanded positive policy coverage with the addition of 14 key managed care providers totaling over 26 million lives. This included BlueCross BlueShield (BCBS) plans associated with a national plan, HCSC, that include Illinois, Montana, New Mexico, Oklahoma and Texas (approximately 14.8 million covered lives). The policy changes are scheduled to become effective in October 2017 for certain plans, and by February 2018 for the remainder. In addition, this is a reversal for many of these plans from negative policy coverage to positive policy coverage.

Q3 2017 Financial Results
Product revenue in the third quarter of 2017 totaled $657,000 compared to $581,000 in the prior year quarter, representing a 13% year-over-year increase. ASPiRA IVD service revenue in the third quarter of 2017 totaled $42,000 and was consistent with the prior year quarter. Total revenue in the third quarter of 2017 was $699,000 compared to $623,000 in the same year-ago quarter, representing an increase of 12%. There were 1,954 total OVA1 tests performed during the third quarter of 2017 compared to the 2,257 OVA1 tests performed in the prior year quarter, a 13% decrease. The volume decrease was primarily due to the previously-announced loss of a one client bill customer, which was concentrated in uncovered

territories (territories not covered by an ASPiRA sales representative) and, to a lesser extent, the impact of hurricanes in two key areas (Texas and Florida). We experienced modest year-over-year growth in covered territories (territories covered by an ASPiRA sales representative). Revenue on a per-test-performed basis increased to $336 in the third quarter of 2017 compared to $257 in the third quarter of 2016, representing a 31% increase.

Cost of product revenue for the third quarter of 2017 totaled $495,000, representing a 7% increase from the prior year quarter due to equipment maintenance costs and higher consulting costs in the third quarter compared to the prior year. Our gross product margin improved to 25% in the third quarter of 2017 compared to 21% in the prior year quarter.

Cost of service revenue was $284,000 for the third quarter of 2017 compared to $356,000 for the same period in 2016. The decrease of 20% was due primarily to consulting costs related to the opening of the lab in the third quarter of 2016 which were not repeated in 2017.

Total operating expenses in the third quarter of 2017 decreased to $2.4 million compared to $3.3 million in the same year-ago quarter, representing a decrease of 26%. The decrease was due to reductions in consulting, marketing services and lower health economics study costs in the third quarter of 2017 compared to 2016.

Net loss for the third quarter of 2017 was $2.5 million as compared to a net loss of $3.5 million in the same year-ago quarter.

As of September 30, 2017, cash and equivalents totaled $7.8 million including net proceeds of $3.6 million from a common stock warrant repricing in August 2017. We repriced 3.8 million common stock warrants with an original strike price of $2.00 per common share to $1.00 per share in exchange for immediate exercise. The company also utilized $1.9 million in cash in the third quarter of 2017. We expect cash utilization to remain under $2.0 million in the fourth quarter of 2017.

Conference Call and Webcast

Vermillion's President and CEO, Valerie Palmieri, will host a call today to discuss results followed by a question and answer period.

Wednesday, November 8th @ 4:30pm Eastern Time

Domestic:	888-417-2254
International:	719-325-4794
Conference ID:	4929135
Webcast:	http://public.viavid.com/index.php?id=126293

Replays, available through November 22nd:

Domestic:	844-512-2921
International:	412-317-6671
Replay PIN:	4929135

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 (203) 993-8300.

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 regarding the number of covered lives for OVA1 by February 2018, CMS pricing of OVA1 and Overa, inclusion of OVA1

on the CLFS and plans with respect to cash utilization. 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) Vermillion’s ability to continue as a going concern and (30) other factors that are described in Vermillion’s Form 10-K for the year ended December 31, 2016 and Form 10-Q for the three months ended March 31, 2017 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.