

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D. C. 20549  

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**FORM 10-K**

- ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the Fiscal Year Ended December 31, 2013.
- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-34810

**Vermillion, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation or organization)

**33-0595156**

(I.R.S. Employer Identification No.)

**12117 Bee Caves Road, Building Three, Suite 100**

**Austin, Texas**

(Address of principal executive offices)

**78738**

(Zip Code)

**Registrant's telephone number, including area code: (512) 519-0400**

**Securities registered pursuant to Section 12(b) of the Act:**

Title of each class to be so registered  
**Common Stock, par value \$0.001 per share**

Name of each exchange on which registered  
**The NASDAQ Stock Market**

**Securities registered pursuant to Section 12(g) of the Act: None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K .

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non - Accelerated filer

Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes  No

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Section 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court. Yes  No

The aggregate market value of voting common stock held by non-affiliates of the Registrant is \$44,321,867 and is based upon the last sales price as quoted on The NASDAQ Capital Market as of June 30, 2013.

As of February 28, 2014, the Registrant had 35,831,776 shares of common stock, par value \$0.001 per share, outstanding.

#### **DOCUMENTS INCORPORATED BY REFERENCE**

Certain information from the registrant's definitive Proxy Statement for its Annual Meeting of Stockholders, scheduled to be held on June 19, 2014, is incorporated by reference into Part III of this report. The registrant intends to file the Proxy Statement with the Securities and Exchange Commission within 120 days of December 31, 2013.

**VERMILLION, INC.**

**FORM 10-K**

**For the Fiscal Year Ended December 31, 2013**

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## PART I

### FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements, as defined in the Private Securities Litigation Reform Act of 1995. These statements involve a number of risks and uncertainties. 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. Readers are cautioned that these forward-looking statements speak only as of the date on which this report is filed with the Securities and Exchange Commission (the “SEC”), and Vermillion, Inc. (“Vermillion” and, together with its subsidiaries the “Company”, “we”, “our” or “us”) does not assume any obligation to update, amend or clarify them to reflect events, new information or circumstances occurring after such date. Examples of language found in forward-looking statements include the following:

- projections of our future revenue, results of operations and financial condition;
- anticipated efficacy of our products, product development activities and product innovations;
- our ability to consolidate the five OVA1 immunoassays on a single mainstream integrated diagnostic automation platform;
- expected competition and consolidation in the markets in which we compete;
- expectations regarding existing and future collaborations and partnerships;
- our belief that particular biomarker discoveries may have diagnostic and/or therapeutic utility;
- achieving milestones in product development, future regulatory or scientific submissions and presentations;
- our continued ability to comply with applicable governmental regulations;
- our continued ability to expand and protect our intellectual property portfolio;
- anticipated future losses;
- expected levels of expenditures;
- expected market adoption of our diagnostic tests, including OVA1;
- results of clinical trials, post-market studies required by the United States Food and Drug Administration (“FDA”), and publications on OVA1;
- the amount of financing anticipated to be required to fund our planned operations;
- our prospects for obtaining support of medical or professional societies (e.g., Society for Gynecologic Oncology (“SGO”), National Comprehensive Cancer Network (“NCCN”) and American Congress of Obstetricians and Gynecologists (“ACOG”)) through “guidelines,” “position statements” and the like;
- the financial or market share projections which could result from positive guidelines or position statements; and
- our expected reimbursement for our products, and our ability to obtain such reimbursement, from third party payers such as private insurance companies and government insurance plans.

Such statements are subject to significant risks and uncertainties, including those identified in Part I Item 1A, “Risk Factors”, that could cause actual results to differ materially from those projected in such forward-looking statements due to various factors, including our ability to increase the volume of OVA1 sales; our ability to market our test through sales channels other than Quest Diagnostics Incorporated (“Quest Diagnostics”); uncertainty in how we recognize future revenue following termination of the Quest Diagnostics Strategic Alliance Agreement; failures by third party payers to reimburse OVA1 or changes or variances in reimbursement rates; our ability to secure additional capital on acceptable terms to execute our business plan; our ability to commercialize OVA1 outside the United States; our ability to develop and commercialize additional diagnostic products and achieve market acceptance with respect to these products; our ability to compete successfully; our ability to obtain any regulatory approval for our future diagnostic products; our suppliers’ ability to comply with FDA requirements for production, marketing and postmarket monitoring of our products; our ability to maintain sufficient or acceptable supplies of immunoassay kits from our suppliers; our ability to continue to develop, protect and promote our proprietary technologies; future litigation against us, including infringement of intellectual property and product liability exposure; our ability to retain key employees; business interruptions; legislative actions resulting in higher compliance costs; changes in healthcare policy; our ability to comply with environmental laws; the potentially low

liquidity and trading volume of our common stock and concentration in the ownership of our common stock; volatility in the price of our common stock; the existence of anti-takeover provisions in our corporate governance documents; actions of activist stockholders; that we do not intend to pay dividends, so our stockholders will benefit from an investment in our capital stock only if it appreciates in value and potential dilution caused by future sale of our common stock or other securities to meet our capital requirements.. We believe it is important to communicate our expectations to our investors. However, there may be events in the future that we are not able to accurately predict or that we do not fully control that could cause actual results to differ materially from those expressed or implied in our forward-looking statements.

## **ITEM 1. BUSINESS**

### **Company Overview**

**Corporate Vision:** To drive the advancement of women’s health by providing innovative methods to detect, monitor and manage the treatment of gynecologic cancers and other related diseases

**Mission Statement:** We are dedicated to the discovery, development and commercialization of novel high-value medical tests that help physicians diagnose, treat and improve outcomes for patients with gynecologic cancers and related diseases. Our tests are intended to detect, characterize and stage disease, and to help guide decisions regarding prognosis and patient treatment. These may include decisions to refer patients to specialists, to perform additional testing, or to assist in the selection or monitoring of therapy and disease progression. A distinctive feature of our approach is to combine multiple biomarkers into a single, reportable result (i.e. index score) that has higher diagnostic effectiveness than its individual constituents. We concentrate our development of novel diagnostic tests in the fields of gynecologic oncology and women’s health, with the initial focus on guiding the referral of women with ovarian cancer to a cancer specialist for surgery. We also intend to address clinical questions related to early disease detection, treatment response, monitoring of disease progression and prognosis through internal development, targeted acquisitions, and collaborations with leading academic and clinical research institutions. Our commercial efforts include direct marketing and sales activities as well as partnerships with leading companies in women’s health.

#### **Strategy:**

We are focused on the execution of three core strategic business drivers in ovarian cancer diagnostics to build long-term value for our investors:

- Maximizing the existing OVA1 opportunity in the United States (“US”) by changing our business relationship with Quest Diagnostics and taking the leadership role in expanding commercialization, payer coverage and medical guidelines
- Expanding our customer base to non-US markets by migrating OVA1 to a global testing platform
- Building an expanded patient base by seeking FDA approval and launching a next generation multi-marker ovarian cancer test to monitor patients at risk for ovarian cancer

We believe that these business drivers will contribute significantly to addressing unmet medical needs for women faced with ovarian cancer and the continued development of our business.

#### **Business:**

Our lead product, OVA1, is an ovarian cancer test system that integrates a software algorithm and blood test cleared by the FDA in September 2009. OVA1 was launched in March 2010 by Quest Diagnostics under the terms of a strategic alliance agreement (as amended, the “Strategic Alliance Agreement”) that we terminated in August 2013. Following the termination, Quest has continued to process and co-promote the test with a small Vermillion field sales force. Novitas Solutions (formerly Highmark Medicare Services), a Medicare Administrative Contractor (“MAC”), issued a favorable coverage decision and has reimbursed for the OVA1 test since 2010. In September 2010, we announced that OVA1 had obtained a CE mark, a requirement for marketing the OVA1 test in the European Union. OVA1 has satisfied all certification requirements to complete its declaration of conformity.

OVA1 addresses a clear unmet clinical need, namely the pre-surgical identification of women who are at high risk of having a malignant ovarian tumor. Statements from the National Institutes of Health (“NIH”), NCCN, ACOG, SGO, Canadian Gynecologic Cancer Group (“GOC”) and the London Advisory Panel recommend the referral of these high risk women to gynecologic oncologists for their initial surgery. Numerous clinical studies and publications support the clinical value of having a gynecologic oncologist perform the initial surgery for ovarian cancer. OVA1 is a qualitative serum test that utilizes five well-established biomarkers and proprietary FDA-cleared software to determine the likelihood of malignancy in women over age 18 with a pelvic mass for whom surgery is planned.

In August 2013, we terminated the Strategic Alliance Agreement with Quest Diagnostics under which we were to develop and commercialize diagnostic tests from our product pipeline (the “Strategic Alliance”). Prior to termination, Quest Diagnostics had

the exclusive right to commercialize OVA1 in the clinical laboratory market until September 2014, with an option to extend such exclusive period in its sole discretion for one additional year.

As part of the termination, we allowed Quest Diagnostics to continue to make OVA1 available as long as (i) Quest Diagnostics continues to make the payments and provide the reports to Vermillion in connection with such activities as would be required under the Strategic Alliance Agreement but for its termination and (ii) Vermillion determines that Vermillion and Quest Diagnostics are negotiating in good faith towards alternative terms under which Quest Diagnostics and Vermillion can work together to make this important product available to healthcare providers and patients. Now that the Strategic Alliance Agreement has been terminated, we plan to make OVA1 available through channels in addition to Quest Diagnostics. Quest Diagnostics has disputed the effectiveness of such termination.

In December 2013, the Centers for Medicare and Medicaid Services (“CMS”) made its final determination and authorized Medicare contractors to set prices for Multianalyte Assays with Algorithmic Analyses (“MAAA”) test Current Procedural Terminology (“CPT”®) codes when they determine it is payable. CMS also validated that an algorithm has unique value by specifying that the gap-fill process and not cross-walk should be used by contractors to price MAAA tests. We expect OVA1 to be priced using the gap-fill method. We will be engaged in that process in 2014 for pricing effective January 1, 2015. This decision also sets a precedent for recognizing the value of biomarker developed tests and recognizing tests on the value they bring to clinical decision-making and healthcare efficiencies.

### **Studies and publications**

The benefit of OVA1 was established in large clinical studies in collaboration with numerous academic medical centers encompassing over 2,500 clinical samples. OVA1 was fully validated in a prospective multi-center clinical trial encompassing 27 sites reflecting the diverse nature of the clinical centers at which ovarian adnexal masses are evaluated. [1] The results of the clinical trial demonstrated that in a clinical cohort of 516 patients, OVA1, in conjunction with clinical evaluation, was able to identify 95.7% (154/161) of the malignant ovarian tumors overall, and to rule out malignancy with a negative predictive value (“NPV”) of 94.6% (123/130). At the 2010 International Gynecologic Cancer Society Meeting, data was presented demonstrating the high sensitivity of OVA1 for epithelial ovarian cancers; OVA1 detected 95 out of 96 epithelial ovarian cancer cases for a sensitivity of 99.0%, including 40/41 stage I and stage II epithelial ovarian cancers. These findings resulted in an overall sensitivity of 97.6% for early stage epithelial ovarian cancers, as compared to 65.9% for the previous single-marker CA125 test using the American College of Obstetricians and Gynecologists (“ACOG”) cutoffs. The improvement in sensitivity was even greater among premenopausal women; for OVA1, sensitivity for early stage epithelial ovarian cancer in premenopausal women was 92.9% compared to CA125 with a 35.7% sensitivity. Overall, OVA1 detected 76% of malignancies missed by the CA125 assay, including all advanced stage malignancies. OVA1 is not indicated for use as a screening or stand-alone diagnostic assay. The study results were published in *Obstetrics and Gynecology* in 2011.

In February 2013 results from a second pivotal clinical study of OVA1, called the “OVA500 study” led by Dr. Robert E. Bristow, Director of Gynecologic Oncology Services at University of California Irvine Healthcare, were published in *Gynecologic Oncology*. The study evaluated OVA1 diagnostic performance in a population of 494 evaluable patients who underwent surgery for an ovarian adnexal mass by a non-gynecologic oncologist. Like the earlier OVA1 validation study, this was a prospective, multi-center study of consecutively enrolled, eligible subjects coordinated through 27 sites across the U.S.A. In the OVA500 study, adnexal surgery patients were only enrolled from non-gynecologic oncology caregivers. As a result, the patient population in this study more closely resembled the intended use population for routine OVA1 testing; women aged 18 years or older, with an adnexal mass requiring surgery, but not yet referred to gynecologic oncologist, and for which the mass was determined to be benign or malignant following enrollment in the study.

Of the 27 sites in each study, only 10 were common to both studies. Therefore, the two studies collectively evaluated 1,024 eligible subjects at a total of 44 sites. Despite differences in population and the number of sites in the two studies, the sensitivity of OVA1 added to clinical impression (also called OVA1 dual assessment) was identical, at 95.7% (88/92). Overall prevalence of malignancy in the OVA500 study was 18.6% overall (92/494) and 11.2% (31/277) in premenopausal surgery patients. These malignancy rates were lower than the 31.2% (161/516) found previously in the earlier OVA1 validation study. This difference is likely explained by the exclusion of subjects enrolled by gynecologic oncologists, a potentially malignancy-enriched subset of all adnexal mass surgeries. Even so, OVA1 sensitivity was 93.5% (29/31) in premenopausal subjects, with or without clinical assessment.

NPV is another critical element of OVA1 performance in the context of a presurgical triage test or referral to a gynecologic oncologist. In the OVA500 study, overall NPV of OVA1 dual assessment was 98.1% (204/208), higher than the 94.6% NPV found in the earlier validation study. In premenopausal subjects, where functional ovarian cysts are more common and gynecologists may elect to operate more frequently, the NPV of OVA1 with or without clinical assessment was 98.6%. In contrast, clinical assessment predicted just 73.9% of malignancies overall, and only 64.5% of premenopausal malignancies. Together, the differential sensitivity

and high NPV of OVA1 strongly confirmed previous findings that support the clinical utility of OVA1 in the presurgical triage of patients scheduled for adnexal mass surgery.

An important additional finding related to medical necessity was the detection of early stage malignancies, since stage I cancers are 90-95% curable if appropriately operated and treated. Of the 92 malignancies in OVA500, 35 were early stage and 28 were stage I: 38.0% and 30.4% of all malignancies, respectively. OVA1 standalone sensitivity in stratifying patients as high-risk was 91.4% (32/35) for all early stage and 89.3% (25/28) for stage I malignancies, respectively. Comparatively, CA125-II sensitivity was 65.7% (23/35) for all early stage and 64.3% (18/28) for stage I malignancies. The success rate of OVA1 classifying a benign mass as low risk, although of secondary importance (considering surgery will be performed regardless), was also measured in the OVA500 study. This statistic (specificity) was 53.5% (215/402) overall, and in premenopausal patients was 61.4% (151/246). Overall, the results strongly and independently confirmed the value of OVA1 in presurgical triage of adnexal mass patients, and sensitive identification of premenopausal and early stage malignancies.

Since many professional medical societies stress the importance of multiple independent clinical trials as so-called “evidence levels”, we also believe that OVA500 study contributes to a higher evidence level relative to OVA1’s utility in the medical management of adnexal masses. Health economic analysis indicates that anticipated benefits of OVA1 include i) more appropriate referrals of women with high risk of malignancy to a gynecologic oncologist and fewer referrals of women at low risk of malignancy; ii) fewer second surgeries as a result of an initial surgery by a generalist on a woman with a malignant tumor; iii) reduced need for a backup surgeon (i.e. specialist) during a surgery by a generalist; iv) more appropriate and efficient administration of intraperitoneal chemotherapy; and longer survival, associated with better quality of life.

In June 2013 a study was published in *Gynecologic Oncology* analyzing the medical records of 13,321 women with epithelial ovarian cancer, the most common type of ovarian cancer, diagnosed from 1999 to 2006 in California [3]. Led by Dr. Robert Bristow, this study demonstrated that only 37 percent of these patients received treatment that adhered to care guidelines established by the NCCN, an alliance of 23 major cancer centers with expert panels that analyze, research and recommend cancer treatments. The work, although initiated separately from any Vermillion-related work, points to a continuing need for better pre-surgical management of patients at risk for ovarian cancer.

The study also found that surgeons who operated on 10 or more women per year for ovarian cancer, and hospitals that treated 20 or more women a year for ovarian cancer, were more likely to adhere to NCCN guidelines and their patients lived longer. Among women with advanced disease — the stage at which ovarian cancer is usually first found — 35 percent survived at least five years if their care met the guidelines, compared with 25 percent of those whose care fell short.

Results of this study were featured on the front page of the New York Times under the headline, "Widespread Flaws Found in Ovarian Cancer Treatment." According to Dr. Bristow, principal investigator of the study, “If we could just make sure that women get to the people who are trained to take care of them, the impact would be much greater than that of any new chemotherapy drug or biological agent.” (NY Times, March 11, 2013, Denise Grady).

In November 2013, we announced that a new study of OVA1 clinical performance in the presurgical detection of ovarian cancer, entitled “Clinical Performance of a Multivariate Index Assay For Detecting Early-Stage Ovarian Cancer” was published in *The American Journal of Obstetrics & Gynecology*. [4] Co-authored by Dr. Robert E. Bristow (University of California Irvine Healthcare) and Dr. Frederick R. Ueland (University of Kentucky), the new analysis focused on presurgical detection of early-stage ovarian cancer among 1,016 ovarian mass surgery patients in two previous pivotal trials conducted in 2007 and 2012. The study compared OVA1 performance in early-stage ovarian cancer to commonly used cancer risk assessment protocols: overall clinical assessment, the CA125 biomarker or modified-American College of Obstetricians and Gynecologists (mod-ACOG) guidelines for evaluation of suspicious pelvic masses. The findings had been presented at the Annual Meeting of the Western Association of Gynecologic Oncologists in Seattle in June 2013.

In a statement regarding this new study, Dr. Bristow stated, “Early-stage ovarian cancer constitutes an important opportunity to improve survival and care for this most deadly gynecologic cancer. However, as evidenced by recent studies, most ovarian cancer patients fail to be referred to the doctors and hospitals best equipped to treat them, resulting in unfortunate consequences. Our new study demonstrates OVA1’s ability to detect the majority of all early-stage ovarian cancers prior to surgery and thereby aid in appropriately involving a gynecologic oncologist in their care. Even among premenopausal patients where primary ovarian cancer prevalence was just 15%, clinical assessment with OVA1 detected stage I ovarian cancer with almost 90% sensitivity. This is a very encouraging development for the diagnosis and treatment of ovarian cancer.”

Also in November 2013, we announced that a new clinical study published in *The American Journal of Obstetrics & Gynecology* has reported superior sensitivity of OVA1 for presurgical triage of ovarian cancer, compared with commonly used risk assessment methods. [5] The new study compared OVA1 performance to benchmark triage methods, within a combined cohort of 770 ovarian mass surgery patients (including 164 malignancies) from two independent but related OVA1 pivotal trials conducted in 2007

and 2012. The study also compared the actual rate of patient referral from non-specialist physicians to gynecologic oncologists (“GO”s) with rates predicted from clinical assessment, OVA1, CA125 or from the modified-American College of Obstetricians and Gynecologists (“mod-ACOG”) guidelines. We also reported the findings on the same day at the AAGL (or American Association of Gynecologic Laparoscopists) “42nd Global Congress of Minimally Invasive Gynecology.”

Dr. Robert E. Bristow, lead author of the study, commented: “Despite widely endorsed treatment standards published by the National Comprehensive Cancer Network, several studies published earlier this year show that only a minority of ovarian cancer patients actually receive treatment by the doctors and hospitals best equipped to care for them. Our new publication shows that the FDA-cleared OVA1 test achieves significantly higher sensitivity than two commonly used methods. And despite lower specificity, the referral rates predicted by OVA1 were roughly comparable to actual clinical practice.”

[1] Bristow RE, et al. 2013. Ovarian malignancy risk stratification of the adnexal mass using a multivariate index assay. *Gynecol Oncol* 128: 252–259.

[2] Ueland FR, et al. 2011. Effectiveness of a multivariate index assay in the preoperative assessment of ovarian tumors. *Obstet Gynecol* 117:1289-1297.

[3] Bristow, RE et al. 2013. Adherence to treatment guidelines for ovarian cancer as a measure of quality care. *Obstet Gynecol* 121:1226-1234.

[4] Longoria TC, et al. 2013. Clinical performance of a multivariate index assay for detecting early-stage ovarian cancer. *Am J Obstet Gynecol* Jan;210(1):78.e1-9.

[5] Bristow, RE, et al. 2013. Impact of a multivariate index assay on referral patterns for surgical management of an adnexal mass. *Am J Obstet Gynecol* Dec;209(6):581.e1-8.

On March 20, 2014, we announced that a new study of OVA1® clinical performance, titled "The Effect of Ovarian Imaging on the Clinical Interpretation of a Multivariate Index Assay," has been released as an online advance publication of *The American Journal of Obstetrics & Gynecology*. The study examines the relationship between two commonly used imaging methods – ultrasound (US) and computed tomography (CT) – and the OVA1 test result, in assessing the risk of ovarian cancer among patients planning surgery for an ovarian mass. OVA1 is an FDA-cleared blood test that measures the levels of five proteins and then uses a proprietary algorithm and software called OvaCalc® to calculate a single risk score.

"This new study advances our understanding of how OVA1 and imaging work together in the pre-surgical assessment of ovarian cancer risk," said study co-author Fred Ueland, M.D., associate professor of gynecologic oncology at the University of Kentucky's Markey Cancer Center. "This is important for two reasons. First, adding OVA1 reduced the number of ovarian cancers missed with imaging alone, by 85 to 90 percent. Recent publications have reinforced that the first surgery is an important opportunity to improve ovarian cancer survival by ensuring that cancers are detected earlier and that they are operated on by the most experienced specialists. Second, this study provides new evidence of how menopausal status, imaging and OVA1 score may interrelate."

Dr. Scott Goodrich of the University of Kentucky led the study in collaboration with colleagues Drs. Fred Ueland and Rachel Ware Miller. The authors compared the performance of each imaging method alone, to the performance of OVA1 alone (for risk stratification), as well as in combination with OVA1. In addition, the authors presented logistic regression models showing how menopausal status, high- or low-risk imaging and OVA1 score interact in the assessment of ovarian cancer risk. The researchers concluded that "serum biomarkers and imaging are a complementary set of clinical tools and that when the OVA1 score is further stratified by imaging risk and menopausal status, there is a better understanding of the clinical risk of ovarian malignancy."

In April 2013, we announced the signing of a cooperative research and development agreement (CRADA) with the U.S. Army Medical Research and Materiel Command (“USAMRMC”). The agreement marks the launch of a project titled, "Cost Reduction Using OVA1 in a Treatment Algorithm for Adnexal Masses in Women," and follows the January 2012 decision by the U.S. Department of Defense to add OVA1 to its testing portfolio. The two-phase study aims to investigate the cost-benefit profile of OVA1 testing as a presurgical standard of care in women with pelvic masses, and assess the clinical utility of OVA1 in a managed care setting.

Phase 1 will retrospectively assess medical outcomes and total cost of care to establish historical benchmarks and estimate potential benefits of OVA1 utilization. Phase 2 will involve a multi-center prospective clinical study within the Western Regional Command to assess OVA1 as a standard of care across a large sector of the U.S. Armed Forces. We believe the project will further support our reimbursement efforts, by gathering data on the real-world impact of OVA1 on medical and health economic outcomes compared with accurate and holistic benchmarks.

In June 2013, the Society for Gynecologic Oncology (“SGO”) issued a new position statement on OVA1. This second SGO statement on OVA1 since its FDA clearance in 2009 represents another significant step toward acceptance of OVA1 as the standard of care for pre-surgically evaluating the risk of ovarian cancer in women with adnexal masses. The statement, entitled “Multiplex Serum Testing for Women with Pelvic Mass”, reads:



“Blood levels of five proteins in women with a known ovarian mass have been reported to change when ovarian cancer is present. Tests measuring these proteins may be useful in identifying women who should be referred to a gynecologic oncologist. Recent data have suggested that such tests, along with physician clinical assessment, may improve detection rates of malignancies among women with pelvic masses planning surgery. [1],[2] Results from such tests should not be interpreted independently, nor be used in place of a physician’s clinical assessment. Physicians are strongly encouraged to reference the American Congress of Obstetricians and Gynecologists’ 2011 Committee Opinion “The Role of the Obstetrician-Gynecologist in the Early Detection of Epithelial Ovarian Cancer” to determine an appropriate care plan for their patients. It is important to note that no such test has been evaluated for use as, nor cleared by, the FDA as a screening tool for ovarian cancer. SGO does not formally endorse or promote any specific products or brands.”

The new statement does two things:

- Lists as references the publications of OVA1's two pivotal clinical studies, comprised of the original FDA validation study published in June 2011 and the OVA500 "intended use" study published in 2013. Together, this offers an extensive, peer-reviewed proof source for physicians and payers to assess OVA1's clinical performance and comparative medical benefits versus today's standard of care.
- Places OVA1 use in the context of current ACOG practice guidelines, where CA125 has been used off-label for many years to predict malignancy before surgery, although with inferior performance as compared to OVA 1.

In June 2013 our collaborators from Johns Hopkins Biomarker Discovery and Translation Center presented data from “proof of concept” work to identify markers with high clinical specificity that may complement OVA1. These results were presented in a poster at the annual meeting of the American Society for Clinical Oncology (“ASCO”) by Dr. Zhen Zhang and co-workers. The study identified a set of 5 biomarkers (CA125, prealbumin, IGFBP2, IL6, and FSH) which optimally reduced false positives among a targeted set of OVA1-positive benign patients. This panel was subsequently tested in a 50/50 cross-validation strategy against a sampling of OVA500 patients (N=384), to evaluate specificity and other diagnostic parameters. At a fixed sensitivity of 90%, the median specificity of models using the new panel in testing was 80.6%. The mean and median absolute improvements over that of OVA1 were 18.6% and 20.3%, respectively. The new panel demonstrated the possibility to improve specificity over that of the existing OVA1 algorithm, while maintaining a high sensitivity in pre-surgical assessment of malignancy. We expect the work to be submitted for publication in 2014.

We in the process of identifying intended use(s) and establishing a regulatory or commercial pathway for a potential next-generation OVA product utilizing this or another new panel. Any actual product development will likely differ significantly depending on a number of technical and commercial factors.

Current and former academic and research institutions that we have or have had collaborations with include the Johns Hopkins University School of Medicine (“JHU”); the University of Texas M.D. Anderson Cancer Center (“M.D. Anderson”); University College London (“UCL”); the University of Texas Medical Branch (“UTMB”); the Katholieke Universiteit Leuven; Clinic of Gynecology and Clinic of Oncology, Rigshospitalet, Copenhagen University Hospital (“Rigshospitalet”); the Ohio State University Office of Sponsored Programs (“OSU”); Stanford University (“Stanford”); the University of Kentucky (“UK”) and the University of California at Irvine.

## **The Diagnostic Market**

The economics of healthcare demand effective and efficient allocation of resources which can be accomplished through disease prevention, early detection of disease leading to early intervention, and diagnostic tools that can triage patients to more appropriate therapy and intervention. According to the May 2009 In Vitro Diagnostics Market Analysis 2009-2024 report, the worldwide market for in vitro diagnostics (“IVDs”) in 2008 was approximately \$40.0 billion. Visiongain, an independent business information provider, predicts that the worldwide market for IVDs will generate nearly \$60.0 billion of sales in 2014. We have chosen to concentrate our business focus in the areas of oncology and women’s health where we have established strong key opinion leader, provider and patient relationships. Demographic trends suggest that, as the population ages, the burden from these gynecologic cancers will increase and the demand for quality diagnostic, prognostic and predictive tests will escalate. In addition, the areas of oncology and women’s health generally lack quality diagnostic tests and, therefore, we believe patient outcomes can be significantly improved by the development of novel diagnostic tests.

Our focus on translational biomarkers enables us to address the market for novel diagnostic tests that simultaneously measure multiple biomarkers. A biomarker is a biomolecule or variant biomolecule that is present at measurably greater or lesser concentrations in a disease state versus a normal condition. Conventional protein tests measure a single protein biomarker whereas most diseases are complex. We believe that efforts to diagnose cancer and other complex diseases have failed in large part because the disease is heterogeneous at the causative level (i.e., most diseases can be traced to multiple potential etiologies) and at the human response level (i.e., each individual afflicted with a given disease can respond to that ailment in a specific manner).

Consequently, measuring a single biomarker when multiple biomarkers may be altered in a complex disease is unlikely to provide meaningful information about the disease state. We believe that our approach of monitoring and combining multiple protein

biomarkers using a variety of analytical techniques will allow us to create diagnostic tests with sufficient sensitivity and specificity about the disease state to aid the physician considering treatment options for patients with complex diseases. Such assays are commonly referred to as IVDMA (also known as In Vitro Diagnostic Multivariate Index Assays), and often utilize advanced algorithms based on logistic regression, pattern recognition and the like. Often, IVDMA algorithms are non-intuitive, and therefore require rigorous clinical validation and error modeling. Vermillion and its collaborators are expert in these areas, and in the case of OVA1, presented both the clinical validation and error modeling in order to gain 510(k) clearance of OVA1, as an IVD software device.

### ***Ovarian Cancer***

**Background.** Commonly known as the “silent killer,” ovarian cancer leads to over 14,000 deaths each year in the United States. The American Cancer Society (“ACS”) estimates that almost 22,000 new ovarian cancer cases will be diagnosed in 2014, with the majority of the patients in the late stages of the disease in which the cancer has spread beyond the ovary. Unfortunately, ovarian cancer patients in the late stages of the disease have a poor prognosis, which leads to the high mortality rates. According to the ACS, when ovarian cancer is diagnosed at its earliest stage, the patient has a 5-year survival rate of 93%. Ovarian cancer patients have up to a 90% cure rate following surgery and/or chemotherapy if detected in stage 1. However, only 19% of ovarian cancer patients are diagnosed before the tumor has spread outside the ovary. For ovarian cancer patients diagnosed in the late-stages of the disease, the 5-year survival rate falls to as low as 18%.

While the diagnosis of ovarian cancer in its earliest stages greatly increases the likelihood of survival from the disease, another factor that predicts survival from ovarian cancer is the specialized training of the surgeon who operates on the ovarian cancer patient. Numerous studies have demonstrated that treatment of malignant ovarian tumors by specialists such as gynecologic oncologists or at specialist medical centers improves outcomes for women with these tumors. Published guidelines from the SGO and the ACOG recommend referral of women with malignant ovarian tumors to specialists. Unfortunately, today, only about one third of women with these types of tumors are operated on by specialists, in part because of inadequate tests and procedures that can identify such malignancies with high sensitivity. Accordingly, an unmet clinical need is a diagnostic test that can provide adequate predictive value to stratify patients with a pelvic mass into those with a high risk of invasive ovarian cancer versus those with a low risk of ovarian cancer, which is essential for improving overall survival in patients with ovarian cancer.

Although adnexal masses are relatively common, malignant tumors are less so. Screening studies have indicated that the prevalence of adnexal masses in postmenopausal women can be as high as 5 percent. Adnexal masses are thought to be even more common in premenopausal women, but there are more non-persistent, physiologic ovarian masses in this demographic group. In a Prostate Lung Colorectal and Ovarian Cancer study, 28,519 post-menopausal women were screened for ovarian malignancy and 4.7% received an abnormal ultrasound. Using the US census of 53 million women over the age of 50, this suggests there are more than 2.4 million adnexal masses in this segment alone. Although many of these do not present to the physician or are not concerning enough to warrant surgery, those that do require evaluation for the likelihood for malignancy could potentially benefit from the use of OVA1.

The ACOG and the SGO have issued guidelines to help physicians evaluate adnexal masses for malignancy. These guidelines take into account menopausal status, CA125 levels, and physical and imaging findings. However, these guidelines have notable shortcomings because of their reliance on tools with certain weaknesses. Most notably, the CA125 blood test, which is cleared by the FDA only for monitoring for recurrence of ovarian cancer, is negative in up to 50% of early stage ovarian cancer cases. Moreover, CA125 can be elevated in numerous conditions and diseases other than ovarian cancer, including benign ovarian masses and endometriosis. These shortcomings limit the CA125 blood test’s utility in distinguishing benign from malignant ovarian tumors or for use in detection of early stage ovarian cancer. Transvaginal ultrasound is another diagnostic modality used with patients with ovarian masses. Attempts at defining specific morphological criteria that can aid in a benign versus malignant diagnosis have led to the morphology index and the risk of malignancy index, with reports of 40-70% predictive value. However, ultrasound interpretation can be variable and dependent on the experience of the operator. Accordingly, the ACOG and SGO guidelines perform only modestly in identifying early stage ovarian cancer and malignancy in pre-menopausal women. Efforts to improve detection of cancer by lowering the cutoff for CA125 (the “Modified ACOG/SGO Guidelines”) provide only a modest benefit, since CA125 is absent in about 20% of epithelial ovarian cancer cases and is poorly detected in early stage ovarian cancer.

### **Commercialization**

Under the terms of the now terminated Strategic Alliance Agreement, Quest Diagnostics had the right to commercialize up to three diagnostic tests from our product pipeline. Quest Diagnostics selected two tests, a peripheral arterial disease blood test and OVA1. We believe Quest Diagnostics no longer has the right to select the final diagnostic test. Pursuant to the Strategic Alliance Agreement, Quest Diagnostics had the exclusive commercialization rights to commercialize OVA1 in the clinical reference laboratory marketplace in each exclusive territory through September 2014 and the right to extend the exclusivity period for one additional year. These exclusive territories consisted of the United States, India, Mexico, and the United Kingdom. Quest Diagnostics had the non-exclusive right to commercialize OVA1 on a worldwide basis outside of these exclusive territories. We terminated the agreement with Quest Diagnostics on August 23, 2013 but the effectiveness of such termination has been disputed by Quest Diagnostics. As part of the termination, we allowed Quest Diagnostics to continue to make OVA1 available as long as (i) Quest continues to make the payments and provide the reports to Vermillion in connection with such activities as would be required under the Strategic Alliance

Agreement but for its termination and (ii) Vermillion determines that Vermillion and Quest are negotiating in good faith towards alternative terms under which Quest and Vermillion can work together to make this important product available to healthcare providers and patients.

Now that the Strategic Alliance Agreement has been terminated, we plan to make OVA1 available through channels in addition to Quest Diagnostics.

## **Customers**

In the United States, the IVD market can be segmented into three major groups: clinical reference laboratories, the largest of which are Quest Diagnostics and Laboratory Corporation of America; hospital laboratories; and physician offices. In 2013, all of our product revenue was generated through Quest Diagnostics. Outside the United States, laboratories may become customers, either directly with us or via distribution relationships established between us and authorized distributors. In 2014, we plan to begin to actively seek out distributors/partners outside the United States for an anticipated 2015 launch.

## **Research and Development**

Our research and development efforts center on the discovery and validation of biomarkers and combinations of biomarkers that can be developed into diagnostic assays. We do this predominantly through collaborations we have established with academic institutions such as JHU and M.D. Anderson as well as through contract research organizations (“CRO’s”) such as PrecisionMed. In addition, we actively seek collaborations and initiate dialog with clinical academics, in order to generate publications, intellectual property or test development in broader areas of gynecologic oncology.

## **Scientific Background**

Genes are the hereditary coding system of living organisms. Genes encode proteins that are responsible for cellular functions. The study of genes and their functions has led to the discovery of new targets for drug development. Industry sources estimate that, within the human genome, there are approximately 30,000 genes. Although the primary structure of a protein is determined by a gene, the active structure of a protein is frequently altered by interactions with additional genes or proteins. These subsequent modifications result in hundreds of thousands of different proteins. In addition, proteins may interact with one another to form complex structures that are ultimately responsible for cellular functions.

Genomics allows researchers to establish the relationship between gene activity and disease. However, many diseases are manifested not at the genetic level, but at the protein level. The complete structure of modified proteins cannot be determined by reference to the encoding gene alone. Thus, while genomics provides some information about diseases, it does not provide a full understanding of disease processes. We are focused on converting recent advances in proteomics into clinically useful diagnostic tests.

### ***Relationship Between Proteins and Diseases***

The entire genetic content of any organism, known as its genome, is encoded in strands of deoxyribonucleic acid (“DNA”). Cells perform their normal biological functions through the genetic instructions encoded in their DNA, which results in the production of proteins. The process of producing proteins from DNA is known as gene expression or protein expression. Differences in living organisms result from variability in their genomes, which can affect the types of genes expressed and the levels of gene expression. Each cell of an organism expresses only approximately 10% to 20% of the genome. The type of cell determines which genes are expressed and the amount of a particular protein produced. For example, liver cells produce different proteins from those produced by cells found in the heart, lungs, skin, etc. Proteins play a crucial role in virtually all biological processes, including transportation and storage of energy, immune protection, generation and transmission of nerve impulses and control of growth. Diseases may be caused by a mutation of a gene that alters a protein directly or indirectly, or alters the level of protein expression. These alterations interrupt the normal balance of proteins and create disease symptoms. A protein biomarker is a protein or protein variant that is present in a greater or lesser amount in a disease state versus a normal condition. By studying changes in protein biomarkers, researchers may identify diseases prior to the appearance of physical symptoms. Historically, researchers discovered protein biomarkers as a byproduct of basic biological disease research, which resulted in the validation by researchers of approximately 200 protein biomarkers that are being used in commercially available clinical diagnostic products.

### ***Limitations of Existing Diagnostic Approaches***

The IVD industry manufactures and distributes products that are used to detect thousands of individual components present in human derived specimens. However, the vast majority of these assays are used specifically to identify single protein biomarkers. The development of new diagnostic products has been limited by the complexity of disease states, which may be caused or characterized by several or many proteins or post-translationally modified protein variants. Diagnostic assays that are limited to the detection of a single protein often have limitations in clinical specificity (true negatives) and sensitivity (true positives) due to the complex nature of many diseases and the inherent biological diversity among populations of people. Diagnostic products that are limited to the detection of a single protein may lack the ability to detect more complex diseases, and thus produce results that are unacceptable for practical use. The heterogeneity of disease and of the human response to disease often underlies the shortcoming of single biomarkers to diagnose and predict many diseases accurately.

### ***Our Solution***

Our studies in ovarian cancer have given us a better understanding of both the disease pathophysiology and the host response. By using multiple biomarkers rather than a single biomarker, we are able to better characterize the disease and host response heterogeneity. In addition, by examining specific biomarkers and their variants, (e.g. post-translational modifications), we believe we can improve sensitivity and specificity over traditional diagnostic biomarkers because these biomarker combinations reflect both the pathophysiology and host response. This is accomplished using novel biomarker panels coupled with multivariate pattern recognition software to identify IVDMA algorithms which can be commercialized as disease-specific assays.

We are applying translational biomarker research, algorithm development tools, and statistical error modeling methods to discover robust associations between biomarker panels and clinically relevant disease endpoints. We plan to develop new IVDMA algorithms and molecular diagnostic tests based on known and newly identified protein markers to help physicians better predict and manage disease and treatment, and thereby improve patient outcomes and overall health economic resource utilization. Examples of diagnostic applications include, but are not limited to: asymptomatic population screening, early detection, triage to specialists, aid in diagnosis, prognosis or disease sub-classification, prediction or selection of therapy, monitoring of therapeutic response or residual disease, monitoring for recurrence or identification of appropriate fallback therapy or clinical trial eligibility.

We therefore anticipate ongoing and new partnerships with leading scientific and clinical institutions who have active proteomic or genomic programs in the area of gynecologic cancers, or with relevant clinical trial interests, with the goal of expanding our product portfolio with relevant solutions to unmet medical needs in women's health.

### ***Addressing the Heterogeneity of Disease***

Our approach is to create a diagnostics paradigm that is based on risk estimation, multiple-biomarker testing and information integration. This is based on the belief that cancer and other gynecologic diseases are heterogeneous and, therefore, that relying on a single disease biomarker to provide a simple "yes-no" answer is likely to fail. We believe that efforts to diagnose cancer and other complex diseases have failed in large part because the disease is heterogeneous at the causative level, meaning that most diseases can be traced to multiple potential etiologies, and at the individual response level, meaning that each individual afflicted with a given disease can respond to that ailment in a specific manner. Consequently, diagnosis, disease monitoring and treatment decisions can be challenging. This heterogeneity of disease and difference in human response to disease and/or treatment underlies the shortcomings of single biomarkers to predict and identify many diseases. A better understanding of heterogeneity of disease and human response is necessary for improved diagnosis and treatment of many diseases.

### ***Validation of Biomarkers Through Proper Study Design***

Analysis of peer-reviewed publications reveals almost daily reports of novel biomarkers or biomarker combinations associated with specific diseases. Few of these are used clinically. As with drug discovery, preliminary research results fail to canvass sufficient variation in study populations or laboratory practices and, therefore, the vast majority of candidate biomarkers fail to be substantiated in subsequent studies. Recognizing that validation is the point at which most biomarkers fail, our strategy is to reduce the attrition rate between discovery and clinical implementation by building validation into the discovery process. Biomarkers fail to validate for a number of reasons, which can be broadly classified into pre-analytical and analytical factors. Pre-analytical factors include study design that does not mimic actual clinical practice, inclusion of the wrong types of control individuals and demographic bias (usually seen in studies in which samples are collected from a single institution). Analytical factors include poor control over laboratory protocols, inadequate randomization of study samples and instrumentation biases (for example, higher signal early in the experimental run compared to later in the experimental run). Finally, the manner in which the data are analyzed can have a profound impact on the reliability of the statistical conclusions.

When designing clinical studies, we begin with the clinical question, since this drives the downstream clinical utility of the biomarkers. With the starting point of building validation into the discovery process, we design our studies to include the appropriate cases and control groups. We further incorporate an initial validation component within the discovery component. We place an emphasis on multi-institutional studies, inclusion of clinically relevant controls, using qualified and trained operators to run assays and collect data. For example, in an August 2004 cancer research paper, which describes the first three biomarkers in the ovarian cancer panel, there were more than 600 specimen samples taken from five hospitals that were analyzed. In the development of OVA1, we analyzed more than 2,500 samples from five additional medical centers prior to initiating the prospective ovarian clinical study for submission to the FDA. In analyzing the complex proteomics data, we take a skeptical view of statistical methodologies, choosing to use a variety of approaches and looking for concordance between approaches, taking the view that biomarkers deemed significant by multiple statistical algorithms are more likely to reflect biological conditions than mathematical artifacts.

Through biomarker discovery efforts conducted predominantly from 2000 through 2007, we have amassed a portfolio of candidate biomarkers identified in retrospective sample sets. Our research and development efforts are now mostly focused on validating these biomarkers in prospective studies. During the period from 2007 through 2008, we conducted a multi-center prospective clinical trial to determine the clinical performance of OVA1, which was submitted to the FDA on June 19, 2008, and cleared by the FDA on September 11, 2009. We have additional markers for ovarian cancer that we plan to evaluate and validate. These activities are outlined below.

### ***R&D-Sponsored Initiatives to Support Market Development of OVA1***

We have two ongoing R&D-sponsored initiatives to support OVA1 market development and adoption as an improved standard of care in the pre-surgical triage and evaluation of adnexal masses. The first is a major new clinical study of OVA1, focused on its performance in the predominantly pre-menopausal non-gynecologic oncologist patient population. The study, called OVA500, has resulted in first publication in the February 2013 edition of *Gynecologic Oncology*, a peer-reviewed journal with the highest impact factor rating of any journal worldwide focused on gynecologic oncology. OVA500 was conducted to confirm and extend the landmark findings of Ueland and Miller, published in *Obstetrics & Gynecology* in the June 2011 edition, with a completely new, prospectively enrolled patient cohort. The findings of OVA500, reported in *Gynecologic Oncology*, are summarized in a preceding section of this annual report on Form 10-K. Three additional follow-on manuscripts were published in peer-reviewed publications in 2013 and early 2014. The second R&D initiative supporting OVA1 is a series of Vermillion-assisted, independent clinical research studies of OVA1. Through this program, Vermillion offers limited support for well-qualified principal investigators in the form of materials, testing services, and scientific consulting. As a result, we are currently in discussion with a number of potential investigators to support new research publications on OVA1's clinical utility, cost-effectiveness, and potential line extensions. While we are not always at liberty to announce such collaborations, at least one study has begun enrolling patients under a clinical institution review board approval.

***New ovarian cancer indications.*** While our focus on supporting the commercialization of OVA1 is our primary priority, we also may extend our ovarian cancer franchise beyond OVA1, enabled by several factors: 1) We have extended and expanded our research and license agreement with JHU to include advancing our platform migration and next-generation diagnostic test; 2) Vermillion enjoys a large and growing portfolio of intellectual property, generated through collaborative research and licensing; 3) The acquisition of Correlologic assets in 2011 brought with it highly curated clinical samples, intellectual property and promising biomarker leads. These have the potential to further amplify our ovarian cancer diagnostic efforts in the future; 4) Clinical collaborations such as the independent clinical research program mentioned above typically include licensing options when valuable intellectual property or product opportunities result; and 5) Vermillion's success in translating biomarkers into FDA-cleared, widely available commercial products creates increasing interest in licensing, co-marketing and/or acquisition of intellectual property and products from academics and technology providers. We believe we are well-positioned in gynecologic oncology and women's health markets to launch new products developed, licensed, co-marketed or acquired by any of these routes.

Our research and development expenses were \$2,595,000 and \$2,216,000 for the years ended December 31, 2013 and 2012, respectively. The increase from the prior year was due primarily to an increase in payments to JHU support our platform migration and next-generation diagnostic test programs as well as expanded personnel and contractor costs to support those programs.

### **Commercial Operations**

We have a commercial infrastructure, including sales and marketing and reimbursement expertise. Our sales representatives work to identify opportunities for communicating the benefits of OVA1 to general gynecologists and gynecologic oncologists alike. In September 2010, we announced that OVA1 was CE marked, a requirement for marketing the test in the European Union. As part of this, OVA1 satisfied all certification requirements to complete its declaration of conformity. We also plan to penetrate markets outside of the United States once we have migrated OVA1 onto a testing platform available globally. In 2014, we plan to begin to actively seek out distributors/partners outside the United States so that we may begin marketing OVA1 outside the United States in 2015.

Approximately 17,004 OVA1 tests were performed in 2013, an increase of 3% over 2012. Additionally, we estimate over 30% of U.S. gynecologic oncologists are supportive or advocating the use of OVA1 for the triage of women with adnexal masses. This broad number of specialists supporting the test indicates an understanding of the clinical need and the ability of OVA1 to serve a significant market to assist physicians in triaging women who need a specialist for surgery from those who can be treated by the primary physician. As of December 2013, over 6,700 accounts had ordered the test, an increase of 26% over 2012.

We continue to develop the market through experienced Territory Development Managers. As market awareness continues to build, these managers are focused on efforts that will have a positive impact on regional payers and create positive coverage decisions. They are working with local key opinion leaders and meeting with medical directors to discuss the clinical need, our technology assessment package and increasing experience and cases studies showing the positive outcomes utilizing OVA1.

There are still obstacles to overcome and significant milestones ahead. First, although the test volume and the number of doctors continue to increase, the average gynecologist will only see about 2 to 4 patients per month who may need our test and additional effort will be required to establish a consistent ordering pattern. Second, insurance coverage and patient bills are a concern to the physician and can disrupt the ordering pattern of a generalist who is supportive of OVA1.

### **Reimbursement**

In the United States, revenue for diagnostic tests comes from several sources, including third-party payers such as insurance companies, government healthcare programs, such as Medicare and Medicaid and patients. Novitas Solutions (formerly Highmark Medicare Services), the Medicare contractor that has jurisdiction over claims submitted by Quest Diagnostics for OVA1, covers OVA1. This local coverage determination from Novitas Solutions essentially provides national coverage for patients enrolled in Medicare as well as Medicare Advantage health plans.

The American Medical Association (“AMA”) CPT Panel approved an application for a Category I CPT code for OVA1 which became effective January 1, 2013. In December 2013, the CMS made its final determination and authorized Medicare contractors to set prices for MAAA test CPT codes when they determine it is payable. CMS also validated that an algorithm has unique value by specifying that gap-fill not cross-walk should be used by contractors to price MAAA tests. We expect OVA1 to be priced using the gap-fill method; and we will be engaged in that process in 2014 for pricing effective January 1, 2015. This decision also sets a precedent for recognizing the value of biomarker developed tests and recognizing tests on the value they bring to clinical decision making and healthcare efficiencies.

As of January 1, 2014, we have coverage from BlueCross BlueShield plans totaling approximately 8.0 million lives. In April 2013, the BCBS Technical Evaluation Center (“TEC”) classified OVA1 as experimental/investigational. Consequently, OVA1 did not meet the TEC’s criteria for coverage.

We believe the TEC assessment classifying OVA1 as experimental/investigational is flawed and rebuttable on multiple points. Most notably, the TEC assessment was conducted during 2012 and did not consider the OVA500 study published in February 2013, the updated SGO statement on the use of OVA1 issued in May 2013 or the June 2013 publication of a comprehensive study on widespread flaws in the care of women with ovarian cancer that can be addressed in large part with the use of diagnostics such as OVA1.

We have undertaken an effort to address the TEC assessment with BCBS plans that still maintain favorable coverage decisions and those that have reversed coverage decisions. However, there can be no guarantee that we will be successful in our appeals of coverage decisions or our rescission request, or that if we are successful, it will have a positive impact on the level of reimbursement or our revenue.

In total, including Medicare and other private payers, approximately 55.9 million patients have access and coverage for OVA1. The Company plans to continue to pursue coverage from additional payers.

New and innovative diagnostic tests often face reimbursement challenges that can affect adoption; the three key focus areas are coding, claims, and coverage or payer adoption. In conjunction with Quest Diagnostics, we are consistently addressing these three areas.

#### Coding

- OVA1 is a new class of diagnostics and therefore no specific code existed at the time of its launch. This is often the case with new diagnostic tests, and companies will bill using a miscellaneous code, which is the path we and Quest Diagnostics implemented. After establishing OVA1 in the market, creating demand and demonstrating the utility of the test, we applied for and received a CPT code specific for OVA1 which was effective beginning January 1, 2013. Achieving the unique Category I CPT code # 81503 was a critical step in our commercialization process.
- Medicare currently reimburses OVA1 at \$516 per test and our test list price is \$650.

#### Claims Process

- In the early launch of a product, claims can be rejected due to lack of medical necessity, lack of payer understanding, or even billing process errors. To address these items, we are engaging with physicians’ offices to assist in the appeals process to the extent we are able to obtain appeals data directly or from Quest Diagnostics. We are using these claims to educate payers and create awareness about the medical necessity of our test.

#### Payer Coverage

- We have continued to focus ongoing efforts toward obtaining national coverage decisions. However, these decisions typically have a much longer lead time due to industry established processes and time frames. In most cases, these entail clinical and technical reviews that are performed on an annual basis.
- We have assembled a Technology Assessment Package to provide a nucleus of materials tailored to each National Plan.

- We have launched a program to aid local key opinion leaders to work with health plans to support coverage for OVA1. These strategic actions are necessary steps to convert those plans representing numerous regional payers and late adopters.

## **Competition**

The diagnostics industry in which we operate is competitive and evolving. There is intense competition among healthcare, biotechnology and diagnostics companies attempting to discover candidates for potential new diagnostic products. These companies may:

- develop new diagnostic products in advance of us or our collaborators;
- develop diagnostic products that are more effective or cost-effective than those developed by us or our collaborators;
- obtain regulatory clearance or approval of their diagnostic products more rapidly than us or our collaborators; or
- obtain patent protection or other intellectual property rights that would limit our or our collaborators' ability to develop and commercialize, or a customers' ability to use our or our collaborators' diagnostic products.

We compete with companies in the United States and abroad that are engaged in the development and commercialization of novel biomarkers that may form the basis of novel diagnostic tests. These companies may develop products that are competitive with and/or perform the same or similar functions as the products offered by us or our collaborators, such as biomarker specific reagents or diagnostic test kits. Also, clinical laboratories may offer testing services that are competitive with the products sold by us or our collaborators. For example, a clinical laboratory can either use reagents purchased from manufacturers other than us or use its own internally developed reagents to make diagnostic tests. If clinical laboratories make tests in this manner for a particular disease, they could offer testing services for that disease as an alternative to products sold by us used to test for the same disease. The testing services offered by clinical laboratories may be easier to develop and market than test kits developed by us or our collaborators because the testing services are not subject to the same clinical validation requirements that are applicable to FDA-cleared or approved diagnostic test kits.

In September 2011, Fujirebio Diagnostics received FDA clearance for Risk of Ovarian Malignancy Algorithm. This test combines two tumor markers and menopausal status into a numerical score using a publicly available algorithm. This test has the same intended use and precautions as OVA1. The Risk of Ovarian Malignancy Algorithm is currently marketed as having utility limited to epithelial ovarian cancers, which accounts for 80% of ovarian malignancies. Based upon the results of a 2013 study, we believe that OVA1 has superior performance when compared to the Fujirebio Diagnostics test.

## **Intellectual Property Protection**

Our intellectual property includes a portfolio of owned, co-owned or licensed patents and patent applications. As of December 31, 2013, our clinical diagnostics patent portfolio included 27 issued United States patents, 17 pending United States patent applications, and numerous pending patent applications and issued patents outside the United States. These patents and patent applications fall into 34 patent families and are directed to several areas of technology. Some, such as ovarian and breast cancer, fall into our corporate focus on gynecologic oncology and women's health. These may be useful either in the development of patent-protected products or to create intellectual property barriers to competing companies. Others, such as PAD, Alzheimer's or other diagnostic technologies are not core assets. However, they may in some cases present out-licensing or royalty opportunities. The clinical diagnostics market includes laboratories engaged in the research and development and/or manufacture of diagnostic tests using biomarkers, commercial clinical laboratories, hospitals and medical clinics that perform diagnostic tests.

In October 2013, we amended our existing research collaboration agreement with the JHU, and we agreed to pay approximately \$1,600,000 through June 2015 for assistance with (1) the migration of the existing OVA1 test to a new platform and (2) the development, submission and launch of a next-generation ovarian cancer diagnostic. Collaboration costs under the JHU collaboration were \$658,000 and \$251,000 for the years ended December 31, 2013 and 2012, respectively. In addition, under the terms of the amended research collaboration agreement, we are required to pay the greater of 4% royalties on net sales of diagnostic tests using the assigned patents or annual minimum royalties of \$57,500. Other institutions and companies from which we hold options to license intellectual property related to biomarkers or are a co-inventor on applications include UCL, M.D. Anderson, UK, OSU, McGill University (Canada), Eastern Virginia Medical School, Aaron Diamond AIDS Research Center, UTMB, Goteborg University (Sweden), University of Kuopio (Finland), The Katholieke Universiteit Leuven (Belgium) and Rigshospitalet.

## **Manufacturing**

We are the manufacturer of OVA1. Components of OVA1 include purchased reagents for each of the component assays as well as the OvaCalc® software. Because we do not directly manufacture the component assays, we are required to maintain supply agreements with manufacturers of each of the assays. As part of our Quality Systems, reagent lots for these assays are tested to ensure they meet specifications required for inclusion in OVA1. Only reagent lots determined by us as having met these specifications are permitted for use in OVA1.

## **Environmental Matters**

### ***Medical Waste***

We have been subject to licensing and regulation under federal, state and local laws relating to the handling and disposal of medical specimens and hazardous waste as well as to the safety and health of laboratory employees. Our laboratories were operated in material compliance with applicable federal and state laws and regulations relating to disposal of all laboratory specimens. We utilized outside vendors for disposal of specimens. We cannot eliminate the risk of accidental contamination or discharge and any resultant injury from these materials. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of these materials. We could be subject to fines, penalties and damages claims in the event of an improper or unauthorized release of, or exposure of individuals to, hazardous materials. In addition, claimants may sue us for injury or contamination that results from our use, or the use by third parties, of these materials, and our liability may exceed our total assets. Compliance with environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development or production efforts.

### ***Occupational Safety***

In addition to its comprehensive regulation of safety in the workplace, the Federal Occupational Safety and Health Administration has established extensive requirements relating to workplace safety for healthcare employers whose workers may be exposed to blood-borne pathogens such as HIV and the hepatitis virus. These regulations, among other things, require work practice controls, protective clothing and equipment, training, medical follow-up, vaccinations and other measures designed to minimize exposure to chemicals and transmission of the blood-borne and airborne pathogens. Although we believe that we have complied in all material respects with such federal, state and local laws, failure to comply could subject us to denial of the right to conduct business, fines, criminal penalties and other enforcement actions.

### ***Specimen Transportation***

Regulations of the Department of Transportation, the International Air Transportation Agency, the Public Health Service and the Postal Service apply to the surface and air transportation of clinical laboratory specimens. Although we believe that we have complied in all material respects with such federal, state and local laws, failure to comply could subject us to denial of the right to conduct business, fines, criminal penalties and other enforcement actions.

## **Government Regulation**

**General.** Our activities related to diagnostic products are, or have the potential to be, subject to regulatory oversight by the FDA under provisions of the Federal Food, Drug and Cosmetic Act and regulations thereunder, including regulations governing the development, marketing, labeling, promotion, manufacturing and export of our products. The Food, Drug and Cosmetic Act requires that medical devices introduced to the United States market, unless exempted by regulation, be the subject of either a pre-market notification clearance, known as a 510(k) clearance or 510(k) de novo clearance, or a PMA. OVA1 was cleared by the FDA in September 2009 under the 510(k) de novo guidelines. OVA1 was the first FDA-cleared blood test for the pre-operative assessment of ovarian masses. We are in the process of establishing a regulatory pathway for our next-generation ovarian cancer test. Clinical studies to support either a 510(k) submission or a PMA application would need to be conducted in accordance with FDA requirements. If the FDA indicates that a PMA is required for any of our potential future clinical products, the application will require extensive clinical studies, manufacturing information and likely review by a panel of experts outside the FDA. Additionally, the FDA will generally conduct a pre-approval inspection for PMA devices.

Even in the case of devices like analyte specific reagents (“ASRs”), which may be exempt from 510(k) clearance or PMA approval requirements, the FDA may impose restrictions on marketing. Our potential future ASR products may be sold only to clinical laboratories certified under the CLIA to perform high complexity testing. In addition to requiring approval or clearance for new products, the FDA may require approval or clearance prior to marketing products that are modifications of existing products or the intended uses of these products. Additionally, the FDA will generally conduct a pre-approval inspection for PMA devices. Our suppliers’ manufacturing facilities are, and, if and when we begin commercializing and manufacturing our products ourselves, our manufacturing facilities will be, subject to periodic and unannounced inspections by the FDA and state agencies for compliance with Quality System Regulations (“QSRs”). Additionally, the FDA will generally conduct a pre-approval inspection for PMA devices. Although we believe that we and our suppliers will be able to operate in compliance with the FDA’s QSRs for ASRs, we cannot assure that we or our suppliers will be in or be able to maintain compliance in the future. We have never been subject to an FDA inspection and cannot assure that we will pass an inspection, if and when it occurs. If the FDA believes that we or our suppliers are not in compliance with applicable laws or regulations, the FDA can issue a Form 483 List of Observations or warning letter, detain or seize our products, issue a recall notice, enjoin future violations and assess civil and criminal penalties against us. In addition, approvals or clearances could be withdrawn under certain circumstances.

Any customers using our products for clinical use in the United States may be regulated under CLIA, which is intended to ensure the quality and reliability of clinical laboratories in the United States by mandating specific standards in the areas of personnel



qualifications, administration, participation in proficiency testing, patient test management, quality control, quality assurance and inspections. The regulations promulgated under CLIA establish three levels of diagnostic tests - namely, waived, moderately complex and highly complex - and the standards applicable to a clinical laboratory depend on the level of the tests it performs. Medical device laws and regulations are also in effect in many of the countries in which we may do business outside the United States. These range from comprehensive device approval requirements for some or all of our potential future medical device products, to requests for product data or certifications. The number and scope of these requirements are increasing. In addition, products which have not yet been cleared or approved for domestic commercial distribution may be subject to the FDA Export Reform and Enhancement Act of 1996 ("FDERA").

**FDA Regulation of Cleared Tests.** Once granted, a 510(k) clearance or PMA approval may place substantial restrictions on how our device is marketed or to whom it may be sold. All devices cleared by the FDA are subject to continuing regulation by the FDA and certain state agencies. As a medical device manufacturer, we are also required to register and list our products with the FDA. We are required to set forth and adhere to a Quality Policy and other regulations. In addition, we are required to comply with the FDA's QSRs, which require that our devices be manufactured and records be maintained in a prescribed manner with respect to manufacturing, testing and control activities. Additionally, we may be subject to inspection by federal and state regulatory agencies. Non-compliance with these standards can result in, among other things, fines, injunctions, civil penalties, recalls, and total or partial suspension of production. Further, we are required to comply with FDA requirements for labeling and promotion. For example, the FDA prohibits cleared or approved devices from being promoted for uncleared or unapproved uses. Labeling and promotional activities are subject to scrutiny by the FDA, which prohibits the marketing of medical devices for unapproved uses. Additionally, the FDA requires us to perform certain post-marketing studies to verify or validate the clinical performance of FDA-cleared tests, as is permitted by their statutory authority.

In addition, the medical device reporting regulation requires that we provide information to the FDA whenever evidence reasonably suggests that one of our devices may have caused or contributed to a death or serious injury, or where a malfunction has occurred that would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

**Foreign Government Regulation of Our Products.** We intend to obtain regulatory approval in other countries to market our tests. Each country maintains its own regulatory review process, tariff regulations, duties and tax requirements, product standards, and labeling requirements. In 2010, we retained the services of the Emergo Group and TUV SUD America Inc. to assist in our efforts to satisfy the regulatory requirements necessary for commercialization in Europe. In September 2010, OVA1 was CE marked, a requirement for marketing the test in the European Union.

## **Employees**

As of December 31, 2013, we had 26 full-time employees. We also engage independent contractors from time to time.

## **Code of Ethics for Executive Officers**

We have adopted a Code of Ethics for Executive Officers. We publicize the Code of Ethics for Executive Officers by posting the policy on our website, [www.vermillion.com](http://www.vermillion.com). We will disclose on our website any waivers of, or amendments to, our Code of Ethics.

## **Information About Us**

We file annual reports, quarterly reports, current reports, and proxy statements, and other information with the Securities and Exchange Commission (the "SEC"). You may read and copy any material we file with the SEC at the SEC's Public Reference Room located at the following address:

100 F Street, NE  
Washington, DC 20549

You may obtain information on the operation of the SEC's Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet website, [www.sec.gov](http://www.sec.gov), that contains reports, and proxy statements, and other information regarding issuers that file electronically with the SEC.

In addition, we make available free of charge under the Investors Relation section of our website, [www.vermillion.com](http://www.vermillion.com), the Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended ("Exchange Act") as soon as reasonably practicable after we have electronically filed such material with or furnished such material to the SEC. You may also obtain these documents free of charge by submitting a written request for a paper copy to the following address:

Investor Relations  
Vermillion, Inc.  
12117 Bee Caves Road, Building Three, Suite 100  
Austin, TX 78738

The information contained on our website is not incorporated by reference in this Annual Report on Form 10-K and should not be considered a part of this Annual Report on Form 10-K.

## **ITEM 1A. RISK FACTORS**

*You should carefully consider the following risk factors and uncertainties together with all of the other information contained in this Annual Report on Form 10-K, including our audited consolidated financial statements and the accompanying notes in Part II Item 8, "Financial Statements and Supplementary Data." The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also materially adversely affect our business, financial condition or results of operations.*

### **Risks Related to Our Business**

***If we are unable to increase the volume of OVA1 sales, our business, results of operations and financial condition will be adversely affected.***

We have experienced significant operating losses each year since our inception and we expect to incur a net loss for fiscal year 2014 and the foreseeable future. Our losses have resulted principally from costs incurred in research and development, sales and marketing, litigation, and general and administrative costs.

All of our revenues have historically been generated from sales of OVA1 tests performed by Quest Diagnostics. If we are unable to increase the volume of OVA1 sales, our consolidated results of operations and financial condition would be adversely affected.

***All of our revenue was derived from Quest Diagnostics during 2013, and there is no guarantee that we will be able to successfully market our test through additional channels in the future.***

All of our revenue during 2013 was derived through our now terminated strategic partnership with Quest Diagnostics and was based on the number of OVA1 tests performed by Quest Diagnostics and the reimbursement rate received by Quest Diagnostics for those tests. Quest Diagnostics has disputed the effectiveness of our termination. We plan to offer OVA1 through additional channels in the future. However, if we are not successful in adding additional sales channels or if we do not experience growing OVA1 test volumes or receive less reimbursement per test than expected, it could have a material adverse effect on our revenue, results of operations and cash flows.

***The consequences of terminating the Quest Diagnostics Strategic Alliance Agreement are uncertain and could materially adversely affect our business, financial condition and results of operations, particularly given that all of our product revenue has historically been generated as a result of tests performed by Quest Diagnostics.***

All of our product revenue in 2013 was generated as a result of OVA1 tests performed by Quest Diagnostics. In August 2013, we terminated the Strategic Alliance Agreement with Quest Diagnostics, and in connection with the termination, we allowed Quest Diagnostics to continue to make OVA1 available as long as (i) Quest Diagnostics continues to make the payments and provide the reports to Vermillion in connection with such activities as would be required under the Strategic Alliance Agreement but for its termination and (ii) Vermillion determines that Vermillion and Quest Diagnostics are negotiating in good faith towards alternative terms. Quest Diagnostics has disputed the effectiveness of the termination. If Quest Diagnostics fails to make such payments or provide such reports or if Vermillion and Quest Diagnostics are no longer negotiating alternative terms in good faith, we may not continue to allow Quest Diagnostics to perform OVA1 tests or we may change the terms on which we provide OVA1 tests to Quest Diagnostics. It is uncertain how Quest Diagnostics might respond to any such action, and it is possible that Quest Diagnostics may commence litigation against us. Quest Diagnostics may also unilaterally terminate its current relationship with us or take other action that might adversely affect our business, financial condition and results of operations. If Quest Diagnostics ceases to perform OVA1 tests and we do not have any other means of performing OVA1 tests, we not be able to generate any product revenue.

***Failures by third party payers to reimburse OVA1 or changes or variances in reimbursement rates could materially and adversely affect our business, financial condition and results of operations.***

All of our product revenue in 2013 was dependent on the amount Quest Diagnostics received from third party payers for performing OVA1 tests, and our future revenues will also be dependent upon third-party reimbursement. Insurance coverage and reimbursement rates for diagnostic tests are uncertain, subject to change and particularly volatile during the early stages of commercialization. There remain questions as to what extent third party payers, like Medicare, Medicaid and private insurance companies will provide coverage for OVA1 and for which indications. The reimbursement rates for OVA1 are largely out of our control. We have had limited visibility into any specific payer-level reimbursement data for OVA1 because such data has been provided to us by Quest Diagnostics once a year as part of the annual revenue true-up process. Quest Diagnostics has advised us that it has experienced volatility in the coverage and reimbursement of OVA1 due to contract negotiation with third party payers and

implementation requirements and that the reimbursement amounts it has received from third party payers varies from payer to payer, and, in some cases, the variation is material.

Third party payers, including private insurance companies as well as government payers such as Medicare and Medicaid, have increased their efforts to control the cost, utilization and delivery of healthcare services. These measures have resulted in reduced payment rates and decreased utilization of diagnostic tests such as OVA1. From time to time, Congress has considered and implemented changes to the Medicare fee schedules in conjunction with budgetary legislation, and pricing for tests covered by Medicare is subject to change at any time. Reductions in third-party payer reimbursement rates may occur in the future. Reductions in the price at which OVA1 is reimbursed could have a material adverse effect on our revenues. If we and Quest Diagnostics are unable to establish and maintain broad coverage and reimbursement for OVA1 or if third party payers change their coverage or reimbursement policies with respect to OVA1, our business, financial condition and results of operations could be materially adversely affected.

***We may need to raise additional capital in the future and if we are unable to secure adequate funds on terms acceptable to us, we may be unable to execute our business plan.***

We may seek to raise additional capital through the issuance of equity or debt securities in the public or private markets, or through a collaborative arrangement or sale of assets. Additional financing opportunities may not be available to us, or if available, may not be on favorable terms. The availability of financing opportunities will depend, in part, on market conditions, and the outlook for our business. Any future issuance of equity securities or securities convertible into equity could result in substantial dilution to our stockholders, and the securities issued in such a financing may have rights, preferences or privileges senior to those of our common stock.

***Our success depends, in part, on our ability to commercialize OVA1 outside the United States, and there is no assurance that we will be able to do so successfully.***

In 2013, virtually all of our product revenue was generated in the United States. In 2014, we plan to begin to actively seek laboratory customers and other distributors and partners outside the United States, so that we may begin directly or indirectly marketing and selling OVA1 outside the United States in 2015. We may not be able to find suitable customers or other distributors or partners outside the United States that are willing to enter into business relationships with us on terms that are advantageous to us or at all. Moreover, we may be prohibited from directly or indirectly marketing or selling OVA1 in various jurisdictions outside the United States if we are unable to obtain applicable regulatory approvals. In addition, we will need to ensure that third-party payers, including insurance companies and government payers, in jurisdictions outside the United States will pay or reimburse for OVA1 tests performed in those jurisdictions.

If we are able to successfully commercialize OVA1 outside the United States, we will become subject to increased costs and risks of doing business outside the United States, including currency fluctuations, the impact of various anti-corruption and similar laws and recessionary trends or economic instability in international markets.

***We may not succeed in developing additional diagnostic products, and, even if we do succeed in developing additional diagnostic products, the diagnostic products may never achieve significant commercial market acceptance.***

Our success depends on our ability to continue to develop and commercialize diagnostic products. There is considerable risk in developing diagnostic products based on our biomarker discovery efforts, as candidate biomarkers may fail to validate results in larger clinical studies or may not achieve acceptable levels of clinical accuracy. For example, markers being evaluated for one or more next-generation ovarian cancer diagnostic tests may not be validated in downstream pre-clinical or clinical studies, once we undertake and perform such studies.

Clinical testing is expensive, takes many years to complete and can have an uncertain outcome. Clinical failure can occur at any stage of the testing. Clinical trials for our next generation ovarian cancer tests, and other future diagnostic tests may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and/or non-clinical testing on these tests. In addition, the results of our clinical trials may identify unexpected risks relative to safety or efficacy, which could complicate, delay or halt clinical trials, or result in the denial of regulatory approval by the FDA and other regulatory authorities.

If we do succeed in developing additional diagnostic tests with acceptable performance characteristics, we may not succeed in achieving commercial market acceptance for those tests. Our ability to successfully commercialize diagnostic products, including OVA1, will depend on many factors, including:

- our ability to convince the medical community of the safety and clinical efficacy of our products and their advantages over existing diagnostic products;

- our success in establishing new clinical practices or changing previous ones, such that utilization of the tests fail to meet established standards of care, medical guidelines and the like;
- our ability to develop business relationships with diagnostic or laboratory companies that can assist in the commercialization of these products in the US and globally; and
- the scope and extent of the agreement by Medicare and third-party payers to provide full or partial reimbursement coverage for our products, which will affect patients' willingness to pay for our products and will likely heavily influence physicians' decisions to recommend or use our products.

These factors present obstacles to commercial acceptance of our existing and potential diagnostic products, for which we will have to spend substantial time and financial resources to overcome, and there is no guarantee that we will be successful in doing so. Our inability to do so successfully would prevent us from generating revenue from OVA1 and future diagnostic products.

***The diagnostics market is competitive, and we may not be able to compete successfully, which would adversely impact our ability to generate revenue.***

Our principal competition currently comes from the many clinical options available to medical personnel involved in clinical decision making. For example, rather than ordering an OVA1 for a woman with an adnexal mass, obstetricians, gynecologists, and gynecologic oncologists may choose a different clinical option or none at all. If we are not able to convince clinicians that OVA1 provides significant improvement over current clinical practices, our ability to commercialize OVA1 will be adversely affected. Additionally, Fujirebio Diagnostics, Inc. announced in September 2011 that it received clearance from the FDA to commercialize its Risk of Malignancy Algorithm ("ROMA") test. The ROMA test is in direct competition with OVA1, and our revenues could be materially and adversely affected if and when the ROMA test is successfully commercialized. In addition, competitors, such as Becton Dickinson, ArrayIt Corporation, and Abbott Laboratories have publicly disclosed that they have been or are currently working on ovarian cancer diagnostic assays. Academic institutions periodically report new findings in ovarian cancer diagnostics that may have commercial value. Our failure to compete with any competitive diagnostic assay if and when commercialized could adversely affect our business, financial condition and results of operations.

We have priced OVA1 at a point that recognizes the value-added by its increased sensitivity for ovarian malignancy. If others develop a test that is viewed to be similar to OVA1 in efficacy but is priced at a lower point, we and/or our strategic partners may have to lower the price of OVA1 in order to effectively compete, which would impact our margins and potential for profitability.

***The commercialization of our diagnostic tests may be adversely affected by changing FDA regulations, and any delay by or failure of the FDA to approve our diagnostic tests submitted to the FDA may adversely affect our business, results of operations and financial condition.***

The FDA cleared OVA1 in September 2009. Our activities related to diagnostic products are, or have the potential to be, subject to regulatory oversight by the FDA under provisions of the Federal Food, Drug and Cosmetic Act and regulations thereunder, including regulations governing the development, marketing, labeling, promotion, manufacturing and export of our products. Failure to comply with applicable requirements can lead to sanctions, including withdrawal of products from the market, recalls, refusal to authorize government contracts, product seizures, civil money penalties, injunctions and criminal prosecution.

The Food, Drug and Cosmetic Act requires that medical devices introduced to the United States market, unless exempted by regulation, be the subject of either a pre-market notification clearance, known as a 510(k) clearance or 510(k) de novo clearance, or a pre-market approval ("PMA"). Some of our potential future clinical products may require a 510(k) or 510(k) de novo clearance, while others may require a PMA. With respect to devices reviewed through the 510(k) process, we may not market a device until an order is issued by the FDA finding our product to be substantially equivalent to a legally marketed device known as a predicate device. A 510(k) submission may involve the presentation of a substantial volume of data, including clinical data. The FDA may agree that the product is substantially equivalent to a predicate device and allow the product to be marketed in the United States. On the other hand, the FDA may determine that the device is not substantially equivalent and require a PMA, or require further information, such as additional test data, including data from clinical studies, before it is able to make a determination regarding substantial equivalence. By requesting additional information, the FDA can delay market introduction of our products. Delays in receipt of or failure to receive any necessary 510(k) clearance or PMA approval, or the imposition of stringent restrictions on the labeling and sales of our products, could have a material adverse effect on our business, results of operations and financial condition. If the FDA indicates that a PMA is required for any of our potential future clinical products, the application will require extensive clinical studies, manufacturing information and likely review by a panel of experts outside the FDA. Clinical studies to support either a 510(k) submission or a PMA application would need to be conducted in accordance with FDA requirements. Failure to comply with FDA requirements could result in the FDA's refusal to accept the data or the imposition of regulatory sanctions. We cannot assure that any necessary 510(k) clearance or PMA approval will be granted on a timely basis, or at all. To the extent we seek FDA 510(k) clearance or FDA pre-market approval

for other diagnostic tests, any delay by or failure of the FDA to clear or approve those diagnostic tests may adversely affect our consolidated revenues, results of operations and financial condition.

***If we or our suppliers fail to comply with FDA requirements for production, marketing and postmarket monitoring of our products, we may not be able to market our products and services and may be subject to stringent penalties, product restrictions or recall; further improvements to our manufacturing operations may be required that could entail additional costs.***

The commercialization of our products could be delayed, halted or prevented by applicable FDA regulations. If the FDA were to view any of our actions as non-compliant, it could initiate enforcement actions, such as a warning letter and possible imposition of penalties. In addition, analyte specific reagents that we may provide would be subject to a number of FDA requirements, including compliance with the FDA's Quality System Regulations ("QSR"), which establish extensive requirements for quality assurance and control as well as manufacturing procedures. Failure to comply with these regulations could result in enforcement actions for us or our potential suppliers. Adverse FDA actions in any of these areas could significantly increase our expenses and reduce our revenue and profitability. We will need to undertake steps to maintain our operations in line with the FDA's QSR requirements. Some components of OVA1 are manufactured by other companies and we are required to maintain supply agreements with these companies. If these agreements are not satisfactory to the FDA, we will need to renegotiate these agreements. Any failure to do so would have an adverse effect on our ability to commercialize OVA1. Our suppliers' manufacturing facilities are subject to periodic regulatory inspections by the FDA and other federal and state regulatory agencies. If and when we begin commercializing and assembling our products by ourselves, our facilities will be subject to the same inspections. We or our suppliers may not satisfy such regulatory requirements, and any such failure to do so may adversely affect our business, financial condition and results of operations.

***If our suppliers fail to produce acceptable or sufficient stock, make changes to the design or labeling of their biomarker kits or discontinue production of existing biomarker kits or instrument platforms, we may be unable to meet market demand for OVA1.***

The commercialization of our OVA1 test depends on the supply of five different immunoassay kits from third-party manufacturers run on automated instruments. Failure by any of these manufacturers to produce kits that pass Vermillion's quality control measures might lead to back-order and/or loss of revenue due to missed sales and customer dissatisfaction. In addition, if the design or labeling of any kit were to change, continued OVA1 supply could be threatened since new validation and submission to the FDA for 510(k) clearance could be required as a condition of sale. Discontinuation of any of these kits would require identification, validation and 510(k) submission on a revised OVA1 design. Likewise, discontinuation or failure to support or service the instruments may pose risk to ongoing operations.

In May 2013, we received notification that the part number for one of the five immunoassay component kits that are used in OVA1 will no longer be supported on the instrument, effective December 2014, as the manufacturer transitions to a newer platform. While we do not anticipate disruption of ongoing operations, failure of the manufacturer to provide extended service or support might harm the business. We are also planning on consolidating the five OVA1 immunoassays onto a single mainstream automated platform and substituting a new immunoassay component kit for the discontinuing kit as a mitigating action. These planned changes will require a 510(k) submission with the FDA. No assurances can be made that the FDA will clear our expected 510(k) submission approving these changes to OVA1 prior to December 2014, or at all.

***If we fail to continue to develop our technologies, we may not be able to successfully foster adoption of our products and services or develop new product offerings.***

Our technologies are new and complex, and are subject to change as new discoveries are made. New discoveries and advancements in the diagnostic field are essential if we are to foster the adoption of our product offerings. Development of these technologies remains a substantial risk to us due to various factors, including the scientific challenges involved, our ability to find and collaborate successfully with others working in the diagnostic field, and competing technologies, which may prove more successful than our technologies.

***If we fail to maintain our rights to utilize intellectual property directed to diagnostic biomarkers, we may not be able to offer diagnostic tests using those biomarkers.***

One aspect of our business plan is to develop diagnostic tests based on certain biomarkers, which we have the right to utilize through licenses with our academic collaborators, such as the Johns Hopkins University School of Medicine and the University of Texas M.D. Anderson Cancer Center. In some cases, our collaborators own the entire right to the biomarkers. In other cases, we co-own the biomarkers with our collaborators. If, for some reason, we lose our license to biomarkers owned entirely by our collaborators, we may not be able to use those biomarkers in diagnostic tests. If we lose our exclusive license to biomarkers co-owned by us and our collaborators, our collaborators may license their share of the intellectual property to a third party that may compete with us in offering diagnostic tests, which would materially adversely affect our business, results of operations and financial condition.

***If a third party infringes on our proprietary rights, we may lose any competitive advantage we may have as a result of diversion of our time, enforcement costs and the loss of the exclusivity of our proprietary rights.***

Our success depends in part on our ability to maintain and enforce our proprietary rights. We rely on a combination of patents, trademarks, copyrights and trade secrets to protect our technology and brand. We have submitted a number of patent applications covering biomarkers that may have diagnostic or therapeutic utility. Our patent applications may or may not result in additional patents being issued.

If third parties engage in activities that infringe on our proprietary rights, we may incur significant costs in asserting our rights. We may not be successful in asserting our proprietary rights and the attention of our management may be diverted from our business, which could result in our patents being held invalid or a court holding that the competitor is not infringing, either of which may harm our competitive position. We cannot be sure that competitors will not design around our patented technology.

We also rely upon the skills, knowledge and experience of our technical personnel. To help protect our rights, we require all employees and consultants to enter into confidentiality agreements that prohibit the disclosure of confidential information. These agreements may not provide adequate protection for our trade secrets, knowledge or other proprietary information in the event of any unauthorized use or disclosure. If any trade secret, knowledge or other technology not protected by a patent were to be disclosed to or independently developed by a competitor, it could have a material adverse effect on our business, consolidated results of operations and financial condition.

***If others successfully assert their proprietary rights against us, we may be precluded from making and selling our products or we may be required to obtain licenses to use their technology.***

Our success depends on avoiding infringing on the proprietary technologies of others. If a third party were to assert claims that we are violating their patents, we might incur substantial costs defending ourselves in lawsuits against charges of patent infringement or other unlawful use of another's proprietary technology. Any such lawsuit may involve considerable management and financial resources and may not be decided in our favor. If we are found liable, we may be subject to monetary damages or an injunction prohibiting us from using the technology. We may also be required to obtain licenses under patents owned by third parties and such licenses may not be available to us on commercially reasonable terms, if at all.

***Future litigation against us could be costly and time consuming to defend.***

We are from time to time subject to legal proceedings and claims that arise in the ordinary course of business, such as claims brought by our clients in connection with commercial disputes, employment claims made by current or former employees, and claims brought by third parties alleging infringement of their intellectual property rights. In addition, we may bring claims against third parties for infringement of our intellectual property rights. Litigation may result in substantial costs and may divert our attention and resources, which may adversely affect our business, results of operations and financial condition.

An unfavorable judgment against us in any legal proceeding or claim could require us to pay monetary damages. In addition, an unfavorable judgment in which the counterparty is awarded equitable relief, such as an injunction, could have an adverse impact on our licensing and sublicensing activities, which could harm our business, results of operations and financial condition.

***Because our business is highly dependent on key executives and employees, our inability to recruit and retain these people could hinder our business plans.***

We are highly dependent on our executive officers and certain key employees. Our executive officers and key employees are employed at will by us. Any inability to engage new executive officers or key employees could impact operations or delay or curtail our research, development and commercialization objectives. To continue our research and product development efforts, we need people skilled in areas such as clinical operations, regulatory affairs and clinical diagnostics. Competition for qualified employees is intense.

If we lose the services of any executive officers or key employees, our ability to achieve our business objectives could be harmed, which in turn could adversely affect our business, financial condition and results of operations.

***Our diagnostic efforts may cause us to have significant product liability exposure.***

The testing, manufacturing and marketing of medical diagnostic tests entail an inherent risk of product liability claims. Potential product liability claims may exceed the amount of our insurance coverage or may be excluded from coverage under the terms of the policy. We will need to increase our amount of insurance coverage in the future if we are successful at introducing new diagnostic products, and this will increase our costs. If we are held liable for a claim or for damages exceeding the limits of our insurance coverage, we may be required to make substantial payments. This may have an adverse effect on our business, financial condition and results of operations.

***Business interruptions could limit our ability to operate our business.***

Our operations, as well as those of the collaborators on which we depend, are vulnerable to damage or interruption from fire; natural disasters, including earthquakes; computer viruses; human error; power shortages; telecommunication failures; international acts of terror; and similar events. Although we have certain business continuity plans in place, we have not established a formal

comprehensive disaster recovery plan, and our back-up operations and business interruption insurance may not be adequate to compensate us for losses we may suffer. A significant business interruption could result in losses or damages incurred by us and require us to cease or curtail our operations.

***Legislative actions resulting in higher compliance costs may adversely affect our business, financial condition and results of operations.***

Compliance with laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, and new regulations adopted by the SEC, are resulting in increased compliance costs. We, like all other public companies, are incurring expenses and diverting employees' time in an effort to comply with Section 404 of the Sarbanes-Oxley Act of 2002. The SEC and other regulators have continued to adopt new rules and regulations and make additional changes to existing regulations that require our compliance. In July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations. Compliance with these evolving standards will result in increased general and administrative expenses and may cause a diversion of our time and attention from revenue-generating activities to compliance activities.

***Changes in healthcare policy could increase our costs and impact sales of and reimbursement for our tests.***

In March 2010, President Barack Obama signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the "PPACA"). Pursuant to the PPACA, beginning in 2013, each medical device manufacturer has paid a sales tax in an amount equal to 2.3 percent of the price for which such manufacturer sells its medical devices. The PPACA also mandates a reduction in payments for clinical laboratory services paid under the Medicare Clinical Laboratory Fee Schedule of 1.75% for the years 2011 through 2015. This adjustment is in addition to a productivity adjustment to the Clinical Laboratory Fee Schedule. In addition to the PPACA, a number of states are also contemplating significant reform of their healthcare policies. We cannot predict whether future healthcare initiatives will be implemented at the federal or state level, or the effect any future legislation or regulation will have on us. The taxes imposed by PPACA have resulted in decreased profits to us, and lower reimbursements by payers for our tests. Other changes to healthcare laws may adversely affect our business, financial condition and results of operations.

***We are subject to environmental laws and potential exposure to environmental liabilities.***

We are subject to various international, federal, state and local environmental laws and regulations that govern our operations, including the handling and disposal of non-hazardous and hazardous wastes, the recycling and treatment of electrical and electronic equipment, and emissions and discharges into the environment. Failure to comply with such laws and regulations could result in costs for corrective action, penalties or the imposition of other liabilities. We are also subject to laws and regulations that impose liability and clean-up responsibility for releases of hazardous substances into the environment. Under certain of these laws and regulations, a current or previous owner or operator of property may be liable for the costs to remediate hazardous substances or petroleum products on or from its property, without regard to whether the owner or operator knew of, or caused, the contamination, as well as incur liability to third parties affected by such contamination. The presence of, or failure to remediate properly, such substances could adversely affect the value and the ability to transfer or encumber such property. Based on currently available information, although there can be no assurance, we believe that such costs and liabilities have not had and will not have a material adverse impact on our consolidated results of operations.

**Risks Related to Owning Our Stock**

***The liquidity and trading volume of our common stock may be low and our ownership is concentrated.***

The liquidity and trading volume of our common stock has at times been low in the past and may again be low in the future. If the liquidity and trading volume of our common stock is low, this could adversely impact the trading price of our shares, our ability to issue stock and our stockholders' ability to obtain liquidity in their shares. The issuance of common stock by us in May 2013 and subsequent warrant exercise in December 2013 involved a significant issuance of stock to a limited number of investors, significantly increasing the concentration of our share ownership in a few holders.

***Our stock price has been, and may continue to be, highly volatile.***

The trading price of our common stock has been highly volatile and could continue to be subject to wide fluctuations in price in response to various factors, many of which are beyond our control, including:

- failure to significantly increase revenue and volumes of OVA1;
- actual or anticipated period-to-period fluctuations in financial results;
- failure to achieve, or changes in, financial estimates by securities analysts;

- announcements or introductions of new products or services or technological innovations by us or our competitors;
- publicity regarding actual or potential discoveries of biomarkers by others;
- comments or opinions by securities analysts or stockholders;
- conditions or trends in the pharmaceutical, biotechnology or life science industries;
- announcements by us of significant acquisitions and divestitures, strategic partnerships, joint ventures or capital commitments;
- developments regarding our patents or other intellectual property or that of our competitors;
- litigation or threat of litigation;
- additions or departures of key personnel;
- limited daily trading volume;
- economic and other external factors, disasters or crises; and
- our announcement of additional fundraisings.

In addition, the stock market in general and the market for diagnostic technology companies, in particular, have experienced significant price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. These broad market and industry factors may adversely affect the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been instituted. A securities class action suit against us could result in substantial costs, potential liabilities and the diversion of our attention and our resources.

***Anti-takeover provisions in our charter, bylaws, other agreements and under Delaware law could make a third party acquisition of the Company difficult.***

Our certificate of incorporation and bylaws contain provisions that could make it more difficult for a third party to acquire us, even if doing so might be deemed beneficial by our stockholders. In connection with our offering of common stock and warrants on May 13, 2013, we entered into a shareholders agreement which, among other things, includes agreements limiting our ability to enter into acquisition and other transactions. These provisions could limit the price that investors might be willing to pay in the future for shares of our common stock. We are also subject to certain provisions of Delaware law that could delay, deter or prevent a change in control of the Company.

***We could face adverse consequences as a result of the actions of activist stockholders.***

Certain of our stockholders may, from time to time, attempt to aggressively involve themselves in the governance and strategic direction of our Company above and apart from normal interactions between stockholders and management. Such activism, and any related negative publicity, could result in substantial costs that negatively impact our stock price and increase its volatility. In addition, such activism could cause a diversion of the attention of our management and Board of Directors and create perceived uncertainties with existing and potential strategic partners impacting our ability to consummate potential transactions, collaborations or opportunities in furtherance of our strategic plan. In addition, such activism could make it more difficult to attract and retain qualified personnel, customers and business partners, which could disrupt the growth of the market for OVA1, delay the development and commercialization of new tests and further adversely affect the trading price of our common stock and increase its volatility. In addition, the activists may have little or no experience in the diagnostics industry or may seek to elect members to our Board of Directors with little or no experience in the diagnostics industry who may have a specific agenda different and apart from the majority of our stockholders.

***Because we do not intend to pay dividends, our stockholders will benefit from an investment in our common stock only if it appreciates in value.***

We have never declared or paid any cash dividends on our common stock. We currently intend to retain our future earnings, if any, to finance the expansion of our business and do not expect to pay any cash dividends in the foreseeable future. As a result, the success of an investment in our common stock will depend entirely upon any future appreciation. There is no guarantee that our common stock will appreciate in value or even maintain the price at which our stockholders purchased their shares.

***We may need to sell additional shares of our common stock or other securities in the future to meet our capital requirements which could cause significant dilution.***

As of December 31, 2013, we had 35,825,673 shares of our common stock outstanding and 1,420,441 shares of our common stock reserved for future issuance to employees, directors and consultants pursuant to our employee stock plans, which excludes



1,447,968 shares of our common stock that were subject to outstanding options. In addition, as of December 31, 2013, warrants to purchase 497,000 shares of our common stock were outstanding. These warrants are exercisable at the election of the holders thereof at an exercise price of \$1.67 per share.

The exercise of all or a portion of our outstanding options and warrants will dilute the ownership interests of our stockholders. Furthermore, future sales of substantial amounts of our common stock in the public market, or the perception that such sales are likely to occur, could affect prevailing trading prices of our common stock and the value of the notes.

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

**ITEM 2. PROPERTIES**

Our principal facility is located in Austin, Texas. The following chart indicates the facility that we lease, the location and size of the facility and its designated use.

<u>Location</u>	<u>Approximate Square Feet</u>	<u>Primary Functions</u>	<u>Lease Expiration Date</u>
Austin, Texas	4,800 sq. ft.	Research and development, clinical and regulatory, marketing, sales and administrative offices	May 31, 2014

**ITEM 3. LEGAL PROCEEDINGS**

From time to time, we are involved in legal proceedings and regulatory proceedings arising out of our operations. We establish reserves for specific liabilities in connection with legal actions that we deem to be probable and estimable. We are not currently a party to any proceeding, the adverse outcome of which would have a material adverse effect on our financial position or results of operations.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

## PART II

### ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our common stock was traded on the NASDAQ Global Market under the symbol "VRML." Effective February 15, 2012, we transferred our listing from the NASDAQ Global Market to the NASDAQ Capital Market.

On March 17, 2014, there were 74 registered holders of record of our common stock. The closing price of our common stock on March 14, 2014 was \$2.75.

The following sets forth the quarterly high and low trading prices as reported by The Nasdaq Global Market and NASDAQ Capital Market for the periods indicated.

	2013		2012	
	High	Low	High	Low
First Quarter	\$ 3.10	\$ 1.97	\$ 3.02	\$ 1.19
Second Quarter	3.24	2.11	2.79	1.62
Third Quarter	4.07	1.03	2.36	1.56
Fourth Quarter	1.48	1.13	1.88	1.13

#### Dividends

We have never paid or declared any dividend on our common stock and we do not anticipate paying cash dividends on our common stock in the foreseeable future. If we pay a cash dividend on our common stock, we also may be required to pay the same dividend on an as-converted basis on any outstanding warrants or other securities. Moreover, any preferred stock or other senior debt or equity securities to be issued and any future credit facilities might contain restrictions on our ability to declare and pay dividends on our common stock. We intend to retain all available funds and any future earnings to fund the development and expansion of our business.

#### Unregistered Sales of Equity Securities

None.

#### Equity Compensation Plan Information

We currently maintain two equity-based compensation plans that were approved by our stockholders. The plans are the Vermillion, Inc. 2000 Stock Plan (the "2000 Plan"), and the Vermillion, Inc. Amended and Restated 2010 Stock Incentive Plan (the "2010 Plan").

**2000 Plan.** The authority of our Board of Directors to grant new stock options and awards under the 2000 Plan terminated in 2010. The Board of Directors continues to administer the 2000 Plan with respect to the stock options that remain outstanding under the 2000 Plan. At December 31, 2013, options to purchase 197,506 shares of our common stock remained outstanding under the 2000 Plan.

**2010 Plan.** The 2010 Plan is administered by the Compensation Committee of our Board of Directors. Our employees, directors, and consultants are eligible to receive awards under the 2010 Plan. The 2010 Plan permits the granting of a variety of awards, including stock options, share appreciation rights, restricted shares, restricted share units, and unrestricted shares, deferred share units, performance and cash-settled awards, and dividend equivalent rights. We are authorized to issue up to 3,622,983 shares of common stock, par value \$0.001 per share under the 2010 Plan, subject to adjustment as provided in the 2010 Plan. At December 31, 2013, options to purchase 1,250,462 shares of common stock remained outstanding under the 2010 Plan.

#### Performance Graph

Pursuant to Instructions to Item 201(e)(6) of Regulation S-K, information is not required.

The number of shares of our common stock to be issued upon exercise of outstanding stock options, the weighted-average exercise price of outstanding stock options and the number of shares available for future stock option grants and stock awards under equity compensation plans as of December 31, 2013, were as follows:

<b>Plan Category</b>	<b>Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights</b>	<b>Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights</b>	<b>Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Shares Reflected in First Column)</b>
Equity compensation plans approved by security holders	1,447,968 <sup>(1)</sup>	\$ 3.36 <sup>(2)</sup>	1,420,441 <sup>(3)</sup>
Equity compensation plans not approved by security holders	-	-	-
<b>Total</b>	<b>1,447,968</b>		<b>1,420,441</b>

(1) Includes outstanding stock options for 197,506 shares of our common stock under the 2000 Plan and 1,250,462 shares of our common stock under the 2010 Plan.

(2) Includes the weighted average stock price for outstanding stock options of \$10.28 under the 2000 Plan and \$2.26 for the 2010 Plan.

(3) Represents shares of our common stock for the 2010 Plan. No future awards shall occur under the 2000 Plan.

#### **ITEM 6. SELECTED FINANCIAL DATA**

Per Item 301(c) of Regulation S-K, information is not required.

## ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*You should read the following discussion and analysis in conjunction with our Consolidated Financial Statements and related Notes thereto, included on pages F-1 through F-19 of this Annual Report on Form 10-K, and "Risk Factors", which are discussed in Item 1A. The statements below contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act. See "Forward-Looking Statements" on page 1 of this Annual Report on Form 10-K.*

### Overview

We are dedicated to the discovery, development and commercialization of novel high-value diagnostic tests that help physicians diagnose, treat and improve outcomes for patients. Our tests are intended to help guide decisions regarding patient treatment, which may include decisions to refer patients to specialists, to perform additional testing, or to assist in the selection of therapy. A distinctive feature of our approach is to combine multiple markers into a single, reportable index score that has higher diagnostic accuracy than its constituents. We concentrate on our development of novel diagnostic tests in the fields of gynecologic oncology and women's health, with an initial focus on ovarian cancer. We also intend to address clinical questions related to early disease detection, treatment response, monitoring of disease progression, prognosis and others through collaborations with leading academic and research institutions.

### *Strategy:*

We are focused on the execution of three core strategic business drivers in ovarian cancer diagnostics to build long-term value for our investors:

- Maximizing the existing OVA1 opportunity in the United States ("US") by changing our business relationship with Quest Diagnostics and taking the leadership role in expanding commercialization, payer coverage and medical guidelines
- Expanding our customer base to non-US markets by migrating OVA1 to a global testing platform
- Building an expanded patient base by seeking FDA approval and launching a next generation multi-marker ovarian cancer test to monitor patients at risk for ovarian cancer

We believe that these business drivers will contribute significantly to addressing unmet medical needs for women faced with ovarian cancer and the continued development of our business.

Our lead product, OVA1, was cleared by the FDA in September 2009. OVA1 addresses a clear clinical need, namely the pre-surgical identification of women who are at high risk of having a malignant ovarian tumor. Numerous studies have documented the benefit of referral of these women to gynecologic oncologists for their initial surgery. Prior to the clearance of OVA1, no blood test had been cleared by the FDA for physicians to use in the pre-surgical management of ovarian adnexal masses. OVA1 is a qualitative serum test that utilizes five well-established biomarkers and proprietary FDA-cleared software to determine the likelihood of malignancy in women over age 18, with a pelvic mass for whom surgery is planned. OVA1 was developed through large pre-clinical studies in collaboration with numerous academic medical centers encompassing over 2,500 clinical samples. OVA1 was fully validated in a prospective multi-center clinical trial encompassing 27 sites reflective of the diverse nature of the clinical centers at which ovarian adnexal masses are evaluated. In 2012, we completed a second pivotal clinical study of OVA1, called the "OVA500 study" and led by Dr. Robert E. Bristow, Director of Gynecologic Oncology Services with University of California Irvine Healthcare. The study evaluated OVA1 diagnostic performance in a population of 494 evaluable patients who underwent surgery for an adnexal mass after enrollment by a non-gynecologic oncologist. In February 2013, the OVA500 study was published in the peer-reviewed journal *Gynecologic Oncology*, which enjoys the highest impact factor rating of any journal worldwide focused on gynecologic oncology. Since many professional medical societies stress the importance of multiple independent clinical trials as so-called "evidence levels", we also believe that OVA500 contributes to a higher evidence level relative to OVA1's utility in the medical management of adnexal masses.

In addition to these pivotal studies, three follow-on studies have been published bringing the number of full research articles on OVA1 clinical performance to a total of five peer-reviewed publications. Together, we believe these data provide strong clinical evidence that OVA1 improves the pre-surgical detection of ovarian cancer, regardless of stage or subtype, in patients undergoing surgery for a suspicious ovarian mass.

In August 2013, we terminated a strategic alliance agreement (as amended, the "Strategic Alliance Agreement") with Quest Diagnostics under which we were to develop and commercialize up to three diagnostic tests from our product pipeline (the "Strategic Alliance"). Prior to termination, Quest Diagnostics had the exclusive right to commercialize OVA1 in the clinical laboratory market until September 2014, with an option to extend such exclusive period in its sole discretion for one additional year. Quest Diagnostics

has disputed the effectiveness of such termination. As part of the termination, we allowed Quest Diagnostics to continue to make OVA1 available as long as (i) Quest Diagnostics continues to make the payments and provide the reports to Vermillion in connection with such activities as would be required under the Strategic Alliance Agreement but for its termination and (ii) Vermillion determines that Vermillion and Quest Diagnostics are negotiating in good faith towards alternative terms under which Quest Diagnostics and Vermillion can work together to make this important product available to healthcare providers and patients. Now that the Strategic Alliance Agreement has been terminated, we plan to make OVA1 available through channels in addition to Quest Diagnostics.

OVA1 was CE marked in September 2010, a requirement for marketing the test in the European Union.

The American Medical Association (AMA) Current Procedural Terminology (CPT®) Panel has approved our Category I CPT code for OVA1 (# 81503), which became effective January 1, 2013.

In June 2013, the Society for Gynecologic Oncology (“SGO”) issued a new position statement on OVA1. This second SGO statement on OVA1 since its FDA clearance in 2009 represents another significant step toward acceptance of OVA1 as the standard of care for pre-surgically evaluating the risk of ovarian cancer in women with adnexal masses. The statement, titled “Multiplex Serum Testing for Women with Pelvic Mass”, reads:

“Blood levels of five proteins in women with a known ovarian mass have been reported to change when ovarian cancer is present. Tests measuring these proteins may be useful in identifying women who should be referred to a gynecologic oncologist. Recent data have suggested that such tests, along with physician clinical assessment, may improve detection rates of malignancies among women with pelvic masses planning surgery. [1],[2] Results from such tests should not be interpreted independently, nor be used in place of a physician’s clinical assessment. Physicians are strongly encouraged to reference the American Congress of Obstetricians and Gynecologists’ 2011 Committee Opinion “The Role of the Obstetrician-Gynecologist in the Early Detection of Epithelial Ovarian Cancer” to determine an appropriate care plan for their patients. It is important to note that no such test has been evaluated for use as, nor cleared by, the FDA as a screening tool for ovarian cancer. SGO does not formally endorse or promote any specific products or brands.”

The new statement does two things:

- Lists as references the publications of OVA1's two pivotal clinical studies, comprised of the original FDA validation study published in June 2011 and the OVA500 "intended use" study published in 2013. Together, this offers an extensive, peer-reviewed proof source for physicians and payers to assess OVA1's clinical performance and comparative medical benefits versus today's standard of care.
- Places OVA1 use in the context of current ACOG practice guidelines, where CA125 has been used off-label for many years to predict malignancy before surgery, although with inferior performance.

In June 2013 our collaborators from Johns Hopkins Biomarker Discovery and Translation Center presented data from “proof of concept” work to identify markers with high clinical specificity that may complement OVA1. These results were presented in a poster at the annual meeting of the American Society for Clinical Oncology (ASCO) by Dr. Zhen Zhang and co-workers. The study identified a set of 5 biomarkers (CA125, prealbumin, IGFBP2, IL6, and FSH) which optimally reduced false positives among a targeted set of OVA1-positive benign patients. This panel was subsequently tested in a 50/50 cross-validation strategy against a sampling of OVA500 patients (N=384), to evaluate specificity and other diagnostic parameters. At a fixed sensitivity of 90%, the median specificity of models using the new panel in testing was 80.6%. The mean and median absolute improvements over that of OVA1 were 18.6% and 20.3%, respectively. The new panel demonstrated the possibility to improve specificity over that of the existing OVA1 algorithm, while maintaining a high sensitivity in pre-surgical assessment of malignancy. The work will be submitted for publication in 2014.

We in the process of identifying intended use(s) and establishing a regulatory or commercial pathway for a potential next-generation OVA product utilizing this or another new panel. Any actual product development will likely differ significantly depending on a number of technical and commercial factors.

In December 2013, the CMS made its final determination and authorized Medicare contractors to set prices for MAAA test CPT codes when they determine it is payable. CMS also validated that an algorithm has unique value by specifying that the gap-fill process and not cross-walk should be used by contractors to price MAAA tests. We expect OVA1 to be priced using the gap-fill method. We will be engaged in that process in 2014 for pricing effective January 1, 2015. This decision also sets a precedent for recognizing the value of biomarker developed tests and recognizing tests on the value they bring to clinical decision-making and healthcare efficiencies.

### **Critical Accounting Policies and Estimates**

Our significant accounting policies are described in Note 1, Basis for Presentation and Summary of Significant Accounting and Reporting Policies, of the Notes to the Consolidated Financial Statements included in this Annual Report on Form 10-K. The Consolidated Financial Statements are prepared in conformity with generally accepted accounting principles in the United States of America. Preparation of the financial statements requires us to make judgments, estimates, and assumptions that affect the amounts of

assets and liabilities in the financial statements and revenues and expenses during the reporting periods (and related disclosures). We believe the policies discussed below are the Company's critical accounting policies, as they include the more significant, subjective, and complex judgments and estimates made when preparing our consolidated financial statements

#### *Revenue Recognition*

Product Revenue. We derive our product revenues from sales of OVA1 through Quest Diagnostics. We recognize product revenues for tests performed when the following revenue recognition criteria are met: (1) persuasive evidence that an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured.

License Revenue. Under the terms of the secured line of credit with Quest Diagnostics, portions of the borrowed principal amounts may be forgiven upon our achievement of certain milestones relating to the development, regulatory approval and commercialization of certain diagnostic tests. We account for forgiveness of principal debt balances as license revenues over the term of the exclusive sales period that Quest Diagnostics received upon commercialization of an approved diagnostic test as we do not have a sufficient history of product sales that provides a reasonable basis for estimating future product sales. We recognize license revenue on a straight-line basis over the original remaining period of Quest Diagnostics' sales exclusivity ending in September 2015 as Quest Diagnostics has disputed the termination of exclusivity in August 2013.

#### *Research and Development Costs*

Research and development costs are expensed as incurred. Research and development costs consist primarily of payroll and related costs, materials and supplies used in the development of new products, and fees paid to third parties that conduct certain research and development activities on behalf of the Company. In addition, acquisitions of assets to be consumed in research and development, with no alternative future use, are expensed as incurred as research and development costs. Software development costs incurred in the research and development of new products are expensed as incurred until technological feasibility is established.

#### *Patent Costs*

Costs incurred in filing, prosecuting and maintaining patents (principally legal fees) are expensed as incurred and recorded within selling, general and administrative expenses on the consolidated statements of operations and comprehensive loss.

#### *Stock-Based Compensation*

We record the fair value of non-cash stock-based compensation costs for stock options and stock purchase rights related to our Amended and Restated 2010 Stock Incentive Plan (the "2010 Plan"). We estimate the fair value of stock options using a Black-Scholes option valuation model. This model requires the input of subjective assumptions including expected stock price volatility, expected life and estimated forfeitures of each award. We use the straight-line method to amortize the fair value over the vesting period of the award. These assumptions consist of estimates of future market conditions, which are inherently uncertain, and therefore are subject to management's judgment.

The expected life of options is based on historical data of our actual experience with the options we have granted and represents the period of time that the options granted are expected to be outstanding. This data includes employees' expected exercise and post-vesting employment termination behaviors. The expected stock price volatility is estimated using a combination of historical and peer group volatility for a blended volatility in deriving the expected volatility assumption. We made an assessment that blended volatility is more representative of future stock price trends than just using historical or peer group volatility, which corresponds to the expected life of the options. The expected dividend yield is based on the estimated annual dividends that we expect to pay over the expected life of the options as a percentage of the market value of our common stock as of the grant date. The risk-free interest rate for the expected life of the options granted is based on the United States Treasury yield curve in effect as of the grant date.

#### *Contingencies*

We account for contingencies in accordance with ASC 450 Contingencies ("ASC 450"). ASC 450 requires that an estimated loss from a loss contingency shall be accrued when information available prior to issuance of the financial statements indicates that it is probable that an asset has been impaired or a liability has been incurred at the date of the financial statements and when the amount of the loss can be reasonably estimated. Accounting for contingencies such as legal and contract dispute matters requires us to use our judgment. We believe that our accruals for these matters are adequate. Nevertheless, the actual loss from a loss contingency might differ from our estimates.

#### *Income Taxes*

We account for income taxes using the liability method. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and the tax bases of assets and liabilities using the current tax laws and rates. A valuation allowance is established when necessary to reduce deferred tax assets to the amounts more likely than not expected to be realized.

Accounting Standard Codification Topic 740-10-50 (“ASC Topic 740-10-50”), “Accounting for Uncertainty in Income Taxes” clarifies the accounting for uncertainty in income taxes recognized in the financial statements in accordance with ASC Topic 740, Income Taxes. ASC Topic 740-10-50 provides that a tax benefit from an uncertain tax position may be recognized when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, based on the technical merits. This interpretation also provides guidance on measurement, derecognition, classification, interest and penalties, accounting in interim periods, and disclosure.

We recognize interest and penalties related to unrecognized tax benefits within the interest expense line and other expense line, respectively, in the consolidated statement of operations. Accrued interest and penalties are included within the related liability lines in the consolidated balance sheet.

#### **Recently Adopted Accounting Pronouncements**

In February 2013, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) number 2013-02, Other Comprehensive Income (Topic 220): Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income to improve the reporting of reclassifications out of accumulated other comprehensive income. ASU 2013-02 requires reporting the effect of significant reclassifications out of accumulated other comprehensive income on the respective line items in net income. The adoption of this ASU on January 1, 2013 did not affect the accompanying consolidated financial statements, but could require additional disclosure, if applicable, in future periods.

In July 2013, the FASB issued ASU number 2013-11, Income Taxes (Topic 740): Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists — a consensus of the FASB Emerging Issues Task Force. ASU 2013-11 generally requires, with some exceptions, an entity to present its unrecognized tax benefits as it relates to its net operating loss carryforwards, similar tax losses, or tax credit carryforwards, as a reduction of deferred tax assets when settlement in this regard is available under the tax law of the applicable taxing jurisdiction as of the balance sheet reporting date. It is effective prospectively for fiscal years, and interim periods within those years, beginning after December 15, 2013. Retrospective application is permitted. We do not anticipate a material impact on our financial position, results of operations or cash flows as a result of this change.

## Results of Operations – Year Ended December 31, 2013 as compared to Year Ended December 31, 2012

The selected summary financial and operating data of Vermillion for the years ended December 31, 2013 and 2012 were as follows:

(dollars in thousands)	Year Ended December 31,		Increase (Decrease)	
	2013	2012	Amount	%
<b>Revenue:</b>				
Product	\$ 2,112	\$ 1,640	\$ 472	29
License	454	454	-	-
Total revenue	2,566	2,094	472	23
<b>Cost of revenue:</b>				
Product	170	131	39	30
Total cost of revenue	170	131	39	30
Gross profit	2,396	1,963	433	22
<b>Operating expenses:</b>				
Research and development	2,595	2,216	379	17
Sales and marketing	4,480	4,653	(173)	(4)
General and administrative	4,184	4,508	(324)	(7)
Total operating expenses	11,259	11,377	(118)	(1)
Loss from operations	(8,863)	(9,414)	551	(6)
Interest income	23	28	(5)	(18)
Interest expense	-	(206)	206	-
Gain on sale of instrument business	-	1,830	(1,830)	-
Gain on litigation settlement, net	-	710	(710)	-
Reorganization items	-	88	(88)	-
Other income (expense), net	21	(182)	203	(112)
Loss before income taxes	(8,819)	(7,146)	(1,673)	23
Income tax benefit (expense)	-	-	-	-
Net loss	\$ (8,819)	\$ (7,146)	\$ (1,673)	23

**Product Revenue.** Product revenue was \$2,112,000 for the year ended December 31, 2013 compared to \$1,640,000 for the same period in 2012. We recognized product revenue for the year ended December 31, 2013 for the sale of OVA1 through Quest Diagnostics. Quest Diagnostics performed approximately 17,004 OVA1 tests during the year ended December 31, 2013 compared to approximately 16,460 tests for the same period in 2012. Product revenue increased \$472,000, or 29%, for the year ended December 31, 2013 compared to the same period in 2012 due to (1) a 14% increase in realized revenue per test, (2) a 22% increase in the number of tests resolved and reported by Quest Diagnostics and (3) a 3% increase in volume of tests performed. Test volumes for territories covered by a Vermillion Territory Development Manager increased by greater than 15% for the year ended December 31, 2013 compared to 2012. This increase was mostly offset by decreases in territories without Vermillion representation.

We recognized \$1,262,000 of deferred revenue in 2013 upon receipt of an annual royalty report from Quest Diagnostics compared to \$816,000 for 2012. The 2013 annual royalty report of \$1,262,000 was based upon 16,745 OVA1 tests reported by Quest Diagnostics as resolved in 2013, or an average of \$75 per test resolved. The resolved volume includes both reimbursed and unreimbursed tests for which the payment status was considered final by Quest Diagnostics as of December 31, 2013. Tests that do not yet have a final resolution for 2013 will be included in a future annual royalty report. By comparison, the 2012 annual royalty report of \$816,000 was based upon 13,709 OVA1 tests reported by Quest Diagnostics as resolved in 2012, or an average of \$60 per test resolved. The royalty report revenue is incremental to the fixed \$50 per test recognized for each OVA1 performed during the year.



**Research and Development Expenses.** Research and development expenses represent costs incurred to develop our technology and carry out clinical studies, and include personnel-related expenses, regulatory costs, reagents and supplies used in research and development laboratory work, infrastructure expenses, contract services and other outside costs. Research and development expenses also include costs related to activities performed under contracts with our collaborators and strategic partners. Research and development expenses increased by \$379,000, or 17%, for the year ended December 31, 2013 compared to the same period in 2012. This increase was due primarily to an increase in payments to JHU support our platform migration and next-generation diagnostic test programs totaling \$261,000 as well as expanded personnel and contractor costs to support those programs. We anticipate that research and development expenses will increase significantly in future periods due to expected costs of our development programs.

**Sales and Marketing Expenses.** Our sales and marketing expenses consist primarily of personnel-related expenses, education and promotional expenses, and infrastructure expenses. These expenses include the costs of educating physicians, laboratory personnel and other healthcare professionals regarding OVA1. Sales and marketing expenses also include the costs of sponsoring continuing medical education, medical meeting participation and dissemination of scientific and health economic publications. Our personnel-related expenses include the cost of our Territory Development Managers, the subject matter experts responsible for market development. Sales and marketing expenses decreased by \$173,000, or 4%, for the year ended December 31, 2013 compared to the same period in 2012 due to lower marketing activity and headcount. However, we anticipate that sales and marketing expenses will increase significantly in future periods due to an increase in our field sales headcount.

**General and Administrative Expenses.** General and administrative expenses consist primarily of personnel-related expenses, professional fees and other costs, including legal, finance and accounting expenses, and other infrastructure expenses. General and administrative expenses decreased by \$324,000, or 7%, for the year ended December 31, 2013 compared to the same period in 2012. The decrease was due to decreases in severance and stock compensation, which were partially offset by the cost of holding two annual meetings in 2013. Also, 2012 included a one-time charge for CEO severance of approximately \$400,000.

**Interest Expense.** Interest expense decreased by \$206,000 for the year ended December 31, 2013 compared to the same period in 2012 as we paid off \$5,894,000 of short-term debt to Quest Diagnostics upon maturity in October 2012. There was no interest expense for the year ended December 31, 2013.

**Gain on sale of instrument business.** Gain on sale of instrument business was \$1,830,000 for the year ended December 31, 2012. This gain was derived from the return in 2012 of funds held in escrow from our 2006 sale of the instrument business to Bio-Rad. There was no gain on sale of instrument business in 2013.

**Gain on litigation settlement, net.** In February 2012, we entered into a Settlement Agreement with Oppenheimer related to losses on our short and long-term investments in previous years. Under the terms of the Settlement Agreement, the total settlement was \$1,000,000 (\$710,000 net after legal fees and costs) all of which was paid in 2012. The gain on litigation settlement represents recognition of the net proceeds received.

## **Liquidity and Capital Resources**

On May 13, 2013, we completed a private placement pursuant to which existing and new investors purchased 8,000,000 shares of our common stock at a price of \$1.46 per share. We also issued warrants to purchase shares of our common stock at a price of \$0.125 per warrant share in the private placement. The proceeds of the private placement were \$13,242,500 (net proceeds of approximately \$11,751,000 after deducting offering expenses). The warrants were exercisable for 12,500,000 million shares of common stock at \$1.46 per share. On December 19, 2013, warrants to purchase 12,086,000 million shares were exercised, and we received additional net proceeds of approximately \$17,647,000 million.

We have incurred significant net losses and negative cash flows from operations since inception. At December 31, 2013, we had an accumulated deficit of \$332,264,000 and stockholders' equity of \$26,766,000. On December 31, 2013, we had \$29,504,000 of cash and cash equivalents and \$3,558,000 of current liabilities. We believe that our current working capital position will be sufficient to meet our working capital needs for at least the next 12 months. We expect cash from OVA1 sales to be our only material, recurring source of cash in 2014.

Our future liquidity and capital requirements will depend upon many factors, including, among others:

- resources devoted to establish sales, marketing and distribution capabilities;
- the rate of product adoption by physicians and patients;
- our plans to acquire or invest in other products, technologies and businesses;
- the market price of our common stock; and
- the insurance payer community's acceptance of and reimbursement for OVA1.

Cash and cash equivalents as of December 31, 2013 and December 31, 2012 were \$29,504,000 and \$8,007,000, respectively. At December 31, 2013 and 2012, working capital was \$26,691,000 and \$5,295,000, respectively.

Net cash used in operating activities was \$8,224,000 for the year ended December 31, 2013, resulting primarily from \$8,819,000 net loss incurred as adjusted for non-cash license revenues of \$454,000, partially offset by \$876,000 of stock-based compensation expense. Net cash used in operating activities also included \$101,000 of cash used from changes in operating assets and liabilities.

Net cash used in operating activities was \$10,398,000 for the year ended December 31, 2012, resulting primarily from \$7,146,000 net loss incurred as adjusted for completion of the 2006 gain on sale of instrument business to Bio-Rad of \$1,830,000 and non-cash license revenues of \$454,000, partially offset by \$1,295,000 of stock-based compensation expense. Net cash used in operating activities also included \$2,472,000 of cash used from changes in operating assets and liabilities mainly driven by the \$2,292,000 decrease of accounts payable and accrued liabilities.

Net cash used in investing activities was \$321,000 for the year ended December 31, 2013 due to the purchase of property and equipment including our IVD instrument purchase to support the platform migration program. Net cash provided by investing activities for the year ended December 31, 2012 was \$1,816,000 due primarily to the receipt of escrow funds upon completion of the 2006 sale of instrument business to Bio-Rad.

Net cash provided by financing activities was \$30,042,000 for the year ended December 31, 2013 due to receipt of \$29,398,000 of net proceeds from sale of common stock and exercise of warrants as well as \$644,000 proceeds from the exercise of stock options. Net cash used in financing activities was \$5,888,000 for the year ended December 31, 2012, which resulted primarily from our \$5,894,000 repayment of short-term debt with Quest Diagnostics in October 2012.

#### **Off-Balance Sheet Arrangements**

As of December 31, 2013, we had no off-balance sheet arrangements that are reasonably likely to have a current or future material effect on our consolidated financial condition, results of operations, liquidity, capital expenditures or capital resources.

#### **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Pursuant to Item 305(e) of Regulation S-K, information is not required.

#### **ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

Our consolidated financial statements, including consolidated balance sheets as of December 31, 2013 and 2012, consolidated statements of operations and comprehensive loss for the years ended December 31, 2013 and 2012, consolidated statements of changes in stockholders' equity for the years ended December 31, 2013 and 2012, consolidated statements of cash flows for the years ended December 31, 2013 and 2012 and notes to our consolidated financial statements, together with a report thereon of our independent registered public accounting firm, dated March 28, 2014, are attached hereto as pages F-1 through F-19.

#### **ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None

#### **ITEM 9A. CONTROLS AND PROCEDURES**

##### ***Evaluation of Disclosure Controls and Procedures***

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and regulations, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Principal Financial Officer, as appropriate, to allow timely decisions regarding required financial disclosure.

An evaluation was performed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Accounting Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rule 13a-15(e) and Rule 15d-15(e) under the Exchange Act, as of December 31, 2013.

Based on that evaluation, our Chief Executive Officer and Chief Accounting Officer have concluded that as of December 31, 2013 our disclosure controls and procedures, as defined in Rule 13a-15(e) and Rule 15(d)-15(e) under the Exchange Act, were effective.

***Management Report on Internal Control over Financial Reporting***

We are responsible for establishing and maintaining adequate internal control over our financial reporting. We have assessed the effectiveness of internal control over financial reporting as of December 31, 2013. Our assessment was based on criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, in Internal Control-Integrated Framework (1992).

Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States of America (“GAAP”). Our internal control over financial reporting includes those policies and procedures that:

- (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and dispositions of our assets;
- (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and board of directors; and
- (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Based on using the COSO criteria, management concluded our internal control over financial reporting as of December 31, 2013 was effective.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management’s assessment of the effectiveness of our internal control over financial reporting as of December 31, 2013, was not subject to attestation by our independent registered public accounting firm pursuant to rules of the SEC that permit a smaller reporting company to provide only management’s report in the Company’s Annual Report on Form 10-K.

***Changes in internal control over financial reporting.***

There was no change in our internal control over financial reporting that occurred during the quarter ended December 31, 2013 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**ITEM 9B. OTHER INFORMATION**

None.

## **PART III**

### **ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

The information regarding our directors, committees of our Board of Directors, our director nomination process, and our executive officers appearing under the heading "Information Regarding the Board of Directors, Committees and Corporate Governance," "Management" and "Section 16(a) Beneficial Ownership Reporting Compliance," of our proxy statement relating to our 2014 Annual Meeting of Stockholders to be held in 2014 (the "2014 Proxy Statement") is incorporated by reference.

Our code of ethics is applicable to all employees, including both our Chief Executive Officer and Principal Financial Officer. This code of ethics is publicly available on our website at <http://www.vermillion.com>.

### **ITEM 11. EXECUTIVE COMPENSATION**

The information appearing under the headings "Board Compensation," "Compensation Discussion and Analysis," "Executive Officer Compensation," "Corporate Governance – Compensation Committee Interlocks and Insider Participation" and "Report of the Compensation Committee" of the 2014 Proxy Statement is incorporated by reference.

### **ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

The information appearing under the heading "Security Ownership of Certain Beneficial Owners and Management" of the 2014 Proxy Statement is incorporated by reference.

See the description regarding our equity compensation plans contained in Item 5 of this Form 10-K and in the notes to our financial statements, attached hereto.

### **ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

The information appearing under the heading "Certain Relationships and Related Transactions" and "Information Regarding the Board of Directors, Committees and Corporate Governance" of the 2014 Proxy Statement is incorporated by reference.

### **ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

The information appearing under the heading "Ratification of the Selection of the Independent Registered Public Accounting Firm for Vermillion" of the 2014 Proxy Statement is incorporated by reference.

## PART IV

### ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) LIST OF DOCUMENTS FILED AS PART OF THIS REPORT:

1. *Financial Statements*

The financial statements and notes thereto, and the report of the independent registered public accounting firm thereon, are set forth on pages F-1 through F-19.

2. *Exhibits*

The exhibits listed in the accompanying index to exhibits are filed or incorporated by reference as part of this Annual Report on Form 10-K.

**VERMILLION, INC.**

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

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Consolidated Balance Sheets at December 31, 2013 and 2012	F-2
Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2013 and 2012	F-3
Consolidated Statements of Changes in Stockholders' Equity for the years ended December 31, 2013 and 2012	F-4
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## **Report of Independent Registered Public Accounting Firm**

Board of Directors and Stockholders  
Vermillion, Inc.  
Austin, Texas

We have audited the accompanying consolidated balance sheets of Vermillion, Inc. (“Company”) as of December 31, 2013 and 2012 and the related consolidated statements of operations and comprehensive loss, changes in stockholders’ equity, and cash flows for the years then ended. These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Vermillion, Inc. at December 31, 2013 and 2012, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

/s/ BDO USA, LLP

Austin, Texas  
March 28, 2014

**Vermillion, Inc.**  
**Consolidated Balance Sheets**  
(Amounts in Thousands, Except Share and Par Value Amounts)

	<b>December 31,</b>	
	<b>2013</b>	<b>2012</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 29,504	\$ 8,007
Accounts receivable	373	137
Prepaid expenses and other current assets	372	348
Total current assets	30,249	8,492
Property and equipment, net	391	142
Total assets	\$ 30,640	\$ 8,634
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 541	\$ 525
Accrued liabilities	1,283	1,074
Short-term debt	1,106	1,106
Deferred revenue	628	492
Total current liabilities	3,558	3,197
Non-current liabilities:		
Long-term deferred revenue	316	770
Total liabilities	3,874	3,967
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, \$0.001 par value, 5,000,000 shares authorized, none issued and outstanding at December 31, 2013 and 2012	-	-
Common stock, \$0.001 par value, 150,000,000 shares authorized; 35,825,673 and 15,200,079 shares issued and outstanding at December 31, 2013 and 2012, respectively	36	15
Additional paid-in capital	358,994	328,097
Accumulated deficit	(332,264)	(323,445)
Total stockholders' equity	26,766	4,667
Total liabilities and stockholders' equity	\$ 30,640	\$ 8,634

See accompanying Notes to Consolidated Financial Statements



**Vermillion, Inc.**  
**Consolidated Statements of Operations and Comprehensive Loss**  
(Amounts in Thousands, Except Share and Per Share Amounts)

	<b>Year Ended December 31,</b>	
	<b>2013</b>	<b>2012</b>
<b>Revenue:</b>		
Product	\$ 2,112	\$ 1,640
License	454	454
Total revenue	2,566	2,094
<b>Cost of revenue:</b>		
Product	170	131
Total cost of revenue	170	131
Gross profit	2,396	1,963
<b>Operating expenses:</b>		
Research and development <sup>(1)</sup>	2,595	2,216
Sales and marketing <sup>(2)</sup>	4,480	4,653
General and administrative <sup>(3)</sup>	4,184	4,508
Total operating expenses	11,259	11,377
Loss from operations	(8,863)	(9,414)
Interest income	23	28
Interest expense	-	(206)
Gain on sale of instrument business	-	1,830
Gain on litigation settlement, net	-	710
Reorganization items	-	88
Other income (expense), net	21	(182)
Loss before income taxes	(8,819)	(7,146)
Income tax benefit (expense)	-	-
Net loss	\$ (8,819)	\$ (7,146)
Net loss per share - basic and diluted	\$ (0.42)	\$ (0.48)
Weighted average common shares used to compute basic and diluted net loss per common share	20,926,336	15,010,868
Net loss	\$ (8,819)	\$ (7,146)
Foreign currency translation adjustment	-	153
Comprehensive loss	\$ (8,819)	\$ (6,993)
<b>Non-cash stock-based compensation expense included in operating expenses:</b>		
(1) Research and development	\$ 76	\$ 127
(2) Sales and marketing	163	203
(3) General and administrative	637	965

See accompanying Notes to Consolidated Financial Statements

**Vermillion, Inc.**  
**Consolidated Statements of Changes in Stockholders' Equity**  
(Amounts in Thousands, Except Share Amounts)

	<u>Common Stock</u>					
	Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
<b>Balance at December 31, 2011</b>	14,900,831	\$ 15	\$ 326,796	\$ (316,299)	(153)\$	10,359
Net loss	-	-	-	(7,146)	-	(7,146)
Foreign currency translation adjustment	-	-	-	-	153	153
Common stock issued in conjunction with exercise of stock options	8,333	-	6	-	-	6
Common stock issued for restricted stock awards	290,915	-	715	-	-	715
Warrants issued for services	-	-	14	-	-	14
Stock compensation charge	-	-	566	-	-	566
<b>Balance at December 31, 2012</b>	15,200,079	15	328,097	(323,445)	-	4,667
Net loss	-	-	-	(8,819)	-	(8,819)
Common stock and warrants issued in conjunction with private placement sale, net of issuance costs	8,000,000	8	11,743	-	-	11,751
Warrant exercises	12,086,641	12	17,635	-	-	17,647
Common stock issued in conjunction with exercise of stock options	371,348	1	643	-	-	644
Common stock issued for restricted stock awards	167,605	-	361	-	-	361
Warrants issued for services	-	-	34	-	-	34
Stock compensation charge	-	-	481	-	-	481
<b>Balance at December 31, 2013</b>	<u>35,825,673</u>	<u>\$ 36</u>	<u>\$ 358,994</u>	<u>\$ (332,264)</u>	<u>-\$</u>	<u>26,766</u>

See accompanying Notes to Consolidated Financial Statements

**Vermillion, Inc.**  
**Consolidated Statements of Cash Flows**  
(Amounts in Thousands)

	<b>Year Ended December 31,</b>	
	<b>2013</b>	<b>2012</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (8,819)	\$ (7,146)
Adjustments to reconcile net loss to net cash used in operating activities:		
Foreign currency loss on liquidation	-	153
Non-cash license revenue	(454)	(454)
Loss on sale and disposal of property and equipment	-	2
Depreciation and amortization	72	86
Stock-based compensation expense	842	1,281
Warrants issued for services	34	14
Gain from sale of instrument business to Bio-Rad	-	(1,830)
Changes in operating assets and liabilities:		
Increase in accounts receivable	(236)	(38)
Increase in prepaid expenses and other current assets	(24)	(31)
Decrease in other assets	-	2
Increase (decrease) in accounts payable and accrued liabilities	225	(2,292)
Increase (decrease) in deferred revenue	136	(61)
Decrease in other liabilities	-	(52)
Reorganization items	-	(32)
Net cash used in operating activities	<u>(8,224)</u>	<u>(10,398)</u>
<b>Cash flows from investing activities:</b>		
Proceeds from the sale of instrument business to Bio-Rad	-	1,830
Purchase of property and equipment	(321)	(14)
Net cash provided by (used in) investing activities	<u>(321)</u>	<u>1,816</u>
<b>Cash flows from financing activities:</b>		
Principal repayment of short-term debt	-	(5,894)
Proceeds from sale of common stock and warrants, net of issuance costs	11,751	-
Proceeds from exercise of common stock warrants	17,647	-
Proceeds from issuance of common stock from exercise of stock options	644	6
Net cash provided by (used in) financing activities	<u>30,042</u>	<u>(5,888)</u>
Net increase (decrease) in cash and cash equivalents	21,497	(14,470)
Cash and cash equivalents, beginning of year	8,007	22,477
Cash and cash equivalents, end of year	<u>\$ 29,504</u>	<u>\$ 8,007</u>
<b>Supplemental disclosure of cash flow information:</b>		
<b>Cash paid during the period for:</b>		
Interest	\$ -	\$ 227
Income taxes	-	-

See accompanying Notes to Consolidated Financial Statements

**Vermillion, Inc.**  
Notes to Consolidated Financial Statements

**NOTE 1: BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING AND REPORTING POLICIES**

***Organization***

Vermillion, Inc. (“Vermillion”); Vermillion and its wholly-owned subsidiaries are collectively referred to as the “Company”) is incorporated in the state of Delaware, and is engaged in the business of developing and commercializing diagnostic tests in the fields of gynecologic oncology and women’s health. In March 2010, the Company commercially launched OVA1™ ovarian tumor triage test (“OVA1”). The Company distributes OVA1 through Quest Diagnostics Incorporated (“Quest Diagnostics”), which had the non-exclusive right to commercialize OVA1 on a worldwide basis, with exclusive commercialization rights in the clinical reference laboratory marketplace in each exclusive territory through September 2014, with the right to extend the exclusivity period for one additional year. These exclusive territories include the United States, India, Mexico, and the United Kingdom. The Company terminated the agreement and exclusivity with Quest Diagnostics on August 23, 2013 but the effectiveness of such termination has been disputed by Quest Diagnostics as discussed in Note 3.

***Liquidity***

On May 13, 2013, the Company completed a private placement pursuant to which existing and new investors purchased 8,000,000 shares of Vermillion common stock at a price of \$1.46 per share. The Company also issued warrants to purchase shares of common stock at a price of \$0.125 per warrant share in the private placement. The proceeds of the private placement were \$13,242,500 (net proceeds of approximately \$11,751,000 after deducting offering expenses). The warrants were exercisable for 12,500,000 shares of Vermillion common stock at \$1.46 per share. On December 19, 2013, warrants to purchase 12,087,000 shares were exercised and the Company received additional net proceeds of approximately \$17,647,000.

There can be no assurance that the Company will achieve or sustain profitability or positive cash flow from operations. However, management believes that the current working capital position will be sufficient to meet the Company’s working capital needs for at least the next 12 months. Management expects cash from OVA1 sales to be the Company’s only material, recurring source of cash in 2014.

***Basis of Consolidation***

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany transactions have been eliminated in consolidation.

***Use of Estimates***

The preparation of consolidated financial statements in accordance with generally accepted accounting principles in the U.S. (“GAAP”) requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. The primary estimates underlying our consolidated financial statements include assumptions regarding variables used in calculating the fair value of our equity awards, income taxes and contingent liabilities. Actual results could differ from those estimates.

***Cash and Cash Equivalents***

Cash and cash equivalents consist of cash and highly liquid investments with maturities of three months or less from the date of purchase, which are readily convertible into known amounts of cash and are so near to their maturity that they present an insignificant risk of changes in value because of interest rate changes. Highly liquid investments that are considered cash equivalents include money market funds, certificates of deposits, treasury bills and commercial paper. The carrying value of cash equivalents approximates fair value due to the short-term maturity of these securities.

***Fair Value Measurement***

Accounting Standards Codification Topic 820 *Fair Value and Measurements* (“ASC 820”), defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. ASC 820 also establishes a fair value hierarchy which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The standard describes three levels of inputs that may be used to measure fair value:

Level 1 - Quoted prices in active markets for identical assets or liabilities.

Level 2 - Observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

If a financial instrument uses inputs that fall in different levels of the hierarchy, the instrument will be categorized based upon the lowest level of input that is significant to the fair value calculation.

### ***Concentration of Credit Risk***

Financial instruments that potentially subject us to a concentration of credit risk consist of cash and cash equivalents and accounts receivable. The Company maintains cash and cash equivalents in recognized financial institutions in the United States. The Company has not experienced any losses associated with deposits of cash and cash equivalents. The Company does not invest in derivative instruments or engage in hedging activities.

Accounts receivable are derived from sales made to a customer located in North America. The Company performs ongoing credit evaluations of its customer's financial condition and generally does not require collateral. The Company maintains an allowance for doubtful accounts based upon the expected collectability of accounts receivable. Accounts receivable at December 31, 2013 and 2012 and revenues for the years then ended are from one customer.

### ***Property and Equipment***

Property and equipment are carried at cost less accumulated depreciation and amortization. Property and equipment are depreciated when placed into service using the straight-line method over the estimated useful lives, generally three to five years. Leasehold improvements are amortized using the straight-line method over the shorter of the estimated useful life of the asset or the remaining term of the lease. Maintenance and repairs are charged to operations as incurred. Upon sale or retirement of assets, the cost and related accumulated depreciation are removed from the balance sheet and the resulting gain or loss is reflected in operations.

Property and equipment are reviewed for impairment when events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. If property and equipment are considered to be impaired, an impairment loss is recognized.

### ***Revenue Recognition***

*Product Revenue:* The Company derives product revenues from sales of OVA1 through Quest Diagnostics. Product revenues are recognized for tests performed when the following revenue recognition criteria are met: (1) persuasive evidence that an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured.

*License Revenue:* Under the terms of the secured line of credit with Quest Diagnostics, portions of the borrowed principal amounts may be forgiven upon achievement of certain milestones relating to the development, regulatory approval and commercialization of certain diagnostic tests (see Note 3). The Company accounts for forgiveness of principal debt balances as license revenues over the term of the exclusive sales period that Quest Diagnostics received upon commercialization of an approved diagnostic test as the Company does not have a sufficient history of product sales that provides a reasonable basis for estimating future product sales. License revenue is recognized on a straight-line basis over the original remaining period of Quest Diagnostics' sales exclusivity ending in September 2015 as Quest Diagnostics has disputed the termination of exclusivity in August 2013.

### ***Research and Development Costs***

Research and development costs are expensed as incurred. Research and development costs consist primarily of payroll and related costs, materials and supplies used in the development of new products, and fees paid to third parties that conduct certain research and development activities on our behalf. In addition, acquisitions of assets to be consumed in research and development are expensed as incurred as research and development costs. Software development costs incurred in the research and development of new products are expensed as incurred until technological feasibility is established.

### ***Patent Costs***

Costs incurred in filing, prosecuting and maintaining patents (principally legal fees) are expensed as incurred and recorded within selling, general and administrative expenses on the Consolidated Statements of Operations and Comprehensive Loss. Such costs aggregated approximately \$475,000 and \$312,000 for the years ended December 31, 2013 and 2012, respectively.

### ***Stock-Based Compensation***

The Company records the fair value of non-cash stock-based compensation costs for stock options and stock purchase rights related to the Vermillion, Inc. Amended and Restated 2010 Stock Incentive Plan (the "2010 Plan"). The Company estimates the fair value of stock options using a Black-Scholes option valuation model which requires the input of subjective assumptions including expected stock price volatility, expected life and estimated forfeitures of each award. These assumptions consist of estimates of future market conditions, which are inherently uncertain, and therefore are subject to management's judgment.

The expected life of options is based on historical data of actual experience with the options granted and represents the period of time that the options granted are expected to be outstanding. This data includes employees' expected exercise and post-vesting

employment termination behaviors. The expected stock price volatility is estimated using a combination of historical and peer group volatility for a blended volatility in deriving the expected volatility assumption. The Company made an assessment that blended volatility is more representative of future stock price trends than just using historical or peer group volatility, which corresponds to the expected life of the options. The expected dividend yield is based on the estimated annual dividends that is expected to be paid over the expected life of the options as a percentage of the market value of our common stock as of the grant date. The risk-free interest rate for the expected life of the options granted is based on the United States Treasury yield curve in effect as of the grant date. The Company uses the straight-line method to amortize the fair value over the vesting period of the award.

The Company also records the fair value of non-cash stock-based compensation costs for equity instruments issued to non-employees. The cost for these options are recalculated each reporting period using a Black-Scholes option valuation model. A change in assumptions used in the calculations, including changes in the fair value of common stock, can result in significant changes in the amounts recorded from one reporting period to another.

### ***Contingencies***

The Company accounts for contingencies in accordance with ASC 450 *Contingencies* ("ASC 450") which requires that an estimated loss from a loss contingency be accrued when (i) information available prior to issuance of the financial statements indicates that it is probable that an asset has been impaired or a liability has been incurred at the date of the financial statements and (ii) when the amount of the loss can be reasonably estimated. Accounting for contingencies such as legal and contract dispute matters requires the use of management's judgment. Management believes that accruals for these matters are adequate. Nevertheless, the actual loss from a loss contingency might differ from management's estimates.

### ***Income Taxes***

The Company accounts for income taxes using the liability method. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and the tax bases of assets and liabilities using the current tax laws and rates. A valuation allowance is established when necessary to reduce deferred tax assets to the amounts more likely than not expected to be realized.

ASC Topic 740, *Accounting for Uncertainty in Income Taxes* clarifies the accounting for uncertainty in income taxes recognized in the financial statements and provides that a tax benefit from an uncertain tax position may be recognized when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, based on the technical merits. This interpretation also provides guidance on measurement, derecognition, classification, interest and penalties, accounting in interim periods, and disclosure.

The Company recognizes interest and penalties related to unrecognized tax benefits within the interest expense line and other expense line, respectively, in the Consolidated Statements of Operations. Accrued interest and penalties are included within the related liability lines in the Consolidated Balance Sheets.

### ***Foreign Currency Translation***

Ciphergen Biosystems KK, the Company's Japanese subsidiary, was liquidated during 2012 and, consequently, the accumulated other comprehensive loss totaling \$153,000 was recognized in the Consolidated Statement of Operations for 2012 and included in Other Expense in the Consolidated Statements of Operations and Comprehensive Loss.

### ***Net Loss Per Share***

Basic net loss per share is computed by dividing the net loss by the weighted average number of common stock shares outstanding during the period. Diluted loss per share is computed by dividing the net loss by the weighted average number of common stock shares adjusted for the dilutive effect of common stock equivalent shares outstanding during the period. Common stock equivalents consist of stock options, restricted stock units and stock warrants. Common equivalent shares are excluded from the computation in periods in which they have an anti-dilutive effect on earnings per share.

### ***Fair Value of Financial Instruments***

Financial instruments include cash and cash equivalents, accounts receivable, accounts payable, accrued liabilities and short-term debt. The estimated fair value of financial instruments has been determined using available market information or other appropriate valuation methodologies. However, considerable judgment is required in interpreting market data to develop estimates of fair value; therefore, the estimates are not necessarily indicative of the amounts that could be realized or would be paid in a current market exchange. The effect of using different market assumptions and/or estimation methodologies may be material to the estimated fair value amounts. The carrying amounts of cash and cash equivalents, accounts receivable, accounts payable, accrued liabilities and short-term debt are at cost, which approximates fair value due to the short maturity of those instruments.

### ***Segment Reporting***

The Company operates one reportable segment.

**NOTE 2: RECENT ACCOUNTING PRONOUNCEMENTS**

In February 2013, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) number 2013-02, Other Comprehensive Income (Topic 220): Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income to improve the reporting of reclassifications out of accumulated other comprehensive income. ASU 2013-02 requires reporting the effect of significant reclassifications out of accumulated other comprehensive income on the respective line items in net income. The adoption of this ASU on January 1, 2013 did not affect the accompanying consolidated financial statements, but could require additional disclosure, if applicable, in future periods.

In July 2013, the FASB issued ASU number 2013-11, Income Taxes (Topic 740): Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists — a consensus of the FASB Emerging Issues Task Force. ASU 2013-11 generally requires, with some exceptions, an entity to present its unrecognized tax benefits as it relates to its net operating loss carryforwards, similar tax losses, or tax credit carryforwards, as a reduction of deferred tax assets when settlement in this regard is available under the tax law of the applicable taxing jurisdiction as of the balance sheet reporting date. It is effective prospectively for fiscal years, and interim periods within those years, beginning after December 15, 2013. Retrospective application is permitted. The Company does not anticipate a material impact on our financial position, results of operations or cash flows as a result of this change.

**NOTE 3: STRATEGIC ALLIANCE AND SECURED LINE OF CREDIT WITH QUEST DIAGNOSTICS INCORPORATED**

Quest Diagnostics is a holder of the Company’s common stock. In July 2005, the Company entered into a Strategic Alliance Agreement (as amended, the “Strategic Alliance Agreement”) with Quest Diagnostics to develop and commercialize up to three diagnostic tests from our product pipeline. In connection with the Strategic Alliance Agreement, the Company entered into a credit agreement with Quest Diagnostics, pursuant to which Quest Diagnostics provided the Company with a \$10,000,000 secured line of credit to be used to pay for certain costs and expenses related to activities under the Strategic Alliance agreement. This line of credit was collateralized by certain of our intellectual property assets. Pursuant to the Strategic Alliance Agreement, Quest Diagnostics selected two diagnostic tests to be commercialized, a peripheral arterial disease diagnostic test (differentiated from our existing program) and OVA1. The credit agreement provided for the forgiveness of portions of the amounts borrowed under the secured line of credit upon the achievement of certain milestones related to the development, regulatory approval and commercialization of certain diagnostic tests. If not otherwise forgiven, the \$10,000,000 principal amount outstanding under this secured line of credit became due and payable on October 7, 2012. Through December 31, 2013, a total of \$3,000,000 has been acknowledged as forgiven by Quest Diagnostics based upon milestone achievement.

The Company believes that in September 2009 when the United States Food and Drug Administration (the “FDA”) cleared our application for a licensed laboratory test of OVA1 to be commercialized, the Company achieved a milestone under the credit agreement, resulting in a \$1,000,000 reduction of the outstanding principal amount borrowed under the credit agreement. However, Quest Diagnostics has disputed whether this milestone has been achieved.

In September 2009, the Company achieved another milestone under the credit agreement, resulting in a \$3,000,000 further reduction in the principal amount borrowed under the credit agreement. Although the Company believed that, following this reduction, the principal balance under the line of credit was \$6,000,000, the Company made monthly payments to Quest Diagnostics on the secured line of credit based on a principal balance of \$7,000,000, resulting in a curtailment of the principal balance of \$106,000. However, Quest Diagnostics has disputed that such additional principal curtailment was made.

On October 12, 2012, the Company paid Quest Diagnostics approximately \$5,894,000 of principal which the Company believes represented payment in full of all then outstanding principal under the secured line of credit. However, the Company continues to show the amount of the liability as \$1,106,000 as of December 31, 2013 and 2012 because Quest Diagnostics has disputed that the \$1,000,000 milestone was met and the \$106,000 principal curtailment was made. There was no interest expense on the secured line of credit for the year ended December 31, 2013 and \$206,000 of interest expense for the year ended December 31, 2012.

Unrelated to the debt dispute described above, on May 23, 2013, the Company sent Quest Diagnostics a notice of default under the Strategic Alliance Agreement relating to a number of its material violations, breaches and failures to perform under the Strategic Alliance Agreement. The Strategic Alliance Agreement states that if a party fails to cure material defaults within 90 days of the date of the notice of default, the other party has the right to terminate the Strategic Alliance Agreement. Quest Diagnostics has disputed the effectiveness of our notice of default. On August 23, 2013, the Company sent Quest Diagnostics a notice of termination. Notwithstanding the termination, the Company agreed that Quest Diagnostics can continue to make OVA1 available to healthcare providers on the same financial terms following the termination while negotiating in good faith towards an alternative business structure. Prior to the termination, Quest Diagnostics had the non-exclusive right to commercialize OVA1 on a worldwide basis, with exclusive commercialization rights in the clinical reference laboratory marketplace in the United States, India, Mexico, and the United Kingdom through September 2014, with the right to extend the exclusivity period for one additional year. Quest Diagnostics has disputed the effectiveness of the Company’s notice of termination.

Accounts receivable from Quest Diagnostics totaled \$373,000 and \$137,000 at December 31, 2013 and 2012, respectively.

**NOTE 4: PROPERTY AND EQUIPMENT**

The components of property and equipment as of December 31, 2013 and 2012 were as follows:

(in thousands)	December 31,	
	2013	2012
Machinery and equipment	\$ 501	\$ 193
Demonstration equipment	33	33
Computer equipment and software	116	114
Furniture and fixtures	75	65
Gross property and equipment	725	405
Accumulated depreciation and amortization	(334)	(263)
Property and equipment, net	<u>\$ 391</u>	<u>\$ 142</u>

Depreciation expense for property and equipment was \$72,000 and \$86,000 for the years ended December 31, 2013 and 2012, respectively.

**NOTE 5: ACCRUED LIABILITIES**

The components of accrued liabilities as of December 31, 2013 and 2012 were as follows:

(in thousands)	December 31,	
	2013	2012
Payroll and benefits related expenses	\$ 548	\$ 464
Collaboration and research agreements expenses	187	133
Professional services	262	236
Tax-related liabilities	42	17
Other accrued liabilities	244	224
Total accrued liabilities	<u>\$ 1,283</u>	<u>\$ 1,074</u>

**NOTE 6: COMMITMENTS AND CONTINGENCIES**

***Operating Leases***

The Company leases facilities to support its business of discovering, developing and commercializing diagnostic tests in the fields of gynecologic oncology and women’s health. On June 1, 2010, Vermillion entered into a noncancelable operating lease for a new principal facility located in Austin, Texas. The lease includes an annual base rent of \$75,000 and annual estimated common area charges, taxes and insurance of \$37,000 and expires May 31, 2014.

Rental expense under operating leases for the years ended December 31, 2013 and 2012 totaled \$96,000 and \$110,000, respectively.

***Noncancelable Collaboration Obligations and Other Commitments***

Vermillion has a research collaboration agreement with The Johns Hopkins University School of Medicine (“JHU”) directed at the discovery and validation of biomarkers in human subjects, including but not limited to clinical application of biomarkers in the understanding, diagnosis and management of human disease through March 2016. In October 2013, Vermillion amended the research and collaboration agreement with the JHU and agreed to pay approximately \$1,600,000 through June 2015 for assistance with (1) the migration of the existing OVA1 test to a new platform and (2) the development, submission and launch of a next-generation ovarian cancer diagnostic. Collaboration expenses under the JHU collaboration were \$658,000 and \$251,000 for the years ended December 31, 2013 and 2012, respectively. Collaboration expenses under the JHU collaboration are included in research and development expenses. In addition, under the terms of the amended research collaboration agreement, Vermillion is required to pay the greater of 4% royalties on net sales of diagnostic tests using the assigned patents or annual minimum royalties of \$57,500.



## ***Gain on Litigation Settlement***

In February 2012, the Company entered into a settlement agreement with Oppenheimer & Co., Inc. (“Oppenheimer”) related to losses on short and long-term investments in previous years. Under the terms of the settlement agreement, the total settlement was \$1,000,000 (\$710,000 net after legal fees and costs), all of which was paid in 2012. The gain on litigation settlement represents recognition of the net proceeds received.

## ***Contingent Liabilities***

### ***Molecular Analytical Systems, Inc. Litigation***

On July 9, 2007, Molecular Analytical Systems (“MAS”) filed a lawsuit in the Superior Court of California for the County of Santa Clara (“Superior Court”) naming Vermillion and Bio-Rad Laboratories, Inc. (“Bio-Rad”) as defendants (the “State Court lawsuit”). In connection with the State Court lawsuit, MAS alleged that the Company breached the license agreement with MAS by transferring certain Surface-Enhanced Laser Desorption/Ionization (“SELDI”) technology to Bio-Rad without obtaining MAS’s consent. MAS listed the value of its claim as in excess of \$5,000,000. Thereafter, the Superior Court ordered that the dispute be arbitrated before the Judicial Arbitration and Mediation Service (“JAMS”). MAS filed its demand for arbitration in 2010 and the arbitration hearing occurred in 2011. On February 23, 2012, an interim arbitration award was issued by the arbitrator. In the interim arbitration award, the arbitrator denied MAS’s claim for breach of the license agreement as well as several other of MAS’s claims. The arbitrator found that MAS was entitled to an accounting concerning our 2% royalty obligation to MAS either through February 21, 2013 or until cumulative royalty payments reach \$10 million, whichever comes first, and ordered that such royalties should be based on total GAAP revenues less revenues attributable to certain excluded entities, not just SELDI-related revenues. Subsequently, the parties agreed to resolve (i) any and all remaining royalty obligations owed to MAS from the Company and (ii) any and all claims for fees and costs that the Company had against MAS in return for Vermillion making a one-time payment to MAS of \$35,000. The Company submitted to JAMS a mutual stipulation consistent with that agreement and the Arbitrator entered a final arbitration award incorporating that stipulation on May 21, 2012. At the Company’s request, the Superior Court (i) confirmed the final arbitration award and (ii) entered the final arbitration award as the final judgment in this case on July 26, 2012.

### ***Bio-Rad Laboratories, Inc. Matters***

On November 13, 2006, the Company completed the “Instrument Business Sale” to Bio-Rad. The Instrument Business Sale included the SELDI technology, ProteinChip arrays and accompanying software. Pursuant to the terms of the sales agreement, the total sales price was \$20,000,000, of which \$16,000,000 was paid by Bio-Rad at the closing of the transaction on November 13, 2006. A total of \$4,000,000 was held back from the sales proceeds contingent upon the Company’s meeting certain obligations, of which \$2,000,000 was subsequently paid and \$307,000 was paid to settle certain employee termination indemnifications in fiscal 2007. From the amounts held back and interest thereon, \$1,830,000 was being held in escrow as of December 31, 2011 to serve as security for the Company to fulfill certain obligations.

In August 2009, Bio-Rad also filed a proof of claim in the bankruptcy case for indemnification of the MAS lawsuit. Management has subsequently received a final arbitration ruling from JAMS and settled the MAS claim. At the Company’s request, the Superior Court (i) confirmed the final arbitration award and (ii) entered the final arbitration award as the final judgment in this case on July 26, 2012. Thus, the Company believes that the possibility of any material loss from the indemnification of the MAS lawsuit is remote.

In connection with the Instrument Business Sale, the Company also entered into a manufacture and supply agreement with Bio-Rad on November 13, 2006, whereby the Company agreed to purchase ProteinChip Systems and ProteinChip Arrays from Bio-Rad. In October 2009, Bio-Rad filed a proof of claim in the bankruptcy case based on certain contract claims and alleged breach of the manufacture and supply agreement for approximately \$1,000,000.

In April 2012, the Company resolved the four contract claims made by Bio-Rad arising from the Instrument Business Sale. In exchange for a final settlement of these non-contingent claims, Bio-Rad received \$700,000 from the escrow account established by the Company for the sale transaction, and the Company was returned approximately \$1,080,000 from the escrow account. The final \$50,000 was returned to the Company in September 2012 after final resolution of the MAS lawsuit. The Company reversed \$375,000 of general and administrative expense accrued in previous periods during the year ended December 31, 2012 representing the accrued estimated liability in excess of the \$700,000 settlement amount. The Company recognized the resulting gain on sale of instrument business of \$1,830,000 from the release of the escrow account during the year ended December 31, 2012.

In addition, from time to time, the Company is involved in legal proceedings and regulatory proceedings arising from operations. The Company establishes reserves for specific liabilities in connection with legal actions that management deems to be probable and estimable. Other than as disclosed above, the Company is not currently a party to any proceeding, the adverse outcome of which would have a material adverse effect on the Company’s financial position or results of operations.

## NOTE 7: COMMON STOCK

### *2013 Private Placement Sale*

On May 13, 2013, the Company completed a private placement pursuant to which existing and new investors purchased 8,000,000 shares of Vermillion common stock at a price of \$1.46 per share. In the private placement, Vermillion also issued warrants to purchase shares of common stock at a price of \$0.125 per warrant share. The proceeds of the private placement were \$13,242,500 (net proceeds of approximately \$11,751,000 after deducting offering expenses). The warrants were exercisable for 12,500,000 shares of common stock at \$1.46 per share and expire on May 13, 2016. On December 19, 2013, certain holders of the exercised warrants to purchase 12,087,000 common shares for net proceeds of \$17,647,000.

The purchase of common stock and warrants qualified for equity treatment under GAAP. The respective values of the warrants and common stock were calculated using their relative fair values and classified under common stock and additional paid in capital. The value ascribed to the warrants is \$9,300,000 and for the common stock is \$3,943,000.

In connection with the private placement, Vermillion entered into a stockholders agreement with the purchasers named in that agreement. Pursuant to and subject to the terms of the stockholders agreement, certain of the investors received rights to participate in any future equity offerings on the same price and terms as other investors. In addition, the stockholders agreement prohibits the Company from taking material actions without the consent of at least one of the two primary investors. These material actions include:

- Making any acquisition with value greater than \$2 million;
- Entering into, or amending the terms of agreements with Quest Diagnostics, provided that such investors' consent shall not be unreasonably withheld, conditioned or delayed following good faith consultation with the Company;
- Submitting any resolution at a meeting of stockholders or in any other manner changing or authorizing a change in the size of the Board of Directors;
- Offering, selling or issuing any securities senior to Vermillion's common stock or any securities that are convertible into or exchangeable or exercisable for securities ranking senior to Vermillion's common stock;
- Amending Vermillion's certificate of incorporation or by-laws in any manner that affects the rights, privileges or economics of Vermillion's common stock or the warrants described above;
- Taking any action that would result in a change in control of Vermillion or an insolvency event;
- Paying or declaring dividends on any securities of the Company or distributing any assets of the Company other than in the ordinary course of business or repurchasing any outstanding securities of the Company; or
- Adopting or amending any shareholder rights plan.

In addition, the two primary investors each received the right to designate a person to serve on Vermillion's Board of Directors. These rights terminate for each stockholder when that stockholder ceases to beneficially own less than 50% of the shares and warrants (taking into account shares issued upon exercise of the warrants), in the aggregate, than were purchased at the closing of the private placement.

## Warrants

Warrants outstanding as of December 31, 2013 and 2012 were as follows:

Issuance Date	Expiration Date	Exercise Price per Share	Number of Shares Outstanding under Warrant	
			December 31, 2013	December 31, 2012
November 1, 2011	October 31, 2013	\$ 3.23	-	21,000
May 1, 2012	April 30, 2014	\$ 3.18	21,000	21,000
November 1, 2012	October 31, 2014	\$ 1.93	21,000	21,000
May 1, 2013	April 30, 2015	\$ 1.88	21,000	-
May 13, 2013	May 13, 2016	\$ 1.46	413,359	-
November 1, 2013	October 31, 2015	\$ 3.89	21,000	-
			497,359	63,000

Vermillion periodically issues common stock warrants to a vendor in exchange for services. The warrants vest pro-rata on a monthly basis over a six month period and expire two years after issuance. The value of the warrants as determined by the Black-Sholes model was not significant and is classified as equity.

### NOTE 8: LOSS PER SHARE

The reconciliation of the numerators and denominators of basic and diluted loss per share for the years ended December 31, 2013 and 2012 was as follows:

(In thousands, except per share data)	Loss (Numerator)	Shares (Denominator)	Per Share Amount
Year ended December 31, 2012:			
Net loss - basic	\$ (7,146)	15,010,868	\$ (0.48)
Dilutive effect of common stock shares issuable upon exercise of stock options, exercise of warrants, and unvested restricted stock awards	-	-	
Net loss - diluted	\$ (7,146)	15,010,868	\$ (0.48)
Year ended December 31, 2013:			
Net loss - basic	\$ (8,819)	20,926,336	\$ (0.42)
Dilutive effect of common stock shares issuable upon exercise of stock options, exercise of warrants, and unvested restricted stock awards	-	-	
Net loss - diluted	\$ (8,819)	20,926,336	\$ (0.42)

Due to net losses for the years ended December 31, 2013 and 2012, diluted loss per share is calculated using the weighted average number of common shares outstanding and excludes the effects of potential common stock shares that are antidilutive.

The potential shares of common stock that have been excluded from the diluted loss per share calculation above for the years ended December 31, 2013 and 2012 were as follows:

	Year Ended December 31,	
	2013	2012
Stock options	1,447,968	1,092,374
Stock warrants	497,359	63,000
Restricted stock units	1,667	8,334
Potential common shares	1,946,994	1,163,708

**NOTE 9: EMPLOYEE BENEFIT PLANS*****2000 Stock Plan***

Under the Amended and Restated 2000 Stock Plan (the “2000 Plan”), options may be granted at prices not lower than 85% and 100% of the fair market value of the common stock for non-statutory and statutory stock options, respectively. Options generally vest monthly over a period of four years and unexercised options generally expire ten years from the date of grant. The authority of Vermillion’s Board of Directors to grant new stock options and awards under the 2000 Plan terminated in 2010. Options to purchase 125,000 and 8,333 shares of common stock were exercised during the years ended December 31, 2013 and 2012, respectively. As of December 31, 2013, options to purchase 197,506 shares of common stock remained outstanding under the 2000 Plan. No additional shares of common stock were reserved for future option grants under the 2000 Plan.

***2010 Stock Incentive Plan***

In February 2010, Vermillion’s Board of Directors approved the Amended and Restated Vermillion, Inc. 2010 Stock Incentive Plan (the “2010 Plan”). The 2010 Plan is administered by the Compensation Committee of the Board of Directors. Employees, directors, and consultants of the company are eligible to receive awards under the 2010 Plan. The 2010 Plan permits the granting of a variety of awards, including stock options, share appreciation rights, restricted shares, restricted share units, unrestricted shares, deferred share units, performance and cash-settled awards, and dividend equivalent rights. The 2010 Plan provided for issuance of up to 1,322,983 shares of common stock, par value \$0.001 per share under the 2010 Plan, subject to adjustment as provided in the 2010 Plan. On December 12, 2013, the Company’s stockholders approved an increase of 2,300,000 in the number of shares available for issuance under the 2010 Plan for a total of 3,622,983 shares. Unexercised options generally expire ten years from the date of grant. Options to purchase 246,348 shares of common stock were exercised during the year ended December 31, 2013. There were no 2010 Plan option exercises for the year ended December 31, 2012.

During the year ended December 31, 2011, the Company awarded 177,000 shares of restricted stock from the 2010 Plan having a fair value of \$724,000 to Vermillion’s executive officers. All such restricted stock vests ratably on a quarterly basis over a three year period beginning on the vesting commencement in March 2011. The Company distributed 6,667 and 78,415 of these shares of common stock to Vermillion’s executive officers during the years ended December 31, 2013 and 2012, respectively.

During the year ended December 31, 2013, the Company issued 160,938 shares of restricted stock from the 2010 Plan having a fair value of \$334,000 to the Board of Directors as payment for services rendered in 2013. During the year ended December 31, 2012, the Company issued 212,500 shares of restricted stock from the 2010 Plan having a fair value of \$414,000 to Vermillion’s Board of Directors as payment for services rendered in 2012.

Subsequent to December 31, 2013, the Company awarded 152,000 shares of restricted stock from the 2010 Plan having a fair value of approximately \$470,000 to Vermillion’s Board of Directors as payment for services in 2014. The restricted stock vest 50% on June 1, 2014 and 25% each on September 1, 2014 and December 1, 2014. Additionally, the Company granted 151,500 stock options with an exercise price of \$2.88 per share to Vermillion’s Chairman of the Board of Directors. The stock options vest over a four year period with 25% of the stock options vesting on December 12, 2014 and the balance in 36 equal monthly installments thereafter. The Company also granted approximately 422,000 stock options with an exercise price of \$3.09 per share to certain Vermillion officers and employees. The stock options vest in 48 equal monthly installments.

The activity related to shares available for grant under the 2000 Plan and 2010 Plan for the years ended December 31, 2013 and 2012 was as follows:

	2000 Stock Plan	2010 Stock Option Plan	Total
Shares available at December 31, 2011	-	628,675	628,675
Options canceled	251,058	136,595	387,653
Reduction in shares reserved	(251,058)	-	(251,058)
Options granted	-	(558,300)	(558,300)
Restricted stock units canceled	-	28,001	28,001
Restricted stock units granted	-	(212,500)	(212,500)
Shares available at December 31, 2012	-	22,471	22,471
Additional shares reserved	-	2,300,000	2,300,000
Options canceled	14,150	68,908	83,058
Reduction in shares reserved	(14,150)	-	(14,150)
Options granted	-	(810,000)	(810,000)
Restricted stock units granted	-	(160,938)	(160,938)
Shares available at December 31, 2013	-	1,420,441	1,420,441

The stock option activity under the 2000 Plan and 2010 Plan for the years ended December 31, 2013 and 2012 was as follows:

	Number of Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value	Weighted Average Remaining Contractual Term
Options outstanding at December 31, 2011	930,060	\$ 12.97	\$ 16	5.90
Granted	558,300	1.54		
Exercised	(8,333)	0.75		
Canceled	(387,653)	21.57		
Options outstanding at December 31, 2012	1,092,374	\$ 4.17	\$ 20	6.23
Granted	810,000	2.05		
Exercised	(371,348)	1.63		
Canceled	(83,058)	8.66		
Options outstanding at December 31, 2013	1,447,968	\$ 3.36	\$ 780	7.94
<b>Shares exercisable:</b>				
December 31, 2013	614,439	\$ 5.09	\$ 297	6.23
<b>Shares expected to vest:</b>				
December 31, 2013	683,494	\$ 2.08	\$ 483	9.21

The range of exercise prices for options outstanding and exercisable at December 31, 2013 is as follows:

Exercise Price				Options Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Life in Years	Options Exercisable	Weighted Average Exercise Price
\$	0.01	-	\$ 1.22	415,000	\$ 1.21	9.08	87,499	\$ 1.15
	1.23	-	1.62	250,012	1.62	8.22	190,902	1.62
	1.63	-	2.70	371,209	2.05	8.14	138,172	2.00
	2.71	-	9.92	301,949	4.23	8.13	89,280	6.19
	9.93	-	29.60	109,798	17.44	1.83	108,586	17.41
\$	0.01	-	\$ 29.60	<u>1,447,968</u>	\$ 3.36	7.94	<u>614,439</u>	\$ 5.09

(in thousands)	Total Intrinsic Value of Options Exercised	Total Fair Value of Vested Options
Year ended December 31, 2013	\$ 291	\$ 550
Year ended December 31, 2012	\$ 7	\$ 525

### Stock-based Compensation

#### Employee Stock-based Compensation Expense

The assumptions used to calculate the fair value of options granted under the 2010 Plan that were incorporated in the Black-Scholes pricing model for the years ended December 31, 2013 and 2012 were as follows:

	Year Ended December 31,	
	2013	2012
Dividend yield	- %	- %
Volatility	79 %	78 %
Risk-free interest rate	1.91 %	1.32 %
Expected lives (years)	6.0	6.0
Weighted average fair value	\$ 1.50	\$ 1.04

The allocation of stock-based compensation expense by functional area for the years ended December 31, 2013 and 2012 was as follows:

(in thousands)	Year Ended December 31,		
	2013	2012	2012
Research and development	\$ 74	\$ 112	
Sales and marketing	163	203	
General and administrative	602	942	
Total	<u>\$ 839</u>	<u>\$ 1,257</u>	

The Company has a 100% valuation allowance recorded against our deferred tax assets and as a result of ASC 718 had no effect on income tax expense in the Consolidated Statement of Operations or the Consolidated Statement of Cash Flows. As of December 31, 2013, total unrecognized compensation cost related to nonvested stock option awards was approximately \$1,233,000 and the related weighted average period over which it is expected to be recognized was 2.14 years.

#### 401(k) Plan

The Company's 401(k) Plan allows eligible employees to defer up to an annual limit of the lesser of 90.0% of eligible compensation or a maximum contribution amount subject to the Internal Revenue Service annual contribution limit. The Company is not required to make contributions under the 401(k) Plan. During the years ended December 31, 2013 and 2012, the Company did not contribute to the 401(k) Plan.

#### NOTE 10: INCOME TAXES

Domestic and foreign components of loss before income taxes for the years ended December 31, 2013 and 2012 were as follows:

(in thousands)	Year Ended December 31,	
	2013	2012
Domestic	\$ (8,819)	\$ (7,052)
Foreign	-	(94)
	<u>\$ (8,819)</u>	<u>\$ (7,146)</u>

Based on the available objective evidence, management believes it is more likely than not that the net deferred tax assets will not be fully realizable due to the history of our operating losses. Accordingly, the Company has provided a full valuation allowance against the net deferred tax assets at December 31, 2013 and 2012. There was no income tax expense or benefit for the years ended December 31, 2013 or 2012.

The components of deferred tax assets (liabilities) at December 31, 2013 and 2012 were as follows:

(in thousands)	Year Ended December 31,	
	2013	2012
Deferred tax assets:		
Depreciation and amortization	\$ 8,698	\$ 8,955
Other	1,651	1,431
Net operating losses	54,005	46,918
Total deferred tax assets	64,354	57,304
Valuation allowance	(64,346)	(57,296)
Net deferred tax assets	<u>\$ 8</u>	<u>\$ 8</u>
Deferred tax liabilities:		
Other	\$ (8)	\$ (8)
Total deferred tax liabilities	<u>\$ (8)</u>	<u>\$ (8)</u>
Net deferred tax asset (liability)	<u>\$ -</u>	<u>\$ -</u>

The reconciliation of the statutory federal income tax rate to the Company's effective tax rate for the years ended December 31, 2013 and 2012 was as follows:

	Year Ended December 31,	
	2013	2012
Tax at federal statutory rate	34 %	34 %
State tax, net of federal benefit	2	3
Valuation allowance	(39)	(31)
Change in warrant valuation	-	-
Net operating loss and credit reduction due to section 382 limitations	-	(35)
Permanent items	(1)	25
Other	4	4
Effective income tax rate	<u>- %</u>	<u>- %</u>

As of December 31, 2013, the Company had a net operating loss of approximately \$146,000,000 for federal and \$121,000,000 for state tax purposes. If not utilized, these carryforwards will begin to expire beginning in 2025 for federal purposes and 2016 for state purposes. As of December 31, 2012, the Company had a net operating loss of approximately \$133,000,000 for federal and \$105,000,000 for state tax purposes.

The Company's ability to use net operating loss credit carryforwards may be restricted due to ownership change limitations occurring in the past or that could occur in the future, as required by Section 382 of the Internal Revenue Code of 1986 ("Section 382"), as amended, as well as similar state provisions. These ownership changes may also limit the amount of net operating loss credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively.

The Company believes that Section 382 ownership changes occurred as a result of the follow-on public common stock offering in 2011 and 2013. Any limitation may result in the expiration of a portion of the net operating loss credit carryforwards before utilization and any net operating loss credit carryforwards that expire prior to utilization as a result of such limitations will be removed from deferred tax assets with a corresponding reduction of the valuation allowance. Due to the existence of a valuation allowance, it is not expected that such limitations, if any, will have an impact on the results of operations or financial position.

The Company has provided a full valuation allowance on the deferred tax assets relating to deferred tax assets. The valuation allowance was \$64,000,000 and \$57,000,000 at December 31, 2013 and 2012, respectively. The increase of \$7,000,000 between 2013 and 2012 is primarily due to adjustments to the domestic deferred tax assets relating to net operating losses.

The Company files income tax returns in the U.S. and in various state jurisdictions with varying statutes of limitations. The Company has not been audited by the Internal Revenue Service or any state income or franchise tax agency. As of December 31, 2013, the federal returns for the years ended 2010 through the current period and most state returns for the years ended 2009 through the current period are still open to examination. In addition, all of the net operating losses and research and development credits generated in years earlier than 2010 and 2009, respectively, are still subject to Internal Revenue Service audit. The federal and California tax returns for the year ended December 31, 2012 reflect research and development carryforwards of \$5,655,000 and \$5,242,000, respectively. The Company has recognized additional deferred tax assets for federal and California research and development credits of \$72,000 and \$54,000 for the year ended December 31, 2013, respectively. As of December 31, 2013, gross unrecognized tax benefits are approximately \$10,064,000 which are attributable to research and development credits. A reconciliation of the change in unrecognized tax benefits is as follows:

(in thousands)	Federal Tax	State Tax	Total
Balance at December 31, 2011	\$ 5,586	\$ 5,191	\$ 10,777
Increase in tax position during 2012	69	51	120
Balance at December 31, 2012	\$ 5,655	\$ 5,242	\$ 10,897
Increase in tax position during 2013	72	54	126
Decrease due to expirations	(687)	(272)	(959)
Balance at December 31, 2013	<u>\$ 5,040</u>	<u>\$ 5,024</u>	<u>\$ 10,064</u>

The increase for the year ended December 31, 2013 relates to a tax position taken during the current year. The increase for the year ended December 31, 2012 is related to tax positions taken during 2012 and prior years. If the \$11,000,000 of unrecognized income tax benefit is recognized, approximately \$11,000,000 would impact the effective tax rate in the period in which each of the benefits is recognized.

No interest or penalties as a result of uncertain tax positions have been recorded as of December 31, 2013 and 2012. Accrued interest and penalties would be included within the related liability in the Consolidated Balance Sheet.

#### **NOTE 11: OTHER RELATED PARTY TRANSACTIONS**

##### ***Consulting Agreements***

On March 18, 2013, the Company entered into a short term consulting agreement for transition services with Mr. Huebner (the "2013 Consulting Agreement"). Pursuant to the terms of the 2013 Consulting Agreement, Mr. Huebner assisted in the integration and transition of the new President and Chief Executive Officer. Mr. Huebner was paid a total of \$45,000 during the three month term of the Consulting Agreement, which expired in June 2013.

On December 3, 2012, the Company entered into a consulting agreement with the former President and Chief Executive Officer and director, Gail S. Page. Pursuant to the terms of the consulting agreement, Ms. Page assisted the Company as needed, including providing advice and recommendations with respect to the development and commercialization of the Company's existing and future



diagnostic tests, and managing and developing relationships with existing and future collaborators and partners. In consideration for such services, Ms. Page was paid a monthly fee of \$18,000. For the years ended December 31, 2013 and 2012, the total amount of consulting fee expense to Ms. Page was \$45,000 and \$18,000, respectively. The consulting agreement was terminated with an effective date of March 15, 2013.

On March 1, 2012, the Company entered into a consulting agreement with the former Vice President of Strategy, who resigned effective February 29, 2012. Pursuant to the terms of the consulting agreement, the former Vice President of Strategy provided consulting services. This consulting agreement was terminated in June 2012. For the year ended December 31, 2012, the total amount of consulting fee expense to the former Vice President of Strategy was \$23,000 and the fair value of continued vesting in restricted stock was \$1,000 until the termination of the consulting agreement.

In November 2011, the Company entered into a consulting agreement with its former Senior Vice President and Chief Science Officer, Eric T. Fung, M.D., Ph.D. Pursuant to the terms of the consulting agreement, Dr. Fung served as the Chief Medical Officer and a member of the Scientific Advisory Board. Dr. Fung's consulting agreement and Scientific Advisory Board services were terminated in June 2012. For the year ended December 31, 2012, the total amount of consulting fee expense for Dr. Fung was \$27,000. During 2012, Dr. Fung also continued to vest in restricted stock with a fair value of \$11,000 until the termination of the consulting agreement.

On June 17, 2011, the Company entered into a consulting agreement with Bruce A. Huebner, a member of the Board of Directors until December 12, 2013. Pursuant to the terms of the consulting agreement, Mr. Huebner provided consulting services regarding sales, marketing, business development and corporate strategy. For the year ended December 31, 2012, the total amount of consulting fees paid to Mr. Huebner was \$5,000. On November 27, 2012, the Company announced the appointment of Mr. Huebner as Interim Chief Executive Officer. Mr. Huebner served in this position until the appointment of Thomas McLain as President and Chief Executive officer on March 18, 2013.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

### Vermillion, Inc.

Date: March 28, 2014

/s/ Thomas H. McLain  
Thomas H. McLain  
President and Chief Executive Officer (Principal Executive Officer)

Date: March 28, 2014

/s/ Eric J. Schoen  
Eric J. Schoen  
Vice President, Finance and Chief Accounting Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<u>Name</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Thomas H. McLain</u> Thomas H. McLain	President and Chief Executive Officer (Principal Executive Officer)	March 28, 2014
<u>/s/ Eric J. Schoen</u> Eric J. Schoen	Vice President, Finance and Chief Accounting Officer (Principal Financial Officer)	March 28, 2014
<u>/s/ James T. LaFrance</u> James T. LaFrance	Chairman of the Board of Directors	March 28, 2014
<u>/s/ James S. Burns</u> James S. Burns	Director	March 28, 2014
<u>/s/ Robert S. Goggin</u> Robert S. Goggin, III	Director	March 28, 2014
<u>/s/ Peter S. Roddy</u> Peter S. Roddy	Director	March 28, 2014
<u>/s/ Carl Severinghaus</u> Carl Severinghaus	Director	March 28, 2014
<u>/s/ Eric Varma</u> Eric Varma	Director	March 28, 2014

## INDEX TO EXHIBITS

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Incorporated by Reference</u>				<u>Filed Herewith</u>
		<u>Form</u>	<u>File No.</u>	<u>Exhibit</u>	<u>Filing Date</u>	
2.1	Findings of Fact, Conclusions of Law and Order Confirming Debtor's (Vermillion Inc.'s) Second Amended Plan of Reorganization Under Chapter 11 of the Bankruptcy Code dated January 7, 2010	8-K	000-31617	2.1	January 12, 2010	
2.2	Asset Purchase Agreement between Vermillion, Inc. (formerly CIPHERGEN Biosystems, Inc.) and Bio-Rad Laboratories, Inc. dated August 14, 2006	14a	000-31617	Annex A	September 12, 2006	
2.3	Amendment to Asset Purchase Agreement between Vermillion, Inc. (formerly CIPHERGEN Biosystems, Inc.) and Bio-Rad Laboratories, Inc. dated November 13, 2006	S-1	333-146354	10.47	September 27, 2007	
2.4	Stock Purchase Agreement between Vermillion, Inc. (formerly CIPHERGEN Biosystems, Inc.) and Bio-Rad Laboratories, Inc. dated November 13, 2006	S-1	333-146354	10.48	September 27, 2007	
2.5	Asset Purchase Agreement between Vermillion, Inc. and Correllogic Systems, Inc., dated November 8, 2011	10-K	001-34810	10.50	March 27, 2012	
3.1	Fourth Amended and Restated Certificate of Incorporation of Vermillion, Inc. dated January 22, 2010	8-K	000-31617	3.1	January 25, 2010	
3.2	Fourth Amended and Restated Bylaws of Vermillion, Inc., as amended effective May 13, 2013	8-K	001-34810	3.2	May 14, 2013	
4.1	Form of Vermillion, Inc.'s (formerly CIPHERGEN Biosystems, Inc.) Common Stock Certificate	S-1/A	333-32812	4.1	August 24, 2000	
4.2	Preferred Shares Rights Agreement between Vermillion, Inc. (formerly CIPHERGEN Biosystems, Inc.) and Continental Stock Transfer & Trust Company dated March 20, 2002	8-A	000-31617	4.2	March 21, 2002	
4.3	Amendment to Rights Agreement between Vermillion, Inc. (formerly CIPHERGEN Biosystems, Inc.) and Wells Fargo Bank, N.A. dated July 22, 2005	8-K	000-31617	4.4	July 28, 2005	
4.4	Second Amendment to Rights Agreement between Vermillion, Inc. (formerly CIPHERGEN Biosystems, Inc.) and Wells Fargo Bank, N.A. dated September 30, 2005	8-K	000-31617	4.5	October 4, 2005	

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
4.5	Third Amendment to Rights Agreement between Vermillion, Inc. and Wells Fargo Bank, N.A., dated September 11, 2007	8-K	000-31617	10.1	September 12, 2007	
4.6	Securities Purchase Agreement by and among Vermillion, Inc. and the purchasers party thereto dated August 23, 2007	S-1	333-146354	10.57	September 27, 2007	
4.7	Form of Securities Purchase Agreement between Vermillion, Inc. and the purchasers party thereto dated December 24, 2009	8-K	000-31617	10.1	December 29, 2009	
4.8	Securities Purchase Agreement dated May 8, 2013, by and among Vermillion, Inc. and the purchasers identified therein, including the Form of Warrant included as Exhibit D thereto	8-K	001-34810	10.1	May 14, 2013	
4.9	Stockholders Agreement dated May 13, 2013, by and among Vermillion, Inc., Oracle Partners, LP, Oracle Ten Fund Master, LP, Jack W. Schuler and other purchasers named therein.	8-K	001-34810	10.2	May 14, 2013	
10.1	1993 Stock Option Plan #	S-1	333-32812	10.3	March 20, 2000	
10.2	Form of Stock Option Agreement #	S-1/A	333-32812	10.4	August 24, 2000	
10.3	2000 Stock Plan and related form of Stock Option Agreement #	S-1/A	333-32812	10.5	August 4, 2000	
10.4	Amended and Restated 2000 Employee Stock Purchase Plan #	10-Q	000-31617	10.6	November 14, 2007	
10.5	Vermillion, Inc. 2010 Stock Incentive Plan #	8-K	000-31617	10.1	February 12, 2010	
10.6	Ciphergen Biosystems, Inc. 401(k) Plan #	10-K	000-31617	10.7	March 22, 2005	
10.7	Form of Proprietary Information Agreement between Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.) and certain of its employees #	S-1/A	333-32812	10.9	August 24, 2000	
10.8	Strategic Alliance Agreement between Vermillion, Inc. (formerly Ciphergen Biosystems, Inc.) and Quest Diagnostics Incorporated dated July 22, 2005	8-K	000-31617	10.44	July 28, 2005	
10.9	Amendment to Strategic Alliance Agreement between Vermillion, Inc. and Quest Diagnostics Incorporated dated October 7, 2009	8-K	000-31617	10.2	October 21, 2009	

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
10.10	Amendment to Strategic Alliance Agreement between Vermillion, Inc. and Quest Diagnostics Incorporated dated November 10, 2010	8-K	000-34810	10.1	November 12, 2010	
10.11	Amendment No. 5 to Strategic Alliance Agreement by and among Vermillion, Inc. and Quest Diagnostics Incorporated and Quest Diagnostics India Private Limited, dated April 2, 2011†	10-Q	001-34810	10.1	May 10, 2011	
10.12	Stock Purchase Agreement between Vermillion, Inc. (formerly CIPHERGEN Biosystems, Inc.) and Quest Diagnostics Incorporated dated July 22, 2005	8-K	000-31617	10.45	July 28, 2005	
10.13	Letter Agreement between Vermillion, Inc. and Quest Diagnostics Incorporated dated August 29, 2007	S-1	333-146354	10.38	September 27, 2007	
10.14	Credit Agreement between Vermillion, Inc. (formerly CIPHERGEN Biosystems, Inc.) and Quest Diagnostics Incorporated dated July 22, 2005	8-K	000-31617	10.47	July 28, 2005	
10.15	Debtor-In-Possession Credit and Security Agreement between Vermillion, Inc. and Quest Diagnostics Incorporated dated October 7, 2009	8-K	000-31617	10.1	October 21, 2009	
10.16	Memorialization Agreement between Vermillion, Inc. (formerly CIPHERGEN Biosystems, Inc.) and Quest Diagnostics Incorporated dated January 12, 2006	S-1	333-146354	10.40	September 27, 2007	
10.17	Patent Security Agreement between Vermillion, Inc. (formerly CIPHERGEN Biosystems, Inc.) and Quest Diagnostics Incorporated dated July 22, 2005	8-K	000-31617	10.48	July 28, 2005	
10.18	Employment Agreement between Vermillion, Inc. and Thomas McLain effective March 18, 2013#	8-K	001-34810		March 13, 2013	
10.19	Consulting Agreement between Vermillion, Inc. and Bruce Huebner dated as of March 18, 2013#	8-K	001-34810		March 20, 2013	

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
10.20	Employment Agreement between Vermillion, Inc. and Marian Sacco dated December 16, 2013#	8-K	001-34810		December 17, 2013	
10.21	Vermillion, Inc. Amended and Restated 2010 Stock Incentive Plan #	8-K	001-34810	10.1	December 17, 2013	
10.22	Employment Agreement between Vermillion, Inc. and William Creech dated January 6, 2014#					√
10.23	Employment Agreement between Eric J. Schoen and Vermillion, Inc. dated April 4, 2012 #	8-K	001-34810	10.1	April 10, 2012	
10.24	Employment Agreement between William Creech and Vermillion, Inc. dated April 4, 2012 #	8-K	001-34810	10.2	April 10, 2012	
10.25	Offer letter from Vermillion, Inc. to Donald G. Munroe dated September 20, 2011#	8-K	001-34810	10.1	September 26, 2011	
10.26	Settlement Agreement and Release between Vermillion, Inc. and Oppenheimer & Co., Inc. dated February 9, 2012	10-K/A	001-34810	10.51	May 30, 2012	
10.27	Employment Agreement between Bruce A. Huebner and Vermillion, Inc. dated November 26, 2012 #	8-K	001-34810	10.1	November 28, 2012	
14.1	Code of Ethics	8-K	001-34810	14.1	December 7, 2010	
21.0	Subsidiaries of Registrant					√
23.1	Consent of BDO USA, LLP, Independent Registered Public Accounting Firm					√
31.1	Certification of the Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					√
31.2	Certification of the Chief Accounting Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					√

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Incorporated by Reference</u>				<u>Filed Herewith</u>
		<u>Form</u>	<u>File No.</u>	<u>Exhibit</u>	<u>Filing Date</u>	
32.0	Certification of the Chief Executive Officer and Chief Accounting Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					(1)
101	Interactive Data Files					(1)

Attached as Exhibit 101 to this report are documents formatted in XBRL (Extensible Business Reporting Language). Users of this data are advised that, pursuant to Rule 406T of Regulation S-T, the interactive data file is deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is otherwise not subject to liability under these sections.

(1) Furnished herewith

# Management contracts or compensatory plan or arrangement.

† Confidential treatment has been granted with respect to certain provisions of this agreement. Omitted portions have been filed separately with the SEC.